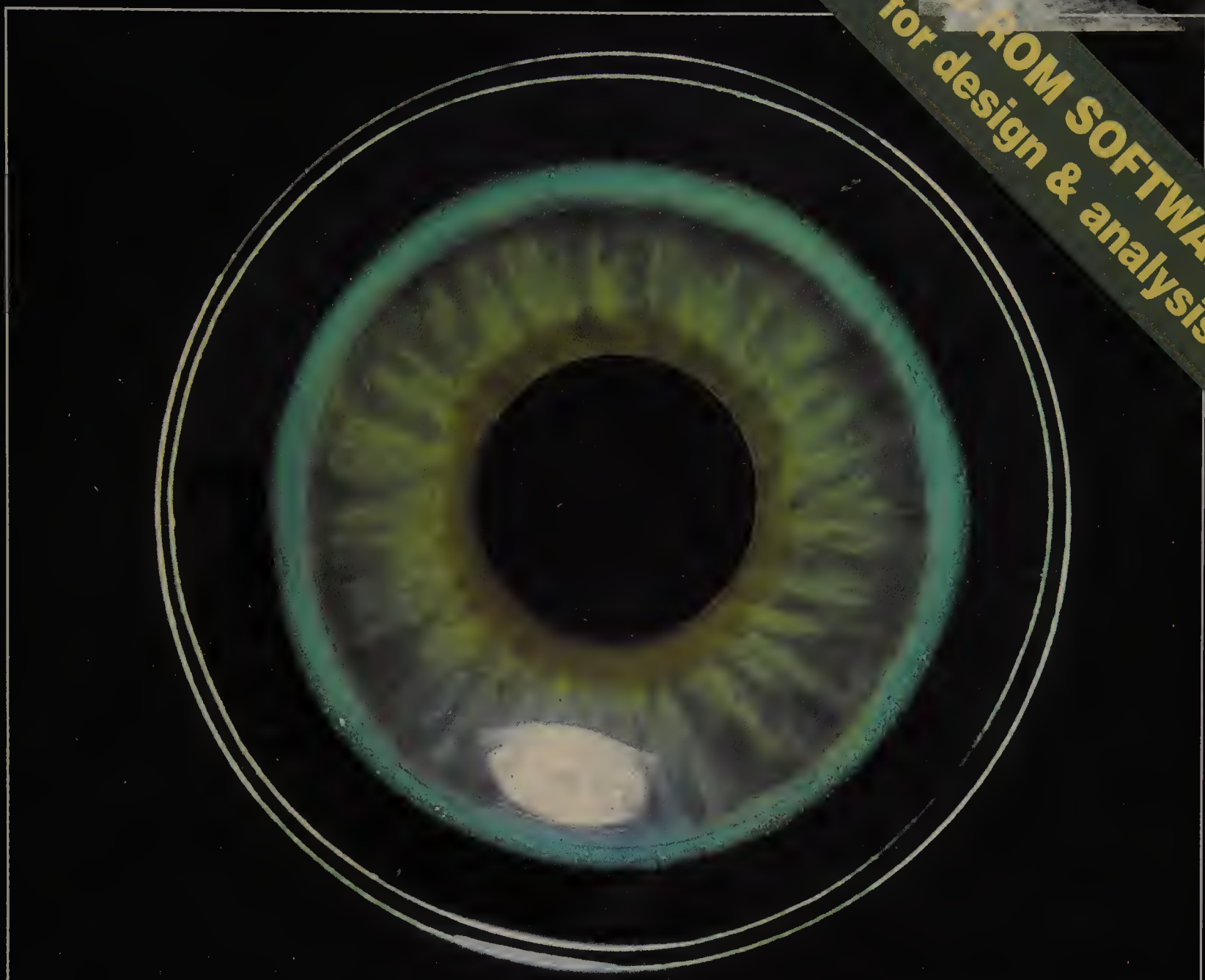
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4th edition

Contact Lenses

Edited by
Anthony J. Phillips Lynne Speedwell

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Contact Lenses

Contact Lenses

Fourth Edition

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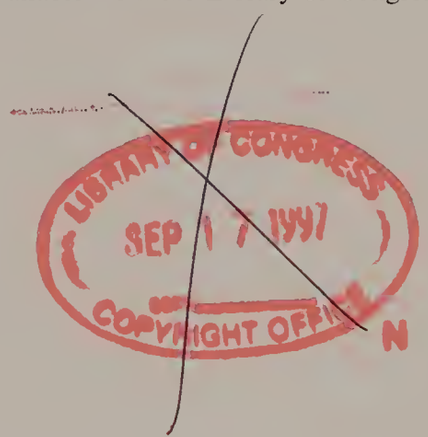
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Contents

List of contributors ix
List of sponsors xi
Preface to the fourth edition xiii
Preface to the third edition xv
Glossary of terms xvii

1 The history of contact lenses 1
A. G. Sabell
General developments in the contact lens field • The development of eye impression procedures • Development in contact lens design and materials • Epilogue: some contact lens personalities

2 Anatomy and physiology of the cornea and related structures 17
G. L. Ruskell
The cornea • The conjunctival sac and the epithelial surface • The eyelids • Corneal innervation • Corneal transparency • Metabolic processes • Tears

3 Contact lens materials 50
B. J. Tighe
Introduction: emergence of the current scene • Nature and properties of polymers • Properties of contact lens materials • Hydrogel materials • RGP materials • The nature and origin of lens spoilation • Addendum 1: Units and terms in permeability measurements • Addendum 2: Abridged patent compilation

4 Drugs and solutions in contact lens practice and related microbiology 93
F. S. Stapleton, A. J. Phillips and G. A. Hopkins
General microbiology • Microbiology of the eye • Contact lens solutions • Formulation • Solutions for rigid lenses • Solutions for hydrophilic lenses • Scleral lens solutions • Ophthalmic preparations

5 Practical optics and computer design of contact lenses 154
Morley W. Ford and Janet Stone
The practical effects of optical differences between contact lenses and spectacles • Optical considerations of contact lenses on the eye • Astigmatism of the front surface of the cornea and the effect of the liquid lens • Power variations as a sequel to other changes • Toric contact lenses • Bifocal contact lenses • Optical changes of the eye caused by contact lenses • Aspects of contact lens design • Optical formulae for contact lens work, with examples to illustrate their use • Examination questions and answers

6 Clinical instrumentation in contact lens practice 232
Keith H. Edwards
Keratometry • Topographical keratoscopy • Slit lamp biomicroscopy • Pachometry • Summary

7 External eye photography 247
David Campbell-Burns
The camera • The lens • Close-up (supplementary) lenses • The film • Illumination • Ultraviolet photography • Slit lamp photography • Exposure • Fundus cameras • Photokeratoscopy • Photography of the corneal endothelium

8 Assessment of patient suitability for contact lenses 258
Janet Stone
Indications and contraindications for contact lens wearing • Psychological influences • Pathological, anatomical and physiological factors • Personal and external factors

9 Patient management and instruction 282
K. W. Atkinson and M. J. A. Port
Introduction • Routine examination • General ocular examination • Insertion and removal of rigid lenses • Insertion and removal of scleral lenses • Insertion and removal of soft lenses • Insertion and removal of composite (Softperm) lenses • Reactions to the first lens • Refraction with contact lenses • Ordering • Selecting a care system • Dispensing contact lenses • After-care • Fitting children's contact lenses • Addendum 1: Instructions to the patient on the care and handling of soft contact lenses • Addendum 2: Instructions on chemical disinfection routines • Addendum 3: Instructions on hydrogen peroxide routines • Addendum 4: Instructions on Optimeyes, Softab and Aerotab soft lens disinfection routines • Addendum 5: Instructions to the patient on the care and handling of disposable lenses • Addendum 6: Instructions to patients wearing rigid gas permeable contact lenses • Addendum 7: More information for contact lens wearers • Addendum 8: Instructions for patients with monovision lenses • Addendum 9: Instructions for orthokeratology patients

10 Rigid gas permeable corneal lens fitting 313
A. J. Phillips
Introduction • Basic requirements • Corneal contour • Mathematical models of corneal curvature • Terms relating to corneal lenses • Forces affecting the lens on the eye • Fluorescein patterns • The general principles of rigid lens fitting • A brief historical review • RGP lens materials • Material and design classification • Contact lens fitting with the EyeSys • Lens fitting designs • Fitting routine of RGP lenses • Lens care and maintenance • Refitting the former PMMA wearer • Fitting sets • Ordering • The written prescription • The final lens • Identification of RGP materials • Summary

11 Soft (hydrogel) lens fitting 358
Andrew Gasson and Martin Lloyd
Introduction • Advantages of soft contact lenses • Disadvantages of soft contact lenses • Patient selection for soft lenses • Visual considerations • Water content and polymers • Classification • Lens thickness and 'thin' lenses • Additional techniques in soft lens fitting • Consulting room procedures and equipment • Clinical routine • Fitting characteristics • Fitting philosophies and soft lens selection • Examples of lens types • Disposable lenses and frequent replacement • Toric soft lenses • Soft lenses for presbyopia • Special features of soft lenses • Instructions to patients • Disinfection of soft lenses • After-care • Lens ageing • General comments on soft lens practice

12 Rigid lens verification procedures 407
Rita Watts
Parameters to be checked • Verification procedures • Addendum I: Dimensional tolerances for hard contact lenses • Addendum II: Optical tolerances of corneal lenses and scleral lenses

13 The verification of hydrogel contact lenses 426
D. F. C. Loran
Manufacture of hydrogel contact lenses • Lens specification • Definitions • Standards • Quality assurance • Verification procedures • Radiuscope (optical microspherometer) • Classification of deposits • Conclusion

14 Toric contact lens fitting 464
Richard G. Lindsay and David I. Westerhout
Fitting toric rigid gas permeable lenses • Indications for the use of toric contact lenses • Forms of toric lens • Optical considerations of toroidal back optic zones • Toroidal front surfaces combined with spherical back optic zones • RGP lens flexure • Checking toric RGP lenses • Fitting toric soft lenses • Criteria for use of toric soft lenses • Design of toric soft lenses • Principles of correction • Methods of fitting • Stock lenses versus custom-made lenses • Limitations of toric soft lenses • Checking toric soft lenses • Trends in toric soft lens design

15 Extended wear lenses 494
Helen A. Swarbrick and Brien A. Holden
Introduction • The ocular environment • Hydrogel extended wear • RGP extended wear • The future of extended wear

16 Bifocal and multifocal contact lenses 540
J. T. de Carle
Introduction • History • Theory of bifocal contact lenses • Types of bifocal contact lenses • Monovision • Choice of bifocal type • Extra measurements needed when fitting bifocal lenses • Fitting procedures for rigid lenses • Scleral bifocal lenses • Hydrophilic bifocal contact lenses • Fitting sets • Conclusion

17 The role of scleral lenses in modern contact lens practice 566
K. W. Pullum
Introduction • Principles of scleral lens fitting • Controlled clearance RGP scleral lens fitting • Eye impressions • Manufacture of the finished lens • Solutions and maintenance of scleral lenses • Scleral lenses in pathological conditions • Problems and complications with scleral lens wear • Conclusion: the role of scleral lenses

18 After-care symptoms, signs and management 609
C. W. McMonnies
Introduction • Interviewing and history taking • Symptom analysis • After-care glossary • Conclusion

19 Orthokeratology 653
J. Mountford
Historical perspectives • Controlled studies of orthokeratology • Modern orthokeratology • A specific approach to fitting the OK series • Is orthokeratology predictable? • Corneal rheology • Anatomical considerations • Clinical experience with accelerated orthokeratology • Refractive surgery and orthokeratology compared • Summary and conclusions

20 Contact lenses in abnormal ocular conditions 693

20.1 Keratoconus 693
E. G. Woodward
Incidence of keratoconus • Symptoms and signs • Management • Contact lens options • Fitting procedure • Patient management

20.2 Aphakia 707
M. J. A. Port
General procedure • Corneal lens fitting (daily wear) • Soft lenses (daily wear) • Extended wear lenses • Refraction • UV protection and tinted lenses • Fitting babies and infants • After-care

20.3 Postkeratoplasty 713
E. G. Woodward
Indications for keratoplasty • Postkeratoplasty therapeutic lenses • Postkeratoplasty optical lenses • Fitting procedures

20.4 Radial keratotomy and photorefractive keratectomy 721
Christine L. K. Astin
Radial keratotomy • Problems with radial keratotomy • Contact lens fitting and problems • Photorefractive keratectomy • Contact lens fitting

20.5 Contact lens fitting in infants and pre-school children 731
Lynne Speedwell
Indications for contact lenses • Corneal topography and physiology • Practicalities and type of lenses • Cosmetic conditions • Therapeutic lenses • Handling of lenses • Lens hygiene • After-care problems

20.6 Cosmetic and prosthetic contact lenses 743
M. J. A. Port
Uses • Types of lenses • Scleral lenses and shells • Corneal lenses • Soft lenses • Ordering cosmetic lenses • General approach with cosmetic lenses

20.7 Contact lenses in other abnormal ocular conditions 758
S. B. Hickson
Therapeutic mechanisms of contact lenses • Selection of therapeutic lenses • Conditions which can benefit from the use of therapeutic contact lenses • Drug delivery • Miscellaneous applications of therapeutic contact lenses • Complications of therapeutic lens use

21 Contact lens manufacturing 777
E. J. D. Proctor
Moulding • Generating/lathing • Additional procedures for RGP lenses • Bifocals • Practitioners' orders • Conclusion • Addendum: European Manufacturing Regulations/British and American approved names for contact lens materials

22 Modification procedures 801
A. J. Phillips
The importance of the practitioner being able to carry out modifications • Modification equipment for corneal lenses • Corneal lens modifications • Points to note when modifying RGP lenses • Scleral lens modifications • Modification of soft contact lenses • Conclusion

23 Special types of contact lenses and their uses 817
Janet Stone
Lenses to aid diagnosis and surgery • Protective lenses • Therapeutic lenses • Contact lenses used for research into visual function • Lenses for sports purposes • Lenses for the partially sighted • Animals' lenses • Miscellaneous lenses

Appendix A Spectacle and ocular refraction, or effective power of spectacle lenses in air at various vertex distances 845

Appendix B List of oxygen permeabilities and refractive indices 849

Appendix C Appropriate drugs and solutions for use with contact lenses 854

Appendix D The CCLRU grading scales 863

Appendix E Instructions for the CD-ROM 868

Index 869

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Preface to the fourth edition

The format of the fourth edition of *Contact Lenses* has changed completely from previous editions. The major change has been the retirement of Janet Stone as co-editor and her replacement by Lynne Speedwell. Janet worked enormously hard for over twenty years in building up the reputation of this book to that which it currently enjoys. Each edition takes some four years to produce and occupies most of the editors' free time. Many hundreds of letters pass between the editors to each other and to the various co-authors before the final result is reached. Fortunately word processors and faxes have made life quicker if not easier since the first edition was begun in the 1960s. Janet has not been allowed to retire completely and has still contributed not only her own three chapters, but she has also been called upon frequently in a consultant editorial capacity.

There are other significant changes: the colour photographs have been incorporated into the body of the text, making reference to them much easier. This is thanks entirely to the generous sponsorship from the companies listed at the front of the book who are at the forefront of the ongoing developments in the contact lens field. A CD-ROM is included with the book and was devised and written by Tony Hough. The Orthokeratology section was developed by John Mountford and Michael Vincent and will help students of Orthokeratology to work out the correct lenses to use in association with Chapter 19. Appendix B, which gives easy reference to the properties of materials, was compiled from innumerable sources by Morley Ford; and Appendix D, the CCLRU grading scale, was kindly sponsored by Vistakon.

There is a comprehensive formula section in Chapter 5, which can be programmed into scientific calculators and computers for working out all aspects of contact lens design.

Contact lens practice never stands still. The main aim of this book is to be less out-of-date than the previous edition in order to help the undergraduate and provide assistance for the qualified practitioner. Every chapter has been re-written to varying degrees, some completely so. The two chapters on scleral lenses have been amalgamated and a new chapter on orthokeratology incorporated.

Several co-authors have retired and we must pass on our grateful thanks for their contribution over the years – John Stewart-Jones, John Francis, Michael Sheridan and Roy Rengstorff. We are fortunate to have been able to replace and add to the group of co-authors, all of the highest international calibre, who have contributed to this fourth edition of the book.

At the Australian end of the editorship there are many people to thank – Professor Doug Coster, Head of the Department of Ophthalmology at the Flinders Medical Centre, Mrs Eva Lefty for the bulk of my chapter typing and to my own staff Sue Peters, Di Ward, Di Culleney, Jill Dale and Moira Jackson for the enormous correspondence typing. Finally to my long-suffering co-editor – thank you, Lynne, for your sense of humour which has kept me going when I felt like packing it all in.

At the UK end, tremendous thanks are due to Janet Stone, who, although she stepped down from the position as co-editor, has continued to be on hand for advice and sympathy when necessary. Thanks also to Nicholas Geddes, Technical Manager of the Department of Medical Illustration, Great Ormond Street Hospital for Children, for the photograph on the front cover. To my co-editor, who persuaded me to take on the task by suggesting that it would not be a major rewrite and then encouraged me to continue when we both found out that it was. And finally, to all the co-authors who deserve our heartfelt thanks, both for their own sections and also for their help in providing extra information where necessary for sections other than their own.

Tony Phillips
Adelaide, Australia

Lynne Speedwell
London, England

Preface to the third edition

The third edition of *Contact Lenses*, to be published at the conclusion of 100 years of contact lens practice, incorporates all the latest thinking and knowledge in the contact lens field. It also includes the terminology agreed in 1986 by the International Standards Organisation.

Since the publication of the second edition the advances of gas permeable hard lenses and extended wear lenses have made a major impact. In addition the specialized uses of contact lenses in keratoconus, aphakia, postkeratoplasty, paediatrics, and as prosthetic devices, have become increasingly important. Knowledge of the technical, physiological and pathological aspects has also increased and a much wider and more profound understanding of the whole field has been achieved. Several new contributors have joined the team involved in the preparation of the book, each of these being an acknowledged expert in his or her specific area.

The editors would like to express their thanks to all the co-authors for the work they have put in, not only into their own chapters but often for advice and comments on other chapters where they may also have had a special interest. In addition, we would like to thank the many contact lens prescription laboratories and solution manfacturers who have provided information and photographs and apologize to readers for any omissions.

We would also like to acknowledge the generous financial support provided by the laboratories in sponsoring the colour plate sections. These vital sections are produced at considerable expense and their sponsorship assists in reducing the overall cost of the book.

Finally we must acknowledge the logistical help of certain individuals: Professor Douglas Coster, Head of the Eye Department at Flinders Medical Centre, Adelaide, for providing the facilities of the Eye Department and many of the colour plates; Jennifer Taylor, Librarian, the British College of Optometrists; Eva Lefty for the enormous volume of typing and correspondence; and all of the many individuals who provided information and help.

Janet Stone,
Shrewsbury

Tony Phillips,
Adelaide

Glossary of terms

The 1986 edition of ISO 8320 has been expanded by the addition of new terms and the omission of ambiguities, and the list below comprises the relevant terms from the 1995 edition. Terms are grouped in sections to enable the reader to find information easily. The list is not complete and only the more commonly used terms are included. The reader is advised to refer to the original document ISO 8320 (1995) for the comprehensive list, which can be obtained from the British Standards Institute, 2 Park Street, London W1A 2BS.

The Table of Symbols is given in its entirety in order to help with the calculations in Chapter 5. The letter *t* indicates thickness and the letter L is no longer used. In France, the abbreviation *e* for *épaisseur* is used, rather than *t* for *thickness*.

2 General terms and definitions

2.1.1 **axial edge lift,** l_{EA}: Distance between a point on the back of a lens at the edge and the vertex sphere, measured parallel to the lens axis. NOTE – This is often a value computed by the manufacturer and may be altered by the edging process.

2.2 **back vertex power,** F'_v: Reciprocal of the paraxial back vertex focal length, in metres, of the optic zone of the lens in air.

2.8 **bi-toric lens**: Lens having both front and back optic zones of toroidal form.

2.9 **blending**: Process of forming a polished transition at a junction. NOTE – This does not constitute the formation of an aspheric zone.

2.10 **carrier**: That part of a lenticular lens peripheral to the front optic zone(s). NOTE – The carrier may be negative, positive or parallel in construction but is radially symmetrical.

2.12 **composite lens**: Contact lens composed of two or more different materials. NOTE – For example, a laminated lens, a fused segment lens or a lens with a rigid centre and a flexible periphery.

2.14 **contact shell**: Appliance similar in form to a contact lens but not designed to correct vision.

2.15 **corneal lens**: Contact lens designed to be worn in its entirety on the cornea.

2.16 **cosmetic lens**: Contact lens specifically designed to change or mask the appearance of the eye. NOTE – Cosmetic lenses are devices which may also be used for therapeutic purposes.

2.17 **cosmetic shell**: Contact shell specifically designed to change the appearance of the eye. NOTE – Cosmetic shells are devices which may also be used for therapeutic purposes.

2.18 **disposable lens**: A lens intended for single use. NOTE – The lens is not intended to be re-used and is discarded after removal from the eye.

2.21 **fenestration**: Specified hole which passes from the front surface to the back surface of a contact lens.

2.22 **front vertex power,** F_v: Reciprocal of the paraxial front vertex focal length, in metres, of the optic zone of the lens, in air.

2.23 **geometric centre,** *c*: Centre of the circle containing the lens edge. NOTE – For a scleral lens, the geometric centre is taken as the centre of the optic zone. For a truncated lens, the geometric centre is taken as the centre of the circle that contains the circular portion of the edge.

2.24 **high water content lens**: A lens whose water content is greater than 65%.

2.25 **hydrogel lens**: A contact lens made of water absorbing (hydrophilic) material having an equilibrium water content greater than or equal to 10% in standard saline (ISO 10344) at 20°C.

2.28 **lens axis**: A line passing through the geometric centre, perpendicular to a plane containing the edge of the lens.

2.29 **lenticular lens**: Lens having a front optic zone made smaller than the total diameter. NOTE – This construction is conventionally used to reduce the centre thickness of a positively powered lens or reduce the edge thickness of a negatively powered lens.

2.31 **low water content lens**: A lens whose water content is less than 50%.

2.32 **mid water content lens**: A lens whose water content is between 50% and 65%.

2.35 **multi-curve lens**: A lens whose back surface is composed of more than three intersecting spherical zones.

2.37 **optic zone**: That part of a contact lens which has a prescribed optical effect. NOTE – The term may be qualified by either the prefix 'back' or 'front' in the case of a surface with a single optical component. In the case of an alternating vision bifocal, the term may be qualified by either the prefix 'distance' or 'near'. In the case of a concentric bifocal, the term may be qualified by the prefix 'central' or 'peripheral'.

2.40 **prism ballast**: The use of prism to create a wedge design for lens stabilization. NOTE – The base of the prism is at or near the bottom of the lens.

2.41 **radial lift,** l_R: Distance between a specified point on the back surface of a lens and the vertex sphere measured along a radius of curvature of the latter.

2.42.1 **frequent replacement lens**: A planned replacement lens for which the replacement frequency is three months or less.

2.42.2 **planned replacement**: A lens for which the manufacturer has recommended a replacement frequency.

2.43 **rigid lens; hard lens**: Contact lens which, in its final form and under normal conditions, retains its form without support. NOTE – The term 'semi-soft lens' is deprecated.

2.44 **rigid (hard) gas permeable (RGP) lens**: Rigid lens which contains one or more components in sufficient concentration to permit oxygen transmission through the lens.

2.45 **sagitta (sagittal depth, sagittal height)**: The maximum distance from a chord, which is perpendicular to the axis of rotation of a surface, to the curved surface.

2.46 **scleral lens**: Contact lens designed to be worn in front of the cornea and on most of the bulbar conjunctiva.

2.48 **soft lens**: Contact lens which requires support to maintain its form.

2.51 **therapeutic lens**: A lens used to maintain or restore the integrity of ocular tissue and which may have a refractive element. NOTE – some therapeutic lenses are used to deliver drugs to ocular tissues.

2.53 **toric lens**: Lens with front and/or back optic zone of toroidal form.

2.54 **toric periphery lens**: Lens with one or more back peripheral zones of toroidal form which surround a spherical back optic zone.

4 Tinted lenses

4.1 **tinted contact lens**: A contact lens containing some coloration for a specified or an intended use.

4.1.1 **enhancing tint**: a coloration which is added to a contact lens in order to alter the apparent iris colour of the wearer.

4.1.2 **handling (visibility) tint**: A coloration added to a contact lens which is intended to improve the visibility of the lens during handling but which is not intended to have any effect on eye colour.

4.1.3 **opaque tinted lens** (eye masking tint lens): A lens containing sufficient colour in order to mask all or most of the natural iris colour. NOTE – This is a colloquial term and not all such lenses are completely opaque.

5 Material properties

5.2 **gas permeability**: Mathematical product of gas solubility and diffusion coefficients.

Permeability =

$$\frac{\text{amount of gas (cm}^3\text{)} \times \text{thickness (cm)}}{\text{area (cm}^2\text{)} \times \text{time(s)} \times \text{pressure difference (mmHg)}}$$

5.2.1 **oxygen permeability,** Dk: The most commonly used gas permeability for contact lens materials. NOTE – units are (cm^2/s) ($ml\ O_2/[ml \times mmHg]$), or $cm^3[O_2] \times cm/cm^2 \times s \times mmHg$. For Dk units in terms of hectopascals instead of mmHg $cm^3[O_2] \times cm/cm^2 \times s \times mmHg \times 0.75$.

5.4 **oxygen flux,** j: Amount of oxygen (μl), per unit of time(s), which diffuses through a unit area (cm^2) of a contact lens under specified conditions. NOTE – The specified conditions include temperature, thickness of the sample and partial pressure of oxygen on both sides of the sample.

5.5 **oxygen transmissibility,** $\frac{Dk}{t}$: Value for oxygen permeability divided by the thickness (cm) of the measured sample under specified conditions.

5.6 **water content**: Proportion by mass of water retained within a lens under specified conditions.

6 Multifocal and progressive power lenses

6.2 **bifocal lens**: A multifocal lens having two portions, usually for distance and near.

6.5 **centre near (CN) lens**: A multifocal or progressive power lens designed to correct presbyopia where the maximum plus (or minimum minus) power is found in the central optic zone of the lens.

6.6 **concentric bifocal lens**: A lens having two optic zones of different power, each having coincident geometric centres. NOTE – This excludes diffractive bifocal lenses.

6.9 **fused segment lens**: Multi-focal lens made from materials of different refractive indices.

6.10 **multifocal lens**: A lens designed to provide two or more visibly divided zones of different corrective powers.

6.11 **peripheral optic zone(s)**: Optic zone(s) surrounding the central optic zone of a concentric multifocal.

6.13 **progressive optical zone**: An aspheric zone designed to provide a continuous change of surface power.

7 Scleral lenses and shells

7.1 **back scleral size**: Maximum internal dimension of the back scleral surface before the sharp edge has been rounded.

7.3 **impression lens**: Scleral lens, the back surface of which has been produced by moulding from a cast of the eye.

7.6 **preformed scleral lens**: Scleral lens, not an impression lens, the back surface of which is of a predetermined form.

7.7 **primary optic diameter**: The diameter of the optic zone before any transition is added. NOTE – In a case where the optic zone is not circular, the longest chord passing through the geometric centre is used.

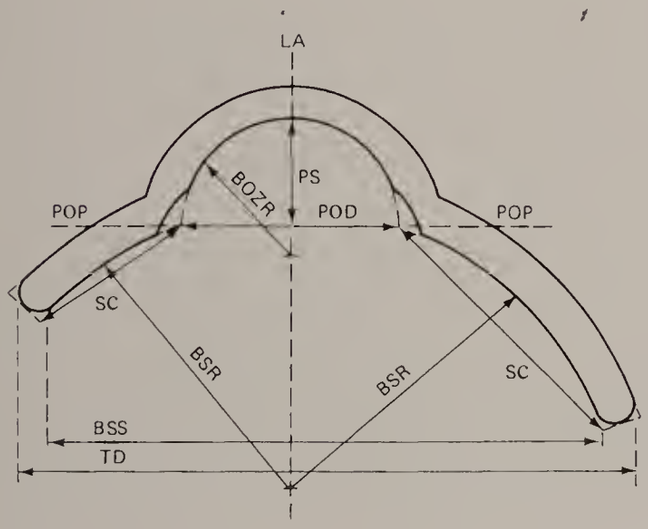
7.8 **primary optic plane**: Plane perpendicular to the lens axis and containing the primary optic diameter.

7.9 **primary sagitta**: Distance along the lens axis from the back vertex of the optic zone to the primary optic plane.

7.10 **scleral chord**: In a specified meridian, the distance from the optic-scleral junction to the junction of the back scleral surface with the edge.

7.11 **scleral thickness**: Thickness of the scleral zone measured normal to the front scleral surface at any specified point.

7.12 **scleral zone**: That zone of a scleral lens (or shell) designed to lie in front of the sclera.



Abbreviation	*Term*
LA	lens axis
BOZR	back optic zone radius
PS	primary sagitta
POD	primary optic diameter
POP	primary optic plane
SC	scleral chord
BSR	back scleral radius
BSS	back scleral size
TD	total diameter
d	displacement

8 Dimensional terms

8.1 **Radius of curvature** (r): NOTE – Radii relating to zones on the back of the lens are designated by a numerical subscript starting with zero (r_0). The subscript becomes larger from the lens centre to the lens edge. Radii relating to the front surface of the lens have a double subscript, the first part of which is the letter a. The second part is a number from zero upwards, for example, r_{a2}. In the case of an aspheric zone, a mathematical equation or expression may be used to describe the curvature of the zone.

8.1.1 **back optic zone radius (base curve)**, r_0: Radius[1] of curvature of the back optic zone of a surface with a single refractive element.

8.1.1.1 **back central optic radius**, r_0: Radius of curvature of the back central optic zone of a multifocal lens.

8.1.1.2 **back peripheral optic radius**: Radius of curvature of a back peripheral optic zone of a multifocal lens.

8.1.2 [2]**back peripheral radius**: Radius[1] of curvature of a back peripheral zone.

8.1.3 **front optic zone radius**: Radius[1] of curvature of the front optic zone of a surface with a single refractive element.

8.1.3.1 **front central optic radius**: Radius of curvature of the front central optic zone of a multifocal lens.

8.1.3.2 **front peripheral optic radius**: Radius of a curvature of a front peripheral optic zone of a multifocal lens.

8.1.4 [2]**front peripheral radius**: Radius[1] of curvature of a front peripheral zone.

8.2 Diameters (∅)

In cases of elliptical shapes, the maximum and minimum sizes are used for measurement purposes. Elliptical zones which are toroidal, or adjacent to a toroidal zone, have their diameter specified on the flattest meridian. In lenses with concentric posterior surface zones, the zones are qualified by a subscript number from zero starting with the innermost zone ($\varnothing_0$). On the anterior surface the number is always preceded by the letter a, for example ($\varnothing_{a0}$).

8.2.1 **back optic zone diameter**: Diameter of the back optic zone on a surface with a single optical component[3].

8.2.1.1 **back central optic diameter**: Diameter of the posterior central optic zone of a concentric multifocal lens.

8.2.1.2 **back peripheral optic diameter**[2]: Diameter of a posterior peripheral optic zone of a concentric multifocal lens.

8.2.2 **back peripheral zone diameter**[2]: Diameter of a back peripheral zone.

[1] On a toroidal zone there will be two values.
[2] May be preceded by first, second, third etc.
[3] The optic zone of a toric periphery lens is usually elliptical in shape.

8.2.3 **displacement of optic** (for lenses other than scleral lenses), *d*: Displacement of the optic zone relative to the lens periphery.

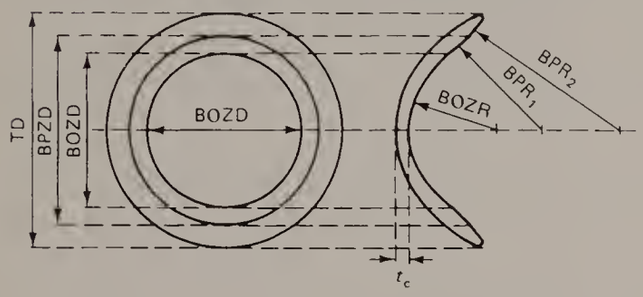
8.2.4 **front optic zone diameter**: Diameter of the front optic zone on a surface with a single refractive element[1].

8.2.4.1 **front central optic diameter**: Diameter of the anterior central optic zone of a multifocal lens.

8.2.4.2 **front peripheral optic diameter**: Diameter of an anterior peripheral optic zone of a multifocal lens.

8.2.5 **front peripheral zone diameter**: Diameter of a front peripheral zone.

8.2.9 **total diameter,** $\varnothing_T$: Maximum external dimensions of the finished lens or shell. NOTE – In the cases of truncated lenses, the short axis is taken as a line passing through the mid-point of the truncation(s) and the lens axis. The major axis is perpendicular to the short axis and also passes through the lens axis.



8.3 Thickness

8.3.1 **axial thickness,** t_A: Thickness of the lens, parallel to the lens axis, at a specified position.

8.3.1.1 **axial edge thickness,** t_{EA}: Axial thickness at a defined point from the edge.

8.3.3 **geometric centre thickness,** t_C: Thickness of the lens or shell at its geometric centre.

8.3.4 **harmonic mean thickness,** t_{HM}: Thickness of a radially symmetrical lens calculated from the expression

$$t_{HM} = \frac{h + 1}{1/t_0 + 1/t_1 + 1/t_2 + 1/t_{3..}} \quad \ldots\ldots\ldots 1/t_h$$

where h + 1 is a series of concentric annuli of equal surface area from the lens geometric centre to the edge of the exposed sample area.

8.3.4 **optical centre thickness**: Thickness of the lens at its optical centre.

8.3.6 **radial thickness,** t_R: The thickness of a lens along a line which passes through the centre of the vertex sphere and intersects the lens at a specified point.

8.3.6.1 **radial edge thickness,** t_{ER}:Thickness of the lens measured normal to the front surface at a specified distance from the edge, for example, $t_{ER(0,2)}$ indicates the radial edge thickness is measured 0.2 mm from the lens edge.

[1] The optic zone of a toric periphery lens is usually elliptical in shape.

9 Table of symbols

Dimension	Symbols	Reference to text
Back optic zone radius	r_0	8.1.1
Back central optic radius	r_0	8.1.1.1
Back peripheral optic radius	r_1, r_2, ...	8.1.1.2
Back peripheral radius	r_1, r_2, ...	8.1.2
Front optic zone radius	r_{a0}	8.1.3
Front central optic radius	r_{a0}	8.1.3.1
Front peripheral optic radius	r_{a1}, r_{a2}	8.1.3.2
Front peripheral radius	r_{a1}, r_{a2}	8.1.4
Back optic zone diameter	$\varnothing_0$	8.2.1
Back central optic diameter	$\varnothing_0$	8.2.1.1
Back peripheral optic diameter	$\varnothing_1$, $\varnothing_2$, ...	8.2.1.2
Back peripheral zone diameter	$\varnothing_1$, $\varnothing_2$, ...	8.2.2
Front optic zone diameter	$\varnothing_{a0}$	8.2.4
Front central optic diameter	$\varnothing_{a0}$	8.2.4.1
Front peripheral optic diameter	$\varnothing_{a1}$, $\varnothing_{a2}$	8.2.4.2
Front peripheral zone diameter	$\varnothing_{a1}$, $\varnothing_{a2}$	8.2.5
Total diameter	$\varnothing_T$	8.2.9
Axial thickness	t_A	8.3.1
Axial edge thickness	t_{EA}	8.3.1.1
Carrier junction thickness	t_{CJ}	8.3.2
Geometric centre thickness	t_C	8.3.3
Harmonic mean thickness	t_{HM}	8.3.4
Peripheral junction thickness	t_{PJ}	8.3.5
Radial edge thickness	$t_{ER\ (suffix)}$	8.3.6.1
Axial lift	l_A	2.1
Axial edge lift	l_{EA}	2.1.1
Radial lift	l_R	2.41
Radial edge lift	l_{ER}	2.41.1
Back vertex power	F'_v	2.2
Front vertex power	F_v	2.22
Displacement of optic	d	7.2; 8.2.3
Luminous transmittance	τ	5.3
Oxygen permeability	Dk	5.2.1
Oxygen flux	j	5.4
Oxygen transmissibility	Dk/t	5.5

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Chapter 1

The history of contact lenses

A. G. Sabell

General developments in the contact lens field p. 1
The development of eye impression procedures p. 6
Development in contact lens design and materials p. 9
Epilogue: some contact lens personalities p. 14

A study of the history of contact lenses is necessary if only to appreciate how fruitful of ideas were our predecessors. It is hoped, therefore, that readers will not pass over this chapter as having little relevance to modern contact lens practice, for it is upon the foundations of the past that we operate today. Likewise, the contributions which we make, may help to cement the structure upon which our successors will continue to build.

Many years have elapsed since the assembly of material for the first history chapter and some comments can now be made on some subsequent developments. Nevertheless the reader is likely to find useful material on more recent events leading up to the individual topics being covered in later chapters.

Continuing development of lenses and care products has demanded huge research expenditure. This has been further increased by demands made by government departments in several countries to safeguard the public from various potential hazards, both real and imaginary. The outcome has been that contact lens manufacturing has been increasingly taken over by large multinational organizations. There has been a reduction in 'custom-made' laboratories where the manufacturer waited to be told by the practitioner what was required for any given patient. This seems to have been replaced by 'off-the-peg' lenses bearing some proprietary name. Since the early 1960s the pharmaceutical industry has expanded its influence within the contact lens world. Gone are the days of the 1950s when one spoke of 'solutionless contact lenses'. Even the manufacturing of some forms of contact lens has been taken over by the pharmaceutical world.

The influence of the academic sector has also brought about considerable changes over the past 30 or so years. A marked increase in numbers of research papers is apparent, some creating changes of a lasting nature while others may give rise to passing fads which, given the passage of time will be seen in better perspective and it is always of interest to the historian to notice from time to time the revision of some long-lost idea.

General developments in the contact lens field

Optical principles

Several well-defined periods of development are recognizable from a survey of the broader aspects of contact lens history. The first of these hinges on theorizing about the optics of neutralization of the corneal surface in water. Experimental work of this period does little more than illustrate something of the optical theory which underlies the use of the contact lens as a vision aid. This period begins with our earliest known reference, by Leonardo da Vinci, and the reader is referred to the detailed papers by Ferrero (1952) and by Hofstetter and Graham (1953) for a fuller description of this work. A useful general paper on Leonardo is that by Gasson (1976). The actual work by Leonardo da Vinci, claimed by some authors to pertain to the history of contact lenses, appears to consist of the construction of a large transparent globe intended to form a model of the human eye. This globe being filled with water, into which the observer immersed his face, resulted in the optical neutralization of the observer's corneas. Other than the fact that the corneal surface is neutralized, it is difficult to see precisely what relevance this has to the history of the contact lens.

The work of René Descartes (1637; *Figure 1.1*) has been well described by Enoch (1956) and does perhaps begin, if somewhat remotely, to have some bearing on the contact lens. The elongated water-filled tube used by Descartes to enlarge the size of the retinal image would certainly have been impossible to wear as an appliance for the correction of vision. Duke-Elder (1970) also cites the experiments of Philip de la Hire around 1685 as having relevance to the history of contact lenses.

The contribution of Thomas Young (1801) provided the immediate stimulus leading to the first optical correction of astigmatism by Airy (1827) and in turn triggered the now famous speculation by Sir John Herschel (1845) (*Figure 1.2*). Herschel's far-seeing comments link the early period associated with optical theories with the beginnings of the

78 LA DIOPTRIQUE

plus prés de luy; ou meſme quelque peu d'auantage, a cauſe que ce ne ſera plus ſur la ſuperficie de l'œil qu'ils commenceront a ſe croiſer, mais pluſtoſt ſur celle du verre, dont l'obiet ſera vn peu plus proche; ils formeront vne image, dont le diametre ſera douze ou quinze fois plus grand qu'il ne pourroit eſtre ſi on ne ſe ſeruoit point de ce verre: & par conſequent ſa ſuperficie ſera enuiron deus cens fois plus grande, ce qui fera que l'obiet paroiſtra enuiron deux cent fois plus diſtinctement. au moyen de quoy, il paroiſtra auſſy beaucoup plus grand, non pas deus cent fois iuſtement, mais plus ou moins a proportion de ce qu'on le iugera eſtre eſloigné. Car par exemple, ſi en regardant l'obiet X au trauers du verre P, on diſpoſe ſon œil C, en meſme ſorte qu'il deuroit eſtre pour voir vn autre obiet, qui ſeroit a 20 ou 30 pas loin de luy, & que n'ayant d'ailleurs aucune cognoiſſance du lieu ou eſt cet obiet X, on le iuge eſtre veritablement a trente pas, il ſemblera plus d'vn milion de fois plus grand qu'il n'eſt. en ſorte qu'il pourra deuenir d'vne puce vn elephant; car il eſt certain que l'image que forme vne puce au fonds de l'œil, lors qu'elle en eſt ſi proche, n'eſt pas moins grande, que celle qu'y forme vn elephant, lors qu'il en eſt a trente pas. Et c'eſt ſur cecy ſeul qu'eſt fondée toute l'inuention de ces petites lunetes a puce compoſées d'vn ſeul verre, dont l'vſage eſt par tout aſſés commun: bien qu'on n'ait pas encores connu la vraye figure qu'elles doiuent auoir: & pource qu'on ſçait ordinairement que l'obiet eſt fort proche, lors qu'on les employe a le regarder, il ne peut paroiſtre ſi grand, qu'il ſeroit, ſi on l'imaginoit plus eſloigné.

Voyés en la page 74.

11

DISCOURS SEPTIESME. 79

Il ne reſte plus qu'vn autre moyen pour augmenter la grandeur des images, qui eſt de faire que les rayons qui vienent de diuers points de l'obiet, ſe croiſent le plus loin qu'il ſe pourra du fonds de l'œil. mais il eſt bien ſans cõparaiſon, le plus important & le plus conſiderable de tous. Car c'eſt l'vnique qui puiſſe ſeruir pour les obiets inacceſſibles, auſſy bien que pour les acceſſibles, & dont l'effet n'a point de bornes: en ſorte qu'on peut en s'en ſeruant augmenter les images de plus en plus inſques a vne grandeur indefinie. Comme par exemple, d'autat que la premiere des trois liqueurs dont l'œil eſt rempli, cauſe a peu prés meſme refraction que l'eau commune, ſi on applique tout contre vn tuyau plein d'eau, comme E F, au bout du quel il y ait vn verre G H I, dont la figure ſoit toute ſemblable a celle de la peau B C D qui couure cette liqueur, & ait meſme rapport a la diſtance du fonds de l'œil; il ne ſe fera plus aucune refraction a l'entrée de cet œil; mais celle qui s'y faiſoit auparauant, & qui eſtoit cauſe que tous les rayons qui venoient d'vn meſme point de l'obiet commencoient a ſe courber dés cet endroit-

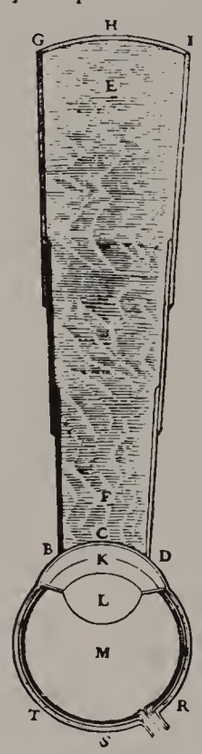


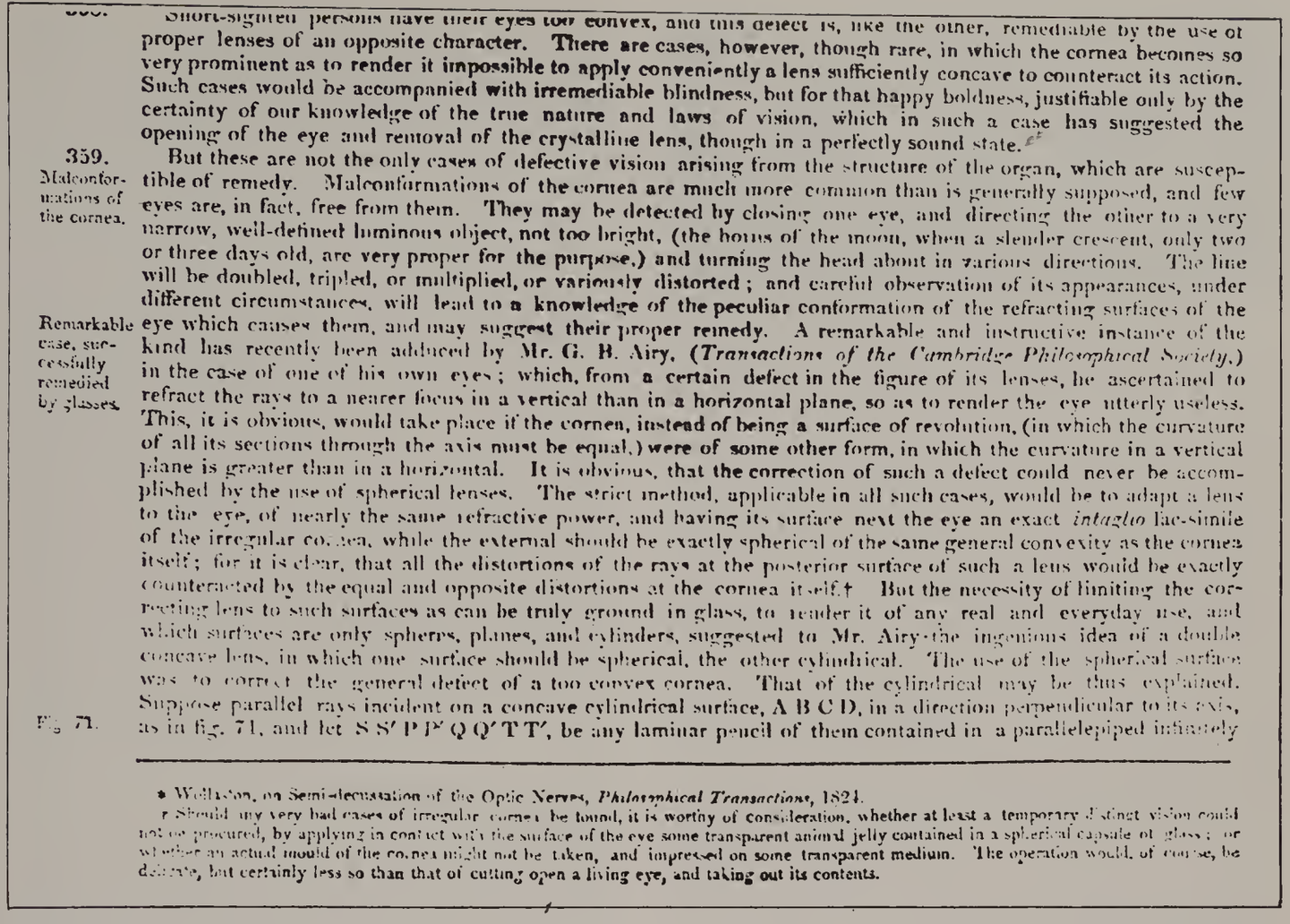
Figure 1.1 Pages from the seventh discourse of René Descartes (1637) showing his contact appliance

clinical struggle. To this man, therefore, should go the honour of envisaging the more important of the present-day areas of clinical application of the contact lens. The reason for some confusion over the dates of Herschel's publications, whether 1827 or 1845, has been discussed by Bennett (1961). Although undoubtedly of great optical significance, the work of this period contributes nothing to the subsequent struggle to achieve tolerance of a corrective appliance which must be worn on the eye of a visually handicapped individual. It might well be claimed that the earlier work had greater relevance to the development of the hydrodiascope by Lohnstein (1896) and Siegrist (1916).

Early practical trials

The second phase, that of practical clinical development, began with the work of Fick (1888), an English translation of which was made by May in the same year. This publication was preceded by two loosely related occurrences. The first was an idea put forward in 1886 by Dr Xavier Galezowsky that a gelatin disc might be applied to the cornea immediately following cataract extraction. This disc was to be impregnated with cocaine and sublimate of mercury which would provide corneal anaesthesia to relieve postoperative pain and an antiseptic cover to prevent infection. This suggestion has been quoted by Mann (1938) although she gives no specific reference to the publication. Despite the horrifying implications of such a procedure, we may see in the proposal not only the first use of a soft and hydrophilic contact appliance but also the forerunner of the hydrophilic lens as a dispenser of ophthalmic medication. The second event preceding Fick's publication was, of course, the frequently described work by the firm of F.Ad. Müller Sohne at Wiesbaden for Dr Theodore Saemisch's patient. This consisted of the supplying of a protective contact device and does not appear to have been intended primarily as a visual aid. Nissel (1965) quotes extensively from the work by Müller (1920) and also that of Müller and Müller (1910), both documents of great interest to the contact lens historian.

There also appeared in 1889 the inaugural thesis of August Müller of Gladbach, presented at the University of Kiel for his degree of Doctorate in Medicine and entitled 'Spectacle lenses and corneal lenses'. This work incorpor-



Short-sighted persons have their eyes too convex, and this defect is, like the other, remediable by the use of proper lenses of an opposite character. There are cases, however, though rare, in which the cornea becomes so very prominent as to render it impossible to apply conveniently a lens sufficiently concave to counteract its action. Such cases would be accompanied with irremediable blindness, but for that happy boldness, justifiable only by the certainty of our knowledge of the true nature and laws of vision, which in such a case has suggested the opening of the eye and removal of the crystalline lens, though in a perfectly sound state.*

359. Malconformations of the cornea.

But these are not the only cases of defective vision arising from the structure of the organ, which are susceptible of remedy. Malconformations of the cornea are much more common than is generally supposed, and few eyes are, in fact, free from them. They may be detected by closing one eye, and directing the other to a very narrow, well-defined luminous object, not too bright, (the horns of the moon, when a slender crescent, only two or three days old, are very proper for the purpose,) and turning the head about in various directions. The line will be doubled, tripled, or multiplied, or variously distorted; and careful observation of its appearances, under different circumstances, will lead to a knowledge of the peculiar conformation of the refracting surfaces of the eye which causes them, and may suggest their proper remedy. A remarkable and instructive instance of the kind has recently been adduced by Mr. G. B. Airy, (*Transactions of the Cambridge Philosophical Society.*) in the case of one of his own eyes; which, from a certain defect in the figure of its lenses, he ascertained to refract the rays to a nearer focus in a vertical than in a horizontal plane, so as to render the eye utterly useless. This, it is obvious, would take place if the cornea, instead of being a surface of revolution, (in which the curvature of all its sections through the axis must be equal,) were of some other form, in which the curvature in a vertical plane is greater than in a horizontal. It is obvious, that the correction of such a defect could never be accomplished by the use of spherical lenses. The strict method, applicable in all such cases, would be to adapt a lens to the eye, of nearly the same refractive power, and having its surface next the eye an exact *intaglio* fac-simile of the irregular cornea, while the external should be exactly spherical of the same general convexity as the cornea itself; for it is clear, that all the distortions of the rays at the posterior surface of such a lens would be exactly counteracted by the equal and opposite distortions at the cornea itself.† But the necessity of limiting the correcting lens to such surfaces as can be truly ground in glass, to render it of any real and everyday use, and which surfaces are only spherps, planes, and cylinders, suggested to Mr. Airy the ingenious idea of a double concave lens, in which one surface should be spherical, the other cylindrical. The use of the spherical surface was to correct the general defect of a too convex cornea. That of the cylindrical may be thus explained. Suppose parallel rays incident on a concave cylindrical surface, A B C D, in a direction perpendicular to its axis, as in fig. 71, and let S S′ P P′ Q Q′ T T′, be any laminar pencil of them contained in a parallelepiped infinitely

Remarkable case, successfully remedied by glasses.

Fig. 71.

* Wollaston, on Semi-decussation of the Optic Nerves, *Philosophical Transactions*, 1824.

† Should any very bad cases of irregular cornea be found, it is worthy of consideration, whether at least a temporary distinct vision could not be procured, by applying in contact with the surface of the eye some transparent animal jelly contained in a spherical capsule of glass; or whether an actual mould of the cornea might not be taken, and impressed on some transparent medium. The operation would, of course, be delicate, but certainly less so than that of cutting open a living eye, and taking out its contents.

Figure 1.2 The footnote in Sir John Herschel's dissertation on light (1845) which constituted the beginning of modern thinking on contact lenses

ates the first known use of the expression 'corneal lens'. August Müller's interests lay in the correction of high myopia (Pearson, 1978), while Fick had been eager to produce usable vision for keratoconus patients.

Almost simultaneously Eugene Kalt in Paris was investigating contact lenses which were undoubtedly of corneal lens form, as 'orthopaedic appliances' in the treatment of keratoconus. This we may regard as laying down the groundwork which has led to the consideration of the contact lens as a means of myopia control and to its use in orthokeratology.

To return to the paper by Fick (1888) which is worthy of being read and re-read by all contact lens practitioners because it contains some astonishingly accurate observations. One wonders, in the light of some of Fick's observations, why the subsequent development of contact lenses took place so slowly. For example, in addition to recommending the use of contact lenses for keratoconus, Fick suggested their potential usefulness in aphakia, as prosthetic/cosmetic lenses and also postulated the use of pinhole contact lenses. He clearly foresaw the future high cosmetic demand for the wearing of contact lenses. Fick is, of course, best remembered for his description of what, much later, became called Sattler's veil or, less commonly, Fick's phenomenon. He recognized that an adaptational process occurred enabling the wearer to become more tolerant, due to the regular usage of the contact lens, and even recognized that air trapped behind the contact lens on insertion retarded the onset of visual clouding. Fick was aware that the cause of this clouding lay in the epithelium.

Thus, by 1890 the foundations had been laid for the correction of visual errors, protection of the exposed cornea, remoulding of corneal shape, neutralization of corneal irregularity and the use of the contact lens as an applicator of ophthalmic drugs. Within this period also, the successes and failures of ocular tolerance had been recognized and the pattern of events set which were to last until about 1930. This second period of development was therefore characterized by a lack of ability to ensure both good tolerance and good vision by the majority of contact lens patients. The reasons for such lack of success were due to the limited understanding of detailed topography and physiology of the anterior segment of the eye and its responses to the contact

lens. Although Fick had, in 1888, made a succession of very relevant observations, it appears that he soon lost much of his interest in the contact lens. In his textbook *Diseases of the Eye and Ophthalmoscopy* (1896), he devoted only eight lines to the use of contact lenses.

In 1889 August Müller had described his own disappointing tolerance of contact lenses. He believed that the discomfort arose from pressure of the scleral zone of the lens on the conjunctiva. He also described the difficulty found in applying his contact lenses without air bubbles and his avoidance of this problem by inserting the lenses under water. From our understanding of the osmotic principles involved, this factor alone would account for a very limited tolerance because corneal oedema would develop within about 15 minutes. Indeed, the physical discomfort which must have resulted from the marked hypotonicity of the liquid behind the contact lens probably accounts for Müller's use of cocaine eye drops prior to inserting his lenses. It would seem, therefore, quite apart from any defects in physical fit of Müller's lenses, that he was doomed to failure by such physiological factors.

Fick (1888) had pronounced on the subject of suitable fluids for inserting contact lenses and had settled on 2% grape sugar solution, which he claimed was capable of giving 8–10 hours wear by his rabbits before corneal clouding developed. It seems likely that, had a slit lamp been available at this time, even of the level of sophistication of that used by Sattler (1938), he would have observed the corneal clouding at an earlier stage. Fick stressed the need for sterilization of his dextrose solution by boiling prior to use and also pronounced on the need for careful disinfection of the lenses themselves. Dor (1892) of Paris recommended the use of physiological saline solution as an insertion medium for contact lenses and this seems to have remained a popular choice up to the early 1940s. Perusal of Fick's 1888 paper shows that he had experimented with 'salt solutions, with various organic additions' and had discarded these in favour of his 2% dextrose. Personal experiences of various contact lens solutions around 1946 with full clearance sealed lenses convinced the author that sodium chloride solutions of various concentrations between 0.5 and 1.5% were usually rejected by patients who complained of smarting sensation and redness of the eyes.

It seems, therefore, that from about 1895 until 1930 an impasse was reached in terms of patient usage of contact lenses. Over this period the choice lay between the blown glass lenses produced by the firm of Müller's of Wiesbaden and the ground glass contact lenses such as those made by Carl Zeiss of Jena. The former were inferior in consistency of optical quality, but superior to the latter in comfort and duration of wearing. The author has described the optical and physical characteristics of several Müller and Zeiss lenses of this period (Sabell, 1980a). This lack of progress in achievement of longer wearing times with good vision did not prevent the development of ideas for utilization of contact appliances requiring only short-term application. Thus, the use of the contact splint to retain a corneal graft in position during healing has been attributed by Mann (1938) to Dr Louis de Wecker in 1900. Ideas progressed on the use of contact lenses in keratoconus and the classic form of the ground Zeiss lens began to emerge. Possibly the development by Koeppe (1918) of contact lenses for gonioscopy and for slit lamp microscopy of the fundus best illustrate the exploitation of short wearing time potential of contact lenses.

Preformed fitting sets

During the 1920–30 period, the trial fitting set as we know it today began to emerge, although Fick had in fact established the principles of preformed fitting on his rabbits around 1887 saying 'after many trials I abandoned the use of the casts and satisfied myself with obtaining glass vesicles, 21, 20, and 19 mm in diameter. ... From a large number of such small glass shells I selected the best-fitting one for each individual rabbit'. The Zeiss preformed development of the 1920–30 period began with Dr W. Stock's four lens set and developed to the massive afocal lens sets devised by Professor Leopold Heine (1929). It would seem then, that although many attempts had been made from way back in the 1880s to produce good impressions of the eye surface, a lack of achievement in this quarter had allowed the preformed lens method to be developed to a reasonable level of sophistication by 1930.

Ophthalmic impressions

It was, therefore, the development of successful methods of making eye impressions to produce accurate casts of the eye surface which opened up the next phase in contact lens development. From this point, around 1930, considerably more information on ocular topography began to accumulate, although one should note that Fick, in 1888, from his plaster of Paris impressions of the eyes of human cadavers had described the aspherical character of the scleral contours with considerable accuracy.

Obrig (1938a) reported rapid strides in the use of moulded contact lenses. By this time he considered the moulded lens to be 'the ideal conception of the perfect contact lens'. He clearly recognized that much intolerance was due to limbal pressure, especially at the nasal and temporal positions. This had been confirmed by the measurement of eye casts and he realized the inaccuracy of trying to assess corneal diameter by direct measurement of the eye itself. In some cases the cast dimensions of the cornea were 3 mm larger than those given by the measurement of visible horizontal iris diameter. From the measurement of a large number of impression casts, Obrig produced his famous table showing average corneal dimensions, which set the pattern of full corneal clearance fitting during the following decade.

The occurrence of limbal pressure from contact lenses was made more easily recognizable by Obrig's discovery (1938b) of the value of blue light with fluorescein solution in the fitting of contact lenses. Solutions of fluorescein had been used in ophthalmology since first introduced by Straub

(1888) for the investigations of corneal lesions and the method of checking corneal clearance had been by the use of the slit lamp, a technique requiring considerable expertise with this instrument. Obrig's method of observation must have contributed greatly to the comfort of many patients. The enormous value of this discovery, leading as it did in later years to considerable improvements in the activating light source, is undeniable. It is hard to envisage the handicap to the development of corneal lenses had this simple step not been taken.

Ocular topography and physiology

The 1930s, then, was a period in which the comfort of contact lenses was improved by the realization that sustained corneal pressure from the lens was undesirable. From this stemmed the large optic zone giving, initially, enhanced comfort to the wearer. This full clearance method of fitting scleral lenses was initiated by Obrig in the USA and became widely accepted in that country and also in the UK in the first half of the 1940s (Dickinson and Hall, 1946). Unfortunately, the advantages gained in comfort by a wide corneal clearance were rapidly eroded by concomitant disadvantages. First, the cosmetic appearance of this type of contact lens was poor. Secondly, the full clearance optic must remain fluid filled if visual performance was to be unimpaired. This called for a glove-like seal by the scleral zone of the lens because loose channels offer the possibility of air seepage and a resultant air bubble behind the optic zone. This zone, in this type of lens, was often fitted steeper than the cornea with a positive liquid lens, which encouraged the location of any air bubble in front of the pupil. The third and major adverse effect of the full clearance optic was the development of Sattler's veil. In a totally sealed lens, Sattler's veil would commence after some 2 hours of wear, visible to the wearer more readily indoors as a faint blue haze resembling tobacco smoke. This haze became gradually more noticeable but without any gross reduction in visual acuity in the early stages. Shortly after onset, the classic rainbow rings, resembling glaucoma haloes, would become apparent. Few patients were able to pursue contact lens wear for more than about 30 minutes after the onset of these symptoms because the developing corneal oedema brought gradual onset of photophobia, blepharospasm, and an unpleasant sensation of heat to the eyes.

It may seem curious that epithelial oedema induced by the wearing of contact lenses, which had been observed as early as 1888, should have attracted little detailed attention until the investigation by Sattler around 1936. A possible explanation may lie in the physical discomfort induced by the ground spherical contact lenses which would often force removal of the lens long before the visual phenomena associated with Sattler's veil became pronounced. The Müller lenses, on the other hand, appear to have been relatively untroubled by Sattler's veil for two possible reasons. First, the very hit-and-miss methods of selection of these lenses and the characteristic aspherical shapes of their scleral zones no doubt allowed loose channels for the relatively free passage of fresh tears to carry off the waste products of corneal metabolism. Secondly, such channels would be likely to allow seepage of air which would accumulate in the optic zone and help retard the onset of veiling. The Müller blown lenses (*Figure 1.3*) were commonly made with white scleral zones akin to artificial eyes and fluorescein assessment on these lenses would have been difficult.



Figure 1.3 Blown glass contact lenses made by Müller's of Wiesbaden (about 1900) showing the white scleral zones. (From the museum, Department of Vision Sciences, University of Aston)

Contact lens solutions

The observation that tonicity and pH of solution may have some bearing on the onset time of Sattler's veil, led to considerable time being wasted during the late 1930s and early 1940s in the search for the ideal contact lens solution. Obrig and Salvatori (1957) describe vividly the wide range of possibilities which were explored. Changes noted in pH of the contact lens liquid during wear led to the trial of buffered solutions such as those formulated by Gifford and Smith (1933), Gifford (1935) and by Feldman (1937). This, in turn, led to the adoption by contact lens practitioners of the term 'buffer solution', used incorrectly to mean any suitable fluid used to form the liquid lens behind an unfenestrated contact lens, a term now rarely heard. It seems likely that this adoption of the term arose out of the supposed mechanical cushioning effect of the reservoir of liquid held behind the contact lens.

However, not all workers were led astray by the apparent comfort of wide corneal clearance, and the search for the 'elixir' of an ideal contact lens solution. Two notable exceptions in the 1930s were A. Mueller-Welt and Joseph Dallos, the latter laying down physiological principles for the fitting of scleral contact lenses which have not been improved on since. Working on the assumption that the natural body fluid offers the best chance of success, Dallos in the 1930s set out to conserve the tear reservoir and to allow for its interchange by fresh tears.

Acrylic contact lenses

Several other developments at this time were to stimulate interest in contact lenses and to herald in the current era of widespread contact lens usage. First was the gradual

introduction of plastics to replace glass. Several plastic scleral lenses which predate the introduction of PMMA have been described by the author (Sabell, 1980b). Early attempts with plastics in the USA failed principally through unsuitability of available materials.

The compromise introduced by William Feinbloom, of a scleral lens using a plastics material for the haptic portion and enclosing a glass optic zone, presented the 'half-way house' in the development of plastic scleral lenses. In his report Feinbloom (1936) acknowledged the name of 'Mr George S. Weith, chief of Research Division of the Bakelite Corporation of America', with having developed this suitable resin.

In Europe, the earliest user of PMMA as a material for contact lenses was Dr Istvan Györffy of Hungary, following the move of Dr Dallos to London shortly before the outbreak of the Second World War. During a visit to Germany in 1938, Dr Györffy's attention was drawn to the acrylic material being produced under the name 'Plexiglas' (Györffy, 1964). According to Anderson (1952) this material had been developed in 1932 by ICI scientists. Györffy appreciatcd the potential of this material for avoiding some of the complexities associated with the production of the Dallos type of glass lenses with which he had been working. On his return to Budapest he developed a technique for moulding this sheet plastic and for grinding the back and front optic surfaces. By late 1938 he had begun to fit these acrylic scleral lenses to his patients and later went on to fit corneal lenses in this material (Györffy, 1940, 1950, 1968, 1980, 1981).

The final introduction in the USA of the all-plastic, moulded scleral lens was made by Obrig Laboratories. In the United Kingdom by contrast, the introduction of acrylic scleral lenses was made with the lathe-turned preformed lenses developed in 1938 by the firm of C. W. Dixey & Son Ltd (1943). The availability of acrylic scleral lenses not only simplified methods of production but also made lens modification quicker and easier to perform. Their introduction also opened the way to the development of successful corneal lenses.

Further improvements in the 1940s of Dallos' minimum clearance lenses (Dallos, 1946; Bier 1945, 1948) transformed patients' wearing times to all-day wear, and the introduction of acrylic materials allowed for the development of corneal lenses.

The development of eye impression procedures

In 1845 Herschel had discussed whether an actual mould of the cornea might not be taken, and impressed on some transparent medium. Fick (1888) explored this possibility and referred to his plaster of Paris eye impressions of rabbits and also of human cadavers. With respect to the rabbits, Fick described his technique in the following terms: 'In one of these animals, I drew the lids and nictitating membrane from the eyeball and filled the resulting sac with plaster of Paris of fluid consistence.' No mention is made of the use of a shell and because the plaster would set to a completely rigid state, such an appliance would seem unnecessary.

August Müller (1889) also mentioned living eye impressions taken in plaster of Paris and regarded it as a potentially suitable technique. From the present viewpoint, the setting characteristics of plaster of Paris make it obvious to most that it is an unsuitable material for reproducing accurately the shape of a living and potentially mobile organ which can be distorted by pressure or indeed from its own movement. This factor apart, the absorbent qualities of the drying plaster must create marked disturbance of the epithelial surface and its mucin coating. Additionally, these very early workers would have had only cocaine eye drops available as a local anaesthetic, a drug which, because of local cellular toxicity, is now regarded as unsuitable for eye impressions even in conjunction with the greatly improved modern impression materials. From around 1890, although various attempts at refining the technique were made, little progress was achieved until after 1930.

In 1928, Joseph Dallos, approaching final qualification as a physician, joined the staff of the No. 1 Eye Clinic at the Royal Hungarian Peter Pázmány University at Budapest (*Figure 1.4*). Dallos quickly developed an interest in the use of contact lenses for correction of visual defects, but was frustrated by the limited choice afforded between the ground Zeiss lenses and blown Müller lenses of the time. Around 1931, Dr Alphons Poller of Zurich had described a material derived from seaweed which was intended for preparation of surface impressions to make anatomical models. Shortly afterwards, in turning his thoughts towards eye impressions, Dallos' attention was drawn to Poller's Negocoll. His first trial with this material was made on a cadaver, the skin of the face, nose and eyelids being reproduced. Between the partially closed eyelids, a section of the corneal surface was reproduced with a smooth polished texture. Dallos prepared a positive cast of this impression in the wax-like substance Hominit (*Figure 1.5*) and the smooth appearance of the visible corneal segment convinced him that Negocoll would be a suitable medium for ophthalmic impressions (J. Dallos, 1977, personal communication). Dallos went on to evolve a satisfactory impression routine by using Müller contact lenses as impression trays. Some early Dallos impression casts were illustrated by the author (Sabell, 1980c). Although he was the originator of the modern impression technique, Dallos was never completely satisfied with the results achieved. After a few years he accumulated a large enough collection of glass shells made from his earlier impressions to enable him to avoid, with most patients, the necessity of taking further impressions. Gradually this set of 'type shells' grew until it contained several thousand shells from which a very near fit could be selected for almost any eye. As Dallos demonstrated, it is not the initial selection or the initial impression which provides the finished lens, but the careful tailoring of this preliminary form to the precise requirements of the individual eye. To this modification procedure



Figure 1.4 The staff of the No. 1 Eye Clinic at the Royal Hungarian Peter Pázmány University, Budapest (about 1930). Dr Joseph Dallos is standing, second from the right. Professor Le Grosz is seated, front row, third from the right

Dallos gave the title 'haptics', which he described in 1936, as 'a new branch of prosthetics'.

Stevens (1936) described an alternative method of eye impressions using Negocoll. In contrast to Dallos' use of a Müller lens as an impression tray, she reverted to the use of aluminium tubes used in the same manner as von Csapody's glass cylinders (1929) which rested on the eye surface and held the lids apart. These metal tubes, about 1 inch (2.5 cm) in length, were squeezed to form an oval section corresponding more nearly to the palpebral aperture.

Obrig at this time was employing a funnel-shaped blown glass shell, some 22 mm in diameter and 7 mm deep, having a handle about 25 mm long. He recommended plugging the hollow blown handle with cotton wool to aid retention of the Negocoll. These shells were marked with coloured spots or lines, red for right and light blue for left, which also served to indicate the position of the nasal canthus on the otherwise round shell. If too much Negocoll was inserted with the shell, it tended to flow out beneath the lids such that it adhered to the eye surface and pulled away from the impression tray during removal. These early glass trays had no perforations to encourage the material to key on.

It is interesting to note that the early Zeiss moulded lenses introduced about 1936, which Obrig (1937) envisaged ordering from his casts, were stated to be oval in shape with



Figure 1.5 The original Homminit cast made from the first impression made by Dallos using the new material 'Poller's Negocoll' (about 1932). The right eyelids and nasal profile of the cadaver are clearly visible. (From the museum, Department of Vision Science, University of Aston)

dimensions of only 20 × 19 mm. In 1938 he described a new design of impression tray and recognized the need to have a range of different sizes to cater for variations in eye size, palpebral aperture, lid tension etc. (Obrig, 1938b). Obrig's choice of material was still Negocoll, but his impression trays, although still of blown glass, were now oval in a range of sizes from 22 × 24 mm to 24 × 26 mm, the bowl being much nearer in shape to that of the Müller contact lens. He reported having performed over 400 impressions and had obviously resolved many of the points of difficulty encountered by earlier workers. He did, however, remark on the necessity in several instances to take up to three impressions of each eye in order to achieve a successful result. Against such problems should be judged therefore, the slightly earlier decision by Dallos to abandon the impression method in favour of using 'type shells'.

It is clear that, with the use of such non-perforated shells, excess Negocoll would be forced outwards into the fornices and it does appear that large particles had to be sought for and extracted following the removal of the impression itself. This problem has been largely eliminated with modern impression materials and perforated trays (*see* Chapter 17). Although attention was paid to the improvement of impression techniques by various workers, for example Chisholm (1940), in developing methods and ideas for fixation and positioning of the eye, it is probably in the field of improved impression materials that most progress has been made. Maisler (1939) described the adaptation to ophthalmic use of 'a reversible hydrocolloid gel' introduced some months earlier by a San Francisco dental surgeon. This material – Kerr's hydrocolloid – was manufactured by the Detroit Dental Manufacturing Company, and was packaged in collapsible toothpaste-type tubes. The tube was immersed in hot water and kneaded to soften the consistency of the material. The hydrocolloid was employed on the eye between 104°F and 100°F (40°C and 38°C). After removal, dental plaster or stone was used to make the positive eye cast. Maisler found that the blown glass impression trays as recommended by Obrig (1938a) were too fragile and described his own trays made in silver which could be made sufficiently thin to be malleable and therefore adjusted in contour to suit the individual eye. Maisler's shells were described as having perforations 'to obtain a better fixation between the gel and the moulding shell'. This may well be the origin of this design feature which is almost universally applied today.

The introduction of cold-water mixed impression materials provided a considerable improvement in this method of fitting contact lenses. Obrig (1943) introduced the first cold alginate impression material intended specifically for ophthalmic work. This was Ophthalmic Moldite, a material used by practitioners for nearly 30 years. By this time he was employing acrylic impression trays in place of his earlier blown glass ones. These new shells also had hollow tubular handles but had perforations around the bowl and he would appear, therefore, to have adopted this feature of the Maisler shells.

By 1945 therefore, cold setting impression materials were firmly established. Dental Zelex was commonly employed in the UK until about 1947 when Obrig Laboratories opened a London branch and Moldite became readily available. Along with the arrival of Obrig Laboratories, came an impression technique new to the UK. This was the so-called 'injection method' which is still widely used.

Steele (1948) drew attention to the development by American optometrists of the technique of taking eye impressions without using any form of anaesthesia. The need for this variation in procedure was brought about by the drugs laws in the USA which necessitated the presence of a physician to instil the local anaesthetic drops. (The same legal restriction also led to the development by US optometrists of the technique of scleral tonometry.) It would seem logical that the injection method was developed so that the patient's eye could remain stationary while the impression material was being applied and avoid unseen contact between the cornea and the impression shell. The author was a subject for a demonstration of this non-anaesthetic method by one of Obrig's staff shortly after the opening of the London branch. It was certainly not a painful process but would have been unsuitable for use on the more apprehensive type of patient because good relaxation is an essential feature of first-class impressions.

Shortly after this time, Jessen and Wesley (1949) published their account of what was claimed to be a new method of taking eye impressions, which they called 'concentric molding'. The technique hinged on the use of a contact lens-like impression tray with no handle. A description was given of the design for such an impression tray, no perforations being mentioned and the description of the procedure suggests that none was employed. The inside of the tray was 'scored or grooved' for good adhesion of the Moldite. The theory behind the concentric method was that, provided the impression tray has the same dimensions and proportions as the finished lens, it will centre itself accurately with its optic zone corresponding to the patient's cornea, therefore, the positioning of the eye by means of visual fixation of the contralateral eye will be unnecessary.

The method of using trays without handles was subsequently developed to a high level of efficiency by F. A. B. Hodd and provided, in certain circumstances, a technique superior to the use of trays with fixed handles.

Returning to the subject of impression materials, the introduction in the UK around 1950 of specifically prepared Ophthalmic Zelex packaged into single-dose plastic tubes is worthy of note. Ophthalmic Moldite had always been available in multiple dose, metal foil packages, so that the introduction of the correctly measured amount of Ophthalmic Zelex supplied in a tube which could be used as a measure for the correct volume of water, did offer a great attraction at first. However, materials packaged in such small quantities appear to suffer loss of their setting characteristics more rapidly than when packaged in greater bulk.

In more recent years there was a reversion to dental alginates as shown by the popularity of materials such as

Tissutex and Kromopan. Storey (1972) also published some observations on the possible use of polysulphide rubber impression materials and the use of silicone rubber impression materials became popular with some practitioners (A. Silk, 1982, personal communication).

As a final observation on eye impressions, the reader's attention is drawn to the work of Dallos (1964) in attempting to apply the technique of precise corneal impressions to the fitting of acrylic corneal lenses. One of these Dallos corneal casts has been illustrated (Sabell, 1980b). It is appropriate to conclude this section on the development of eye impressions by quoting Obrig and Salvatori (1957): 'The original work of Dallos in discovering and proving the use of Negocoll as a practical, satisfactory medium for making accurate moulds of the living human eye has done more than anything else to make modern contact lenses a reality.'

Development in contact lens design and materials

Fick (1888) described the contact lens as 'a thin glass shell bounded by concentric and parallel spherical segments'. Graham (1959) contended that this description could only be interpreted as 'the simple form characteristic of corneal lenses'. Fick, in fact, went on to describe his initial experiment using large rabbits and, from his plaster casts of these animals' eyes, he concluded that 'the radius of curvature of the cornea did not differ materially from that of the sclera, and the eyeball of the rabbit is pretty nearly a sphere'. After having a number of shells blown over the rabbit casts, Fick 'abandoned the use of the casts and satisfied myself with obtaining glass vesicles 21, 20 and 19 mm in diameter and with having a segment separated from these, the base of which was distant but a few millimetres from the equator of the sphere'. From these stock sizes he selected the best fit for each individual rabbit. Thus, Fick was the first to use a preformed lens approach.

Fick concluded, from his plaster casts of the eyes of a cadaver, that 'the cast of a human eye shows very plainly that the cornea is the segment of a sphere of smaller radius of curvature than the rest of the globe'. He then described having a glass sphere made and then 'a portion of this small glass globe was heated and a protrusion blown out'. Fick himself wore this first human lens for 2 hours and described his observations. Later, other subjects repeated these wearing trials. It would seem, therefore, that his first human lenses were of scleral form and that single segment types were, in fact, scleral lenses for rabbits and not corneal lenses for human eyes. Indeed, Fick's first paper on the subject was published before any of his patients were actually wearing a contact lens and was concerned with the results of his preliminary experiments and with speculation as to useful fields of application for the appliance. The lenses which he subsequently requested Professor Abbe to make for him are described as having an optic radius of curvature of 8 mm with a diameter of 14 mm and a scleral band of 3 mm width having a radius of curvature of 15 mm. This made a total diameter of just under 20 mm – decidedly a scleral contact lens.

What is certainly interesting and has a bearing on contact lens design, is that Fick recognized the following features, many of which were not utilized until many decades later:

- From the cast of the human eye 'the radius of curvature of the conjunctiva increases steadily from before, backwards as we would naturally expect when we consider that only in the immediate neighbourhood of the cornea does the conjunctiva lie directly on the globe, while further back it is separated from this by a constantly thickening layer of tendons, connective tissue, fat and muscles'.
- 'Concerning the clouding of the cornea, it was easily demonstrated that it was produced solely by the liquid. For if a glass be applied without filling it with liquid, the cornea will remain clear.'

Thus, Fick recognized the factor which has provided the limitation to usefulness of scleral lenses with spherical scleral zones. He had observed the crucial feature on which the fenestrated scleral lens was to be based many decades later as a means of solving the very phenomenon of corneal clouding with which his name was to be associated. Fick is usually, and rightly credited with an interest in correcting the sight of keratoconus patients. Such patients may have central corneal opacification for which he described the treatment of iridectomy, often followed at that time by corneal tattooing. He described the potential usefulness of a pinhole contact lens, as 'a contact lens which has been rendered opaque except opposite the artificial pupil'. This device he suggested as an alternative to corneal tattooing which too often resulted in severe infection of the eye.

Several authors have attributed the suggestion of contact lenses for aphakia to later writers, but Fick in 1888 wrote 'at the same time the high degree of hypermetropia in aphakia could be diminished by increased curvature of the glass cornea'. Fick described also the potential use of the cosmetic (prosthetic) contact shell 'by the use of a contact lens upon which the iris and a black pupil is painted'. In retrospect, therefore, Eugen Fick showed an astonishing insight into the future of the contact lens field.

Scleral lenses

The development of design in the Zeiss ground lens is an interesting study. Mann (1938) stated that the Zeiss ground lens was first produced in 1911. The first traces of a preformed fitting set approach was introduced by Stock (1920) with a four lens set. Its originator was himself a sufferer from keratoconus and intended this four lens set primarily for the investigation of that condition. Dallos (1936) credited Professor Hans Hartinger with the idea of blending the sharp junction between optic and scleral zones of the Zeiss lens and Zeiss trade literature of around 1933 offered the option of a totally blended transition. Over the course of the 1920s an increasing range of back scleral radii

was added to the original 12 mm standard radius, first, a choice of three radii 11.0 mm, 12.0 mm and later 13.0 mm. The 0.5 mm steps were then added and ultimately, according to Dallos (1936), a full range in 0.25 mm steps from 10.0 mm to 14.0 mm became available.

Around this time the 'afocal lens approach' of Professor Leopold Heine was also being evolved. This offered a choice of a large range of afocal Zeiss lenses of varying back optic zone radii with which a wide range of ametropias could be corrected purely by means of the liquid lens. The ultimate range of back optic zone radii extended from 5.0 mm to 11.0 mm and eventually these could be procured in steps of 0.1 mm. Towards 1930 it had become the practice to grind some optical power on to the Zeiss prescription lens so that a total correction could be achieved partly from the liquid lens and partly from the optical power of the contact lens. However, such optical power was limited to the order of ±7.00 D. It was not until 1933 that Dallos made the suggestion that if the front optic diameter be restricted to some 8 mm, much higher optical values would become possible and a great saving effected in thickness and weight.

Another of the major contributions by Dallos to contact lens technology in the early 1930s was the development of glass moulding as a means of producing the initial contact shell. It became necessary to perfect a series of stages by which the Negocoll impression and its resultant Hominit positive could be transposed via plaster of Paris into a brass die suitable for the glass moulding procedure. This process was described in some detail and illustrated by the author (Sabell, 1980d). Moreover, it was important that such shells should be capable of being optically ground and polished in the central zone in order to form the clinically important link between the wearable, but optically imperfect, Müller lens and the optically good, but less well tolerated, Zeiss lens. From this point on, therefore, a third method of manufacturing contact lenses had begun, a method which was to dominate the field until well into the 1950s. It was a method equally applicable to the new acrylic materials which were to be introduced some 10 years later.

Dallos' earlier attempts at glass moulding were made in the bacteriology laboratory of the No. 1 Eye Clinic, Budapest, and were originally made of sections of cleaned photographic plates. The earliest attempts (*Figure 1.6*) were made with equipment no more elaborate than a standard laboratory tripod with bunsen burner to heat the glass plate. The metal die, which is an essential feature in the process of moulding a glass contact lens, was held by means of forceps, or some other suitable attachment, in the hand of the technician. When the glass had reached a suitable temperature as judged by its colour, the metal die was quickly thrust through the softened glass plate and the source of heat removed. On removal of the heat, the glass solidifies so rapidly that unlike moulding acrylic materials it is not strictly necessary that the die should be held in a mechanically rigid clamp. Later, presses as developed by Dallos and his team became rather more sophisticated and an example of one produced in the early 1940s is shown in *Figure 1.7*.



Figure 1.6 The results of initial experiments at moulding sheet glass made by Dallos in Budapest (about 1932). (From the museum, Department of Vision Sciences, University of Aston)

It is interesting that by 1938, Dallos, although still thoroughly disenchanted with the Zeiss lens, was also showing signs of moving away from eye impressions. With respect to the Zeiss lens he said '... the scleral periphery of these spherical glass bowls will reach the conjunctiva and touch it, but only over certain circumscribed areas. These areas are always at the edge of this ring-shaped scleral part, either on the peripheral margin, or on the limbus inside, so that even if the glass does rest on the scleral conjunctiva it never fits with its surface, but rather with sharp edges'. We were later to see, using this same reasoning, the introduction by Forknall (1948) of the 'offset scleral lens'.



Figure 1.7 A Dallos gas-operated press for the moulding of glass contact shells (about 1942). Two gas jets heat the glass blank from above and below simultaneously, while the bunsen burner heats the brass die in readiness for the moulding process. (From the museum, Department of Vision Sciences, University of Aston)

Dallos went on to develop the method of type-shell fitting which set him far ahead of his contemporaries in the achievement of long tolerance combined with good visual results. The natural outcome of these complexities in scleral lens fitting was to encourage rather than discourage an interest in the potential of the spherical preformed lens. Further impetus was given to preformed fitting in England by the introduction of the PMMA lenses of C. W. Dixey & Co. whose first experiments led to the introduction of their 'flexible contact lenses' in 1938. It is also interesting to see how the wheel has now come full circle, and the rigid gas permeable scleral lenses are usually fitted by the preformed method (*see* Chapter 17).

The 'flexible contact lens' was, at first, a plastic replica of the Zeiss lens, but the manufacturing process was unique and marks the introduction of the fourth major lens-making process. According to Ridley (1946), Dixey's were the first to use a precision lathe for cutting contact lenses from solid blocks of ICI Transpex material. This lathe-cutting process allowed much greater variability in dimensions than was readily obtainable from the glass-grinding methods of Zeiss. The Dixey lenses were of the same order of thickness as the Zeiss lens but could be made thinner (down to 0.3 mm) without becoming excessively fragile. Thus, a saving of about 60% on the weight of the glass Zeiss lens could be achieved. Dallos consistently condemned this flexibility which resulted from very thin acrylic lenses, which he saw as an obstacle to achieving the precision of corneal fit which he required (J. Dallos, personal communication).

This interest in preformed lenses was further accentuated by the introduction, between 1945 and the end of 1948, of a number of apparently new ideas. From America came a new concept by Feinbloom who had pioneered the early transition from glass to plastics. Feinbloom (1945) discarded the concept that the weight of a scleral lens was best supported over as broad an area as possible. He felt that a minimal tangential touch would not only evoke less sensation but would enable a better balance on the toroidally shaped sclera, and he introduced the 'Feincone lens'. At this time, no toric preformed scleral lenses were in regular production and the only alternative lay in the impression. The Feincone lens was, however, in the American tradition set by Obrig, a full clearance lens and therefore did nothing to reduce the effects of Sattler's veil. Watson (1947) commented on its prominent appearance and, introducing his 'Kelvin lens', he described his attempts at improving cosmetically on this American design. A fitting set of these Kelvin conic lenses was described and illustrated by Sabell (1980b). Curiously, a second conical design was announced in the same issue of *The Optician*, by Cohen (1947), whose design was also manifestly based on Feinbloom's lens. These designs were reviewed by McKellen (1949).

Also based on the Feincone lens was the 'wide angle lens' of Nissel (UK), introduced in 1947. This and the other two conical designs mentioned had one aim in common – to reduce the vast numbers of permutations introduced by the Dixey system. In theory, it was possible to order well over 3000 different Dixey lenses without repeating oneself, and this did not include variations in optical power. By standardizing the diameter of the optic zone and relating the apical cone angle of its transition region to a fixed relationship with the back optic zone radius, a considerable reduction in permutations was achieved by the wide angle design.

This post-war period saw the introduction of two other concepts worthy of note. The first, by Bier and Cole (1948), was introduced as a small set of preformed fitting shells intended to supplement the fitting sets of Dixey lenses then in use. This was the 'transcurve lens' and its originators claimed cosmetic superiority by virtue of a larger total diameter than that of the Dixey-type preformed lens. The most significant contribution associated with the transcurve lens was the introduction of the separate corneal measuring caps now referred to as FLOMS (fenestrated lenses for optic measurement). In the author's opinion, these provide one of the most useful aids for teaching students the fundamental principles of the optic fit.

The second of these post-war concepts was the 'offset lens' of Forknall (1948), designed with an aspherical scleral zone to obtain a more even pressure on the sclera. This also aided simplification of fitting by eliminating the need to adjust the scleral zone radius when the total diameter was changed. As McKellen (1963) later pointed out, this design was neglected by most contact lens practitioners and the concept achieved wider prominence only after its re-introduction by Ruben within the sphere of corneal lenses around 1966. For details of all these lenses, see Chapter 17.

One should not end this account of aspheric scleral lens development without reference to the lenses of A. Mueller-Welt. Starting with experience of making and fitting artificial eyes, Mueller-Welt established the ability to grind optical surfaces on blown lenses and later, using acrylic materials, expressed a preference for polymerization in making the initial shell rather than cutting or grinding. Mueller-Welt (1950) described the design of his lenses as having a capillary tear layer over the cornea and retaining an air cushion beneath the scleral zone. This part of the lens may incorporate several areas of differing curvature, seeking to take account of the anatomy of the insertions of the four recti muscles. Thus, with these two designs we can see the preformed advocates attempting to reproduce, in mathematical terms, the natural asphericity achieved by the practitioners using the impression or 'type-shell' approach to fitting.

Glass and acrylic corneal lenses

For some time after 1948, corneal lenses were believed by many to have originated with those devised by Tuohy and by Wöhlk. These lenses have been described by Bier (1957) and it is interesting to note that, while the name of Tuohy is much more widely known as a corneal lens pioneer, the lenses being used at that time by Wöhlk more nearly conform in size to those corneal lenses in use today.

However, Obrig and Salvatori (1957) and Graham (1959) put forward evidence of the attempted use of corneal lenses from as early as 1888. According to Graham, one of the first to draw attention to earlier usage of corneal lenses was Emerich Rakoss, who published a paper entitled 'How new is the corneal lens?' in May 1950. Both authors referred to the lenses by M. Kalt of Paris as being of corneal lens design.

There can be little doubt, however, that August Müller of Kiel University was the first to use the name corneal lenses – 'Hornhautlinsen' – although it is doubtful whether this is an accurate description of the type of lens which he employed because it was described as having a scleral radius of 12.0 mm.

Experimental corneal lenses were made by Carl Zeiss and were described by von Rohr and Stock (1912). The purpose of these lenses was to induce artificial ametropia for subjective testing of various designs of spectacle lens.

Some years later, H. J. M. Weve used glass corneal lenses to aid observation of the retina during detachment surgery. This lens was referred to by Mann (1938), and Obrig and Salvatori (1957) again published a letter from Weve on their use. These authors also quoted Zeiss records as showing a number of companies and institutions to whom glass corneal-type contact lenses were supplied in the 1935/36 period.

It is safe to assume that, while these early glass corneal lenses may have been of value for experimental work or as aids to eye surgery, they were unsuccessful as routine corrective appliances for ametropia. Obrig and Salvatori (1957) quote from a letter by Dr L. L. Forchheiner saying that these lenses could not be worn satisfactorily owing to their weight. Graham (1959) published a comparison of dimensions between a Zeiss-made 1932 glass corneal lens of thickness 0.6 mm and a 1948 acrylic lens of thickness 0.3 mm. Apart from thickness, these lenses were of similar dimensions and allowing for the specific gravity of the two materials, it would appear that the glass lens would be at least four times the weight of the plastic one. One must also bear in mind the surface characteristics of the two materials. Glass wets more readily and has a more wettable surface when on the eye. This factor has been quoted to account for a preference for glass artificial eyes by patients who have changed over to wearing an acrylic prosthesis. Because successful performance and comfort of a corneal lens depends on the ability of the upper lid to raise the lens on the cornea after each blink, it seems unlikely that glass would be a suitable material for a corneal lens. Thus, the key factor necessary for successful development of corneal lenses was the development of polymethyl methacrylate around 1932 and its introduction as a contact lens material around 1938 by Györffy in Hungary, Obrig in the USA and by C. W. Dixey and Company in England. Indeed, it may well be claimed that Dixey's development of the first precision lathes for cutting PMMA scleral lenses also played, indirectly, a major part in the success of the corneal lens.

By 1952, the Tuohy lens had become well known and yet was still a poor competitor with the scleral lenses of that period. It was not until the introduction of the single curve 'Microlens', with a total diameter of 9.5 mm in 1954 that corneal lenses appeared to offer an effective alternative to scleral lenses. This lens (Dickinson, 1954), devised jointly by W. P. Söhnges in Germany, Frank Dickinson in England and John C. Neil in the USA, proved a considerable improvement on the larger Tuohy lenses.

Bier (1957) considered 2.00 D of corneal astigmatism to represent the limit of usefulness for the Tuohy lens. By contrast, the 'Microlens' allowed fitting of up to 4.00 D of corneal toricity. Both designs, produced a hard apical pressure zone which tended to result in apical corneal erosions. With this factor in mind, the smaller and thinner microlens had obvious advantages and its designers specified that centre thickness should be calculated on the basis of an afocal lens of centre thickness 0.2 mm.

With these early corneal lenses, most patients preferred what would today be regarded as an alarmingly flat fit. This situation tended to persist until the introduction of multi-curve lenses of the late 1950s having a narrow but very flat edge bevel. These became popular as the 'Sphercon' lenses introduced into the UK by John de Carle (1953).

Concern over corneal apical erosion and corneal curvature changes resulting from long periods of microlens wear led to the establishment by Bier (1956a,b) of a new principle of fitting. His 'contour lens' of similar size and thickness to the 'microlens' could, by virtue of its smaller back optic zone diameter (BOZD), be fitted nearly in alignment with the central zone of the cornea, thereby minimizing to a considerable degree the central erosion problem. Edge clearance was still maintained by a peripheral curve some 1.25 mm wide. Bier postulated that flatter corneas were likely to require a greater peripheral curve flattening relative to back optic zone radius (BOZR) than steeper corneas. He therefore recommended fitting sets in which the degree of peripheral flattening ranged from 0.3 mm at the 7.3 mm BOZR region to 0.7 mm at the 8.5 mm end of the range. This system does make for some complications in using such a set and from about 1960 it became more common to employ fitting sets with a standard peripheral flattening throughout the full lens range. It is interesting to note that with later trends to establish fitting sets having a constant edge lift, we moved back towards the principle established loosely by Bier in 1956. With his introduction of the contour lens, Bier also laid down the principles of apical clearance fitting, producing a slightly modified design of lens for this purpose. This mode of fit, however, was not popular and did not gain acceptance until later design changes allowed its full exploitation.

Two main changes in design paved the way to apical clearance fitted corneal lenses. The first of these was the Sphercon lens which was a modification of a slightly earlier American design of the same name. The popularity of these lenses developed in the UK over the early 1960s and established firmly the multi-curve principle.

The second feature, also seen in the Sphercon range of lenses, was the reduction of total diameter with fitting sets of standard lenses around 9.20 mm and smaller lenses of 8.70 mm.

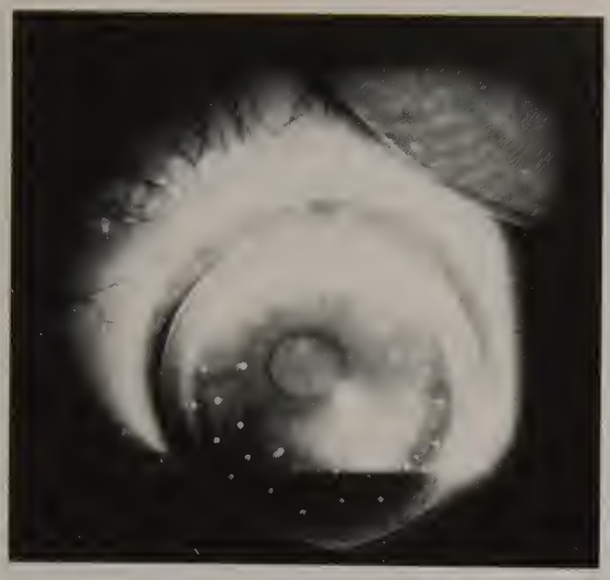


Figure 1.8 A multifenestrated PMMA corneal lens made in the USA around 1970. A laser beam was used to produce the 40 fenestrations simultaneously

The trend towards narrower intermediate and peripheral zones in tri-curve, tetra-curve and penta-curve corneal lenses at this time led, via blending of transitions, to the manufacturing of various continuous back surface designs. Thus the late 1960s were characterized by the establishment of a series of aspheric corneal lenses ranging from the tangential conic periphery designs of Thomas (1968) and Stek (1969) through the continuous offset bi-curve principle (Ruben, 1966; Nissel, 1967), to the lathe-cut continuous aspheric lens of Nissel (1968). Over this period, and before the wider acceptance of the small ultrathin PMMA lenses, fenestration was frequently employed with corneal lenses to minimize central corneal oedema.

Unfortunately, the fenestration of such steep corneal lenses seemed to encourage the so-called 'dimple veil' (*see* Chapter 18). Occasionally the urge to fenestrate corneal lenses seems to have got out of hand (*Figure 1.8*). Despite the enhanced tear exchange, this particular patient had developed extensive superior corneal neovascularization. Recent attempts at multiple fenestrations produced by laser are still being assessed.

We have thus reached the present-day period with a wide range of corneal lens designs, including toric and multifocal lenses available for selection by practitioners in order to fit successfully the vast majority of prospective patients.

A discussion of rigid corneal lenses should not end without reference to the 'Apex lens' of Fraser and Gordon (1967). This, like the scleral design of Lewis (1970) was a lens designed specifically for the hospital service. The name 'Apex' – said to be derived from 'aphakic experiment' – clearly defines its area of application. It is a large corneal/perilimbal design which, in an aphakic prescription, is necessarily fairly thick and heavy. The great advantage of this design which has been discussed by Ruben (1967) lies, for aphakics, in the stability of vision resulting from the limbal locating characteristics (*see* Chapter 20.2). However, the long-term use of this type of lens may lead to corneal neovascularization.

'Soft' lenses

The announcement in the *New Scientist* on 18 January 1962 that O. Wichterle and D. Lim in Prague had developed contact lenses made of a new 'hydrocolloid' material did not give rise to any great elation elsewhere. The short report announced that the Czechs had, with the new soft lenses, been able to achieve wearing times of up to 8 hours in 10% of patients fitted. The bi-curve hard corneal lenses of the late 1950s further improved by multi-curve designs similar to those in wide use today enabled some 75% of patients to achieve 12–16 hours of continuous daily wear. The prospect, therefore, of 8 hours' tolerance from the hydrophilic lens did not raise much enthusiasm (Wichterle *et al.*, 1961). The hidden potential in the Czechoslovakian lens lay in the ability, by employing mass production methods, to provide cheap 'off-the-peg' contact lenses which might be fitted in a matter of minutes.

Dreifus (1978) reviewed the early work leading to the announcement of hydrophilic plastics for medical applications and described the investigations using experimental animals to assess toxicity to the intraocular tissues and to determine the effect of the early hydrogel (soft) lenses on corneal metabolism. He described some of the initial resistance by clinicians to the use of this new and revolutionary form of contact lens, some of the early clinical experiences using these Geltakt lenses, the original experimental forms, and the later Czechoslovakian commercially distributed Spofalenses.

Morris (1980), in reviewing soft lens progress, suggested prepacked supplies of soft lenses so that one year's supply of, say, four pairs could be dispensed at one time.

The attraction of a disposable lens lay in the hope of reducing patients' poor compliance with cleaning regimes. The centenary year of Fick's publication, 1988, saw the introduction by Messrs Johnson & Johnson of their disposable extended wear soft lens system. The running costs of this and the more recent daily disposable 'Acuvue' lens, introduced in 1995, are appreciably higher than those of conventional extended wear soft lenses and in this respect we are still a long way from the original Czech dream of a cheap, disposable, visual correction.

The second hope of the Czechs was that, being a very flexible material, a single back surface curve, steeper than the human cornea would suffice and such a lens could be pressed into place and would conform to all corneal contours. The original lenses therefore had an aspherical back surface derived from the centrifugal force employed in their spin-casting mode of fabrication. Visual instability rapidly forced the multiplication of back surface curves and led to lens design studies such as that of Larke and Sabell (1971). From around 1967, the availability of buttons of the dehydrated HEMA material allowed development of lathe-cutting techniques and the application of

conventional back surface designs as had been employed in various hard corneal and perilimbal lenses. Turner (1964a,b) commented 'disadvantages in the use of hydrophilic gel contact lenses have led to experiments with silicone'. A further statement in this paper is interesting in the light of subsequent developments: 'it is not possible to maintain stability in a hydrophilic gel when we have a combination of only 25 per cent of plastic macromolecular structure, and 75 per cent of water.' In discussing the observable 'Sattler's veil' in some patients using the hydrogel lenses of the period, Turner makes the prophetic statement: 'The soft plastics are such a new and revolutionary development it must be expected that we shall have to face many greater problems than this before we are fully satisfied and completely happy with the results.' This paper also discusses difficulties of soft lens measurement and problems arising from both heat and chemical systems of disinfection. It sounds strange to us today to read 'that daily wear lenses should be sterilised at least once every two weeks, if not once each week'.

Over the years we have seen the worldwide explosion in contact lens-related research into corneal physiology. This has run concurrently with the great interest, often commercially inspired, in the development of new contact lens materials. The great obsession of the the importance of oxygen to the corneal well being was questioned by Dallos (1980). While practitioners were well aware of the necessity to ensure good tear exchange behind both scleral and PMMA corneal lenses, it appeared to be the advent of the hydrogel lens which turned thoughts towards the possibility of diffusion of oxygen through the lens material itself. The early belief that the original low water content hydrogel lenses were oxygen permeable was dispelled by research of workers such as Hill and Fatt (1964). Nevertheless, investigations into corneal uptake of oxygen, following occlusion by various forms of contact lens, stimulated the development, first of high water content materials such as Permalens and Sauflon and, more latterly, of the ultrathin soft lens in lower water content material.

Rigid gas permeable lenses

Towards the end of the 1970s a growing disillusionment on the part of many practitioners with flexible forms of contact lenses led to the popularity of rigid gas permeable (RGP) corneal lenses. The advent of RGP materials offered some relief from the limited correction of corneal astigmatism by the early spherical flexible lenses. With soft lenses, the added complexity and cost of maintenance systems still proves a disadvantage and the inability to effectively remove some forms of deposit remains a source of frustration. RGP materials have allowed a return to the fitting of larger corneal lenses. With PMMA, the trend over the 1970s had been towards very small and ultrathin lenses, in an attempt to minimize corneal oedema and corneal warping. The small PMMA lenses sometimes gave rise to complaints of edge flare, especially in patients who had previously worn larger corneal lenses. The increased visual stability afforded by the larger RGP lenses was therefore welcomed by practitioner and patient alike.

Unhappily the new materials, apart from being more susceptible to mechanical damage than PMMA, have also shown themselves more prone to surface deposits although not so badly as the hydrogels. RGP lenses are therefore more demanding of specialized care systems than their impermeable predecessors.

Epilogue: some contact lens personalities

The years since the preparation of the first edition of this book have seen the deaths of several notables of the contact lens world.

On 27 June 1979 Joseph Dallos died. His early work formed the pivot between the previous 40 years of strictly limited progress in the contact lens field and the next 40 of rapid progress and expansion, leading us to the present-day situation. Obituary notices were published in the *Journal of the British Contact Lens Association* by George Nissel (1979), erstwhile brother-in-law of the deceased, and also by M. Ruben (1979) in the *British Medical Journal*. The author (Sabell, 1979) also published a review of the work of Joseph Dallos in September of that year.

The death of George Nissel referred to above, occurred unexpectedly in Switzerland on 12 September 1982. An obituary notice written by Mr S. L. Sasieni (1982) appeared soon after, which outlines Nissel's career as a foremost contact lens manufacturer (*see also* Ruben, 1983).

The sudden death of Peter Madden at the early age of 59 years, on 25 November 1983, left a sad and noticeable gap in the ranks of the contact lens fraternity of the UK.

Geoff McKellen, who died on 25 January 1985 at the age of 81 years, had a career in the contact lens field which began prior to the Second World War.

No attempt has been made in this chapter to deal with the history of contact lens instrumentation or solutions. Neither has any detailed consideration been possible of development of knowledge relating corneal physiology and pathology on the use of contact lenses. One day, perhaps, a detailed history of contact lens manufacturing will be written, but such items must wait for the future and it is time for the reader to turn to a consideration of present-day knowledge and techniques.

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Chapter 2

Anatomy and physiology of the cornea and related structures

G. L. Ruskell

The cornea p. 17
The conjunctival sac and the epithelial surface p. 24
The eyelids p. 27
Corneal innervation p. 29
Corneal transparency p. 34
Metabolic processes p. 37
Tears p. 41

When the first version of this chapter was written the task of selecting items for inclusion was quite simple. The few pages allocated were sufficient to cover or at least mention most relevent information. Since then 25 years of nearly exponential growth of knowledge imposes a requirement for stricter selectivity. But the criterion remains the same – contact lens practitioners should be familiar with the structure and function of those tissues bearing the unnatural burden of a contact lens, especially with those items known to be affected by the changed environment. Aware that the text may not provide adequate coverage to meet a reader's needs or curiosity, a lengthy reference list is provided.

The cornea

The cornea occupies about 7% of the area of the outer coat of the eye and has a very regular layered structure composed of: (1) epithelium; (2) anterior limiting layer or Bowman's layer; (3) substantia propria or stroma; (4) internal limiting layer or Descemet's layer; and (5) endothelium.

The epithelium
(epithelium anterius corneae)

The outermost layer of the cornea is a squamous stratified epithelium, from five to eight cells thick, and probably the most regular of its type in the body (*Figure 2.1a*). The layer is thinnest centrally, increasing from about 50–60 μm, 3 mm from the centre (Reinstein *et al.*, 1994), to about 70 μm near the limbus, and continues on to the conjunctiva where in most positions it thickens (but *see* **Conjunctiva**) and shortly loses its smooth, regular surface. The basal cells are columnar with a nucleus which is spherical or slightly oval containing dispersed chromatin (euchromatic). The cytoplasm contains many intermediate filaments mostly grouped into bundles (tonofilaments), free ribosomes, sparse mitochondria, a little granular endoplasmic reticulum, glycogen granules and occasional Golgi complexes. They are covered by several layers of cells that become smaller, flatter and broader with distance from the base; the nuclei become more ovoid and finally disciform in the squamous superficial cells. The first two or three rows of suprabasal cells often overlap the apices of more than one underlying cell and are called umbrella or wing cells (*Figure 2.1a*). The organelles are similar throughout the epithelium except that filament aggregation is not observed in the squamous cells and they often contain numerous small vesicles.

Hemidesmosomes attach the basal cells to the epithelial basement membrane. They are so numerous they occupy at least one-third of the area of the membrane. Hemidesmosomes are macula junctions continuous with basal cell tonofilaments and consist of local thickenings with increased density of the plasma membrane (the lamina densa) opposite a thickened zone of the basement membrane. The lighter interval between the two thickened membranes (lamina lucida) contains numerous fine connecting filaments. On the opposite side of the junction the basement membrane is attached to the underlying stroma by means of anchoring filaments which in turn are attached to fine branched collagen structures called attachment plaques (Gipson *et al.*, 1989).

Cell borders are characterized by shallow interlocking ridges covering most of their surfaces, with little space between cells. The ridges are least frequent in the apposed membranes of basal cells. Cells are joined by many desmosomes and relatively infrequent gap junctions (*Figure 2.1c*) and at the epithelial surface adjacent cells are joined by tight junctions (zonulae occludentes); unlike the other junctions they girdle the cells and form the closest of contacts without achieving complete fusion. They limit

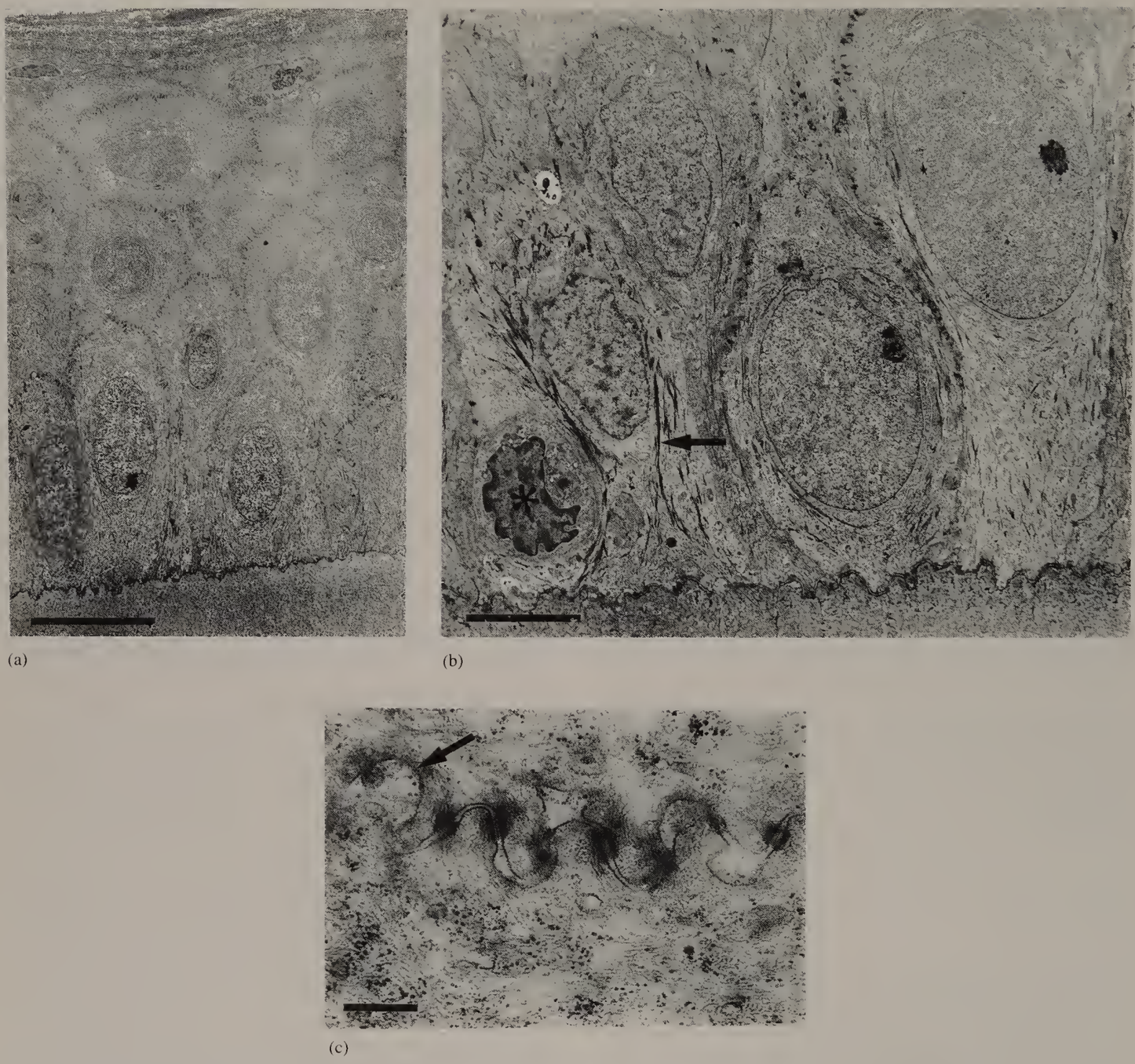


Figure 2.1 Electron micrographs of corneal epithelium. (*a*) Section close to the limbus. The squamous cell layers contain many vesicles (unstained) and the surface microvilli can be seen. Marker = 20 μm. (*b*) Detail of the basal region. Desmosomes give the cell perimeters a speckled appearance. Note the slightly undulating basement membrane and the dense intermediate filaments or tonofibrils (*arrow*). A Langerhans cell is marked with an asterisk. Marker = 10 μm. (*c*) Reciprocal ridges of apposed cell membranes, desmosomes and a gap junction (*arrow*) are shown. The cytoplasm contains intermediate filaments mainly radiating from the desmosomes, and many free ribosomes. Marker = 0.5 μm

permeability, permitting access to the intercellular space from the tear film, or *vice versa*, only through discrete ion selective pores (Gumbiner, 1993). Desmosomes are attached to the cytoplasmic tonofibrils forming a girder-like desmosomal-cytoskeletal network supporting the epithelium layer. Gap junctions contribute to intercellular adhesion and are probably communicating junctions permitting ionic exchange.

Corneal surface

In contrast to the surface cells of the skin, those of the cornea are normally unkeratinized and they retain their organelles – which suggests that metabolic processes are still functioning. Superficially the cells present a smooth surface when examined at medium magnification through a light microscope but with electron microscopy it resembles

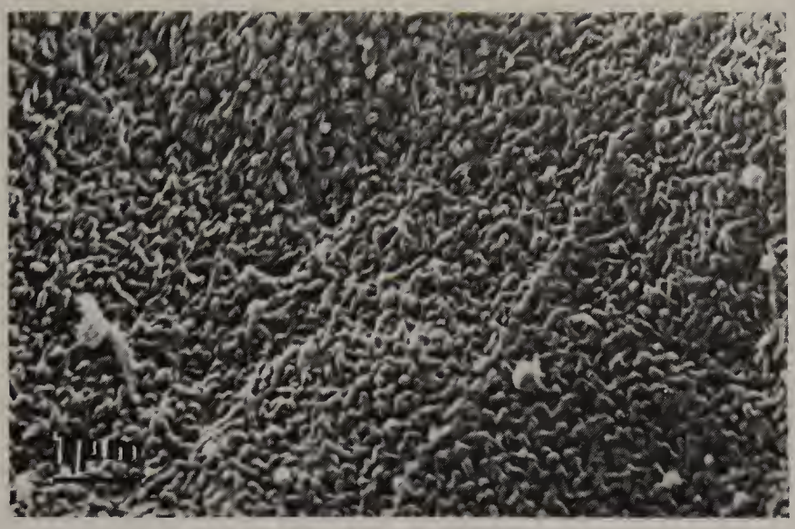


Figure 2.2 Scanning electron micrograph of the surface of the cornea showing microvilli and microplicae with a line marking the borders of adjacent epithelial cells

the pile of a carpet. The superficial squamous cells form tightly packed microvilli and/or microplicae (*Figures 2.1a, 2.2*) up to 0.75 μm in height in man. As cells slough from the surface, desmosomes must split to achieve detachment and cytoplasmic extrusion at these points may be responsible for the microvilli development, as suggested by *Figure 2.3* (Pedler, 1962). Differences in the appearance of surface cells can be observed by specular (McFarland *et al.*, 1983) or scanning microscopy (Pfister and Burstein, 1977). The latter technique reveals light, intermediate and dark cells, the difference being related to the surface form which probably changes with age (Lemp and Gold, 1986). Surface cells are very flat and broad and natural differences in degree of overlap account, at least in part, for the great variation reported in exposed surface areas.

A similar or slightly modified surface pattern is found in most wet epithelia and in each case the resultant increase in surface area provides the benefit of enhanced molecular adherence. The immediate molecular attachment to the surface of the corneal epithelium, as in other cases, is the glycocalyx, a thin glycoprotein layer produced by the surface epithelium. In an elegant study by Watanabe *et al.* (1993) the corneal and conjunctival glycocalyx was shown to be absent until the eyes were opened after birth.

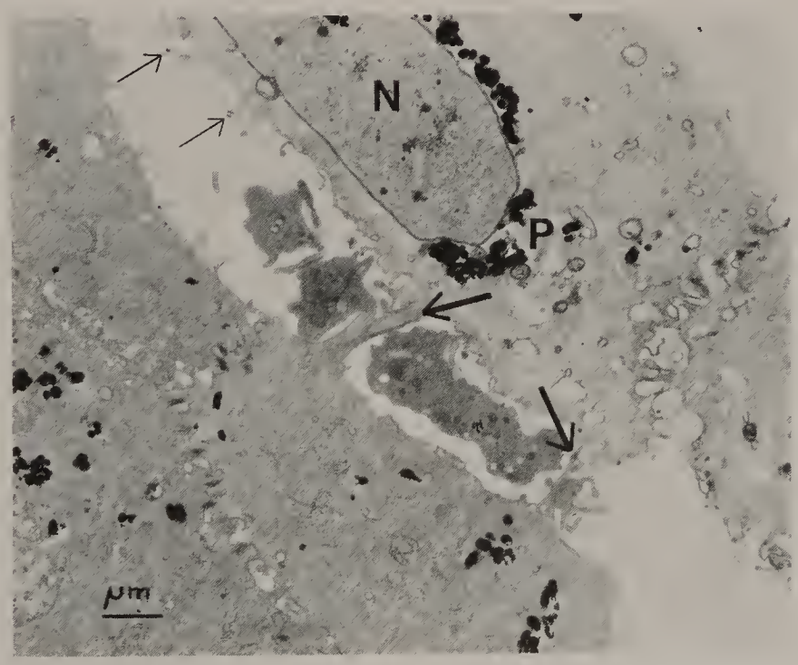


Figure 2.3 Electron micrograph showing partial detachment of surface cells from the perilimbal epithelium prior to sloughing. Cytoplasmic extrusions opposite desmosomes (thick arrows) mark the persisting attachment zones. Desmosomes have broken away from the attached cells and are suspended from microvilli of the detaching cell (thin arrows). **N**, nucleus; **P**, pigment granules

Cell production and corneal trophism

Generation of new cells occurs mainly in the basal cell layer (Machemer, 1966). Epithelial mitosis appears to display a circadian rhythm in rats, being most common at 2–7 a.m. and least common at 2–7 p.m. (Cardoso *et al.*, 1968; Fogle *et al.*, 1980; Lavker *et al.*, 1991). Basal cells make room for new ones by migrating to the next layer and subsequently to the surface, becoming squamosed and sloughed away by the action of the eyelids. These cells constitute the greater part of proteinous material found in tears.

Autoradiographic studies of epithelial cell nuclei, labelled with tritiated thymidine, indicate that the life cycle of cells is 3.5–7 days in a variety of young animals (Hanna and O'Brien, 1960; Süchting *et al.*, 1966). By arresting the division of cells at metaphase with colchicine, Bertanlanffy and Lau (1962) determined that 14.5% of epithelial cells are renewed daily in rats. Assuming surface cells desquamate at the same rate, and all cells are resident for a similar period, then the epithelium could be fully regenerated in 7 days. More recent work suggests that 14 days are required to achieve complete turnover of the corneal epithelium (Cenedella and Fleschner, 1990). The life cycle of corneal epithelial cells in man was estimated, from the results of isotope studies of enucleated eyes, to be about 7 days in duration (Hanna and O'Brien, 1961).

Cell renewal, a feature of all epithelia, is dependent upon stem cells and the cornea is no exception. The stem cell is a slowly cycling basal cell that divides to produce a replica of itself and a transient amplifying cell with the capacity to proliferate before differentiation. The self-renewed stem cell remains basal and the transient amplifying cell is responsible, by relatively rapid division, for cell turnover. There is strong evidence to show that the cornea is exceptional in lacking stem cells, and the cell cycling described above is dependent on transient amplifying cells migrated from the limbal conjunctiva, the product of stem cells located in large numbers on the limbal basement membrane (Schermer *et al.*, 1986; Cotsarelis *et al.*, 1989). This implies that there is a constant centripetal flow of epithelial cells to the cornea; suggestive evidence of this traffic may be seen in individuals with pigmented conjunctivas who sometimes display short, linear strands of pigment encroaching the cornea, most noticeable at the inferior limbus (Davanger and Eversen, 1971). The centripetal movement from the limbus may be restricted to the vertical meridian (Lauweryns *et al.*, 1993). These observations indicate that a healthy cornea is dependent upon a healthy limbus.

Adrenaline (epinephrine) and sympathectomy decrease the mitotic rate in rats (Friedenwald and Buschke, 1944a). If, as seems probable, the decrease is related to innervation and not simply to circulating adrenaline, applicability to man depends on whether or not the human cornea receives an adrenergic innervation; this matter remains unsettled but the balance of evidence favours its presence (Toivanen *et al.*, 1987; Marfurt and Ellis, 1993). Appropriate regulation of mitosis is obviously of importance in the maintenance of corneal epithelial trophism and of the cornea as a whole. Sensory denervation of the cornea also decreases the mitotic rate (Sigelman and Friedenwald, 1954), delays wound healing and increases epithelial permeability (Beuerman and Schimmelpfennig, 1980), and may result in the clinical condition of neurotrophic keratitis. Corneal lesions induced by neonatal sensory denervation were shown to be limited by sympathectomy (Abelli *et al.*, 1993). This surprising result suggests that a balance in neuronal activity between sympathetic neurones and trigeminal sensory neurons may be critical for maintaining the normal trophism of the cornea.

Langerhans cells

In common with skin, Langerhans cells are present in the corneal epithelium (Sugiura, 1965). They are far smaller than epithelial cells with a limited perikaryon, numerous long thin processes and are generally to be found on or close to the basement membrane (*see Figure 2.1b*). They are present at birth throughout the layer and subsequently their number reduces with distance from the limbus so that none is normally present in the centre of the adult cornea (Chandler *et al.*, 1985). Derived from bone marrow, with a life span of weeks, they migrate from the conjunctival epithelium which receives them from the bloodstream. Langerhans cells are an integral component of the local immune response to microbial and possibly other antigens. In response to various corneal insults their number increases substantially (Lewkowicz-Moss *et al.*, 1987). They bear HLA-DR antigens and may provide the first signal in host sensitization to a corneal graft leading to rejection (Rodrigues *et al.*, 1987; Braude and Chandler, 1983; Treseler *et al.*, 1984).

Epithelial damage

In the context of this book it is appropriate to consider at some length the reactions of the epithelium to damage. The smallest corneal wounds, less than a pin head in size, are covered in about 3 hours by the neighbouring basal cells which send pseudopodia to cover the excavated area (Friedenwald and Buschke, 1944b). Normal mitosis is inhibited and plays no part in healing. Although these observations were made on rats, a similar time course probably obtains in man: a small lesion observed using fluorescein stain one day and absent the next is a common clinical observation. Such lesions, often caused by a small foreign body trapped beneath a contact lens, are usually circumscribed, full-thickness detachments of epithelium. The basement membrane is often left in place (Khodadoust *et al.*, 1968). If a somewhat larger area of the cornea is denuded, cells from all layers of the surrounding epithelium migrate and flatten to cover the wound. In this event, mitosis is again at first inhibited but, after a few hours, it recommences and takes an active part in repair. In experiments on rabbits, Mann (1944) found that an area 2–3 mm in diameter will become covered within 24 hours,

and in 3 days the area will have a normal appearance as determined by fluorescein staining. The time course of repair is independent of the cause of the lesion except in the case of burns, when it is delayed, and the time course applies whether or not the underlying tissues are affected. Other experiments on rabbits have shown that the establishment of a tight adhesion of newly regenerated epithelium takes only a few days if the basement membrane is largely intact, but initially the new epithelium is not firmly attached to the stroma and is very susceptible to damage (Khodadoust *et al.*, 1968). Tight junction reformation is swift (McCartney and Cantu-Crouch, 1992) and may re-establish the epithelial barrier well before the layer is firmly attached to the stroma. These studies suggest it is prudent to discontinue wearing contact lenses for a few days after incurring significant epithelial damage.

If the lesion lies close to the limbus, conjunctival cells will take part in the migration, as may be ascertained by the movement into the cornea of pigment cells from the limbus in rabbits; and the same process was confirmed in man by observations on Negro patients (Mann, 1944). Such migration may represent an acceleration of a normal slow centripetal movement of epithelial cells (Buck, 1985). After massive or total denudation of the corneas of rabbits, it was found that 50% coverage occurs after 24 hours, 75% after 48 hours (Langham, 1960), and total coverage takes from 4 to 12 days (Mann, 1944; Heydenreich, 1958; Khodadoust *et al.*, 1968). On completion of coverage of the cornea, the epithelium is one or two cells thick (Khodadoust *et al.*, 1968), and after 2 weeks it is two to three cells thick (Heydenreich, 1958), but several weeks pass before the epithelium is of normal thickness and adhesion structures are adequately reformed (Gipson *et al.*, 1989). Langham found that normal thickness may be attained in one region of a previously completely denuded cornea while another remains uncovered.

Three hours following epithelial abrasions in rabbits, polymorphonuclear leucocytes appear in the basal lamina and at the edge of the abrasion. Epithelial cells bordering the abrasion are flattened and develop surface ruffles and filopodia at their free edges (Pfister, 1975). The ruffles and the long, fine filopodia extend to form attachments to the basal lamina giving the impression of a capacity to draw the cells forward into the area of the defect. Epithelial cells bordering a defect appear to increase their water content and surface area, facilitating the production of cell extensions (Cintron *et al.*, 1982).

One might expect that epithelial repair slows with age, and Marré (1967) found that this was so in rabbits; but the difference in rate of repair in 4- to 6-month-old and 4- to 6-year-old animals was very slight.

There is evidence to suggest that chemotactic substances liberated from the epithelium are responsible for initiating the early stages of healing both in the epithelium and in the stroma (Weimar, 1960). Immediately after deep corneal wounding in rats, a period of proteolytic activity gives rise to the invasion of the cornea by polymorphonuclear leucocytes and to phagocytic activity by the stromal cells. The epithelium appears to be the source of the proteolytic enzymes which trigger these early responses to injury.

Anaesthetics – being protoplasmic poisons – necessarily alter cellular metabolism, and Friedenwald and Buschke (1944a) showed that, if these or other agents such as adrenergic drugs are applied locally in experimental animals, mitosis is inhibited. Gunderson and Liebman (1944) found that the epithelial healing process in guinea-pigs was delayed by anaesthetics. Healing was retarded by inhibition of both mitosis and migration. This effect varied with concentration and tonicity but not with pH. If local anaesthetics are applied excessively, epithelial and possibly stromal opacification is caused, accompanied by the eruption of cells and bleb formation. The whole cornea will stain in this condition. Certain synthetic anaesthetics have a less toxic effect on the epithelium than cocaine (Gunderson and Liebman, 1944; Boozan and Cohen, 1953; Rycroft, 1964), but with prolonged use they are all capable of producing serious corneal damage (Epstein and Paton, 1968). Wound healing may also be slowed by some antibiotics and antimicrobials (Nakamura *et al.*, 1993); high concentrations of fluoroquinolones and peptides slowed cultured corneal epithelial migration but aminoglycosides had little effect and penicillins none.

The epithelium in contact lens wearers is subject to the development of microcysts at basal cell level that are often visible only with the most careful inspection. All 45 subjects taking part in a controlled study developed microcysts during 6 months of continuous wear of soft contact lenses (Humphreys *et al.*, 1980). The subjects were symptomless and the cysts disappeared 10 weeks or so after lens wear was discontinued. A variety of other cellular changes may occur (Bergmanson and Chu, 1982).

Imprinting of the corneal epithelium by corneal contact lenses has been reported by Dixon (1964) and others in a small proportion of patients. Imprinting usually takes the form of a raised crescent inferiorly. If the eye has been bandaged, or if pressure is exerted through the eyelids, the epithelium wrinkles (Bron, 1968). This gives rise to a quick fading mosaic which is made visible with fluorescein staining. Generally, contact lenses are not thought to interfere with the smooth topography of the corneal surface but subtle refractive irregularities can be observed with computerized analysis (Ruiz-Montenegro *et al.*, 1993). It has been argued by Cochet that the softness or fragility of the epithelium is variable and he observed a marked fragility in 5% of patients seeking to wear contact lenses (Guilbert, 1963). Fragility was determined by fitting an engraved spherical cone to the Goldmann applanation tonometer and assessing the extent of imprinting when applied to the cornea, a soft epithelium contraindicating the use of lenses.

Imprinting in rabbit corneal epithelium was accompanied by the loss of a wing cell layer and increased mitosis (Greenberg and Hill, 1973) indicating a faster turnover of cells, but this has been questioned and a reduced turnover claimed (Hamano *et al.*, 1983).

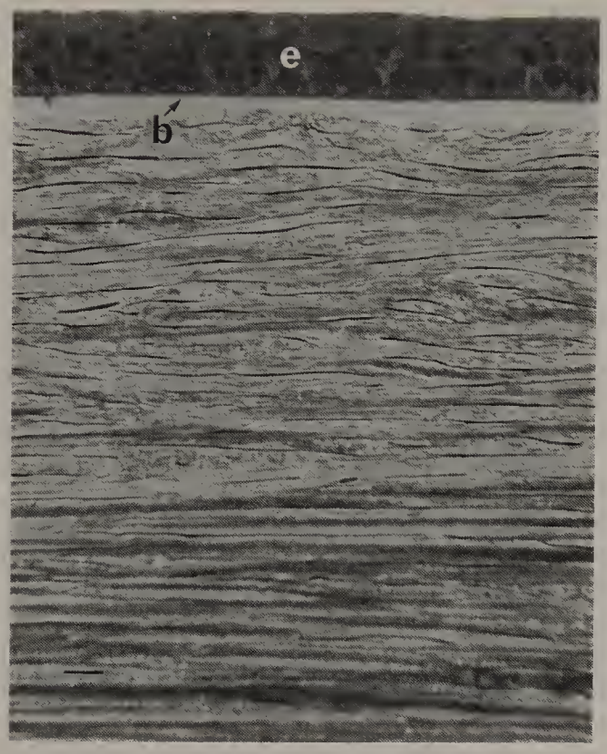


Figure 2.4 Light micrograph of the anterior half of the cornea in transverse section. The difference in density of the lamellae of the stroma is partly attributable to a difference in fibril orientation. The slight irregularity of the lamellae underlying Bowman's layer (**b**) is a normal feature. **e**, epithelium. Marker = 20 μm

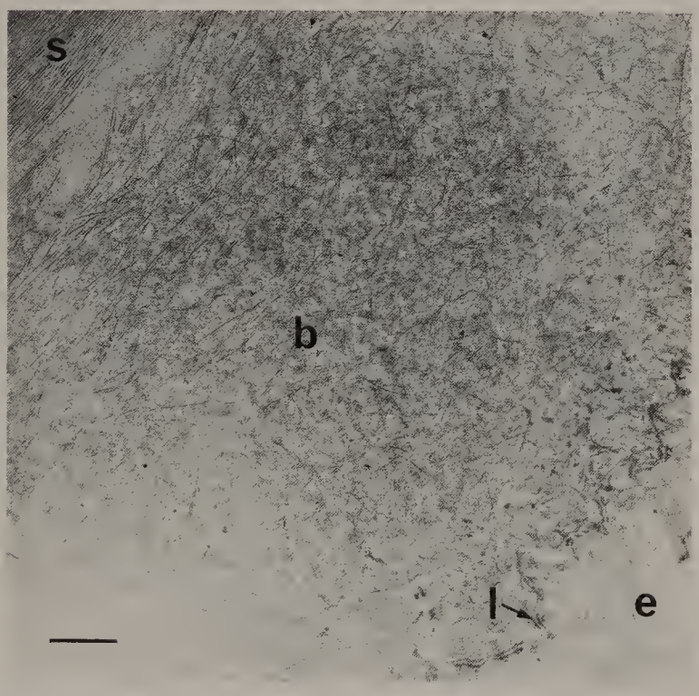


Figure 2.5 Electron micrograph of Bowman's layer (**b**). Note the random orientation of the collagen fibres. Bowman's layer merges with the stroma (**s**) in which the fibrils are regularly orientated. The basement membrane of the epithelium (**e**) is not smooth; the densities opposite the membrane are hemidesmosomes (the arrow indicates one). Marker = 1 μm

Bowman's layer
(lamina limitans anterior)

Beneath the fine basement membrane of the epithelium is a cell-free layer of uniform thickness of about 12 μm terminating at the limbus which, histologically, appears homogeneous (*Figure 2.4*). Electron microscopy reveals a fine randomly orientated mesh of collagen fibrils (*Figure 2.5*). It is modified anteriorly where the anchoring filaments of the basement membrane and associated structures mentioned earlier are found; these also have a collagenous composition. Over the whole of its area, the layer is penetrated by fine unmyelinated nerve fibres which pass from the stroma to the epithelial cells; the nerve fibres lose their Schwann cell sheaths as they leave the stroma.

The frequency of epithelial damage without involvement of this layer is evidence of its relative toughness; but if it does become damaged, fibrous scar tissue is laid down, resulting in a permanent opacity – although some reduction of the initial scar area usually occurs. To ascribe a stronger tendency for this layer to retain scar tissue compared with the underlying stroma is questionable in view of their similar structural elements. Significant mechanical damage to Bowman's layer by a contact lens, however grossly mishandled, is an unlikely occurrence.

The stroma
(substantia propria cornea)

The stroma constitutes 90% of the corneal thickness and gives the cornea its strength. It is remarkable for its regular structure and the absence of blood vessels, which are the two basic features on which corneal transparency rests. The stroma consists of about 200 layers of lamellae of collagen fibrils. The fibrils, which are buricd in a matrix of proteoglycans, have a periodicity which is characteristic of collagen (*Figure 2.6*). There are no elastic fibres in the adult human cornea (Alexander and Garner, 1983). Collagen fibrils are of a regular size at any given depth in the stroma but they vary between an average of 19 nm in the anterior layers and 34 nm in the posterior layers in man (Jakus, 1961).

A majority of the lamellae have a similar thickness (1.5–2.5 μm) and they lie parallel to each other except in the anterior third where some lamellae run obliquely (*see Figure 2.5*). Fibrils within a lamina are strictly parallel but the fibrillar orientation in adjacent lamellae is angled, tending to be arranged orthogonally (Jakus, 1964). A bias of lamellar orientation has been claimed but the direction is not agreed as results appear to differ according to the technique used. For example, polarized light studies indicate a diagonal upward and outward bias (Schute, 1974) whereas by X-ray diffraction vertical and horizontal orientations predominate (Meek *et al.*, 1987). Towards the periphery, some lamellae lie approximately concentric with the limbus (Kokott, 1938; Polack, 1961). The lamellae probably continue uninterrupted across the cornea without latcral changes in direction but to what extent they

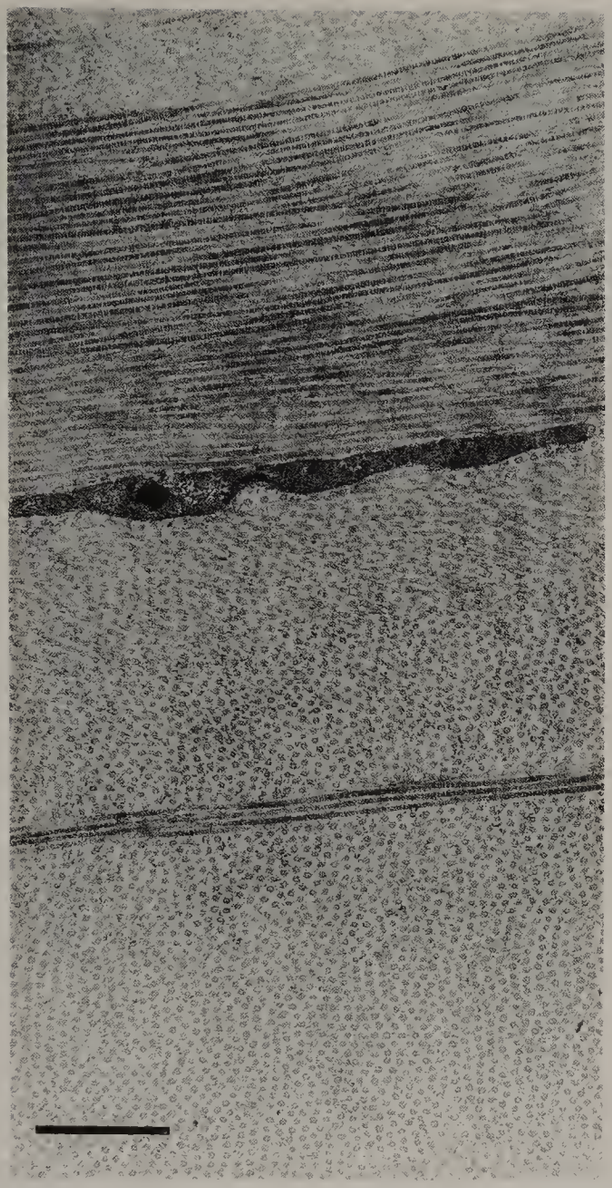


Figure 2.6 Electron micrograph of stromal lamellae showing different fibril orientation and lamellar thicknesses. A keratocyte process is interposed between two of the lamellae. Marker = 0.5 μm

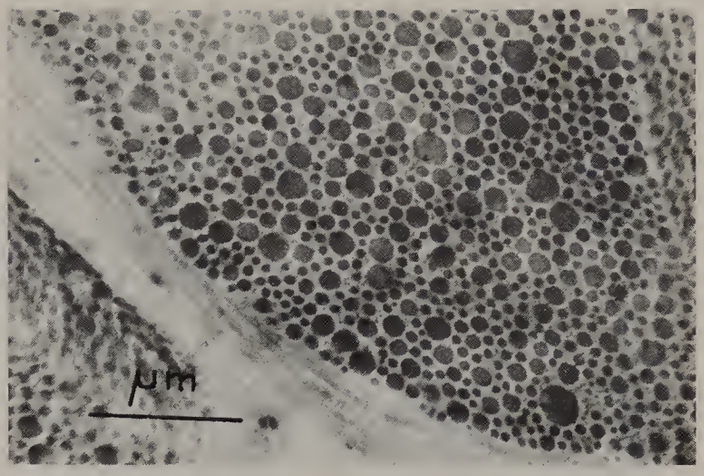


Figure 2.7 Electron micrograph of a transverse section through collagen fibrils of the scleral spur. The difference between adjacent collagen fibril diameters is marked

extend into the sclera is unclear (Meek *et al.*, 1987). Their widths are difficult to measure; most are up to 250 μm but some appear to be in excess of 1 mm. Although an impression of discreteness of adjacent lamellae prevails when viewing the ultrastructure of the stroma, at least in the posterior two-thirds, here and there, slightly oblique branches connect one lamella with another. This arrangement explains the ease with which the deep stroma may be split parallel to the surface, as in preparation for corneal lamellar grafts.

At the corneoscleral margin, the stromal lamellae undulate, branch and probably interweave. The fibrils of single lamellae remain parallel to each other but their diameters vary tenfold or more (*Figure 2.7*), and some variation in diameter is present throughout the sclera. At the deep surface of this region, the canal of Schlemm and the corneoscleral meshwork are located; a description of their structure and relationships is beyond the scope of this chapter.

The matrix of the stroma is composed largely of glycosaminoglycans (GAGs) covalently bound to protein, constituting proteoglycans. The two major types are keratan sulphate and chondroitin sulphate. Their filamentous structure has been demonstrated (Hirsch *et al.*, 1989), and the filaments attach through their core proteins to collagen fibrils, bridging the spaces between them. Details of this 'bottle brush' organization are uncertain but a model has been proposed that explains the manner in which the matrix influences the regular separation of collagen fibrils (Scott, 1992). During oedema resulting from a compromised endothelium, GAGs are lost from the cornea (Anseth, 1969; Kangas *et al.*, 1990).

The main cellular element of the stroma is the keratocyte (corneal fibrocyte, corpuscle or fixed cell), which is a flattened, dendritic cell disposed in the interface between adjacent lamellae (*Figure 2.6*). In a single interface, the cell bodies are well spaced across the cornea but their thin, lengthy processes are so extensive that many come into contact with processes from neighbouring cells, giving the appearance of a delicate wide-mesh network (*Figure 2.8*). This is repeated at each lamellar interface. The nuclei of these cells are flat, approximately oval discs embedded in a sparse perikaryon. More than one nucleus may be present.

There is good evidence that the fibrocytes of the cornea display a phagocytic function (Klintworth, 1969; Fujita *et al.*, 1987). Polymorphonuclear leucocytes and mast cells are present in the periphery of the stroma. Autoradiographic studies of thymidine-labelled nuclei reveal little or no evidence of DNA synthesis among the keratocytes, which indicates that they seldom divide (Hanna and O'Brien, 1961; Machemer, 1966).

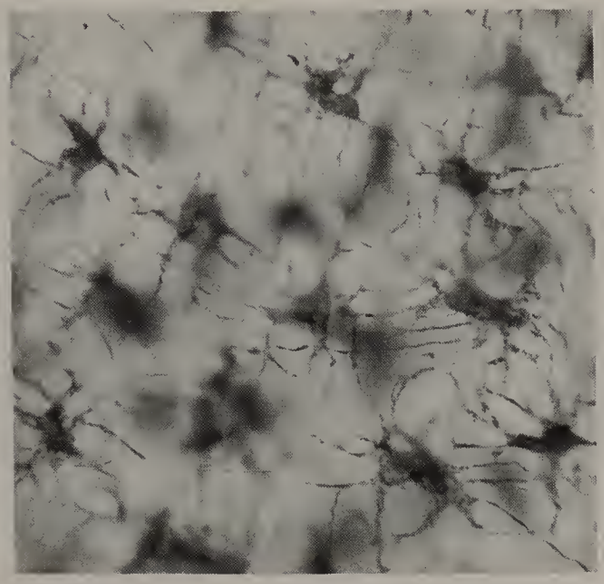


Figure 2.8 Stromal keratocytes. The full thickness of the cornea is viewed from the front and focused at a superficial stromal level. The keratocytes in focus probably all lie at a single lamella interface. Marker = 20 μm

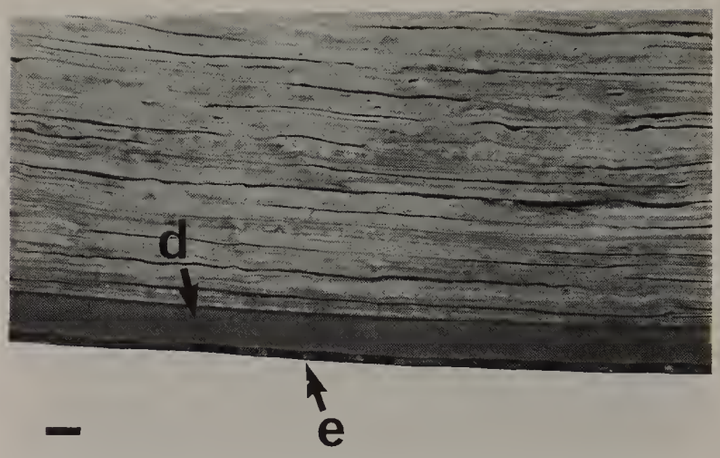


Figure 2.9 Structures of the cornea bordering the anterior chamber. **d:** Descemet's membrane, **e:** endothelium. Marker = 10 μm

Descemet's layer
(lamina limitans posterior)

Descemet's layer is a product of the endothelium and is thinner than Bowman's layer in the young, but it thickens continuously throughout life, rapidly during gestation and the first postnatal year when it is about 5 μm thick, then slowly, increasing by approximately 1.3 μm each decade (Murphy *et al.*, 1984). Corneal stroma thickness, by comparison, is unchanged. Descemet's layer appears devoid of internal structure under the light microscope but electron microscopy reveals a fine regular organization anteriorly. In tangential sections, it has a two-dimensional lace network appearance with a repeating hexagonal unit with seven dense nodes marking the angles; these are connected by fine filaments of equal length. The networks are stacked in depth in register as revealed by transverse sections. Dark bands are discernible perpendicular to the plane of the cornea consisting of columns of dark granules, which are the nodes of the tangential section network (Jakus, 1964). In contrast, the posterior part of this layer has the same fine granular appearance in whichever plane it is sectioned and it shows no signs of a patterned organization. The granular layer is thinner at birth, becoming thicker than the fibrillar layer with age.

The endothelium
(endothelium camerae anterioris)

This deepest layer of the cornea lacks the thin basement membrane usually associated with endothelia. The endothelium consists of a single thin layer of predominantly hexagonal cells which present a smooth surface to the anterior chamber (*Figure 2.9*). Seen in tangential sections, the cell borders are ill-defined because of the oblique cell interfaces and the interdigitation of broad processes of adjacent cells. The nucleus may have an oval or a kidney shape and the cytoplasm often appears granular. The cells are well stocked with organelles, especially mitochondria, and the endoplasmic reticulum is prominent. Near the posterior border of this layer, the intercellular space is reduced to form a tight junction of 10 nm width which presumably restricts the movement of substances in and out of the cornea between the endothelial cells (Iwamoto and Smelser, 1965). A few mitotic patterns occur in very young but not adult animals (Sallmann *et al.*, 1961) and cell division probably ceases before birth in man (Murphy *et al.*, 1984). Cells increase in size during growth of the eye and probably spread to cover damaged areas when injured.

The endothelial mosaic is not quite regular because some variation in size (and in number of facets) or polymegethism occurs. This increases with age and is exaggerated as a consequence of wearing PMMA or low Dk contact lenses. Lens-induced increments in polymegethism develop quickly and progress slowly and the irregular mosaic pattern, readily seen by specular microscopy, persists at least as long as the contact lenses continue to be worn (Stocker and Schoessler, 1985). Polymegethism may indicate a loss of endothelial functional capacity (Rao *et al.*, 1979) and perhaps explains the corneal exhaustion phenomenon (*see* Chapter 18, p. 617) when rigid contact lenses cannot be tolerated after many years (Stocker and Schoessler, 1985).

The conjunctival sac and the epithelial surface

The conjunctiva is a mucous membrane which lines the posterior surface of each eyelid, reflecting sharply at the fornix to line the anterior eyeball, where it becomes continuous with the corneal epithelium. The subdivisions of the conjunctiva are shown in *Figure 2.10*. The opposite

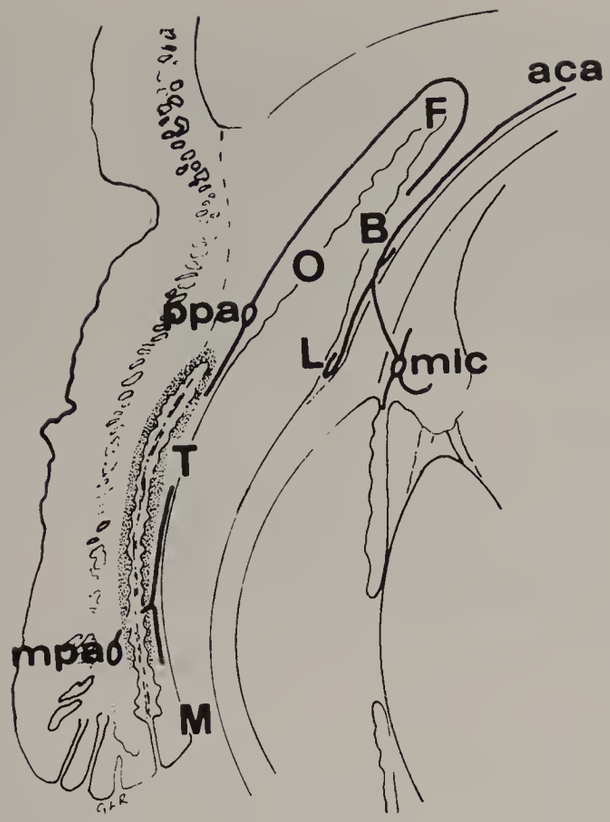


Figure 2.10 The subdivisions of the conjunctiva and the principal sources of blood. **B**, bulbar; **F**, forniceal; **L**, limbal; **M**, marginal; **O**, orbital; **T**, tarsal. The marginal, tarsal and orbital parts constitute the palpebral conjunctiva, **aca**, anterior ciliary artery; **mic**, major iridic circle; **mpa**, marginal palpebral arcade; **ppa**, peripheral palpebral arcade

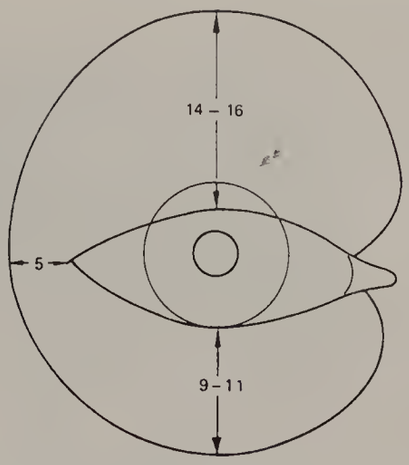


Figure 2.11 Approximate contours of the fornix and the dimensions of the unextended conjunctival sac in millimetres when the eye is open. (Based on the data of Whitnall (after Baker) and Ehlers)

faces of the conjunctiva are presumably in contact, apart from a very thin liquid film. Estimates of the depth of the sac vary, and the measurements of the sac superiorly and inferiorly are presented in *Figure 2.11*. The circumference of the sac has a mean value of about 9.5 cm, and Ehlers showed that the circumference varies with the width of the palpebral fissure. The conjunctiva covering the eyeball (bulbar), and especially that of the fornix, is thrown into numerous horizontal folds and consequently the sac is potentially larger than is shown in *Figure 2.11*. Ehlers (1965b) found that the sac may be distended inferiorly to 14–16 mm and superiorly to 25–30 mm, which is more than enough to lodge a displaced contact lens.

The wet, unkeratinized conjunctival epithelium presents a surface of fine packed microvilli or microplicae about 0.75 μm in height, which are present in all areas. The marginal and limbal epithelia are stratified and substantially thicker (up to 12 cells) than elsewhere. Cells are tightly packed in both these areas presenting a regular smooth surface to rival that of the cornea. The tarsal surface is also smooth but a subtarsal fold is often present, marking the marginal termination of the tarsal plate in the upper eyelid, where small foreign bodies are inclined to lodge. Intercellular attachments are predominantly by desmosomes, and hemidesmosomes attach cells to the basement membrane with a similar anchoring mechanism already described in the cornea. A few gap junctions are present, and tight junctions girdle the apical walls.

In the tarsal area, the marginal stratified epithelium quickly gives way to a layer of mainly cuboidal cells three or four deep (*Figure 2.12*). Beyond the tarsal plate, the orbital conjunctival epithelium thickens as the cells become columnar and the intercellular gaps increase, the stability of the layer being aided by reciprocal thin digital processes joined at or near their tips by desmosomes. The spaces facilitate folding of the layer without jeopardizing cell integrity. Little change in thickness occurs at the fornix or, at first, in the bulbar conjunctiva, but then it gradually thickens, the spacing between cells reducing as they become less columnar and more stratified on approaching the limbal region. Here the layer varies from 3 to 12 cells thick according to position in relation to the limbal palisades of Vogt. These are structures of the conjunctival stroma and consist of mainly parallel linear ridges of fibrous connective tissue up to 1 mm in length radially arranged, packed 5–10 per mm of limbal circumference and terminating very close (0.5 mm or less) to the cornea. The conjunctival surface is smoothed by an epithelium ridged in complementary fashion to fill the troughs between palisades where it is 10–12 cells thick, whereas at the crests it reduces to 3 or 4 cells. Palisades regularly occur sagittally, most clearly at 6 o'clock, but are often barely discernible or absent horizontally. They may be seen most clearly using a slit-lamp microscope in a pigmented conjunctiva.

Goblet cells are present in large numbers (*Figures 2.12, 2.13*). They are often stated incorrectly to be absent from the marginal epithelium where their frequency is low, increasing slightly in the tarsal area (*Figure 2.12*), then rapidly in the orbital conjunctiva. A high density is maintained in the fornix and in the neighbouring bulbar conjunctiva, gradually reducing towards the limbus where there are none. Goblet cells are most numerous in the lower

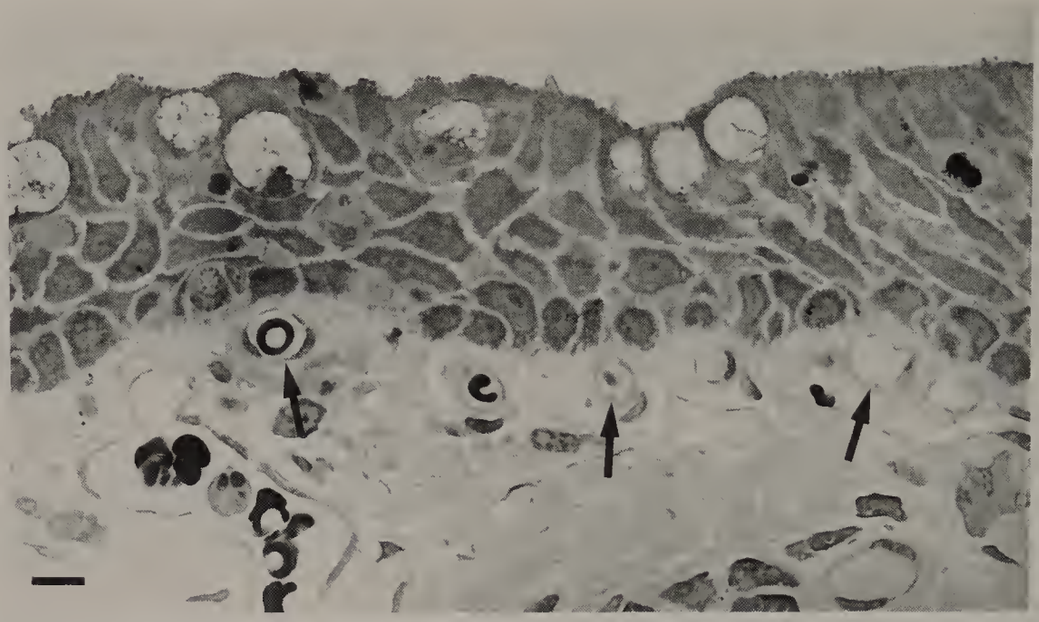


Figure 2.12 Conjunctiva from opposite the margin of the upper eyelid tarsal plate. The epithelium is four or five cells thick and contains a few goblet cells. Numerous capillaries (*arrows*) lie adjacent to the basement membrane. Further from the margin the epithelium thins slightly. Marker = 10 μm

nasal conjunctiva reaching a maximum density at the plica semilunaris and caruncle; exposed areas of the bulbar conjunctival have none (Kessing, 1968). Pockets of increased density occur in the crypts of Henle which are saccular invaginations of the conjunctiva opening on to the surface through a narrow pore; most are located in the orbital conjunctiva close to the tarsal plate. Goblet cell density in the bulbar conjunctiva is greatest in children, falling to 50% of maximum in young adults, a level largely maintained in the following decades.

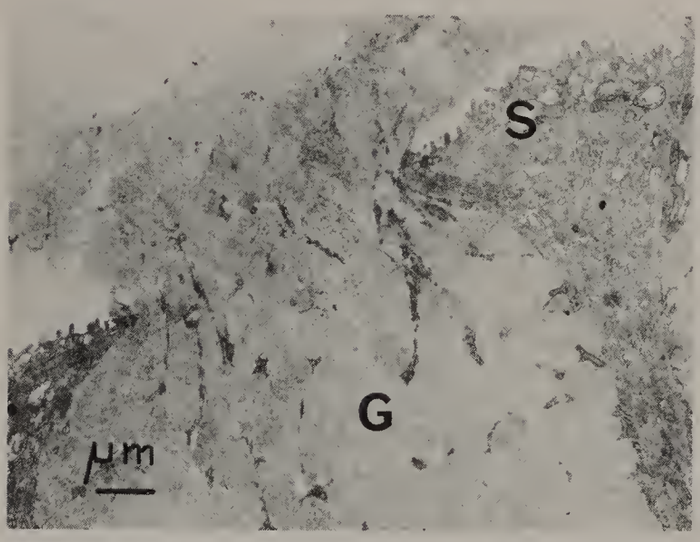


Figure 2.13 Electron micrograph of the apex of a conjunctival goblet cell. Nearly all the cytoplasm consists of secretion granules (**G**). The conjunctival surface is indicated by the microvilli of adjacent supporting cells (**S**). The material extruding from the apex of the cell includes secretion granules and other organelles of which granular endoplasmic reticulum can be recognized

Mucin secreted from goblet cells forms the deepest layer of the tear film, interposed between the watery phase of tears and the hydrophobic cell membranes, and it is vital for adhesion of the film. It is an example of the several services the conjunctiva provides for the cornea.

No information is available regarding the turnover rate of cells in the conjunctival epithelium except at the limbus, where tritiated thymidine-labelled basal cells are sloughed away after 132–154 hours in rats – which according to Süchting *et al.* (1966), is rather slower than in the corneal epithelium. It is likely that the turnover rate of cells is much reduced in the glandular parts of the conjunctiva. The goblet cells, which are apocrine glands, probably survive total evacuation of their secretion granules and become recharged, as appears to be the case in goblet cells of the gut (Freeman, 1962).

Many of the superficial cells of the conjunctival epithelium have vesicular inclusions capable of discharging their mucoprotein content onto the surface of the epithelium. The long branched mucoprotein chains remain attached to the cell membrane on the surface and provide an anchor for the mucus layer secreted by the goblet cells, according to Dilly (1985). They represent the glycocalyx of the surface cells and the vesicle-bearing surface cells of the cornea and those of the whole conjunctival surface produce their own glycocalyx. This thin layer appears first in the newborn animal on first opening the eyes (Watanabe *et al.*, 1993). Vesicles in the bulbar conjunctiva increase in number in contact lens wearers (Greiner *et al.*, 1980). Some cells also appear to have the capacity to remove substances from the surface of the conjunctiva by ingestion through pinocytotic vesicles which then discharge into the intercellular spaces. Substances subsequently pass to the subepithelium for removal by the vascular system (Steuhl and Rohen, 1983).

The conjunctival epithelium normally receives a number of migratory cells consisting of Langerhans cells, melanocytes and leucocytes, mainly T-lymphocytes of both suppressor and helper types and neutrophils. The number of leucocytes is low in the healthy conjunctival epithelium. Langerhans cells are largely concentrated at the limbus and, as in the cornea (p. 20), they lie on or close to the basement membrane. Melanocytes are small, dendritic and mainly basal, characteristics they share with Langerhans cells, with which they are easily confused histologically if they lack melanosomes. Melanosomes are commonly absent from white-skinned caucasians (the possibility of pigmentation increasing with age), whereas they are regularly present in other races. Epithelial cells accumulate pigment by donation from melanocytes and are incapable of generating their own pigment. They are derived from the neural crest.

A slight circumscribed elevation of the bulbar conjunctiva, called a pinguecula, may occur opposite the palpebral aperture close to the limbus on one or both sides. Pingueculae are yellow with a fatty appearance due to their content of connective tissue subjected to elastoid degeneration. Pingueculae are uncommon in young eyes but occur frequently in elderly people, especially among those exposed to high levels of ultraviolet radiation, and they are therefore more common in countries close to the extremes of latitude.

The blood vessels of the bulbar conjunctiva tend towards a radial arrangement. Arterioles pass from the anterior ciliary arteries before they penetrate the sclera and others pass round the fornix from arterioles of the palpebral conjunctiva (*see Figure 2.10*). At the limbus, capillaries are again radially disposed mainly within the palisades and form fine vascular loops at the margin of the cornea. Venules pass back, converge and anastomose frequently and many of the larger venules lie adjacent to the arterioles. The sclera overlaps the cornca anteriorly about the vertical meridian so that transparency loss is gradual across the transition. Consequently, the limbal vessels may give the impression of penetrating the cornea. Many of the conjunctival capillaries are closed in the normal eye but irritation of the cornea or conjunctiva will increase the number and size of blood-bearing vessels.

Small lymphatic vessels are present in the conjunctiva including fine lymphatic capillaries that extend to the corneoscleral border, often within palisades. They drain into larger subconjunctival vessels.

Lymphocytes are a normal resident of the conjunctival stroma, especially in the palpebral region, where there are also discrete, dense accumulations accommodated in lymph follicles or nodules. Most of these lie in the orbital and peripheral tarsal conjunctiva, immediately underlying the epithelium which is modified opposite the follicle. They appear topographically as translucent, white or yellowish elevations up to 1 mm in diameter. They enlarge and become more numerous and broadcast in certain maladies. Papillae are another form of inflammatory cell accumulation, with lymphocytes predominant (Kessing, 1966). The distinction between papillae and follicles is far from clear but, respectively, they are usually stated to have centrally and peripherally located blood vessels. Enlarged papillae occasionally infiltrate much of the tarsal area in contact lens wear or in the presence of other substantial foreign bodies such as a prosthetic eye – this is the well-known condition of giant papillary conjunctivitis (*see* Chapter 18, p. 627 and *Figure 18.24. See also* Appendix D).

The upper conjunctiva receives a limited sensory innervation from the ophthalmic nerve; the lower conjunctiva is usually stated to be innervated by the infraorbital branch of the maxillary nerve which Oduntan and Ruskell (1992) found to be an inconstant source in monkeys, the ophthalmic nerve being at least the major provider of sensory fibres. A few sensory terminals enter the epithelial layer where they lie on the basement membrane or between basal cells (Macintosh, 1974) but most appear to be associated with blood vessels (Stone and McGlinn, 1988). Infrequent complex encapsulated terminal forms are present in the stroma of the bulbar conjunctiva in man, and these are presumed to be sensory (Lawrenson and Ruskell, 1993). They occur more frequently in the upper temporal quadrant and especially at the limbus in association with the palisades. Sympathetic nerves from the superior cervical ganglion and parasympathetic nerves from the pterygopalatine ganglion are also found in the bulbar conjunctiva in primates (Macintosh, 1974; Ruskell, 1975) and sub-primates (ten Tusscher *et al.*, 1988; Elsas *et al.*, 1994), both being substantially vasomotor.

The eyelids

The skin of the eyelids is very thin. The epidermis consists of only six or seven layers of epithelial cells beneath the keratinized surface layer. At the lid margin, the epithelium thickens and becomes moist and the keratinized layer terminates in front of the orifices of the tarsal glands. Here the epithelium is continuous with that of the marginal conjunctiva where the epithelium is the thickest in the eyelid. The dermis contains small sweat glands. The hairs of the skin are extremely fine and short and, where the skin is regularly folded upon itself in the palpebral furrows, the hairs barely extend beyond their follicles. Sebaceous glands associated with the hairs are commensurately small.

Nearly a third of the thickness of the eyelid is made up of the striated orbicularis oculi muscle, which is bordered anteriorly and posteriorly by loose non-adipose connective tissue. The orbicularis is a thin muscle surrounding the palpebral aperture and extending well beyond the orbital margin on to the face. Structurally and functionally, the muscle is divisible into orbital and palpebral portions. Most of the orbital portion lies beyond the orbital margin and its border describes a horizontal ellipse approximately. It is continuous with the palpebral portion, which itself is clearly divisible into preseptal (lying in front of the orbital septum) and pretarsal parts, the latter terminating near the palpebral margins. Jones (1961) described the orbicularis muscle with considerable precision. He showed that the fascicles of the

pretarsal muscle are broadest in the central region of the eyelid, tapering laterally to terminate just beyond the outer canthus. In contrast, the fascicles of the preseptal muscle maintain a regular width, terminating laterally in the raphé, where fibres of the upper and lower eyelids meet. A weak lateral palpebral ligament joins the posterior face of the raphé to the lateral orbital margin at the orbital tubercle. The upper fascicles of the orbital division are continuous with the lower ones laterally. The palpebral furrows or sulci mark the transition from pretarsal to preseptal portions. The divisions of the orbicularis oculi taper and fuse medially and they are anchored to the orbital margin by the strong medial palpebral ligament. Jones (1961) distinguished separate ligaments of the three portions of the muscle and each of them possessed a deep and a superficial ligament or head. According to Jones, the deep heads of the inferior and superior preseptal muscles terminate in the fascial sheet bridging the lacrimal fossa laterally (the lacrimal diaphragm). This structural arrangement – which has been questioned by Brienen and Snell (1967) – figures prominently in a postulated mechanism of lacrimal liquid drainage. The whole of the orbicularis is innervated by the facial nerve.

Behind the orbicularis oculi lies the tarsal plate, which may be regarded as the skeleton of the eyelid. It consists of a very dense plate of fibrous tissue that has a base close to the lid margin. In the upper lid, it extends to the level of the superior palpebral furrow and its upper boundary describes an arc from the medial to the lateral canthus. In the lower lid the plate is only a third as deep.

If pressure is applied inwards and downwards along the superior palpebral furrow, using the fingers or a glass rod, and the lid margin is pulled upwards, the upper lid may be everted. This position is maintained without assistance by the strength of the tarsal plate, provided that the eyes are directed downwards. This manoeuvre is used to permit inspection of the palpebral conjunctiva. When the eyes look upwards, the lid reverts to its normal position. Foreign bodies are frequently lodged in the conjunctiva between the base of the upper tarsal plate and the lid margin where the subtarsal sulcus is formed.

Eversion of the lid reveals the tarsal (meibomian) glands, which are buried within the tarsal plate. The glands run nearly the full length of the tarsus and, in fact, beyond the tarsus at the lid margin, and they are arranged approximately parallel. There are about 25 in the upper eyelid and about 20 in the lower eyelid. The openings of the gland ducts are disposed in a single row along the lid margin, behind the lashes. The glands are sebaceous and holocrine, the ruptured pyknotic cells forming the oily secretion. Overflow of tears is prevented by a coating of tarsal gland secretion along the lid margins, and this is extended in a thin film across the precorneal tear layer (*see* Tears, p. 41).

Tarsal glands quite commonly become infected, forming a chalazion or internal stye. Although not painful itself, the chalazion frequently produces a small, hard, discrete elevation of the inner surface of the eyelid, and irritation of the cornea may ensue. Irregularity of the tarsal conjunctiva of whatever cause potentially presents a problem for the contact lens wearer. Hodd, in a personal communication, suggested that in numerous cases of lens intolerance a chalazion is the culprit.

The palpebral conjunctiva lines the posterior face of the eyelids. It is firmly attached to the tarsal plate by a thin fibrous subepithelial layer that is rich in capillaries and venules. There is good evidence that the vessels nourish the cornea when the lids are closed. Some small lymphatic vessels are also present in this layer, and they communicate with other lymphatics of the eyelids at the upper and lower margins of the tarsal plate. The epithelium is described above (pp. 25–27).

The levator palpebrae superioris is a striated muscle with the function of elevating the upper eyelid. It therefore opposes the action of the orbicularis oculi. The levator passes above the superior rectus muscle within the orbit and it has a broad tendonous insertion in the lid. Part of the insertion terminates at the upper border of the tarsus, and the remainder passes in front of the tarsus between the fascicles of the orbicularis to the skin. The levator is innervated by the oculomotor nerve.

A thin layer of smooth muscle – the superior tarsal muscle of Müller – contributes to the elevation of the eyelid. It is a short muscle connecting the inferior fascial sheath of the levator with the upper margin of the tarsus. The superior tarsal muscle is innervated by sympathetic nerve fibres, and it has a weak action compared to that of the levator. This is suggested by the difference in the sizes of the two muscles and by the observation that sympathectomy produces a modest depression of the upper lid compared with the marked ptosis after oculomotor neurectomy. The specific role of the superior tarsal muscle in effecting elevation of the lid is uncertain. An inferior tarsal muscle is found in the lower lid with attachments to the fascial sheaths of the inferior rectus and inferior oblique muscles and to the inferior tarsus. No counterpart to the levator palpebrae superioris is present in the lower lid. The limited capacity to depress the lid is therefore produced by contraction of the inferior rectus muscle and the inferior tarsal muscle.

Structure of the eyelid margin

The line of tarsal gland orifices at the margins of the lids marks the sharp transition from unkeratinized epithelium of the conjunctiva posteriorly to the keratinized epithelium of the skin. Two or three irregular rows of cilia, or eyelashes, emerge from the skin in front of the tarsal gland orifices. The lashes are thick and strong, and those of the upper eyelid are longer and more numerous. The lash follicles are disposed between the terminations of the pretarsal portion of the orbicularis muscle and the lid margin and they lack arrectores pilorum. Lashes are replaced two or three times a year and regrow quickly after epilation. They are normally curved outwards, but in rare instances they may grow inwards to touch the cornea and give rise to pain.

Paired sebaceous glands (of Zeis) open into the lash follicles, and their oily secretion moistens the lashes. Sweat

glands (of Moll) are also present in small numbers in the lid margins. Unlike sweat glands elsewhere, they are uncoiled and possess a wide lumen. Although they sometimes open into lash follicles, they usually exhibit the common feature of sweat glands of opening directly onto the skin.

Small bundles of striped muscle fibres (of Riolan) are present immediately beneath the skin of the lid margins. Most of these lie anterior to the tarsal gland ducts but a few are present posterior to the ducts. In general, they run approximately parallel to the lid margins but some fibres pass obliquely between the ducts. It has been postulated that these fibres control the lumina of the ducts. However, this appears unlikely other than as an occurrence incidental to their function of maintaining the lid margins in apposition to the eye during lid closure.

The conjunctival face of the eyelid margins receives the richest innervation (Munger and Hulata, 1984; Baljet *et al.*, 1989), and the density is reduced substantially in the remainder of the palpebral conjunctiva.

The eyelid sometimes catches the edge of a corneal contact lens. This problem is caused by the lens periphery standing off from the cornea, but an unusual configuration of the posterior margin of the eyelid might be a predisposing factor. However, Shanks (1965) employed a moulding technique to examine this feature in a small group and found little variation between individuals.

Lid movements

In waking hours the upper eyelid is very active as a result of spontaneous blinking. A basic rhythm of blinking occurs at an approximate frequency of 12 blinks per minute (King and Michels, 1957; Carney and Hill, 1982), with considerable variation between individuals and circumstances. Alterations of the rate of blinking are produced by many factors such as anxiety, noise or a stuffy atmosphere – but, interestingly, not by a dry atmosphere. A blink is completed in less than one-third of a second. During this period, the eye makes a rapid upwards and inwards movement and returns. Ginsborg (1952) found this movement to be between 20 and 100 minutes of arc nasally and between 40 and 70 superiorly when the eyes were initially in the primary position but the direction and extent varies with the initial position of the eyes. In secondary positions of gaze, there is a tendency for the eye to move towards the primary position during blinking (Ginsborg and Maurice, 1959). This small displacement is insufficient to account for the movement of a contact lens relative to the eye during a blink; clearly it is the traction of the eyelid that causes the lens movement. The blink rate is reduced when contact lenses are worn, the more so with rigid lenses (Brown *et al.*, 1973).

If closure of one eye is prevented by holding the lid when a person attempts to shut both eyes, a movement upwards and outwards is usually seen. This displacement is known as Bell's phenomenon and it is most strikingly displayed in some cases of facial paralysis (Bell's palsy). The movement is far greater than that induced by blinking as measured by Ginsborg.

Closure in blinking is produced by relaxation of the levator followed by contraction of the palpebral portion of the orbicularis oculi. The whole orbicularis and frequently the accessory muscles contract when the eyes are squeezed shut. This may occur reflexly (optical blinking or menace reflex) together with a backward movement of the head when, for example, the eyes are exposed to a dazzling light, or when a tonometer or contact lens approaches the eye. All contact lens practitioners, however considerate their manner, must have faced the problem of a patient's prolonged blepharospasm prior to the initial insertion of a contact lens.

Gordon (1951) held that in downward gaze, as in reading, the orbicularis muscle plays no active part and that relaxation of the levator is alone responsible for the partial closure of the palpebral aperture. In upward gaze, contraction of both the levator and the frontalis muscle occurs.

Corneal innervation

The cornea is served by 70–80 small sensory nerves. They issue from ciliary nerves which branch from the ophthalmic division of the trigeminal nerve. They enter the sclera from the uvea at the level of the ciliary body and pass anteriorly to enter the cornea radially and predominantly in the middle corneal layers. Other nerves from the same source enter the cornea superficially. They enter the conjunctival epithelium from the subepithelial tissue at the limbus and pass directly into the corneal epithelium at basal cell level (Lim and Ruskell, 1978). A minority of the nerve fibres entering the cornea possess a myelin sheath but this is lost at the limbus or within 0.5 mm of entering the cornea. Rarely myelin persists a little further and, exceptionally, even to the centre of the cornea. Such fibres are, of course, opaque and they present a striking picture when viewed through a biomicroscope. The perineurium and the fibres and cells of the endoneurium also terminate at the limbus. Only the nerve fibre bundles advance into the cornea. Each bundle consists of several axons enclosed by a Schwann cell sheath (Matsuda, 1968).

Initially, the fibre bundles of each nerve are grouped together. These separate and spread, overlapping and running together with branches from neighbouring nerves producing the plexiform arrangement seen in full thickness preparations of the cornea under low magnification with methylene blue stain (Zander and Wedell, 1951a; Oppenheimer *et al.*, 1958) or with a stain for acetylcholinesterase (*Figure 2.14*). The plexus is particularly dense beneath Bowman's layer.

Axons separate and some divide at intervals and form fine terminal branches, some of which may lose their Schwann cell investment; the terminal axons follow a lengthy and tortuous course between the stromal fibrils. They bear numerous small bead-like varicosities, with a final, often larger one marking the end of the axon.

Fibres from single nerve bundles at the limbus may be distributed to as much as two-thirds of the area of the cornea. Consequently, there is a considerable overlapping of

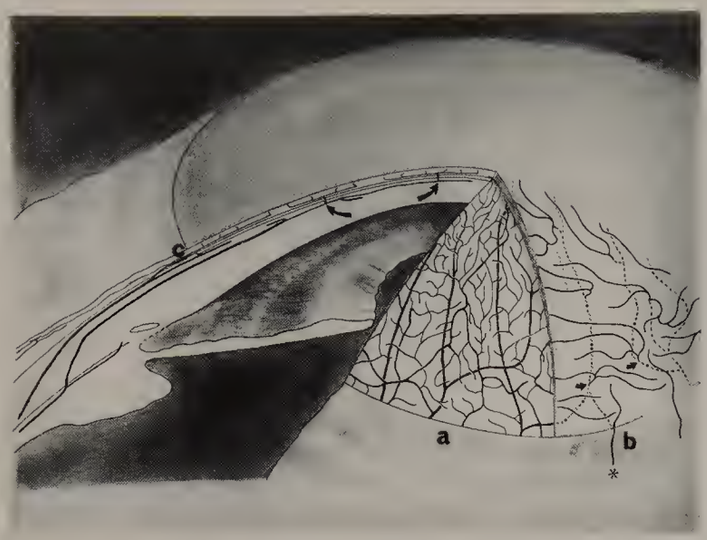


Figure 2.14 Anterior structures of the eye with a segment removed to reveal a meridional section; the topographical appearance of the stromal nerves of the cornea is presented at **a** (the epithelium is removed), and the epithelial nerves at **b**. The small arrows opposite **b** indicate examples of stromal nerve (dotted) penetration to the epithelium. The large arrows similarly show the penetration from the subepithelial plexus of nerves. The branch at **c** enters the conjunctival epithelium very close to the cornea and crosses into the epithelium directly

nerve fibres from different nerve bundles. Measurements of receptive fields of the cornea of the cat recorded from ciliary nerves are consistent with the anatomical arrangement of nerve fibre bundles and indeed, overlapping of receptive fields of single nerve fibres has been demonstrated (Belmonte and Giraldez, 1981). This arrangement explains why sensitivity persists in all areas of the cornea subsequent to large, full-thickness, perilimbal incisions as undertaken in the surgical treatment of cataract and glaucoma (Schirmer and Mellor, 1961). It also explains inability to localize stimuli on the cornea.

The epithelium receives a prolific supply of terminal nerve fibres which pass perpendicularly from the plexus of the anterior stroma and penetrate Bowman's layer. The small nerve fibre bundles lose their Schwann cell investment before entering the epithelium whereupon the fine naked axons disperse and turn sharply to lie nearly parallel to Bowman's layer. They probably arborize (Ueda *et al.*, 1989) as they pass between the basal cells. Varicosities similar to those present in the stroma occur in the epithelium. Such axons may run a course, often with little weaving, up to a length of 2 mm with fine beaded branches issuing from them directed through successive layers of epithelial cells nearly to the surface of the cornea (Schimmelpfennig, 1982; Tervo *et al.*, 1985). Matsuda (1968) observed epithelial nerve terminal beads of two types in rabbits and man; one contained mitochondria and the other contained both mitochondria and vesicles. Beads without vesicles probably serve a sensory function, and those with vesicles are probably motor, he suggested.

This leads to the unsettled problem of whether or not the cornea has an autonomic innervation in man. There is no reliable evidence of parasympathetic fibres in the cornea of any species and in studies demonstrating the parasympathetic neurotransmitter VIP (vasoactive intestinal polypeptide) in various tissues of the eye, none is found in the cornea (Miller *et al.*, 1983; Stone *et al.*, 1986a). Support for a sympathetic innervation has been strengthened (Toivanen *et al.*, 1987; Ueda *et al.*, 1989; Marfurt and Ellis, 1993) but doubt persists (Stone *et al.*, 1986b; ten Tusscher *et al.*, 1989). Their possible functions were considered earlier under *Cell production and corneal trophism* (p. 20).

Variety in their chemistry suggests that sensory fibres may consist of functionally distinct subgroups; some contain the neuropeptide substance P (Tervo *et al.*, 1981; Stone *et al.*, 1982), which is recognized as a neurotransmitter in the central nervous system, and others, of unknown chemical identity, do not (Lehtosalo, 1984). Calcitonin gene-related protein (CGRP), another neuropeptide identified in the cornea, may coexist with substance P in the same terminal (Stone *et al.*, 1986b). Various functions of corneal nerves are mentioned in these papers but none can yet be attributed to a specific nerve fibre form.

Sensitivity of the cornea and conjunctiva

Common experience and the earliest measurements of surface sensitivity indicate that the sensitivity of the cornea is probably unsurpassed by that of any other part of the body. The measurement of threshold sensitivity has been practised throughout this century but it is probably true to state that progress has only recently been made in calibrating the stimulus with accuracy. Notwithstanding, the technique of aesthesiometry remains blunted by uncertainties, and the data it provides – whether absolute or relative – can only be accepted with caution in so far as they apply to the cornea and conjunctiva. The stimulus employed was classically a fine hair or a series of hairs of different lengths and weights applied to the surface of the cornea but, more recently, a nylon monofilament has been used. The force exerted is measured in weight per unit area of contact. The area of contact is assumed to remain constant and the weight or pressure is varied. The method of varying the unsupported length of monofilament between the holder and the point of contact is usually employed in corneal aesthesiometers. Pressure on the instrument is increased until the monofilament bends and the force required to achieve this end-point for any length of monofilament is precalibrated. The length of monofilament is decreased until a threshold response is elicited. The shorter the length of monofilament the greater the pressure required to bend it. An electronic aesthesiometer, making use of an induction coil to produce preset forces of the stimulus body placed in contact with the cornea before measurements are taken, is now available (Draeger, 1984). Threshold and differential responses may be measured electrophysiologically in experimental animals.

The sensitivity of the cornea varies from a maximum apically to a minimum at the periphery with a considerable

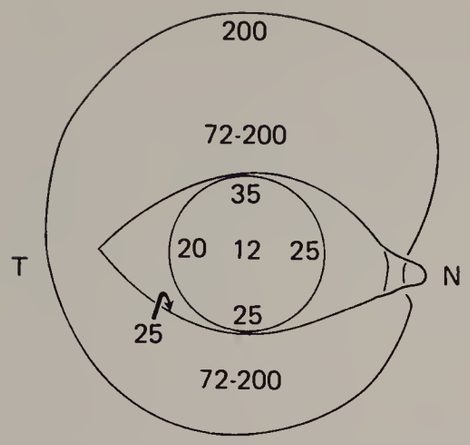


Figure 2.15 Touch thresholds (in mg/mm^2) representing a synthesis of published results. Absolute values vary according to the technique used and those shown are considered the most likely to be obtained with careful use of hand-held 0.12 mm nylon suture Cochet–Bonnet aesthesiometer. Lower thresholds would be obtained using a 0.08 mm instrument with mechanical control of application and microscopic viewing. The arrow indicates the marginal conjunctiva normally in contact with the eye

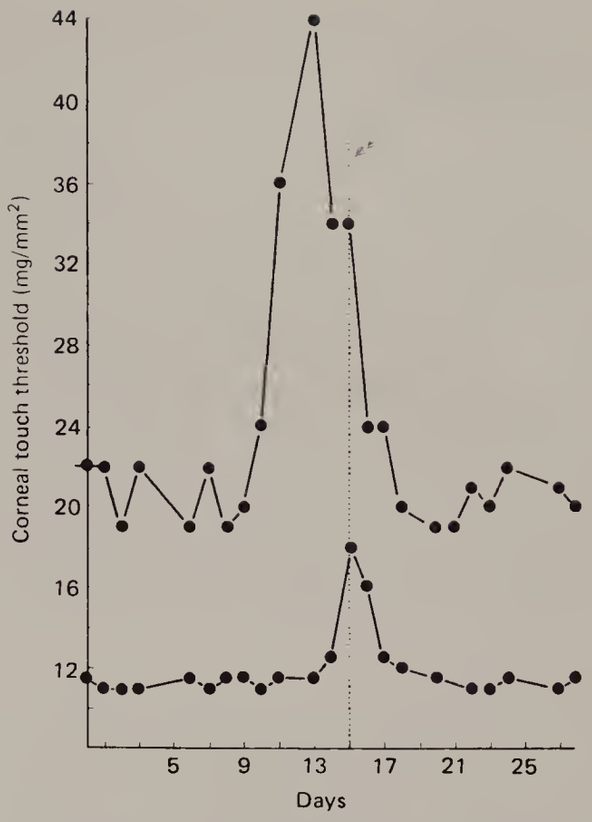


Figure 2.16 Relationship between corneal touch threshold and number of days of the menstrual cycle of two women. Days are numbered from the assumed occurrence of ovulation and the dotted line represents onset of menstruation. (From Millodot, 1974, *Br. J. Ophthamol.*, **58**, pp. 752–756, by kind permission of the author and publishers)

drop in sensitivity at the limbal conjunctiva. Sensitivity reduces further to a minimum at the fornix, then increasing again at the lid margins (Boberg-Ans, 1955; Cochet and Bonnet, 1960; Schirmer and Mellor, 1961).

Sensitivity increases sharply from the tarsal to the marginal conjunctiva and then reduces slightly at the narrow strip of conjunctiva contributing to the occlusal surface of the eyelid (McGowan *et al.*, 1994). Using a nylon monofilament the average central threshold stimulus is about 15 mg/mm^2 and the peripheral corneal threshold is highest at the 12 o'clock position where the cornea is normally partially covered by the eyelid (Draeger, 1984; Millodot, 1984). A summary of threshold values is given in *Figure 2.15*. According to Cochet, in a personal communication, Sédan observed an annular zone of raised sensitivity (lower threshold) about 4 mm from the centre of the cornea in 30 per cent of cases and Draeger (1984) claimed to find the increase regularly with his instrument.

Sensitivity varies with age. In a study of 150 patients whose ages ranged between 10 and 90 years, Boberg-Ans (1956) found a peak sensitivity in young patients three times that of his oldest patients, a slightly greater difference than that found by Millodot (1977). Most of the sensitivity reduction occurs between the ages of 50 and 65 years (Jalavisto *et al.*, 1951) or even later (Sédan *et al.* 1958). Sensitivity is usually approximately the same in both eyes, and there is no reliable evidence to indicate a difference in sensitivity between the sexes but it is worth noting Millodot and Lamont's (1974) observations that the average sensitivity in nine women was approximately halved during the premenstruum and at the onset of menstruation (*Figure 2.16*). Moreover, women may exhibit a transient reduction of sensitivity in the later weeks of pregnancy (Millodot, 1977; Riss and Riss, 1981). Corneas display a diurnal variation in sensitivity with about a third greater sensitivity as the day progresses from morning to evening (Millodot, 1972). Perhaps the most striking variation is that displayed between people of different iris colour. Millodot (1975b) found that blue-eyed people have a greater sensitivity than those with dark-brown irides (*Figure 2.17*). Non-white people with dark-brown irides have less sensitive corneae than Caucasians with similar iris colour. On average, non-white people have four times less sensitive corneas than blue-eyed people and half as sensitive corneae as brown-eyed Caucasians.

Depression of corneal sensitivity as a consequence of limbal transection for cataract extraction is surprisingly slight. The threshold value adjacent to the incision is raised to little more than twice the normal (Schirmer and Mellor, 1961) but recovery of sensitivity was found to be negligible over a period of 2 years (Draeger, 1984). The survival of nerve fibres entering the cornea across half its circumference is adequate to maintain a high degree of sensitivity over the whole of the cornea. One might expect some recovery of sensitivity subsequent to a limbal incision if one is free to extend Zander and Weddell's (1951b) observations on rabbits to man. They found that normal innervation was recovered in favourable cases 9 months after keratotomy of up to one-third of the corneal

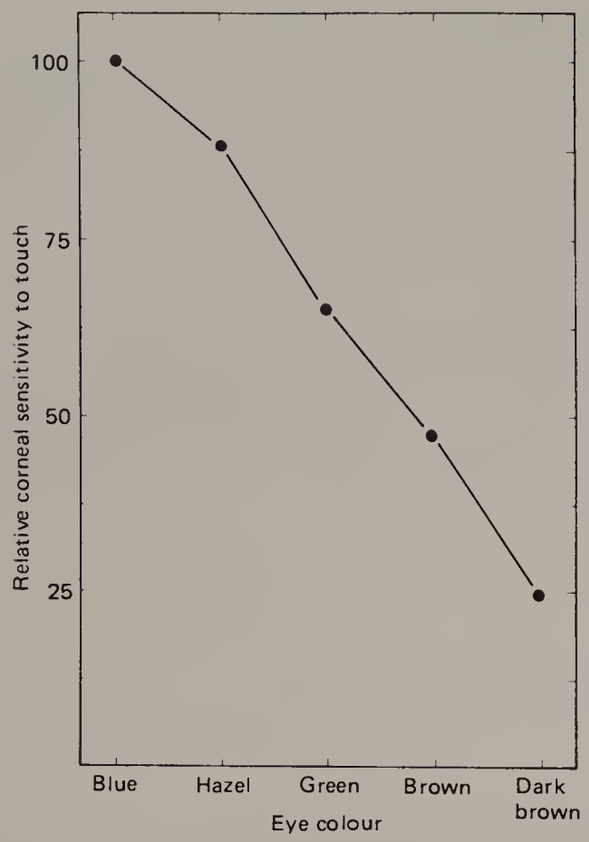


Figure 2.17 Relative corneal sensitivity to touch as a function of the colour of the iris (112 subjects). The dark brown group consists of non-white subjects. The sensitivity is the reciprocal of the touch threshold measured in mg/mm^2 and the group with greatest sensitivity has been assigned 100. (From Millodot, 1975b, by kind permission of the author and publishers)

circumference, but the speed of regeneration of corneal nerve fibres is related to age, being more rapid in the young (Rexed and Rexed, 1951).

The opportunities to study reinnervation of corneal transplants in man are obviously rare and the limited information available so far suggests that epithelial reinnervation may reach normal levels, whereas stromal reinnervation is sparse (Tervo *et al.*, 1985). Recovery of sensitivity in the transplant area after several years is practically nil in some cases and slow and fractional in others (Ruben and Colebrook, 1979; Lyne, 1982; Draeger, 1984; Macalister *et al.*, 1993).

All diseases affecting the cornea tend to reduce sensitivity and a summary of conditions studied by aesthesiometry is available (Millodot, 1984). Contrary to common belief, keratoconus provides an example of reduced sensitivity (Millodot and Owens, 1983; Bleshoy, 1986). The reduction is largely confined to the central cornea but with little or no correlation with cone steepness. The general polyneuropathy of diabetes is expressed in the cornea by a reduced sensitivity (O'Leary and Millodot, 1981). Low sensitivity is also associated with the inherited condition of albinism (Millodot, 1978).

The effects of contact lenses on corneal sensitivity

Corneal sensitivity is reduced as a result of wearing hard contact lenses. Sensitivity testing, in the past, produced some extraordinarily discrepant results with claims that sensitivity reduces to a fraction of the normal level with the use of hard contact lenses or, contrariwise, that lenses are commonly innocent of any effect when fitted properly. Freehand aesthesiometry and possibly bias must take the blame for the confusion. When the aesthesiometer is attached to a biomicroscope, it provides stability, improved control of application speed and adequate visibility. As a result, sensitivity reduction of relatively modest proportions is recorded as a routine response to contact lens wear. Millodot (1975a,b) used the Cochet–Bonnet nylon aesthesiometer under controlled conditions. Touch threshold value was approximately doubled on average in 11 young subjects after wearing PMMA contact lenses for 8 hours (*Figure 2.18*). Sensitivity reduction was proportionately similar for the central and peripheral cornea and full recovery occurred 2 hours after removal of the lenses. Lower eyelid margin sensitivity was substantially reduced by wearing PMMA contact lenses (Lowther and Hill, 1968).

Sensitivity reduction is chronic and slowly progressive and after some years of daily PMMA contact lens wear

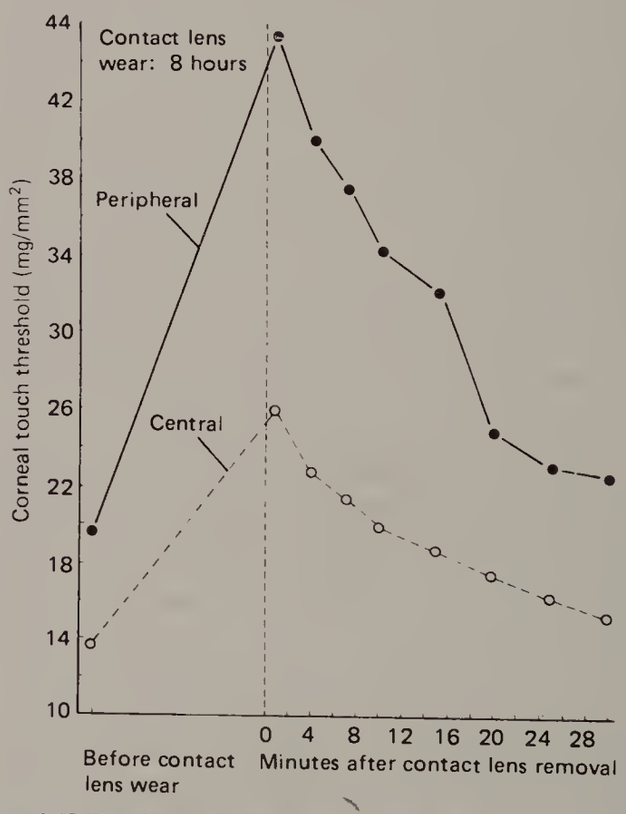


Figure 2.18 The effect of PMMA contact lenses on corneal touch threshold averaged from the eyes of 11 subjects. Thresholds before lens insertion and at frequent intervals after 8 hours wear are plotted. Threshold at the centre of the cornea is about half that at the periphery. Recovery of sensitivity after contact lens removal is comparable in both positions. (After Millodot, 1975a)

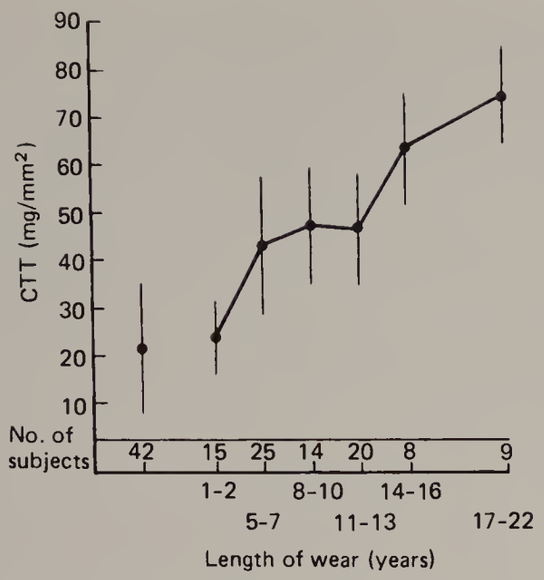


Figure 2.19 Chronic sensitivity reduction in PMMA contact lens wearers using a daily wear routine. The corneal touch threshold (CTT) was measured early in the day before insertion of lenses. Vertical lines represent ±s.d. (From Millodot, 1976, by kind permission of the author and publishers)

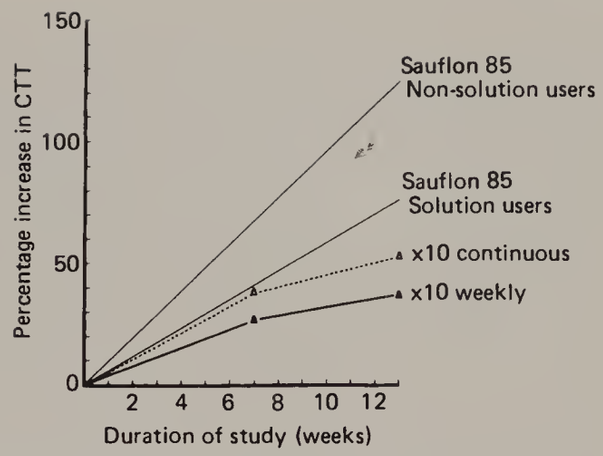


Figure 2.20 Variation in corneal touch threshold with two types of high water content soft lenses worn differently. The Sauflon data were taken from the 20-week study of Larke and Hirji (1979) referred to in the text. ×10 is assumed to be an abbreviation for another type of extended wear lens. (From Millodot, 1984, by kind permission of the author and publishers)

corneal sensitivity no longer returns to a normal level upon removal of the lenses. *Figure 2.19* shows a considerable reduction in sensitivity after 5–8 years lens wear reducing further after 15–21 years with a threefold rise or more in threshold, yet the wearers displayed no symptoms and corneal oedema was insignificant. Some of the long-term wearers in the group abandoned their lenses and normal levels of sensitivity returned after 1–3 months confirming that contact lens wear was responsible for the reduction (Millodot, 1978). The corneal sensitivity of long-term PMMA lens wearers improved substantially when transferred to rigid gas permeable lenses (Bergenske and Polse, 1987). Most of the improvement occurred within seven days and was maintained for the remainder of the six month period of the study. The new touch threshold was claimed to be similar to normal levels.

Soft contact lenses also depress corneal sensitivity but the amount is relatively small. In the earliest studies, Larke and Sabell (1971) found none while Knoll and Williams (1970) observed a loss that was not statistically significant. However, when sensitivity was measured subsequent to the removal of soft contact lenses, a small but significant increase was found (Millodot, 1974). Evidently sensitivity had been reduced. This loss was probably obscured in earlier studies by the diurnal increment of sensitivity as the day progresses.

The long-term effect of soft contact lenses on sensitivity is unknown but the results of short-term prospective studies imply that reduction of sensitivity is again chronic and progressive. Extended wear lenses appear to hasten the process as sensitivity was more than halved after 20 weeks (Larke and Hirji, 1979); the reduction was slightly less when a lens cleaning solution was used at 8-week intervals. The rate of sensitivity loss evidently also depends upon the nature of the lens material (*Figure 2.20*).

Oxygen deprivation appears to be the major cause of corneal sensitivity loss and, presumably, mechanical assault is responsible for eyelid margin effects. The cornea in sleep is deprived of atmospheric oxygen (*see* p. 40) and after sleep sensitivity is found to be depressed. When deprivation is extended by taping the lids, sensitivity reduction is much increased (Millodot and O'Leary, 1980). When atmospheric gases are controlled by using goggles, sensitivity reduction is highly correlated with time of exposure to reduced oxygen levels.

Schirmer (1963) suggested that in determining the suitability of patients before prescribing contact lenses corneal sensitivity should be taken into account but in particular, he valued the degree of tolerance to a sustained stimulus as a better criterion. He also suggested that high tolerance and low sensitivity would be suitable features for successful contact lens wear on the evidence of his data using his instrument. At the present time, there appears to be little reason to promote the routine use of aesthesiometry in contact lens practice and it must be remembered that the technique is not without hazard.

Sensibility of the cornea and conjunctiva

One associates the sensations of pain and irritation with the cornea, possibly to the exclusion of any others. Von Frey and his co-workers (*see* Strughold, 1953) proposed and maintained this view over several decades against the evidence of other groups who claimed that the cornea exhibits several sensibilities. The problem is of broad interest in that von Frey postulated the well-known correlation between specific forms of cutaneous sensory end-organs with particular functions. Free nerve endings mediate pain sensitivity, according to this hypothesis and, as

we have seen, the cornea is populated exclusively by them. The qualitative evaluation of sensitivity is of limited practical importance to the contact lens practitioner, but the cornea is a structure which is at the centre of an engaging physiological dispute and a brief account of the views of the opponents of von Frey's conception of cutaneous sensitivity may be of interest.

Lele and Weddell (1956) claimed that the sensibilities of touch, cold, warmth and pain may be experienced if the cornea is suitably stimulated. Strughold (1953) himself, although a principal proponent of the von Frey concept, appeared to concede the possibility of touch sensibility as distinct from irritation. Nafe and Wagoner (1937) claimed that either touch or pain sensations may be elicited from the cornea according to the intensity of the stimulus. Based on the understanding that pain impulses conducted by the trigeminal nerve – and therefore including those initiated in the cornea – are chiefly presented at the caudal end of the nucleus of the spinal trigeminal tract in the lower brainstem, Sjoqvist (1938) incised the tract at this level in cases of trigeminal neuralgia. This procedure effectively reduces the sensibility of pain while sufficient tactile sensibility is retained to avoid the possibly blinding consequences associated with total anaesthesia which results from the alternative operation of trigeminal neurectomy (Rowbotham, 1939; Grant *et al.*, 1940). Patients treated by this procedure experience no discomfort if the cornea is moderately stimulated, and they recognize the predominating sensation as touch.

One is, perhaps, at liberty to conclude from this evidence that the sensation of touch is fully differentiated from pain, but it is noteworthy that in cats the representation of pain sensation is spread throughout the nucleus of the spinal trigeminal tract (Eisenman *et al.*, 1963; Kerr, 1963). The separate representation of pain in the trigeminal nerve nucleus is inconsistent with the 'gate control' theory of Melzack and Wall (1965). They argued that pain is experienced as a consequence of increased strength of any form of stimulation sufficient to release the central inhibition set up by activity of cells of the substantia gelatinosa. On this basis, Sjoqvist's incision may be considered to so reduce total sensory input that the threshold for pain is not reached or the gate is not opened.

Perhaps the most controversial aspect of corneal sensibility is that of temperature. Von Frey concluded, from experiments in which he stimulated the cornea with cooled and heated rods, that temperature sensations were absent. He also noted the absence of Ruffini endings and Krause end-bulbs. In the adjacent conjunctiva, Strughold and Karbe (1925) found many warm and cold spots. Employing intravital staining of nerves and the low magnification level of the biomicroscope, they concluded that warm spots related to Ruffini endings and cold spots to Krause end-bulbs. These observations supported their view that warmth and cold sensibilities are not experienced from the cornea. Subsequent studies by Weddell and Zander (1950) and Oppenheimer *et al.* (1958) unequivocally rejected this correlation in the conjunctiva. Complex nerve endings are rare and irregularly occurring, and in some species they are altogether absent. They therefore cannot be considered to relate to the function of temperature reception. This leads to the conclusion that morphologically unspecialized nerve endings are related to a variety of sensibilities, and that absence of all but free nerve endings in the cornea does not preclude the reception of stimuli giving rise to sensations other than pain.

Nafe and Wagoner (1937) concluded from their experiments that both warm and cold sensations are absent from the cornea. Lele and Weddell (1956), in challenging the validity of these experiments, pointed out that these investigators were searching to establish that vascular receptors are responsible for the sensations of warmth and cold and that it was in their interest to find a negative response to these stimuli in the avascular cornea. Kenshalo (1960) showed that thermal changes may be recognized by the cornea, but he claimed that the quality of the sensation is irritation rather than warmth. The temperature difference required for threshold sensitivity was found to be much in excess of that necessary in the conjunctiva, lips and skin. However, the detectable temperature changes in Lele and Weddell's subjects, employing short-duration warm and cold air jets, indicated an accurate discrimination: a cold jet was never confused with a warm jet. Although the elicited sensations were equated approximately with those of warmth and cold, these workers recognized them to be somewhat singular in quality.

Temperature responsive corneal neurones have been identified in animals. Electrical recordings from rabbit anterior segments studied *in vitro* revealed cold-, mechano-, mechano/heat- and chemosensitive units (MacIver and Tanelian, 1993) with different conduction rates (delta and C fibres) and related to different fibre orientations in the epithelium. For example, fibres running perpendicular to the corneal surface gave C fibre cold or chemosensitive responses. In another study cold receptors, preferentially located at the periphery of the cornea, were identified in cats *in vivo* and distinguished from polymodal (mechanical, heat, chemical) receptors (Gallar *et al.*, 1993).

The disputatious nature of this subject defies adequate summary but the weight of evidence suggests that touch (irritation) and pain are neurologically distinguished only as a consequence of stimulus strength difference, whereas specific receptors for cold and polyreceptors for heat are likely. The evidence for chemoreceptors is slender but common experience encourages acceptance of their presence. Unlike skin receptors, they are all low threshold nociceptors whatever their preferred stimulus.

Corneal transparency

The most obvious and simple explanation for the transparency of the cornea is that its components all have the same refractive index, but a number of easily observed factors discount this. For instance, an anatomist might doubt the validity of this explanation because the structure of the cornea in unstained sections is discernible using phase

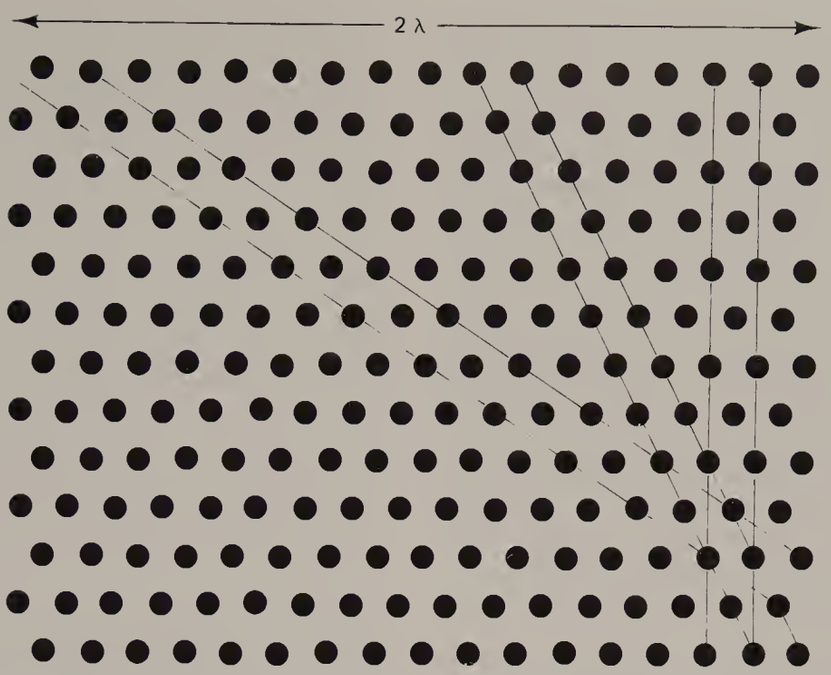


Figure 2.21 Lattice arrangement of the fibrils of the corneal stroma. If lines were drawn joining the adjacent fibrils, they would describe a lattice. The parallel lines pass through rows of fibrils and represent light wave fronts. The rows of fibrils may act as diffraction gratings (Maurice, 1957) and hence, wave fronts of widely differing orientations may traverse the stroma

contrast microscopy which is dependent on refractive index differences. Similarly, cellular detail is discernible in the living eye with a biomicroscope. The birefringence of the cornea is evident from the interference figures it displays when examined with polarized light, and this property has been examined in detail (Naylor, 1953; Stanworth and Naylor, 1953).

Cogan and Kinsey (1942), accepting a difference in refractive index of the stromal components, proposed that refraction at their surfaces is minimized as a consequence of a limited liquid component, and one may point to the phenomenon of scleral transparency *in situ* in the dehydrated state in support of this. But this concept is at variance with the facts that the liquid component is of the order of 80% by weight and collagen fibrils constitute only 18% of the volume of the stroma.

Caspersson and Engström (1946) postulated that the fibrils of the stroma are positioned parallel to the surface of the cornea in rows which are perpendicular to it. Light rays would be refracted to and fro along a row of fibrils and finally emerge undeviated. The gaps between fibrils were considered to be 'plugged' by the mucoid ground substance of graduated refractive index with a peak equal and adjacent to that of the fibril, thereby avoiding reflection at interfaces. This scheme is untenable for a number of reasons – one of which is that it accounts only for light rays of normal incidence.

No satisfactory hypothesis explaining the transparency of the cornea as a whole has appeared, but Maurice (1957, 1962a) offered an explanation of the transparency of the stroma. His hypothesis is precisely stated and does not invoke extravagant assumptions. It embraces light of all incidences and satisfactorily explains how transparency is lost in various circumstances. Maurice proposed that the stromal fibrils, which were found to have a refractive index of about 1.55 in the dry state, are so arranged as to behave as a series of diffraction gratings permitting transmission through the liquid ground substance (refractive index 1.34). We have already seen that the fibrils in adjacent regions of the stroma are of remarkably regular diameter and that they are probably regularly spaced so that, neglecting the curvature of the cornea, in any plane a reasonable facsimile of a diffraction grating exists. It is of interest to note that the fibrils of the opaque sclera do not show these properties. A diffraction grating eliminates scattered light by destructive interference and permits the transmission of light energy maxima at angles θ to a normally incident beam, the angles depending on the physical characteristics of the grating and the light. Accordingly, $\sin \theta = m\lambda/d$, where m is any integer and d is the space between grating elements. The fibrils are the grating elements which, it is suggested, are disposed in an hexagonal lattice as shown in *Figure 2.21*. Only the first of the energy maxima applies because the grating or fibril interval is shorter than the wavelength of light i.e. $\lambda/d > 1$, and the equation is only satisfied when m is zero and consequently θ is 0°. In this manner the transmission of normally incident light through the stroma, without deviation or significant scattering, is explained. As shown in *Figure 2.21*, a light beam of other than normal incidence is covered by the hypothesis simply by considering an oblique lattice plane. Other planes can be drawn, and together they explain the transmission of light through the cornea at different incidences. The lattice theory has been questioned – for example, Smith (1969) argued that Maurice's

calculations of refractive index differences were incorrect – but the theory has gained wide acceptance as a reasonable explanation of transparency of the stroma.

The slight irregularities of collagen fibril separation as seen with the electron microscope were regarded by Maurice as preparation artefacts. Others have taken them into account such as Hart and Farrell (1969) who computed the probability distribution function for the relative position of fibrils from electron micrographs. They found that the mathematical summation of the phases of light waves scattered by the partially ordered array gave magnitude and wavelength dependence of the scattered light in good agreement with that found experimentally. Benedek (1971) presented proof that the scattering of light is produced only by fluctuations in the index of refraction of wavelengths larger than one-half the wavelength of light in the medium. Since the index fluctuations are far shorter than this value, transparency of the stroma is explained without the need for a perfect lattice of collagen fibrils. It has the added advantage of explaining the transparency of Bowman's layer.

When the cornea is oedematous, its transparency is reduced and this may be explained in terms of the lattice theory in that the regularity of the fibrillar spacing is disturbed by the excess liquid and the efficiency of fibrils as grating elements is reduced. Local pressure on the cornea reduces transparency in the compressed region, again as a result of fibril disarray, but normal transparency returns immediately the pressure is withdrawn, allowing the forces maintaining the regular fibrillar spacing to operate once more. The haze and haloes around bright lights which may become noticeable when contact lenses are worn are the result of corneal swelling, and again this may be explained in terms of the lattice theory. Alternatively, transparency loss with oedema may be explained by the formation of spaces within the stroma free of collagen fibrils and larger than the critical size of half the wavelength of light.

The maintenance of corneal transparency is clearly dependent on the forces which limit its hydration. These forces are very susceptible to disturbances such as that produced by a contact lens. Corneal hydration undoubtedly follows the insertion of a contact lens; some lenses are worse offenders than others and some persons are more affected than others. The dehydrating forces are discussed in the following section.

Maintenance of corneal transparency

The cornea functions in a liquid environment and yet it has the capacity to maintain a steady solid/liquid ratio of about 1:4. If this ratio is increased by liquid uptake, the cornea loses its transparency. As the excised or damaged cornea is remarkably hygroscopic (the excised cornea in water increases to about four times its normal thickness), we may conclude that the transparent, living cornea, as a significant part of its workload, has to pump out water.

The integrity of its surface layers is essential for maintenance of corneal transparency, indicating that the pump operates through them. It is widely accepted that the endothelium carries the major burden in this active process, and much evidence supports this view. The pumping function could explain the high oxygen consumption by the endothelium per unit volume compared with that of the epithelium (Freeman, 1972). In experiments on rabbits, Maurice (1972) showed that the endothelium has the capacity to pump out water up to 12 times its own thickness in an hour. But both epithelium and endothelium have been shown to act as inert partial barriers to ion and liquid influx under experimental conditions such as hypothermia or anoxia, when the pump cannot be working, and therefore one may consider the pump to complement the action of the structural barriers in effecting deturgescence of the cornea. The barrier characteristics of the limiting layers are different in that the epithelium is far more impermeable to organic ions than is the endothelium, while the endothelium is more resistant than the epithelium to diffusion of water (Maurice, 1951; Donn *et al.*, 1963).

The pump probably operates by expelling ions from the stroma to the fluids bathing the cornea, setting up an osmotic flow of water from the cornea. It is therefore an active process and if corneal metabolism is inhibited the pump cannot operate and the cornea swells and loses transparency due to the uptake of water. A 'metabolic pump' is therefore actively transporting substances across the surface layers. Active transport describes the movement of a substance across a biological membrane against an electrochemical gradient, requiring the use of energy. The potential gradient results from the inequality of distribution of electrolytes on the two sides of the membrane.

The importance of metabolic forces is established by experiments in which both transparency loss and thickening occur when the temperature is reduced to a level sufficient to inhibit metabolism followed by recovery when the temperature is raised (Davson, 1955; Harris and Nordquist, 1955; Mishima, 1968). Deprivation of oxygen or the application of metabolic inhibitors such as ouabain also produce reversible swelling and opacification of the cornea (Trenberth and Mishima, 1968).

Recovery of normal thickness at body temperature after cooling of the excised cornea, whether or not the epithelium is present, vividly demonstrates that deturgescence is substantially the responsibility of the endothelium (Harris and Nordquist, 1955). A punctate lesion of the corneal endothelium causes a well-circumscribed region of stromal opacification opposite the lesion, suggesting that liquid intake is confined to the traumatized zone by the vigorous activity of the adjacent endothelium (Langham, 1960).

The precise nature of the pump is not known but there is little doubt that more than one type of ion is involved. Hodson and Miller (1976) demonstrated active transport of HCO_3^- from endothelium to aqueous activated by the enzyme carbonic anhydrase located adjacent to the posterior membrane of the endothelium.

The enzyme catalyses the conversion of carbon dioxide and water into bicarbonate and hydrogen ions. Bicarbonate is then actively transported to the aqueous humour. They showed that the endothelial pump was partly inhibited when

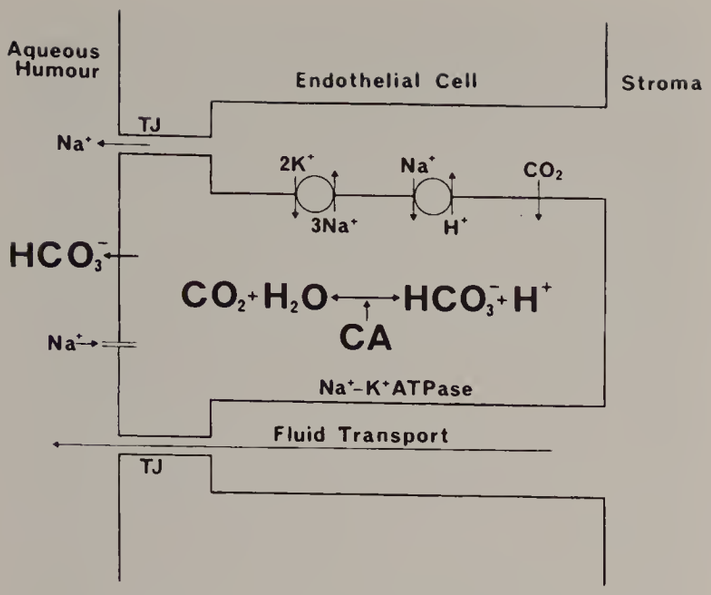


Figure 2.22 Scheme to show the principal components of the endothelial pump. The major factor is the combination of exogenous and endogenous CO_2 to form bicarbonate ions which act as a substrate for the endothelial transport mechanism resulting in translocation of bicarbonate ions to the aqueous. This mechanism is catalysed by carbonic anhydrase (**CA**) with hydrogen ions as a by-product. The carrier protein Na^+-K^+-ATPase, located in the lateral membranes, is responsible for transport of Na^+ to the intercellular space and presumably past the tight junctions (**TJ**) to the aqueous. It may also be indirectly coupled to the Na^+-H^+ exchange shown. The osmotic gradient generated by the active transport of these ions draws water out of the stroma into the aqueous. Opposing this outward pump is an inward 'leak' from the aqueous humour into the hygroscopic corneal stroma – the 'pump-leak' hypothesis. At steady-state stromal thickness, the fluid gain of the leak is offset by the fluid loss due to the pump

carbon dioxide and bicarbonate were removed from the cornea. The presence of Na^+ and HCO_3^- were found to be necessary for the full activity of the pump in maintaining the dehydrated cornea (Hodson, 1977) indicating that the transport of bicarbonate was linked to that of sodium probably in the manner indicated in *Figure 2.22*. The enzyme Na^+–K^+ATPase is present in the lateral walls of endothelial cells and probably contributes to the endothelial pump by promoting active transport of sodium from the cell to the aqueous. Ouabain, a specific inhibitor of this enzyme, causes corneal swelling (Geroski and Edelhauser, 1984) and prevents reversal of oedema induced by cooling (Brown and Hedbys, 1965). Other ions have also been implicated in the pump. Removal of the epithelium *in vivo* does lead to some hydration of the cornea but to a lesser extent than when the endothelium is removed (Maurice and Giardini, 1951). Corneal swelling in rabbits caused by removing the epithelium is reversed first at the periphery as cells from the conjunctiva slowly migrate across the cornea, while the remaining denuded area stays swollen. This situation is maintained even after 72 hours when 90% of the cornea is covered (Langham, 1960). The contribution of the epithelium to corneal deturgescence is unlikely to be attributable to its inert barrier characteristics alone, and a chloride pump acting through the epithelium to move water from the corneal stroma to the tear film has been identified in rabbits (van der Heyden *et al.*, 1975; Klyce and Wong, 1977; Beekhuis and McCarey, 1986). Whether or not the chloride pump, reviewed by Klyce and Bonanno (1988), is generally applicable is uncertain as there is evidence of a chloride pump working in the opposite direction in man (Fischer *et al.*, 1978).

At the corneoscleral junction there is a potential liquid leak into the cornea, but Maurice (1962b) calculated that the endothelium has more than sufficient pumping power to deal with the influx of water from this region.

In summary, it has been shown that the surface layers of the cornea constitute inert, partial barriers to water influx with metabolic pumps acting across them opposing the swelling pressure of the corneal stroma. The nature of the pumps remains uncertain, but they are vigorous – particularly across the endothelium – and they probably consume a large proportion of corneal cellular energy.

Metabolic processes

The following description of the metabolic processes in the cornea is confined to a consideration of glucose metabolism. De Roetth (1950) showed that carbohydrate metabolism predominates in the cornea as indicated by a respiratory quotient of unity, and glucose is the principal monosaccharide of this process. Much of the energy released in the metabolism of glucose is used in the phosphorylation of ADP (adenosine disphosphate) to ATP (adenosine triphosphate), and energy is stored in this form. The efficiency of a metabolic pathway may therefore be measured in terms of the number of ATP molecules produced. The processes of greatest importance in the metabolism of glucose are, first, the glycolytic pathway followed by the tricarboxylic or citric acid cycle and, second, the oxidation of glucose directly by the pentose phosphate pathway or hexose monophosphate shunt. These will be considered in turn and then related specifically to corneal metabolism.

Glycolysis

In this complex glycolytic process, enzymes called dehydrogenases act as catalysts for each stage in the process and finally split the glucose molecule into two molecules of pyruvic acid. In the third of the four stages of the glycolytic process, liberated energy is used to form two molecules of ATP from ADP and inorganic phosphate.

Under anaerobic conditions, pyruvic acid is converted to lactic acid without significant liberation or uptake of energy. Under aerobic conditions, glucose metabolism does not stop at this point but continues until the final products are carbon dioxide and water. This further breakdown is brought about by the citric acid cycle. During the cycle, carbon dioxide and hydrogen atoms are released. The hydrogen atoms, at

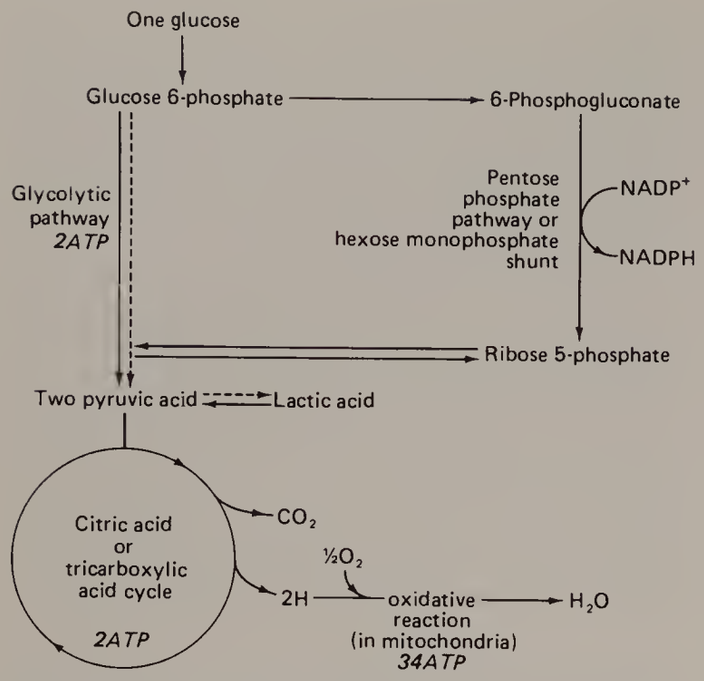


Figure 2.23 Outline of glucose metabolism in the cornea. Free oxygen does not take a direct part in the citric acid cycle, but its presence is essential and the cycle cannot operate in anaerobic conditions. Note the reversible connections between the pentose phosphate and glycolytic pathways

length, become oxidized to form water and the combined cycle and oxidative processes synthesize a further 36 ATP molecules (*Figure 2.23*).

Hexose monophosphate shunt

Although the glycolytic pathway just described is the principal pathway for the oxidation of glucose, others are available. Of these, the hexose monophosphate shunt is the most important. In this process, glucose 6-phosphate takes part in a cyclic mechanism which, rather than producing ATP for general metabolic functions, has the main purposes of providing reducing power in the form of NADPH (reduced nicotinamide adenine dinucleotide phosphate) which can be used for biosynthesis and to produce the ribose 5-phosphate necessary for the synthesis of nucleotides and nucleic acids. Due to the rapid production of epithelial cells, the cornea has a substantial requirement for these molecules.

Carbohydrate metabolism in the cornea

Glycolysis is predominantly exhibited in the epithelium. The high level of enzyme and pyridine nucleotide concentration and the rate of oxygen consumption indicate that the endothelium also has a high glycolytic activity, but the relative inaccessibility of this layer has limited studies upon it. In contrast, the stroma shows very little metabolic activity. Tissues exhibiting aerobic glycolysis accumulate lactate because the glycolytic pathway is more efficient than the aerobic mechanisms which cause the combustion of pyruvate to carbon dioxide and water (Langham, 1954).

Anaerobic glycolysis alone, with its low energy yield, is evidently inadequate to maintain the cornea in its normal state as, in the absence of oxygen, the cornea swells and loses its transparency (Heald and Langham, 1956, and many others).

Kinoshita and his colleagues demonstrated that the hexose monophosphate shunt is unusually active in the cornea (Kinoshita and Masurat, 1959; Kinoshita, 1962). They estimated that, in the bovine corneal epithelium, about 65% of the glucose is metabolized by way of the glycolytic pathway followed by the citric acid cycle and 35% by means of the hexose monophosphate shunt. Kuhlman and Resnick (1959) estimated that, in the total cornea of rabbits, up to 70% of glucose is oxidized to carbon dioxide via the shunt mechanism. There is evidence that the metabolism of the corneal layers is interrelated. For example, it is found that lactic acid, which is produced in all layers of the cornea, cannot be utilized in the absence of the epithelium (Hermann and Hickman, 1948).

About 95% of total corneal lactate was found in the stroma in rabbits (Chen and Chen, 1990), but only 32% was produced there. The epithelium was the source of 47% and the endothelium 21%.

Sources of metabolites

The avascularity of the cornea promotes enquiry into the possible routes of metabolite supply. There are clearly three possibilities: from the perilimbal blood vessels, from the aqueous humour and from the tear liquid. A common method of investigation is to alter the availability of metabolites from one of these possible sources and note if the cornea shows any alteration.

There is little reason to doubt that the perilimbal blood vessels provide metabolites for the cornea – at least, for the peripheral cornea – but that this route is of limited importance is indicated by experiments and observations where blood flow has been interrupted. Gunderson (1939) noted that corneal transparency was unaltered in his patients following complete peritomy of the cornea. Scarification of the conjunctiva in cases of perilimbal melanomas, and experimental thermocoagulation of the perilimbal tissues in rabbits, fails to interfere with corneal transparency. Diffusion of radioactive substances from the limbus into the cornea following subconjunctival or systemic injection has been observed. These substances are found to be in greater concentration peripherally than centrally (Maurice, 1951; Pratt-Johnson, 1959). Maurice (1962b) found that large molecules are the most likely to diffuse to the central cornea, and the conditions for this occurrence are least favourable for oxygen and glucose.

The question of the relative importance of tears liquid and aqueous humour as sources of glucose for the cornea appears to be settled in favour of the aqueous, but it is still uncertain whether or not the tear liquid route is of any practical importance. Bock and Maumenee (1953) inserted

thin polythene sheets between stromal lamellae in rabbits and observed a thickening of the overlying stroma with complete degeneration of the epithelium in the central zone after 2 days. The deep underlying stroma and the endothelium were normal during this period and the epithelium maintained its integrity when the polythene sheet was trephined with several 2 mm holes. The conclusion was reached that the epithelium and stroma are dependent on the aqueous humour for metabolites. These results were not altogether consistent with later studies. For example, water-impermeable polypropylene sheets inserted between stromal lamellae in cats were tolerated for more than a year without pathological changes, deep or superficial to the sheet (Pollack, 1962). In similar experiments, Knowles (1961) reported an absence of pathological changes for periods of up to 10 weeks in rabbits. Clearly, the deeper layers may flourish when isolated from the anterior layers and hence the aqueous must be a source of metabolites for the cornea. It is unlikely that much glucose moves in the other direction, from the tears to the cornea, as the concentration of 2.6 mg/100 ml in tears in man (Giardini and Roberts, 1950) is far too little to be of much significance in the nourishment of the cornea (Maurice, 1962b). Glucose concentration is more than 10 times as great in the aqueous (Reim *et al.*, 1967). A reduction in epithelial glycogen and ATP as well as glucose was demonstrated following the insertion of intralamellar membrane barriers (Turss *et al.*, 1970) and these changes could not be prevented by tarsorrhaphy or the topical application of glucose.

Thoft and Friend (1972) observed a passive diffusion of a labelled amino acid through the endothelium. The rapid turnover of epithelial cells demands a considerable utilization of amino acids in the synthesis of protein and, as expected, the concentration was high. It was actively accumulated by the epithelium only after it had appeared in the stroma, suggesting that none was taken up from the tears despite their rich amino acid content (Balik, 1958). It appears that epithelium has a very low permeability to amino acids and glucose.

The utilization of atmospheric oxygen by the cornea through the tear film has been demonstrated in a number of ways. In man, symptoms of corneal irritation together with the haze and haloes known as Sattler's veil (Finkelstein, 1952) were experienced when the cornea was deprived of atmospheric oxygen (Smelser, 1952; Smelser and Ozanics, 1952). These symptoms were induced 2.5 hours after pumping nitrogen saturated with water vapour into tight-fitting goggles. The introduction of oxygen relieved the symptoms. Langham (1952) exposed the eyes of rabbits to a pure oxygen atmosphere for 3–3.5 hours and found that the lactic acid concentration in the cornea was reduced by a third. Using a nitrogen atmosphere for the same period of time, lactic acid concentration was increased by a third. These observations indicated an increase in aerobic glycolysis in the first case and a decrease in the second, again establishing that atmospheric oxygen is utilized by the cornea. Hill and Fatt (1964) measured the rate of oxygen uptake by the corneal epithelium in man by using oxygen electrodes embedded in a tight-fitting scleral lens with an oxygen-filled reservoir between the lens and cornea. They observed a rapid reduction in the oxygen tension in the reservoir as a result of oxygen uptake by the cornea. A rate of oxygen uptake of 4.8 $\mu l/cm^2$ per hour was calculated from their results. However, Farris *et al.* (1967), using the same technique, interpreted their data differently to arrive at a figure of 1.4 $\mu l/cm^2$ per hour.

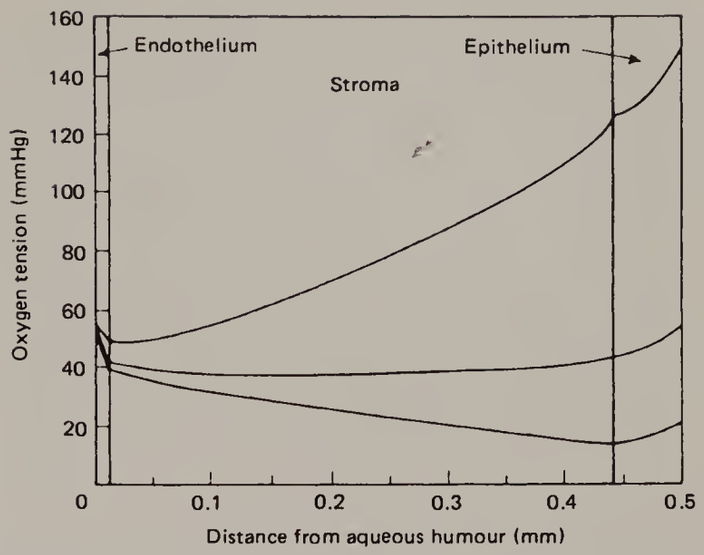


Figure 2.24 Summary of oxygen tension profiles for various conditions based on measuremcnts made under each condition at the epithelial surface in rabbits. The curves joining the surface points were calculated. The upper and middle curves represent the eye in open and closed conditions respectively. The lowest curve represents the profile with a soft contact lens of low permeability on the eye. (Modified from Fatt *et al.*, 1974)

Langham (1952) concluded that the rabbit cornea also utilizes aqueous oxygen. The lactic acid concentration decreased from a value of unity to 0.7, 3–3.5 hours after introducing an oxygen bubble into the anterior chamber. The concentration was increased to 1.26 if nitrogen was used in place of oxygen. But whether provision of oxygen to the endothelium is the responsibility of the tear film or the aqueous is open to debate. Barr and his co-workers found an oxygen gradient reducing from the front surface of the cornea to the anterior chamber in rabbits and concluded that atmospheric oxygen normally diffuses through the full thickness of the cornea to the anterior chamber (Barr and Roetman, 1974; Barr *et al.*, 1977). On the other hand, Fatt and Bieber (1968) and Fatt *et al.* (1974) concurred with Langham on the basis of calculated oxygen distribution profiles through the cornea, knowing the partial oxygen pressures at the two surfaces, stromal consumption, diffusion coefficients and solubility. The profile (*Figure 2.24*) displays a trough at the stromal aspect of the endothelium indicating that the endothelial layer receives oxygen from the aqueous. However, the crucial datum at the deep surface is difficult to determine and is supported by a single measurement.

Although equivalent data in man are limited, Fatt and Bieber believed that the oxygen distribution profiles in rabbits 'represent, at least qualitatively, the situation in the human cornea'. When the lids were closed long enough for equilibrium levels to be reached, the partial oxygen pressure at the epithelium reduced from 155 mmHg to the same level (55 mmHg) obtaining at the endothelial surface (*Figure 2.24*), with a trough within the stroma. Under these circumstances, it appears, first, that the vessels of the palpebral conjunctiva must provide the epithelium with oxygen because if contact between these surfaces is prevented the partial oxygen pressure falls to zero. Earlier, Langham (1952) reached the same conclusion. Secondly, the altered profile suggests that aqueous oxygen is being used now by deeper structures of the cornea. This interpretation is based on the assumption that aqueous oxygen level is maintained, whereas Barr and Silver (1973) claimed that it reduces as oxygen levels at the anterior surface of the cornea are reduced. Similar studies of the carbon dioxide partial pressures indicated that corneal and aqueous carbon dioxide passed out to the tears when the lids were open, but when they were closed some passed to the aqueous from the cornea.

The effects of contact lenses on corneal metabolism

A contact lens presents a barrier between the cornea and the atmosphere, and from the foregoing it follows that the most likely interference with corneal metabolism is that a contact lens might cause deprivation of oxygen with a consequent reduction in aerobic glycolysis. Oxygen uptake by the tears in front of the lens would continue but transference of oxygen through the lens is substantially impeded especially with PMMA, thick soft lenses or low Dk rigid gas-permeable lenses. Lens movement will facilitate tears exchange at the lens perimeter which is the principal route for oxygen and carbon dioxide exchange with PMMA lenses.

Presumably the cornea can comfortably tolerate a reduction of the partial oxygen pressure at the epithelial surface from 155 mmHg (or a concentration of 21%) to 55 mmHg (7.5%), for this occurs when the lids are closed for some length of time as shown in *Figure 2.24*. But corneal metabolism is altered by the changed environment in sleep (which the middle profile of the Figure may represent) as expressed by a slight oedema, thickening by about 4% (Mandell and Fatt, 1965), and sensitivity reduction (Millodot, 1972). These responses to sleep are largely attributable to reduced oxygen, but raised corneal temperature, lowered pH and hypotonicity of tears may contribute. A claim that oxygen levels of only 11–19 mmHg are required to avoid oedema (Polse and Mandell, 1970) has been questioned and evidence was produced that a figure of about 10% (70–75 mmHg) is necessary (Holden and Mertz 1984).

Farris *et al.* (1967), using an oxygen electrode, observed a transient increase in oxygen uptake by the corneal epithelium measured immediately after PMMA lenses had been worn for a period of 8 hours but even after only 2 minutes wear, a large increase in oxygen uptake occurred (Hill and Leighton, 1968). Corneal oxygen replenishment on resumption of normal access from the tear film accounts for the increase. The level of oxygen deprivation caused by wearing lenses was found to be slightly greater than that caused by lid closure for 5 minutes (Farris *et al.*, 1967) Following the argument of Fatt and his colleagues, aqueous oxygen utility extends deeper than the endothelium when the level of tears liquid oxygen is depressed by the presence of a contact lens (*Figure 2.24*).

Interference with normal corneal metabolism will produce a thickening and a reduction of transparency of the cornea. The thickening observed with lens use varies between individuals and depends on the type and material of the lens. Numerous early studies of the effect of PMMA lens wear produced figures of corneal thickness increase of 4–8%, usually measured after 8 hours wear. *Figure 2.25* shows a typical result and adds a temporal profile of recovery following lens removal. Epithelial swelling contributes to thickening (Farris *et al.*, 1971) and curvature changes occur sufficient to reduce spectacle-corrected visual acuity (Ruiz-Montenegro *et al.*, 1993).

Initial claims that soft lenses in general do not cause corneal swelling were not confirmed and the swelling incurred may compare with that associated with PMMA lenses (Bailey and Carney, 1973; Polse *et al.*, 1975). Oxygen transmission characteristics and mean thickness of the material used are the major factors in determining the amount of swelling which varies from practically nothing up to 5% or exceptionally 8% according to the lens type (Holden and Mertz, 1984; Weissman *et al.*, 1988). Much has been written favouring the concept that oedema reduces as the eyes adapt to contact lenses but specific data are often lacking. Some recovery from oedema may occur but it is slow (Farris *et al.*, 1971) and incomplete. Evidence of sustained oedema may be found with greater facility. It is worth noting that corneal thickening with soft contact lenses is, at most, little more than the 4% or so incurred normally during sleep (Mandell and Fatt, 1965).

When lenses are worn continuously, lens and sleep-induced effects are compounded and swelling is consequently greater than with daily wear. Holden and Mertz (1984) measured a thickening of 7–15% on awakening after a single day/night cycle of wear, varying according to soft lens type, and reducing to 1–6% during the course of the day. The corneal thickness increases persisted for the 7 days of the study. Corneal swelling with rigid gas permeable lenses is similar in amount to that induced with soft lenses when the two types are matched for oxygen transmissibility (O'Neale *et al.*, 1984).

Other studies of overnight swelling reveal an apparent reduction as the wearer becomes experienced, suggesting a degree of adaptation (Armitage and Schloessler, 1988). However, the claim for adaptation has been challenged. Corneal thickness was measured in experienced unilateral extended wear patients and the changes in stromal thickness

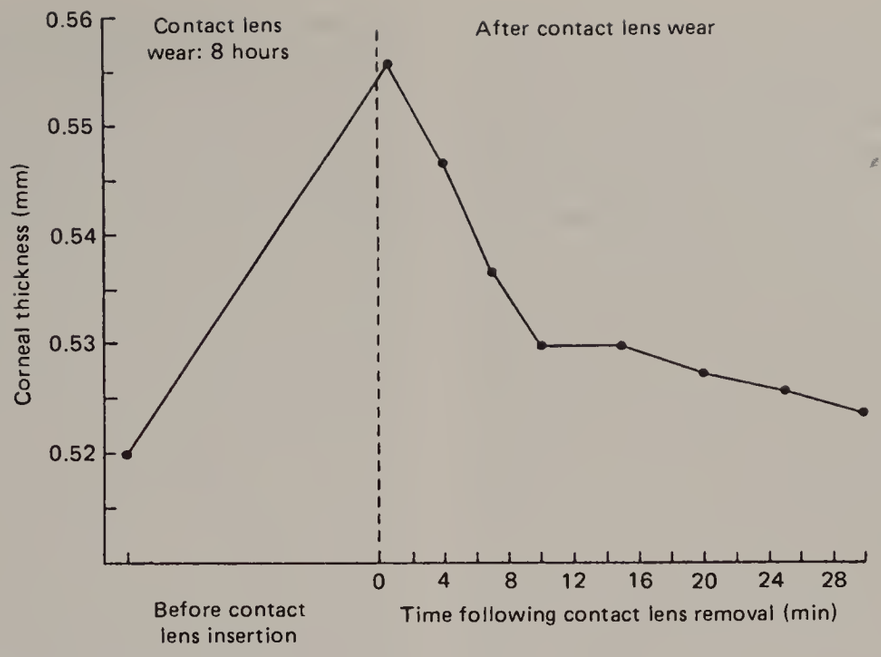


Figure 2.25 Relationship between central corneal thickness and the wearing of PMMA contact lenses for 8 hours. Each point represents the mean of 11 subjects. (After Millodot, 1975a)

of the hydrogel lens-wearing eye relative to the control eye compared. Lens wear was then discontinued and comparison of the thickness over a 33-day period revealed a thinner stroma in the lens-wearing cornea (Holden *et al.*, 1985). These authors concluded that the underlying response of the corneal stroma to extended wear is a gradual thinning. It follows that in studies of overnight swelling, the apparent reduction with experience is misleading because the cornea is already swollen. The thinning may be caused by loss of stromal ground substance (Kangas *et al.*, 1990). Extended wear lenses also induce epithelial thinning of the order of a few microns and, after some weeks, microcysts develop; these are small (15–50 μm) irregularly shaped dots (Holden *et al.*, 1985). Both long-term soft and rigid lens wear cause an increase in endothelial polymegethism but endothelial cell density is probably unaffected. Daily or extended wear soft lenses may also produce vertical striae and although corneal curvature is reputed to be unaltered, topographic changes have been reported (Ruiz-Montenegro *et al.*, 1993).

Alterations in glycolysis have been measured after fitting contact lenses to experimental animals. The corneas of guinea-pigs fitted with scleral lenses became thicker and less transparent and the lactic acid content increased rapidly (Smelser and Chen, 1955). An increased lactic acid content would be expected as a result of reduced aerobic glycolysis. Hirano's (1959) observation of depleted glycogen content in rabbit corneas fitted with PMMA corneal lenses indicates an increased consumption of glycogen by means of the less productive anaerobic glycolytic cycle in an endeavour to compensate. Morley and McCulloch (1961) also observed an increased lactic acid content in both the stroma and epithelium of rabbits fitted with contact lenses and, in addition, they observed a slight decrease of oxidized pyridine nucleotides and a decrease in the percentage of protein in the epithelium. These results suggest that both aerobic glycolysis and protein synthesis were reduced.

Tears

The basic secretion of tears is largely derived from the lacrimal gland, with small additional contributions from the accessory lacrimal glands, the mucous conjunctival glands and the sebaceous tarsal (meibomian) glands. A conjunctival gland or goblet cell is shown in *Figure 2.13* in the process of releasing mucin granules into the tear film. The lacrimal gland has usually been classified as a serous gland, but its cytology and histochemistry suggests some variety of output (Ruskell, 1969; Allen *et al.*, 1972), and an additional mucous secretion was suggested but this is uncertain.

It has been proposed that the lacrimal gland does not take part in the basic secretion of tears because the eye remains moist if the lacrimal gland is congenitally absent, or when the gland is removed or its motor nerve supply is interrupted. It may be true that the eye usually remains sufficiently moist for comfort in these circumstances with retention of an optically adequate corneal surface, but denervation or removal of the gland none the less produces a radical reduction in the basic secretion of tears (Golding-Wood, 1964; Ruskell, 1969).

Superimposed on the basic secretion are the phasic increments in secretion induced reflexly by mechanical or chemical irritation and by psychogenic factors. To distinguish between the two, the words 'lacrimation', to describe reflex tears, and 'weeping', for psychogenic tears, have been suggested.

The precorneal film

Wolff (1948) considered the precorneal film to consist of a triple-layered structure with a central watery phase made up of the serous secretion of the lacrimal gland and constituting the bulk of the film. A thin superficial oily layer was thought to issue from the tarsal glands and a deep layer of mucoproteins from the conjunctival glands.

Wolff's postulated structure is widely accepted but some matters of detail, long thought to have been resolved, are now matters for debate, not least among these is the question of the thickness of the total film and of its parts. Using a variety of techniques, there was reasonable agreement that the precorneal tear film measured from 6 to 9 μm in thickness (Ehlers, 1965a; Mishima, 1965), reducing by about 20% 5 seconds after a blink and by 50% after 30 seconds. Prydal *et al.* (1992) more recently confounded the established view by claiming a thickness of 34–45 μm using laser interferometry and confirmed by confocal microscopy. These extraordinary figures are close to the thickness of the epithelium. Moreover, they considered the film to be composed substantially of mucin rather than an aqueous layer with some dispersed mucin (Holly and Lemp, 1971).

The presence of a thin superficial lipid layer is suggested by the coloured interference fringers which may be observed with a biomicroscope. Further evidence of the surface film and of its origin is provided by Mishima and Maurice (1961), who demonstrated in rabbits that tear film evaporation increases at least tenfold in the absence of tarsal gland secretion. This amount of increased evaporation is approximately that expected of water in the absence of a surface lipid film. Despite this apparently straightforward evidence for tarsal gland function, when secretion, expressed from human tarsal glands, was spread over a saline solution no significant reduction in evaporation was observed (Brown and Dervichian, 1969). Although the experimental conditions of this study are not beyond criticism, the results serve to stimulate at least discussion of the matter.

The lipid layer extends from its sources at the openings of the tarsal glands at the lid margins to cover the tear film, and provides a stable interface between the aqueous layer and air. It is approximately 0.1 μg thick (Norn, 1969), varying substantially with the size of the palpebral aperture and time of exposure. It compresses and thickens as the eyelids close, thinning gradually following a blink. In contrast to the remainder of the tear film the lipid layer does not take part in the flow of tears from lateral to medial canthi and is essentially an independent part of the film. Lipid does not normally enter the conjuctival sac.

Mucins from the conjunctival goblet cells form the deepest layer of the precorneal tear film and are absorbed by the epithelium producing a wettable hydrophilic surface essential for tear film stability (Holly and Lemp, 1971; Holly, 1973). The deep, glycoprotein part of the layer (or the glycocalyx referred to earlier) is surface-active and hydrophobic and is responsible for attachment to the surface epithelial cell membrane. The strongly hydrophylic mucous portion is exposed to the aqueous layer. Earlier estimates of its thickness of 0.02–0.04 μm (Holly, 1973) need to be reviewed. The figure of 0.8–1.0 μm obtained by direct measurement of the preserved mucous layer in histological preparations of the guinea-pig cornea (Nichols *et al.*, 1984) suggests that the mucous layer might constitute a large fraction of the total tear film thickness in man.

The precorneal tear film increases in thickness at the lid margins where a meniscus of tear fluid, the marginal tear strip, is formed but a thinning may occur along the line joining the film with the meniscus. Tear fluid flows medially within the marginal tear strips, hence the alternative name of lacrimal river or *rivus lacrimus*.

There is little flow across the cornea between blinks. The limited flow and the uniform thickness are the consequences of the 'framing' function of the eyelids which is eliminated if the eyelids are withdrawn from the eyeball, causing a spotty drying of the precorneal film.

Apposition of the eyelid margins during blinking permits replenishment of lipid from the tarsal glands which is then spread across the surface of the reconstructed film as the eyelids part. Similarly, mucus is spread over the corneal and conjunctival epithelium by the massaging action of the eyelids. It should be added that the spreading of the tear film is facilitated by the movement of the eyelids across the cornea. In the presence of a contact lens, the interfacial tension at three surfaces has to be considered. The desirable establishment of low interfacial tension at the two surfaces of the contact lens is partly related to the nature and condition of the lens.

Function of tears

Tear liquid is essential for the maintenance of the normal optical properties of the cornea. Without it, corneal metabolic processes are impaired, as noted earlier, with consequent loss of transparency. Further, the excellent refracting surface which the smooth tear film provides would be lost and an irregularly refracting, desiccated epithelial surface would be substituted. Tear liquid is the lubricant for eyelid movement over the cornea and the medium for flushing away foreign matter which potentially endangers the optical integrity of the cornea.

Tears have antibacterial properties. Lysozyme, the enzyme originally described by Fleming (1922) in tear liquid, is selectively bacteriolytic by destruction of the cell wall providing a degree of protection against certain Gram-positive bacteria lodged in the conjunctival sac. Claims for the presence of a non-lysozyme antibacterial factor (NLAF) in tears with far greater activity than lysozyme have been criticized. It is argued that inappropriate analytical methods were used giving grossly misleading results. However, the presence of some NLAF activity is broadly agreed. Lactoferrin, present in abundance in tears (Kijlstra *et al.*, 1983), has non-specific bactericidal properties (Arnold *et al.*, 1977) and moreover may have an anti-inflammatory function (Veerhuis and Kijlstra, 1982). Among the antibody

proteins, IgA and IgG are prominent in tears but other immunoglobulins are present (*see also* Chapter 4, p. xx).

Tear drainage

Much of the tears liquid lies in the marginal tear strips presenting a concave cylindrical free surface. Medially, the strips terminate in the so-called lacrimal lake which is often described as a reservoir of tear liquid bathing the caruncle and bounded by the inner canthus and the free edge of the plica semilunaris. This delimitation obviously changes as the eye moves from the primary position. But, as Wolff (1948) pointed out, under normal circumstances the inner canthus is moist but does not contain a pool of fluid. The punctum lacrimale of each papilla is turned in towards the cornea and interrupts the marginal tear strip.

Drainage of tears is initiated by the movement of tear liquid from the marginal tear strips through the punctum and into the canaliculus by capillary attraction. This is facilitated by the continuous movement of liquid nasally which is effected by lid closure. Closure occurs first at the outer canthus and then, progressively, to the inner canthus. If a very small spot of dye is applied to a marginal tear strip, blinking will cause the dye to spread towards the punctum; it will neither move to the fornix nor to the outer canthus (Ehlers, 1965b).

The canaliculi are embedded in the orbicularis muscle so that on contraction of the muscle the canaliculi are closed and shortened and the tear liquid is driven into the lacrimal sac. Regurgitation is prevented by the simultaneous closure of the ampulla of each canaliculus. The muscular activity amounts to a milking action rather than a peristalsis. The preseptal portion of the orbicularis muscle is claimed to have a deep insertion from each lid to the lacrimal diaphragm which is the lateral fascial wall of the lacrimal sac, with the consequence that contraction causes a lateral movement of the lacrimal diaphragm. It follows that the sac becomes dilated and it is thought to produce a reduction of the pressure in the sac which produces a siphoning of tear liquid. This postulated mechanism (Jones, 1961), which constitutes a lacrimal pump, would appear to demand closure of the 'valve' of Hasner which occludes the nasal exit of the nasolacrimal duct (ostium lacrimalis), in order to create an effective vacuum for siphoning. This probably does not occur and pressure measurements within the sac, which may be compressed rather than dilated upon blinking, reveal little change during eyelid movement (Maurice, 1973). Further, the existence of the necessary structures for operating the lacrimal pump, postulated by Jones, has been questioned (Brienen and Snell, 1967). Hence, it appears that an elaborate pumping mechanism may not be present and that gravitation alone may account for the movement of the tears out of the lacrimal sac.

Tear output

The daily output of tears is usually considered to be rather less than 1 g. This figure is based on the data of Schirmer (1903) but it has been questioned because of the probable inaccuracy of his measuring technique. Another test that measures the rate of dilution of a stain applied to the marginal tear strip, probably introduces less error but results are not consistent. Originally, Nover and Jaeger (1952) calculated the surprisingly high average rate of 14 g of tear secretion daily, but Kirchner's (1964) results were similar to those of Schirmer. However, Norn (1965) subsequently reported a daily tear output of 15–30 g measured from 186 eyes. The instillation of a stain (rose bengal and/or fluorescein) will obviously tend to elevate the recorded figure for basic tear secretion both by its own bulk and by its irritant effect. The method neither involves the aspiration of tears nor neglects to account for tears escaping through the puncta, and these are important shortcomings of other tests, some of which also share the error invoked by corneal irritation. Hence, it may be tentatively concluded that the lacrimal secretion normally produced is well in excess of 1 g as suggested by Schirmer but rather less than the 15–30 g measured by Norn.

In a study of a large number of full-term infants, Penbharkkul and Karelitz (1962) encountered shedding of tears as early as 5.5 hours of age and as late as 84 days. The onset of lacrimation occurred during the first 4 weeks in a majority of infants and in most it occurred first with crying associated with hunger and pain. Sjögren (1955) used nasal irritants to determine the onset of reflex lacrimation in infants and found that it occurred in all but 13% during the first few weeks of life.

With advancing years, basic tear secretion decreases gradually: the difference between the sexes is negligible (Norn, 1965) except in early adult life, when females have a higher rate of secretion (Henderson and Prough, 1950; de Roetth, 1953). Sex differences concerning psychogenic tears or weeping are clearly a separate matter.

Schirmer's popular tears secretion test is unsatisfactory as a precise quantitative test for tear secretion but it is of considerable value in comparing the production of tears between eyes of a pair and between eyes of different persons (*see* Chapters 8 and 11).

Neural control of tears

Irritation of the cornea, conjunctiva, nasal mucosa and of any area served by the trigeminal nerve causes reflex lacrimation. The trigeminal nerve is responsible for the sensory input of the reflex pathway and if it is blocked, or surface anaesthesia applied, reflex lacrimation is abolished. The paths of the central nervous system associated with psychogenic weeping are unknown, and a knowledge of the link between the trigeminal nerve and the facial nerve in the reflex lacrimation pathway is lacking.

Both parasympathetic nerve fibres (from the pterygopalatine or sphenopalatine ganglion) and sympathetic nerve fibres (from the superior cervical ganglion) have been thought to be responsible for motor control of lacrimal gland secretion but in experiments on cats and monkeys, only parasympathetic fibres could be shown to exercise this

control (Botelho *et al.*, 1966; Ruskell, 1969, 1975). The gland has a limited sensory innervation (Matsumoto *et al.*, 1992). There is no clear evidence of motor control of the tarsal and conjunctival glands although control of the former has been suggested (Chung *et al.*, 1996).

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Chapter 3

Contact lens materials

B. J. Tighe

Introduction: emergence of the current scene p. 50
Nature and properties of polymers p. 51
Properties of contact lens materials p. 57
Hydrogel materials p. 71
RGP materials p. 77
The nature and origin of lens spoilation p. 83
Addenda:
1 Units and terms in permeability measurements p. 88
2 Abridged patent compilation: hydrogel materials p. 89

Introduction: emergence of the current scene

The early years of the 1990s have seen more advances in the contact lens field than the late 1970s and the 1980s. This is true for the three interacting aspects of the area given below and not simply for materials technology. To anyone concerned with the development of contact lens materials, as with any aspect of biomaterials science, the biomedical device cannot be considered in isolation from the total environment in which it is used. In the case of contact lenses this means that three related topics, namely: (a) the lens and the material; (b) the eye and the wear regime; and (c) the care solution and the care regime, must be considered together. The consequence of this is that a major movement in one of these three areas is capable of exerting a marked influence on one or both of the others.

The most significant change in recent years, has been the advent of the disposability concept as an economic reality. This was brought about by the incursion of Johnson & Johnson, a major pharmaceutical company, into the contact lens field. The establishment of Vistakon as a contact lens company, using a combination of lens fabrication technology pioneered, but not perfected by Danalens, together with a known lens material of dubious stability, previously sold as Vistamarc, brought Acuvue to the contact lens world. The success has been breathtaking. Ironically, the material could only succeed as a disposable lens; its highly ionic nature produces dramatic parameter changes in solutions of different pH. In the range of care solutions that were available on the UK market at the beginning of the 1970s (i.e. just before regulation) the material suffered disastrously from instability problems and was never a serious option.

High water content anionic hydrogels, classified in the FDA system as Group IV materials (*see* pp. 73 and 87), have recently moved from a position of insignificance to one of growing importance in the contact lens field. The stability problem is, of course, reduced as lens centre thickness is reduced – not easily achievable by earlier lathe-based technology, but relatively simple, once the problems of cast polymerization of the material in the presence of a diluent had been overcome. This type of production, sometimes called wet cast polymerization, means that the lens does not swell on hydration; the diluent is simply exchanged for saline in the hydration step. This not only reduces problems assoeiated with expansion, it produces better optics – provided that a suitable plastic has been chosen for the fabrication of high surface quality lens moulds. The resultant lens, with a combination of centre thickness and compliance that makes minimal demands on base curve variation, has produced a convenience revolution in the contact lens market.

The convenience of disposable lenses has been matched by a revolution in disinfection systems, where the advent of care systems based on one or other of the polymeric cationic antibacterial agents has brought one step solutions to match the mood created by the success of disposable lenses. Ironically, we are seeing old technology at work here, just as in the case of the disposable lenses. The Bausch & Lomb ReNu system is based on a polymeric biguanide developed as an antibacterial by ICI decades ago under the trade name Vantocil. In subsequent years it was patented (but never marketed) for contact lens use by Smith and Nephew. One of the problems encountered was the fact that biguanide concentrations that gave good antibacterial activity produced a significant incidence of adverse ocular reactions. Current products aim to work at lower concentration in the window between effectiveness and adversc reaction using a surfactant to aid efficacy.

The purpose of these comments is not to extol the virtues of any product, whether lens or solution. The point at issue is that through imaginative exploitation of established technologies, the pattern of usage of lens materials has now been changed dramatically – probably irreversibly. The requirements for disposability are not the same as the requirements for a two-year lifetime lens, which needed some capability to tolerate use in combination with a range

of care solutions and intensive cleaners. Manufacturing technology has been the driver of prime importance, with daily disposable lenses now becoming available at a realistically competitive price.

Against this background there has been a general increase in interest of larger companies in the contact lens industry in addition to Johnson & Johnson (e.g. Ciba Geigy, Wesley Jesson and 3M). This has had several effects. One such effect has been a move away from lenses fabricated by lathe-cutting in prescription houses from polymer blanks supplied by small material manufacturing concerns, to the in-house control of matcrial manufacture, lens fabrication and the supply of finished lenses by a smaller number of larger concerns. These two distinct types of lens source have always coexisted. It is the balance between them that has changed. One effect has been the interest of the larger production units in cheaper methods of lens fabrication (such as direct cast-polymerization of lenses) and the economies of scale. This has led, naturally, to a strong marketing campaign for the concept of disposable and frequent replacement lenses, which goes hand-in-hand with the aforementioned economies of scale. A consequence of this trend has been the repackaging of well-established materials in the form of 'new' frequent replacement lenses. The Vistakon Group IV material, Etafilcon A, for example, is similarly available as Acuvue and Surevue lenses, differing principally in centre thickness.

Despite these changes, the drive for new lens materials is keener than ever. Problems of microbial keratitis, the perennial interest in safe extended wear, wearer discomfort, fears of long-term material intolerance in daily disposable wear: these and other issues mean that there will be a need for improved materials for many years to come. Additionally, the improvements in lens manufacturing technology brought about by the economics of frequent replacement provide opportunities for design of new materials and new care systems to complement them.

A number of ideas have emerged during this period which may form the basis for new and interesting contact lens materials. Amongst these are the non-hydrogel gas permeable materials, including silyl acetylene polymers, pentafluorostyrenes, urethane siloxanol acrylates and poly-perfluoro-alkylene oxide copolymers. New hydrogel materials have reached the market place in recent years including Atalfilcon, based on polyvinyl alcohol and sold by Ciba as Excelens, and Netrafilcon, based on a methacrylate-modified substituted acrylamide material, sold by Pilkington Barnes-Hind as Gentle Touch. There has been a great deal of activity in the field of low water content materials with high oxygen permeability that are effectively hybrids of RGP and hydrogel technology. This is an area that promises to overcome the problems associated with conventional hydrogels, namely that of achieving adequately low levels of hypoxia and corneal swell in extended wear without producing corneal staining or other adverse reactions. Whether these materials will achieve these goals in clinical practice, whilst maintaining adequate patient satisfaction, remains to be seen.

The aim of this chapter is to provide systematic information on which the nature and behaviour of both existing and emerging materials can be understood. The subsequent sections are presented under five headings:

- Nature and properties of polymers
- Properties of contact lens materials
- Hydrogel materials
- RGP materials
- Nature and origin of contact lens spoilation.

The historical aspect of the development of contact lens materials is quite interesting and is covered in detail in Chapter 1. Glass was used exclusively for some years and it was conventional for lenses to be individually ground. When polymethyl methacrylate began to replace glass in the 1940s it was because of its toughness, optical properties and physiological inactivity coupled with ease of processing by existing turning techniques. It was not, therefore, in any sense a purpose-designed polymer and yet, as will be seen, it possesses a combination of properties that are difficult to surpass in a thermoplastic or conventional elastomeric polymer. There have been many attempts to find alternative materials but it was not until hydrogels appeared on the scene that any serious competitor emerged. In order to appreciate the reasons for this, it is necessary to review briefly some of the general characteristics of 'polymers', which is a general term for a group of materials that includes plastics (both thermoplastics and thermosetting), fibres, rubbers (or more correctly elastomers) and hydrogels.

Nature and properties of polymers

We can all readily appreciate the differences in behaviour between gases, liquids and solids. It is helpful to consider the difference in molecular make-up of these three groups before dealing with polymers as a particular class of solid materials.

In gases, we are dealing with a collection of individual small molecules well separated from each other and moving rapidly and randomly in the space that encloses them. The resistance that a gas offers to anything moving through it is, therefore, negligible. When we move to liquids we are talking about a 'condensed' phase and although the molecules are still small individual entities, the resistance to motion within them is greater. (Think, for example, of the difference in ease of movement in the air and in a swimming pool.) Motion in a liquid can be likened to placing a hand into a large bag of ball-bearings or marbles. There is some resistance, but the hand can move by displacing the ball-bearings if the force that it exerts is greater than the force of attraction between the individual ball-bearings.

In the case of solid materials the individual molecules are packed more efficiently. Alternatively, it could be said that the forces of attraction between them have increased. In the absence of reasonably strong deforming forces, the material retains its shape whereas a liquid, of course, will take the

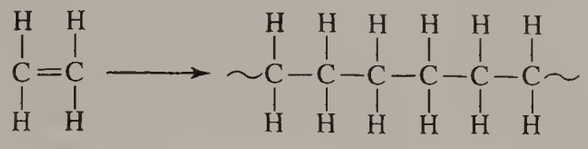
shape of the vessel into which it is poured – being deformed simply by the force of gravity. There are within this group of solid materials all sorts of different behaviours ranging from that of toffee or thick treacle to that of metals. Toffee and treacle are in some aspects liquid-like in their behaviour and in some respects resemble solids.

If solids, then, are materials in which the constituent molecules are well packed together we have to consider in more detail the way in which the molecules are packed or associated or bonded together since this will play a large part in determining the strength of the material in question. Metals, ceramics or glasses, and polymers represent three different types of solid material in which the constituent atoms or molecules are linked together in quite different ways producing different types of behaviour in passing from one class to another.

The unique properties of polymers arise from the ability of certain atoms to bond together to form stable covalent bonds. Foremost among such atoms is carbon (C) which can link together with four other atoms either of its own kind or alternatively atoms of, for example, hydrogen (H), oxygen (O), nitrogen (N), sulphur (S) or chlorine (Cl) and hence most of the polymers we are concerned with fall within the realm of organic chemistry or the chemistry of carbon compounds. These polymers may be purely natural (such as cellulose), modified natural polymers (such as cellulose acetate) or completely synthetic (such as polymethyl methacrylate).

The single characteristic that unites these and other polymers is that, as the name (polymer) suggests, they are composed of many units linked together in long chains. Thus, if we can imagine a molecule of oxygen and a molecule of water enlarged to the size of a tennis ball (the molecular size of water and oxygen is very similar) a molecule of polymethyl methacrylate on the same scale would be of similar cross-sectional diameter but anything up to 200 feet in length. It is the gigantic length of polymers (sometimes called macromolecules) in relation to their cross-sectional diameter that gives them their unique properties.

Most of the polymers that we shall be concerned with are synthetic and prepared from monomers by the process of polymerization. In this way, the simplest polymer, polyethylene, is obtained by polymerization of ethylene monomer.

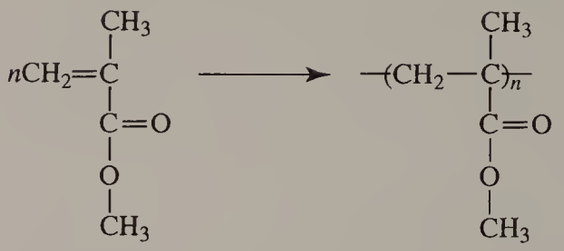


This is more usually represented by a general equation showing the conversion of n ethylene units to a polyethylene chain that is n units long, i.e.:

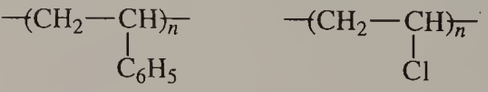


In a commercial polymer n might have a value of several thousand.

The polymerization of methyl methacrylate can be shown in a similar manner.



The structure enclosed within the bracket is known as the 'repeating unit' and it is conventional when writing the name of the polymer to indicate precisely what this is. Thus, we should write poly(ethylene) or poly(methyl methacrylate) but since these are well-known commercial polymers the brackets are often omitted. The same is true of polystyrene (*a*) and polyvinyl chloride (*b*):



(*a*) (*b*)

To indicate that a polymer contains more than one type of repeating unit obtained by polymerizing together two different monomers the term 'copolymer' is used. Thus, by copolymerizing styrene and methyl methacrylate, a styrene-methyl methacrylate copolymer is obtained. This would more correctly be described as poly(methyl methacrylate-costyrene). Although the term 'copolymer' is a general one and can be used to describe polymers obtained from mixtures of more than two monomers, the term 'terpolymers' is frequently used for the specific case of a polymer produced by the polymerization of three monomers. The more common usage, however, is that involving the term 'copolymer' to describe a polymer obtained from at least (but not necessarily exactly) two different monomers.

Perhaps the best way of visualizing the way in which polymer molecules arrange themselves is by taking several pieces of string to represent individual molecules. The most usual arrangement will be a random one in which the pieces of string are loosely entangled (in a heap or ball rather than being extended). It is the interaction and entanglement of the individual molecules in this way that gives polymers their characteristic physical properties. By changing the chemical nature of the polymer chain and its arrangement we can change the physical properties and thus obtain either flexible, elastomeric behaviour or, at the other extreme, hard, glassy behaviour.

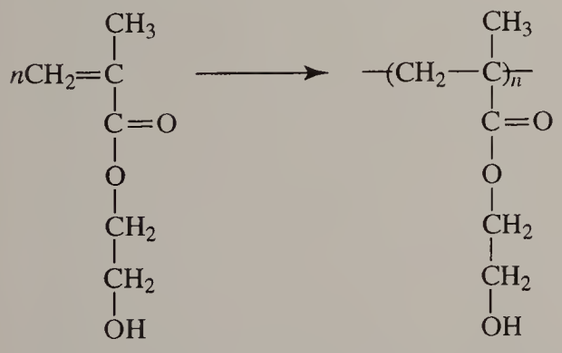
These variations arise from differences in mobility of the constituent polymer chains. Thus, at very low temperatures all polymers are hard and glassy. As the temperature is raised, however, the thermal energy of the system increases and eventually the individual polymer chains will possess enough energy to begin to undergo rotation. If we think of the tangled string as a plate of spaghetti at this point, the rotational energy

that it achieves would be enough to give it the mobility of a plate of worms. In terms of physical properties this corresponds to a change from glassy behaviour to rubbery or leathery behaviour and the temperature at which this occurs is known as the 'glass – rubber transition temperature' (T_g). This temperature will depend on the chemical nature of the polymer, which for natural rubber is below 0°C and for polymethyl methacrylate is above 100°C. Hence at room temperature natural rubber is readily deformed whereas polymethyl methacrylate is glassy.

There are several additional subtleties involved in the design of polymers that have the ability to undergo the large deformation with instantaneous recovery, which is characteristic of ideal elastomeric behaviour. Despite this, the principle of intramolecular mobility and the glass transition temperature is the fundamental factor and provides an adequate basis for understanding the difference between 'hard' and 'soft' lens materials.

A hard glassy thermoplastic material such as polymethyl methacrylate or polyvinyl chloride can be converted into a flexible material by the incorporation of a 'plasticizer'. This is a mobile component, often an organic liquid having a high boiling point, that will act as an 'internal lubricant'. Its presence separates the polymer chains, and allows them to move more freely. Its function is to lower the temperature at which the transition from glassy to flexible behaviour takes place. Thus, polyvinyl chloride in its unmodified state is a rigid glassy material and will be familiar as the clear corrugated roofing material. When a plasticizer is incorporated the material is converted into the flexible material used, for example, as 'vinyl' seat coverings in cars. In these cases, pigments and various processing aids will also have been added in order to enable the polymer to be produced in a variety of colours and textures.

An almost identical principle is involved in the formation of so-called 'hydrogel' polymers. The structure of polymethyl methacrylate can be made more hydrophilic by the incorporation of hydroxyl groups. The simplest structure that can be made in this way is poly(2-hydroxyethyl methacrylate) which is obtained by polymerizing 2-hydroxyethyl methacrylate monomer:



The monomer and polymer are often referred to as HEMA and PHEMA,* respectively.

*In clinical practice the term 'HEMA' is used for simplicity but actually refers to 'PHEMA'.

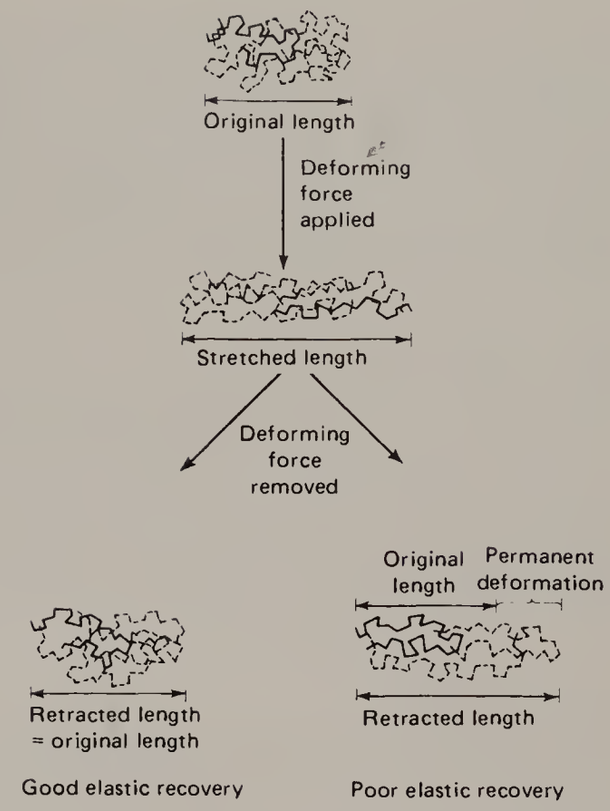


Figure 3.1 Diagrammatic representation of the deformation of entangled polymer chains illustrating both good and poor elastic recovery

In the dry state polymethyl methacrylate and poly(2-hydroxyethyl methacrylate) have very similar characteristics – both are hard glassy polymers as their structures would indicate. Whereas polymethyl methacrylate is relatively unaffected by water (it absorbs approximately 0.5% of its own weight), the more hydrophilic poly(2-hydroxyethyl methacrylate) swells to form an elastic hydrogel. The water acts as a plasticizer in the manner previously described. It behaves as an 'internal lubricant' and allows the chains to move more freely with respect to each other. As a result the glass transition temperature of the hydrogel is well below room temperature whereas that of the dehydrated polymer is about 100°C.

It is necessary to describe one more molecular feature that is required in elastic polymers (both hydrogels and synthetic elastomers), that is the 'cross-link'. So far polymer chains have been considered to be individual molecular species unattached to each other. In some cases, however, it is necessary to link individual chains to their neighbours at intervals along each polymer backbone. In this way, a polymer 'network' is formed and the frequency at which these linkages occur is called the 'cross-link density'. The necessity for doing this can be best understood by considering *Figure 3.1* which illustrates good and bad elastic behaviour. To obtain good elastic behaviour the chains must be mobile enough to change their positions when a deforming force is applied but they also need some restraining links to ensure that they are able to return to their

original positions. The incorporation of an excessively large number of cross-links will restrict deformability and destroy elastic behaviour. For good elastic behaviour, the upper limit of cross-link density is in the region of one cross-link per 100 backbone atoms. The theoretical basis of elastic behaviour in polymers is much more complex than this but the simplified picture given above enables the behaviour exhibited by the types of polymer that are important in contact lens usage to be understood.

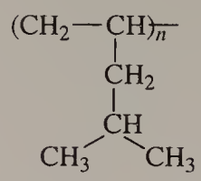
Polymer classification

It is convenient to consider the polymers that have been used or suggested for use as contact lens materials under four headings: (1) thermoplastics, (2) synthetic elastomers, (3) hybrid rigid 'gas permeable' copolymers (RGP materials) and (4) hydrogels. Each group has its own characteristic advantages and disadvantages which may be best illustrated by taking a typical member of each group and making a comparative list of appropriate properties.

The thermoplastics

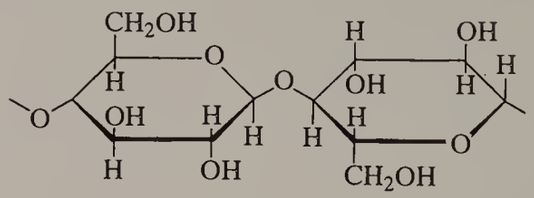
The thermoplastics are the group of polymers that are capable of being shaped or moulded under the application of heat and pressure but which at room temperature are fairly rigid, possibly showing some flexibility but certainly not elastic. Foremost among this group is polymethyl methacrylate which, following its introduction in the 1940s, was the most widely used contact lens material for the next 30 years. It is apparent that several of its advantageous properties are shared by other thermoplastics. Among these properties are optical clarity, processibility, toughness and ease of sterilization, but rigidity and virtual impermeability to oxygen are obvious disadvantages, which now prevent the material from being considered even for daily wear. Although rigidity is a prime factor in producing discomfort, it does permit the lens to be fitted in such a manner as to promote the flow of tear fluid behind the lens, thus compensating to some extent for the absence of oxygen transmission through the lens itself. This does mean, however, that attempts to reduce the rigidity of the lens material to any marked extent have the consequence of requiring a greater permeability of the lens to oxygen. It was largely to improve on the behaviour of polymethyl methacrylate in these two areas that other polymers were suggested as replacements.

At first sight the task of finding an improved material would not seem too difficult since almost all thermoplastics are less rigid and more oxygen permeable than polymethyl methacrylate. Materials patented for contact lens use range from simple structures such as polyethylene (Studies Inc., 1969) and polyvinyl chloride (Rosen, 1969) to complex copolymers of tetrafluoroethylene with perfluoro-2-methylene-4-methyl-1, 3-dioxolane or with hexa-fluoroacetone and ethylene (Dupont, 1971). None of these materials, however, achieved any success largely because of inadequate surface properties, a point which will be elaborated in due course. More promising results were obtained with both poly(4-methyl pent-l-ene), a form of which is known commercially as TPX (Kamath, 1970):

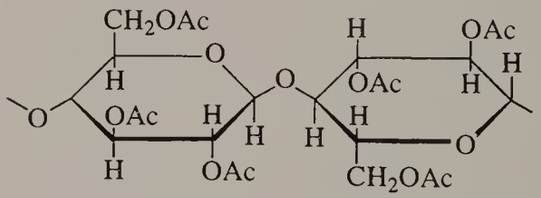


and with cellulose esters such as cellulose acetate butyrate.

The structures of cellulose such as cellulose acetate, cellulose acetate butyrate or cellulose acetate propionate are quite different from those of the carbon-backbone polymers previously considered. Cellulose itself consists of a series of rings or cyclic structures linked together by oxygen atoms:



The hydroxyl groups in the polymer can be partially or completely reacted (replaced by acetyl groups). If all three hydroxyl groups in each ring are acetylated the resultant polymer is cellulose triacetate, which was marketed as the textile fibre Tricel.



Two variations now become apparent. In the first place, some of the hydroxyl groups may be left unreacted (the average number of hydroxyl groups per ring that have been reacted is referred to as the 'degree of substitution'). Secondly, propionyl (CH_3CH_2CO–) or butyryl ($CH_3CH_2CH_2CO$–) groups may be used wholly or partially in place of acetyl groups. Cellulose acetate butyrate therefore describes the case in which we have some acetyl, some butyryl and usually some free hydroxyl groups. This highlights one of the problems with this material in that, unlike polymethyl methacrylate and other polymers previously discussed, it does not have a fixed composition. For this reason, supplies from different sources can have somewhat different properties. In general, higher concentrations of free hydroxyl groups will result in a greater tendency to take up water and will produce more hydrophilic surfaces. On the other hand, increasing the relative concentrations of butyryl groups produces greater flexibility and a slight increase in oxygen permeability.

Poly(4-methyl pent-l-ene) and cellulose acetate butyrate resemble each other in many ways. Both polymers are less rigid and less brittle than polymethyl methacrylate – they can conveniently be described as tougher. It is debatable however, whether greater flexibility improves comfort. Poly(4-methyl pent-l-ene) is unique in having a glass transition temperature between room temperature and the temperature of the eye ($T_g \simeq 29°C$). In principle this should mean that the polymer is more resistant to deformation and damage during handling at room temperature, but when placed in the eye its flexibility and therefore comfort should increase. In practice, however, the increase in flexibility makes virtually no difference to comfort. This will be clarified when the effect of rigidity modulus on lens comfort and visual performance is discussed (pp. 59–61). The most relevant point is that the flexibility associated with these two polymers is very much less than that associated with elastomers and hydrogels.

The oxygen permeability of both cellulose acetate butyrate and poly(4-methyl pent-l-ene) is appreciably (of the order of 100 times) greater than that of polymethyl methacrylate. This is not as advantageous as it may seem at first sight, however, since even in the case of poly(4-methyl pent-l-ene) which is by far the more permeable of the two, a lens of minimal centre thickness prevents normal functioning of the cornea during the closed eye condition. This point will be discussed in more detail in the general context of oxygen permeability requirements (p. 67; *see also* p. 361).

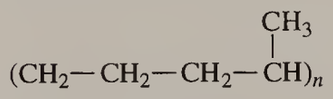
In certain other respects, cellulose acetate butyrate has some advantages over poly(4-methyl pent-l-ene). Although it has a variable composition, it is possible to produce a grade of polymer that will be adequately wettable and able to sustain a film of tear fluid. On the other hand, poly-(4-methyl pent-l-ene) lenses have to undergo surface treatment to enable them to do this. In addition, cellulose acetate butyrate is easier to process.

On balance there is only slight advantage over polymethyl methacrylate in the case of either poly(4-methyl pent-l-ene) or cellulose acetate butyrate. Neither polymer is sufficiently flexible to produce substantially greater comfort and neither polymer has a sufficiently high oxygen permeability to make them candidates for extended wear. In neither case is lens fabrication as straightforward as with PMMA but, despite the fact that CAB suffers from poor dimensional stability, its better processability and lack of need for surface treatment have enabled it to retain a small share of the market. One potential advantage of this group (thermoplastics) is the fact that it can be used to make lenses by melt pressing. This type of rigid lens fabrication process has, however, never been widely used and the thermoplastics have never quite delivered the balance of properties required for successful contact lens use. Some of the problems associated with surface treatment of flexible thermoplastics and results of a clinical trial with poly(4-methyl pent-l-ene) were presented in more detail elsewhere (Larke *et al.*, 1973a,b; Ng *et al.*, 1976).

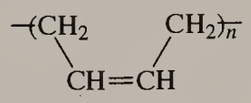
The synthetic elastomers

The synthetic elastomers are the group of polymers which are not only flexible but show rubber-like behaviour, i.e. they are capable of being compressed or stretched and when the deforming force is removed they instantaneously return to their original shape. They consist of polymer chains that possess high mobility and which are cross-linked at intervals along the polymer backbones. Their properties are in many ways intermediate between those of thermoplastics and hydrogels. Thus, they possess to a degree the toughness associated with the former group of materials and the softness of the latter. In this sense they are ideal candidates for contact lens usage. Unfortunately, however, they possess one inherent disadvantage. The molecular features required for true elastic behaviour invariably produce polymers with hydrophobic surfaces. All polymers in this group require some form of surface treatment, therefore, to render them sufficiently hydrophilic for use as contact lenses. In general, it has been the absence of a suitably permanent treatment that has prevented their use on a wide scale.

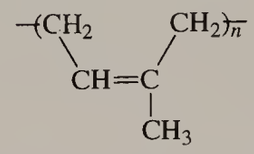
In addition to natural rubber itself many synthetic elastomers were patented in connection with contact lens manufacture (Dow Corning, 1967). These include ethylene propylene terpolymer (EPT) which may be simply represented as



cis-polybutadiene

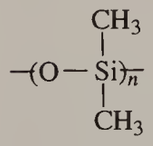


and *cis*-polyisoprene



which is synthetic natural rubber.

These polymers have oxygen permeabilities more than 100 times greater than that of polymethyl methacrylate and the most significant member of this group has an oxygen permeability over 1000 times greater. Hence this polymer, silicone rubber or poly(dimethyl siloxane), has received considerable attention as a contact lens material.



The high oxygen permeability arises from the backbone of alternate silicone and oxygen atoms which has not only

great freedom of rotation but a much higher solubility for oxygen than polymers with all-carbon backbones.

Surface-treated silicone rubber lenses were developed in the mid-1960s (Becker, 1966; Dow Corning, 1967) and found clinically to have little effect on corneal respiration (Hill and Schoessler, 1967; Burns *et al.*, 1971). Despite the apparent attraction of a soft yet tough, highly oxygen permeable material, problems have been encountered in its clinical use (Bitonte and Keates, 1972). Not the least of these is the fact that surface treatments tend to be non-permanent and to cause some reduction in the optical qualities of the lens surface and hence surface-treatment techniques are still being investigated. Lenses made of current materials are used only rarely and are discussed in Chapter 11. In conclusion it is appropriate to note that because of the nature of the materials, elastomer lenses are normally produced by some form of compression moulding technique.

The hybrid rigid gas permeable materials

The third group (hybrid rigid gas permeable materials) combine to a degree the ease of preparation of PMMA and the oxygen permeability of silicone rubber. The history and underlying chemistry of this group of materials is more fully described in a subsequent section (*see* pp. 78–79).

The hydrogels

The fourth group, hydrogels, is also potentially the largest in terms of structural variety. These are hydrophilic polymers which are plasticized by the water they absorb and can be described as soft, elastic, water-containing gels. The first of these to achieve commercial significance, PHEMA, was developed by Wichterle and his co-workers in Czechoslovakia as a general purpose surgical material (Wichterle and Lim, 1960, 1961, 1965). PHEMA is in many ways typical of other hydrogels and unfortunately the terms have been used synonymously on many occasions. The range of properties obtainable with hydrogels is extremely wide and with this class of material it is possible to 'purpose-design' or 'tailor-make' polymers for contact lens use.

Before turning to a fuller consideration of the nature and properties of hydrogels and RGP materials, however, it is necessary to discuss those material properties that are important in the design and function of contact lenses together with the various ways in which the lenses themselves are fabricated. Chapters 10 and 11 should also be consulted for discussions on material characteristics in relation to the fitting requirements for particular types of eye and refractive error.

Routes to lens manufacture

As a prelude to reviewing the property requirements of lens materials, it is appropriate to outline the routes by which monomers are converted into polymers in lens form. As will become apparent, the use of some routes makes demands on the properties of hydrogel in its dehydrated state. The four types of formation considered (lathe-cut lenses, spin-cast lenses, static cast polymerization lenses, and melt pressed lenses) are used to widely differing extents. Because of factors such as production costs and interest in disposable lenses, the less labour intensive techniques, particularly static cast polymerization, are finding more widespread use. The introduction of daily disposable lenses provides a further platform for this technology.

Lathe-cut lenses

The monomers are bulk polymerized in tubular moulds using conventional free radical techniques. Polymer rods 10–15 mm in diameter with lengths of 20 cm upwards are prepared and sliced into buttons 5–10 mm thick for the lathe-cutting operation. Alternatively the polymerization may be carried out in individual button-shaped moulds.

Conversion of the button to lens form involves first mounting the button in the lathe – either manual or automatic – to cut and polish the back curve, then reversing the button and mounting onto a brass stub by means of a pitch adhesive in order that the front surface and edge of the lens may be cut and polished (*see* Chapter 21). The polish consists typically of alumina dispersed in a hydrocarbon or silicone oil fluid.

Removal of the lens from the mounting stub and cleaning all traces of adhesive and polish involves the use of solvents (such as chlorinated hydrocarbons) and surfactants. This process, which is still the most widely used in lens manufacture, places demands on those mechanical properties of the lens material that govern susceptibility to high speed cutting and polishing. In particular the generation of heat in these operations places a lower limit on the glass transition temperature of the polymers. The technique is equally useful for PMMA, hydrogels and RGPs.

Spin-cast lenses

This process was developed by Wichterle and is described in his patents. A mixture of liquid monomer, cross-linking agent, initiator and optionally a diluent such as ethylene glycol, is introduced into a concave mould. The mould is rotated about its central axis (i.e. spun) during the polymerization and the centrifugal force results in the direct formation of a lens form. The mould may be fabricated from glass or polymers such as polypropylene and nylon. The quality of the mould surface has a direct influence on that of the front surface of the lens. The technology involved in this form of lens production was extended and developed by Bausch & Lomb Inc. in the USA, who are now the foremost users of this type of soft lens production.

Static-cast polymerization lenses

This technique also involves the direct conversion of monomer mixture into lens form. In principle a two part mould fabricated from a flexible polymer such as polypro-

pylene or nylon is filled with monomer mixture which subsequently polymerizes. The mould is opened yielding the finished lens, ready for hydration. In a variant of this process a water-soluble diluent is incorporated with the monomers before polymerization.

In practice a great deal of design skill is needed in overcoming the problems associated with filling and closing the mould, and with contraction during polymerization but especially in obtaining good and reproducible edge quality. The lenses are inspected and checked following hydration and it is common for appreciable numbers to be rejected at this stage. Because the unit production cost is potentially low this technique and variants of it are now the most important form of high volume soft lens production.

Melt-pressed lenses

Although techniques of this type have been used commercially for the production of poly(methyl methacrylate) and silicone rubber lenses, their use in hydrogel and RGP lens manufacture does not appear to have gone beyond the patent literature and pilot scale work. The monomers are polymerized to give a linear polymer which is isolated and converted to sheet, powder or granules, depending upon the type of mould to be used. The next stage involves use of conventional compression or injection moulding techniques, sometimes with a subsequent cross-linking stage which may involve irradiation. The moulded lens may require edging and local polishing to remove moulding flash, prior to hydration. The major problems in melt processing techniques lie in achieving a balance of flow and cross-linking in these highly functionalized polymers together with good mould release without the addition of conventional processing aids.

Each of the foregoing techniques has its own particular requirements in terms of monomer and polymer properties. In contrast to the behaviour of the lens in the eye, which makes demands on the behaviour of the hydrated polymer, manufacturing techniques frequently make behavioural demands on the polymer in its completely dehydrated state.

Properties of contact lens materials

The following properties are among the most important in affecting the performance of materials as contact lenses:

- Density.
- Refractive index.
- Optical transmittance.
- Dimensional stability with respect to time, temperature, pH and tonicity.
- Surface properties.
- Water content.
- Mechanical properties, including tensile strength, tear strength and rigidity modulus.
- Permeability to oxygen, carbon dioxide etc.
- Ocular compatibility.
- Toxicity and chemical stability.
- Method and ease of sterilization.

The relative importance of the various properties will depend on whether the lens is intended for daily wear or extended wear. In addition, some properties such as refractive index and density vary by relatively small amounts within the range of polymers that are suitable for contact lens use. Consequently, the potential value of a material is not greatly affected by its density or refractive index.

Similarly, the dimensional stability of a material with respect to changes in temperature is less important than the reversibility of any changes that occur. This aspect of lens behaviour will usually be most important during heat sterilization procedures, if these are employed. To a lesser extent, some dimensional changes with changing pH and tonicity can be tolerated provided that such changes are reversible and small over the range of pH and tonicity encountered on the eye. Dimensional stability with respect to time is extremely important since instability will result in irreversible flattening or distortion of the lens. Dimensional instability in PMMA is invariably the result of strain induced during lens manufacture. With RGP materials, however, water uptake results in a degree of plasticization of the matrix and this causes dimensional instability, particularly flattening.

One of the problems associated with the measurement of mechanical properties of lens materials is that no single property measurement reflects accurately the 'in use' situation. 'Tensile strength' indicates the resistance of the material to deformation under tension, 'tear strength' the resistance of the material to tear propagation from a notch or imperfection and 'rigidity modulus' the resistance to deformation under compression. The first two give some indication of the behaviour of a material during handling whilst the third indicates the extent to which the eyelid will deform it. Thus, a 'hard' or rigid material would have a high rigidity modulus, whereas a 'soft' material would have a much lower value. Whilst a low rigidity modulus is associated with greater comfort, in extreme cases poor visual stability is encountered, thereby setting a lower limit to this property.

Attempts have been made to define the properties of the 'ideal contact lens' (Kamath, 1969) but in view of the divergence of clinical preference in relation to the wide range of lenses presently available, such an approach is unlikely to succeed. It is possible, however, to define acceptable ranges of certain situations (i.e. daily wear, extended wear, rigid lenses, soft lenses). It is useful in doing this to compare the properties of a member of each of the three classes of 'pure' (i.e. excluding 'hybrid' RGP) material previously discussed. It is also useful to include for comparison the properties of the cornea although collection of the relevant information in this case is not easy (Kamath, 1969; Tighe, 1976; Corkhill, *et al.*, 1990).

A comparison of various properties of polymethyl methacrylate, poly(dimethyl siloxane) or silicone rubber,

Table 3.1 Properties of representative contact lens materials (all reported at 25°C unless otherwise stated)

	Polymethyl methacrylate (thermoplastics)	*Silicone rubber (elastomers)*	*PHEMA (hydrogels)*	*Cornea*
Density (g/cm^3)	1.18	1.10	1.16	1.03
Refractive index	1.49	1.43	1.43	1.37
Dimensional stability with respect to:				
Time, Temperature, pH, Toxicity	Generally good unless strain induced during processing	Generally good	Generally good	
Surface wettability				
Critical surface tension (dyn/cm)	39	25	$\simeq$ 50	$\simeq$ 30
Equilibrium water contact angle (°)	65–70	$\simeq$ 96	$\simeq$ 20	$\simeq$ 47
Water content (%)	$\simeq$ 0.5	$\simeq$ 0	$\simeq$ 39	$\simeq$ 8
Tensile strength (dyn/cm^2)	$\simeq 50 \times 10^7$	$\simeq 10 \times 10^7$	$\simeq 0.5 \times 10^7$	$\simeq 5 \times 10^7$
Rigidity modulus (dyn/cm^2)	$\simeq 1 \times 10^{10}$	$\simeq 8 \times 10^7$	$\simeq 5 \times 10^7$	$\simeq 10 \times 10^7$
Tear strength (g/mm)	Strong but brittle	$\simeq$ 2000	$\simeq$ 10	$\simeq$ 1500
Oxygen permeability (0.1 mm thick sample)				
$*P_g$ (ml(STP) mm)/(cm^2s cmHg)	$\simeq 1 \times 10^{-10}$	$\simeq 5000 \times 10^{-10}$	–	–
$*P_d$ (ml(STP) mm)/(cm^2s cmHg)	$\simeq 1 \times 10^{-10}$	$\simeq 1500 \times 10^{-10}$	75×10^{-10}	$\simeq 300 \times 10^{-10}$

*The interrelationship of P_g, P_d and Dk are discussed on p. 67–70 and in Addendum 1.

PHEMA hydrogel and the cornea is presented in *Table 3.1*. In the light of these figures and the preceding discussion it will be apparent that relatively few properties are absolutely critical in determining whether or not a material is suitable for contact lens use. From the point of view of lens description, rigidity modulus and surface wettability will be sufficient to define the material (in the commonly used terms) as rigid hydrophobic, soft hydrophobic or soft hydrophilic (corresponding to each of the three classes). In addition, the oxygen permeability will indicate whether the material is suitable for daily wear only or may be investigated as an extended wear candidate. Most of the other properties are either relatively unimportant or affect only convenience of use and ease of handling (tensile and tear strengths for example). In either case, absolute limits cannot be put on their magnitude although in the case of both tear and tensile strengths it should be as high as possible.

If an alternative approach is taken, that of considering the contact lens as an extension of the cornea, a similar conclusion is reached. Thus, the lens must allow the cornea to respire normally, it must resist the deforming force of the eyelid and it must permit a continuous tear film to be maintained on the lens. These factors can be discussed in terms of mechanical properties, surface properties and oxygen permeability. Some attempt must therefore be made to put quantitative limits on these important properties.

The underlying problem that has bedevilled the field of contact lens materials has been the lack of adequate standardization. Whereas legislation and common scientific practice have made it possible to compare most pharmaceutical products, one with another, no such situation exists with contact lenses. Given the relative explosion in the number and types of material that have become available, this is a serious problem. Even the activities of the Food and Drugs Administration (FDA) in the USA have failed to produce a satisfactory and generally observed basis for the assessment and comparison of different lens materials of the same type with respect to an adequate range of properties. The following section outlines the type of information that can be obtained, and its relevance to contact lens performance. An agreed international basis for the determination and reporting of such properties is still not fully developed.

Mechanical properties

It is generally believed that variations in mechanical properties of what are essentially polymers whose properties lie in a tough to glassy regime (the RGPs) are less critical in relation to clinical performance than is the case with soft elastic hydrogels. This does not mean to say that the mechanical properties of RGPs are unimportant in this respect, but they are more obviously related to problems associated with manufacturing and durability. Perhaps for this reason, less attention has been given to determination of mechanical properties of rigid contact lens materials, than has been given to, say, permeability or wettability. It is important, however, to recognize the important clinical consequences of dimensional instability of some RGPs and the fact that this instability has its roots in the underlying mechanical properties of the materials. For this reason determination, with reasonable accuracy, of some fundamental mechanical properties of materials in the form of contact lenses is a desirable aim. This is in fact a major problem, for although many test procedures, techniques and materials' characteristics are known in the field of mechanical properties they are not designed for small curved samples of changing cross-section. To provide a basis for discussion, the types of information obtained in conventional mechanical testing must first be outlined.

In general, mechanical property testing involves the application of a deforming force to a sample and a concurrent study of the way that the sample responds. The results are often expressed as strength or modulus. The strength of a material is usually defined as the force per unit area required to cause failure when the material is subjected to a particular type of test procedure (e.g. tensile, shear, impact, tear). The modulus is defined as the true stress (i.e. force per unit area) required to produce a true unit strain (i.e. deformation) in the direction of the force (e.g. tensile modulus, rigidity modulus). The most common types of mechanical property tests are described below but first it is necessary to comment on the units used.

Several different units of stress are used (e.g. tsi, ton weight per square inch; psi, pound weight per square inch; kg or kgf/mm^2, kilogram weight per square millimetre, and dyn/cm^2, dynes per square centimetre). The SI unit of stress is N/m^2 (newtons per square metre), but this is an extremely small quantity and MN/m^2 (mega-newtons per square metre, equal to 10^6 N/m^2) is a more useful unit. The units are related in the following way:

$$\begin{aligned} 1\ \text{dyn/cm}^2 &= 0.1\ \text{N/m}^2 = 10^{-7}\ \text{MN/m}^2 \\ &= 1.45 \times 10^{-5}\ \text{psi} \\ &= 6.46 \times 10^{-9}\ \text{tsi} \\ &= 1.02 \times 10^{-8}\ \text{kg/mm}^2 \end{aligned}$$

Some of the ways in which this information is obtained are outlined below.

Examination of materials under tension

A polymer specimen is stretched if a tensile stress is applied to it. The tensile test is normally carried out with a tensometer (which measures the extension produced as the load is applied). A stress-strain curve produced in this way provides wide-ranging mechanical data of the material under test:

- how strong it is, i.e. the ultimate tensile strength of the material;
- how much it can be deformed before fracture, i.e. the elongation at break of the material;
- how stiff it is, i.e. the tensile modulus (Young's modulus) of the material;
- how tough it is, which can be determined from the area under the whole stress-strain curve.

In addition, the profile of the stress-strain curve provides valuable guidance as to the mechanism of failure of the specimen.

The relationships, with appropriate units, are shown below.

$$\text{Tensile strength} = \frac{\text{Load at break (N)}}{\text{Cross-sectional area (m}^2\text{)}} \qquad \text{Units: N/m}^2$$

$$\text{Tensile modulus} = \frac{\text{Stress (N/m}^2\text{)}}{\text{Strain}} \qquad \text{N/m}^2$$

$$\text{Percentage elongation at break} = \frac{\text{Extension at break (m)}}{\text{Original length (m)}} \times 100\% \qquad \text{Unit: \%}$$

Examination of materials under compression: rigidity modulus

The test selected for a given polymeric material should relate to the stresses it will experience in service. However, simulating the actual service conditions of the polymer in experimental tests may prove difficult since no single commercially available technique can provide all the experimental conditions for testing polymers in different applications. The nearer the experimental conditions are to the service conditions, the more potentially significant will be the results. A useful and significant test for soft lens materials is the time-dependent deformation and recovery of the materials under successive periods of load application and removal. Unlike ideally elastic materials, most polymers are viscoelastic (i.e. they deform time-dependently when a load is applied to them and recover time-dependently when the load is removed) and this may result in a progressive deformation of the materials.

Instruments for the study of deformational properties under compression are fundamentally similar. Typically, the instrument allows the indentation of any test sample (e.g. in the form of a thin film or coating) by a small sphere under a small constant load, to be measured as a function of time. The recovery of the specimen after the load has been removed can also be measured as a function of time. Both the indentation and recovery curves are recorded automatically and the time scales of each can be set separately. Because wide variation of both magnitude of load and indenter diameter or form is possible, a wide range of material properties can be monitored with this technique. The non-destructive nature of the method coupled with its ability to handle small specimen sizes make it particularly suitable for the examination of contact lens materials. As a consequence, values of the rigidity modulus for a wide range of types of material are known and some general comments on the relationship with clinical performance can be made.

The value of the rigidity modulus indicates the force (stress) necessary to compress (strain) the material by a given amount. It is therefore a bulk property and has units of 'force per unit area' such as lb/in^2 or dyn/cm^2. Although this gives a good indication of the flexibility of the material, it bears no relationship to properties that are measured in tension, such as tensile strength and tear strength. Some indication of the way in which the rigidity modulus is related to comfort and visual performance is given in *Figure 3.2*. The two latter parameters are expressed in arbitrary units since a general rather than precise relationship is intended.

It is apparent from the figure that there are two regions (**A** and **C**) in which the visual performance has deteriorated. Region C corresponds to the low rigidity modulus associated

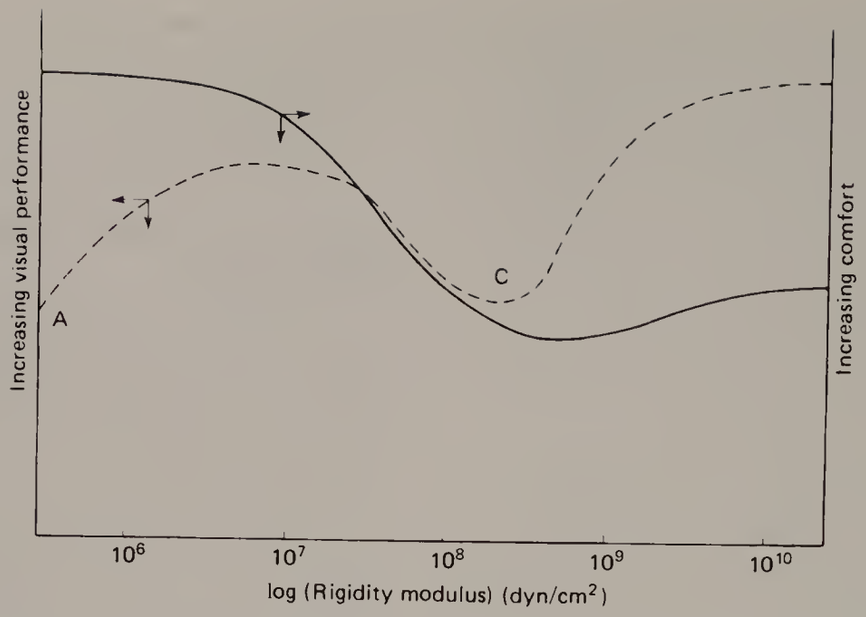


Figure 3.2 The general relationship between the rigidity modulus of a contact lens material and the comfort (—) and visual performance (– –) of the lens

with some hydrogels, often of high water content. In this case, the poor visual performance is due to the inability of the material adequately to resist the deforming force of the eyelid. Region A corresponds to flexible thermoplastics that have poor elastic recovery and poor dimensional stability. Plasticized polyvinyl chloride of the type encountered in vinyl seat coverings is an example of polymers showing this behaviour. Here the material is insufficiently rigid for the lens to be fitted as a conventional rigid lens but insufficiently flexible and elastic to be accommodated to the corneal profile in the way that conventional 'soft' lenses are.

This illustrates the difficulty in achieving a balance between comfort, visual performance and flexibility and in particular the problems associated with a 'semi-rigid' lens which would otherwise have many attractive features. In practical terms, materials in regions C and A are unsuitable for contact lens usage. Although the exact limits are difficult to define, it is apparent from clinical studies that poly(4-methyl pent-l-ene) or TPX is approaching the point where reduced rigidity (in comparison with polymethyl methacrylate) results in some loss in visual performance when conventional fitting techniques are used (Larke *et al.*, 1973 a,b; Ng *et al.*, 1976).

Rigidity modulus and related measurements were made on a wide range of contact lens materials using a microindentation apparatus (Ng, 1974; Tighe, 1976). This technique enables samples of similar thickness to that of contact lenses (0.1–0.4 mm) to be studied. Rigidity modulus measurements are made by measuring the deformation produced in the sample by a spherical indenter to which a series of loads is applied. *Figure 3.3* illustrates the relationship between log load and log indentation for a spherical indenter of 0.16 mm radius. Materials of decreasing rigidity are found on moving from left to right and it is relevant to note that the cornea corresponds to line *g*. From this figure it is also easy to appreciate that under a load (say, 1 gram) that causes moderate deformation of elastomers, hydrogels and the cornea (*f*–*h*), the effect on the group of thermoplastics (*a*–*e*) is negligible. Thus, although we can detect manually the difference in flexibility or rigidity

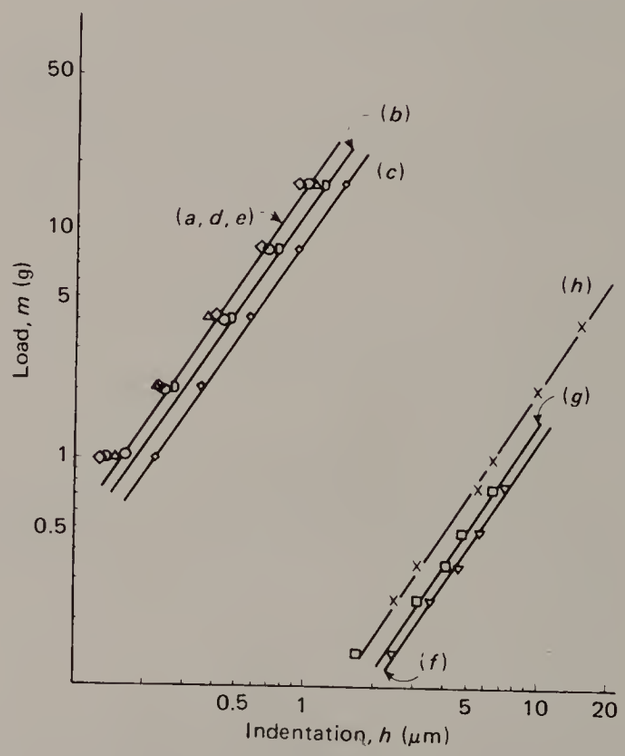


Figure 3.3 Microindentation studies. The correlation of a log(load) with log (indentation) for various materials: (*a*) △ PMMA; (*b*) D polystyrene; (*c*) ◇ poly(4-methyl pent-l-ene); (*d*) ○ dehydrated PHEMA; (*e*) ◇ dehydrated HEMA-styrene (90:10); (*f*) ∇ PHEMA hydrogel; (*g*) □ HEMA-styrene (90:10) hydrogel; (*h*) × EPT

between, say, polymethyl methacrylate and a 'semi-rigid' plastic such as poly(4-methyl pent-l-ene), the cornea is unable to detect any difference.

This point is illustrated more clearly when the micro-indentation technique is used with a flattened indenter and load calibrated to produce a pressure similar to that exerted by the eyelid ($\simeq 2.6 \times 10^4$ dyn/cm^2). Using this procedure the deformation and recovery of polymer samples of contact lens thickness under eyelid load can be studied. No detectable deformation is produced in any of the thermoplastic polymers previously discussed. It must be remembered, however, that this is compression of a supported material and not 'flattening' of an unsupported lens which does begin to occur with less rigid polymers.

Indentation studies of this type under eyelid load correlate well with clinical studies. Although the ideal elastic behaviour exhibited (*Figure 3.4*) by synthetic elastomers under these low loads is preferable, appreciable deviations from this situation still produce acceptable clinical behaviour. Thus, materials whose behaviour is more time dependent (i.e. less than instantaneous deformation and recovery) produce acceptable visual stability levels in lenses provided that the overall deformation is not more than about 2%. PHEMA itself shows reasonably good elastic behaviour under eyelid load as illustrated in *Figure 3.5*.

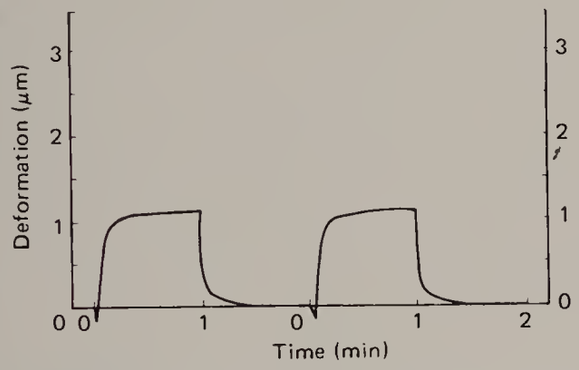


Figure 3.4 Deformation properties of ethylene–propylene terpolymer under eyelid pressure

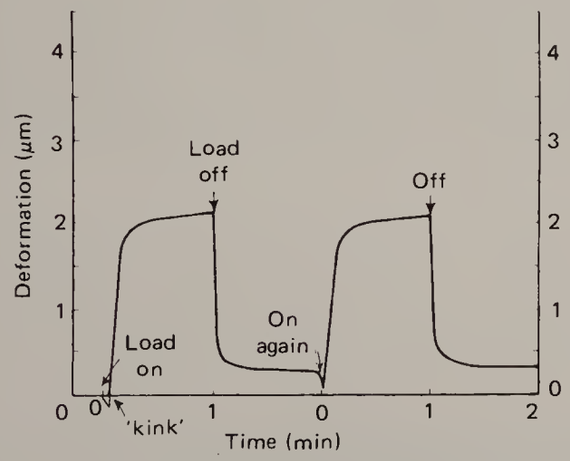


Figure 3.5 Deformation properties of PHEMA under eyelid pressure

Hydrogels whose deformational behaviour is characterized by large ($\simeq$ 5%) and rapid initial deformation that does not reach equilibrium within one minute and shows poor recovery, invariably give rise to lenses whose visual stability is unacceptable. Some early, fragile, high water content hydrogel lenses tended to behave in this way.

Hardness tests

Hardness can be defined as resistance to penetration. In a hardness test an indicator is pressed on the surface of the material under test, and the extent to which it sinks in for a given pressure and time is an inverse measure of the hardness. In this respect the test is related to compression testing. There are many hardness testers available commercially and suitable for plastics and rubbers, including the Vickers indenter, the Rockwell hardness tester and the Shore durometers. They may be divided into three categories.

(1) Hardness tests that measure the resistance of a material to indentation by an indenting probe (e.g. Brinell, Vickers and Shore durometers). Some tests measure the indentation with the load applied and some measure the residual indentation after the load is removed.
(2) Hardness tests that measure the resistance of a material to scratching by another material (e.g. the Bierbaum scratch test, the Moh hardness test). Similar techniques are commonly used in paint testing and involve pulling the sample beneath a loaded indenter.
(3) Hardness tests that measure recovery efficiency or resilience (e.g. the various Rockwell testers).

Many of the hardness tests are a combination of categories (1) and (3).

There is no common method of measurement in these tests. For example, the Rockwell α scale hardness test measures the depth of penetration with the load applied, whereas the Rockwell R, L, M and E scale tests measure depth caused by a spherical indenter after most of the load has been removed. In these methods the amount of rebound or recoverable deformation is important. The Vickers Microhardness test differs again, in that a microscope is used to measure the diagonals of the pits left by a diamond-shaped indenter on a square base. There is a linear relationship between the depth of impression and the hardness number. Each of the hardness methods uses an arbitrary scale and, although the scales can be approximately compared, precise correlation is not possible.

Hardness testing using these various instruments is a fairly convenient method for comparing the relative hardness of materials, and results are being increasingly quoted in overviews of contact lens materials. The plethora of methods and difficulty of comparing them mean that they can, realistically, only provide supplementary information to that obtained by micropenetrometry which provides direct indentation results and can also be used to calculate rigidity modulus.

Other mechanical tests: tear, flex, creep

Various additional types of mechanical test may be used, but in general they are less readily adapted to contact lens studies; some of these are briefly described here.

Tear strength test

Tear strength is the force required to propagate a tear in a notched specimen and is expressed as force per unit length of the resultant tear. The result depends on many factors such as depth of notch, mode of applying the tearing force, thickness of specimen and temperature of test. This property is particularly important for hydrogels but no satisfactory comparative technique for use on lens materials has yet been developed.

Flexural test

The specimen is flexed repeatedly until it fractures. The number of flex cycles to break measures the flexural resistance of the material. The flex can be repeated in linear extension, bending without tension, or with a combination of bending and extension. This property should not be confused with the resistance of a lens to flexural deformation. Behaviour of this type is related to the deformational tests previously described and its relationship to clinical performance has been reviewed by Fatt (1987).

Creep test

Plastics often tend to become distorted if they are constantly loaded. Creep tests are therefore important for polymeric materials in service. A creep test records deformation against time for a constant stress over a relatively long period of time, in contrast to the conventional tensile and compression testing techniques previously described which measure short-term response. Thus, when a load is applied to a polymer specimen, there is a short-term elastic deformation, followed by the relatively slow deformation or creep. A creep test is normally carried out in tension rather than compression. Creep is particularly important in polymers whose behaviour lies between truly elastic on one hand, and rigid and glassy on the other. In the contact lens field the 'rigid gas permeables' frequently show poor rigidity and are subject to creep. This manifests itself in dimensional instability and occurs in response to internal or external stresses imposed on the lens. It has been reported that high plus and high minus lenses can behave quite differently and, additionally, there is a clear material dependence (Kerr and Dilly, 1988). Much of the dimensional instability in RGPs occurs upon hydration and is a consequence of the hydrophilic monomers that are incorporated to overcome the hydrophobicity of siloxy-and fluoromethacrylates. For this reason observation of differences between the tensile stress–strain curves of non-hydrated and hydrated lens materials provides a useful short-term method for creep prediction.

Surface properties: general principles

The wetting of contact lenses is important because the maintenance of a precorneal tear film in the form of a thin capillary layer has long been recognized as a primary requirement for the physiological compatibility of lens and patient. Defining in quantitative terms the surface characteristics that are necessary to produce this behaviour has, however, only relatively recently been attempted.

The terms 'hydrophilic' and 'hydrophobic' have been widely and often misleadingly used in this connection. When used to refer to bulk properties they mean simply water-loving and water-hating, respectively. In this sense a dehydrated hydrogel can be said to be hydrophilic since it imbibes water to form a gel. When the terms are used in connection with surfaces they have a more specific meaning. The term 'hydrophilic' used in this sense means that water will spread spontaneously on the surface, whereas 'hydrophobic' implies that water will not spontaneously spread on the surface. Many contact lens materials are referred to as hydrophilic when, by this definition, they are not so. The position is complicated by the fact that when contact lens materials are referred to, the implication is that they are wetted by tear fluid rather than by water itself. These, then, are some of the aspects of the subject that must be taken into account.

The most convenient way of assessing wettability is by the contact angle. The simplest method for measuring this is by observing the formation of a sessile drop of liquid (delivered, for example, by a hypodermic syringe) on the solid surface. The image of the droplet may be projected or photographed and the contact angle (θ) is the angle enclosed by the surface and the tangent to the droplet–surface interface (*Figure 3.6*). Thus, a liquid which spontaneously wets or spreads on a surface has a contact angle of zero. A hydrophilic surface, is one on which water exhibits a zero contact angle.

The wetting of the cornea by tear fluid can be treated in a similar way although it is a much more complex process – *see* Chapters 2 and 8. It was recognized some 30 years ago that the epithelial surface is too hydrophobic to be spontaneously wetted by tears (Mishima, 1965) and is thought to be covered by a lipid layer (Ehlers, 1965). The resultant surface would itself be relatively hydrophobic and the early hypothesis to explain the fact that tears wet the cornea was that the conjunctival glycoproteins also adsorb on the corneal surface thus rendering it

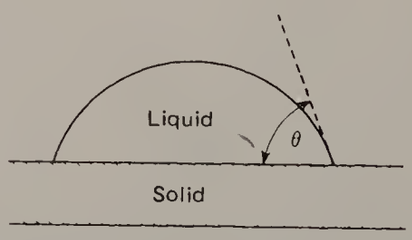


Figure 3.6 Droplet of liquid resting at equilibrium on a solid surface showing the contact angle (θ)

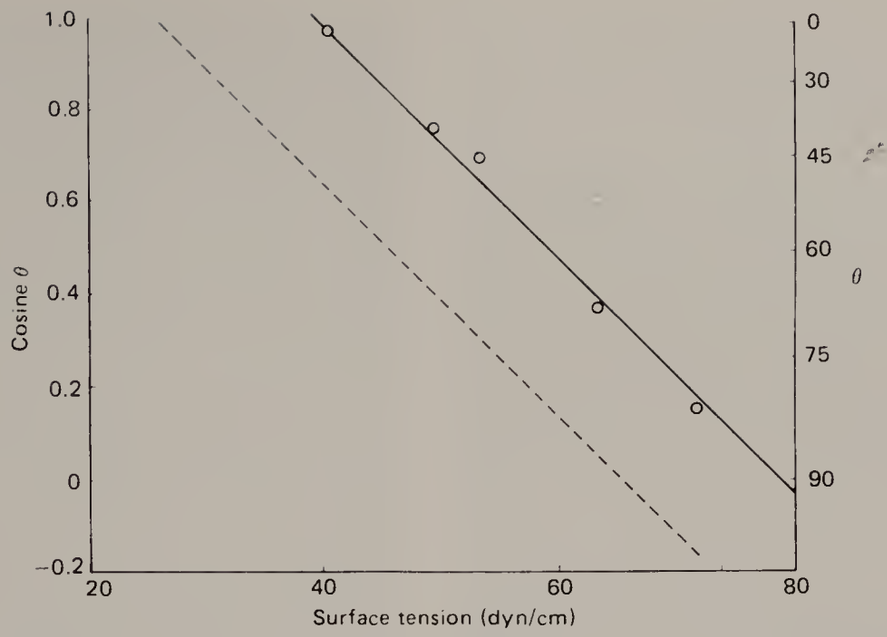


Figure 3.7 Determination of the critical surface tension of polymers by the method of Fox and Zisman (1980) illustrating the difference in wettability and critical surface tension of polymethyl methacrylate (—) and silicone rubber (– –)

wettable. Current views favour the concept of a viscous gel layer of glycoprotein (mucin) at the corneal interface rather than any form of specific interaction or adsorption (Bright and Tighe, 1993). Although the structure and function of tears are complex (Mishima and Maurice, 1961; Wolff, 1976; Holly, 1986), for the purpose of studying interactions with polymers we can consider the fluid to be an aqueous liquid whose surface tension has been reduced to approximately 46 dyn/cm by the presence of surfactants or wetting agents. It should be noted, however, that this value for the surface tension of tear fluid (Miller, 1969) has been thought by some workers to be too high (Lemp *et al.*, 1970). The surface tension of pure water by comparison is 72.8 dyn/cm.

Definitions

It was Thomas Young who first indicated that forces acting on the droplet (*see Figure 3.6*) when it has reached equilibrium may be resolved and expressed by the relationship:

$$\gamma_{sv} - \gamma_{sl} = \gamma_{lv} \cos \theta$$

where

γ_{sv} is the free energy or surface tension at the interface of solid and vapour
γ_{sl} is the free energy or surface tension at the interface of solid and liquid
γ_{lv} is the free energy or surface tension at the interface of liquid and vapour and
θ is the contact angle.

This provides a basis for the quantitative description of wettability of the substrate, together with the spreading of a liquid on that substrate, and their relation to the contact angle. As θ diminishes and approaches zero, the liquid approaches the condition where it will spread on the surface.

This condition is referred to as spontaneous wetting of the surface (in contrast to the situation where a mechanical force is used to induce spreading) and leads to the simplest relationship between the wettability of the surface and the ability of liquids of different surface tension to wet it. *Figure 3.7* shows such a relationship and illustrates the concept of 'critical surface tension' of the substrate. Figures of this type are obtained by measuring the contact angle of a series of liquids of known surface tension on the substrate in question. The results are plotted in the form $\cos\theta$ (y axis) against surface tension of the wetting liquid (x axis), a function which is, in many cases, linear. This enables a line to be extrapolated on the graph to a point corresponding to spontaneous wetting, i.e. $\cos\theta = 1$. The value of the surface tension obtained in this way, which would correspond to that of a liquid just able to spontaneously wet the substrate, is known as the critical surface tension of the substrate. Liquids having surface tensions equal to, or less than, the critical surface tension of a given substrate would be expected to wet or spread on that surface.

A rather more precise description of surface properties arises from the analysis of the interaction of forces of different kinds across interfaces. Fundamental to this philosophy is the concept of the free energy of a surface. It is convenient to regard this as the equivalent of a solid or liquid surface tension, but being composed of two components. The first of these components is characteristic of the relatively non-polar background forces in molecules of the van der Waals type, and is known as the dispersive, or non-polar, component. The second originates principally from molecular dipoles and is known as the polar component.

Thus for a liquid

γ_l (total) = γ_l (dispersive) + γ_l (polar)

and for a solid:

γ_s (total) = γ_s (dispersive) + γ_s (polar)

The abbreviations γ_s^d, γ_s^p, γ_l^d and γ_l^p are normally used.

A useful concept that arises from this treatment is that of interfacial tension between two liquids or between a liquid and a solid. The greater the interaction of forces of the same type across the interface, the lower will be the interfacial tension at that interface, and vice versa. For this reason, two liquids such as water and octane, which have very different balances of polar and dispersive forces, show little interaction at their interface and are thus immiscible. On the other hand, water and ethyl alcohol both have strong polar contributions which operate across an interface resulting in the miscibility of these two liquids. In the same way, the interfacial tension between a liquid and a solid is a measure of the interaction between these materials. In the study of biocompatibility of materials with different biological environments, the desirability of achieving a low interfacial tension between the biomaterial and its environment is well recognized. The concept is equally valid in relation to ocular compatibility and will undoubtedly become more widely accepted as the limitations of currently quoted 'wetting angles' become recognized and research methodologies in this area become more sophisticated.

Two important equations must be quoted. The first of these illustrates the way in which the operation of forces across the interfaces are calculated, the basis of which is the so-called 'geometric mean' concept. Thus, for a solid and a liquid, the interfacial tension is given by:

$$\gamma_{sl} = \gamma_s + \gamma_l - 2(\gamma_s^d \gamma_l^d)^{1/2} - 2(\gamma_s^p \gamma_l^p)^{1/2}$$

Because the polar component of water is relatively high (51.0 dyn/cm) it is obvious from this equation that a low interfacial tension with water or with aqueous systems can only be achieved by solids that themselves have appreciable polar character.

The second equation, which was developed by Owens and Wendt, utilizes this principle in such a manner that measurements of contact angles with two different liquids enables the unknown polar and dispersive components of a given solid to be determined. This assumes that two liquids of known polar and dispersive components have been chosen. Owens and Wendt's expression in the general form is shown below:

$$1 + \cos\theta = \frac{2}{\gamma_l}[(\gamma_s^d \gamma_l^d)^{1/2} + (\gamma_s^p \gamma_l^p)^{1/2}]$$

Rearrangement enables two readily solved simultaneous equations to be generated and γ_s^d and γ_s^p thereby determined.

Measurement techniques

Some comments on the types of measurements that are made, the results that they yield and the problems associated with their measurement and interpretation are important. The most common method for measuring surface properties involves the use of a sessile droplet of liquid, introduced onto the surface of the material by a hypodermic syringe. The introduction and measurement are carried out in air, which means that the liquid will be in equilibrium with its vapour. This is essentially the condition described in Thomas Young's relationship, referred to above. Before considering the use that can be made of such information, some comments on factors that affect the form of the droplet and its contact angle on the material substrate are necessary.

In the first place, the liquid is responding to the *surface* forces in the polymer, emphasizing that this leads to the measurement of *surface* properties. The liquid–solid interaction is thus greatly influenced by minute traces of surface impurities, such as those caused by handling, and accumulated during storage. Careful cleaning of the surface (using dilute surfactant followed by rigorous washing with pure water and careful drying under vacuum) is therefore essential. The techniques developed by Zisman (Fox and Zisman, 1950) in his extensive work on surface energetics still provide a sound basis for studies of this type.

Secondly, there is normally a difference between a contact angle produced as a droplet advances over the surface, on being dispensed from the hypodermic syringe, and the contact angle made with the surface as the droplet recedes if it is drawn back into the syringe. These two angles, the so-called 'advancing' and 'receding' contact angles are often conceptually regarded as the advancing angle over a dry or unwetted surface and the receding angle as liquid withdraws over a previously wetted surface. The difference between them is referred to as contact angle hysteresis. The measurement normally used in surface characterization is referred to as the equilibrium advancing contact angle, and is taken immediately after the advancing droplet has been allowed to come to rest.

Other factors that can influence the experimentally determined contact angle are droplet size and surface roughness (or rugosity). The rule of thumb with respect to droplet size is that it is important to be consistent and not to use too large a droplet, otherwise distortion of the idealized droplet shape occurs. The effect of rugosity is rather more complex, but in essence a roughened surface will give a lower contact angle than a smooth surface of the same material. This emphasizes the need to ensure that equally smooth surfaces are used when making comparisons. This can be quite difficult with fabricated articles such as contact lenses.

Inverted bubble or droplet measurement techniques are fundamentally different from those involving the measurement of a sessile drop in air. The inverted methods require the sample to be immersed in a liquid (usually water) and a droplet of a second liquid (or air) to be introduced beneath the sample surface. It is obviously essential that the droplet is of lower density than the immersion fluid. When the density difference is large, as in the case of air, the influence of droplet (i.e. bubble) distortion and the importance of

droplet (bubble) size is much greater than in the case of the sessile drop experiment. The method is valuable in the study of hydrated surfaces, and was cleverly adapted by Hamilton (1972) to the study of polar components of surface energy of solids. This is achieved in principle by choosing a liquid whose dispersive component is the same as that of water (e.g. octane, γ^d = 21.8 dyn/cm), thus allowing a direct correlation to be made between contact angle and polar component of surface free energy. One of the greatest difficulties of this method is that of exact determination of the tangent to the droplet at its point of contact with the solid, and thus measurement of the contact angle. When this technique is used with an air droplet (sometimes referred to as the captive air bubble technique), the contact angle is conceptually similar to that obtained when a 'receding' angle is measured by the sessile water droplet in air procedure. When a contact lens wetting or soaking solution is used instead of water the contact angle produced has no fundamental significance to either surface characterization, or to the prediction of eye–lens compatibility.

Additional variants of the two broad types of measurement technique outlined above involve the use of a vertically mounted specimen (lens or flat plate) which is immersed in, withdrawn from or contacted against the wetting liquid. The principle of these methods has long been recognized and their relevance to contact lens wetting phenomena described several years ago (Larke *et al.*, 1973a). More recently, attempts were made to use them as a basis for 'new' methods of measuring the wetting behaviour of lenses in an attempt to achieve better correlation with behaviour *in vivo*. In reviewing their success in this respect, Pearson (1987) highlighted variations both in magnitude of wetting angles obtained and even in rank order with a small group of RGPs.

Clinical significance

The information that can be obtained from these relatively simple techniques, if used with care and precision, is considerable. In the first place, sessile drop measurement in air with liquids of different surface tension can be used in the form of a Zisman plot (*see Figure 3.7*) to determine the critical surface tension of a solid. Ideally, four or five liquids should be used, none of which should interact strongly with the substrate. The critical surface tension gives an idea of the gross wettability of the substrate and is most useful in the case of solids that do not exhibit an appreciable polar component of total surface energy.

A more precise description of surface properties may be obtained by using two or more liquids whose surface tensions have known polar and dispersive components. Sessile drop measurement in combination with Owens and Wendt's analysis allows polar and dispersive components of surface energy to be determined. Water, methylene iodide and formamide are among the most commonly used liquids in this type of experiment. Inverted droplet measurements are very useful, but their interpretation is open to more debate. Even Hamilton's apparently straightforward correlation of contact angle with polar surface energy component has been the subject of some doubt. The principal reason for this is the effect of mutual solubility of the liquids on their surface tensions and the extent to which this is important in what are almost instantaneous measurements. A more general problem with these methods is their conceptual similarity to receding angle techniques. Thus, the impinging droplet or bubble displaces water from the hydrated surface, and the extent to which the resultant interface is dominated by a residual interfacial water layer is not certain.

All these measurements have some part to play in the surface characterization of contact lens materials. No single contact angle measurement can predict the complex interaction of a lens with tears. Furthermore, although critical surface tension (γ_c) is a useful parameter, the fact that lens materials need a degree of polarity in order to sustain the all important tear fluid layer suggests that it is not wholly adequate. It does, however, provide a useful basis upon which to discuss the susceptibility of a lens to the initial wetting process by tears. *Figure 3.7* enables polymethyl methacrylate and silicone rubber to be compared in this respect.

The figure illustrates the fact that tear fluid having a surface tension of 46 dyn/cm or slightly lower is only just able to wet the polymethyl methacrylate sample used in this experiment. The practice of using viscous wetting solution with methyl methacrylate and RGP lenses helps to establish the necessary continuous tear film on insertion. By contrast the silicone rubber sample shown on the same graph would require a liquid having a much lower surface tension ($\simeq$ 25 dyn/cm) in order for it to be spontaneously wetted. The function of surface treatment of this type of polymer is to increase the critical surface tension of the material.

Variations in the slope and indeed the shape of plots of the type shown in *Figure 3.7* do occur especially when liquids capable of hydrogen bonding with the surface are used, as they must be in contact lens work. Failure to take this into account has resulted in calculated values for the critical surface tension of the cornea that are excessively low. Even when this fact is taken into account it will be seen that the critical surface tension of the cornea ($\gamma_c \simeq$ 35 dyn/cm) is similar to, but somewhat lower than that of polymethyl methacrylate ($\gamma_c \simeq$ 39 dyn/cm).

There are several important observations that must be made on these figures. The first is that these surfaces are unexpectedly wetted by a liquid of higher surface tension (46 dyn/cm). We can take into account the fact that 46 dyn/cm is thought to be a conservatively high estimate of the surface tension of tear fluid and the unique nature of the corneal surface. The most important reason, however, since it applies to all surfaces, is the occurrence of contact angle hysteresis, which, as previously mentioned, is the difference between advancing contact angle observed when a liquid boundary advances over a clean dry solid surface and the receding contact angle observed when a liquid boundary recedes from a previously wetted surface. The former (advancing) value is used in experimental work *in vitro* because it is far more reproducible. The latter value, which is significantly lower is, however, important in the contact lens situation *in vivo*. This

is because the establishment of the tear film, corresponding to the advancing contact angle, is assisted mechanically by the eyelid and sometimes by the use of wetting solutions. The receding angle, however, dictates whether the formed film will be stable or will break up on the lens surface. This difference, although significant, is relatively small and is not sufficient to sustain tear films on polymers having critical surface tensions significantly lower than polymethyl methacrylate.

This raises the second point. Although there are many alternative thermoplastic polymers that might have competed with polymethyl methacrylate in contact lens use, there are few (suitable in other respects) that share its similarity in critical surface tension to the cornea. This is probably the major single reason that polymethyl methacrylate occupied the unique position that it did for so long. None of the RGP materials currently available has achieved a comparable combination of molecular regularity and surface energy. Early clinical studies in conjunction with surface treatment of polymers (Larke *et al.*, 1973a; Pedley, 1976) indicated that for a material to be useful for contact lens fabrication it should have an equilibrium advancing contact angle (θ) with water of not greater than 65–70°. This is, in fact, a better single criterion than the critical surface tension because of the aforementioned effects of polarity and hydrogen bonding on the determination of the latter.

However, single 'wetting angle' or contact angle measurements are of limited value in predicting clinical behaviour. Whereas they can provide a broad distinction between materials that are so non-wettable as to be clinically dangerous, and materials that are capable of sustaining a tear film, they give little guidance beyond that. Since they are so widely quoted some comment on differences in measurement protocol is appropriate. Lenses are soaked and thus to a degree 'hydrated' before use, but the tendency of the front lens surface to become partially dehydrated in wear is well known. Thus, the 'dry' contact angle will give a useful guide to initial tear film stability under the least advantageous conditions. Soaking in saline and in proprietary wetting solutions illustrates the wettability of the lens under the most advantageous, but not necessarily most representative, conditions. The least physiologically representative method of measuring the 'wettability' of the lens is to pre-soak the material and then measure a receding contact angle using, not water, but a low surface tension wetting solution to make the measurement. The equivalent of this is to immerse the sample in wetting solution and use the inverted air bubble technique. Measurements of this sort are unrepresentative of any clinical or physiological situation but are commonly used by manufacturers to demonstrate how wettable their own materials are. In all these methods of measurement a ±2° 'error bar' must be allowed, because this is the limit of reproducible measurement. It is plainly nonsensical therefore to quote values to an accuracy of 0.1° as is sometimes done, especially in commercial literature.

These points taken together illustrate the need for standardization in measurement of contact lens properties by materials scientists and manufacturers, especially the need to define the measurement conditions accurately when quoting results. It is, unfortunately, common to read in manufacturers' literature claims for a particular wetting angle without any indication of the wetting liquid, the state of hydration or degree of pre-soaking of the material, or even the technique used to make the measurement. The difference between a sessile drop contact angle measured with water on a surface and a captive (inverted) air bubble contact angle measured in a proprietary wetting solution can be as much as 40–50°. Figures quoted in the absence of any definition of measurement conditions are therefore meaningless as a basis of comparing the behaviour of competitive materials.

The fundamental lack of correlation between a single contact angle, however measured, and behaviour during wear, relates to the fact that when the lens is inserted into the eye a 'biological interface conversion' process begins. The fact that lenses produce lower measured contact angles after wear illustrates this point (Madigan and Holden, 1986; Morris and Tighe, 1986). This conversion process in part relates to the structured way in which the tear film wets the cornea, a point previously discussed, and is dependent upon the interfacial tension established between tears and the polymer surface. It has been demonstrated that the interfacial tension varies with both polar and non-polar interactions between the liquid and solid, and therefore simple 'wetting angle' correlations with clinical behaviour are poor, as they take no account of these parameters. With contact lens research, as is already commonplace in other areas of biomaterials work, attention will undoubtedly turn to more complete surface energy characterization. Even so, it is difficult to achieve a match between biological processes, which take place at a molecular level, and the macroscopic probe techniques that are currently available for surface characterization.

Although it might be anticipated that hydrogel polymers would present no problems in relation to wettability, this is not the case and relates to a further point arising from critical surface tension data. Hydrogels are readily wetted by tear fluid and are capable of sustaining a tear fluid layer, but they present a considerable problem in their tendency to accumulate proteinaceous and other material on the lens surface during use. In addition to any specific interaction of such debris with functional groups on the surface of the polymer, there is a general principle involved. This is the observation (Schonhorn, 1972) that the adhesion of a mobile phase to a solid substrate increases as the surface becomes more wettable (i.e. as its critical surface tension increases). There is then a desirable limit to the wettability of polymers for contact lens use. Hydrogels are not truly hydrophilic (in terms of the precise definition stated earlier) since they exhibit an equilibrium advancing contact angle of around 20°. If this value could be raised it would be possible to retain wettability by tear fluid while decreasing the problems of lens cleaning. Perhaps the best analogy here is that of non-stick domestic pan linings. Scrambled egg, which in some respects resembles the proteinaceous debris in question, adheres strongly to high energy metal surfaces but relatively weakly to the low energy poly(tetrafluoroethylene) surfaces

used as pan coatings. It was shown (Barnes *et al.*, 1974; Pedley and Tighe, 1974; Tighe and Gee, 1984) that by structural modification it is possible to produce hydrogels whose critical surface tensions are substantially lower (i.e. less wettable by tear fluid) than would be predicted from their water contents and bulk structural considerations.

Oxygen permeability

The importance of oxygen to corneal metabolism is well known and the physiological consequences of oxygen deprivation in this respect are discussed elsewhere, particularly in Chapters 2 and 15. Contributions to our knowledge of the effect of contact lenses of different types have been made (Hill and Fatt, 1964; Hill, 1966; Hill and Schoessler, 1967; Hill and Augsburger, 1971). Confusing information has been published, however, on the actual values of oxygen permeability for different contact lens materials, particularly hydrogels.

Two questions must be addressed. What level of oxygen permeability is required to satisfy the corneal requirements, and how can the permeability of the materials be reliably measured in a manner that reflects their use in the eye? The oxygen requirement of the cornea has been expressed in various ways, including a direct figure for oxygen consumption and the minimum partial pressure of oxygen required to maintain normal corneal metabolism. It must be pointed out that these quantities are impossible to measure in such a manner as to give unambiguous results and do not, in their use, influence corneal behaviour. Thus, the value accepted as the minimum partial pressure of oxygen required to prevent corneal oedema (11–19 mmHg, Polse and Mandell, 1970) has been progressively updated to 23–37 mmHg (Mandell and Farrel, 1980), 40 mmHg (O'Neal *et al.*, 1984) and even 74 mmHg (Holden *et al.*, 1984). Since the work on which the latter figure is based may also be interpreted as showing an exponential decline in corneal thickness, and yet the error bars on the relevant measurement are within the same order of magnitude, the difficulty in obtaining an absolute correlation can be appreciated. These comments are not intended as a criticism of the excellent work and contributions to scientific knowledge of the groups involved, but rather an indication of the problems in this difficult field. A useful overview of the history of the topic was compiled by Efron and Brennan (1987). Before the information on minimum partial pressure of oxygen can be translated into a property requirement for contact lens materials, some consideration of the principles and definitions involved in oxygen permeability is required.

Definitions

The important texts in modern membrane science are agreed upon the use of the simple fundamental definition:

$$P = DS \tag{1}$$

for the transport of the gas through a polymer membrane. In this expression, P is the permeability coefficient for a given polymer-permeant (i.e. gas) system, D is the diffusion coefficient of the gas through the polymer, and S is the solubility of the gas in the polymer. In order to correlate the permeability coefficient (P) with the rate at which the gas passes through a membrane of given dimensions (area and thickness) for a given gas pressure, the equation:

$$j = \frac{PA}{t} \Delta p \tag{2}$$

is used. Here j is the flux of the gas (volume passing through in unit time), A is the membrane area, t is the membrane thickness, and Δp is the pressure difference across the membrane. The flux, j, is sometimes expressed by the symbol Q, or F, or its components (volume per unit time).

Since the oxygen passing through the contact lens is consumed by the cornea, it is apparent that, in principle, it should be possible to balance this consumption requirement with the oxygen flux through a contact lens of given dimensions and given conditions, and to define the required lens behaviour in terms of a permeability P. Among the people who have carried out this sort of analysis, Fatt's work (Fatt and St Helen, 1971) has had the greatest long-term influence. He represented the previous equations as

$$j = \frac{\mathrm{Dk}}{t} (p_t - p_o) \tag{3}$$

where p_t is defined as the oxygen pressure at the front surface of the lens, and p_o as the oxygen pressure behind the lens (i.e. at the corneal surface). It is apparent that p_o should correlate with the minimum oxygen tension for normal corneal function. Fatt chose to use K to represent gas solubility instead of the more usual term S. For this reason, the contact lens literature favours the use of the term Dk whereas in membrane science, DS or more commonly P is used. Thus Dk (or more simply P) is the permeability coefficient for a given material, whereas Dk/t or P/t refers specifically to the permeability (transmissibility) of a sample of that material of a given thickness (such as a contact lens). The values of the permeability coefficient are frequently different when, on one hand, the membrane separates two gas phases and, on the other, the membrane separates two liquid phases. The difference between these values, referred to as P_g and P_d respectively, is associated with the so-called 'barrier effect' or 'boundary effect' and has considerable significance in contact lens work.

The first point to note is that conventional 'gaseous' oxygen permeability coefficients (P_g) obtained for the transport of oxygen from the gas phase through the polymer film to another gas phase are not applicable to contact lens work. Values determined in this way are useful in the food packaging industry, for example, and commercial apparatus for this type of measurement is readily obtainable. Measurements made in this way are inapplicable in the present context because: (1) materials such as hydrogels are progressively dehydrated under these conditions and will give erroneous results, and more important; (2) these methods do not simulate the situation of the contact lens on the eye. In order to do this it is necessary to measure the transport of oxygen

dissolved in one aqueous phase through the polymer and into another aqueous phase. This value is referred to as the 'dissolved' oxygen permeability coefficient (P_d).

The experimental difficulties associated with these measurements are quite severe on samples that are often fragile. Although measurements on thermoplastics and elastomers are easier to make than on hydrogels, there is with all hydrophobic polymers a barrier effect resulting from the interfacial tension between the polymer and aqueous phase. In order to obtain P_d values on such polymers, therefore, measurements on samples of various thicknesses must be made. Because of this barrier effect, hydrophobic polymers transport oxygen much less efficiently from water phase to water phase (as on the eye) than from gas phase to gas phase. This has meant that over-optimistic predictions were made for polymers such as ethyl cellulose, polystyrene and poly(4-methyl pent-l-ene) on the basis of their quoted gas-gas (P_g) permeabilities. When measurements of the 'dissolved' oxygen permeabilities have been made the disappointing clinical performance of such materials is understood.

Measurement techniques

Several different experimental procedures for determining oxygen permeability may be distinguished. In each case, oxygen at a known effective concentration passes from the donor side of the cell through the membrane (of known thickness and cross-sectional area) to a receiver side, also of known volume, where it is sensed.

In a gas to gas transport system, the donor side is initially at a positive pressure with respect to the initially evacuated receiver side. The increase in pressure of the receiver side is monitored (usually manometrically) and the rate of transport of oxygen, and thus the permeability coefficient for the membrane, may be calculated.

In a liquid to liquid cell, the liquid is preferably stirred on both sides of the membrane, the concentration on the donor side being initially set at some positive level relative to the receiver side. The increase in concentration on the receiver side is monitored and since the volume of liquid on the receiver side is known, the permeability coefficient is again calculated. The difference between gas–gas transport and this procedure is that the former method leads to the gaseous permeability coefficient (P_g) whilst the liquid–liquid cell yields the dissolved oxygen permeability coefficient (P_d). Since the sensitivity and accuracy of the measurement system used on the receiver side deteriorates as the receiver volume increases, attempts are made to minimize this volume. As a result, modified systems may advantageously be used in which the donor side is stirred and the receiver side is of minimal, but accurately known, volume and contains a built-in detector.

It has been shown to be particularly important to stir the high concentration side of the membrane in order to minimize surface layer effects. Studies have shown that although failure to stir the low concentration side of the membrane produces a drop of only some 3% in the measured transport properties of the membrane, this figure increases dramatically and the reproducibility becomes poor if the high concentration side is not stirred.

Thus, the least satisfactory, but in many ways most convenient system, forms the basis of the technique frequently used to measure the permeability coefficient (expressed as Dk, *see above*) of contact lenses. In this, the lens is clamped directly onto the detector electrode. The system (the polarographic electrode technique) has several shortcomings. First, the donor side is unstirred, secondly the thickness of the contact lens normally shows a centre-to-edge variation and thirdly, because the lenses vary in curvature, the volume of the receiver side is not accurately fixed. In practice, this last point should be less important in this system, because the technique is not usually operated in the manner that measures rate of increase in oxygen concentration of the receiver side of the cell, but rather the resultant equilibrium oxygen consumption by the electrode. The ability to do this relies on the assumption that oxygen transported to the receiver side is efficiently consumed by the electrode sensor, and that, as a result, the partial pressure of oxygen on the receiver side is always effectively zero. With very permeable samples, however, these assumptions are not justified. In all cell configurations, it is important to have an oxygen-tight seal of the membrane separating donor and receiver chambers, but this again is difficult to achieve with the format and samples involved in contact lens measurement.

The inherent problems associated with the polarographic technique and the use of the Dk (as distinct from the P_g, P_d approach) are illustrated in the controversies over the Dk values of RGP materials (Andrasko, 1986; Brennan *et al.*, 1986a,b; Fatt, 1986). It is clear that the polarographic electrode technique is convenient for the determination of approximate values of oxygen permeability but is inadequate as a primary standard. The way in which the Dk term was used to describe permeabilities failed to take into account the difference between gaseous (i.e. P_g) and dissolved (i.e. P_d) values and the nature of the boundary layer effect (the nature and importance of which is described in the next section). Although methods are available to do this (Fatt, 1986) the fundamental shortcomings of the polarographic electrode technique will always limit its accuracy. Further comments are contained in the section dealing with commercial RGP materials.

A description of suitable apparatus for 'dissolved' oxygen permeability measurements was given (Ng, 1974; Ng and Tighe, 1976a) and its application to both hydrogels (Ng and Tighe, 1976b) and non-hydrogels (Ng *et al.*, 1976) discussed. Measurements were made at both 25°C and 34°C, i.e. at room temperature and the temperature of the cornea respectively.

The boundary effect

The nature of the barrier or boundary effect and its experimental isolation was first effectively described by Hwang *et al.* (1971). Ng *et al.* (1976) indicated its relevance to contact lens materials and the point was reiterated by others (Refojo *et al.*, 1977; Refojo and Leong, 1979; Peppas *et al.*, 1981).

When measurements are made in the gas phase, oxygen dissolves directly in the polymer at the membrane–gas interface and the permeability coefficients show no dependence on thickness. When measurements are made in the condensed liquid phase, oxygen dissolved in this phase is hampered in its subsequent dissolution in the membrane by the presence of a structured water layer at the aqueous interface with the polymer membrane. The presence of a stagnant boundary layer in unstirred systems is well known, but the residual effect described here is observed even when the liquid is agitated. As a result, when polymer membranes of progressively decreasing thickness are used, the proportional contribution of this barrier becomes greater, a point illustrated by plotting the inverse of the apparent permeability coefficient (P_d) against the inverse of the thickness (t). Extrapolating to infinite thickness (i.e. $^1/_t = 0$) produces permeability coefficients similar to those obtained in the gas phase. In this treatment increased slope corresponds with increased barrier effect, and zero slope implies the absence of such effect (as in gas to gas measurements). In summary, values of P_g are independent of sample thickness, whereas individual values of P_d vary with the thickness of the specimen used. The major consequence of this effect for RGP contact lens materials is a function of the fact that improved oxygen permeability has only been achieved at the expense of some sacrifice in wetting properties. As a result, attempts to improve transport properties of a contact lens by reducing centre thickness are with these, as with all non-hydrophilic materials, faced with the law of diminishing returns, because of the residual boundary layer effect. This point is illustrated by considering the relationship between corneal oxygen requirement and polymer permeability.

The relationship of corneal oxygen requirement to the thickness and dissolved oxygen permeability coefficient (P_d) of a material can be approached in various ways. The minimum partial pressure of oxygen (sometimes called oxygen tension) required at the anterior surface of the epithelium, for the purpose of demonstrating the principle of the calculation, may be taken to be somewhere in the range 11–19 mmHg quoted by Polse and Mandell (1970). The average value (15 mmHg) has been validated in more recent work (Mandell, 1988) and used in calculations from Irving Fatt's group (Lin, 1992). The important point is made that these measurements, made on the naked eye, have a good degreee of reliability in contrast to the widely differing values deduced for the minimum acceptable oxygen tension under a contact lens, and are more suitable to transport calculations. This value can then be inserted (as p_2) in a relationship (Fatt and St Helen, 1971) which enables the oxygen flux (F) across the epithelial surface under a tight fitting contact lens to be determined, i.e.

$$F = \alpha p_2^{\beta}$$

In this equation α and β are two empirical constants having the values $\alpha = 0.24 \times 10^{-6}$ [ml(STP)]/(cm^2 s mmHg^{½}) and $\beta = 0.5$. This calculation indicates that the critical (or minimum) oxygen flux through a contact lens should be 0.93×10^{-6} ml (STP)/cm^2 per s. In alternative units this is approximately 3.5×10^{-6} l/cm^2 per h. This value compares well with independently determined values which range from 2.8 to 7.8×10^{-6} l/cm^2 per h and can, therefore, be taken as a minimum but sufficient oxygen flux (F) to maintain corneal transparency. (For explanation of units *see* Addendum 1, p. 88.)

One way in which this information can be used is by comparing it with values obtained from the equation relating oxygen flux, thickness and dissolved oxygen permeability coefficient for contact lenses.

$$F = \frac{P_d}{t} \times \Delta p$$

t is the contact lens thickness and Δp is the pressure difference across the lens. Since the minimum partial pressure of oxygen required by the naked eye has been taken as 15 mmHg and since the generally accepted values for open and closed eye in the absence of a lens (Fatt and Bieber, 1968) are 155 mmHg and 55 mmHg respectively:

Δp (open eye) = 140 mmHg
Δp (closed eye) = 40 mmHg

These values will be reduced as the desirable minimum partial pressure required by the cornea is raised above 15 mmHg, which is accepted to be the case during lens wear. The calculation is best carried out with the value for the naked cornea in the first instance.

Figure 3.8 shows the result of this calculation for various contact lens materials and must be used in conjunction with the 'critical' F value of 0.93×10^{-6} ml(STP)/cm^2 per s. The first point of interest is the boundary effect seen clearly here with the hydrophobic materials. It is because of this that the gaseous oxygen permeability coefficients give a misleadingly optimistic picture of the suitability of a polymer for contact lens use. In the case of a poly(4-methyl pent-1-ene) lens of 0.1 mm centre thickness the 'dissolved' permeability coefficient is about half the 'gaseous' figure. Using the latter figures one would predict that such a lens, or a similar RGP material, might just allow the cornea to respire normally even in the closed eye condition. Not only is this situation impossible with a lens of this thickness but as the figure shows, reducing lens thickness is of virtually no value since the boundary effect is the controlling factor at this point. Although silicone rubber shows a boundary effect, its oxygen permeability is so high that this does not interfere with the oxygen flux requirements of the cornea.

PHEMA hydrogel having an equilibrium water content of 39% and a 'dissolved' oxygen permeability coefficient of 145×10^{-10} (ml O_2 mm)/(cm^2 s cmHg) at 34°C and in the form of a contact lens 0.2 mm thick would give an oxygen flux just sufficient for the corneal requirement in the open eye condition but quite insufficient in the closed eye situation.

An alternative approach is to take the experimentally determined figures for the oxygen consumption of the cornea under normal conditions and calculate the relationship between oxygen permeability coefficient (P_g) and lens thickness. This was done by Ng (1974) for both open eye and closed eye conditions and used as a basis for predicting

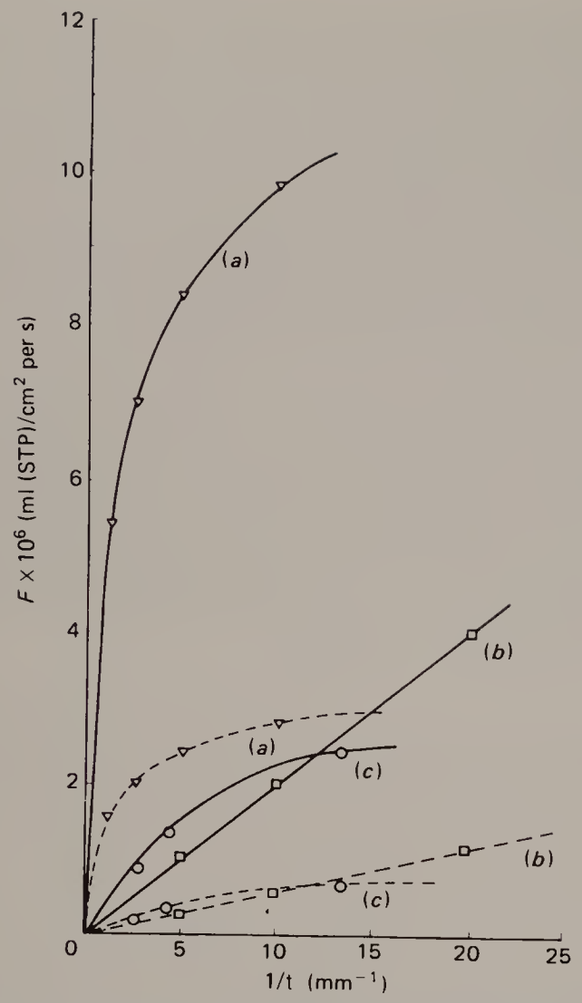


Figure 3.8 The correlation of oxygen flux (F) through the contact lens with inverse of lens thickness (t) at 34°C for various materials under open (—) and closed (– –) eye conditions. (*a*) Silicone rubber; (*b*) PHEMA; (*c*) poly(4-methyl pent-1-ene)

continuous wear requirements (Ng and Tighe, 1976b). The relationship is shown in *Figure 3.9* for the range of corneal oxygen consumption figures suggested by various workers. This figure indicates that for lenses having a centre thickness of the order of 0.15 mm the minimum dissolved oxygen permeability coefficient (P_d) requirements for open and closed eye conditions are 8 and 32 $\times$ 10^{-11} (ml O_2 mm)/(cm^2 s cmHg) respectively. It is interesting to note that the latter figure is of the same order as values quoted for the oxygen permeability of corneal tissue.

These calculations indicate that the concept of extended wear is reasonable *in principle*. Equally, the magnitude of the predicted permeabilities of materials for successful use in extended wear depend upon many assumptions. Even when variables related to the design and fit of a lens are taken out of the equation, many more uncertainties exist. These include the previous debate relating to corneal oxygen consumption, the role of eye movement during sleep, the solubility of oxygen in tear fluid (as distinct from water) and the person-to-person variations, as well as the diurnal variations that affect these factors. The practical demonstration of the underlying validity of these calculations lies in the fact that the existing commercial hydrogel materials used for extended wear lie within the bounds delineated in *Figure 3.9*.

Whereas initially hydrogel polymers were the major group of materials to be considered in extended wear, more recently rigid gas permeable materials have been developed whose permeability exceeds that of conventional high water content hydrogels. Indeed, it has been suggested that the inherent 'upper ceiling' on hydrogel permeabilities, coupled with the problems of poor strength and corneal staining associated with ultrathin, high water content lenses makes hydrogels fundamentally unsuitable for safe extended wear. This viewpoint is challenged by the proponents of the use of hydrogels for extended wear, who point to the unsatisfactory features of current RGP materials. The nature of these two groups of materials are explored in more detail below, together with the characteristics of commercially available materials of each type.

Much recent interest has been generated by work on low water content hydrogels with a high Dk but, as yet, no

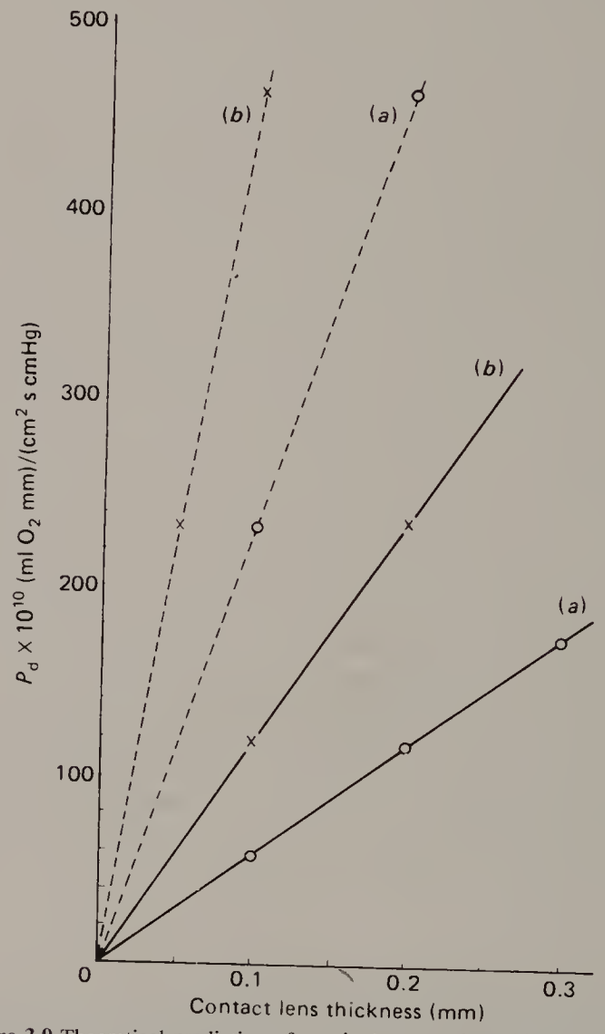


Figure 3.9 Theoretical prediction of required contact lens thickness from the 'dissolved' oxygen permeability coefficient for an oxygen flux of 3.5 or 7.0 μl/cm^2 per h under both open (—) and closed (– –) eye conditions, at 34°C. (*a*) 3.5 μ/cm^2 per h; (*b*) 7.0 μ/cm^2 per h

significant and widespread clinical studies have been carried out on these novel materials.

Hydrogel materials

It is simplest to regard hydrogels as 'washing line' polymers having a long (i.e. the 'washing line') backbone as described in an earlier section from which a variety of chemical groups may be suspended (the 'washing'). The function of the chemical groups in hydrogels is primarily to attract and bind water within the structure. Greater physical stability is achieved by fastening the 'washing lines' together at intervals by the use of cross-links. Some of the monomers used to achieve these structures have been previously described, to which the following may be usefully added.

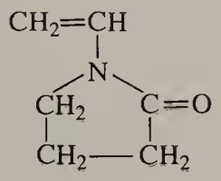
2-Hydroxyethyl acrylate and methacrylate.
2-and 3-hydroxypropyl acrylate and methacrylate.
Acrylic acid and methacrylic acid.
Acrylamide and N-substituted acrylamides.
Methacrylamide and N-substituted methacrylamides.
N-Vinyl pyrrolidone and other *N*-vinyl lactams.
Glycidyl acrylate and methacrylate.
2-Aminoethyl acrylate and methacrylate.

These can be copolymerized in various combinations with each other and with hydrophobic monomers such as:

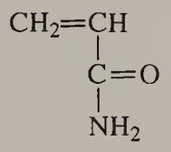
Methyl, ethyl or propyl acrylate or methacrylate.
Methoxyethyl or ethoxyethyl acrylate or methacrylate.
Cyclohexyl methacrylate.

Some of these monomers have been mentioned previously. Of the others, the following are particularly important:

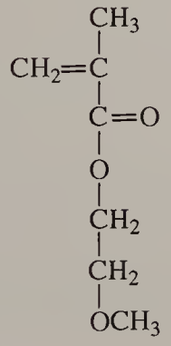
N-Vinyl pyrrolidone:



Acrylamide:

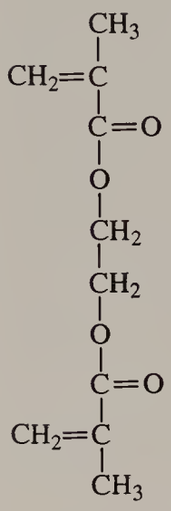


Methoxyethyl methacrylate:



The incorporation of cross-links is usually achieved by copolymerizing small (of the order of 1%) quantities of divinyl compounds such as:

ethylene glycol dimethacrylate with the monomer mixture.



Hydrogels formed in this way (i.e. in which the network is linked together by primary chemical bonds) are the most satisfactory type for contact lens usage. There are, however, other classes of hydrogel (for example polyelectrolyte complexes and microcrystalline gels such as those of cellulose or collagen) which either because of fabrication difficulties or instability under condition of changing pH and tonicity are less suitable for this application.

The foregoing overview of the properties of the cornea and its dependence upon the coherence of the tear film and availability of atmospheric oxygen provides the range of basic information required to understand the principles of materials design and selection for contact lens applications.

The patent literature

A useful picture of the development of commercial hydrogel lenses can be obtained by looking at the patent literature. The chemistry of many of the materials used commercially today is based on ideas described in patents that had been published by the early 1970s. A brief overview of these developments will provide a useful background to the information on commercially important material types, although little protection of the significant ideas seems to have been provided by the patents. The situation in RGP materials was similar, until recent successful patent litigation was undertaken. Comprehensive reviews of the patents in this field have been compiled (Pedley *et al.*, 1980; Kishi and Tighe, 1988) and the information relating to their assignment and publication is detailed therein. An abbreviated compilation is listed in Addendum 2 (p. 89). The growth of the patent literature in this area has been affected by several factors. The extensive evaluation of novel hydrogel struc-

tures in the contact lens field, in comparison to the initial dependence upon PHEMA in other biomedical areas, was largely a result of the comparative ease of clinical investigation in the former case. It has also been greatly influenced by the fact that the consequences of biocompatibility problems in the eye are slight in comparison with those involving blood contact. In addition, the specific permeability requirements for extended wear have led to the exploration of compositions that produce relatively high equilibrium water contents. Another major feature was the initial lack of restrictive legislation in either Europe or America followed in 1968 by the decision of the Federal Food and Drugs Administration to classify soft contact lenses as a drug. This had the effect of limiting the exploratory clinical work carried out in the USA since that time and served to curtail activity in the clinical field. In contrast, patent activity in the UK began slowly but showed marked growth in the 1970s. Of the other countries showing activity, Japan has continued to show the most marked growth in published patent specifications.

The 1960s and the work of Wichterle

The earliest hydrogel patents are those of Wichterle and his co-workers, whose work has already been mentioned. In subsequent years, these have been expanded and enlarged covering both the processes for lens production and the composition of materials. The claims of the original patents encompass the formation of sparingly cross-linked soft and elastic hydrogels both by polymerization of hydrophilic monomers and alternatively by the cross-linking of preformed hydrophilic (water-soluble) polymers. Although the latter method, which is typified by the cross-linking of polyvinyl alcohol with adipic acid, is a useful hydrogel-forming reaction, it is not readily adapted to the manufacture of contact lenses. The polymerization of hydrophilic monomers, such as 2-hydroxyethyl methacrylate (HEMA) in the presence of ethylene glycol dimethacrylate (EGDMA), however, is ideally suited to lens formation. The major lens-forming processes suggested by Wichterle included polymerization of the monomers *in situ* in a rotating contact lens mould, as well as bulk polymerization in rod or button form followed by shaping of the polymer to lens form and then hydrating. It was not until the invention was taken up in the USA that commercial success was obtained. The success of this original work may be judged, however, from the fact that a major proportion of the soft lenses sold today are based, directly or indirectly, on Wichterle's patents.

Although Wichterle's original patents envisaged the use of monomers other than HEMA, their primary concern was with the technique of manufacture of hydrogels *per se* and particularly with their application in the contact lens field. The specific advantages of monomers other than HEMA were not described and their role has been largely unexploited, except in the contact lens field. Thus although Wichterle's patents in the period 1961–68 mentioned the possible use of some other monomers (for example, acrylamide, methacrylic acid and dimethylaminoethyl methacrylate), no indication was given of the benefits that these might confer either in terms of the physical properties of hydrogels or improved characteristics of the lenses formed from them. It was not until the early 1970s that the patents began to appear in which such benefits were described. The major feature of the large number of claims published at this time was the use of *N*-vinyl pyrrolidone (usually referred to simply as vinyl pyrrolidone and abbreviated as NVP). Two methods of use of vinyl pyrrolidone in hydrogels can be distinguished. These are graft copolymers and random copolymers (more correctly called statistical copolymers). Using the washing line analogy, random copolymers consist of two or more types of washing attached in random (rather than perfectly alternating) sequence along the line, or polymer chain. In a graft copolymer, a washing line is first assembled and additional pieces of washing attached so that they trail from the existing pieces in short secondary chains. The appearance is thus something like a comb with irregular and rather long teeth.

Vinyl pyrrolidone patents

The distinction of the first patent publication involving the use of a poly(vinyl pyrrolidone) (PVP) backbone onto which 2-hydroxyethyl methacrylate was grafted must go to H. R. Leeds whose American patent application was filed in October 1968 and published some 2 years later. Shortly afterwards (first filing July 1969) Maurice Seiderman described a similar process involving the use of polyvinyl pyrrolidone backbone onto which, in addition to HEMA, vinyl pyrrolidone monomer was grafted. The use of other monomers such as lauryl methacrylate, cyclohexyl methacrylate, 2-aminoethyl methacrylate and methacrylamide as modifiers was also described and water contents as high as 87% were claimed.

The third group of workers whose contribution to the hydrogel patent literature in the polyvinyl pyrrolidone graft copolymer field must be considered are O'Driscoll and Isen. Although the date of first filing (November 1969) is slightly later than that of Leeds and Seiderman, the patents are important because they formed the basis both of the Griffin lens and of later continuation patents assigned to Warner-Lambert and American Optical Corporation.

Because of its great hydrophilicity the use of vinyl pyrrolidone offers the obvious advantage over simple PHEMA, of increased water contents. In addition to the graft copolymers described above, NVP may be used to produce high water content gels by simple copolymerization of mixtures of monomers. The earliest patent to describe such copolymers and their advantages in the contact lens field is that of Robert Steckler (file date April 1969). The patent describes copolymerization of 60–90% by weight of an *N*-vinyl lactam (e.g. *N*-vinyl pyrrolidone) with 40–10% vinyl or acrylate ester (e.g. vinyl acetate, HEMA or methyl acrylate) to produce hydrogels with water contents ranging

from 35 to 95%. In the succeeding years over 200 hydrogel patents relating to contact lens materials have been published, covering novel monomers, novel cross-linking agents and modified methods of polymerization. Relatively few of these have achieved commercial significance, and none has yet had the influence of the key patents described above. This is clearly demonstrated by reference to the range of commercial materials that have been developed over the years.

Commercial lenses, materials and their properties

It is virtually impossible to keep abreast of the worldwide position relating to the appearance and disappearance of commercial materials but it is instructive to take a look at the range of materials available. *Table 3.2* shows names, principal components, water contents and manufacturers of various materials and lenses. The list includes significant historical materials and also examples of materials marketed in several lens forms which differ in, for example, design and centre thickness. Many of the properties of hydrogels are controlled predominantly by the amount of water in the gel. It is more convenient to describe the properties of hydrogels as a class of materials, noting how these are affected by the water and by the polymer matrix. The simple, but effective FDA classification involves four groupings:

I low water content non-ionic;
II high water content non-ionic;
III low water content ionic;
IV high water content ionic.

(*see also* Chapter 21, *Table 21.3* and Appendix B).

Water content

This is the most important single property of hydrogel and is more correctly called the equilibrium water content (EWC). Some confusion has arisen between this term and 'water uptake'. If a dry polymer takes up its own weight of water its equilibrium water content, which is defined as:

$$\frac{\text{Weight of water}}{\text{Weight of hydrated gel}} \times 100\%$$

will be 50%. It is important to define the temperature at which the measurement was made and whether this was made in pure water or saline solution. It will become apparent that the water content of a gel measured in water at 20°C can be quite different from its value at eye temperature and in isotonic saline.

PHEMA hydrogel has an equilibrium water content of approximately 39% (depending upon conditions of measurement). This can be progressively reduced by copolymerizing with increasing amounts of a hydrophobic monomer such as methyl methacrylate, cyclohexyl methacrylate or the fluoroalkyl methacrylates and siloxy methacrylates that form the basis of RGP materials. This, in principle, is the approach used in the preparation of the emerging silicone hydrogel materials. In practice, however, the problems of compatibility of very hydrophobic monomers with HEMA are difficult to overcome. The water contents of hydrogels can, on the other hand, be progressively increased by copolymerizing with increasing amounts of a more hydrophilic monomer such as vinyl pyrrolidone or acrylamide (e.g. N, N-dimethyl acrylamide). Vinyl pyrrolidone and acrylamide can alternatively be copolymerized with, for example, methyl methacrylate. The water contents of the resultant polymers are dependent upon the relative proportions of hydrophilic and hydrophobic monomers. Leaving aside the sophistications of graft *vs* random copolymerization and spin-cast *vs* bulk polymerized materials we can use this as a basis for categorizing available lens material. The compositional information gives a useful overview of the ways in which a range of water contents may be achieved.

Dimensional stability

Since the linear swell and volume swell shown by hydrogels on hydration is a direct consequence of the volume of water absorbed, any phenomenon that causes a change in water content will cause a change in lens dimensions.

PHEMA is an extremely stable hydrogel and variations in temperature, pH and tonicity have relatively little effect on its water content. The use of monomers that are more hydrophilic than HEMA invariably incurs some penalty in this respect, whether the monomer is more hydrophilic because of a basic nitrogen atom (as in *N*-vinyl pyrrolidone and acrylamide) or an acidic hydrogen atom (as in methacrylic and acrylic acid). The precise combination of monomers used can have a marked effect on the stability of the material. This is illustrated with respect to temperature changes in *Figure 3.10*. Several features are noteworthy including: (1) the uniquely regular behaviour of PHEMA; (2) the decrease in water content in other cases between 20°C and 40°C, which is attributable to an increase in hydrophobic interaction or bonding in the gel; and (3) the dramatic increase in water content with concurrent onset of translucency shown by some compositions at temperatures above 60°C. This type of instability would be undesirable in a lens that was to be heat sterilized since, although the behaviour is reversible, it leads to progressive deterioration of the polymer network. The figure also shows how increasing the cross-link density decreases the freedom of chains to rotate, thereby restricting the ability of the polymer network to expand with increasing temperature.

The sensitivity of water content to tonicity is similarly affected by monomer structure (*Figure 3.11*). In general, hydrogels show some small decrease in water content when the equilibration solution is changed from pure water to isotonic saline. It should be emphasized, however, that such a change, and others induced by changing the nature of the storage solution, are much greater than those brought about by tonicity variations in the eye. Variations with respect to pH are more marked and monomer dependent, as minima in

Table 3.2 Some examples of soft contact lenses and lens materials (*see also* Appendix B)

Name	*Manufacturer/ supplier*	*Principal components**	*Water content*	*USAN† nomenclature*	*FDA Group*
Accugel	Strieter Labs	HEMA, PVP, MA	47%	Droxifilcon-A	(III)
Accusoft	Ophthalmos Inc	HEMA, PVP, MA	47%	Droxifilcon-A	(III)
Acuvue	Vistakon	HEMA, MA	58%	Etafilcon-A	(IV)
AO Multivue	American Optical	HEMA	38%	Tefilcon	(I)
Aquaflex	UCO Optics	HEMA, VP, MMA	43%	Tetrafilcon-A	(I)
Calendar	Wesley Jessen	VP, MMA	74%	Surfilcon A	(II)
CD	Igel	HEMA	38%	Polymacon	(I)
Comfort Flex	Capital Contact Lens	HEMA, BMA, MA	43%	Deltafilcon-A	(III)
Cristelle	Lunelle	VP, MMA	78%	Lidofilcon	(II)
Classic	Wesley Jessen	HEMA, VP, MMA	43%	Tetrafilcon-A	(I)
CSI	Wesley Jessen	MMA, Glyceryl, Methacrylate	41%	Crofilcon-A	(I)
Custom Flex	Custom Contact Lens	HEMA, BMA, MA	43%	Deltafilcon-A	(III)
Durasoft	Wesley-Jessen	HEMA, EEMA, MA	38%	Phemefilcon-A	(III)
Excelens	Ciba	PVA, MMA	64%	Atlafilcon	(II)
Eurolens	Wesley Jessen	HEMA	38%	Polymacon	(I)
Flexlens	Flexlens Inc	HEMA, VP	46%	HeFilcon-A	(I)
Focus	Ciba	HEMA, PVP, MA	55%	Vifilcon-A	(IV)
Frequency 38	Aspect	HEMA	38%	Polymacon	(I)
Frequency 55	Aspect	HEMA, MA	55%	Ocufilcon-D	(IV)
Frequency 73	Aspect	HEMA, VP	73%	–	(II)
Gelflex	Dow Corning	HEMA, MMA, TEGMA	36%	Dimefilcon-A	(I)
Gentle Touch	Wesley Jessen	MMA, DMA	65%	Netrafilcon-A	(II)
Hoya Soft	Hoya Corporation	HEMA Copolymer	35%	–	(I)
Hydralens	Ophthalmos Inc	HEMA, PVP, MA	47%	Droxifilcon-A	(III)
Hydro-Curve (I)	Wesley Jessen	HEMA, VP	46%	Hefilcon-A	(I)
Hydro-Curve (II)	Wesley Jessen	HEMA, Diacetone, Acrylamide, MAA	55%	Bufilcon-A	(IV)
Hydrocon	Kontur Kontact Lens	HEMA, PVP	56%	–	(II)
Hydroflex	Zeiss (Wöhlk)	HEMA	38%	Polymacon	(I)
Hydron	Hydron Europe	HEMA	38%	Polymacon	(I)
Igel-68 (plus other water contents)	Igel Optics	MMA, VP, CMA	68%	Xylofilcon-A	(II)
Lunelle	Essilor	AMA, VP	70%	–	(II)
Medalist	Bausch & Lomb	HEMA	38%	Polymacon	(I)
Menicon Soft	Toyo Contact Lens	HEMA, VA, PMA	30%	Mafilcon-A	(I)
Naturvue	Automated Optics	HEMA, VP	43%	Hefilcon-A	(I)
Newvues	Ciba	HEMA, PVP, MA	55%	Vifilcon-A	(IV)
Omniflex	Hydron Europe	MMA, VP	70%	Lidofilcon-A	(II)
Optima	Bausch & Lomb	HEMA	38%	Polymacon	(I)
Permalens	Wesley Jessen	HEMA, VP, MA	71%	Perfilcon-A	(IV)
Permaflex	Wesley Jessen	MMA, VP	74%	Surfilcon-A	(II)
Permaflex Thin	Wesley Jessen	HEMA, VP, MMA	43%	Tetrafilcon-A	(I)
Precision UV	Wesley Jessen	VP, MMA	74%	Vasurfilcon-A	(II)
Prima	Igel	MMA, VP, CHA	68%	Xylofilcon-A	(II)
Rythmic	Lunelle	VP, MMA	73%	Lidofilcon	(II)
Sauflon-50	Contact Lens Mfg‡	VP, MMA	50%	Lidofilcon	(II)
Sauflon-70	Contact Lens Mfg‡	VP, MMA	70%	Lidofilcon-A	(II)
Sauflon-PW	Contact Lens Mfg‡	VP, MMA	80%	Lidofilcon-A	(II)
SeeQuence	Bausch & Lomb	HEMA	38%	Polymacon	(I)
Snoflex-50	Vista Optics	MMA, VP, MHPM	52.5%	–	(II)
Sof-Form	Salvatori	HEMA, BMA, MA	43%	Deltafilcon-A	(III)
Softcon	American Optical	HEMA, PVP, MA	55%	Vifilcon-A	(IV)
Soflens	Bausch and Lomb	HEMA	38%	Polymacon	(I)
Soft Mate II	Wesley Jessen	HEMA, Diacetone, Acrylamide, MAA	55%	Bufilcon-A	(IV)
Softsite	Paris Contact Lens	HEMA, VP	46%	Hefilcon-A	(I)
Spectrum	Ciba	HEMA, PVP, MA	55%	Vifilcon-A	(IV)
Surevue	Vistakon	HEMA, MA	58%	Etafilcon-A	(IV)
Tripol-43	Capital Contact Lenses (Comfortflex Hydrophilics)	HEMA, BMA, MA	43%	Deltafilcon-A	(III)
Vistagel A (plus other water contents)	Vista Optics	MMA, VP	60%	–	(II)
Weicon	Ciba	HEMA	38%	–	(I)
Weflex-55	Zeiss (Wöhlk)	AMA, VP	55%	–	(II)

*HEMA = 2-hydroxyethyl methacrylate; VP = N-vinyl pyrrolidone; PVP = Polyvinyl pyrrolidone (i.e. graft copolymer); MA = methacrylic acid; MMA = methyl methacrylate; BMA = butyl (probably isobutyl) methacrylate; AMA = alkyl methacrylate; MPHM = 3-methoxy-2-hydroxypropylmethacrylate; CMA = cyclohexyl methacrylate; EEMA = ethoxyethyl methacrylate, PMA = pentyl methacrylate, VA = vinyl acetate, TEGMA = triethylene glycol methacrylate, DMA = N,N-dimethyl acrylamide.

† USAN = United States Adopted Name Council. Many USAN equivalents exist: eg. Hefilcon (B&L Toric, Miracon); Deltafilcon (Aquasoft, Custom Flex, Metrosoft, Soft Form Toric, Softics, Softflow, Softact); Lidofilcon (B&L 70, CV 70, Genesis 4, Hydrosight 70, Q&E 70, Lubrisof, PDC 70, N&N 70). Tefilcon (AO Multivue, Cibasoft, Cibathin, Torisoft, Softint, Bisoft) Polymacon (CustomEyes 38, Vesoft, Synsoft, Cellusoft, Soform II, Omega, Cooper 38, Metrosoft II)

‡ Cantor and Silver in the UK.

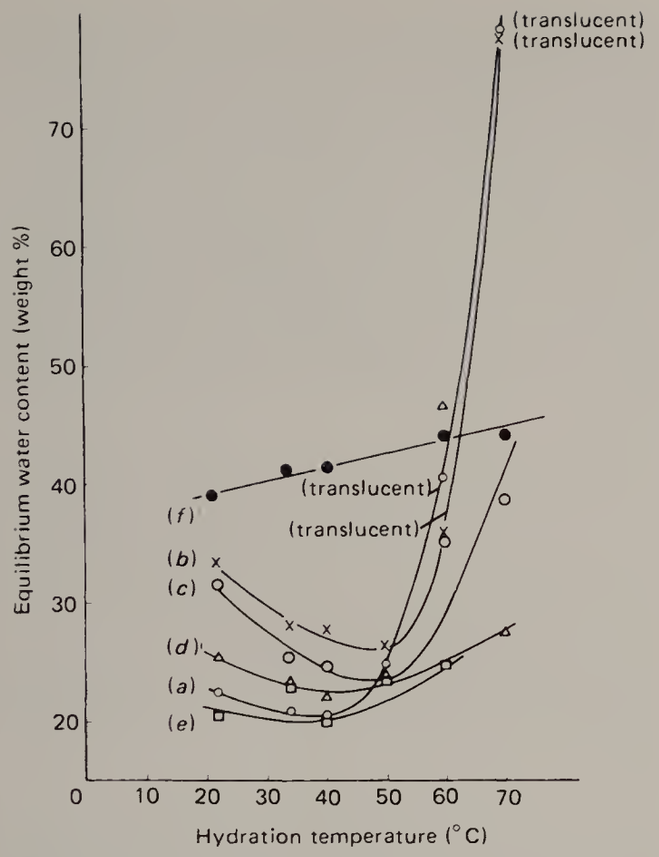


Figure 3.10 Effect of temperature on the equilibrium water contents of various hydrogels based on hydroxypropyl methacrylate (HPMA) and *N*-vinyl 2-pyrrolidone (NVP). (*a*) HPMA; (*b*) HPMA:NVP (80:20); (*c*) HPMA:NVP (80:20) + 1% EGDMA; (*d*) HPMA:NVP (80:20) ± 5% EGDMA; (*e*) HPMA:NVP (80:20) + 10% EGDMA. The gels are cross-linked with ethylene glycol dimethacrylate (EGDMA). PHEMA (*f*) is shown for comparison

water content are often observed with varying pH. The pH changes involved in such studies are also vastly greater than those occurring diurnally or on a patient-to-patient basis on the eye, which lie well within one pH unit.

Mechanical properties

In its dehydrated state, PHEMA (and indeed most other hydrogel forming polymers) is hard and brittle. In this it resembles polymethyl methacrylate. When swollen in water, however, it becomes soft and rubber-like with a very low tear and tensile strength. This lack of mechanical strength has a profound effect on the lifetime of the lens. Although the water content has a marked effect on mechanical strength, the chemical structure of the polymer can also play a large part in determining its value. This point is illustrated by comparing the tensile strength of PHEMA with that of cellophane. Bixler and Michaels (1968) reported that cellophane with a water content of 55% has a tensile modulus of nearly 5 times and an ultimate strength of over 50 times that of PHEMA.

Although water content plays a large part in controlling the mechanical properties in hydrogels, it is only one of several factors. It is possible to produce stable high (>70%) water content gels. Considerable interest centres on the preparation of synthetic hydrogels which more closely mimic the composite hydrophilic gels, such as articular cartilage and the cornea, which are found in nature.

The elastic behaviour and rigidity of hydrogels is, consequently, closely governed by monomer structure and effective cross-link density, which includes not only covalent cross-link but also ionic, polar and steric interchain forces. By use of modified monomer combinations and cross-linking agents, high water content polymers with reasonable stability and elasticity can be prepared. There are now commercially available high water content lenses which are vastly superior in strength to the earlier generation of fragile gels of similar water content based on HEMA-vinyl pyrrolidone. Making hydrogels with good elastic response and reasonable rigidity is much less of a problem than overcoming the poor tear strength of such materials. Unfortunately, however, the problem of poor tear strength is fundamental to these materials and, although interpenetrating network techniques have been used to produce optically clear 'composite' hydrogel wound dressings having high tear strength, the principles have not yet been extended to commercially available contact lenses.

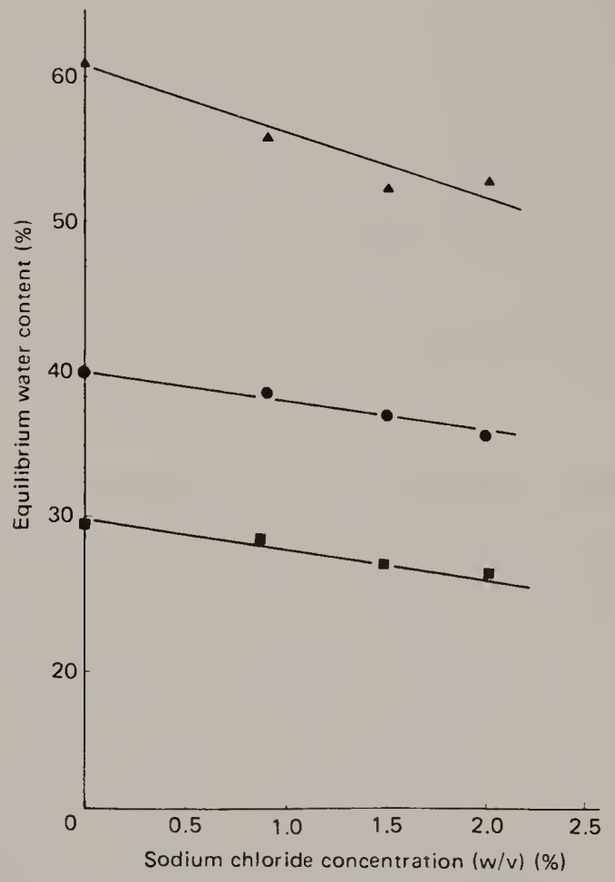


Figure 3.11 The equilibrium water contents of some hydrogels in hydrating solutions of various sodium chloride concentrations at 20°C. ▲ HEMA:NVP:styrene (47.5:47.5:5); ● PHEMA; ■ HEMA:styrene (95:5)

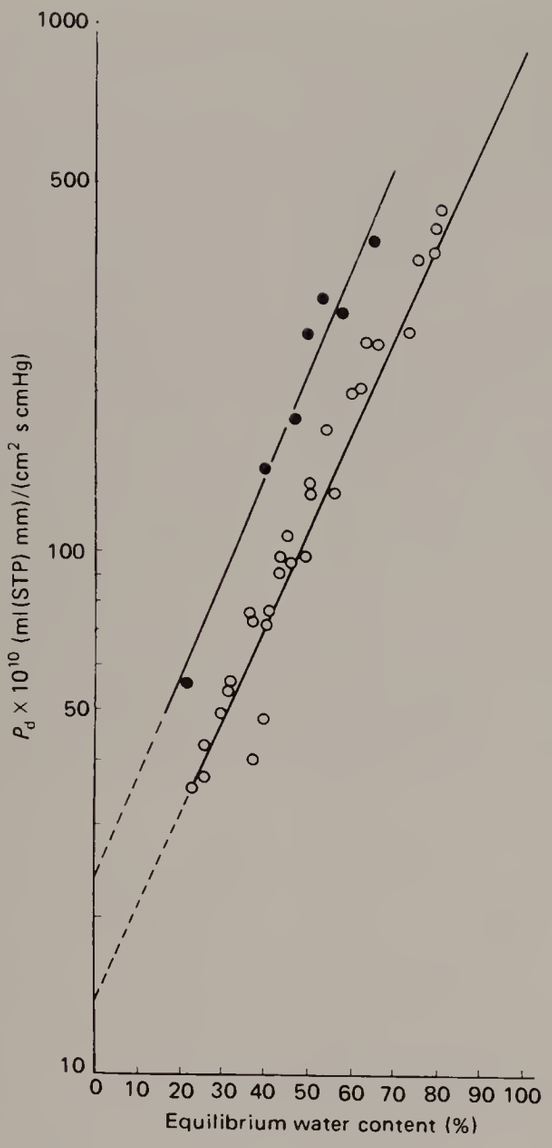


Figure 3.12 The variation of log dissolved oxygen permeability coefficient (P_d) as a function of water content for various hydrogels at 25°C (○) and 34°C (●)

Oxygen permeability (see also *Addendum 1*)

This topic has been discussed at some length and it is only necessary at this point to indicate that oxygen permeability of hydrogels is governed by the water content (*W*%) at water contents of around 30% and above. This is illustrated in *Figure 3.12*, which demonstrates the change in oxygen permeability at 25°C and 34°C for those materials whose Dk value is wholly water-dependent. Permeability, at 34°C, changes according to the expression

$$P_d = 24 \times 10^{-10} e^{0.0443W} \text{ (ml (STP) mm)/(cm}^2\text{s cmHg)}$$

Although the increase in oxygen permeability coefficient when changing the temperature from 25°C to 34°C is quite marked (a factor of approximately two, given the same water content at both temperatures), this may not be representative of the change in P_d for a given hydrogel. The reason for this is the previously discussed observation that many hydrogels decrease in water content with increasing temperature in this region. To calculate the oxygen permeability of a hydrogel at 34°C then, it is necessary to use the value of the water content determined at that temperature. Thus a value for P_d of 350×10^{-10} (ml O_2 mm)/(cm^2 s cmHg) at 34°C would be given by a gel having a water content of something over 60% at that temperature. The water content of that same gel at 25°C might, however, be nearer 70%. According to the more modest of the corneal requirement predictions discussed earlier, this would represent the minimum water content required for an extended wear lens having an average thickness of around 0.15 mm.

PHEMA hydrogel having an equilibrium water content of 39% and a 'dissolved' oxygen permeability coefficient of 145×10^{-10} (ml O_2 mm)/(cm^2 s cmHg) at 34°C and in the form of a contact lens 0.2 mm thick would give an oxygen flux just sufficient for the corneal requirement in the open eye condition but quite insufficient in the closed eye situation. One advantage of hydrogels is the virtual absence of a boundary layer effect, because of the low interfacial tension with water. This means that thinner samples of the materials give progressively more effective net transport.

It has been long realized that in the region shown by dotted lines in *Figure 3.12* the oxygen permeability is more dependent upon the nature of the comonomers than on the water content of the hydrogel (Pedley and Tighe, 1974). Even simple structural changes can be used to demonstrate the principle of permeability enhancement in low water content hydrogels (Corkhill *et al.*, 1991). By incorporating the type of monomers used in RGP materials dramatic permeability enhancement can be achieved. Practical problems associated with this approach include maintenance of compatibility (and thus transparency) within the copolymers, achievement of adequate wettability and manipulation of mechanical properties to produce a lens with an acceptable balance of comfort, dimensional stability and ease of fitting. It is anticipated that these silicone hydrogels and related materials will suffer from water loss to a lower extent than is the case with high water content materials. As a result it may be possible to use thinner lenses without a high incidence of corneal staining. Preliminary clinical reports appear to be promising but materials are not yet generally available for evaluation.

Optical transmittance

Transparency is an essential requisite of a hydrogel for contact lens use but not all hydrogels are optically transparent. Translucence and opacity in hydrogels is associated with microphase separation of water which produces regions of differing refractive index within the gel. Although it is possible to synthesize hydrogels that show this type of behaviour (e.g. by making copolymers with large blocks or segments of hydrophobic and hydrophilic monomers rather then randomly dispersing them), in contact lens usage the unwanted onset of translucency

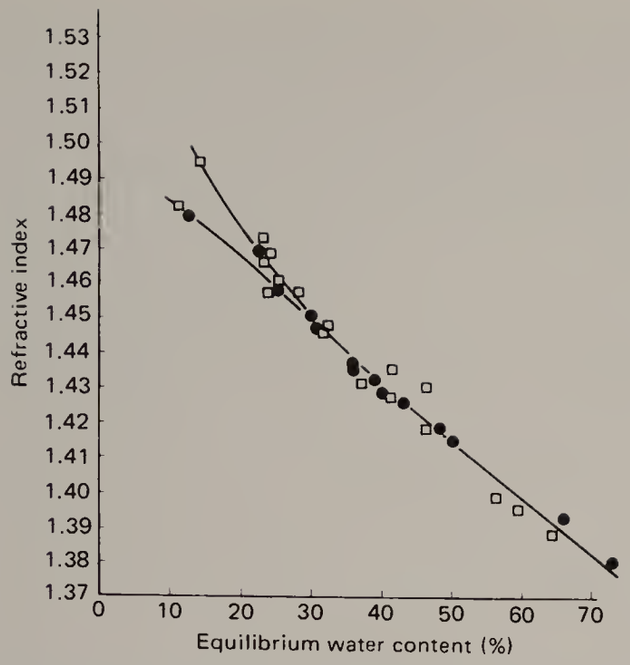


Figure 3.13 Refractive indices of various hydrogels as a function of their equilibrium water contents at 20°C (●) and 34°C (□)

assumes greater importance. This is usually associated with sudden or large changes in temperature which induce the gel to absorb excessive quantities of water. This point, which has been illustrated in *Figure 3.11* with respect to the thermal stability of hydrogels is, fortunately, normally reversible.

Density

The density of hydrogel polymers depends upon both the water content and the monomer composition. Very low water content (and fairly rigid) gels containing styrene as the hydrophobic monomer have the greatest densities of the common hydrogels. These are around 1.22 g/ml at 10% water content and 20°C. These materials are currently used as membranes, rather than contact lenses but some of the emerging generation of low water content, high Dk hydrogels are likely to lie in this general region. Typical contact lens copolymers containing HEMA and the more hydrophilic monomers decrease progressively from around 1.16 at 38% water content to around 1.05 at 75% water content (all at 20°C).

Refractive index

Refractive index again decreases progressively with increasing water content. The variation is almost linear with water content, and the results for hydrogels of the various types indicated above lie within a fairly narrow, almost rectilinear band, decreasing from 1.46–1.48 at 20% water content to 1.37–1.38 at 75% water content. This point is illustrated in *Figure 3.13*. This figure also illustrates the point that refractive index measurement can be used as a rapid method of determining the approximate water content of an unknown gel. The method suffers from inherent inaccuracies, including the assumption that dehydrated hydrogels all have the same refractive index (whereas they can be very different). Despite this, the procedure is convenient and enables the approximate water content of a lens to be determined quickly (*see* Chapter 13).

Surface properties

It is apparent that hydrogels do not suffer deficiencies in terms of inherent wettability. Indeed, it may be desirable to reduce their ability in this respect. One related factor that contributes to the comfort of hydrogels is the low coefficient between the lens and the eyelid. This frictional interaction is much greater with elastomers of similar bulk rigidity (such as ethylene propylene terpolymer and silicone rubber) even after surface treatment. Hydrogels are, however, not truly hydrophilic (in terms of the precise definition stated earlier p. 62) since they exhibit an equilibrium advancing contact angle of around 20°. If this value could be raised, however, it may be possible to retain wettability by tear fluid while decreasing the problems of lens cleaning.

The fact that such a variety of structures is possible in hydrogel chemistry, coupled with the fact that equilibrium water content, oxygen permeability, mechanical properties and surface characteristics are interrelated with structure in different ways, makes it possible, in principle, to design hydrogels to fulfil a wide range of functions. That range includes contact lenses for both daily and extended wear. It is somewhat paradoxical that the hydrophilic nature of these materials, although overcoming the initial problems of the tear film instability, has given rise to a variety of surface-related problems associated with lens spoilation (*see also* Chapters 4 and 13).

RGP materials

History and patent literature

Scientists have studied the interrelation of polymer structure and polymer properties for many years. When the need to modify poly(methyl methacrylate) or PMMA to improve its oxygen permeability arose, there was therefore no difficulty in knowing where to look for polymers having high permeabilities. The problems lay in combining such polymers (silicone rubber, for example) with PMMA to achieve a balance of properties. This problem arose because different types of reactions are used in the formation of the two materials. This can be illustrated by using the picture of polymers such as PMMA and hydrogels as 'washing line' polymers. They have a long backbone (i.e. the string or 'washing line') from which a variety of chemical groups may be suspended (the 'washing'). The function of the chemical groups in hydrogels is primarily to attract and bind water within the structure. PMMA has much less hydrophilic 'washing' and remains glassy in water because it has

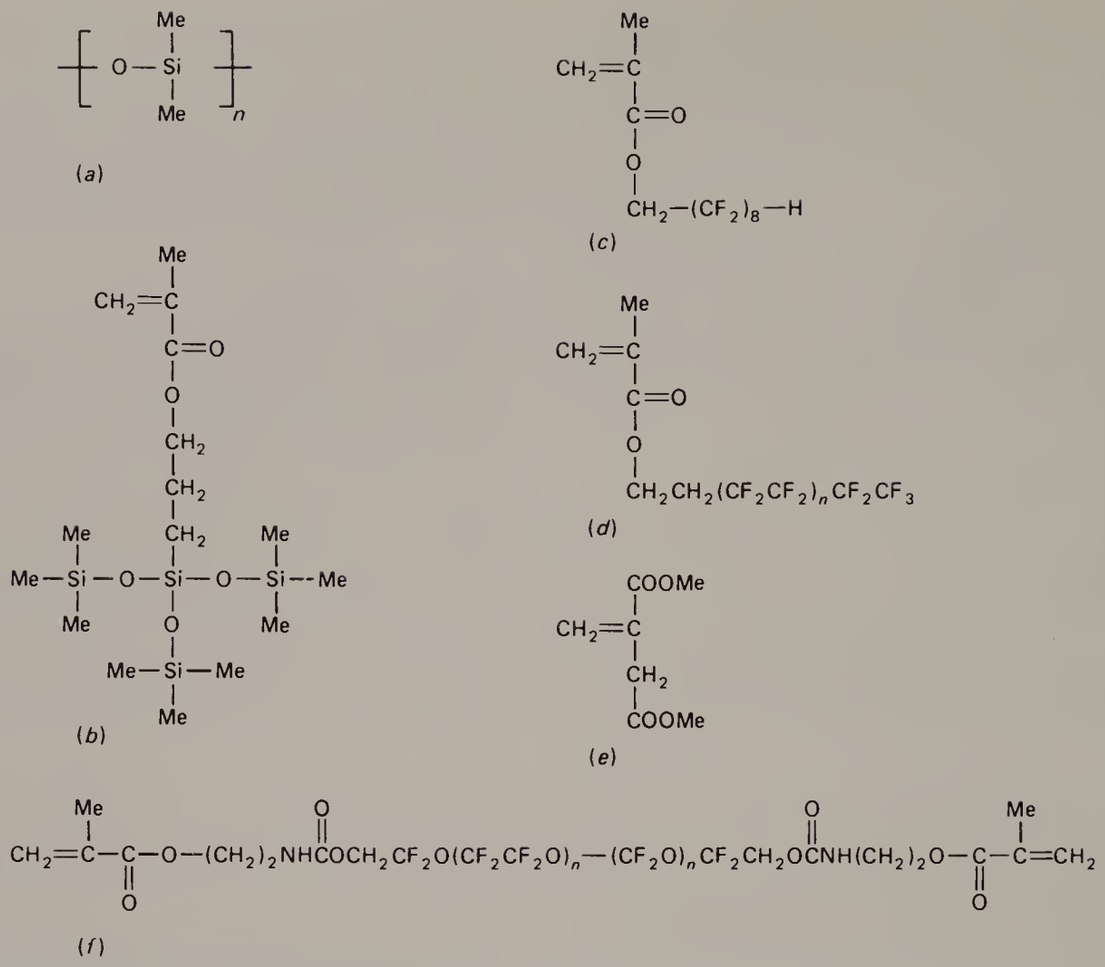


Figure 3.14 RGP material structures: (*a*) poly(dimethylsiloxane); (*b*) tris(trimethylsiloxy)-γ-methacryloxypropylsilane; (*c*) 1,1,9-trihydroperfluoronyl methacrylate; (*d*) perfluoroalkylethyl methacrylate; (*e*) dimethyl itaconate; (*f*) typical perfluoro-ether dimethylacrylate

very little appetite for moisture. Greater physical stability is achieved by fastening the 'washing lines' together at intervals, by the use of cross-links. In order to incorporate an individual 'monomer' unit into such a structure it is necessary that the monomer should have a carbon-to-carbon double bond. Some (fairly exotic) examples are shown in *Figure 3.14b–f*. Without the double bond the washing cannot be pegged onto the washing line and when it is pegged onto the line, the double bond is converted into a normal single bond.

Other types of polymer, of which silicone rubber is one example, can be regarded as 'poppet bead' polymers. The individual units are joined just like the individual beads on a 'poppet bead' necklace. There is no 'washing' hanging from the chain and the properties of the polymer are controlled by the structure of the poppet beads themselves. *Figure 3.14a* provides an illustration of this type of polymer chain. The fundamental problem that prevented simple PMMA–silicone rubber combinations from being prepared is that the 'washing line' and 'poppet bead' chemistries are incompatible and beads cannot be inserted into the washing line. The siloxymethacrylates that form the basis of current gas permeable technology get round this problem in a well recognized, but nevertheless quite ingenious, way. Short segments of the poppet bead chain are turned into 'washing' by attaching them to a chemical intermediate that contains the necessary double bond. This can be seen in the structure of the siloxymethacrylate monomer (*Figure 3.14b*) which in essence consists of the individual units of silicone rubber structure pasted onto a modified methyl methacrylate molecule. On the basis of this simple picture, the story of the gas permeable patents can be unfolded. An abbreviated compilation is listed in Addendum 2.

Silicone rubber

Among the earliest non-hydrogel polymers that offered any competition to PMMA was silicone rubber itself. This material, which is substantially poly(dimethylsiloxane) (*Figure 3.14a*) has the highest oxygen permeability of any commercially available polymer (being around 1000 times more permeable to oxygen than PMMA). It is furthermore softer and flexible, and in this respect resembles hydrogels, but unlike hydrogels is exceptionally hydrophobic. Silicone rubber is such an important precursor to many of the current RGP materials that the appropriate technology as disclosed in the patent literature must be taken as a basis for later developments.

The earliest silicone rubber patents were concerned with methods of lens manufacture, particularly the use of compression moulding techniques together with questions of mould design, that were able to produce finished lenses with high quality edges. Similarly, attention was paid to methods for improvement of the mechanical strengths of poly(dimethylsiloxane)-based compositions. Many of these patents resulted from the work of the Dow Corning Corporation.

The major stumbling-block to the successful use of silicone rubber-based lenses has, however, been inadequate wetting properties rather than lack of toughness or durability. This is reflected in a large number of patent specifications that describe the methods of producing hydrophilic silicone rubber surfaces. The difficulty in obtaining clinically acceptable and permanent hydrophilic surfaces, however, is reflected in the relative lack of success of silicone rubber as a contact lens material. The earliest methods of surface treatment described involved direct chemical attack by alkyl titanate or chlorosulphonic acid followed by hydrolysis. More sophisticated treatments involving a range of both ionizing and non-ionizing forms of radiation soon followed, often in conjunction with *N*-vinyl pyrrolidone (NVP) or 2-hydroxyethyl methacrylate (HEMA), to assist in achieving a hydrophilically modified substrate. Although the methods differ in detail and complexity, they are all essentially free radical reactions.

It is apparent, therefore, that the extremely high oxygen permeability of silicone rubber is exceptionally difficult to harness in the form of a clinically acceptable contact lens because of the hydrophobic nature of the polymer and the difficulty generating a permanent hydrophilic surface (*see Figure 20.5.6*). A series of patents describe attempts to overcome this latter difficulty with some compromise in oxygen permeability by utilizing other flexible polymers that are more readily and permanently surface treated. The first group of these are the carbon-based elastomers such as ethylene–propylene–terpolymer, *cis*-polyisoprene, styrene–butadiene copolymers, *cis*-polybutadiene, polyurethane elastomers and natural rubber. An early patent filed by the Dow Corning Corporation seeks coverage for the use of these materials in contact lenses. The technique subsequently used for final lens production is compression moulding.

Some flexible thermoplastics materials have been suggested as being suitable for contact lens manufacture in the patent literature, but none of these has achieved clinical significance. One interesting proposal involves the heating and subsequent quenching of polyethylene to reduce crystallinity and thereby increase optical clarity. Another describes the use of thermoplastics in general and polyvinyl chloride in particular to produce lenses of complex laminated design with a flexible central portion.

The Gaylord patents – harnessing silicon

A major advance in the development of RGP contact lens materials that are susceptible to the conventional lathing and lens polishing processes, is found in the work of Gaylord (1974–78). There are two distinct aspects of this work. The first encompasses the use of siloxy derivatives of methacrylate monomers (e.g. tris(trimethyl-siloxy)–γ-methacryloxypropylsilane (*Figure 3.14b*) and the second the use of fluoroalkyl methacrylates (e.g. 1,1,9-trihydroperfluorononyl methacrylate – *Figure 3.14c*). Both these lines of work have been subsequently developed and form the basis of most existing commercial gas permeable contact lens materials. *Figure 3.14b* is often referred to as 'tris monomer' and has been the most widely used monomer in siloxymethacrylate contact lens materials. The widely used fluoromethacrylate monomers are much simpler than that shown in *Figure 3.14c*, however.

The Gaylord patent describing the copolymerization of series of fluoroalkyl acrylates and methacrylates with methyl methacrylate is not unique. It was pre-dated by three significant patents describing the use of chemically similar materials in contact lens applications. The first of these was filed in 1967 and assigned to Du Pont by Girard, Sampson and Soper. In particular, it describes the advantages of contact lenses prepared from polymers derived from perfluoroalkylethyl methacrylates (*Figure 3.14d*) in terms of its relatively low refractive index (1.39) in comparison to the value of 1.49 for methyl methacrylate. In a subsequent patent, also assigned to Du Pont by A. E. Barkdoll, a wider range of polymers based primarily on various perfluoro (methyl vinyl ether) tetrafluoroethylene copolymers are described together with means of rendering them hydrophilic. The main thrust of the patent is the production of soft flexible materials processable by compression moulding, but attention is drawn to the fact that the lenses thus produced are appreciably more oxygen-permeable than PMMA. At the same time, a third Du Pont patent filed in the name of C. S. Cleaver draws together some of the features of the Barkdoll and the Girard patents. Thus Cleaver describes copolymers of fluoroalkyl methacrylates with methyl methacrylate, the production of lens blanks which were then machined and polished to prescription lenses and the advantageously high oxygen permeability of the resultant lenses.

Although Cleaver's concept of the fluorine-containing contact lens was first filed in mid-1971 (a full year before the date of filing of the Gaylord patent), over a decade elapsed before significant commercial use was made of fluorocarbon-based contact lenses. The reason reflects the immediate advantage in oxygen permeability of the siloxymethacrylates over the relatively simple fluorinated methacrylate esters described by Gaylord or the Du Pont workers.

Within a 12-month period in 1978 and early 1979, at about the time of appearance of Gaylord's third patent, three workers began to file their separate series of patents related to siloxymethacrylate-based contact lens materials. These were, in advancing order of the priority date for the first written filing, Kyoichi Tanaka (Toyo Contact Lens Co. Ltd), Edward Ellis (Polymer Technology Corporation) and Nick Novicky whose later patents (and presumably rights to the

earlier) were assigned to Syntex (USA) Inc. The Ellis and Novicky patents form a clear line of continuation from Gaylord's early work and, because of this, are best considered together. Tanaka's work, for which parallel filings exist in Japan and the USA, has some slight and significant differences mainly concerned with the inclusion of a hydroxyl group into the siloxy monomer to improve wettability.

Early in 1978, two patents were filed in the names of Edward Ellis and Joseph Salamone that used Gaylord's basic concept with slight but significant modification. The more important of these uses Gaylord's basic composition based on *Figure 3.14b* but claims novelty in the additional use of methacrylic acid (a hydrophilic monomer referred to but not exemplified by Gaylord) to improve surface wettability, and by the incorporation of an itaconate ester (e.g. dimethyl itaconate – *Figure 3.14e*). This composition forms the basis of the Boston range of gas permeable materials.

The Japanese patents

The first Japanese patent in this field has already been referred to. Although not vitally significant in its own right it marks the beginning of a growing number of patents based on Japanese work. These are worth considering in some detail since most of them are not easily accessible (being in the original Japanese) but, additionally, they do contain some interesting ideas and a wealth of information. Since 1980, a very marked expansion in Japanese patent coverage has emerged, principally as a result of work assigned to Hoya Lens K. K. and Toyo Contact Lens Co. Ltd, with the significant additional incursion of Syntex and Paragon Optical into the Japanese patent literature. Many of this group of patents deal with concepts that have been outlined above in connection with the development of ideas in the US patent literature. A significant number of original ideas have emerged during this period, however, which may form the basis for new and interesting contact lens materials. These include silyl acetylene polymers, pentafluorostyrenes, urethane siloxanol acrylates and polyperfluoro alkylene oxide copolymers.

The Japanese patents assigned to Hoya and Toyo provide valuable information on the use of fluoroalkyl methacrylates in conjunction with siloxymethacrylates, and the properties of fluoroalkyl methacrylates themselves. The properties, specifically the permeabilities of the individual homopolymers, are carefully described in preparation for their use in the later mixed-monomer patents. It is interesting to compare the increase in relative permeability along the series of homopolymers methyl methacrylate, trifluoroethyl methacrylate, hexafluoroisopropyl methacrylate (1:60:100). The ground is clearly seen in this patent for the development of fluorine-containing siloxy-methacrylate gas permeable materials (e.g. Equalens, Fluoroperm, Menicon SP) which penetrated the UK and American markets towards the mid-1980s. It is in the Japanese patents, however, that the relationship between composition and permeability of these materials is described. Patents filed by American companies appeared later and contained less information.

The readily discernible trend in methacrylate-based contact lens materials described in the patent literature and discussed here is one of increasing oxygen permeability. Although a range of variants has been disclosed, the essential structural developments have centred around the incorporation of higher proportions of more highly branched siloxy derivatives, and the use of fluorocarbon in the place of hydrocarbon substituents. Much attention has been paid in the patent literature to the comprehensive coverage of all possible structural variants of Gaylord's original disclosures, published in 1974. Despite this, little that is truly new has appeared since then, although the number of 'new' materials continues to grow steadily. The underlying principles that govern oxygen permeability of RGPs are all contained in the patents described above. Some advances have been achieved in surface modifications to improve wettability. (*See* Chapter 10.)

Commercial RGP materials and their properties

The influence of the disclosures, previously outlined and contained in the patent literature, is reflected in the nature and the properties of commercially available contact lens materials. Some commercially available RGP materials together with information on chemical type, oxygen permeability, wettability, mechanical properties and refractive index are shown in *Table 3.3*. This information has been compiled from various sources including manufacturer's literature, reviews and results of other workers, and measurements made in these laboratories. In addition, values for PMMA and cellulose acetate butyrate are included for comparison. A variety of additional materials exist, all based on various aspects of the principles discussed in the previous section. These include OTC V and VII (Ocular Technology), Siloxycon 14 (Neefe), Medicon (AIT), Oxycon and Oxycon 32 (Biomedic Polymers) together with Revlens (Biocontacts), based on butyl acrylate.

As discussed earlier, the major problem in making comparisons between materials and particularly in comparing manufacturers' claims is that no rigid standardization of experimental techniques exists. These factors, coupled with the debatable relevance of existing measurements *in vitro* to the clinical performance of materials, present a major problem to the clinician in selecting materials on the basis of manufacturers' literature.

Complications in making true oxygen permeability measurements on materials arise from the curvature and varying thickness of individual contact lens samples, the thickness dependence, and the lack of widely available standards for instrument calibration especially in the high Dk region in which many of the recently developed materials are claimed to lie.

The problems associated with the use of increasing quantities of siloxymethacrylates to achieve high oxygen

Table 3.3 Some commercial RGP materials and their properties (*see also Table 10.3* and Appendix B)

Name of lens and manufacturer	*Material type*	*Dk × 10^{-11} (standard units)*	*Contact angles (°)*		*Hardness*	*Refractive index* (n)
			Dry	*Soaked*		
Aquila (Ciba Vision)	Fluoromethacrylate siloxy copolymer	143‡				
Alberta N (Calgary Corneal Contact)	Fluoroalkyl itaconate–siloxane copolymer	42‡; 25†	85†	40,52†	120 R†	1.445
Alberta XL 30 [GP IV, = Sil-O_2-Flex]	Siloxymethacrylate copolymer	12.8*; 22‡	65*	28†		1.48
Boston II (Polymer Tech. Corp.)	Siloxymethacrylate – itaconate copolymer	10*; 12–14†,‡	65*; 80†	33, 42†	85 SD, 83 SD†	1.46
Boston IV	Siloxymethacrylate – itaconate copolymer	14*; 19, 24†; 26‡	79*; 90†	30†; 17‡	119 R†	1.468
Equalens (Polymer Tech.)	Fluoromethacrylate – siloxy copolymer	72‡	55*; 94†	30‡; 60†		1.439
Equalens II	Fluoromethacrylate – siloxy copolymer	120†				
Fluorofocon A (3M)	Perfluoropolymer	95†; 90‡; 70 (20°C)‡		44†		1.40
Fluoroperm (Paragon)	Fluoromethacrylate – siloxy copolymer	92‡		16‡	81 SD	1.471
Hyperm (David Thomas)	Siloxymethacrylate copolymer	12*; 18‡	71*	24‡	84 SD†	1.47
Menicon Super EX (Toyo)	Fluoromethacrylate – siloxy copolymer	162‡		20†		
Optacryl 60 (Optacryl Inc.)	Siloxymethacrylate copolymer	9*; 12‡; 18‡	65*; 76†	25†	85 SD†; 88 SD‡	1.467
Optacryl K	Siloxymethacrylate copolymer	21†; 32‡	82†	25–30†	83 SD†; 86 SD‡	1.467
Optacryl EXT	Siloxymethacrylate copolymer	54†; 59‡	92†	<30‡	81 SD†; 82 SD‡	1.464
Optacryl Z	Siloxymethacrylate copolymer	67, 70†; 84‡	91†	25–30†,‡	78 SD†; 80 SD‡	1.461
Oxyflow (Contact Lens Supp.)	Siloxymethacrylate copolymer	20*; 28‡	72*	35†	84 SD†	
Polycon I (Wesley Jessen)	Siloxymethacrylate copolymer	3.1†; 5‡	67*; 83†	30†; 34†	83 SD†	1.49
Polycon II	Siloxymethacrylate copolymer	6.5*; 6.5†; 12‡	77†	25†; 32† 15‡	84.5 SD†	1.473
Polycon HDK	Siloxymethacrylate copolymer	50‡		25†	85 SD‡	1.465
Paraperm O_2 (Paragon Optical Inc.)	Siloxymethacrylate copolymer	8†; 12‡	80†	46†; 23†	85 SD†; 86 SD‡	1.48
Paraperm EW	Siloxymethacrylate copolymer	32, 49†; 56‡	68*; 92†	26†	10.6 V†; 82 SD‡	1.475
Paraperm O_2 Plus	Siloxymethacrylate copolymer	31†; 39‡	91†		11.3 V†; 84 SD‡	
Paraperm EW2	Siloxymethacrylate copolymer	92†; 97‡		16‡	81 SD‡	1.471
Quantum I (Bausch & Lomb)	Fluoro methacrylate siloxy copolymer	92‡				
Quantum II	Fluoromethacrylate–siloxy copolymer	210‡				
PMMA	Polymethyl methacrylate	0.1*	63–67*,†	15–35*,†	88.5 SD†	1.49
CAB (= Cabcurve; GP II; Meso; Paracab; Persecon)	Cellulose acetate butyrate	4–8*,†	62–65*,†	12–31*,†	77.5 SD†	

*These laboratories; †various published sources; ‡manufacturers' literature; Dk values at *20°C, †,‡35°C; hardness, V = Vickers, SD = Shore, R = Rockwell (R).

permeabilities are twofold. First, incompatibility, phase separation and deterioration in mechanical properties limit the amount of such monomers that can be incorporated. Secondly, their use requires the incorporation of hydrophilic monomers containing hydroxyl, carboxyl, amide or lactam groups to improve wettability. It is well recognized that developments that have produced higher oxygen permeabilities have led to problems with mechanical properties, and that such problems are quite common. Despite this, the currently used mechanical property measurements do not indicate any clear distinction between materials. There is certainly no accepted basis upon which the durability of existing materials can be correlated with presently used mechanical property measurements.

Similar problems arise with the measurement of wettability by contact angle techniques. In this case, contact angle hysteresis, the effect of soaking on water uptake and thus the wettability of materials, coupled with the use of the inverted or captive air bubble technique in solutions other than water, combine to produce wide variations in the reported values for a given material. On the other hand, use of a low surface tension wetting solution in combination with the captive air bubble technique produces a low contact angle with almost any polymer. Such measurements are of no clinical significance, nor do they provide any rational basis for comparing the surface properties of different candidate materials.

The properties listed in the table reflect these points. The variation in values quoted for some materials is quite alarming. It is possible to imagine the indignation that would be caused among the motoring fraternity if the top speed, acceleration, engine capacity and fuel consumption of cars were quoted with such unreliability. This is not to suggest that the manufacturers are guilty of misrepresentation but rather that no concensus view on standardized test procedures has yet been finalized.

The need for improved test methods

Whereas biomaterials research has been advancing, the methodology commonly used for testing contact lenses has stood still. One of the problems is that the questions that were asked about the properties of materials in the past are not sufficiently discriminating today. As a result we have inherited a mixture of concepts and methodologies that are inappropriate to present day requirements. It is important that steps are taken to remedy the situation. It is in the interests of both practitioners and manufacturers to produce methods of test that reflect the relative merits and shortcomings of different RGP materials. Some of the current problems and potential improvements are outlined below. Many of the comments also apply to the measurement of soft lens properties.

Oxygen permeability

In the early 1970s, for example, it was sufficient to know whether the oxygen permeability of a hard lens material was appreciably greater than that of PMMA or about the same. The scale of values for available materials was limited. It was convenient to use a technique in which a lens could be placed on a polarographic electrode and measured directly. As the available materials have increased in permeability, however, so has the relative importance of the errors associated with this technique.

There are many areas of membrane science in which the oxygen permeability of materials is studied. The understanding of the difference between gas phase transport and that in the aqueous phase, together with the effect of thickness and of boundary layer phenomena has been in place for many years.

It is logical that a series of 'Gaylord' compositions should be prepared and their permeability characteristics determined using sound and well-established experimental techniques. These would then provide calibration standards for the simple polarographic electrode cell used in contact lens work. This would mean that the polarographic electrode method would cease to be a candidate for a role that it cannot readily fulfil – that of a primary standard technique.

Surface properties

The field of contact lens surface properties has also become more complex with the passage of time. The water wettability of materials provides a good primary indication of the ability of tears to form a coherent and stable layer on the surface of the material. It tells nothing of the compatibility of the material with tears. Unfortunately, the inverted air bubble technique has recently been used as a standard in contact lens work. The measurement is made after an air bubble is allowed to impinge, from underneath, onto the surface of the sample, which is suspended in an aqueous liquid. This is the most difficult type of contact angle to measure correctly since it involves judging where the base of a distorted sphere just impinges on a surface. More importantly, the air bubble has to displace water from the surface of the sample, which is frequently pre-soaked. Since all the siloxymethacrylate gas permeable materials contain appreciable amounts of hydrophilic monomer to improve surface wettability they all retain a strongly adsorbed water layer at the surface under these conditions. Not surprisingly, therefore, very similar and very low so-called 'wetting angles' are obtained with current gas permeable materials. What is measured in each case is the value for a diffuse layer of water on a polymer surface. The values are similar to those obtained by this technique with hydrogels. The biological and biochemical events at surfaces, on the other hand, occur at a molecular level and do not recognize the diffuse water layer 'barrier' that is sensed by macroscopic 'droplet' techniques. This is the underlying reason for the lack of relevance to clinical practice of the 'wetting angle', as presently measured. Characterization of polymer surfaces has developed a great deal.

In addition well-established techniques exist which enable the detailed surface energy components, rather than a single 'wetting angle', to be determined. Biomaterials science makes widespread use of such methods; the contact lens community could profitably do the same. Predicting compatibility *in vivo* from tests *in vitro* is never entirely successful. Increasingly, however, it enables differences between the performance of materials to be successfully predicted. In addition the use of biological probes, such as animal cells, and interaction with biological sera provide useful information in the development of new biomaterials. The area is complex, but offers several approaches that will improve considerably on the captive air bubble technique, and will have some relevance to clinical performance.

Mechanical properties

Little organized work is done on mechanical properties at present, but the values quoted are almost invariably related to the hardness of the material. Although hardness tests have some place in contact lens characterization, they do not reflect the type of mechanical failure or problems that normally arise. Such problems are usually associated with fracture, chipping or splitting (*see Figures 18.32, 18.33*) or distortion. Mechanical properties of polymers are of paramount importance in many fields. A vast number of testing methods have been devised for different applications. It would be fairly straightforward to adapt suitable methods for measuring resistance to fracture and distortion. A useful way of comparing lenses is by use of tensile stress-strain analysis on both dry and soaked lenses or discs. With care, reproducible stress-strain curve parameters can be obtained which tell a great deal about the behaviour of individual materials.

The nature and origin of lens spoilation

Probably the most persistent problem affecting the use of lenses is biocompatibility. This topic is usually referred to as ocular compatibility, or spoilation, in the contact lens field. The problem of deposit formation on soft contact lenses is similar to many other situations in which materials come into contact with biological solutions. Thus, the deposition of tear fluid debris, the clotting of blood on a foreign surface, the formation of dental plaque, marine fouling and the fouling of membranes used in biochemical separations are all examples of the same fundamental phenomena (Baker and Tighe, 1981). The initiating processes in all these interactions are referred to as biological interface conversion processes and they can be readily studied in the eye whereas they can only be studied with considerable difficulty in, for example, blood contact devices. The reason for this is obvious. Whereas a contact lens may be removed and analysed after only a few minutes wear, it is difficult to conceive of a surgical technique that would allow implantation and removal with equal rapidity in a blood contact situation. The eye, therefore, presents a unique opportunity for *in vivo* studies of biocompatibility provided that the detailed nature and composition of the tear film are sufficiently understood.

The nature of the tear film

The tear film covering the cornea was first suggested to have a three-layered structure by Wolff in 1948 (*see* Chapter 2). It consists essentially of the superficial lipid layer, the aqueous below this and an adsorbed mucin layer adjacent to the epithelium. The superficial lipid layer is believed to comprise about 1% of the total thickness (about 0.1 μm thick); the middle aqueous layer represents over 98% of the tear film and is 7 μm thick; and the inner mucoid layer is most commonly quoted as comprising under 0.5% of the film, being 0.02 to 0.05 μm thick. More recent observations have shown however, that mucins become diluted towards the aqueous layer and interact with and mask the hydrophobicity of the lipids, making the delineation of different tear film layers somewhat arbitrary.

The tear components and their origins

The secretory apparatus responsible for tear formation consists of the main and accessory lacrimal glands (source of the aqueous tear components), the meibomian glands (which secrete lipids) and the conjunctival goblet cells (which secrete mucous glycoproteins). The accessory lacrimal glands supply the minute-to-minute supply of tears, while the main lacrimal gland functions as a back-up reflex system by flooding the eye in response to injury, irritation or emotions (reflex tearing). The various secretions contribute to a complex mixture which include proteins, enzymes, lipids, metabolites, electrolytes, hydrogen ions and also drugs excreted in tears. The content and reliability of literature sources relating to tear chemistry has been reviewed by Bright and Tighe (1993).

Protein components

These are found chiefly in the middle aqueous layer which originates from the main lacrimal gland located in the superior temporal aspect of the orbit, and from accessory lacrimal glands (glands of Krause and of Wolfring, the infraorbital gland and the glands of the plica and the caruncle) lining the surface of the conjunctiva. The total concentration of proteinaceous substances in the tear fluid is variously estimated to be between 0.3 and 7.0%. The concentrations vary depending on whether the tears are unstimulated, emotional or irritant-induced. Using electrophoretic techniques, more than 60 protein components can be detected in normal tear fluid. Of these, more than 20 have been shown to be secreted by the lacrimal gland. The major tear proteins are albumin, tear-specific prealbumin, lactoferrin, lysozyme and the immunoglobulins. Lysozyme, lactoferrin and albumin are the most important in deposit formation, existing in approximately equal concentrations, with the first two being positively charged and the third

negatively charged. Lysozyme with a molecular weight of around 16 kD is the smallest, being less than a quarter of the mass of the others.

Lipid components

The superficial lipid oily layer is secreted by the meibomian glands and the glands of Moll and Zeis which are situated at the edge of the eyelids. The composition of meibomian lipids in humans has been found to vary considerably between individuals (Tiffany, 1985). The principal non-polar component of the tear film lipid has been identified as a mixture of waxes and sterol esters, with the sterol esters accounting for nearly one-third of the mixture. Chromatographic analysis has demonstrated the presence of all lipid classes in the meibomian secretion: hydrocarbons, wax esters, cholesterol esters, triglycerides and, in lesser amounts, diglycerides, monoglycerides, fatty acids, cholesterol and phospholipids (Tiffany, 1978).

Mucous component

The inner mucoid layer is secreted by specialized conjunctival cells in the Crypts of Henle and the glands of Manz. The composition of the mucous layer, which is the innermost layer of the tear film, consists of around 1% each of salts, free protein and glycoprotein together with a balance of water.

The electrolyte content resembles that of serum or bile. Other constituents include immunoglobulins, salts, urea, glucose, leucocytes, tissue debris and enzymes such as β-lysin, peroxidase and lysozyme. The glycoproteins, or mucins, are 50–80% carbohydrate, with the oligosaccharides attached to a protein backbone of molecular weight $2.0–15.0 \times 10^6$ daltons, which is composed of about 800 amino acid residues. Serine and threonine comprise 40% of the total amino acid and form the O-glycosidic link with the side chains which cover approximately 63% of the backbone. The sugar side chains are composed of up to 12 sugar residues, which in human mucous secretions are made up of the same five monosaccharides: galactose, N-acetylgalactosamine, N-acetylglucosamine, fucose and N-acetylneuraminic acid (sialic acid). The link with the protein backbone is formed by galactose, and the terminal sugar group is either fucose or sialic acid (Marriott, 1983). Other sugar residues may bear ester sulphate groups, and these, together with the sialic acid groups, provide mucin with its overall negative charge. The structure means that areas of both sugar and protein are exposed to the solution, although the former predominate. The presence of cysteine amino acids enables the formation of disulphide bridges between or within molecules, and proline residues allow the molecules to bend and assume random structures in solution. Cross-linking through disulphide bridges produces polymers of high molecular weight that bind to similar polymers by weak interactions of the carbohydrate chains to form a gel. Mucin has an important part to play in corneal wettability and tear stability although the precise mechanisms of interaction with the corneal surface is subject to discussion.

Manifestations of lens spoilation

Lens spoilation only became a major materials problem with the advent of hydrogel lenses providing, as they did, greater comfort and allowing extended wearing times. The term spoilation encompasses the physical and chemical changes in the nature of hydrogel contact lenses and the various extraneous deposits which may impair the optical properties of the lens or produce symptoms of discomfort and often intolerance to the wearer. The reported incidence of lens spoilation (which, in earlier clinical records varies from less than 10% to over 80% of extended wear lenses) occurs in most cases in some 3–6 months of daily or especially extended wear, although it has been observed within 48 hours of wear. The advent of disposable and frequent replacement wear regimes has reduced the incidence of the more dramatic manifestations of spoilation but has not diminished its overall clinical importance.

Although it is convenient to divide the observed types of spoilation into different classes, such classification is largely artificial, as there is considerable overlap and systematic analyses of the results of spoilation are rarely undertaken in conjunction with clinical reports relating to incidence. The classfication is best regarded, therefore, as a grouping of various related types of clinically observed phenomena. An indication is given of the current view of the occurrence, chemical composition and potential aetiology for each clinically observed 'class' of lens spoilation (Bowers and Tighe, 1987). These categories are of additional importance in that they provide valuable information about the ultimate interactive products of tear components with each other and with the lens material, thereby enabling deductions about the earlier stages of the spoilation process to be made.

Discrete elevated deposits

Probably the most chemically complex manifestations of ocular incompatibility are discrete elevated deposits, the so-called 'white spots' varying in diameter up to around 1 mm and found on the anterior lens surface (*see Figure 18.42*). They are also referred to in the contact lens literature as mucoprotein–lipid and mucopolysaccharide deposits. Tripathi *et al.* (1980) cite the deposition of mucoprotein–lipid deposits on lenses as a major cause of spoilation, with a reported incidence of up to 80% of patients fitted, a figure that is much higher than the incidence in general clinical practice.

There is a considerable variation in the reports of the chemical composition of this group of deposits between patients, which has given rise to continued speculation as to their origin. Much of the variation arises from differences in quality and sensitivity of the analytical work. As previously mentioned, tear solutes include many proteins, amino acids, mucin, glycoproteins, glucose and lipids (phospholipids,

neutral fats, fatty acids, cholesterol and its esters), calcium, potassium, chloride, bicarbonate, phosphate and urea. Individual variations exist, especially in the mucoprotein content and in the meibomian secretions, and this may be further influenced by the stimulus of contact lens wear. The tears are a constant source of many of the components of deposits, togethers with the products of normally desquamating epithelial cells and, in pathological conditions, necrotic tissue and altered tear components.

Mucoprotein–lipid deposits lead to a decrease in visual acuity and give rise to injury of the cornea and palpebral conjunctiva. Patients with such deposits on their lenses often show clinical conditions such as contact lens-induced papillary, giant papillary, follicular and other allergic conjunctivitis (*see Figure 18.24*). It is thought that these conditions result either from mechanical irritation of the deposits on the conjunctiva or the adsorbed proteins providing an antigenic stimulus initiating an autoimmune response (Allansmith *et al.*, 1977).

Lens coatings

A major class of spoilation involves surface films, coatings and plaques. One group of these, made up of discrete deposits, with overall dispersion, are the 'protein' films. Such films are characterized by a thin, semi-opaque, white superficial layered structure which appears to consist of denatured protein. The films vary in their extent of lens coverage as seen in *Figure 18.40*, ranging from small patches to complete covering of the lens surface. The general accumulation of protein films on soft lenses leads to an increase in surface haziness and surface rugosity. A decrease in visual acuity is due both to lens opacity and to poor lens movement on the eye. Red eye, increased irritation and conjunctivitis are typical patient responses to such lenses. These deposits have been variously attributed to mucoproteins, albumin, globulins, glycoproteins and mucin.

Although Karageozian (1976) reported that protein films consist mainly of denatured lysozyme, Hathaway and Lowther (1976), reported that albumin, as well as lysozyme, forms marked deposits in a short period of time. Subsequent work has shown that proteinaceous films contain all tear proteins but that the nature of the lens material affects the ratio of individual proteins in the deposited layer.

Inorganic films are similar in gross appearance to protein films although their incidence is lower. Heavy inorganic films often cause damage to the lens surface (*see Figures 18.27, 18.44, 18.45, 18.46*), since the material may penetrate into the lens matrix. They are frequently covered with protein that smooths the underlying rough inorganic material, composed mainly of calcium phosphate. The deposit may well be hydroxyapatite, the thermodynamically stable phase of calcium phosphate commonly encountered in biological conditions. Once nucleated, hydroxyapatite will grow directly from slightly super saturated solutions like tears. The mechanism discussed by Bloomfield *et al.* (1978) which leads to corneal calcification, may contribute to hydrophilic lens calcification, although this has not been widely recognized. Briefly, the release of calcium and phosphorus from injured cells could increase the amount of calcium–phosphorus product locally. The activation together with release of such cellular enzymes as alkaline phosphatase and adenosine triphosphatase which are present in corneal cells, also may lead to local calcification. These enzymes have pyrophosphatase activity, i.e. they cause the hydrolysis of pyrophosphate to phosphate. Pyrophosphates are inorganic compounds that are widely distributed in the body and act as physiological inhibitors of calcification in soft tissues. It is clear that phosphate buffered contact lens solutions increase the probability of calcium phosphate formation on lens surfaces, especially if the solution contains a measurable calcium ion concentration.

Microbial spoilation

One of the most serious hazards of soft lens wear is spoilage due to invasion and contamination by microbial organisms. Separate studies have produced similar figures for the occurrence of this type of spoilation. They have indicated that in one set of patients some 24% of lenses showed problems related to the presence of pathogenic organisms and in others about 30% of patients carried such organisms (Ericksen, 1978; Roth, 1978; Ruben, 1978). Normally the lens surface can be expected to have traces of microorganisms due to the presence of harmless flora, including fungi of the conjunctival sac. Many species of fungi and yeasts have been identified on soft lenses (*see Figure 18.43*). Among these are the yeasts of the *Rodotonita* species, *Candida tropicales, fusarium* and *albicans* together with fungi such as *Aspergillus fumigatus, Aspergillus niger* and *Penicillium* sp. Additionally, the presence of the fungus *Cephalosporium acremonium* on and within a therapeutic soft lens has been noted. Factors which may influence soft lens infiltration by fungi include enzymatic activity, produced by the fungus, which leads to polymer degradation, thus providing a matrix and nutrient source for fungal growth. Protein deposits and other debris are thought to predispose lenses to fungal invasion. Prevention, through adequate cleaning and disinfection procedures, must be practised because microbial colonies, once established, are extremely difficult to eradicate.

Several workers reported the presence of bacteria on both the anterior and posterior surfaces. Fowler, *et al.* (1979) found bacterial cells on the anterior surface of several lenses; each lens surface was found to be contaminated with dried mucus. Some bacteria were scattered randomly over the surface, with no apparent attachment to the surface of the lens, whereas others were attached to the coated surface by thin, flagella-like pseudopodia 0.1–1.3 μm in diameter. The distal ends of these structures were free and unattached to the surface. Several bacteria were actually embedded in the surface coating, whilst others were aggregated around clumps of mucus. It would therefore appear that bacteria

may use the lens coating as a nutrient source, and as a result of their attachment and proliferation may provide antigenic mass (*see also* Chapter 4).

Lens discoloration

An increase in incidence of discoloration or loss of lens transparency has been linked with several factors including nicotine from cigarettes, topical adrenaline and topical vasoconstrictors as well as components from the tear fluid. The possible nature of discoloration is described in various papers of which the most noteworthy is that of Kleist (1979). Yellow or brown discoloured lenses (*Figure 18.19*) have been found to contain granular particles deposited just below the lens surface. This is believed to be structurally similar to melanin, the skin pigment, and to be immobilized within the hydrogel matrix. Adrenaline and other similar compounds used in eye medications may play a potential role in lens discoloration since they may be taken up by the lens. Adrenochrome is believed to be a possible precursor of melanin, therefore the presence of adrenochrome in eye medications may enhance the natural production of melanin. Similarly, melanin production is stimulated by nicotine and the other polycyclic aromatic compounds in tobacco smoke; it is not a direct discoloration but a nicotine-stimulated biochemical mechanism. Some preservatives, notably chlorhexidine derivatives and sorbic acid, appear to enhance discoloration in some circumstances. This is discussed further in Chapter 4.

More recent work has clarified many of the chemical pathways involved, highlighting the fact that the hydrogel simply acts as an inert matrix for these reactions; discoloration reactions involving the lens polymer itself being extremely rare (Corkhill *et al.*, 1990; Franklin and Tighe, 1991).

The chemistry of lens spoilation: the role of lipids

A fascinating problem in contact lens spoilation is the mechanism of formation of 'white spots'. These have parallels in other body sites and are similar to deposits encountered on heart valves and bile duct prostheses together with ureteral and urethral implants. White spot formation is a consequence of long-term wear of all the generic soft lens materials currently used in contact lens practice. The detailed morphology and chemical composition of these deposits is now well established.

The results indicate that the structure is complex and not predominantly composed of one single component, as has been suggested in the past. Perhaps, not surprisingly, all the major components of the tear film are represented in the deposit structure. However, of greater significance is the distinct internal stratification of the deposit structure, in which a flat basal layer appears to be the primary interfacial region between the deposit structure and the lens matrix. Although protein is undoubtedly present, the proteinaceous interface does not appear to form the basis of the interfacial process that eventually leads to deposit formation. Furthermore, the primary basal layer does not exhibit a particularly high level of calcium deposition, which suggests that the formation of discrete deposits of this type does not result from the development of an inorganic calcareous layer upon which an organic layer is overlain. Histochemical studies suggest that the deposits are predominantly composed of lipid species such as cholesterol, together with cholesterol esters and unsaturated lipids. Morphological information provides evidence that unsaturated lipoidal material is concentrated at the interface and appears to form the basis for deposit formation which is the result of the successive laying down of globular structures which become tightly packed together to form a complex multi-layered structure consisting of three distinctive, yet interactive sub-layers.

Additionally, small patches of predominantly lipoidal material are located on the lens surface, even before deposit formation occurs. These elevated plateaux, varying in size from 20 to 200 μm, are too small to be noticeable to the naked eye and appear to form the basis on which white spots develop and upon which, once initiated, they grow quickly. The existence of these lipoidal patches correlates with the primarily lipoidal basal layers common to all complex elevated white spot deposits. They offer an explanation for the common deposit composition and morphology encountered on soft contact lenses, and the fact that they appear to be little affected by bulk lens chemistries, wear protocol or lens application.

The earlier literature on the subject of lipids in contact lens deposits contained some disagreement on the identity of deposited lipids (Rapp and Brioch, 1984; Hart *et al.*, 1986). By the use of sensitive high performance liquid chromatography techniques it is possible to detect all the previously mentioned lipid classes, however. These include cholesterol, cholesterol esters, monoglycerides, diglycerides and triglycerides, fatty acids and fatty alcohols. The study of the early stages of these spoilation processes requires sensitive analysis of the biochemical species deposited on the surface of individual lenses after only a few minutes wear. Such analytical work shows a relatively high concentration of unsaturated fatty acids at the immediate interface, whilst cholesterol based lipids appear to contribute significantly to the deposit mass.

A typical spread of fatty acids laid down on a PHEMA lens during daily wear reveals some twenty in number, together with triglycerides and cholesterol esters. Calibration of the system enables the identification of individual fatty acids in order of ascending molecular weight. Arachadonic (20:4), Arachidic (20:0), Linolenic (18:3), Linoleic (18:2), Oleic (18:1), Stearic (18:0), Palmitoleic (16:1) and Palmitic (16:0) are readily identified, together with a small cluster of lower molecular weight components (Abbott *et al.*, 1991). In the foregoing list the bracketed figures refer to the number of carbon atoms and the number of double bonds in each individual fatty acid. In general the greater the number of double bonds, the more reactive will that particular fatty acid be in the development of insoluble lipid-based deposits.

It is essentially the interaction of these unsaturated fatty acid lipids with the lens surface that preconditions the lens to the formation of discrete elevated deposits. This mechanism, arising from the evaporation of the tear film, is independent of protein adsorption which will be an ongoing interfacial process. One important aspect of the overall process is the relatively high solubility of water insoluble lipids within the hydrogel polymer itself (as distinct from water within the gel). The mechanism of immobilization of the unsaturated lipids at the lens surface is one of polymerization. This is a well-known process and is identical to the 'drying' of early linseed oil-based paints in the presence of air and sunlight. (Linseed oil, just like the tear film, contains unsaturated fatty acid derivatives.) Once formed, these small (50–100 μm in diameter) lipoidal 'islands' with free fatty acid groups can interact with calcium. Indeed the role of calcium appears to be more important than is that of protein, since calcium functions as a deposit stabilizing component.

Because the interaction and subsequent chemical reactions of lipids with the hydrogel matrix are of such importance in the spoilation chemistry, the underlying reasons for their interaction with hydrogels must be considered. One mechanism is simply the interaction of the carboxyl groups of fatty acids with hydrogen bonding sites at the dynamic hydrogel interface. (Both the polarity and total surface energy of these hydrogels are appreciably higher than that of natural tissue.)

The other mechanism is similar to that occurring in discoloration reactions. The penetration usually arises because molecules are taken into the lens matrix that have some solubility in water but greater solubility in the polymers. Many species do this but they usually remain undetected unless the molecules involved are coloured. In some cases their presence leads specifically to deposit formation which usually appears to be quite unconnected with the primary penetration process – that is, the true culprit remains undetected as is certainly the case with lipid penetration and the problems that this produces. Fluorescence spectroscopy used at various stages of the extraction process, shows the substantial proportion of lipid that penetrates the lens matrix and which non-destructive extraction techniques cannot remove. The combined picture produced by the various techniques is clear and consistent. The reality of this migration process is illustrated by the fact that relatively hydrophobic steroids such as progesterone are some two hundred times more soluble in PHEMA hydrogel than is a water-soluble sugar molecule of similar size, such as sucrose.

Effect of material structure on spoilation behaviour: the role of proteins

Although several different monomer combinations are used in soft lenses, their behaviour is conveniently subsumed under the four US FDA classification groups of generic soft lens materials (I, low water content non-ionic; II, high water content non-ionic; III, low water content ionic; IV, high water content ionic). Of these, the high water content ionic Group IV materials are set apart by their relatively porous negatively charged networks. They are the only group of materials into which the low molecular weight (< 20 kD) positively charged protein lysozyme can diffuse. Of the remainder, the great similarity in behaviour stems from the fact that *N*-vinyl pyrrolidone and 2-hydroxyethyl methacrylate are almost invariably employed as the hydrophilic centres.

Individual patient (and indeed individual eye) variations are as important as material variations. Whereas protein variations between left and right eye of individuals are negligible, the local glandular origin of lipids produces significant left/right eye variation in lipid levels in around 30% of patients examined. Studies indicate clearly that protein accumulation is highly material dependent, whereas lipid deposition is primarily patient dependent. Furthermore, since all existing soft lens materials are based on carbon backbones and have substantial hydrophobic segments, lipid partitioning into the lens matrix is common to all materials, although non-ionic Groups I and II do deposit more lipid than non-ionic Groups III and IV (Bontempo and Rapp, 1994). Jones *et al.* (1997) found that those materials based on *N*-vinyl pyrrolidone accumulate more lipid than those based on polyvinyl alcohol, and Group II lenses attract more lipid than any other group.

The term 'ionic' does not necessarily indicate equally enhanced deposition in all lenses so termed, although highly charged lenses inevitably sustain higher levels of charged protein (e.g. lysozyme) deposition and some protein penetration. Because lysozyme is a small and relatively conformationally stable protein, the question of greater importance is the effect of material chemistry on the conformational stability of the other tear proteins found at the polymer surface.

The results of the spoilation studies using non-hydrogel methacrylate-based lens materials indicate that these materials are also capable of attracting all tear components from the eye. The time profile of spoilation differs from that of soft lenses principally in that soft lenses act as a reactive matrix, in which chemistry leading typically to discoloration and white spot formation occurs in the long term. Thus penetration of lipid into non-hydrogels occurs but in the absence of calcium ions within the matrix, the calcium–lipid complex formation necessary to the growth of white spots cannot occur.

There is, then, a difference between the deposition, immobilization and chemical conversion of biological components at synthetic surfaces (which is undesirable) and the establishment of a deposited layer in which dynamic exchange of adsorbed components takes place with the bulk biological fluid (as occurs in nature). The differential susceptibility of lens materials to adsorb and chemically convert protein and lipid appears to increase with time. For this reason, the least protein-resistant materials, such as the highly ionic Group IV Vifilcon A- and Etafilcon A-based lenses, are suitable only for disposable or frequent replacement wear regimes. The most

protein-resistant materials are those with very low surface charge such as Atlafilcon and Crofilcon, which do not contain charged groups or HEMA. Because HEMA is difficult to purify and, in practice, is always associated with small amounts of methacrylic acid, PHEMA itself always carries a small and somewhat variable surface charge. Materials such as Tetrafilcon also contain small amounts of slightly basic monomer that offset this effect to some extent. However, the attraction of lysozyme to the surface of the lens is not necessarily clinically disadvantageous. Current research is more concerned with the nature and immunological state of surface protein, rather than the amount. It has been demonstrated that lysozyme remains substantially unchanged in conformation and retains its biological activity when associated with lens polymers. On the other hand, Group II materials, which have little or no surface charge and fairly high water contents, tend to attract albumin to their surface, which is much more readily denatured than is lysozyme.

In summary, then, studies of protein interaction with various lens materials show that both size and charge of the proteins are influential in their interaction with contact lenses. Relative deposition rates of different proteins on high water content ionic (Group IV) lenses show that the charge of proteins is more important than the size in the uptake by lens material. As a result, positively charged lysozyme is taken into the matrix of Group IV materials, whereas tear-specific pre-albumin which has the same size but no charge, is not.

Similarly, in the case of protein uptake by different lens materials, the charge on the material is the dominant factor, rather than its water content. As a result, negatively charged Group IV lenses take up lysozyme whereas Group II materials, which have no specific charge and similar water content, do not.

These effects of size and charge mean that not only lysozyme but also lactoferrin penetrate the matrix of Group IV lenses, while neither albumin nor tear-specific pre-albumin are absorbed. The penetration of lactoferrin into the matrix of Group IV lenses is, however, much less than that of lysozyme, because of its greater size (74 kD). Lysozyme, which is much smaller (16 kD) is quite mobile in the Group IV lens matrix and can leach out into storage solutions at a significant rate. Furthermore, the biological activity of the protein remains unchanged after the absorption and desorption processes.

A more general underlying message, applicable to all biomaterials is that lipid interaction with the polymer surface and penetration into the polymer matrix modifies the polymer-host interface and changes the course of the biological interface conversion processes. In essence, changes to material chemistry within the hydrogel family, produce changes in the rate at which the various spoilation processes occur, but do not inhibit them. There is clearly a great deal to be done in understanding the nature of the initiating steps in order to effect more marked changes in spoilation resistance. Daily disposable lenses will certainly reduce the importance of lens spoilation. The long-term effects of successive daily insult to the eye with a non-biologically conditioned lens cannot be predicted, however. Experience in other areas of biomaterials suggests that we may see examples of material-specific chronic intolerance in years to come.

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Addendum 1

Units and terms in permeability measurements

Manufacturers' literature and, indeed, work by independent authors express properties in a variety of terms and units. This addendum provides some explanatory notes and conversion factors.

Oxygen permeability

The most important term in this work is the oxygen permeability coefficient, P, which is the amount of gas passing in unit time through a unit area of membrane subjected to a unit gas pressure gradient (i.e. pressure difference per unit thickness) across the membrane. The difference between 'dissolved' and 'gaseous' coefficients (P_d and P_g) is discussed in the text (*see* p. 67–70). The units in both cases are (ml(STP) mm)/(cm^2 s cmHg) or one of the equivalents listed below. The oxygen permeability coefficient is equal to the product of the oxygen diffusion coefficient (D) and its solubility (S), i.e. $P = D \times S$. The units of D are cm^2/s and those of S, ml/cm^3 per cmHg, e.g. ml O_2/cm^3 (H_2O) per cmHg.

Two additional terms that are sometimes used are oxygen flux (F), which is the volume of gas passing per unit time through unit area of a membrane under given experimental conditions (for example, pressure difference, temperature) and oxygen transmission rate (TR) which is the amount of gas passing in unit time through a unit area of a membrane of given thickness under unit gas pressure gradient. The units of F are ml/cm^2 per s and those of TR, ml (STP)/(cm^2 s cmHg). In order to convert transmission rates (sometimes referred to as transmissibility, *see* Chapter 11, p. 361) to permeability coefficients the value is multiplied by sample thickness; for example, $TR \times$ sample thickness = P.

To convert oxygen flux values to permeability coefficients, it is first necessary to change the volume of gas to its value under conditions of standard temperature and pressure (STP) and then to multiply by sample thickness and divide by the oxygen pressure gradient across the sample; for example, F (converted to STP) $\times$ sample thickness $\times$ 1/oxygen pressure gradient = P.

The units of P are preferably (ml(STP) mm)/(cm^2 s cmHg) but may contain alternative terms for thickness (cm, mm), time (min^{-1}, h^{-1}, day^{-1}), volume (cm^3), area (m^2, 100 in^2) or pressure gradient (atm^{-1}, mmHg^{-1}). In addition,

units are sometimes 'simplified' by dividing or multiplying top and bottom by a common factor such as cm or mm. One of the most common examples is the conversion:

$$\frac{\text{ml(STP)cm}}{\text{s cm}^2\,\text{mmHg}} \times \frac{\text{cm}}{\text{cm}} = \frac{\text{ml(STP)}\,\text{cm}^2}{\text{s cm}^3\,\text{mmHg}}$$

The two sets are identical but the right-hand units may now be expressed as:

$$\frac{\text{ml O}_2\,\text{cm}^2}{\text{s ml mmHg}}$$

or (cm^2/s) $(\text{ml O}_2/\text{ml} \times \text{mmHg})$ as used by Fatt (*see* Chapter 11)

When dealing with strange or unrecognizable units it is advisable to (1) change millilitres to cubic centimetres and (2) try multiplying both top and bottom of the equation by the same factor, for example

$$\frac{\text{cm}}{\text{cm}}$$

until one of the recognizable forms of units listed below is reached. Remember also that the value quoted may be an oxygen flux or transmission rate, especially if the determination was carried out on a lens. In such cases the quoted figure must be multiplied by sample thickness, or thickness and pressure gradient, as indicated above.

The more commonly encountered units of oxygen permeability are related as shown below.

1 $(\text{ml(STP)mm})/(\text{cm}^2\,\text{s cmHg})$
or $\text{ml(STP)}\,\text{mm}\,\text{cm}^{-2}\text{s}^{-1}\text{cmHg}^{-1}$
or $(\text{cm}^3\text{(STP)}\,\text{mm})/(\text{cm}^2\,\text{s cmHg})$
or $\text{cm mm s}^{-1}\,\text{cmHg}^{-1}$

is equivalent to

0.1 $(\text{ml(STP)}\,\text{cm})/(\text{cm}^2\,\text{s cmHg})$
or $\text{ml(STP)}\,\text{cm}\,\text{cm}^{-2}\,\text{s}^{-1}\,\text{cmHg}^{-1}$
or $(\text{cm}^3\text{(STP)cm})/(\text{cm}^2\,\text{s cmHg})$
or $\text{cm}^2/\text{s per cmHg}$
or $(\text{cm}^3\text{(STP)}/(\text{cm s cmHg})$

is equivalent to

0.1 $(\text{ml(STP)}\,\text{mm})/(\text{cm}^2\,\text{s mmHg})$
or $\text{ml (STP)}\,\text{mm}\,\text{cm}^{-2}\,\text{s}^{-1}\,\text{mmHg}^{-1}$
or $(\text{cm}^3\text{(STP)mm})/(\text{cm}^2\,\text{s mmHg})$
or $(\text{cm mm})/(\text{s mmHg})$
or (cm^2/s) $(\text{ml O}_2/\text{ml mmHg})$ as illustrated in the example above

is equivalent to

0.01 $(\text{ml(STP)cm})/(\text{cm}^2\,\text{s mmHg})$
or $(\text{cm}^3\text{(STP)cm})/(\text{cm}^2\,\text{s mmHg})$
or $(\text{cm}^2/\text{s per mmHg}$
or $(\text{cm}^3\text{(STP))}/(\text{cm s mmHg})$

is equivalent to

7.6 $(\text{ml(STP)cm})/(\text{cm}^2\,\text{s atm})$
or $(\text{cm}^3\text{(STP)}\,\text{cm})/(\text{cm}^2\,\text{s atm})$
or $\text{cm}^2/\text{s per atm}$
or $(\text{cm}^3\text{(STP)}/(\text{cm s atm})$

is equivalent to

2.59×10^{12} $(\text{ml(STP) ml})/(\text{day m}^2\,\text{atm})$
or $(\text{cm}^3\text{ (STP) ml})/(\text{day m}^2\,\text{atm})$

is equivalent to

16.5×10^{10} $(\text{ml(STP)ml})/(\text{day (100 in)}^2\text{atm})$

is equivalent to

1.02×10^{10} $(\text{in}^3\text{ ml})/(\text{day (100 in)}^2\text{ atm})$

is equivalent to
$7.69 \times 10^{-6}\,\text{cm}^4/\text{s}$ per dyn.

Addendum 2

Abridged patent compilation: hydrogel materials

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Wichterle, O. (1970) (to Czeskoslovenska Akademie Ved) Method of manufacturing soft and flexible contact lenses. US Patent 3 496 254

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Abridged patent compilation: RGP and related materials

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Chapter 4

Drugs and solutions in contact lens practice and related microbiology

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General microbiology p. 93
Microbiology of the eye p. 96
Contact lens solutions p. 104
Formulation p. 104
Solutions for rigid lenses p. 105
Solutions for hydrophilic lenses p. 110
Scleral lens solutions p. 141
Ophthalmic preparations p. 141

This chapter is divided into four major sections covering general microbiology, microbiology of the eye, contact lens solutions and ophthalmic preparations. This first section will describe general features of micro-organisms associated with human disease, microbiology of the eye and organisms associated with ocular disease, ocular defence mechanisms and how these may be affected by contact lens wear.

General microbiology

A wide range of micro-organisms are implicated as causative agents in infective and inflammatory disease. A detailed description of these is outside the scope of this text, however a summary of relevant characteristics will assist our understanding of some interactions between organisms and the ocular and contact lens environment.

Chemical composition

Micro-organisms consist of nucleic acids and proteins. The nucleic acids may be either DNA (deoxyribonucleic acid) or RNAs (ribonucleic acids). DNA serves to code genetic information which determines the phenotype of the organism and RNA molecules participate in protein synthesis. Each organism also contains a unique array of enzymes which determine its metabolic activity. These enzymes regulate cellular reactions and the biosynthesis of macromolecules from nutrients derived from the environment.

Physical composition

The structural unit of fungi and algae is termed a eukaryotic cell, and is more complex than the prokaryotic cell of bacteria. Prokaryotic cells have a single chromosome (genome), whereas eukaryotic cells have multiple chromosomes. Eukaryotes and prokaryotes also differ in their transmission and expression of genetic material, metabolic processes, and entry and exit of metabolites. Bacterial cells have an average diameter of approximately 1–2 μm, viral cells <0.5 μm, fungal cells 3–5 μm and protozoans 15–30 μm.

Micro-organisms are commonly unicellular or acellular and include most bacteria, algae, viruses, protozoans and some fungi. Most of these cells are bounded by a cytoplasmic membrane, a double layered structure of lipid and protein, which encloses all structures and molecules for the maintenance of biological function. It acts as a semi-permeable membrane and controls the passage of solutes between the cell and external environment.

Multicellular organisms may arise from a single cell, however single cells may also attach to each other to form threads or filaments, while still functioning as a single cell. Some bacteria and algae exist in this form. Coenocytic structures are those not composed of discrete cellular sub-units, but which have a continuous cytoplasm. Such organisms, including some fungi and algae, grow in size without undergoing cellular division.

Bacteria

Bacteria are classified according to their morphology, staining characteristics, growth requirements, biochemical type or antigenic structure (Sleigh and Timbury, 1981).

Morphology

- Spherical, known as cocci. Depending on the plane in which cocci divide, they may form pairs (diplococci), fours (tetrads), chains or clusters.
- Cylindrical, known as bacilli or rods. Coccobacilli have a more rounded appearance.
- Helical, known as spirochaetes.

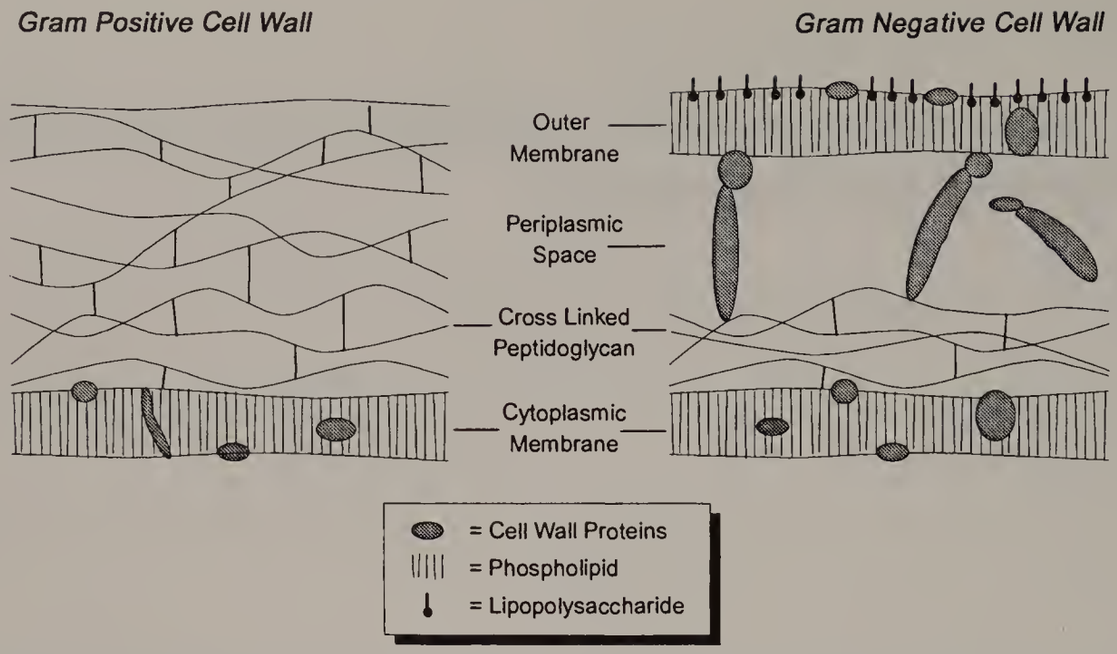


Figure 4.1 Gram-positive and Gram-negative bacterial cell walls. The cytoplasmic membrane of the Gram-positive organisms is surrounded by a thick cross-linked peptidoglycan layer. Gram-negative organisms, in contrast, have a thinner peptidoglycan layer and outer protein membrane with lipopolysaccharide, enclosing the periplasmic space

Cell wall

Bacteria are grouped by their Gram staining reaction*, which reflects the structure of the cell wall. The cell wall of Gram-positive organisms comprises a cytoplasmic membrane surrounded by a thick peptidoglycan layer (a mucopeptide of alternating N-acetyl muraminic acid and N-acetyl glucosamine), cross-linked with peptide sub-units and interspersed with teichoic or teichuronic acid (*Figure 4.1*). In contrast, Gram-negative organisms have a cytoplasmic membrane, with a smaller peptidoglycan layer, surrounded by an outer protein membrane and lipopolysaccharide, enclosing the periplasmic space. External structures may also be present, such as flagella, pili and capsules. Flagella are filaments of the protein flagellin, which are responsible for bacterial motility. Pili are shorter filaments of the protein pilin which emerge from the cytoplasmic membrane. These are responsible for bacterial adhesion and the transfer of genetic material. Capsules are frequently a polysaccharide matrix comprising the outermost layer of certain bacteria. Capsules are a major determinant in the virulence of an organism, which act by protecting the bacteria from phagocytosis and from other antimicrobial agents.

* The Gram staining procedure involves sequentially staining a heat fixed smear of bacterial cells with crystal violet, iodine, decolorizing with an organic solvent and counterstaining. Gram-positive bacteria resist decolorization and remain stained dark blue. Gram-negative bacteria decolorize and take up a red/pink counterstain.

Growth requirements

Bacteria can be further classified according to their environmental requirements for growth.

Atmospheric conditions:

- Aerobes – require oxygen for growth
- Facultative anaerobes – grow in the presence or absence of oxygen
- Anaerobes – grow only in the absence of oxygen
- Microaerophiles – grow in the presence of trace oxygen and carbon dioxide

Temperature range for optimal growth:

- Thermophile: 55–80 °C
- Mesophile: 25–40 °C
- Psychrophile: below 20 °C

Bacteria may also be differentiated based on carbohydrate metabolism, protein metabolism, enzyme production or other specific biochemical reactions. For organisms which are biochemically similar, other methods of typing include:

- Bacteriophage typing – differentiation on the basis of susceptibility to various bacterial viruses.
- Bacteriocine typing – differentiation on the basis of inhibitory protein (bacteriocine) production. Organisms produce proteins which inhibit the growth of other members of the same species.
- Immunological techniques – differentiation on the basis of antigenic structure.
- DNA typing – differentiation at the DNA level.

Bacteria and disease

Bacteria may cause disease either by direct invasion of tissue and subsequent replication of microorganisms, or through toxin or enzyme production, which may in turn activate the immune system, causing an inflammatory tissue response. Dead or dying bacteria also release toxins. In disease associated with Gram-negative organisms, endotoxin has been implicated as a cause of major tissue damage. Endotoxin is an outer membrane component of Gram-negative organisms, comprised of lipopolysaccharide (LPS), which is known to cause antibody and cytokine production, neutrophil migration and complement activation.

Fungi

Fungi can be either unicellular organisms which reproduce by budding (yeasts) or multicellular organisms (moulds) which extend filaments (hyphae) and interweave to form a mycelium (Dixon and Fromtling, 1991). Dimorphic fungi exist in either form depending on environmental conditions. All fungi are either aerobes or facultative anaerobes. Structurally, fungi are larger than bacteria, contain multiple chromosomes, with the cytoplasm containing mitochondria and endoplasmic reticulum. There are four main groups of fungi, which are differentiated on the basis of spore type and mode of spore production. Asexual spore production involves mitotic division, and sexual production involves miotic division. All four groups may include both yeasts and moulds.

- **Zygomycetes/Phycomycetes** Asexual or sexual spores termed sporangiospores, which are contained in a walled sporangium. Group includes *Rhizopus* spp. and *Mucor* spp.
- **Ascomycetes** Asexual or sexual spores termed ascospores, produced exogenously within a containing sac. Group includes *Arthroderma* spp. and *Saccharomyces* spp.
- **Basidiomycetes** Asexual or sexual spores termed basidiospores, produced exogenously within a club-shaped cell. Group includes the mushrooms, *Amanita* spp. and *Agaricus* spp.
- **Deuteromycetes** Sometimes called Fungi Imperfecti, as this group is unable to reproduce sexually. The spores are termed conidia. Group includes *Aspergillus* spp., *Candida* spp., *Alternaria* spp., *Phoma* spp. and *Penicillium* spp.

Fungi and disease

Fungal disease in humans frequently includes infections of keratinized tissue, such as ringworm. Generally fungi are unable to penetrate deeper in the body due to inhibitory factors present in serum, hence systemic infections are rare. Fungi often induce indolent chronic disease processes, but depending on the host response, this may range from mild to severe. Yeasts are a major cause of infections particularly in immunosuppressed hosts such as cancer sufferers undergoing chemotherapy, AIDS sufferers, transplant patients and other long-term corticosteroid users. Endocarditis and fungaemia due to indwelling catheters are common manifestation of yeast infections.

Viruses

Viruses are acellular obligate parasites, which differ from cellular organisms in structure, chemical composition and mode of growth. They exist in either an extracellular or intracellular form. The extracellular form or virion comprises DNA or RNA molecule(s) within a protein coat or capsid (see Stainer *et al.*, 1981, for review). The virion contains no structures for growth or multiplication and therefore requires a host cell to undergo replication. Viruses are specific for either animal, plant or bacterial cells (bacteriophages), and invade by binding to cell surface receptors and penetrating the cell membrane. In the intracellular phase, the capsid disappears, and the genetic material and specific capsid proteins of the virus are replicated by the host cell.

Viruses and disease

Viruses relevant to human disease include herpes, rubella, flu, AIDS, mumps, adeno, smallpox and papilloma. Members of certain virus groups have also been shown to be oncogenic (tumour producing) in animals, although their role in human cancers is unclear.

Protozoans

Protozoans comprise a number of groups of unicellular organisms. Members are subdivided into four classes, based on motility and reproduction. Each of these groups contain isolates capable of human infection.

- **Mastigophora** Flagellate protozoans in which motility is achieved by means of flagella. This group includes parasitic gut protozoans, such as *Giardia* spp., along with *Trichomonas* spp. which causes genitourinary tract infections and *Trypansoma* spp. which causes sleeping sickness.
- **Rhizopodia** Amoeboid protozoans in which motility is achieved by the extension of pseudopodia and reproduction is by binary fission. Most are free living organisms which phagocytose smaller organisms in soil or water. Human infectious agents include *Entamoeba* spp., which causes amoebic dysentery, *Naegleria* spp., which causes meningocncephalitis and *Acanthamoeba* spp., which causes ocular infections (*Figure 4.2*).
- **Sporozoa** Non-motile or gliding protozoans. These reproduce by multiple fission. Those of human significance include *Plasmodium* spp., which causes malaria and *Toxoplasma* spp., which causes disseminated infections.

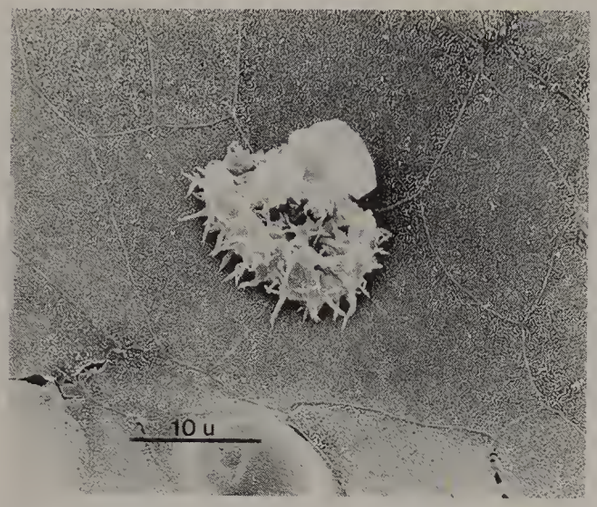


Figure 4.2 Scanning electron micrograph of an *Acanthamoeba* trophozite on human corneal epithelium. The shell of a cyst is attached to it, from which presumably it has recently emerged

- **Ciliata** Ciliated protozoans which move using cilia present on the cell surface. These are less frequently implicated in human disease, but *Balantidium* spp. may cause dysentery.

A more comprehensive review of general microbiology can be found in the following publications: Balows, A., Hausler, W. J., Herrmenn, K. L., Isenberg, H. D. and Shadowmy, H. J. (eds), *Manual of Clinical Microbiology*; Stainer R. Y., Adelberg, E. A. and Ingraham, J. L. (eds), *General Microbiology*; Sleigh, J. D. and Timbury, M. C. (eds), *Notes on Medical Bacteriology.*

Microbiology of the eye

The human eye may be sparsely colonized by several organisms, the most common of which include coagulase-negative Staphylococci and *Corynebacterium* spp. (Soudakoff, 1954; McNatt *et al.*, 1978; Perkins *et al.*, 1975; Rauschl and Rogers, 1978; Ugomori *et al.*, 1990). Such organisms are part of the spectrum of the normal skin flora and are generally considered to be non-pathogenic. It has been estimated that 50% of individuals harbour organisms at some time, and a recent study has shown that immediately upon eye opening, increased numbers of such presumed non-pathogenic organisms are present (Holden *et al.*, 1993). Increased flora appears to be present on the lid compared with the conjunctiva (Larkin and Leeming, 1991), and the conjunctival fornices may harbour small numbers of anaerobic organisms, *Propionibacterium* and *Peptostreptococcus* being the commonest genera (Perkins *et al.*, 1975; Fleiszig and Efron, 1992b). However, it is unclear whether this flora comprises resident or temporary organisms, since only small numbers of organisms are consistently cultured. It appears that a state of equilibrium exists, whereby organisms are constantly cleared from the ocular surface, rather than leading to persistent and increased colonization with time.

Microorganisms in ocular disease

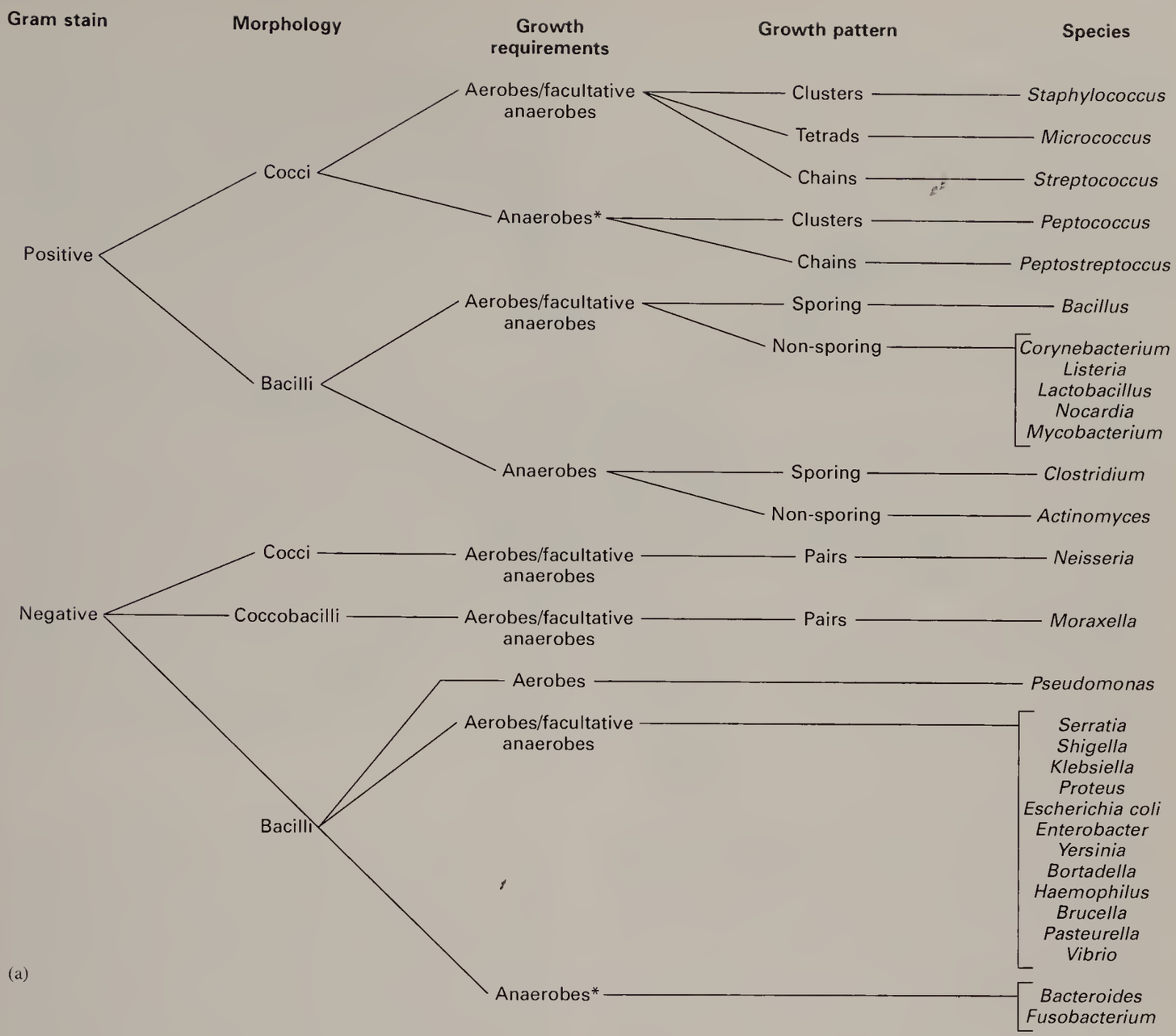
The bacterial species associated with ocular infections are opportunistic pathogens, mainly facultative anaerobes or strict aerobes, although anaerobic organisms have been associated with canaliculitis (Seal *et al.*, 1981). Blepharitis is commonly associated with staphylococci, particularly *Staphylococcus aureus*, although *Staphylococcus epidermidis* may be associated with blepharitis in a compromised host. The organisms most frequently associated with acute conjunctivitis include: *Staphylococcus aureus, Streptococcus pneumoniae, Streptococcus pyogenes* (Wilson, 1979) and *Haemophilus influenzae* (Seal *et al.*, 1982), less commonly *Proteus* spp. (Piccolo, 1989), *Moraxella* spp. and anaerobic species (Perkins *et al.*, 1975) may also be associated. In infants, bacterial conjunctivitis may be caused by *Neisseria* spp. Viral conjunctivitis is frequently attributed to herpes, adenovirus and chlamydiae. Bacterial keratitis is frequently associated with *Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus pneumoniae, Pseudomonas aeruginosa* and less commonly by other Gram-negative organisms, such as *Moraxella* spp. and *Serratia* spp. (Limberg, 1991). Fungi are also a major cause of keratitis, particularly in agricultural environments, with *Candida* spp., *Aspergillus* spp. and *Fusarium* spp. being some of the most common.

Corneal infection in contact lens wear is commonly a bacterial process although, less commonly, fungi (Wilhelmus *et al.*, 1988) and *Acanthamoeba* spp. (Stehr-Green *et al.*, 1989) have also been reported. *Pseudomonas aeruginosa*, a ubiquitous Gram-negative organism, is the causative agent in up to 70% of culture proven cases of lens-associated keratitis (Galentine *et al.*, 1984; Schein *et al.*, 1989). Other Gram-negative causative organisms include *Serratia* spp. (Lass *et al.*, 1981), *Proteus* spp. (Alfonso *et al.*, 1986) and *Pseudomonas* spp. (Wilson *et al.*, 1981). Of the Gram-positive species, *Staphylococcus aureus* is the most common causative agent in microbial keratitis (Galentine *et al.*, 1984). The association between microbial conjunctivitis and contact lens wear is, however, not well established, although *Staphylococcus aureus* has been implicated as a causative agent. Other common inflammatory responses such as acute red eye (Baleriola-Lucas *et al.*, 1991) and sterile peripheral infiltrates (Bates *et al.*, 1989) have been associated with the presence of Gram-negative bacterial contamination of the contact lenses or lens care materials.

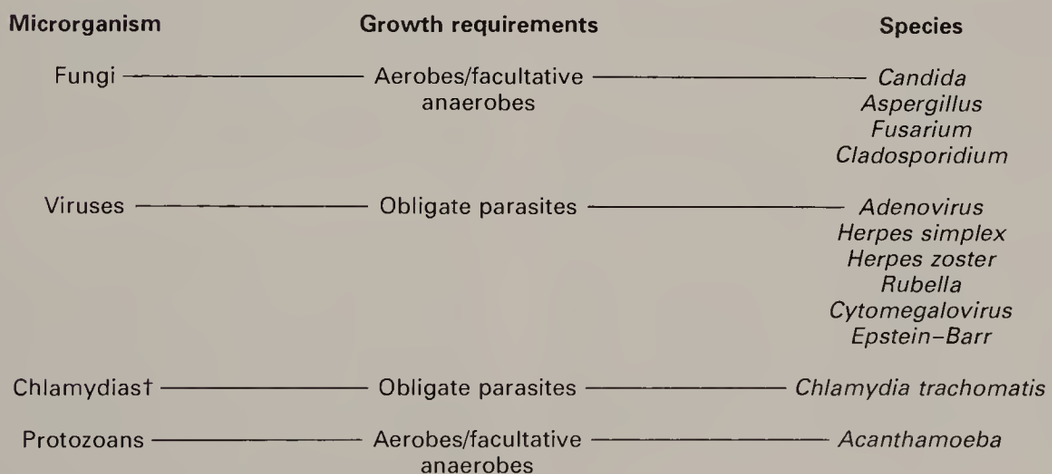
Figures 4.3a and *b* summarize the common organisms associated with ocular infections and their classification.

Ocular defence mechanisms

Several mechanisms have evolved to prevent invasion or damage by pathogens or toxins. These can be divided into immune and non-immune mechanisms.



(a)



(b)

* In this simplified classification, anaerobes include microaerophilic organisms.

† Chlamydias were once believed to be large viruses as they are intracellular parasites; however, they demonstrate cellular characteristics of bacteria, and are usually classified as bacteria. In the ocular environment *C. trachomatis* causes trachoma and inclusion conjunctivitis.

Figure 4.3 (*a*) Classification of common bacteria associated with external ocular infections. (*b*) Classification of common organisms associated with external ocular infections

Non-immune mechanisms

1. Blinking and tear flow

Basal tear production occurs at a rate of 1 µl/minute and with the action of blinking, an active tear flow washes the ocular surface and sweeps debris and microorganisms towards the puncta (Holly and Lemp, 1977). Rapid tear production, reaching 50 µl/minute (Holly, 1981) during reflex tearing, further enhances this process.

2. Intact epithelium and epithelial cell desquamation

An intact corneal epithelium prevents penetration by micro-organisms. The majority of opportunistic pathogens require epithelial trauma to effect adherence and are unable to adhere to intact cells (Stern *et al.*, 1982; Stern *et al.*, 1985). Certain organisms may cause infection in the absence of an epithelial defect, these include *Neisseria gonorrhoae, Corynebacterium diphtheriae* (Hyndiuk *et al.*, 1986) and *Acanthamoeba* spp.

Cell desquamation sheds adherent organisms along with sloughed cells, such that to maintain persistent colonization of a mucosal surface requires adherence to newly exposed epithelial cells. Frequent desquamation inhibits surface colonization by micro-organisms.

3. Antibacterial tear proteins (Smolin, 1987)

Lysozyme A bacteriolytic protein synthesized by the lacrimal gland, which comprises 20–40% of the total tear protein. Lysozyme cleaves bonds in the rigid peptidoglycan layer of Gram-positive and some Gram-negative organisms (*see Figure 4.1*), rendering them more susceptible to lysis. Gram-negative organisms with a lipopolysaccharide layer above the peptidoglycan layer are less susceptible to lysozyme.

Lactoferrin and transferrin Both proteins are involved in non-specific defence through their iron binding capability. Transferrin is a serum-derived protein and lactoferrin is derived from the lacrimal gland. Each protein binds two iron atoms, preventing their uptake by micro-organisms. Lactoferrin may also have a direct antimicrobial effect (Arnold *et al.*, 1982) against certain Gram-positive and Gram-negative organisms, by destabilization of the bacterial outer membrane. Additionally lactoferrin acts as an opsonin for certain micro-organisms (Rainard, 1993), rendering them more suceptible to phagocytosis. Lactoferrin also modulates complement activation via the classical pathway (Kijlstra and Jeurissen, 1982; Rainard, 1993) and may modulatc the inflammatory responses by regulating lymphocyte proliferation and cytokine production (Kijlstra, 1991).

Tear lipocalins (Tear-specific pre-albumin/proteins migrating faster than albumin – PMFAs) – a group of antibacterial proteins present in tears but not in serum and produced by the lacrimal gland (Bonavida *et al.*, 1969; Delaire *et al.*, 1992). These proteins are not related to albumin, and their precise functions and mode of action remains unknown (Selsted and Martinez, 1982), although they are known to have a bacteriostatic effect. Protein G is thought to be a denatured form of tear-specific pre-albumin, visible on gel electrophoresis (Baguet *et al.*, 1992).

Interferon An antiviral agent, induced by virus presence in the tear film.

Betalysin A protein thought to have similar activity to lysozyme, whereby bacterial cell membranes are ruptured. Its precise function remains controversial (Ford *et al.*, 1976; Janssen *et al.*, 1984).

Other tear components include serum proteins such as albumin (Smolin, 1987), fibronectin, vitronectin, laminin and complement proteins (*Figure 4.4*). These are thought to leak into the tear film from the conjunctival capillaries (Janssen and van Bijsterveld, 1983). Increased leakage of both fibronectin (Fukuda *et al.*, 1993 and vitronectin (Sack *et al.*, 1993) from serum occurs overnight. Such serum proteins are likely to act as opsonins, enhancing bacterial phagocytosis. Bacteria are known to possess adhesins for binding to these serum protcins, although the exact role of such molecules in preventing ocular infection and inflammation is not clear.

4. Ocular mucin

A large glycoprotein of molecular weight 200 kD which exists as a membrane bound layer on the ocular surface and extends into the aqueous layer. This mucin layer is comprised primarily of carbohydrates and is produced by conjunctival goblet cells with some elements from the lacrimal gland and other conjunctival cells. Mucin is likely to prevent an antigen contacting and adsorbing to the epithelial cell membrane and may enhance removal and lysis of microorganisms from the ocular surface. Mucin also binds strongly to bacteria and facilitates clearance from the ocular surface. Mucin has been implicated as a protective mechanism in bacterial keratitis since, in the absence of mucin, bacterial adherence to the cornea is increased (Fletcher *et al.*, 1993).

5. Resident mucosal biota

Resident mucosal biota is likely to mediate normal defence mechanisms. *Propionibacterium* spp. havc been implicated in non-specific defence mechanisms in non-ocular sites (Roszkowski *et al.*, 1990). Ocular biota studies have implied that a synergistic relationship between *Staphylococcus epidermidis* and *Corynebacterium* spp. exists whereby *Staphylococcus epidermidis* produces growth factors for *Corynebacterium* spp. (Allansmith *et al.*, 1969; Rauschl and Rogers, 1978). Additionally normal biota may produce antimicrobial agents which inhibit colonization by pathogenic organisms (Jensen and Gluud, 1985). In the

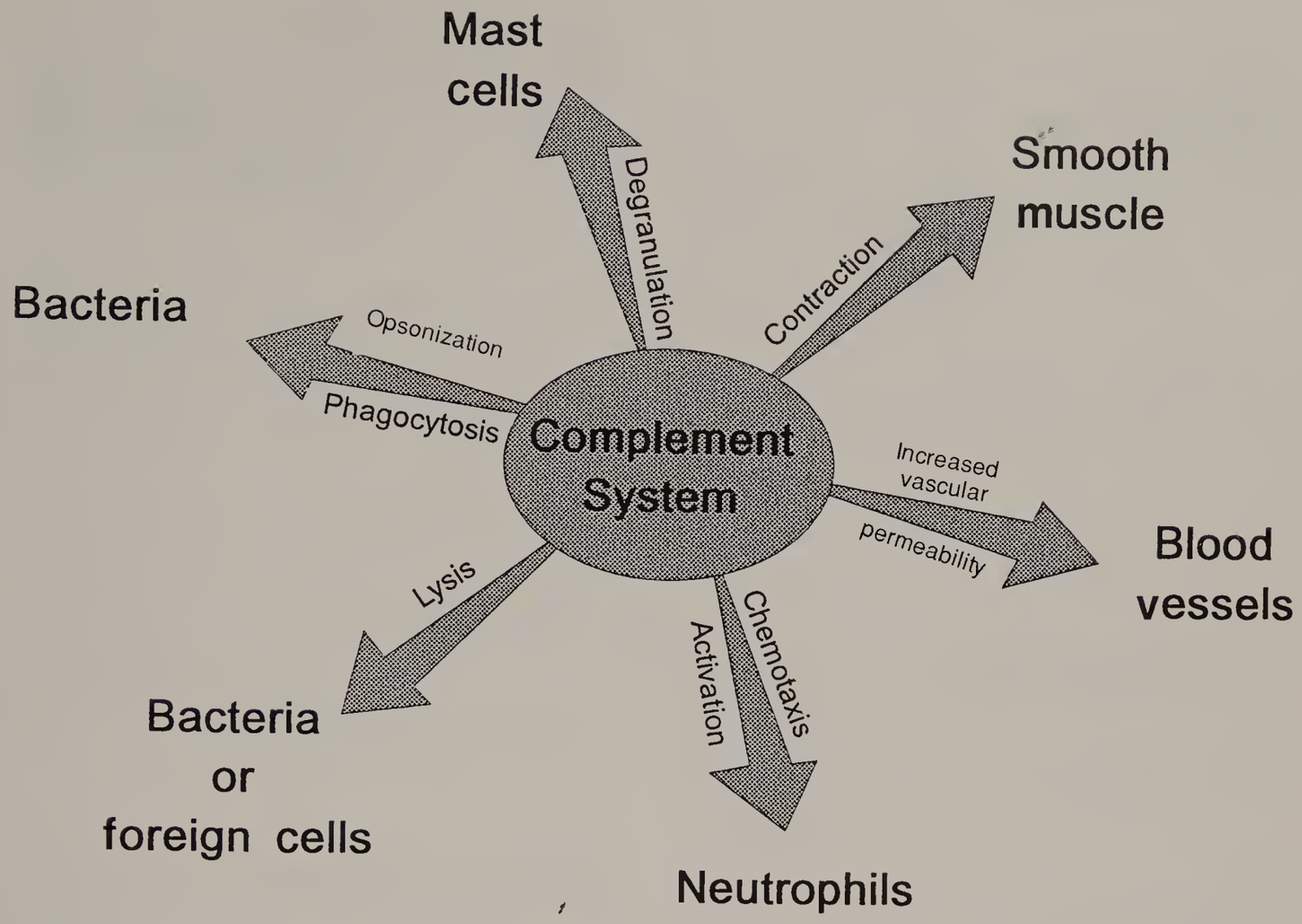


Figure 4.4 Simplified functions of the complement system

nasal mucosa, there is evidence that *Staphylococcus epidermidis* and *Corynebacterium* spp. retard colonization by *Staphylococcus aureus* (Drutz and Mills, 1980).

These factors may be significant in maintaining normal ocular biota and defence mechanisms. The mechanisms for such biota modulation are not always clear, although biocompetition of organisms for metabolites, production of toxins or antibacterial products by resident biota, have been postulated.

6. Anti-adherence factors

There is some evidence that the cornea produces non-specific anti-bacterial adherence factors. One possible candidate is fibronectin, which is present in both serum and connective tissue. In the cornea, it enhances epithelial cell adhesion, migration (Fukuda *et al.*, 1990) and wound healing (Nishida, 1988) *in vitro* and may also be released through damage to corneal epithelial cells. Fibronectin has been shown to modulate bacterial adherence to epithelial cells in other mucosal systems (Woods *et al.*, 1981). It has been postulated that lens wear may reduce levels of fibronectin present on the corneal epithelial cell surface and facilitate bacterial adherence (Fleiszig and Efron, 1988). Other non-specific anti-adherence factors may include surfactant agents present in tears and possibly sIgA (*see below*).

Immune mechanisms

Secretory IgA (sIgA)

Mucosal surfaces produce a secretory component which binds to serum IgA, to produce a specific protective mechanism. In the ocular environment, sIgA is produced by plasma cells within the lacrimal gland (Franklin, 1989). Several functions of sIgA have been postulated, including inhibition of bacterial adherence to epithelial surfaces, neutralization of toxins and viruses, and prevention or modulation of antigen uptake by epithelial cell membranes (McNabb and Tomasi, 1981). SIgA also activates the alternative complement pathway, and there is some evidence that sIgA and lysozyme have a synergistic lytic effect on bacteria in the presence of components of the alternative complement pathway (*Figure 4.5*) (Hill and Porter, 1974).

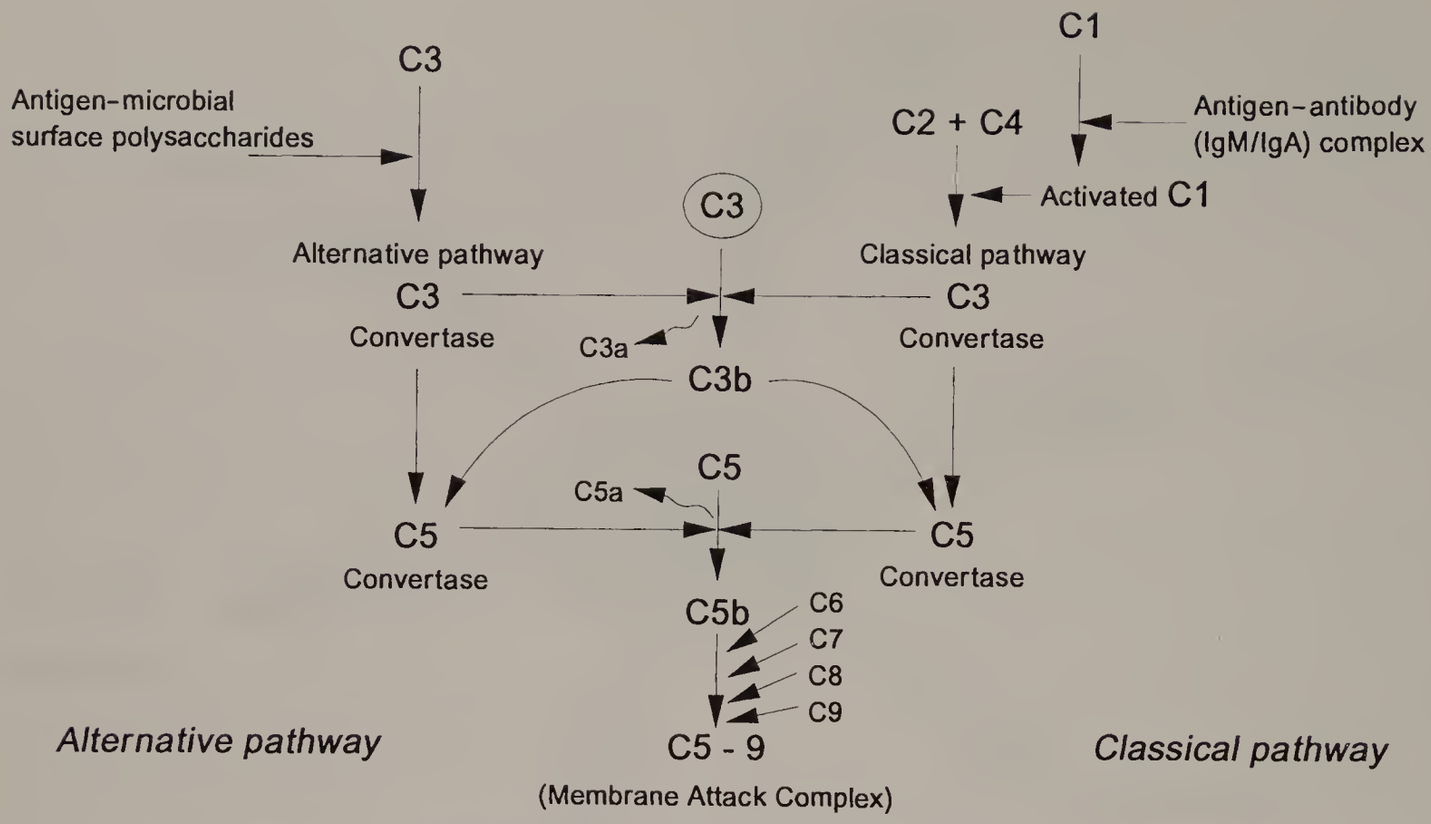


Figure 4.5 Simplified complement pathway, showing the classical and alternative complement pathways

IgG

An immunoglobulin present in serum and tears, which acts as an opsonin, assisting in the removal and lysis of bacteria and neutralization of viruses. It is produced by the conjunctival epithelium and to a lesser extent by the lacrimal gland. IgG is known to activate the classical pathway of complement, resulting in the release of anaphylotoxins and membrane attack complex. Levels of IgG increase significantly during acute inflammation, due to increased vascular permeability. Raised tear IgG has been reported in cases of viral corneal ulcers (Lal *et al.*, 1990) and in adenovirus conjunctivitis (Gupta and Sarin, 1983), although in bacterial corneal ulcers, tear IgG remains unchanged.

IgE

A tear immunoglobulin derived from serum, although a locally synthesized component is also likely. IgE is responsible for Type I hypersensitivity reactions, and specific IgEs are present in the tears of individuals with ocular allergic diseases (Leonardi *et al.*, 1993).

IgM

An immunoglobulin present in serum and in trace amounts in tears (Coyle and Sibony, 1986).

Cell-mediated immune responses

Cellular components present in the tear film include desquamated epithelial cells and leucocytes. In acute inflammation or injury, these include polymorphonuclear leucocytes, lymphocytes, plasma cells, lysozomal components, cytokines, leukotrienes, prostaglandins, heparin and macrophages. Both pro- and anti-inflammatory mediators are present. Complement proteins are also present in small quantities in the tear film, although whether these components are functional remains to be established.

Effects of eye closure

A recent observation has shown differences in tear composition between open and closed eye tears. Scrum protein levels were shown to increase during eye closure, suggesting leakage from local blood vessels. Additionally activated complement proteins were present (Sack *et al.*, 1992b) and activation of plasmin occurred (Sack *et al.*, 1992a). Levels of sIgA increased massively, with a concomitant increase in numbers of polymorphonuclear leucocytes and sloughed epithelial cells (Tan *et al.*, 1993). From these findings, the closed eye environment appears to represent a state of subclinical inflammation, possibly in response to increased numbers of microorganisms. This could represent a protective mechanism in normal eye closure, to prevent microbial colonization during sleep, when other mecha-

nisms such as tear flow and lysozyme levels are reduced. However, such a potential inflammatory environment would also render the ocular tissue at a higher risk of immune mediated damage. It has been postulated that vitronectin, a multidomained glycoprotein, has a major role in the inhibition of plasmin and complement mediated tissue damage, and raised levels of vitronectin have been demonstrated in the closed eye environment (Sack *et al.*, 1993).

Effects of contact lens wear in modifying the inflammation/infection defence mechanism

Contact lens wear has the potential to modify the susceptibility of the cornea to infective and inflammatory disorders, although the exact mechanisms by which this occurs are likely to be multifactorial and have not been fully established. Possible relevant factors and how they relate to both specific and non-specific ocular defence mechanisms are summarized in *Table 4.1*, and will be discussed in more detail in the following section. These effects of lens wear include interference with tear flow dynamics, epithelial microtrauma, altered ocular biota, altered tear proteins and lens/bacteria interactions.

Disruption of normal tear resurfacing and tear flow dynamics

This will result in less efficient clearing of debris and micro-organisms from the ocular surface. It is well established that tear exchange with hydrogel lenses is limited (Polse, 1979)

Table 4.1 Summary of ocular defence mechanisms and their modification during lens wear

Ocular defence mechanism	*Effect of contact lens wear*
Blinking and tear flow results in the removal of debris and micro-organisms	Limited tear exchange with hydrogel lenses Less efficient clearing of debris Disruption of normal lid/tear resurfacing mechanism
An **intact corneal epithelium** inhibits bacterial adherence. Organisms adhere to damaged cells and infection requires an epithelial defect.	Microtrauma due to metabolic and mechanical effects
Cell desquamation prevents persistent colonization of the ocular surface	Reduced desquamation rate, such that there is the potential for retaining organisms at the ocular surface for longer
Antibacterial tear proteins: Lysozyme – bacteriolytic; acts by cleaving bonds in peptidoglycan layer Lactoferrin – chelates iron, destabilizes the bacterial outer membrane, opsonizes organisms, modulates inflammatory response and complement activation Tear lipocalins – bacteriostatic effect, precise mode of action unknown. Beta lysin – ruptures bacterial cell membranes **Serum proteins** act as opsonins, including albumin, laminin, fibronectin. Vitronectin may also have an additional role in modulating the inflammatory response.	Levels of these tear proteins appear to be unaffected by lens wear, however little information is available on the effect of lens wear on serum proteins
Mucin prevents antigens coming into contact with the epithelial cell membrane and enhances removal and lysis of organisms. Mucin binds strongly to bacteria and in the absence of mucin, bacterial adherence to the cornea is enhanced.	Mechanical effects may affect conjunctival goblet cells and mucin production is affected Stagnation of mucin under a lens may inhibit the normal protective role
Resident mucosal biota may prevent colonization by pathogenic organisms by competing for metabolites, producing toxins and antibacterial products	Lens wear may disrupt the normal ocular biota, although this has not been proven in all cases. Inhibition of clearing of pathogenic organisms may occur. The lens may act as a vector for organisms to the cornea. Bacterial adherence to and colonization of lenses may enable organisms to proliferate and to be retained at the ocular surface for prolonged periods
Immunoglobulins. sIgA, IgG and IgM have a variety of functions including inhibition of bacterial adherence, neutralization of toxins, modulation of antigen uptake, opsonization and activation of complement	Uncomplicated lens wear appears not to modify the levels of tear immunoglobulins, although individual variations are often large and small differences may not be detected
Anti-adherence factors such as fibronectin and sIgA	It has been postulated that lens wear may reduce cell surface fibronectin and enhance bacterial adherence
Cellular tear components, including pro- and anti-inflammatory agents are present in the tear film	The effect of lens wear on these components is unclear
Overnight sub-clinical inflammatory environment. During eye closure, sIgA increases and numbers of polymorphonuclear leucocytes increase. This may be a response to the increased bacterial load associated with eye closure	The effect of lens wear on the overnight recruitment of inflammatory mediators is not clear

and further stagnation of tears under lenses will occur during overnight wear.

Epithelial microtrauma

Contact lens wear causes epithelial microtrauma through hypoxia and mechanical effects. Epithelial metabolism (Thoft and Friend, 1975), enzyme activity (Ichijima *et al.*, 1992) and cell mitosis (Hamano *et al.*, 1983) are reduced. Additionally, morphological changes (Lemp and Gold, 1986) and epithelial fragility (Millodot and O'Leary, 1981) have been reported. Animal models have established that lens wear causes impaired epithelial adherence to the basement membrane (Madigan *et al*, 1987) and reduced hemidesmosome density (Madigan and Holden, 1992).

Altered cell desquamation

Contact lens wear alters the life cycle of epithelial cells, resulting in reduced desquamation rate (Hamano *et al.*, 1983). This may enable persistence of organisms on the epithelial surface. In addition, sloughed epithelial cells from contact lens wearers have been shown to adhere more organisms compared with those from non-lens wearers (Fleiszig and Efron, 1992a). This implies further biochemical changes in epithelial cells following wear of lenses.

Altered tear proteins

Levels of tear lysozyme, albumin and lactoferrin have been shown to be unaffected by lens wear (Farris, 1986). Levels of IgG and IgM were also found not to be altered by hydrogel lens wear (Mannucci *et al.*, 1984). There is some controversy as to the effect of lens wear on IgA levels. Studies have reported increased (Mannucci *et al.*, 1984; Temel *et al.*, 1990), unchanged (Sengor *et al.*, 1990) and decreased (Yinding *et al.*, 1987) levels of IgA in lens wear. However, all studies have reported tear IgA levels within the normal range.

It appears that uncomplicated lens wear does not modify the levels of most tear proteins. However, individual variations are often large, and small changes due to lens wear may not have been detectable in these studies.

The effect of contact lens wear on the overnight subclinical inflammatory situation is not understood. The increased risk of microbial and inflammatory disorders with overnight lens use would imply that the equilibrium between improved microbial clearing and immune mediated tissue damage may be disrupted in the presence of a lens worn overnight. It is possible that overnight wear of a lens coated with bacteria results in increased contact between immunoglobulins, polymorphonuclear leucocytes and bacteria/antigens causing an increased inflammatory response and the release of cytokines.

Altered mucin

Lens-induced mechanical effects on the conjunctiva may affect goblet cells, and lens wear has been shown to affect mucin production (Versura *et al.*, 1987), which may enhance bacterial adherence to the cornea. Stagnation of mucin under a lens may also inhibit the normal protective role of mucin.

Non-specific effects

It is well established that lens wear alters both tear pH and temperature under the contact lens. These effects may modify the metabolism of corneal epithelial cells, causing biochemical changes, or may enhance bacterial proliferation.

Disturbances to the resident ocular biota

Alteration of the normal ocular biota during contact lens wear may suppress the ocular defence mechanism and enable colonization by pathogenic organisms. Here again, there is considerable controversy in the literature as to what effect contact lens wear has. Increased conjunctival biota has been reported in hydrogel lens wearers (Morgan, 1979; Callender *et al.*, 1986; Larkin and Leeming, 1991), although the spectrum of organisms was not found to differ. This increase in conjunctival biota may be secondary to quantitative changes in lid margin biota (Larkin and Leeming, 1991). In one study, the conjunctival biota could be related to the contaminants of the contact lens storage case (Morgan, 1979), although no such association was confirmed in a more recent study (Fleiszig and Efron, 1992a). An alteration in the spectrum of organisms was found to occur in a mixed group of rigid and soft lens wearers (Hovding, 1981), where increased numbers of both sterile cultures and Gram-negative organisms were isolated. Other studies, however, have reported no differences in conjunctival biota between lens wearers and non-lens wearers (Tragakis *et al.*, 1973; Rauschl and Rogers, 1978). Despite finding no significant overall differences between wearers and non-lens-wearing controls, Fleiszig and Efron (1992a) found an increased rate of positive cultures in former lens wearers and associated with certain modes of lens wear and disinfection system. Amongst aphakic extended wear lens users, fewer pathogens were recoverable compared with a group of preoperative cataract patients (Smolin *et al.*, 1979).

Increased conjunctival colonization by pathogenic non-resident organisms has been previously demonstrated during extended wear of gas-permeable hard lenses (Fleiszig and Efron, 1992b). Where pathogens are present, adherence of organisms to the contact lens itself may occur, with subsequent lens colonization and the normal mechanism for clearing micro-organisms on eye opening may be impeded. Adherence and colonization of lenses by patho-

genic organisms has been reported in association with lens-related keratitis (Stapleton *et al.*, 1991) and high numbers of pathogenic organisms have been recovered from lenses during episodes of acute adverse responses (Baleriola-Lucas *et al.*, 1991). One possibility is that pathogenic organisms adhere more strongly to lenses and are not removed as easily as normal biota. Disruption to the normal ocular biota may suppress the production of antimicrobial substances produced by resident organisms to inhibit colonization by pathogenic organisms. Non-resident organisms additionally produce proteases which degrade sIgA, which may further compromise the defence mechanisms.

Inhibition of the clearing of pathogenic organisms from the eye during lens wear may be one of several factors modulating this alteration in biota with lens wear. This alteration in biota has been reported as persisting subsequent to ceasing lens wear (Fleiszig and Efron, 1992a). It is not clear however, whether this effect is limited to wearers discontinuing lens wear due to adverse responses, which may have been associated with alterations to the ocular biota.

Lens/bacteria interactions

There is evidence to suggest that the contact lens may act as a vector for organisms to the cornea, either by prolonging retention of organisms on the ocular surface or by organisms colonizing the lens surface in eye. Bacteria have been shown to adhere to unworn and worn lenses *in vitro* (Dart and Badenoch, 1986; Duran *et al.*, 1987; Miller and Ahern, 1987; John *et al.*, 1989). Adherence mechanisms *in vitro* and *in vivo* are likely to differ significantly, and it is controversial whether organisms adhere in greater numbers to worn or unworn lenses (Miller *et al.*, 1988; Aswad *et al.*, 1990; Butrus and Klotz, 1990; Boles *et al.*, 1992). Adhesion is dependent on the lens surface and material characteristics and on the species and strain of organism. It has been demonstrated that bacterial cell surface hydrophobicity is an important determinant of adherence to hydrogel lenses (Klotz *et al.*, 1989).

Bacterial adhesion is relevant in retaining organisms on a lens surface sufficiently for colonization to occur. The predominant mode of growth for bacteria within natural ecosystems is within glycocalyx enclosed microcolonies, forming a biofilm on inert surfaces (Costerton and Irvin, 1981), mucosal surfaces (Gristina and Costerton, 1984), in osteomyelitis (Gristina *et al.*, 1985) and on the surfaces of prostheses (Jacques *et al.*, 1992). Motile bacterial cells, lacking this protective mechanism (swarmer or planktonic cells), are released from the body of the biofilm to invade surrounding tissues or to colonize further surfaces. Within this favourable adherent environment, propagation of organisms is enhanced and enclosed organisms are protected from host defences (Gristina and Costerton, 1984) and antibiotics (Anwar *et al.*, 1990). Formation of such a bacterial biofilm on lenses will result in increased numbers of organisms and prolonged exposure to the cornea. This has been demonstrated in an animal model, with a well-developed biofilm present within 3 days (Dart *et al.*, 1988). A polysaccharide rich biofilm has been demonstrated on lenses incubated with bacteria *in vitro* (Stapleton *et al.*, 1993), on worn lenses *in vivo* (Slusher *et al.*, 1987) and on lenses from wearers with culture-proven microbial keratitis (Holland *et al.*, 1988; Stapleton *et al.*, 1991). The role of biofilm formation in lens-related disease is unclear. However a bacterial biofilm on a contact lens or within a lens storage case renders organisms more resistant to the antimicrobial effects of lens care systems (McCulloch *et al.*, 1988) and will enable organisms to persist on a lens surface, with the potential for tissue damage, either directly or via toxin production.

Potential sources of such contaminating organisms include the ocular biota as described above, endogenous body sites and exogenous environmental sites. Studies of lens contamination have shown that the majority of lenses are contaminated subsequent to patient handling (Hart and Shih, 1987; Mowrey-Mckee *et al.*, 1992a,b). However, lens contamination subsequent to wear is less frequently observed (Mowrey-Mckee *et al.*, 1992a,b); Hart *et al.*, 1993), with coagulase-negative staphylococci the most common isolate. Additionally, Gram-negative organisms are infrequently isolated from lenses of asymptomatic wearers (Hovding, 1981; Hart *et al.*, 1993). In the absence of adhesion and colonization, it appears that normal skin biota is cleared from the lens surface. These studies imply that the fingers are a major source of lens contamination, but that during uncomplicated wear, organisms are removed from the lens surface. Other potential endogenous sources include the upper respiratory tract or gut (Ryan, 1984), although it does appear that contact lens wearers who develop corneal infections are not invariably carriers of the causative organism (Stapleton *et al.*, 1995). Gram-negative organisms associated with lens-related infections tend not to be commensal organisms but are ubiquitous in the environment. *Pseudomonas aeruginosa* is found in moist exogenous environments such as water, soil or vegetation (Ryan, 1984). *Acanthamoeba* spp. have been isolated from the domestic water environment and dust (Seal *et al.*, 1992), and a link has been shown between the amoebic isolate from the corneal ulcer and water supply (Kilvington *et al.*, 1990). It is possible that the fingers may transmit a small inoculum of organisms from such sources to the lens or lens care materials, where under certain conditions adherence and colonization may occur.

Contact lens storage cases have been confirmed as a source of causative organisms in both microbial keratitis (Mayo *et al.*, 1987) and possibly in sterile keratitis (Bates *et al.*, 1989). Additionally, significant bacterial contamination of the lens cases of asymptomatic wearers has been reported (Pitts and Krachmer 1979; Callender *et al.*, 1986; Wilson *et al.*, 1990). Lens storage case contamination has occurred despite reportedly good compliance with a prescribed care regime (Donzis *et al.*, 1987). Contamination of lens storage cases by *Acanthamoeba* spp. has also been reported in

asymptomatic wearers (Donzis *et al.*, 1987; Wilson *et al.*, 1990; Devonshire *et al.*, 1993). Coexisting bacterial contamination in cases with *Acanthamoeba* spp. is thought to be a prerequisite, as amoebae use bacteria as a food source. The persistence of organisms within lens cases despite good lens hygiene, may be related to bacterial biofilm formation. Production of a polysaccharide glycocalyx is enhanced in a nutrient-limited environment (Costerton *et al.*, 1987), and bacteria within a biofilm in lens storage cases has been demonstrated (Campbell and Caroline, 1990; Wilson *et al.*, 1990; Liotet and Rault, 1992). Growth within a biofilm is known to provide resistance to antimicrobial agents, and this has been shown, for a range of lens disinfection regimes, against biofilms artificially generated within lens storage cases (Wilson *et al.*, 1991). Bacteria enclosed within a biofilm on hydrogel lenses (McCulloch *et al.*, 1988) and within lens cases have been shown to be significantly more resistant to antimicrobial agents compared with free bacteria in solution (Wilson *et al.*, 1990). Biofilms within lens storage cases may persist despite compliant hygiene procedures (Campbell and Caroline, 1990), the addition of fresh disinfecting solutions (Wilson *et al.*, 1990) and extensive air drying.

By these strategies, the lens may act as a vector either for organisms derived from the lens case or care materials, or by amplifying a small inoculum derived from environmental sources.

Bacteria/cornea interactions

Bacterial infection of a tissue requires initial bacterial adherence and epithelial trauma has been shown to be a prerequisite for bacterial adherence to the cornea (Hazlett *et al.*, 1975; Ramphal *et al.*, 1981; Hyndiuk, 1981). Interaction then occurs between the bacterial cell and the damaged epithelial cell membrane, followed by bacterial invasion. This process is complex and multifactoral, possibly involving selective receptors, such as carbohydrate moieties, exposed on damaged cells. In an immature mouse model, the host receptor was thought to be sialic acid (Hazlett *et al.*, 1986), and other carbohydrate residues such as mannose may be relevant in other models (Spurr-Michaud *et al.*, 1988). Pili have been shown to mediate bacterial binding to buccal epithelial cells *in vitro*, although non-piliated bacteria also adhere to and penetrate corneal epithelial cells (Hazlett *et al.*, 1991).

If a bacterial glycocalyx is present on the surface of a contact lens during wear, it is possible that a corneal/bacterial glycocalyx may also develop since *Pseudomonas aeruginosa* has been shown to develop a glycocalyx on mucosal surfaces. However, animal models of contact lens-associated infection have been unable to demonstrate a bacteria/cornea glycocalyx, and keratitis has not been shown in the absence of an epithelial defect (DiGaetano *et al.*, 1986).

Contact lens solutions

Formulation

Although contact lens solutions and eye drops are both pharmaceutical products, the way in which they are used puts different requirements on their formulation and presentation. As distinct from contact lens solutions which may remain in use for 3–4 weeks, eye drops in contact lens practice are for single diagnostic or prophylactic use only. Any problems that could arise from the long-term use of drops are most unlikely to appear because their use will be short. Small, single-use containers are the ideal presentation for eye drops but would not always be cost effective for contact lens solutions.

However, contact lens solutions and eye drops do have some requirements in common, e.g. sterility, safety, efficacy.

Sterility is not only important when the solution is first manufactured, but also for its recommended useful life. Single-use containers do not require the presence of a preservative as they are disposed of immediately after first use. Multiuse containers (eye drops and solutions) need an antimicrobial preservative to prevent micro-organisms invading the sterile environment of the solution. These will be discussed below.

Two other factors that are important when considering the formulation of ophthalmic solutions are pH and tonicity. The pH of an ophthalmic solution can affect its therapeutic effect, comfort, stability, sterility and viscosity (Hind and Goyan, 1947).

Ophthalmic drugs are, in most instances, alkaloid salts (salts of weak bases and strong acids) which at a pH of above 7 (i.e. an alkaline pH) become free bases, insoluble in water but soluble in lipids. The corneal epithelium (*see Figure 2.1*) is a cellular layer whose cells are joined by desmosomes. There are minimal intracellular spaces, and so to pass the epithelium, drugs must pass through the lipoprotein cell membranes, i.e. they must be lipid soluble. Thus, a high pH will facilitate passage through the epithelium. The stroma, containing few cells, favours water-soluble substances while the endothelium again is more permeable to substances soluble in lipids.

Thus, for a drug to pass through the cornea, its solubility must swing from lipid soluble to water soluble, to lipid soluble, and back to water soluble again to dissolve in the aqueous.

A high pH, therefore, although increasing passage through the epithelium, may inhibit passage through the stroma. Also, a high pH is irritating and the drug may precipitate from the eye drops or become unstable and be hydrolysed. Brawner and Jessop (1962) found that contact lens solutions with a neutral pH were less irritating than those with acidic reactions.

Tears contain one or more buffer systems which will keep the pH between 7.2 and 7.6. When a drop is applied to the eye it will be buffered to this range irrespective of its normal pH unless it is highly buffered itself. It is therefore questionable whether buffering eye drops is useful.

The eye can tolerate solutions with osmotic pressures between the equivalent of 0.5 and 2.0% sodium chloride (0.9% is isotonic) with little or no discomfort, and there is no justification for raising the tonicity of hypotonic solutions (solutions with an osmotic pressure less than the tears) to an exact isotonic value. Solutions of eye drops, as normally prepared, are generally hypotonic. Notable exceptions are 10% phenylephrine and 30% sulphacetamide sodium which are hypertonic and therefore cause some stinging, initially, on instillation. Eye lotions, however, because of the larger amounts used, should be isotonic.

Solutions for rigid lenses

The solutions and drops commonly available for use with the various types of contact lenses are given at the end of the book in Appendix C.

Historically the large majority of corneal lenses were manufactured from polymethylmethacrylate (PMMA), which is still used today, but to a minimal extent. The advent of rigid gas permeable materials has resulted in additional requirements for lens solutions. For example, cellulose acetate butyrate (CAB) lenses appear prone to lipid deposits but only minimally to protein deposits. The negative surface charge of the silicone-acrylate group of materials attracts both protein and lipid deposits so that a denatured surface layer of protein may build up on the lenses of some patients.

The majority of rigid lens materials tend to be hydrophobic, such that they are not readily wetted by the tear fluid. In order to avoid discomfort, therefore, the lenses need to be wetted before being placed on the eye. A second consequence of the hydrophobic nature of the plastics is that hydrophobic substances present on the eye or fingers, in soaps and cosmetics, readily adhere to the lens surface. These substances are therefore likely to irritate the eye by disruption of the tear film on lens insertion, and are also likely to be present on the lenses on removal from the eye. Rewetting solutions for use with lenses *in situ* may therefore be necessary and, further, the lenses should always be cleaned immediately upon removal from the eyes.

Despite the hydrophobic nature of the material surface, rigid lens polymers are capable of absorbing a small quantity of liquid. PMMA for example absorbs approximately 2% of its volume and hydration of the lens affects its performance on eye (Phillips, 1969). Complete hydration enhances the lens wettabilty, improving patient comfort and reducing mucus adherence to the lens. Additionally, due to surface expansion, the curvature of a dehydrated corneal lens alters significantly (depending on power and thickness) over the first few hours of wear as the lens becomes hydrated. This again may affect patient comfort (as the fit is temporarily incorrect) and vision (as an incorrect tear lens is induced). Similar effects are observed in RGP lenses (*see* Chapter 10).

The hydrophobic nature of rigid lens materials plus the effect of the liquid content when hydrated, has necessitated the formulation of four types of contact lens solutions and gels, each with its own specific functions: wetting solutions, cleaning agents, storage (soaking) solutions and rewetting agents. In addition, some solutions with combined functions, e.g. storage and cleaning, have been developed, and are known as multipurpose solutions.

Each group of contact lens solutions must conform to the following prerequisites:

- They must be sterile, stable and transparent.
- All solutions must be harmless to the eye if instilled undiluted.
- They must have no adverse effect on the contact lens material for which they are intended.
- They must be compatible with all other solutions used for the same lens material.
- In addition to being sterile, if presented in multidose form, all solutions should be self-sterilizing.

Although the constituents vary with different proprietary brands, the following include those main ingredients normally incorporated.

Preservative(s)

Those commonly used include benzalkonium chloride (0.004–0.01%), chlorbutol (0.4%), phenylmercuric acetate or nitrate (0.002–0.01%), thimerosal (0.001–0.01%), chlorhexidine digluconate (0.002–0.01%), and cetylpyridinium chloride (0.001–0.01%). Ethylenediamine tetraacetate (EDTA; 0.01–0.1%), a chelating agent, may also be incorporated to enhance the antimicrobial activity of the bactericide in the wetting solution. It was demonstrated by Gould and Inglima (1964) that solutions containing either benzalkonium chloride or chlorbutol, when compounded with a 0.1% EDTA solution, displayed a marked increase in activity against *Pseudomonas aeruginosa*. Further, by removal of metal ions from the bacterium cell wall, resistance to the bactericidal agent was prevented from building up. There is some doubt if the enhancing effect of EDTA is as effective with phenylmercuric nitrate (Brown, 1968) and Richards and Reary (1972) showed a reduction in

the efficacy of thimerosal when EDTA was added in acid media.

Details of preservatives are given in Appendix C at the end of the book.

Viscosity-building agent(s)

Methylcellulose, polyvinyl alcohol, hydroxypropylmethylcellulose (hypromellose) and hydroxyethylcellulose may be used to increase the viscosity of the solution and act as lubricant and 'clinging agents'.

Wetting agent(s)

Polyvinyl alcohol, as well as having good viscosity-building properties is also often used for its good adhesive and wetting properties. Krishna and Brow (1964), using 1.4% polyvinyl alcohol in isotonic saline solution, found it had a greater surface contact time than 0.5% methylcellulose in isotonic saline solution. They also found that, unlike methylcellulose, polyvinyl alcohol does not retard regeneration of corneal epithelium. The liquid polymer polyvinyl pyrrolidone is also used for its good spreading and wettability on the eye and lens surfaces (Hill and Terry, 1974).

Isotonic and buffering agents

Sodium and potassium chloride may be added to make the solution isotonic with tears. However, the importance of isotonicity has been over-emphasized in the past – especially for the small quantities involved in inserting a contact lens – and and a range of 0.7–1.2% sodium chloride solution equivalents is acceptable.

The normal range of tear liquid pH is from 7.0 to 8.5. Not only does this vary from person to person but there is also a daily temporal variation within the same individual (Carney and Hill, 1975). For this reason, a solution may show a pH range of 6.0–8.5 with greater initial comfort nearer to the physiological average of 7.2 (Brawner and Jessop, 1962). The solution should either not be buffered or only weakly buffered in order to allow the solution to adjust to the pH of the tear liquid as quickly as possible. Borate, bicarbonate and particularly phosphate buffers are those commonly used.

Colouring agents

Apart from the easier differentiation between two solutions, they serve little use, and may act as an irritant or give rise to an allergic response. They are now rarely used.

Water

The water that is used in pharmaceutical products is purified water. This is similar to distilled water but is produced either by distillation or by passing water through an ion-exchange column.

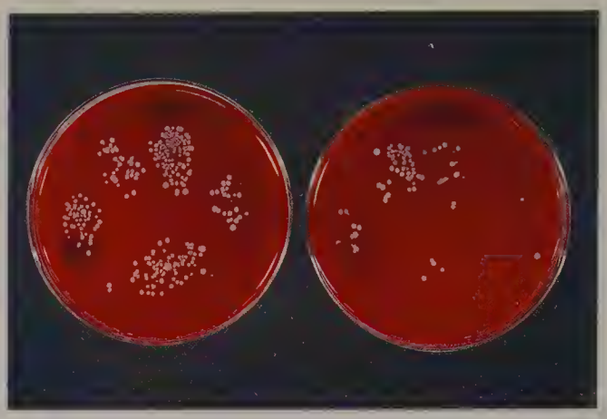


Figure 4.6 Hygiene and hand-washing. Two agar plates are shown with a practitioner's finger and thumbprint before (*left*) and after (*right*) hand-washing. The reduction but not complete elimination of bacterial colonies is clearly visible

The inclusion of a bactericidal agent is obviously essential in most solutions used in contact lens practice. But of equal importance is the hygiene observed by the individual in making sure that hands are washed thoroughly (*Figure 4.6*), and are free of all traces of creams and nicotine prior to handling the lenses.

Cleaning agents

One of the most important aspects of any lens care regimen is the use of a prophylactic cleaning step in the normal daily hygiene routine to remove mucus, dirt, cosmetics and other environmental contaminants prior to overnight storage of the lens in a disinfectant solution. From a microbiological point of view, a clean lens is far easier to disinfect than a dirty lens as the removed contaminants cannot inactivate the preservative. Furthermore, these deposits can build up in time to levels sufficient to interfere with vision, lens wettability and wearing comfort unless adequate prophylactic cleaning is carried out daily. As lens cleaning is accomplished outside the eye and the cleaning product used to effect the cleaning is not meant for direct instillation, it is possible to use slightly stronger cleaning agents than could normally otherwise be tolerated.

Although anionic, non-ionic, and amphoteric (balanced positive and negative constituents) surfactants are currently used in contact lens cleaning products, preference seems to favour non-ionic and amphoteric cleaners (Shively, 1975). These cleaning agents emulsify lipids, solubilize debris and remove accumulated contaminants most favourably in an alkaline (pH 7.4 and above) environment. Following rinsing in preserved or aerosol saline or in cooled boiled tap water the lens surface is clean and ready for overnight storage. It should be mentioned that cleaning hydrophobic and semi-hydrophobic lenses with various household cleaners such as laundry detergents, dishwashing compounds, skin cleansers and hair shampoos cannot be recommended because of their offensive and harsh actions on the lens surface or potential for damage to the cornea. This group of cleaners normally contains strong anionic detergents, caustic chemicals or

detrimental solvents. Additionally, it is well known that *an*ionic detergents interact with commonly used *cat*ionic preservative agents such as benzalkonium chloride, chlorhexidine digluconate or acetate and cetylpyridinium chloride resulting in deposition of a water-insoluble film on lenses with resultant discomfort for the wearer.

Specific itemization of constituents in various cleaning products cannot be given as most of these agents are regarded as proprietary to the lens solution manufacturer. Where these details are not available, manufacturers should be requested to provide information to support claims made for their cleaning products.

Even though cleaning products are not meant for use on the eye, it is important that they are packaged sterile and are self-disinfecting due to repeated exposure to the environment during use. This is normally accomplished by the use of preservative agents (*see above*).

Isotonicity is not considered necessary in cleaning products as these products are not meant for direct instillation. Viscosity agents are incorporated by some manufacturers to increase the contact in between cleaner and lens. Viscosity agents also thicken the cleaning solution to prevent it running out of the hand during cleaning.

Finally, although these products are meant for use outside the eye, it is important that no irreversible ocular insult occur should they be accidentally transferred to the eye.

Cleaning products are routinely used by rubbing the solution on the lens surfaces and massaging the debris and contaminants off the lens surfaces with the fingers. This is then followed by a saline rinse to remove the contaminants. However, various mechanical lens cleaning devices for wearer usage have emerged, mainly in the USA, which appear to facilitate this cleaning process. The use of an adjunctive cleaning solution is still, of course, required. The advantage of these devices appears to be for those wearers with poor manual dexterity and to reduce the continual surface scratching through the use of the fingers.

Soaking solutions

On removal from the eye and after cleaning, corneal lenses should be stored in a specially formulated soaking solution. This serves the following functions:

- By means of the bactericidal agent it contains, it should sterilize the lens and maintain its sterility.
- Maintenance of the hydrated equilibrium of the lens while it is not being worn.
- Prevention of the hardening of any ocular secretions remaining on the lens and to loosen the adhesion of any accumulated mucus.

Phillips (1969) reviewed the arguments in favour of storing a corneal lens in a soaking solution. The advantages of this form of storage over dry storage include improved lens surface wetting, visual performance and patient comfort, less corneal staining and lens abrasion and greater evidence of freedom from bacterial contamination. Further, due to hydration and dehydration, the curvature of a lens stored dry fluctuates every time it is placed on or removed from the eye. A lens stored in a soaking solution retains a constant curvature.

Soaking solutions also contain the antibacterial agents listed above. Slightly higher concentrations or two synergistic agents are often employed because decontamination is one of the major functions of the storage solution. Solubilizing agents are also often incorporated to loosen the attachment of any debris still attached to the lens. Soaking solutions should not irritate if transferred to the eye.

It is important to realize that the capability and efficacy of the solution to disinfect lenses is related to changing of the storage solution each day and cleaning out the lens case as the effectivity of the preservative will be reduced with each disinfection cycle by contaminants adhering to the lens surface such as mucus, atmospheric dust etc., and even cellular constituents released from dead and dying cells. If too many cycles of disinfection are carried out in the same volume of solution, the concentration of bactericide will be reduced to an inefficient level or worse, to such an extent that, for example, a resistant pseudomonad may actually grow in the solution. Responsibility for correct instruction of the lens wearer in this aspect of lens hygiene rests with the practitioner.

The importance of proper storage cases for use with soaking solutions must also be emphasized. Sufficient fluid volume must be contained to enable adequate diffusion of adsorbed contaminants into the solution and also to provide sufficient quantities of available preservative. Identification for each right and left lens must be provided, preferably also with tactile projections. Colour coding of container caps is also helpful.

Caps should be screw threaded to prevent solution loss even under such conditions as pressurized aeroplane cabins. Storage cases should not contain any materials which may be irritant to the eye such as plasticizers found in the sponge rubber inserts sometimes formerly used. For the reasons listed above, it is not sufficient to issue the patient with lens mailing containers for permanent use as storage cases. Storage cases should be replaced frequently, probably every 3–6 months.

Wetting solutions

The functions of a wetting solution may be listed as follows:

- By acting as a lubricant between the surfaces of the lens and of the cornea and lids, its cushioning effect minimizes discomfort to the patient during initial insertion of the lens and subsequent wearing. This, in turn, encourages the prolonged wearing of lenses.
- By its action of encouraging even distribution of tears over the lens, it improves the optical performance.
- It acts as a mechanical buffer between lens and finger during the act of lens insertion and thus prevents lens contamination. This same buffer action prevents discomfort and possible corneal insult should the lens be inserted too rapidly.

- The wetting agents within the solution make it a suitable daily cleaning solution for many wearers for use following lens removal.

There is available to the practitioner a very wide choice of commercially produced wetting solutions. Some have fairly simple formulations, others appear more complex. However, all wetting solutions should have the following essential properties in addition to the criteria listed above:

- They must have an adequate wetting effect on the lens material even in high dilution.
- They must contain a viscous additive so that the solution adheres to the lens while it is being inserted and creates a protective cushion effect.

Artificial tears/rewetting agents

When no contact lens is present the precorneal film has the primary role of resurfacing the cornea with a hydrophilic coating with every blink, because there is no actual flow of tears across the cornea. Introduction of the lens disturbs this corneal resurfacing process and the lens itself becomes the surface which the precorneal film must coat with a hydrophilic layer. Further, this fluid film easily ruptures when adjacent to the boundary of a solid object such as a contact lens placed in the film. When this phenomenon is associated with incomplete blinking, corneal staining in the peripheral–horizontal (3 and 9 o'clock) regions can often be detected, presumably indicating areas of localized corneal desiccation. When the precorneal film is unable to spread over the lens due to lipid contamination (presumably arising from meibomian gland hyperactivity due to irritation of the inner lid margins), then decreased visual acuity and possible patient discomfort results.

In view of the above problems, rewetting solutions* have been designed for use with the lens *in situ*. These solutions contain wetting agents such as polyvinyl alcohol or Polysorbate 80, or highly viscous solutions containing polyvinyl pyrrolidone. Some are intended for use with rigid lenses and some with soft lenses, but those for use with soft lenses are really suitable for both types.

An artificial tears solution is indicated in conditions where natural tear liquid is reduced (*see* Chapter 8). A number of proprietary preparations* are available to the practitioner. Such solutions may be preservative-free or contain benzalkonium chloride (0.004–0.01%), chlorbutol (0.5%), thimerosal (0.02%), EDTA (0.05–0.1%) or polyhexamide as preservatives; polyvinyl alcohol, hypromellose or hydroxyethylcellulose as wetting and viscosity-building agents; and sodium, potassium or magnesium chloride to provide solution isotonicity. Again, depending on the preservative, some of these are not suitable if soft lenses are worn. This rules out those containing chlorbutol and benzalkonium chloride.

Some cellulose acetate butyrate lenses should not be stored in solutions containing benzalkonium chloride as a slow reaction occurs with the material over a period of several months. The lens takes on a light straw colour, fluoresces a light blue under ultraviolet light, and a change in back optic zone radius (BOZR) results.

* Appendix C, at the end of the book/gives more details of these preparations for rigid and soft lenses.

Multifunctional solutions

Multifunctional solutions are generally intended to combine the actions of cleaning and storage – or wetting, cleaning and storage – in one single product. The rationale behind the manufacture of such solutions is that some wearers will not carry out correct lens hygiene procedures due to the confusion of the multiplicity and expense of the solutions they must use. Most contact lens practitioners come across patients who omit one or more steps of the hygiene regimen simply because they run out of the appropriate solution. Often this step is then permanently omitted. For this reason multipurpose solutions have significantly increased in popularity.

The basic components of combination cleaning and storage solutions are similar to the individual solutions with these functions. Most cleaning ingredients are non-ionic or amphoteric (Shively, 1975) for the reasons mentioned earlier. Most combination wetting and storage solutions are similar in formulation to wetting solutions but with a lower viscosity. The authors have found that patients with lens mucus problems have sometimes benefited by storage of the lenses in combination solutions containing wetting agents such as polyvinyl alcohol, presumably due to surface adsorption of the wetting agent.

As might be expected, the combination of different lens hygiene functions into multifunctional solutions has elicited discussion about a possible compromise of efficacy in these products. For example, the relatively high viscosity required for a mechanical buffer action is contrary to the low viscosity required for diffusion of surface contaminants into the storage solution. Further, solution viscosity of any degree would appear to retard bactericidal activity as was shown by the poorer performance of all combination wetting and soaking solutions tested by Norton *et al.* (1974) compared to soaking solutions alone.

Solution interactions with rigid lenses

The majority of formulations appear suitable for use with RGP lenses. However, controversy exists as to whether benzalkonium chloride is bound to silicone–acrylate material surfaces or not (Rosenthal *et al.*, 1986; Sterling and Hecht, 1988). Rosenthal *et al.* (1986), utilizing highly sensitive fluorescence spectroscopy, showed minimal absorption of chlorhexidine digluconate to silicone–acrylate surfaces, but below a clinically significant level. They postulated that the positively charged chlorhexidine molecules probably bind to free carboxylate groups on the lens surfaces by electrostatic attraction and behave like a classic surface agent that forms a typical monolayer (*see below*). When the anionic binding sites of the silicone–acrylate polymer become saturated, no further uptake occurs. This explains their observation that chlorhexidine adsorption

reached a plateau at a relatively low surface concentration.

In contrast, the continuing uptake of benzalkonium chloride found by these workers, beyond that which would be expected to occur if it was adsorbed as a monolayer, suggests that the mechanism of adsorption is one of self-aggregation whereby molecules of benzalkonium chloride bind to each other in layers. Like the chlorhexidine molecules, benzalkonium is positively charged and its initial adsorption may be the result of similar electrostatic forces. However, its longer hydrophobic chain may orient itself on the lens surface so as to create a template to which the hydrocarbon tails of adjacent benzalkonium molecules can adhere by the mechanism of hydrophobic interaction. As a result, benzalkonium, unlike chlorhexidine, can continue to form adherent layers on the lens surface with a potential for eventually reaching toxic concentrations, especially with sensitive individuals. Furthermore, because of its longer hydrocarbon chain, the binding strength of benzalkonium chloride to silicone–acrylate polymers due to hydrophobic interaction is greater than that of chlorhexidine digluconate and it resists removal even by vigorous cleaning. In addition to its potential toxicity, adsorbed benzalkonium chloride intensifies the hydrophobicity of the lens surfaces. This reduced wettability may facilitate the adhesion of other hydrophobic elements present in tears and thereby accelerate the formation of surface deposits. Clinical findings appearing to confirm these laboratory findings were reported by Herskowitz (1987).

One RGP storage solution (Boston/Bausch & Lomb Elite Solution) has been formulated to take advantage of the electrostatic interaction postulated above. A cationic hydrophobic polyelectrolyte component competes with both chlorhexidine and lipid molecules for the anionic binding sites on the polymer thus theoretically reducing the concentration of adsorbed chlorhexidine and minimizing lipid deposition.

In contrast, Wong *et al.* (1986) found clinically insignificant levels of benzalkonium chloride adsorbed to silicone-acrylate lenses after 16 days' continuous exposure to a wetting and soaking solution preserved with benzalkonium chloride (Allergan's Wet-n-Soak). They pointed out that the effectiveness of benzalkonium chloride is readily decreased by serum and proteins so that, whatever small amount is accumulated on the lens, is inactivated within the tear environment and therefore is of no consequence. In addition, any small amount of benzalkonium chloride left on the lens will be inactivated upon cleaning with detergent cleaners provided this cleaning is carried out. Similar results were reported by Hoffman (1987) and Bevington *et al.* (1988), and Richardson *et al.* (1980) for CAB material.

While controversy still exists over the use of this preservative for silicone–acrylate materials, it is pertinent to report the increase in problems found by UK practitioners when the thimerosal preservative formerly used in Alcon's Soaclens was temporarily replaced with benzalkonium chloride (Anon, 1985). As with hydrophilic lenses, practitioners should be constantly alert to the potential problems of preservative sensitivity and also the importance of lens cleaning because preservative binding to surface deposits may also occur.

Manufacturers claim improved wettability following the use of various storage and cleaning regimens (Benjamin and Simons, 1984). However, most studies are carried out on new lenses and highly variable results are obtained on worn and therefore deposited lenses. Because of their susceptibility to protein and lipid deposits described above, silicone–acrylate will often, but not always, develop a layer of denatured protein which may be difficult to remove and cause loss of tolerance and vision.

Both soft and rigid lens surfactant cleaners can be used on a daily prophylactic basis. Soft lens cleaners (*see below*) utilizing hypertonicity as a cleaning method will have no effect although others, such as Alcon's Polyclens (Opti-Clean), will work equally well for RGP as well as PMMA and hydrogel materials. Other cleaners are formulated specifically for RGP lenses such as the Boston/Bausch & Lomb Cleaner. These contain a very fine, soft abrasive in suspension with friction enhancing agents that mechanically break the bond between the lens surface and debris.

Protein removing tablets

In addition to daily cleaning, patients may be advised to utilize protease enzymes to remove denatured protein, although not usually at the same frequency as hydrogel lens wearers. Any of the protein removing tablets can be used for RGP lenses including Ultrazyme, which is specifically to be used with hydrogen peroxide solutions (*see below*). The length of time that RGP lenses should be left in the protein removing solution may be different from that for soft lenses and care should be taken to follow the manufacturer's instructions.

Some RGP materials are recommended to be used with one solution specifically designed for the lens material, e.g. Menicon O_2 solution for use with the Menicon O_2 lens, due to the surface charge of the lens material.

Silicone rubber lenses

Silicone rubber lenses are manufactured from approximately 40% cross-linked dimethyl polysiloxane (silica) mixed with siloxane polymer as a filler, and the entire mixture heated at a high pressure in order to achieve further polymerization and cross-linking. The silica helps to determine the refractive index of the final lens which lies somewhere between 1.49 and 1.56. Although the material is highly transmissive to oxygen and other gases, water adsorption is negligible (0.4% compared with 1.5–2.0% for PMMA) and lens parameters are not normally affected by the storage solution characteristics (Phares, 1972a), the solution being used for its antibacterial function only. The extremely hydrophobic nature of silicone lenses makes them difficult to wet and remain wettable during wear



Figure 4.7 Silicone rubber lens with hydrophobic surface caused by excessively vigorous surfactant cleaning for 4 months which damaged the hydrophilic lens coating. (Courtesy of D. Westerhout)

(*Figures 4.7, 4.8*). Wetting solutions containing polyvinyl alcohol or cellulose derivatives and formulated for conventional RGP lenses are not adequate wetting agents for silicone lenses (Krezanoski, 1972a). They may be used with safety, however, with the exception of solutions containing chlorbutol as this is bound or adsorbed onto the lens surface. This concentrating effect of the preservative causes marked ocular discomfort. To overcome its hydrophobic nature, silicone lenses have been surface coated with a more hydrophilic material (although this suffers from the expected disadvantage that it eventually wears off) or treated to produce surface molecular reorientation (Shively, 1975). Special wetting agents were also investigated in an attempt to overcome the wetting problem (Krezanoski, 1972a). Most cleaners designed for RGP lenses are only partly effective in maintaining silicone lens surfaces in a clean state. Two manufacturers produced solutions specifically for storing silicone rubber lenses although these are no longer available.

Combination Lenses

Combinations of differing classifications of material into a single lens are now available, for example a rigid gas permeable optic portion with a polyhydroxyethyl methacrylate (PHEMA) periphery e.g. Softperm. This appears to allow the optical quality of a rigid lens to be partly combined with the comfort of a soft lens although, of course, it raises potential problems from the lens sterility and wetting point of view.

In each instance the practitioner must consult the manufacturers' literature extremely carefully to decide which solutions may or may not be used with each material. Both verbal and written instructions must be given to each patient who should also be advised not to use any unlisted solutions without first checking with the prescribing practitioner. The constant development of new materials requires practitioners to be always up to date with current literature and constantly aware of potential toxic or hypersensitivity problems.

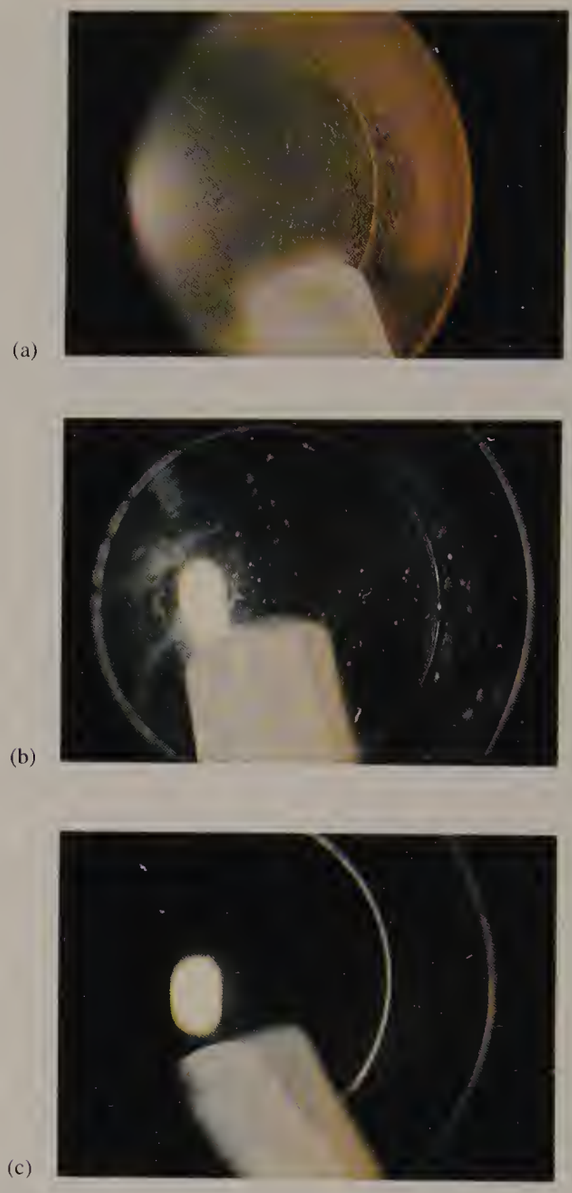


Figure 4.8 Silicone rubber contact lens. (*a*) Heavily protein contaminated after only 3 months' use. (*b*) The same lens after cleaning with 5% sodium hypochlorite and rinsing in saline. (*c*) The same lens after a further rinse with distilled water now showing a clean surface. (Courtesy of D. Westerhout)

Solutions for hydrophilic lenses

Details of many of the drops and solutions available for soft lenses are given in Appendix C.

During the early stages in the development of hydrophilic lenses it was thought that the hydrophilic nature of the surface would obviate the need for most solutions because wetting agents were unnecessary, and for the same reason it was thought that cleaning would also be unnecessary. However, over the years, the complexities of dealing with new materials for use in contact with the eye has become increasingly apparent. Hydrophilic lenses are made from many materials, include differing additives and have widely varying physical and physiological properties.

Perhaps the most difficult problem that has arisen with hydrophilic lenses is that of disinfection. Fortunately a considerable number of conjunctival sacs do not contain pathogenic bacteria. Smith (1954) reported 5000 cases in which swabs were taken from the conjunctival sacs of apparently normal eyes. Of these cases, 47% showed no bacterial contamination in the sac. Other authors quote between 20 and 70% as the incidence of sterile conjunctival sacs (Duke-Elder, 1965). In general, the majority of the conjunctival flora are harmless saprophytes involved in the destruction of dead cells. Only 25% of conjunctival sacs appear to contain potential pathogens (Smith, 1954). Bacteria such as *P. aeruginosa* are rarely found in the sac. *Staphylococcus aureus* is found more often but still only in a minority of cases (2–15%). Even if an organism is a potential pathogen, it has been established that the conditions in the sac are likely to reduce the virulence of the organism. This is due in part to its relatively low temperature, in part to the action of the lysozyme in the tears, and in part to the mechanical action of blinking and the sluicing effect of the lacrimal secretion. In addition to the physical and chemical factors inhibiting the pathogens, non-pathogens also contribute to the protection of the eye by competing with the pathogens for nutrients. These factors combine to provide a relatively stable protective system for the eye against infection (*see* p. 98).

There are, however, many examples of how changes in the prevailing conditions can disrupt this balance: for example, keratoconjunctivitis sicca due to insufficient or inadequate tears; exposure keratitis due to the inability of the lids to sweep the cornea, and even bandaging the eye which causes an increase in the number and virulence of organisms. Contact lenses unfortunately interfere with the eyes' defence mechanisms. Hydrophilic lenses in particular prevent the lids from sweeping the cornea and interfere with the tears washing the cornea. They probably raise the corneal temperature and can also induce breaks in the corneal epithelium. In reports that appear in the literature of corneal infection occurring in otherwise 'normal' contact lens wearers, one of the main causes has been found to be the introduction of significant bacterial contamination either on the lens or via contaminated solutions. While bacteria appear unable to penetrate the intermolecular 'pores' of hydrophilic lenses (Knoll, 1972; Matas *et al.*, 1972) except possibly into defects in older lenses (Poster, 1972; Tripathi and Ruben, 1972), the tear liquid absorbed by the lenses serves as an excellent bacterial culture medium.

Furthermore, surface irregularities in the lens occurring during manufacture (Matas *et al.*, 1972; Filppi *et al.*, 1973) and eye secretions adhering to the lens surface may permit a nidus to form where bacteria can aggregate and possibly be protected from disinfection processes.

It was also pointed out by Ruben (1966) that fungi can grow into hydrophilic lenses and Filppi *et al.* (1973) showed penetration by *Aspergillus fumagatus*; and Dallos and Hughes (1972) penetration by *Thrichotecium roseum* (this latter mould sometimes being found in tap water). The mechanism of penetration is probably by means of enzymes which cause degradation of the lens material and permit entry of the fungal hyphae (*see Figure 18.43*).

Lenses which show spots on or within the lens substance should not be dispensed even though they may not necessarily be fungal growth and could, for example, be rusting ferrous particles (Loran, 1973). Even though there is no apparent damage to the lens there is always a possibility that endotoxins synthesized by the fungus are bound within the plastics. Fungi will quickly overcome the preservative in any disinfecting solution unless the solution is replaced at daily intervals. Thus, as well as antibacterial activity, any methods of soft lens disinfection must also have a high fungicidal capability.

A further problem occurring with hydrophilic lenses is that of deposits adhering to the lens surfaces (*see Figures 18.27, 18.41–42, 18.44–45*). The main sources of these deposits are ocular secretions, tap water contaminants which may have been absorbed by the lenses, eye drops, finger dirt, eye make-up and contaminants introduced during manufacture and from the atmosphere. The bulk of deposits, however, are mucoproteins from the tear liquid. Also found are calcium (Ruben *et al.*, 1975), iron and other insoluble divalent and trivalent metal salts. Environmental and occupational factors also affect the cleanliness of lenses. Rusting ferrous particles are commonly seen in the surface of the lenses or deeper if introduced during manufacture (or possibly from high speed projectile particles) (*see Figure 18.46*). Some eye drops containing phenylephrine, adrenaline or berberine cause discoloration and some preservatives from sterilizing and hydrating solutions may concentrate in the matrix of soft lenses causing either discoloration (*see Figure 18.19*) or surface filming and consequently discomfort to the patient (Ganju and Cordrey, 1975). Handling the lenses may transfer a variety of contaminants such as lipstick, mascara, oily creams, detergents and nicotine to the lenses if strict personal hygiene is not observed. Furthermore, Wilson *et al.* (1971) found fungal contamination in 12% of eye make-up samples and bacterial contamination in as high as 43% of samples.

Repeated disinfection by boiling and to a lesser extent with chemical disinfecting solutions denatures the surface mucoprotein, slowly building up a tenacious irregular surface layer. This may cause symptoms of discomfort, lowered acuity, lens discoloration and conjunctival injection and possibly an apparent change in fitting and power. For these reasons daily cleaning is necessary to prevent surface deposits from building up and rejuvenating products to remove deposits already present. Current trends are towards regular replacement of lenses and the development of biomimetic materials which resist surface deposition.

Because of the gradual build-up of deposits on the lenses, a more effective cleaning treatment is required at periodic intervals depending on the patient, lens material, method of disinfection etc. Ganju and Cordrey (1975) and Gasson (1975) showed measurable drops in ultraviolet and visible light transmission through lenses after a few months, which had not been correctly cleaned. Typically

this was around 15% for visible light, and Gasson noted that some 15% of soft lens wearers noted a reduction in acuity after 6 months wear. Because of the nature of the material most soft lenses cannot be repolished as with hard or rigid lenses, and the development of enzymatic and oxidative systems developed during the 1970s and beyond, some for use by the patient and others for use by the practitioner.

Finally, it is not uncommon for hydrophilic lens wearers to experience some discomfort or temporary drop of vision while the lenses are worn. Ignoring physical causes such as lens movement or distortion, the cause may vary from inadequate tear formation and a dirty lens, to personal idiosyncrasies. To overcome the problem, products have been developed which rehydrate and clean the lens *in situ*. These products are especially helpful in cases where the front surface of the lens has become dehydrated, for example due to low environmental humidity, causing a change in lens curvature resulting in discomfort and impairment of vision.

The usual sequence of events during soft lens wear and care is for the lens to be cleaned on removal from the eye then rinsed and disinfected or sterilized. Different solutions may be used for these stages or single multipurpose solutions (*see below*). It may be necessary to rinse the lens with sterile unpreserved or preserved physiological saline before lens insertion into the eye. Also, prior to or during wear a rewetting solution may be used. From time to time special cleaning or rejuvenating procedures may be necessary, utilizing further special solutions or compounds.

Methods of disinfection

Heating methods

The American Food and Drugs Administration (FDA) regulations state that methods for soft lens hygiene should fulfil the requirements for disinfection. This is defined as 'the physical or chemical process producing destruction of pathogenic microorganisms' (United States FDA, 1973). This definition does not imply the destruction of bacterial spores because these are at a resistant stage, but only of vegetative micro-organisms. Mould spores are considered to be reproductive stages and resist heat only slightly better than vegetative forms of bacteria. Total sterility is only achieved by autoclaving for 15 minutes at 120 °C and 15 lb/in^2 (103.5kPa) pressure and for this reason moist heat units which destroy vegetative micro-organisms are often described as 'asepticizors' rather than 'sterilizers'.

Heating was suggested thirty years ago by Ruben (1966) and Morrison (1966) and was recognized by the FDA in 1972 as the first approved method of disinfection for use with soft lenses. Although the physical requirement for disinfection is 80 °C for 10 minutes, the temperature achieved inside the Bausch & Lomb lens carrying case during a normal asepticizing cycle is 96 °C for approximately 20 minutes (Mote *et al.*, 1972). Typical heating cycles are shown in *Figure 4.9*.

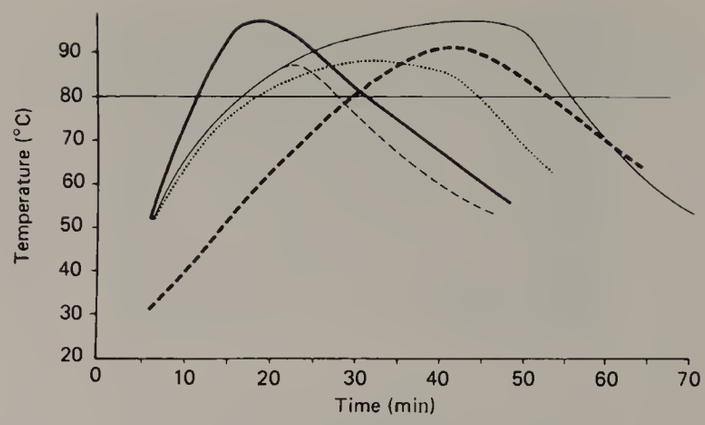


Figure 4.9 Time-temperature cycle of the saline contained within the contact lens cases of several different manufacturers. —— Allergan; ... Alcon Micro-Therm; – – – Pilkington Barnes-Hind; —·— Bausch & Lomb long cycle; ––– Bausch & Lomb short cycle. (Reproduced by kind permision of Bausch & Lomb.) Some units are no longer available

Boiling, and particularly repeated boiling, may possibly cause molecular breakdown or degradation of the lens material over a period of time thereby shortening the life of the lens. Mandell (1974), however, states that the temperature at which this occurs rapidly for HEMA material is probably about 30 °C higher than that normally used in the asepticizing process so that any breakdown of the molecular structure probably occurs at an extremely slow rate. All current lens materials are stable below 85 °C. Dallos and Hughes (1972) tried to achieve sterilization by pasteurization at 70–73 °C. They found that representative samples of heat-resistant pathogenic bacteria were killed after heating for 2 minutes at 70 °C. These writers recommended daily pasteurization with the unit heating up to 72 °C (i.e. slightly higher than required) over a 2–3-hour period and remaining at 72 °C for 30 minutes.

Units used in practice immerse the lens storage container, which keeps the lenses in a suitable saline solution, in steam from boiling water. The temperature reached inside the lens case is typically around 96 °C for 20 minutes. The efficacy of these asepticizing units was demonstrated by Knoll (1972) using bacteria, a fungus and a virus; Mote *et al.* (1972), using Gram-positive and Gram-negative bacteria, a spore former and a fungus; Hydron Lens Ltd (1972) using a selection of pathogenic bacteria; Filppi *et al.* (1973) using the fungus *A. fumagatus*; Busschaert *et al.* (1974) using a selection of bacteria, fungi and bacterial spores; and Richardson *et al.* (1993) using the fungus *Beauveria bassiaria*, known for its ability to grow into the matrix of soft lenses. Ludwig *et al.* (1986) and Connor *et al.* (1989) reported thermal disinfection as being more effective against the protozoa *Acanthamoeba* sp. than chemical disinfecting methods. Busschaert and his co-workers found, however, that bacterial spores were occasionally able to survive the asepticizing cycle; Tragakis *et al.* (1973) also found the fungus *A. fumagatus* sometimes survived asepticization (possibly by sporulating) and Bernstein *et al.* (1973),

in contrast with the other workers listed above, found 20% of unopened Soflens cases to be contaminated after asepticization by the patient. This number increased to 86% contamination of the cases a few hours after opening, although presumably the lenses would normally be in the wearers' eyes by this time.

In their study, one patient showing bacterial contamination of her container and an eye infection admitted to changing the saline solution only every 2–3 days. The importance of daily asepticization and the use of fresh solution after surfactant cleaning must therefore be greatly impressed on the patient. Some manufacturers produce pre-prepared saline solution containing thimerosal or sorbic acid, as an added method of disinfection following asepticization should the container be opened and bacteria inadvertently allowed to enter. Bacteria may also be sucked in from the outside as the container cools and patients must be advised to use the correct screw-cap container and to make sure it is firmly tightened. Similarly, a loose cap may allow loss by evaporation of the water within the container causing hypertonicity of the saline solution, alteration of the lens dimensions and subsequent discomfort on lens insertion.

In some countries sterile, unpreserved, physiological saline is available in 500 ml bottles with jet dispenser nozzles but compressed air powered saline sprays or single use formulations (such as saline sachets, e.g. Salettes; or tubes, e.g. Amidose, which are used once and discarded) are the only forms of sterile unpreserved saline which should be used for rinsing the lenses after cleaning or prior to insertion. Saline can also be prepared from specially manufactured salt tablets or granules shaken up with the correct quantity of purified or distilled water. Neither of these types should be used with lenses (Jenkins and Phillips, 1986). There have been reports of stromal keratitis and ulceration in patients using home-made saline contaminated by *Acanthamoeba* sp. (Epstein *et al.*, 1986). Physiological saline solution preserved with thimerosal and EDTA or sorbic acid is also suitable for the boiling of lenses. The commercially available brands of preserved saline solution are also included in Appendix C. However, the use of preserved salines in thermal units increases the risk of hypersensitivity to preservatives bound to the lens surface deposits (because of the greater incidence of bound surface deposits generally found with heat disinfection methods) and lens discoloration if thimerosal is used as the preservative.

One major problem with boiling is that mucoproteins present on the lens become coagulated or denatured on the lens surface by the asepticizing process. The film thus formed may cause lens discomfort, loss of acuity, loss of transparency, conjunctival injection and possibly a change in lens fitting and power. It may also reduce lens porosity and thereby aid the formation of corneal oedema. For this reason daily cleaning is a necessity prior to boiling (*see below*).

Lenses may also be pasteurized by utilizing an ordinary household vacuum flask. The flask is pre-heated with boiling water then refilled with boiling water. The lenses, in their tightly capped container and stored in saline, are then carefully dropped into this flask which is left uncapped overnight.

Since some lens materials, especially polymers containing methacrylic acid, absorb up to 38 times more protein than PHEMA (Stone *et al.*, 1984), normal heat disinfection methods may cause considerable denaturation and lens discoloration. The lower heat temperatures utilized are claimed to reduce this problem and yet provide adequate disinfection even against heat-resistant organisms such as *Streptococcus faecalis*.

Practitioners using trial lenses stored in saline solution should boil them at frequent intervals once they have been cleaned and re-sealed in order to kill bacteria which may have survived earlier boiling by sporulating. Lenses received from the manufacturer should ideally have been autoclaved and therefore be sterile. Lenses which have been used on a patient's eye should be boiled or preferably autoclaved (Litvin, 1977), before being returned to the lens rack. Alternatively, hydrogen peroxide can be used to disinfect lenses (*see below*).

The use of autoclaving by laboratories to achieve lens sterilization would not, however, appear to be without its drawbacks. Larke (1974) noted that the pH of lens storage saline solution is usually acidic in the region of 5.5–6.5 following autoclaving and often therefore gives rise to ocular irritation. In addition, should the lens vial remain unopened for a matter of weeks or months, the pH will continue to fall and may reach 4.0–4.5. The absorption of atmospheric carbon dioxide with the formation of weakly dissociated carbonic acid would seem a possible mechanism and this seems to be a problem in lens vials which have gas permeable silicone rubber stoppers.

The advantages of boiling or asepticizing as a method of lens disinfection may therefore be summarized as follows:

- It is generally accepted as an effective method of lens disinfection and is recognized as such by health authorities throughout the world.
- After the initial purchase of the boiling unit it is the least expensive method.
- Where unpreserved saline solution is used (*see* earlier paragraph) there is no risk of allergy or hypersensitivity to any preservative.

The disadvantages may be summarized as follows:

- After the fees for the fitting and supply of soft lenses, the additional cost of the asepticizor often makes it initially prohibitive.
- There is a high risk of micro-organism build-up if the procedure is not carried out daily and fresh saline solution prepared daily (Brown *et al.*, 1974).
- Certain bacterial spores may survive asepticizing and may cause lens damage if the boiling is not carried out daily to destroy vegetative forms of the organism.
- Because the saline solution does not contain a preservative, there is a slight risk of microorganisms being

transferred onto the lens from the fingers. Such a possible case was cited by Storey (1973).

- Of the various methods of hydrogel disinfection, heating methods cause the greatest denaturing effect of ocular secretions remaining on the lens surface with the accompanying disadvantages mentioned above and greater risk of problems such as giant papillary or contact lens-associated papillary conjunctivitis (*see* Chapter 18).
- Repeated heat disinfection may cause slow degradation of the polymer structure thereby reducing the life of the lens. It should be emphasized that this effect undoubtedly varies from material to material. Thermal methods shorten the life of most hydrogel lenses by around 25%, largely because of exacerbated deposit formation.
- Following from the above, the technique is not a universal one suitable for all lens materials and some materials degrade very quickly with repeated heat sterilization.
- Although not as slow for lens disinfection as some soft lens storage solutions (*see below*) the method is not rapid, taking approximately 1 hour and possibly a further hour for cooling and for the lens dimensions to return to normal (Loran, 1974). Again, although quicker than some hydrogen peroxide disinfection procedures, the method is slightly more time-consuming for the patient than the use of soft lens storage solutions.
- There are occasions when it is impossible to asepticize by boiling, for example, while travelling.

Because of these disadvantages few manufacturers now produce thermal disinfection units.

Chemical disinfection

Hydrogen peroxide

The first method of chemical disinfection was by means of 3% hydrogen peroxide (Isen, 1972). The need for an alternative to heating methods arose because the lens material used by Isen did not stand up well to repeated boiling. Although tending to fall out of favour after its initial introduction because of the prolonged nature of the neutralizing step (*see below*), it has been revived in recent years.

The antimicrobial efficacy of hydrogen peroxide has been well known for over 100 years. The 3% solution is possibly the most effective disinfecting agent available in contact lens practice today and will kill large numbers of micro-organisms very quickly (Levine *et al.*, 1981; Penley *et al.*, 1985). It has a broad antibacterial spectrum but exposure times of 1 hour (Penley *et al.*, 1985) and 4 hours (C. Jenkins, 1986, personal communication) have been recommended to ensure adequate antifungal and antiprotozoan activity.

The stability of dilute solutions is highly pH dependent (Schumb *et al.*, 1955) and for this reason the 3% solutions used in contact lens practice are now adjusted to an approximate pH of 4–5. In addition 'stabilizers' are also necessary, e.g. phosphates, which complex iron. As the pH rises, so more stabilizer is required to prevent peroxide breakdown.

In the original method described by Isen, the lenses were soaked for 5 minutes in 3% hydrogen peroxide which is highly acidic having a pH of 3.0–4.0. This was therefore neutralized by exposure to 0.5% sodium bicarbonate in 0.9% sodium chloride for 1 minute and the lenses then immersed in 0.9% sodium chloride for 15 minutes. The lenses were then stored overnight in isotonic saline solution. Feldman (1971) and Gasset *et al.* (1975) described modifications to the neutralizing step but these were very time-consuming.

The technique underwent a revival during the late 1970s with the introduction by American Optical of a platinum catalyst to break down residual hydrogen peroxide:

$$2Pt + 2H^+ + H_2O_2 \rightarrow Pt_2 + 2H_2O$$
$$Pt_2 + H_2O_2 \rightarrow 2Pt + 2H^+ + O_2$$

Lenses were first soaked in 3% hydrogen peroxide (Lensept) for 10 minutes as the disinfection step, and then placed in a second container, in preserved saline (Lensrins) to maintain sterility, and containing a platinum-coated plastic disc as catalyst. The technique had the advantage that it eliminated the time-consuming elution/neutralization steps of earlier methods because this is done, usually overnight, by the catalyst. The major disadvantages were the slow action of the catalyst (4 hours for complete neutralization) should patients forget to transfer lenses to the second container before retiring at night and the fact that platinum is easily poisoned so that the catalyst needed replacing after approximately every 100 uses.

As a further simplification of the system, American Optical introduced the AOSept system (currently produced by Ciba Vision) where the hydrogen peroxide is mixed with physiological saline and the combined mixture placed directly in the container with the platinum disc. Because of the slow action of the platinum catalyst, the lenses are disinfected before the hydrogen peroxide is broken down. The method thereby becomes a 'one-step' system eliminating the need for a separate neutralizing step and the risk of severe ocular stinging if patients forget this step. A further advantage is the elimination of the need for preservatives in the saline. Stability of the hydrogen peroxide at the relatively high pH (6.5) necessitated by this method is maintained by the higher level of stabilizers incorporated. Anger *et al.* (1990) have criticized the AOSept system as the hydrogen peroxide concentration falls to below 1% in less than two minutes. It was felt that the antimicrobial efficacy of the solution is compromised, particularly with regard to fungal and amoebic contamination.

In the Allergan 'Oxysept' (Ultracare or Omnicare) systems a preserved saline or tablet respectively containing the catalyst 'catalase' is used. Catalase, present in blood, potatoes and other plant and animal tissues, is an enzyme, a specific biochemical catalyst, that rapidly increases hydrogen peroxide decomposition (Gyulai *et al.*, 1986). Commercial material is derived from bovine or canine liver or fungal tissue. The major advantage of the system is the rapid

neutralizing step (10 minutes in the two-step or 45 minutes in the one-step methods) and the biocompatibility of the catalyst. The disadvantages are the relative instability of catalase, the need for a preservative (thimerosal) in the neutralizing solution method,* and the relatively short exposure to the full 3% hydrogen peroxide concentration. In order to improve the latter point Oxysept 1-step (Omnicare 1-step) is now available with the catalase neutralizing tablet coated with hydroxypropyl methyl cellulose (HPMC) which delays full release of the neutralizer for approximately one-half hour. This improves both antibacterial and, in particular, antifungal activity as well as possibly improving cleaning efficacy.

Hydrogen peroxide can also be neutralized by reaction with various chemical agents in the other, neutralizing agents.

1. Sodium pyruvate (Ciba Vision)
   $CH_3COCOONa + H_2O_2 \rightarrow$
   (Sodium pyruvate)
   $CH_3COONa + CO_2 + H_2O$
   (Sodium acetate)
2. Sodium sulphite (Allergan)
   $Na_2SO_3 + H_2O_2 \rightarrow Na_2SO_4 + H_2O$
   (Sodium sulphite) (Sodium sulphate)
3. Sodium thiosulphate (Bausch & Lomb)
   $2Na_2S_2O_3 + H_2O_2 \rightarrow Na_2S_4O_6 + 2\ NaOH$
   (Sodium thiosulphate) (Sodium tetrathionate)

All three methods have the advantage that neutralization is achieved fairly rapidly (10–30 minutes) and they are relatively stable with biocompatible by-products. All suffer the disadvantage of requiring separate disinfection and neutralization steps and the need for a preservative in the neutralizing medium to maintain lens and solution sterility. Most manufacturers are producing unit dose neutralizing solutions to provide preservative-free systems.

Failure to neutralize the hydrogen peroxide in the lens will cause severe transient discomfort and the need for immediate lens removal! The eye may remain hyperaemic and show mild corneal superficial punctate staining to sodium fluorescein for several hours. Serious eye damage has not been reported, although Knopf (1984) reported recovery taking several days in a patient with a previous history of blepharo-conjunctivitis.

Because no gas is released in the thiosulphate and sulphite reactions, a pressure vent is not required in the lens storage case. Carbon dioxide is formed during the pyruvate reaction but a special case is not required because the gas dissolves in aqueous solution producing a bicarbonate ion. The oxygen produced in the catalytic neutralization of the platinum and catalase methods restricts the case usage to the domestic situation because solution leaks from the vents when it is used as a transportation vessel.

* Where the neutralizer is available in unit dose form no preservative is present.

The Allergan Oxysept One-Step (Omnicare) incorporates vitamin B_{12} (methylcobalamin) in the neutralizing tablet to indicate that the tablet has been added. The solution is turned a pale pink. Vitamin B_{12} is mainly found in animal products and was utilized because it is unaffected by hydrogen peroxide and is extremely unlikely, in the concentration used, to cause a hypersensitivity reaction. It should be emphasized to wearers that the colour merely indicates that the tablet has been added and **not** that complete neutralization has occurred.

Jones *et al.* (1993) pointed out that FDA Group IV (ionic, high water content lenses – typically many disposable lenses) lens wearers may complain of lens discomfort and show tightness of lens fit after 20 minutes neutralization of hydrogen peroxide. In this case a longer (60 minute) neutralization step may be optimal.

Piccolo *et al.* (1990) found minimal effects on RGP lens parameters from hydrogen peroxide storage although 22% of lenses exhibited a very small amount of lens warpage.

The Center for Disease Control in the United States has set out guidelines for the adequate disinfection of contact lenses in regard to HIV. These include heat and hydrogen peroxide as recommended methods for soft lenses and hydrogen peroxide for RGP lenses. Hydrogen peroxide in conjunction with Miraflow cleaner has also been shown (Ghajar and Houlsby, 1988) to be highly effective in eliminating the cysts of acanthamoeba. These issues are also relevant for the disinfection of trial lenses.

Controversy exists as to whether hydrogen peroxide actually reduces or removes lens contaminants by its oxidizing action or if deposits are simply bleached and therefore less visible although still present. Johnsson (1984), from protein assay work, found no significant reduction with heat disinfection (known for its protein denaturing ability) and hydrogen peroxide over 12 months of patient wear. Keil (1993), however, showed that hydrogen peroxide disinfection alone can remove up to 40% of protein deposits each time lenses are disinfected. Billig *et al.* (1984) reported a significant reduction in the need for enzymatic treatment once patients were swapped to a hydrogen peroxide disinfection method.

Excess surfactant cleaner left on lenses and transferred to the hydrogen peroxide disinfecting solution will cause frothing and possible solution loss. Surfactant cleaners should therefore be thoroughly rinsed from the lens. Some manufacturers incorporate alcohol in the cleaner to aid rinsing from the lens prior to disinfection.

Because of its good antimicrobial activity, its mild cleaning action, and ability to prevent or reduce lens discoloration, hydrogen peroxide methods of lens disinfection have become increasingly popular.

Chlorhexidine and thimerosal preserved saline storage solutions

The inconvenicnce of the boiling and early hydrogen peroxide disinfection routines meant that alternative methods were looked for with emphasis on the search for

simple storage and rinsing solutions which would be non-irritant to the eye and harmless to lens materials.

The first and major problem was that of the adsorptive or binding ability of most hydrogel materials. Because hydrophilic lenses have the ability to take up water, they will of necessity absorb an aqueous solution of chemical which might be presented to them. This should not create a problem if the solution by itself is safe on the eye. A potential problem arises, however, if the soft lens adsorbs (or loosely complexes with certain molecules on the lens surface) the preservative from the solution, because this will then be concentrated on the surface. Unfortunately, many of the commonly used rigid lens solution preservatives are strongly bound by hydrogel materials. These preservatives are harmful to living bacterial cells and will generally be damaging to the corneal epithelial cells if present in higher than normal concentrations.

Benzalkonium chloride (a cationic preservative) has been shown to be a strong soft lens binder whereas thimerosal (an anionic preservative) is not (Sibley and Yung, 1973). It would appear, therefore, that electrostatic forces are involved. Chlorhexidine as a cationic preservative is also bound (Sibley, 1973, cited by Browne *et al.*, 1974) but as it has a large molecular structure and a very weak cationic action its binding capacity is about one-sixth that of benzalkonium chloride (Hind, 1975). Various authors have shown that for most patients the amount of preservative bound to the lens is insufficient to cause ocular irritation (Krezanoski, 1972a; Phares, 1972b; Brown *et al.*, 1974; Hind, 1975). Other workers have mentioned the binding ability of the other commonly used rigid lens preservatives, phenylmercuric nitrate and chlorbutanol (Krezanoski, 1972b; Ganju, 1974), but EDTA does not appear to be bound to any significant degree. Surprisingly, Lerman and Sapp (1971), from laboratory and clinical experiments, determined that the concentration of benzalkonium chloride and chlorbutol normally used in ophthalmic preparations was bound to an insufficient degree to cause ocular irritation. This unexpected result may be due to the fact shown by Otten and Szabocsik (1976) that the final formulation of the solution has a significant effect on the binding ability of the preservative, although they were unable to offer any explanation for this.

Although chlorhexidine is only minimally bound to clean lens material, it is very effectively bound to protein deposits on the lens surface and, unfortunately, this exacerbates the binding effect. Not only does this reduce the efficacy of the solution but the increased concentration of bound preservative causes symptoms of ocular discomfort over a period of time as the lens contaminants build up, often leading to lens rejection (Hind, 1975). Further, there is the danger of a sudden release of preservative from the lens to the cornea if there is a pH change, fluid movement across the lens or replacement by ions present in the tear liquid (Ganju, 1974). Daily cleaning of the lens is therefore of paramount importance (*see* Optimeyes *below*).

Most of the soft lens storage or soaking solutions may also be used for rinsing lenses following lens cleaning. However, any solution of physiological saline is equally suitable for this rinsing procedure. Unpreserved sterile saline solution may be used, e.g. in aerosol form, or one of the multipurpose solutions. Preserved saline solutions specially formulated for lens rinsing are also available (*see* Appendix C *below*).

For the reasons discussed above it is obvious that patients with soft lenses must be adviscd not to use any solutions intended for rigid lenses or other therapeutic eye drops without discussing it with their practitioner (*see below*). It is also important that soft lens solutions contain the least possible amount of preservative in order to minimize any binding effect to the lens material or contaminants. The usc of minimal quantities of preservative has led to criticism of the antibacterial efficacy of these solutions.

Norton *et al.* (1974), using proprietary soft lens storage solutions, found that none was able to disinfect a standard laboratory contamination of 10^6 organisms/ml of *P. aeruginosa, S. aureus, M. luteus* and *C. albicans* in less than 24 hours, many taking 48 hours. These workers also found discrepancies between different solutions containing similar quantities of the same preservatives and postulated two reasons for this. First, that all the solutions were packaged in plastic containers and some preservatives may be adsorbed by the plastics. This could result in reduced concentration of preservative available in the solutions and would depend on such factors as the type of plastics used and the time stored (which is why manufacturers now date-stamp solution bottles). Secondly, that the solutions used are complex and usually contain viscolizers such as hydroxyethylcellulose and polyvinyl alcohol, buffering agents, electrolytes and surfactants, all of which may influence the antibacterial performance of the preservative.

Holden and Markides (1971) found that a solution of 0.001% thimerosal took over 24 hours to kill an inoculum of *S. aureus*, and 6–24 hours for an inoculum of *P. aeruginosa*. Grosvenor *et al.* (1972) and Baker and Remington (1972) all found that lenses stored in the same solution and supplied by manufacturers were often received highly contaminated. Charles (in Davis *et al.*, 1973) noted that this solution was also ineffective against clumped groups of bacteria. Similar results to those of Holden and Markides (1971) were found for *S. aureus* by Lindeman-Meester (1974) using 0.002% thimerosal plus 0.1% EDTA. Tragakis *et al.* (1973) found that high concentrations (10^7/ml) of *Proteus vulgaris* were able to survive 24 hours exposure to 0.005% chlorhexidine. Feldman (1971) found this concentration of chlorhexidine to be effective against several bacteria but to be ineffective against the fungus *A. fumagatus*. Similar results against fungi were stated by Charles (in Davis *et al.*, 1973).

It would appear from the above, and the results of other workers, that of the two commonly used preservatives suitable for soft lens storage solutions – chlorhexidine and thimerosal – chlorhexidine is the more effective but has poor fungicidal capacity. Thimerosal is slower acting but is known to be more effective as an antifungal. For this reason many solutions utilizing these preservatives make use of

both agents, chlorhexidine at 0.0005–0.005% and thimerosal at 0.001–0.0025% strengths, and they may also incorporate EDTA at 0.01–0.1%. The incorporation of EDTA is both for enhancement of the bactericidal effect of the main preservative, and the postulated, but unproven, advantage of reducing calcium ions which may eventually form deposits on the lens. However, Morton (1985) found a reduction in antimicrobial activity when EDTA and thimerosal were used in combination.

The solutions are made isotonic and may contain liquid polymers such as polyvinyl pyrrolidone, and possibly surfactants to act as cleaning agents. Hampson (1973) stated that lenses stored in an acidic pH solution took two to three times as long to settle and become comfortable as those stored in a slightly alkaline pH solution. For this reason most manufacturers moderately buffer solutions to a neutral or slightly alkaline pH.

From the accumulated evidence it would appear that chlorhexidine–thimerosal disinfecting solutions are able to cope with all levels of bacterial and fungal contamination normally encountered. There is evidence that very large levels of contamination may take several hours for disinfection, although even this should be coped with during the overnight storage period. Higher levels of contamination should be greatly reduced by cleaning and rinsing prior to storage (*see below*).

The major disadvantage of the chlorhexidine–thimerosal combination has been the relatively high incidence of reported patient hypersensitivity or toxic reaction cases, with thimerosal as the major culprit (Mondino and Groden, 1980; Rèetschel and Wilson, 1982). Nevertheless, chlorhexidine–thimerosal preserved solutions have been used successfully by millions of hydrogel wearers for over two decades.

Other chemical disinfection systems

Because of some of the disadvantages associated with chlorhexidine–thimerosal storage solutions, alternative methods of lens disinfection have been developed (although some are no longer in use). Specificity, greater antibacterial and antifungal activity, reduced incidence of ocular reaction, reduced binding to lens materials and protein, and additional cleaning action have been sought. These are summarized below in alphabetical order.

Alkyl triethanol ammonium chloride

This solution (Hydrocare by Allergan) combines thimerosal with a quaternary ammonium compound, alkyl triethanol ammonium chloride, to provide the disinfecting action. The disinfecting action reported by the manufacturer is slow but effective and is reported not to concentrate in the lens (Shively, 1975). However, the disadvantages are the relatively high concentrations of thimerosal used and the fact that some patients complain of stinging on lens insertion (Morgan, 1979).

In addition to acting as an antimicrobial agent, the alkyl triethanol ammonium chloride is also used for its surfactant properties, and two other surfactants – Polysorbate 80 and propylene glycol – are also included to give the solution a cleaning as well as a disinfecting action.

Benzyl alcohol (phenylmethanol)

Although first introduced as a bactericide in 1947, benzyl alcohol has only been used as a preservative in contact lens solutions in the last decade.

In higher concentrations, it is used for its anaesthetic as well as its bactericidal properties, for example in dental cavity work. However, there is no apparent anaesthetic effect at the 0.1% level used in current contact lens preparations.

Benzyl alcohol is claimed to be non-cytotoxic but effective as a bactericidal and viricidal agent (Anon, 1987; Feldman *et al.*, 1992). It is also claimed to have a low affinity to rigid gas permeable lens materials and lower ocular sensitivity reactions compared to benzalkonium chloride, chlorhexidine and thimerosal. However, Klein *et al.* (1954) warned against dangers from *P. aeruginosa* infections in eye drops by permitting concentrations below 0.9%. For this reason current products also incorporate either EDTA or sorbic acid as co-preservatives.

Dymed

Dymed is the proprietary name for the preservative polyhexanide [poly(1-hexamethylenebiguanide hydrochloride)]. Dymed is currently used by Bausch & Lomb in a range of products and is claimed to show very low patient reactivity.

Polyhexanide was originally developed by ICI in the UK and is used as the swimming pool bactericide and algaecide, Baquacil. Its particular application in this usage is its antimicrobial action even in high dilution. In contact lens solutions it is commonly used at a strength of 0.00004%.

As a biguanide, polyhexanide belongs to the same pharmaceutical family as chlorhexidine. Both are cationic disinfectants which adsorb onto the often negatively charged bacterial cell surface, disrupt the cytoplasmic membrane releasing potassium ions and other cytoplasmic constituents, cause precipitation of cell contents and the death of the cell. Ikeda *et al.* (1984) report greater activity of this group against Gram-positive bacteria and less against Gram-negative bacteria.

Green *et al.* (1989) found no effect on corneal wound healing at concentrations of 0.00003–0.00005%. However, one product (Boston Advance Conditioning Solution) utilizes Dymed at 0.0015%, some 30–50 times greater than that normally used. Begley *et al.* (1991) showed that this concentration is significantly more toxic to rabbit corneal epithelium but major problems with human contact lens wearers have not been widely reported.

Halazone

Marketed under the name Aerotab (Sauflon), this product resembles Softab (*see below*) in that it is a chlorine-release tablet system.

Halazone [4-(dichlorosulphamoyl) benzoic acid] is commonly used in the disinfection of drinking water by virtue of its chlorine release. Indeed its first usage for this purpose was in the trenches in World War I (Sykes, 1965)! In the Aerotab form approximately 8 parts per million available chlorine is present when dissolved in saline, a slightly higher figure than the comparative Softab value. However, bactericidal activity is also dependent on pH and organic load and chlorine-based systems are very dependent on these additional factors. Little or no ocular irritancy is claimed even if the solution is inserted directly into the eye immediately after dissolving the tablet. Tablets should be protected from the light.

The main disadvantages of all chlorine systems are:

- Their poor antifungal and anti-*Acanthamoeba* action.
- The need for careful pre-cleaning since biodebris easily inactivates chlorine-based systems (*see* Sodium dichloroisocyanurate *below*).

Iodophors

This was an alternative lens disinfection system based on an iodophor in an isotonic polymeric vehicle which appeared to show good clinical results (Johnson and Littlewood, 1975). When the iodophor (in a phosphoric or citric acid diluent) was placed in combination with a complementary neutralizing medium preserved with sorbic acid, EDTA and sodium borate, the iodine was reduced to the iodide ion. A coloured indicator was incorporated into this system. When the solution and the lenses became colourless there was a remaining preservative action, but the lenses could be safely inserted direct from the solution. Disinfecting time was stated by the manufacturer to be 2 hours. The concentration of active (diatomic) iodine was 0.005%, and there appeared to be the definite advantage of no binding effect of the preservative (although J. Stone, 1976, personal communication, reported pronounced stinging if first used on old, and therefore probably contaminated, lenses when disinfection should be followed by boiling to prevent this problem). Slightly more attention and cooperation was required on the part of the patient in the correct preparation of the disinfecting solution because neutralization was essential, due to the diluent having a pH of less than 5.0. The cost of iodophors was high compared to other disinfectant methods and for these reasons the system is no longer available.

Microwaves

Preliminary work has shown that domestic microwave ovens are able to sterilize hydrogel lenses (Anon, 1986). However, for true sterilization the lenses must be in the dry state, rotated to avoid 'cold spots' in most ovens, and then rehydrated with sterile (unit dose or preserved) saline afterwards. At the present time this is considered impractical for general use.

Kerr (1985) has described the use of domestic microwave ovens as a heating unit to pasteurize lenses by placing them in 15 ml saline in open containers and then bringing the saline to boiling point. The unit should then be shut down, the lenses allowed to cool, and the caps replaced. Patients should be warned of the dangers of leaving caps screwed firmly on the container when using a microwave oven because of the risk of container explosion when saline boiling occurs. Vented containers able to withstand heat are preferable, e.g. AOSept container.

Rohrer *et al.* (1986) obtained lens dehydration in 2 minutes, viral inactivation in 4 minutes and complete sterilization in 8 minutes using a rotating 'rotisserie' to avoid 'cold spots' in the microwave oven.

Harris *et al.* (1989a) and Harris *et al.* (1990) showed that, by acting as a heat unit, microwave disinfection is effective in 2 minutes or less, even if a large number of (trial) lenses (40) are treated at the same time. Hatch and Paramore (1990) showed that microwave disinfection has no clinical effect on lens parameters but caution that any long-term effect on the lens material was not studied. Merindano *et al.* (1991) also cautioned that the variety of output and design, e.g. rotatable or stationary plates, means that not all microwave ovens may be adequate for safe disinfection of hydrogel lenses.

Optimeyes

Although strictly a chlorhexidine-based product, the differences between this and general chlorhexidine preserved solutions justify its being treated as a separate disinfection system.

Optimeyes was developed by Professor David Davies and his team at the University of Bath, England (Anthony, 1991). The design criteria were:

- to develop a product that was simple to use, thereby assisting compliance;
- to enable simple but effective cleaning to remove biodebris from lenses;
- to improve attention to and cleaning of lens storage cases;
- to keep product costs to a minimum to assist the above.

It was decided at the outset by the University of Bath group that potable (or drinkable) tap water would provide the most readily available and cheapest diluent. In most countries tap water is pre-treated with chlorine to eliminate all but small numbers of micro-organisms (and these are rarely pathogenic to the eye). However, tap water is non-isotonic; it contains chlorine which needs to be removed and other unwanted inorganic salts such as magnesium and calcium ('hardness'); and finally the pH needs adjustment to that of human tears (around 7.2). In addition, an antimicrobial agent needs to be added. It was also decided that the product should be available in tablet form since this is also readily

portable and requires only low cost packaging compared to liquid disinfectants, again helping keep costs down.

Each tablet therefore contains:

- a 'sequestering' agent which removes unwanted inorganic salts from the tap water;
- a neutralizer for the chlorine in tap water;
- a buffering agent to alter the pH to the physiological norm;
- urea (rather than the usual sodium chloride) to bring the tonicity to that of the normal tear level (the use of urea is novel and is discussed below);
- chlorhexidine digluconate as the disinfectant (*see below*). One Optimeyes tablet in 10 ml of water produces a disinfection solution containing 0.004% chlorhexidine gluconate.

Chlorhexidine was selected as the antimicrobial agent as it has a wide spectrum of activity against micro-organisms. The Bath team were aware that chlorhexidine was perceived by many practitioners as a cause of irritancy in soft lens wearers. A careful study of the literature, however, showed that the reports of hypersensitivity were associated with the use of solutions containing thimerosal as well as chlorhexidine and that most authorities felt that thimerosal was the cause of the irritancy not the chlorhexidine.

The Bath group were also aware that optimization of chlorhexidine's antimicrobial activity needs careful formulation as it is very sensitive to its ionic environment. For this reason urea rather than sodium chloride was incorporated into the product. Urea is non-irritant to the eye and is known to prevent the hydrogen bond formations between the lens and preservative molecules which would otherwise occur. The formula arrived at both maximizes the antimicrobial activity of chlorhexidine and reduces its absorption into hydrogel lenses. This minimizes the possibility of build-up with subsequent release of unacceptable quantities from the lenses onto the cornea.

One additional value of the prevention of hydrogen bonding by urea is the minimization of protein bonding to contact lenses. Clinical trials have shown that the need for enzymatic (protein-removing) tablets is significantly reduced or possibly removed altogether in some cases. Thus Optimeyes does not actually clean protein from lenses, but minimizes its attachment in the first place (D. Davies, personal communication).

Optimeyes represents a novel approach in contact lens disinfection with the following advantages:

- Simplicity of use.
- Adequate rinsing of both lens and container since, with tap water as the diluent, adequate volumes can be used. Allowing the container to air-dry between usage may reduce microbial replication.
- Less expensive than many other products.
- Reduces or removes the need for enzyme tablets in most cases.
- Wide range of antimicrobial activity, especially *Acanthamoeba*.
- The product is suitable for all soft and RGP lens materials with the exception of FDA Class III and IV products (i.e. high water ionic materials such as Permalens, Durasoft 3, Hydrocurve II, Acuvue etc.).

The disadvantages are:

- As with all products some patients will still experience irritancy with the product.
- It remains to be seen whether further reactions to the product will be found as lenses age due to chlorhexidine adsorption onto the lens or attachment to accumulating protein. In theory this risk should be minimal because of the product formulation. The risk of sensitivity reactions may possibly be worse in old, i.e. already proteinized, lenses.
- Ready availability of drinking water is essential. The product has been criticized (Hay and Seal, 1993) in situations where the wearer uses water from mixer taps where the first drawn water may arise from both hot tank and cold mains supply, or if the wearer lives in a high-rise flat. For these reasons first drawn water should not be used but ideally, cool, boiled water from a kettle.
- If enzyme tablets are found to be necessary then a suitable diluent is still necessary, e.g. saline.
- Approval is still awaited for use with FDA Class III and IV materials.
- Earlier usage of chlorhexidine found that it turned some hydrogel lenses slightly brown in colour. However, these were commonly the Class III and IV materials.
- Some practitioners have expressed concern that less compliant patients may be tempted to use tap water without the tablet or prior to inserting the lenses in the eyes.

p-Hydroxybenzoic acid (Nipastat)

The hydroxybenzoates are active against moulds, fungi and yeasts but less active against bacteria. The higher esters are the most effective but are limited by lower solubility. Unlike sorbic acid, the hydroxybenzoates are active at pH 7–9. Mixtures of two or more esters are likely to be more effective than the use of a single ester, because in this way a higher total concentration of preservative can be obtained in the solution and, in addition, the mixture may be active against a wider range of organisms.

Ganju and Thompson (1975) reported a solution (*see* Appendix C) containing a mixture of methyl, ethyl, propyl and butyl esters of *p*-hydroxybenzoic acid (Nipastat) in combination with a water-soluble polymer complex and reported success in its use as a lens disinfectant. It should be noted, however, that the numbers of micro-organisms challenged were low compared with other workers and that the first subculture was not taken until after 8 hours exposure to the preservative. The work of Hugo and Foster (1964) also showed that it is not always entirely effective in eliminating contamination by *P. aeruginosa*. *Martindale's Pharmacopoeia* (Anon, 1982) reports that concentrations of 0.2% are necessary for safe bactericidal concentration but

that at this level the solution may be an irritant to the eye. As its name would suggest, the solution should be regarded as bacteriostatic and it should not therefore be presented with high microbial challenges.

The *p*-hydroxybenzoates show a very slight tendency to concentrate on hydrophilic lens surfaces in a similar manner to chlorhexidine. The advantage of this preservative is that it is non-mercurial and contains no quaternary ammonium compound, thereby providing a possible alternative for patients showing an allergy or sensitivity to chlorhexidine–thimerosal preserved solutions.

Polyquad

Polyquad (Alcon) is a large polymeric molecule* which, when used as a preservative, resists diffusion into the lens matrix minimizing the toxic or hypersensitivity reaction found with chlorhexidine–thimerosal preserved solutions. Greater antibacterial and antifungal activity is claimed by the manufacturer than thimerosal, alkyl triethanol ammonium chloride plus thimerosal, or sorbic acid.

As a cationic detergent, the preservative is bound ionically to the methacrylic acid used in some hydrogel materials and toxic keratitis may result. Polyquad preserved solutions were initially therefore reserved for materials with a water content of 45% or less which did not contain methacrylic acid. Reformulation has eliminated this problem and the preservative is now considered suitable for use with lenses of any material or water content.

Potassium sorbate/sorbic acid

Sorbic acid is used by several solution manufacturers as an alternative preservative to the chlorhexidine–thimerosal combination. It is commonly used as the potassium salt because this is considerably more water soluble and has identical actions.

Sorbic acid has antibacterial and antifungal properties. It is active against moulds and yeasts and, to a lesser degree, against bacteria, the fungistatic activity being increased in saline solution. It is not effective above about pH 6.5 with an optimum pH of around 4.5. Solutions of 0.1% sorbic acid stored in polypropylene, polyvinyl chloride, polyethylene or glass containers showed a marked loss of potency except when refrigerated or when an antioxidant such as sodium metabisulphite was also present (McCarthy, 1973). Sorbic acid solutions should also be protected from the light.

Although popular with many practitioners and patients, it will, as with all preservatives, cause reactions in some patients. Josephson and Caffrey (1986) report a sensitivity reaction in 15% of patients using a 0.1% preserved solution. *Martindale's Pharmacopoeia* (Anon, 1982) specifically mentions its potential for ocular irritancy in topical solutions. Callendar *et al.* (1986) reported poorer lens disinfection results with sorbic acid-preserved solutions than alkyl triethanol ammonium chloride combined with thimerosal.

* The molecular weight of polyquad is 5000 compared to chlorhexidine 359, polyhexanide (Dymed) 1300, sorbic acid 112 and thimerosal 405.

Tighe *et al.* (1991) pointed out that sorbic acid concentrated within the matrix of soft lenses, particularly those of higher water content, with which it can interact. These interactions are very weak in HEMA-based materials, but greater with the more polar groups used in many extended wear materials. It is this interaction combined with the chemical reactivity of sorbic acid that provides the basis for accelerated lens discoloration in certain situations (such as photochemical activation or heat disinfection) or when left for prolonged periods in the storage solution.

Sodium dichloroisocyanurate (Halane)

Marketed under the name 'Softab' (Alcon) this product breaks down in water to form hypochlorite. Because hypochlorite is not stable in aqueous solution it will spontaneously break down to form chlorine and sodium chloride. The 3–5 parts per million (ppm) chlorine liberated is adequate to disinfect the solution in approximately 4 hours as well as providing a mild cleaning action (Brewitt and Conrads, 1986) although this does not obviate the need for a surfactant cleaner. At 3–5 ppm the chlorine level is already below the ocular irritation level and this is further reduced after the overnight soaking period (Parker, 1983).

The main advantages of the system are minimal risk of patient sensitivity, simplicity in use and minimal risk in cases of poor compliance (compared to hydrogen peroxide), portability when combined with unit dose saline, ability for use with hypotonic saline in patients showing marginal dry eye problems, and the mild cleaning action in addition to its disinfection properties.

The main disadvantage of any chlorine-based system is the neutralization of the antimicrobial action by biodebris. Whilst pre-cleaning of lenses is essential prior to **any** disinfection technique (*see below*) it becomes of vital importance in the use of any chlorine-based system (Copley, 1989; Quinn, 1992). In addition, chlorine systems have weak antifungal activity (Lowe *et al.*, 1992) and should not therefore be used in patients with a known history of system fungal infections (e.g. *Candida* sp.), for long-term lens storage, or in climates favourable to fungal growth. Its efficacy against *Acanthamoeba* is also poor.

Sonification

Ultrasound is the range of sound waves of higher frequency than those to which the human ear is sensitive. The auditory range is approximately from 100 cycles/second (100 Hz) to 15 000 or 16 000 cycles/second (15 or 16 kHz). Above 16–20 kHz, the sound waves result in no sense of hearing in the human ear and are referred to as ultrasound.

The cleaning action of ultrasound units is produced by a process known as cavitation. The ultrasound waves produced by transducers in the unit create frictional forces within the liquid medium. This produces both heat and the liberation of microscopic bubbles. These bubbles redissolve almost immediately, producing an implosion or 'cavitation' effect. Because most cavitation occurs at, or very close to, solid surfaces, contact lenses immersed in a

cleaning tank are claimed to benefit from boundary or surface cavitation.

The microbiological action of ultrasound arises by three mechanisms:

1. The purely mechanical strain put on the cell wall by the sudden application, and the equally sudden release, of pressure.
2. The cavitation effect of fluid within the cell.
3. The rise in temperature produced by ultrasound.

Charles (1975) first pointed out the possibility of using sonic oscillation for cleaning and disinfecting hydrogel lenses. However, his tests showed that sonification for as long as 2–3 hours was necessary to kill an inoculum of *P. aeruginosa*. Spores were also somewhat resistant to this procedure. Because only small volumes can be treated at a time, ultrasound has found little use in conventional microbiology and therefore little evidence exists as to its efficacy and what evidence exists is often contradictory. Nevertheless it can be stated that:

(a) the efficacy of antimicrobial activity is more related to the *intensity* of wave emission than to its frequency;
(b) cavitation becomes more difficult and less intense as the frequency is increased, thus requiring a higher power input to produce any effect.

These points therefore place a limitation on the manufacturer of patient units where size, weight, cost and heat generation must all be balanced against the desired cleaning and antimicrobial activities.

At least two ultrasonic contact lens units are currently available. The 'Lenso Clean' utilizes a 33 kHz unit over a 10-minute cycle (Anon, 1984). Both cleaning and low temperature disinfection are claimed.

The 'Sonasept' unit (SMC Metal Tech Co.) utilizes three time/temperature settings – hard lenses, low water and high water content lenses. Examination of the latter unit by both Phillips *et al.* (1989) and Shuley (1993) have shown microbial survival except at the highest temperature, low water content setting, whilst Efron *et al.* (1991) found survival at all three settings. At its highest temperature (60–70°C) the unit would appear to function as a marginally effective low heat unit only and with little or no apparent antimicrobial action from the ultrasound. Scanlon (1991) was also unable to demonstrate satisfactory disinfection with ultrasound units combined with ultraviolet light.

Erikson (1985) claimed that ultrasonic devices can markedly increase the effectiveness of Allergan's enzyme cleaner on soft lenses. Kerr (1988) reported surface calculi reduced smoothly down to the level of the lens surface with Miraflow (Ciba) in the unit as cleaning agent. Liprofin (Alcon) is also likely to work effectively at the temperature induced by current ultrasonic units. Kerr also reported that most RGP lenses (including fluoropolymers) appear to be effectively cleaned and dimensionally unchanged. Conversely Phillips *et al.* (1989) showed that whilst ultrasonic cleaning does reduce surface deposits on HEMA lenses, a conventional cleaning routine of manual surfactant cleaning and regular enzymatic treatment is likely to remove considerably more. Fatt (1991) questioned the ability of a universal ultrasonic device to effectively clean all types of contact lenses. The problem is that a hydrogel lens in saline does not present a significant boundary as the refractive difference between the lens and solution is minimal. The difference also decreases with increasing water content of the lens. Thus, ultrasound wave energy which adequately cleans but does not damage a PMMA lens, would pass through a hydrogel lens relatively undisturbed.

Further work is now awaited on the full antimicrobial safety and long-term cleaning action of any upgraded ultrasonic units, particularly if inexpensive, unpreserved saline alone is utilized. The use of relatively costly, larger volumes of cleaners would negate the advantages of these expensive units and restrict them to practitioner usage. The use of preserved saline to enhance antimicrobial activity would provide no advantage over current chemical disinfection methods, unless a significant cleaning action was also obtained.

Trimethoprim

Trimethoprim has been used for many years in the treatment of urinary tract disorders. Its antibiotic-like action specifically inhibits bacterial dihydrofolate reductase (an enzyme essential to bacterial growth), while exhibiting very little effect against the mammalian enzymes. Studies done with this drug show that at dosages lower than the therapeutic level, it is an effective preservative for contact lens solutions (Feldman, 1985). In addition, the bactericidal properties are enhanced by such agents as EDTA and sorbic acid giving a synergistic effect. Studies appear to show minimal binding to the lens surface or deposits, or incidences of hypersensitivity. The future of this preservative will depend upon the reaction of the various regulatory bodies to the use of a systemic-drug as a contact lens preservative and fears that its widespread use will enable the build-up of bacterial immunity (Anon, 1980).

Perhaps another reason for its not having been further developed is that it is stated in *Martindale's Pharmacopoeia* (Anon, 1989) to have little activity on its own against *P. aeruginosa* presumably indicating its usage in combination with sorbic acid and EDTA.

Ultraviolet radiation

Ultraviolet has been proposed as a method of contact lens disinfection. Harris *et al.* (1993) found for both RGP and hydrogel lenses that three commonly found bacteria, *E. coli*, *S. epidermidis* and *Serratia marcescens* showed decimal reduction values (D values)* within 1–300 seconds following exposure to 253.7 nm wavelength UV radiation. Gritz *et al.* (1990), however, found that UV-C radiation (less than 290 nm) killed all test organisms in 20 minutes or less, longer exposure (2 hours or greater) destroyed soft lenses and caused RGP lenses to lose their optimal quality and

* D values describe the time taken to reduce the number of viable organism in the original inoculum by one log unit.

become brittle. UV-B radiation (290–320 nm) required 3 hours to kill the organisms although the fungus Aspergillus was not killed even after 6 hours of exposure. Minor changes to the elasticity modulus and tensile strength of the soft lens material was found and the Polycon II RGP lens tested faded slightly in colour. Conversely, Harris *et al.* (1993) found no clinically significant change in soft lens parameters after 20 hours' UV exposure with the exception of FDA Group 2 lenses which showed small but possibly clinically significant increases in power, centre thickness, diameter and water content.

Jacobs (1986) pointed out that ultraviolet disinfection is ineffective against the AIDS virus.

The advantages of chemical disinfecting solutions may therefore be summarized as follows:

- Generally they are convenient, and for the patient who may already have had rigid lenses, they fit into a similar pattern.
- The initial cost is low.
- They are portable.
- They are generally effective for all micro-organisms normally encountered.
- Sporulating bacteria are destroyed if they revert to their vegetative form.
- There appears to be no effect on the life of the lenses.
- There is less coagulation of mucoprotein left on the lens than with heat sterilization.

Set against these are the following disadvantages:

- Chemical disinfecting solutions are more expensive in the long term.
- There is a risk of some binding with certain antimicrobial agents and this applies particularly if the lens is not cleaned prior to being placed in the solution.
- There is some risk of ocular irritation by solution constituents.
- The solutions may be less effective against large influxes of micro-organisms.
- The solution method is slow, often taking 6–8 hours to be certain of complete disinfection.
- Many preservatives still cause slight coagulation of any mucoprotein remaining on the lens surfaces.
- Most solutions have minimal cleaning action despite the incorporation of surfactants, and still necessitate the use of separate cleaning compounds. The newer multi-purpose solutions, e.g Renu (Bausch & Lomb), Complete (Allergan), are the exceptions to this. They still require a rub and rinse step prior to disinfection, albeit with the same solution.
- The possibility exists that solutions may be suitable for use with only specified lens materials.

Practitioners occasionally find that paticnts using heating methods of disinfection will change to chemical disinfection, for example, on holiday when mains electricity may not be available or may be the wrong voltage. While many patients experience no difficulties with alternating disinfection methods it can sometimes give rise to problems. First, it has already been mentioned above that heating methods of disinfection accelerate the denaturation of proteinaceous deposits on the lens surface. Chlorhexidine then binds more strongly to these deposits than to the lens surface and gives rise to a toxic or allergenic response. Secondly, there is good evidence that tear protein bound to contact lens surfaces can cause an immune response (Allansmith *et al.*, 1977; Refojo and Holly, 1977). The present understanding of this process is that the adsorbed protein molecule undergoes changes that may be accelerated by alternating dry/wet and hot/cold conditions, as well as by mechanical rubbing from fingers and lids. The altered denatured protein may then no longer be recognized as 'self' and becomes capable of provoking an autoimmune response (McMonnies, 1978).

Conversely, practitioners may wish their patients to change from chemical disinfection of their lenses to heat disinfection, or from one chemical disinfection method to another, as may be done if a patient is thought to have developed an adverse reaction to a particular preservative. Before doing so all traces of the existing preservatives should be removed from the lenses by either:

- soaking the lenses in at least three changes of unpreserved physiological saline solution at room temperature during a period of 24 hours; or
- boiling in unpreserved physiological saline solution, replenishing and then re-boiling.

The properties of a soft lens disinfecting solution may therefore be listed as follows (modified from Cureton and Sibley, 1974):

- The solution should be capable of disinfecting the lenses in 4–6 hours or less.
- The antimicrobial agents used should not easily be inactivated by small amounts of proteins, lipids or other tear components.
- The solution should be isotonic and either non-buffered or lightly buffered to a pH approximating that of the average tear liquid.
- The antimicrobial agents used should not bind to protein or other lens surface deposits from the eye.
- The solution should not react with or adsorb to soft lens materials, or the container materials.
- The solution should be non-irritating and non-toxic to the ocular tissues.
- The cost of the regimen should encourage good compliance.

In addition, the combination of a cleaning action with the disinfectant/storage action is helpful.

Cleaning solutions and methods

While the lens is on the eye, the mucin in the tear fluid is adsorbed onto the surface of the lens in the same way that it is adsorbed onto the epithelium of the cornea. Mucin and other proteins of the tears such as lysozyme

remain in their natural state when attached to the soft lens surface in the eye. As long as the soft lens remains in the environment of the tear fluid (i.e. in the eye) there will not be an excessive protein film build-up. However, as mentioned earlier, drying of the lens surface between blinks and daily removal of the lens, over a period of time, results in the denaturing of adsorbed proteins. This process occurs very slowly when the lenses are stored in a cold sterilizing solution but more rapidly when they are boiled. The problem is compounded by lipid secretions from the meibomian glands which can also bind to the lens surfaces, forming a lipoprotein film that is difficult to remove and which can impair visual acuity and cause discomfort. Further, chlorhexidine and other preservatives will bind to this film, increasing both their concentration and contact time with the eye and causing a burning sensation (Hind, 1975) and a sudden release of adsorbed preservative may also cause marked irritation.

In addition, the bound preservative loses its disinfecting ability so that the solution takes longer to sterilize the lens. The surface film may itself serve as a growth medium for bacteria and fungi and may actually protect micro-organisms trapped within it. Cureton and Hall (1974), Hind (1975) and Thompson and Mansell (1976) showed a marked improvement in the time taken for disinfection where lenses were cleaned prior to storage. This presumably arose from the combined effect of physically reducing the number of micro-organisms by cleaning and rinsing, and also by removing or reducing surface contaminants and thereby enhancing the disinfectant action of the boiling or chemical solution.

In addition to the lipoprotein surface film, various salts, divalent or trivalent ions (for example calcium) and other contaminants such as environmental pollutants, chemical vapours, cosmetic ingredients, water impurities, nicotine, oils and dirt from the fingers, and preservative and active ingredients from ophthalmic products may be present in the adsorbed or absorbed state.

The cleaning problem is further complicated by the fact that different lens materials are affected by contaminants in different ways. Some lens materials become cloudy and hazy and accumulate rough deposits which may be impervious to ordinary cleaning procedures. Other lens materials become discoloured and occasionally form deposits in the form of white spots (*see* Chapter 3) (Ganju and Cordrey, 1975). Contaminants are often visible to both patient and practitioner with the naked eye, and the patient should be instructed to cease wearing any lens showing any opaque area on its surface.

Surface deposits are often seen with the slit lamp and usually take the form of roughness of the lens surface appearing between blinks. Removing the lens from the eye, holding it with a suitable pair of tweezers, and allowing it to air dry will often disclose previously invisible deposits.

Cleaning methods have therefore been developed for daily and/or periodic use and fall into three categories: surfactants, enzymatic systems and calcium preventing solutions.

Surfactants

This is the largest group of products. Their cleaning property depends upon their ability to lower the surface tension of oil or solid–water interfaces. Surfactant cleaners will help remove lipids, mascara, some types of aerosol spray, lipstick, facial make-up, calcium salts before deposition, and protein before it becomes denatured. Because of the porous nature of hydrophilic lenses and their interaction with many ionic compounds, the selection of a surfactant is limited to a non-ionic block copolymer (Ganju and Cordrey, 1975). Surfactant cleaners should be designed to be safe and cause minimal or no ocular discomfort if accidentally instilled into the eye, to be readily rinsed off the lens by the rinsing or storage solution, and to be compatible with all hydrophilic lens materials and accessories. Solutions are often made slightly viscous to facilitate handling and possibly formulated at an alkaline pH to maximize protein removal (Hind, 1975). Phillips (1980) found few surfactants formulated at an alkaline pH, however, and presumably the need for differing pH values for maximum surfactant or preservative activity becomes an overriding factor.

In using a surfactant cleaner, oil droplets are first broken up by physical dispersion. These would then normally coalesce on contact. However, the surfactant forms a surface monolayer with the ions, oriented with the polar end 'buried' in the surface of the oil droplet. Thus a surface electrical charge is established which causes mutual repulsion (*Figure 4.10a*) between any two droplets that approach one another and coalescence is prevented. It should be

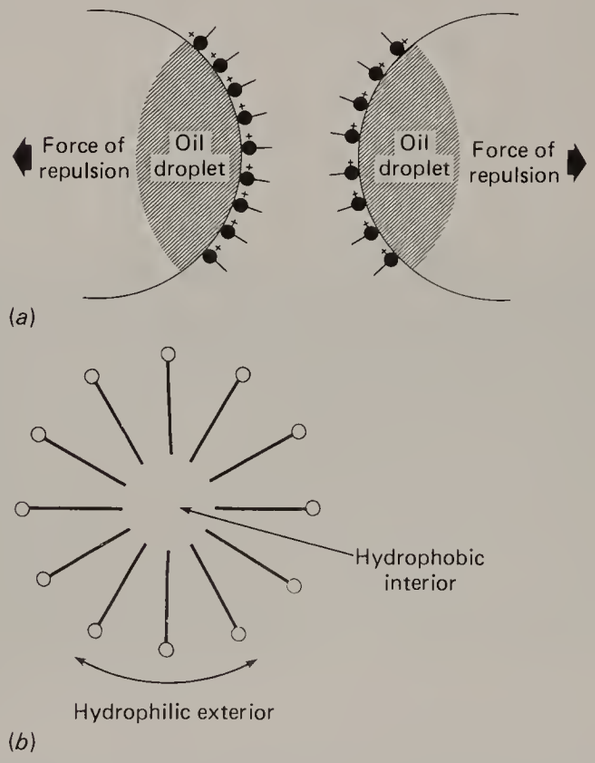


Figure 4.10 (*a*) Orientation of surfactant molecules on lipid droplets. (*b*) Typical micelle structure

stressed, however, that the essential act of cleaning is the initial mechanical dispersion.

A similar effect – of the detergent forming a surface monolayer in an aqueous environment – is what lowers the surface tension and hence gives rise to the term 'surfactant'.

It is important to realize that the formation of a monolayer is not an energetically stable structure. Detergents will, at a certain concentration, form molecular arrangements known as micelles in the solution (*Figure 4.10b*) and it is these structures that are energetically more favourable, i.e. they use less energy to accomplish the same objective.

Thus surfactant cleaners aim at using a concentration of detergent which achieves its critical micelle concentration or CMC. This is, in practice, very difficult as several excipients of the formulation will interfere with the formulation of the CMC. Equally, increasing the surfactant concentration beyond that necessary to form its CMC will not improve the efficacy of the solution and may increase the risk of ocular irritancy. Little evidence exists in comparing the efficacy of different surfactant cleaners and patients generally use that product advised by their practitioner, or select on a basis of availability, cost or preference for a particular solution viscosity.

In order to improve or enhance the efficacy of normal surfactants several laboratories have marketed modified or 'improved' surfactant cleaners.

Hypertonic solutions

Two such solutions, InstaCare (Ciba Vision), and the in-eye cleaner, Clerz (Ciba Vision), incorporate a hypertonic saline element (1.2%,) so that deposits in the lens surface matrix are drawn out by osmotic pressure before emulsification by the surfactant.

In the case of Ciba's InstaCare (Quick Care) Starting Solution (ISS), the hypertonicity (1.2%) of the solution is not only used to aid in cleaning but largely as a means of assisting in the antimicrobial action of the product. The product is similar to Miraflow (*see below*) in that it contains 20% isopropyl alcohol. By combining the hypertonicity and the alcohol, D values of 5 seconds are claimed. A rapid cleaning and disinfection action is therefore possible. The alcohol effectively dehydrates the lens; the product is used with InstaCare Finishing Solution (IFS) for rinsing and overnight storage. This contains a boric acid buffer and 50–60 parts per million hydrogen peroxide, both products providing a bacteriostatic effect. Thirty seconds of cleaning is recommended with ISS followed by 15 seconds rinsing with IFS. The product is also useful for practitioners wishing to disinfect trial sets in regular usage and where there is a risk that conventional cold disinfection systems may not have adequate time for disinfection.

Combined storage solution and cleaner

Allergan's Hydrocare solution incorporates surfactants into the disinfecting solution itself so that this may be used for both cleaning and disinfecting purposes. The main preservative, alkyl triethanol ammonium chloride, has surfactant properties. In addition Polysorbate 80 and propylene glycol are incorporated for surfactant and cushioning functions.

Allergan's Complete is also a multi-purpose solution preserved with TrisChen (a biguanide) plus EDTA and Tyloxapol as a surfactant and lubricant.

In Alcon's Opti-Free the citric acid used as part of the buffering system also acts as a cleaning agent.

Incorporation of alcohol

Miraflow and InstaCare (Ciba Vision) incorporate 20% isopropyl alcohol as a lipid solvent as well as a surfactant. These cleaners are also hypertonic which further aids the cleaning action (Brezinski *et al.*, 1986).

Ghajar and Houlsby (1988) reported that cleaning lenses for 20 seconds in Miraflow followed by disinfection in an amoebacidal solution such as 3% hydrogen peroxide should inactivate *Acanthamoeba* cysts present as contaminants on the lens surface.

Omnicare Daily Cleaner (Allergan) incorporates 4% ethanol although this is mainly to aid in rinsing the surfactant from the lens prior to storage in hydrogen peroxide. Surfactant remaining on the lens in hydrogen peroxide may cause excess frothing.

Incorporation of polymeric beads

Alcon's Polyclens (Opti-Clean) is a multipurpose cleaner suitable for both rigid and hydrogel lenses. It combines a surfactant and fine polymeric beads of ground plastic. As the 'beads' of plastic are from a soft material (nylon) and are combined with a surfactant there appears to be minimal or no abrasive effect on the lens surface material (*Figure 4.11*). Nevertheless, over-zealous use of friction-enhanced cleaners can both thin and add negative power to RGP lenses (Boltz, 1989). Phillips and Czigler (1985) demonstrated the effectivity of the cleaner with hydrogel lenses and the reduced need for enzymatic cleaners (*see below*). The disadvantages of the cleaner were stinging if not adequately rinsed from the lens, and the greater quantities of rinsing fluid needed.

Mechanical agitators

Both battery powered (*Figure 4.12a*) and manually operated (*Figure 4.12b*) mechanical agitators are available to assist in the use of surfactant cleaners and are particularly useful for those patients with rough skin or poor dexterity where problems may occur with normal digital cleaning.

Enzymatic systems

An enzyme is an organic catalyst, i.e. it aids a chemical change in other bodies without undergoing change in itself, and is formed by living cells but is not dependent on their



(a) (b)

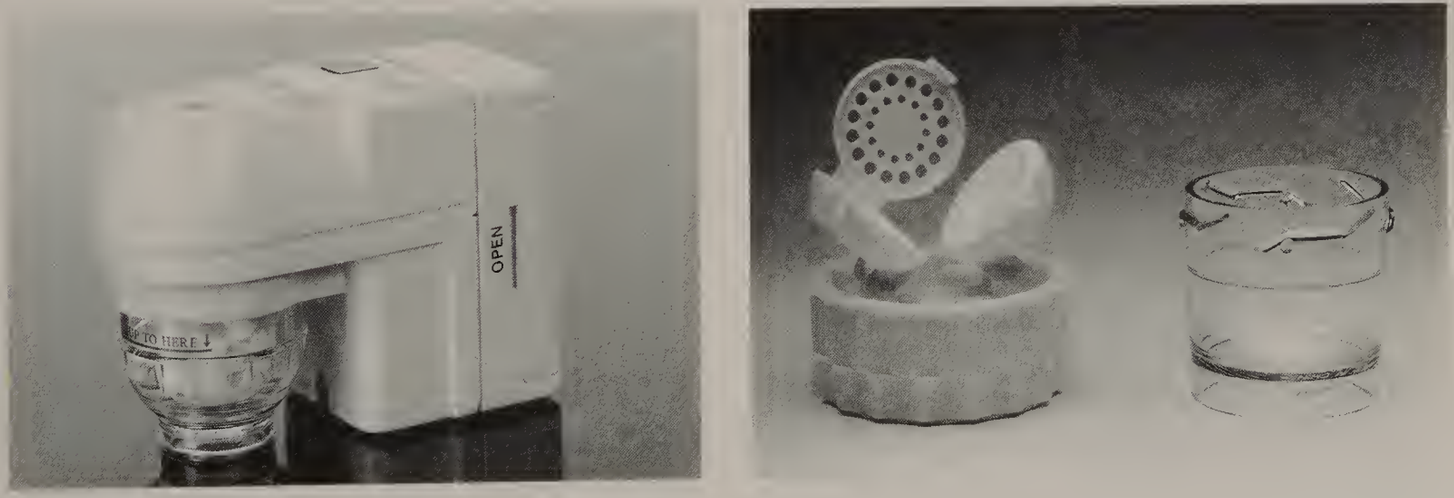
Figure 4.11 Polymeric beads contained in Polyclens (Opti-Clean). (*a*) Rinsed; (*b*) coated with surfactant. (From Phillips and Czigler, 1985, and reproduced by kind permission of *Clinical and Experimental Optometry*)

presence for its action. However, a number of enzymes require simple ions as activators and will not function in their absence. All enzymes are proteins, but not all proteins are enzymes. There are currently four types of enzyme preparation available.

1. Papain tablets (Hydrocare and Prymecare)

Papain is derived from the dried and purified latex of the pawpaw fruit (*Carica papaya*) tree and normally used as a meat tenderizer and in the manufacture of chill-proof beer.

Papain is an endopeptidase, i.e. it catalyses the cleavage of peptide bonds in the interior of a protein molecule (*Figure 4.13*) and has a broad substrate specificity, i.e. will act upon peptides, amides, esters and thioesters. It therefore acts as a proteolytic enzyme and proteins are thereby broken down to shorter peptide chains, e.g. dipeptides, tripeptides etc. It can be seen that an important step with the use of enzymatic cleaners is the use of a surfactant cleaner to



(a) (b)

Figure 4.12 (*a*) A battery powered mechanical agitator; (*b*) Pilkington Barnes-Hind's Hydromat, a manually operated mechanical agitator

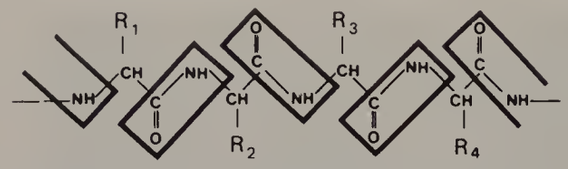


Figure 4.13 The basic primary structure of a protein molecule. R = residue of each amino acid; □ = peptide bond

disperse these molecules and residual enzyme *after* the cleaning procedure. Lens structure is not affected because the enzymatic activity is specific for peptide linkages (Blanco *et al.*, 1975).

Numerous studies exist on the efficacy of papain. The following serves to emphasize important points. Tsuda *et al.* (1977) reported the incidence of deposits on Toyo material lenses which were cleaned daily with a surfactant cleaner.

- After 3 months 59% showed obvious surface deposits.
- After 3–5 months 78% showed obvious surface deposits.
- After 6–8 months 82% showed obvious surface deposits.
- After 9–11 months 89% showed obvious surface deposits.

Patients were then put onto weekly papain treatment (*Figure 4.14*). It can be seen from *Figure 14a* that even with badly coated lenses the incidence of both heavy and light deposits was significantly reduced. From *Figure 4.14b*, it can be seen that new lenses were not kept free of heavy

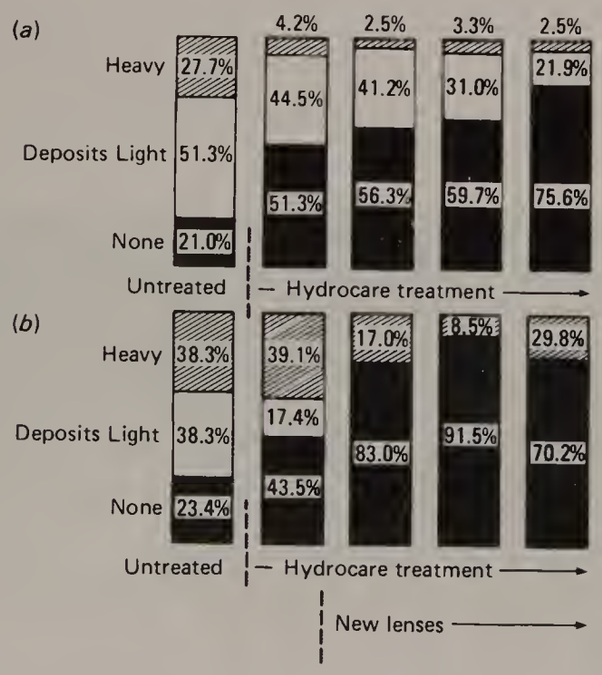


Figure 4.14 Effect of Hydrocare enzyme treatment used weekly as seen at approximately 2-monthly intervals: (*a*) on heavily deposited lenses; (*b*) lenses were replaced at the third visit. (Modified after Tsuda *et al.*, 1977, and reproduced by kind permission of *Optometry Today*)

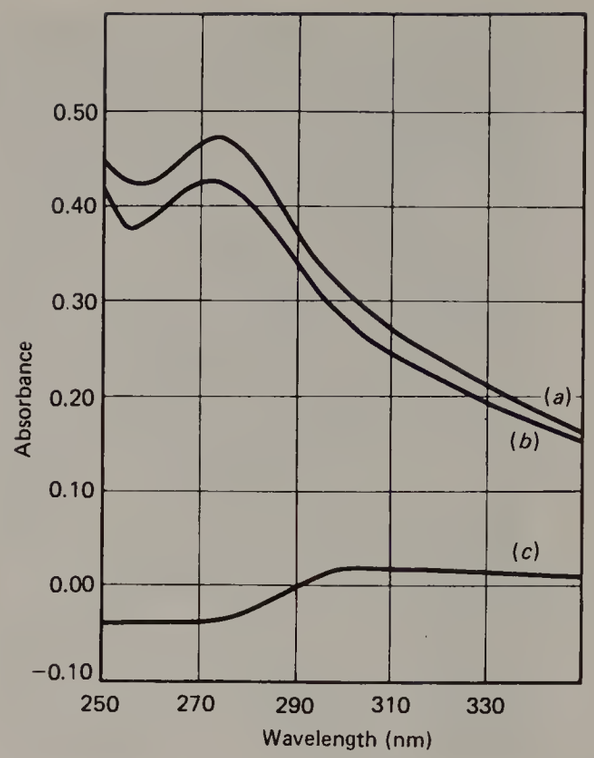


Figure 4.15 Ultraviolet absorption spectra of human worn hydrophilic lenses. (*a*) Absorbance of uncleaned lens. (*b*) After ×8 cleanings with surfactant cleaner. (*c*) After a single cleaning with papain enzyme. (After Karageozian *et al.*, 1976, and reproduced by kind permission of *International Contact Lens Clinic*)

deposits entirely. However, it should still be noted that after approximately 6 months, almost a third of all patients still showed slight deposits. In other words the technique, along with all other patient cleaning methods, is not 100% effective.

In another study by Karageozian *et al.* (1976), ultraviolet absorption spectra of human-worn hydrophilic lenses were measured after cleaning with a commercially available surfactant and with papain enzyme cleaner (*Figure 4.15*).

The disappearance of the ultraviolet absorbing protein after a single enzyme treatment is striking. While the paper was critical of the cleaning value of surfactant cleaners, the deposits were *denatured* protein and, from earlier discussion, it would be surprising if there was any cleaning effect at all. The slight cleaning effect shown by the surfactant in the figure is presumably the abrasive effect of palm cleaning which has *physically* removed some of the surface film.

McClure *et al.* (1977) showed the effect of weekly papain cleaning on lenses which had been worn for varying periods without cleaning (*Figure 4.16*). The improvement in visual acuity once enzymatic treatment had begun is again striking. However, it is interesting once more to note that the acuity recovery with the older, more heavily deposited lenses, was not to the original level and presumably indicated the inability of the enzyme to remove *all* the residual deposits. In addition, it shows the importance of starting patients on the regimen from the very beginning of lens wear.

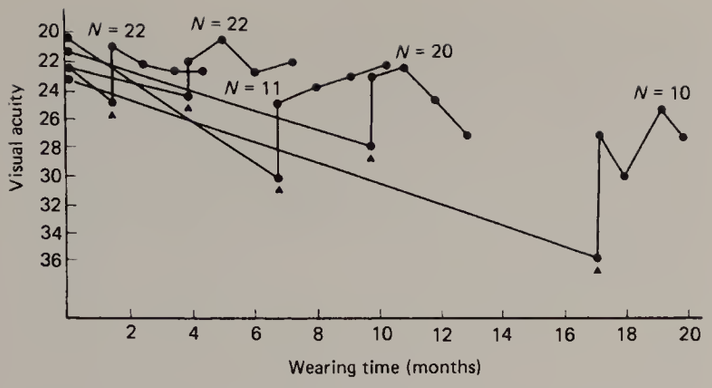


Figure 4.16 The effect of soft lens wearing time and weekly papain cleaning on visual acuity. Graph describes mean visual acuity as a function of wearing time. Weekly enzyme cleaning was begun at ▲. Five separate groups of patients were used. (After McClure *et al.*, 1977)

One potential disadvantage of papain is that some patients experience discomfort or mild conjunctival hyperaemia after its use (Fichman *et al.*, 1978; Bernstein *et al.*, 1984). It is essential that high water content lenses are not soaked for more than 2–3 hours in the enzyme solution (less for some patients) and that careful surfactant cleaning is carried out after the treatment. This cleaning is also important in removing enzyme by-products which may otherwise reattach to the lens surface. Because enzymatic treatment does not disinfect the lenses, they should be put through a disinfection cycle after the cleaning procedure. For lenses disinfected by thermal methods, this will also destroy any residual enzyme.

Baines *et al.* (1990) showed that both papain and pancreatin (*see below*) enzymes removed only about 75% of adsorbed protein after 24 hours of treatment. However, the standard 2-hour treatment was less than half as effective. Because of the anaphylactic properties of papain in certain patients some manufacturers now recommend shorter incubation times (20 minutes) which may be insufficient to remove most of the adsorbed proteins.

In order to avoid patent restrictions and to attempt to gain greater cleaning efficacy, and provide an alternative to those patients sensitive to papain, different enzymes have been gradually introduced.

2. Pronase (Amiclair)

Amiclair tablets (Abatron) contain a mixture of three enzymes: a bacterial protease isolated from *Bacillus subtilis* (Subtilisin A); a lipase isolated from *Rhizopus arrhizus* var. *delomar*; and pronase, a proteolytic enzyme obtained from *Streptomyces griseus* which is stated to remove mucus. Additionally, the product contains EDTA which is stated to aid in reducing calcium deposit formation.

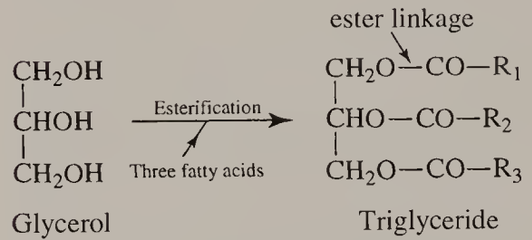
Interestingly, pronase is itself a protease so that the system contains two proteases, presumably to attempt to cover the range of protein or protein-containing deposits. Pronase was first isolated from *Streptomyces griseus* as a by-product from the industrial production of streptomycin (D. Lloyd, 1979, cited by Phillips, 1980). It exhibits an extremely broad specificity and is able to effect a 60–80% hydrolysis of many proteins. Normally the extent of protein hydrolysis by any protease is limited to 10–30% and even then almost all of the resulting digestion products are polypeptides. Pronase was found to be capable of hydrolysing various kinds of peptide bonds in protein until the majority of amino acids making up the protein were liberated as individual free amino acids. This peptidase is capable of splitting not only terminal peptide bonds, but also internal peptide bonds of proteins and so does not fall into the traditional classification, i.e. exopeptidase or endopeptidase. Presumably the claim that pronase removes mucus from soft lenses is because mucus contains albuminous substances such as mucin and albumin, collectively known as the glycoproteins (proteins covalently linked to carbohydrates), and found in deposits on soft lenses.

Lipases are enzymes widely distributed in plants and present also in the liver, gastric and pancreatic secretions which break down fats to the constituent fatty acids and glycerol by a hydrolysis reaction. Lipids can be generally classified as:

Lipids

Triglycerides – fats/oils, based on physical difference
Phospholipids – e.g. lecithin
Sphingolipids
Steroids – e.g. cholesterol/cholesteryl esters

Structurally speaking lipids are esters. In the triglycerides the alcohol is glycerol which is esterified with fatty acids. Thus:



(where R_1, R_2 and R_3 are fatty acids)

Various fatty acids combine to form a variety of triglycerides which are the most abundant lipids found in both plants and animals. They are commonly designated as the neutral fats. If the fatty acid is esterified with an alcohol of higher molecular weight than glycerol then the resulting compound is called a wax.

The action of lipases may be summarized as:

- Lipases attack the ester linkage (*see above*) of triglycerides (fats) breaking them first to diglycerides, then to monoglycerides and subsequently to glycerol with the liberation of fatty acids at each step. The rate of reaction will decrease as the degradation tends towards completion.

- The ultimate breakdown product, glycerol, is freely soluble in water but fatty acids, monoglycerides and diglycerides are either sparingly soluble or totally insoluble. For this reason surfactant cleaning following lipase action is also essential.
- It has already been stated that lipases will only attack the triglyceride fraction of lens deposits. With the different classes of lipids which may be present in human tears, it would not be too presumptious to assume that these other classes would not be affected by lipase action, e.g. phospholipids are only degraded by phospholipase, lipoproteins are only degraded by lipoprotein lipase. This latter enzyme catalyses the hydrolysis of triglycerides only when in association with protein.

Thus, considering the specificity of lipases one may require a 'cocktail' of enzymes to remove all lipid deposits on lenses. For this reason the current name of 'lipase' is 'glycerol ester hydrolase' which is a more acceptable and accurate description of the enzyme's function. Nevertheless, it can be argued that the incorporation of a lipase can only add to the cleaning process albeit by a debatable amount.

3. Pancreatin tablets (Alcon Polyzym)

Pancreatic extract tablets may be expected to contain the following: trypsin, chymotrypsin and carboxypeptidase as proteases; amylase (to break down polysaccharides (mucins); deoxyribonuclease; lipase.

Schachet (1983) found an improvement with the use of the multi-enzyme, although the opposite was found by Kjellsen *et al.* (1984). Because lipids and mucins are easily removed by surfactant cleaning, the only stubborn lipid deposit is that found in the white calculi seen occasionally on lens surfaces. These are not removed by either surfactant or enzymatic cleaning probably due to the presence of calcium salts of fatty acids. It would appear therefore that differences are most likely to revolve around the efficacy and speed of the various proteases present. Unfortunately, there are few independent assessments and the main advantage to the practitioner is in the choice of products now available so that where patients show sensitivity to specific enzymes, an alternative can be provided.

Baines *et al.* (1990) showed that whilst both papain and pancreatin removed about 75% of adsorbed proteins over a 24-hour soaking period, papain was faster acting over a shorter (2–4-hour) period. However, when the lenses were re-incubated in protein the papain-treated lenses re-adsorbed a significantly greater amount of protein than the pancreatin-treated lenses. It would seem, therefore, that whilst papain is a slightly faster acting enzyme cleaning agent, pancreatin may reduce the amount of protein re-adsorption, possibly by blocking the adhesion sites.

4. Subtilisin (Allergan Ultrazyme and Bausch & Lomb Sensitive Eyes)

The subtilisins are alkaline serine proteases (i.e. proteases having a particularly reactive serine amino acid at their catalytic site) produced by various species of Bacillus, in particular *B. subtilis* and *B. licheniformis*. Due to its thermostability the enzyme is industrially very important and is produced in large quantities for this purpose. It has also been found to be useful in the contact lens field. The enzyme functions optimally at around pH 8–11 (Vita *et al.*, 1985) and has an action similar to chymotrypsin but broader specificity.

The advantages claimed for subtilisin are minimal binding or adsorption property to hydrogel lens material, longer peak action time allowing cleaning to continue during the overnight period, minimal evidence of subsequent ocular irritation due to residual enzyme and, in the case of the Allergan product (Subtilisin A), the enzyme is formulated to work in the acidic environment of hydrogen peroxide. In practice this is likely to be achieved by the incorporation of a suitable agent to raise the solution pH to an optimum alkaline level for maximum enzymatic activity. Not only does this reduce the number of cleaning steps for the patient because enzyme cleaning and disinfection are carried out simultaneously, but subtilisin has a synergistic antimicrobial effect with hydrogen peroxide significantly reducing kill times for the yeast *C. albicans* which normally has a slow kill time in hydrogen peroxide (C. Jenkins, 1986, personal communication). In addition, hydrogen peroxide acts as a 'substrate modifier', i.e. it exposes more peptide linkages to the enzyme, so that a more efficient cleaning action is produced. Other enzymatic cleaners also incorporate substrate modifiers, e.g. cysteine in papain enzyme.

Finally, the Allergan enzyme has *N*-acetylcysteine incorporated. This product is well known for its mucolytic properties.

From the discussion above it can be seen that after removal of the lenses, whatever the chosen method of disinfection, the patient should be strongly advised to carry out a prophylactic daily surfactant cleaning step prior to the disinfection procedure. This reduces the majority of loosely bound surface deposits and significantly reduces microbial contamination. In addition, surfactant cleaning is essential after enzymatic cleaning to remove the enzyme breakdown products. Because surfactant cleaners are largely effective for lipids and unbound protein, most practitioners also advise weekly or fortnightly enzymatic (or equivalent) cleaning in addition, to remove or reduce bound denatured protein. Patients using heat disinfection must be advised to carefully rinse cleaning solutions from the lens prior to being placed in the asepticizor unit, because certain cleaners may be baked on, forming a white film and making the lens unwearable (Davis *et al.*, 1973).

Although more frequently used with hydrogel lenses due to their greater affinity to bind protein, enzymatic cleaning is used with any type of contact lens as a means of removing bound protein and is particularly applicable in those patient groups susceptible to deposit-related problems such as giant papillary conjunctivitis (Korb *et al.*, 1983).

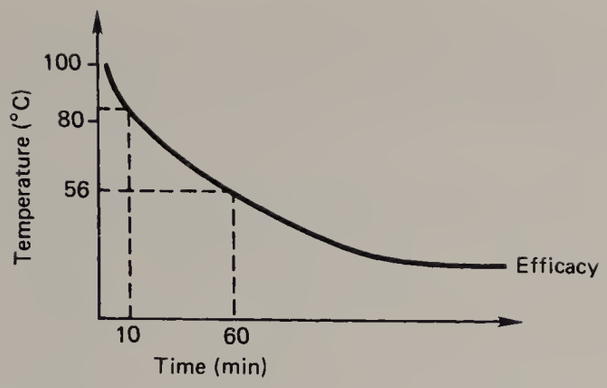


Figure 4.17 Time–temperature efficacy curve of Allergan's Calcium Deposit Preventer solution

No advantage has been found in enzyme cleaning daily-wear programmed-replacement lenses where the replacement period is three months or less (Allen *et al.*, 1992).

Calcium preventing solutions

Some patients are prone to lay down areas of calcium carbonate or phosphate in the lens structure. In addition, the white calculi sometimes seen on (especially) high water content hydrogels are lipids often combined with calcium salts. These salts will not be removed by surfactant or enzymatic cleaners.

Allergan's Hydrocare and Calcium Deposit Preventer contains a heat-activated chelating agent (sodium hexametaphosphate) which removes calcium ions present in or on the lens matrix. The time-temperature curve is shown in *Figure 4.17*.

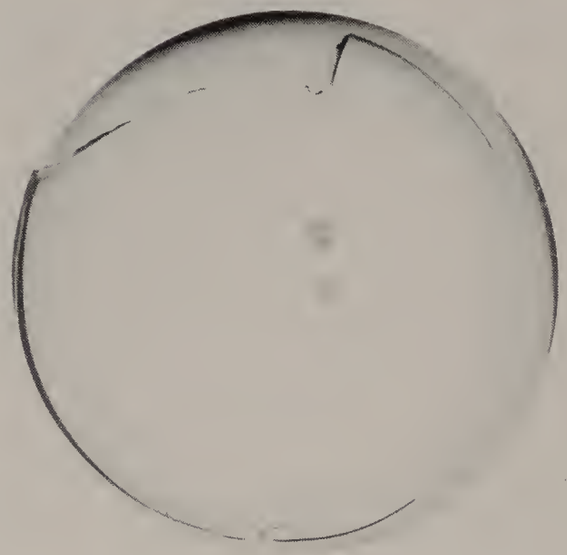
It can be seen that the solution can only be used by patients using a thermal disinfection method. However, it may be used by practitioners as a rejuvenating method in a heat-controlled bath with a magnetic stirrer at 60 °C for 1 hour. The effectivity of this method is shown in *Figure 4.18b*.

Rejuvenating systems

As lenses age, deposits accumulate both on the surface and within the surface matrix of the lens. Great individual variation is found in both speed and degree of deposit accumulation although patient thoroughness in following their practitioner's instructions plays a major role. Patients complain of reducing comfort, vision, decreasing tolerance and possibly discoloured lenses. The practitioner may see the surface deposits by slit-lamp examination although these are more obvious as the lens cools and dries off the eye. In addition, the lens appears to tighten in fitting as protein displaces water from the surface matrix. Irregular protein deposition may cause a 'pie-crust' effect of the lens edge and limbal injection and superficial corneal staining may occur due to the tighter fitting and possible reduced oxygen transmission. In this situation the practitioner must decide whether to replace or attempt to rejuvenate the lens. This, in turn, will depend upon the degree of deposition, the age of the lens, the replacement cost and the patient's financial status.



(a)



(b)

Figure 4.18 (*a*) Hydrogel lens showing cluster of large calculi deposits. (*b*) Same lens cut in half (and damaged in the process). The left half was cleaned with Calcium Deposit Preventer and the right half with Liprofin

Due to the high overhead costs of producing relatively small quantities of practitioner rejuvenating cleaners, only one is now currently available. This is an oxidizing agent but is stronger than that available as a patient cleaning systems (*see above*).

Oxidation was originally defined as the addition of oxygen to a compound. This definition was later extended to include the removal of hydrogen from a compound. Better understanding of the principles involved has led to

the current definition in which oxidation is defined as 'a process in which electrons are removed from a species'. Reduction is the opposite process, i.e. electrons are added. Both processes must occur simultaneously and are hence often known as redox reactions.

In the cleaning of hydrogel lenses we are interested in the fact that the end products of the oxidation of proteins (and most other deposits) are of low molecular weight (i.e. are small), and are often water-soluble (i.e. they are easily dispersed). It can be seen that the effect is, in fact, the same as for an enzyme. The difference is the mode, speed and/or degree of reaction, plus the fact that the reaction is not specific for proteins, and many other lens contaminants may also be broken down by the oxidation process. The main advantage, therefore, of oxidizing systems is the broad range of activity against lens deposits. These systems are used increasingly less as the trend towards frequent replacement and disposability continues.

Liprofin (Alcon)

Liprofin is an inorganically-based active substance, largely sodium perborate, which is water soluble. On being heated it evolves reactive oxygen which decomposes both organic and inorganic substances. If the solution is heated to boiling point, the oxygen radicals are liberated very rapidly and only partial removal of heavy deposits occurs. From experimentation, a temperature of 50–60 °C over a period of 2–4 hours has been found to produce a highly efficient cleaning ability and to cause no change in lens dimensions. To improve cleaning ability, constant agitation is preferable and for simplicity this can be done by means of a magnetic stirrer.

After Liprofin cleaning, the lens should be rinsed thoroughly, cleaned with a surfactant cleaner and then soaked in a saline solution for at least 30 minutes. The method is highly effective as a sterilizing method being effective against bacteria, fungi and even viruses. Care should be taken in the cleaning of high water content lenses as parameter changes may occur with this product.

Oxidative cleaning and changes in lens parameters

One of the first oxidative cleaning solutions used for soft lenses was sodium hypochlorite (Milton). This bleach removed all discoloration and traces of mucoprotein within 15 minutes. However, after two to three such treatments lenses began to alter in curvature and/or power. Diluting the solution reduced the problem although it still occurred more slowly and occasionally lenses became distorted. De Carle (1979, cited by Phillips, 1980) reported that this change took place even with a 10 times dilution (i.e. 0.10% sodium hypochlorite). In the case of Permalenses the lens total diameter increased by about 0.2 mm per cleaning.

There appears to be little doubt that excessive or prolonged use of stronger oxidizing agents will result in breakdown or alteration of the lens polymer. Relatively old lenses with small cracks or nicks will probably be damaged by oxidative cleaning methods. Where inorganic deposits, such as calcium, are removed, a small pit may be left in the lens.

However, provided they are used minimally to 'rescue' lenses not responding to other cleaning techniques, there appears to be no significant change in lens dimensions (Phillips, 1980). In a study of three hydrogels cleaned with Monoclens, Ganju (1977) found a very small flattening of back optic zone radius (BOZR), a small reduction in negative power, and a small increase in total diameter (TD), but all at clinically insignificant levels.

Tighe (1979, cited by Phillips, 1980) believes the reasons for the small parameter changes are as follows: any polymer containing HEMA is likely to contain carboxyl (-COOH) groups as a result of the presence of methacrylic acid. When these are treated with salts of weak acids (e.g. sodium bicarbonate), or any solution of a salt that has become alkaline, the carboxyl groups are partially converted to their appropriate salt. Even a small amount of this type of change produces a measurable increase in water content – hence the increase in diameter plus some slight flattening of the lens. Permalens and several other lens materials do this. In Permalens the presence of vinyl pyrrolidone aggravates the situation because the nitrogen can 'quaternize' and stabilize the effect. In summary, Tighe argues that:

- It is an effect of an alkaline salt, especially a sodium salt, and not oxidation that causes the parameter changes.
- All HEMA-containing polymers will alter to some extent.
- The purity of the HEMA monomer used is important.
- It is worse with high water content vinyl pyrrolidone containing materials.

Factors influencing the prescribing of hydrogel disinfection and cleaning procedures

Over the past two decades, prescribing habits have swung backwards and forwards between the various methods as they became available. A few practitioners still prescribe one single technique to the exclusion of all others although it is more common to prescribe methods most applicable to each individual patient. The following points may provide guidance:

- Lens material: chemical disinfection techniques are indicated where a particular material, especially a high water content one, is affected by heat. Materials prone to discoloration should be disinfected with a hydrogen peroxide method.
- Daily or extended wear lenses: the relatively infrequent cleaning of an extended wear lens indicates a more thorough cleaning procedure, e.g. improved surfactant plus enzymatic cleaner. A hydrogen peroxide procedure is also commonly used for its additional mild cleaning effect.

- History of general or ocular allergies, or other factors which may indicate a patient likely to show a solution allergy or toxic reaction. The following patients may be considered as possible candidates to show sensitivity to chemical disinfection preservatives:
  - strong history of general allergies;
  - history of eyes that overreact to ordinary stimuli, e.g. tiredness, alcohol, cigarette smoke;
  - signs of overly reactive or sensitive eyes by external examination, e.g. injected conjunctiva, engorged limbus;
  - dry eyes or tear film abnormality;
  - former hard or RGP lens wearers, i.e. previous exposure to certain preservatives;
  - high water content lenses worn on daily basis, i.e. regular exposure to high preservative levels;
  - sensitivity exhibited by special tests, e.g. conjunctival smears, skin scratch or patch testing.

  In these cases, the practitioner should be prepared to transfer the patient to a preservative-free system or possibly prescribe a thermal disinfection method. However, in a retrospective study, Young (1985) was unable to identify patients who showed solution sensitivity from an investigation of their allergic history alone.
- Tear flow and type of lacrimal fluid: as mentioned above the dry-eyed patient is often more prone to preservative reactions. Additionally, the dry-eyed patient is more susceptible to deposit formation. The patient exhibiting a high tear lipid level should be prescribed an enzymatic cleaner containing a lipase and use an improved lipid solvent surfactant, e.g. Miraflow.
- Patient's occupation and hobbies: occupations which involve travelling or patients who go camping, for example, are better advised to use chemical disinfection. Certain industrial occupations may indicate specific regimens, e.g. patients experiencing a high incidence of rust spots will find their appearance minimized if chemical rather than thermal disinfection is used.
- Patient's personality and intelligence: it usually becomes apparent to practitioners very quickly, the degree of cooperation and conformity to instructions that they are likely to experience from each patient. At the extreme end some patients should be rejected as contact lens candidates if they are not likely to fully cooperate or understand instructions. In general, for less intelligent groups, practitioners may feel an automated thermal unit or a multipurpose solution is ideal. In such cases, the protease cleaning may be omitted and hydrogen peroxide systems are best avoided.
- Patient's general health and current systemic or ocular medication: practitioners are increasingly becoming aware of the relevance of general health and systemic medication on contact lens wear and deposit formation. For example the dry eye found in certain arthritis cases will commonly exacerbate a deposit problem. The hyperlipid secretion in acne vulgaris will produce differing deposits. In such cases the cleaning regimen must be modified or strengthened as appropriate. The effect of systemic medication is discussed below.
- In the case of disposable or programmed-replacement lenses enzymatic systems are not normally necessary (Allen *et al.*, 1992). Where the lenses are worn for extended wear and the programmed-replacement period is longer than one month then enzymatic cleaning becomes more appropriate. Mid- and high-water content ionic lenses are not ideally disinfected in hydrogen peroxide systems as these lenses may take up to 1 hour before returning to their original parameters. One-step peroxide methods are more appropriate but as hydrogen peroxide systems are often slightly more expensive than conventional cold disinfection solutions the advantages of using these systems may be questionable. The importance of a separate surfactant cleaning process in all disposable systems **must** be stressed to the patient. As many patients have selected disposable lenses for their overall convenience and simplicity of use there is often a preference for combination cleaning and storage (multi-purpose) solutions.
- Climate: patients living in tropical and subtropical climates should be warned that many contact lens solutions are not stable above 25°C. Heat disinfection possibly using preserved or unit-dose saline may be preferable. Surfactant cleaners and any other solutions should be stored in a refrigerator when not in use.
- Previous deposit problem and type: in spite of all possible care many problems with solution reactions and deposit problems are found only once wear has begun. It becomes extremely important that practitioners are prepared to monitor each patient and modify cleaning and disinfection procedures when appropriate. Patients should be warned in advance that this may become likely to avoid concern if problems do, in fact, occur.

  Practitioners should be capable of recognizing solution allergy or toxic reactions and, in the case of deposit problems, recognizing the type of deposit problem and being able to prescribe the appropriate remedy.

The following signs and symptoms are commonly found in cases of adverse solution reactions:

- Discomfort on insertion, possibly slowly improving if wear is continued.
- Photophobia.
- Epiphora.
- Conjunctival hyperaemia, especially limbally.
- Decreased wearing time.
- Possible mild diffuse superficial punctate keratitis staining with sodium fluorescein.
- Possible intraepithelial microcysts and/or perilimbal infiltrates if the condition has been present for some time.

Patients with GPC are not only found to have more overall allergies but are particularly likely to show an allergy to thimerosal preserved solutions (Begley *et al.*, 1990).

Deposits are laid down on hydrogel lenses almost as soon as the lens is placed in the eye. The main source of deposit is lysozyme protein (Karageozian, 1974). Lipid may also be present from the meibomian glands and by finger contact. Mucus will be present secreted by the conjunctival goblet cells and calcium salts may also be deposited from the lacrimal fluid. In addition, make-up, aerosol sprays of hair lacquer and deodorant etc., may contaminate the lens. These deposits will gradually increase, in spite of patient cleaning, until symptoms occur.

Patients experiencing a clinically significant deposit problem may complain of mild discomfort, poorer vision, slight photophobia and loss of tolerance. The practitioner may find a myopic shift in the prescription, a fall in best acuity, a 'roughened' lens surface appearance visible by slit-lamp microscopy, a tighter (or occasionally looser) fitting lens and possible lens discoloration (*see Figures 18.19, 18.40, 18.41*). Some deposits are best identified in the eye by slit-lamp microscopy; others are best seen by removing the lens, air drying and cooling it, and then examining it against a diffuse light source. Scanning electron microscopy, morphological stains and dark field microscopy provide further means of identification although these are not commonly available to the practitioner.

There are two types of protein film, the most common of which produces a white, partially opaque layer covering all or part of the lens (*Figure 4.19*) Alternatively protein may be almost invisible, often not being recognized by slit-lamp examination until it begins to crack. It may sometimes be visible by air drying. In such cases, the subjective symptoms are often the main guide to the presence of the protein.

Lipid appears as greasy or smeary deposits on the lens surface that change in pattern on blinking (*see Figure 18.16*). Lipid deposition is sometimes worse in patients using chlorhexidine-preserved solutions because this induces surface hydrophobicity.

Pigment deposits in soft lenses are usually yellow to brown, the discoloration gradually increasing with lens age (*see Figure 18.19*). They appear to be made up of a melanin-like polymer derived from the polymerization of aromatic compounds in the tears (Ruben, 1976). Because melanin is formed by oxidative polymerization, the rate of melanin formation may be increased by thermal disinfection procedures. Pigmentary deposits may fluoresce slightly under ultraviolet light.

Micro-organisms such as fungi and yeasts can grow on and into hydrogel materials if proper lens disinfection is not carried out. They may be observed as white or coloured filamentary growths that grow through the lens polymer. The fungal hyphae may extend from one lens surface to the other and cannot be removed so that the lens damage is permanent (*see Figure 18.43*).

Calcium salts form a hazy white surface layer often resembling protein (*see Figure 18.27*). The main cause of inorganic films appears to be precipitation and growth of calcium phosphates from tears while the lens is in the eye. Tear chemistry and tear production are important factors. Poor blinking, insufficiency of tears, or low tear film break-up time seem to be associated with these deposits (Koetting, 1976). The presence of protein films may also predispose the lens to the build-up of inorganic materials because the protein-covered lens surface becomes more hydrophobic and more likely to dry between blinks. The end result seems to be alternate layers of protein and calcium so that cleaners for both types of deposit are necessary and removing the protein merely exposes the rough underlying inorganic material. Calcium phosphate may form as a result of interaction between free calcium ions in the tears and phosphate buffers used in certain solutions. The resulting calcium phosphate is insoluble and is precipitated out within the lens matrix.

Another calcium-containing deposit is composed of insoluble crystalline growths known as lens calculi. They are also referred to as jelly bumps, barnacles and mulberry-like growths and appear as small white elevations on the lens surface (*Figure 4.18* and *see Figure 18.42*). Careful examination will often reveal that these deposits are an annulus, the central 'hole' of which is filled with mucus (*see Figures 18.44, 18.45*). Because the outer annulus can be demonstrated to be mainly lipid on which secondary calcium salts have deposited, it can be postulated that they originate from lipid build-up around dry spots on the lens surface. This lipid ring builds up until it eventually protrudes through the tear film. Formation is largely a matter of the lens wearer's tear chemistry. Certain wearers are susceptible to the formation of this deposit and it will rapidly reform on replacement lenses. They are more commonly seen on extended wear lenses. Their effect on the eye is minimal until they reach a fairly large size. Removal (described below), unless done early, commonly leaves a pit in the lens surface. Roth (1987) notes that calculi may appear following systemic antibiotic therapy indicating a change in tear chemistry.

Mercurial deposits are grey to black discoloured patches. They were more commonly seen in thermally disinfected lenses utilizing thimerosal-preserved saline and are less common in chemically disinfected lenses. The primary cause of mercurial deposits in well-documented cases appears to be due to the re-use of the same preserved saline or cold disinfection solution. As the contaminant load of the solution increases with each re-use, the thimerosal decomposes to a greater extent and finally mercurial decomposition products begin to precipitate in the lens matrix (Petricciani and Kreszanoski, 1977). Although these deposits would appear to be non-toxic to the eye, they consist of insoluble compounds, probably the very insoluble black mercuric sulphide, and are difficult to remove. The answer lies in their prevention.

Rust-coloured spots are small, discrete red-to-orange spots seen within the lens matrix (*see Figure 18.46*). Occasionally discomfort is caused but generally the patient is asymptomatic. They are usually related to penetration of iron-containing foreign bodies into the lens. These rapidly oxidize to form ferrous oxide which spreads over a small area within the lens matrix.



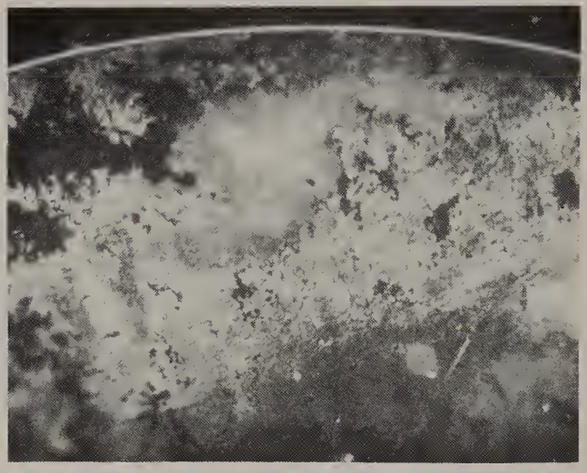
(a)



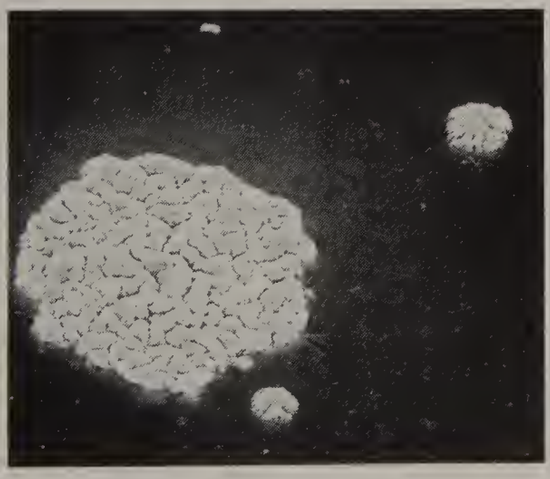
(b)



(c)



(d)



(e)



(f)

Figure 4.19 Protein film on a hydrogel lens. (*a*) Early stage spreading across the lens surface. (*b*) Later stage now covering most of the lens surface. (*c*) Final stage where the lens surface is completely covered. (*d*) Deposits as seen by dark field microscopy. (*e*) Isolated protein deposit as seen by scanning electron microscopy showing the convoluted surface shapes commonly seen. The polishing marks on the lens surface can clearly be seen. (*f*) Rod-shaped bacteria on top of a protein film (Flinders Medical Centre)

Once deposits have been identified, the patient's regimen should be modified as follows. Alternatively, a more frequent lens replacement scheme should be used. In practice both tactics may be adopted.

For protein deposits

- Chemical disinfection is better than heat.
- Use 'improved' surfactants, e.g. Polyclens (Opti-Clean), Boston Cleaner etc.
- Use a hydrogen peroxide system with the lens in peroxide overnight if possible, e.g. Oxysept, Mirasept systems etc.
- Use proteolytic enzyme weekly.
- If thermal disinfection is indicated for other reasons, a low heat unit may be preferable or pasteurization.
- Prescribe a non-ionic lens material as these are generally more protein resistant, i.e. ACLM 'Filcon *a*' materials or FDA Group I or Group II materials (*see* Chapter 3).
- Prescribe a 'deposit resistant' lens, for example Wesley Jessen's Classic or Biocompatible's Proclear, where lenses of these water contents (medium and high respectively) are required.

For lipid deposits

- Less of a problem with thermal disinfection.
- Avoid chlorhexidine-preserved solutions because this increases surface hydrophobicity and allows lipid adhesion.
- Use specific lipid cleaners, e.g. Miraflow.
- Use in-eye cleaners, e.g. Clerz, Revive etc.
- Utilize enzyme cleaners containing a lipase, e.g. Amiclair, Polyzym etc.
- Avoid FDA Groups I or II materials (*see* Chapter 3, p. 87).

For calcium deposits

- Less with thermal disinfection.
- Use hydrogen peroxide (low pH dissolves calcium).
- Use proteolytic enzyme weekly as sometimes secondary to protein.
- Check blink action; advise accordingly; use in-eye lubricants if necessary.
- Use sequestering agent, e.g. Hydrocare plus Calcium Deposit Preventer, only activated in thermal disinfection.
- May be worse with tight fitting lenses.
- Prescribe glyceryl methyl methacrylate (CSI) material lenses (Levy, 1984).

For calculi

- Use lipid solvent cleaner, e.g. Miraflow.
- Use lipase-containing enzyme.
- Utilize in-eye lubricants in extended wear cases and remove and clean more frequently.
- Often worse in tear potassium deficiency cases (*see below*), e.g. patients on systemic antihypertensives or diuretics with no potassium supplements; some cases of renal stones etc. Possibly helped if potassium sorbate preserved solutions are used. Refer to general practitioner if necessary.
- Check blink action.

For rust spots

- Less visible with chemical disinfeetion.
- Hydrogen peroxide disinfection systems may make them less obvious.

For discoloured lenses

- Switch lens material if NVP-containing polymer being used with thermal disinfection, or switch to chemical disinfection.
- If considered due to nicotine from smoking, the patient should be advised accordingly.
- If considered due to heavy protein deposition refer to the appropriate section above.
- Utilize non-thimerosal preserved saline if thermal disinfection used.
- Use hydrogen peroxide system for disinfection.
- Check systemic medication (*see below*).
- If an ionic high water content material is being used avoid storing for long periods in sorbic acid-preserved solutions.

For dry-eyed patients

Since deposit problems are exacerbated for the dry-eyed patient the following advice may be helpful. It should be emphasized that there is no panacea for this group of patients.

- Use Softab or Aerotab system and dilute the saline by 20–50% with boiled distilled water. This temporarily increases the water content of the lenses which is then slowly released onto the eye.
- Saline dilution may also be utilized with thermal disinfection, but thermal disinfection is best avoided since this exacerbates the deposit problem to which dry-eyed patients are particularly prone.
- Use in-eye lubricants frequently. Rengstorff (1987, personal communication) reports significant help with the use of vitamin A-containing eye drops.
- Re-soak lenses for 15–30 minutes during the day or swap to pre-soaked spare pair.
- Improve cleaning routine because deposits are more likely in this group which in turn exacerbates the dryness symptoms.
- Refit with a lens material containing a high percentage of 'bound' to 'free' water (see Chapter 11). A non-ionic, low water content lens appears to perform best.
- Refit with a 'deposit resistant' lens.

- Consider a trial with temporary collagen punctal occlusion.

The normal approach to assisting the dry eye patient (checking adequate fluid intake, the effect of systemic medication, possible vitamin deficiency, etc) should not be forgotten (*see* Chapter 18). In addition, for the contact lens wearer, lid massage (Shuley and Collins, 1992) and meibomian therapy (Paugh *et al.*, 1990) may also be of help. Patients with dry eyes often succeed with RGP lenses (*see below*, Reduced tear secretion).

Deposits, lens discoloration and systemic and ocular medication

Practitioners are becoming increasingly aware of the effect of drugs and solutions on soft lens deposits and discoloration. As knowledge increases so special advice can be given prior to lens issue and in solution prescribing. The following is a summary of the limited information currently available.*

Sympathomimetic eye drops

Repeated instillation of eye drops containing substances such as adrenaline (epinephrine), phenylephrine (neosynephrine) or other readily oxidized sympathomimetics can cause brown, grey or black lens discoloration and lens stiffening (Miller *et al.*, 1976).

Hydrogen peroxide will cleave the melanin particles produced and soften the lens again.

Tetrahydrozoline (Visine) may also cause lens discoloration.

Alcohol

Hart (1986) reports from retrospective analysis that lens wearers who consume more than four alcoholic drinks a week are 10 times more likely to experience lens lipid deposits. This may possibly arise from the diuretic effect of alcohol (*see below*).

Disulfiram (Antabase), a drug used in the management of chronic alcoholism, has caused a reaction with rigid lens wear similar to that which would occur if alcohol was imbibed. The reaction, reportedly related to the PVA in the wetting solution (Newson and Hayer, 1980), consisted of flushing, dry mouth, a prickly sensation, dizziness, nausea, vomiting and weakness.

Aspirin

Acetylsalicylic acid (aspirin) taken orally is excreted into the tears (Valentic *et al.*, 1980). This drug may be absorbed into hydrogel lenses and cause epithelial irritation since aspirin is a known irritant (Miller, 1981).

* The availability of the products listed in this section will vary from country to country and should be checked with the local authorities.

Clofazimine

Clofazimine is used in treatment schedules for multibacillary leprosy and in Type 2 lepra reactions. It is also sometimes used in *Myobacterium avium* complex infections in HIV patients.

Adverse reactions to clofazimine are dose-related, the most common being red and brown disoloration of the skin especially on areas exposed to sunlight. The conjunctiva may show some signs of red and brown pigmentation and discoloration of the hair, tears, sweat, sputum, breast milk, urine and faeces may occur (Anon, 1993).

Although discoloration of hydrogel lenses has not yet been reported with this drug its strong pigmentary effect make this highly likely.

Diagnostic eye drops

Both sodium fluorescein and rose bengal can concentrate in hydrogel lenses. Natural diffusion out is reasonably quick in high water content lenses. Hydrogen peroxide, Liprofin, or boiling in distilled water (a form of purging) all help speed up the process.

High-molecular-weight Fluorexon still diffuses into hydrogel lenses but more slowly.

Diet

Calculi deposits, mainly lipid, are commonly found in patients who regularly ingest cholesterol-rich foods (Hill and Terry, 1976).

Gold

Systemic gold injections given for rheumatoid arthritis have been reported as causing ocular inflammation and adversely affecting contact lens wear (Shovelin, 1990).

Hormone replacement therapy (oestrogen)

Patients using HRT may develop irritation with their contact lenses (Anon, 1995), probably due to the altered hormone levels (*see also* Oral contraceptives, p. 136 and Hormonal factors p. 629, Chapter 18).

Hypokalaemia

Hypokalaemia is the condition of low blood potassium levels. The patient may experience arrhythmia (destabilized cardiac rhythm) and/or muscle cramps. It commonly occurs if a diuretic is prescribed, e.g. frusemide (Lasix) (which increases potassium excretion) with no potassium ion compensation also prescribed, e.g. Slow-K.

Patients exhibiting hypokalaemia have been observed to show hyperlipidaemia (Knochel, 1984), higher tear lipid levels (Hart, 1986), and increased lens calculi.

Norwood (1983) reported patients with kidney stones also showing lens calculi. Many people who form calcium stones have excess urinary calcium. In addition, certain clinical states may diminish stone inhibitor excretion, one of which is hypokalaemia (Kanig and Conn, 1985).

Hart (1986) has measured low tear potassium levels in patients who show definite tear lipid problems and postulates that the use of potassium sorbate-preserved solutions for lens storage may help.

Nasal decongestants

Brompheniramine, phenylephrine and phenylpropanolamine have been reported (Banes, 1985) as causing increased sensitivity to contact lens wear, although it was not stated if this was due to reduced tear secretion or not. As mentioned above, adrenaline and phenylephrine in nasal decongestants may turn soft lenses grey, black or brown if repeatedly instilled into the eye (Sugar, 1974).

Nicotine

Soft lenses have been reported to turn yellow or yellow-brown in wearers who are heavy smokers (Kleist, 1979), although it is not clear if this is from finger or atmospheric contamination. Hicks (1985) reported a nicotine-stained lens from a tobacco chewing patient. Regurgitation through the canaliculi is postulated as the causative mechanism (*see also* Chapter 3).

Nitrofurantoin

Available as tablets, capsules or suspension (Furadantin and Macrodantin), this drug is a synthetic antibacterial used almost exclusively for urinary tract infections. It increases tear flow and turns the urine and soft lenses brown. The profuse lacrimation and ocular irritation can easily be confused with a contact lens problem (Hopkins, 1985).

Oral contraceptives

Farrall (1976) showed that a reduction in tear output with associated drop in lysozyme and relative increase in globulin-type protein was to be expected when women first take oral contraceptives, change to another type or cease to take it. The effects of increased corneal oedema, reduced lacrimal secretion and increased mucus and lipid content of the tear film may last a few weeks but will gradually subside. The more modern, low oestrogen dose tablets produce only infrequent problems to the contact lens wearer.

De Vries (1985) also reported a higher frequency of calcium deposit problems in women taking oral contraceptives, the problem being greater in the higher oestrogen dosage group.

Phenolphthalein

Available as Agarol (suspension), Kest (tablets), Veracolate (tablets), Alophen (pills) and Ford (pills), phenolphthalein is used as a purgative in malabsorption syndromes such as pancreatic dysfunction etc. Because the products are mainly available as over-the-counter preparations, they are unfortunately often used as slimming aids by virtue of the diarrhoea produced. The urine and faeces are turned pink to red and contact lenses pink (Aucamp, 1980).

Preservatives in therapeutic eye drops

Contrary to earlier thinking, the preservative used in common and infrequently administered therapeutic eye drops appears unimportant. Although preservatives may be used which theoretically bind and concentrate in hydrogel lenses, this does not cause an observed clinical problem in practice due to the small amount of preservative present and the short contact time (Lemp, 1978), unless the treatment is long term, e.g. in chronic glaucoma.

However, many therapeutic eye drops cause stinging in PMMA lens wearers, possibly due to pre-existing corneal insult, oedema, or the effect of the solution on the tear film and its break-up time (BUT).

Phenazopyridine hydrochloride

Phenazopyridine (Pyridium) produces a topical anaesthetic effect on the mucosa of the urinary tract. It is used as palliative therapy in cystitis, prostatitis and urethritis. Phenazopyridine turns urine reddish-brown and may also discolour soft lenses this colour (Aucamp, 1980). One report has been made of a lens turning grey when a patient taking this drug used a thermal disinfection routine (Barnard, 1984).

Phenazopyridine produces keratitis sicca in dogs (Slatter, 1973).

Reduced tear secretion

Drugs that cause reduced tear secretion may affect lenses of all types but, in particular, hydrogel lenses. Drugs affecting tear flow may be divided into the following categories:

- Anticholinergic drugs such as atropine and hyoscine (scopolamine). These are often sold as over-the-counter cold and 'flu preparations, antidiarrhoeals (diphenoxylate hydrochloride, Lomotil) and some sedatives.
- Antihistamines: these reduce both aqueous and mucous secretions. Most antihistamines have, to some extent, antimuscarinic actions. It is this which produces any side-effects that occur. Typical examples are promethazine (Phenergan), chlorpheniramine (Piriton) and trimeprazine (Vallergan).

- Psychotropic drugs with an anticholinergic action, for example tricyclic antidepressants, e.g. amitriptyline (Tryptanol), imipramine (Tofranil), doxepin (Sinequan), and neuroleptics, e.g. benztropine (Cogentin) and benzhexol (Artane).
- Diuretics.
- Beta-blockers, e.g. practolol (now discontinued) and in some cases, atenolol, and oxprenolol (Banes, 1985).
- Certain general anaesthetics: tear flow may be reduced 30 minutes after the inhalation of nitrous oxide, halothane or enflurane (Krupin *et al.*, 1977).
- Phenazopyridine (Pyridium).
- Higher dose oestrogen oral contraceptives.
- Appetite suppressants: diethylpropion (Tenuate Dospan).
- Anti-allergic: sodium cromoglycate (Opticrom) (Banes, 1985).
- Anti-Parkinsonism drugs.
- Although not listed as a known side-effect, Bergmanson and Rios (1981) reported dry eye symptoms and the adherence of a hydrogel lens to the cornea in a patient prescribed the mild analgesic Darvocet-N 100.

  Darvocet-N 100 was a combination of dextropropoxyphene 100 mg and 650 mg paracetamol. Dextropropoxyphene is used as the napsylate or hydrochloride salt and, although structurally related to the narcotic analgesic methadone, does not compare to it in analgesic potency. The combination with paracetamol or aspirin is reported to produce greater analgesia than either drug administered alone.

  The various drug combinations may be supplied as Capadex, co-proxamol, Distalgesic, Doloxene, Paradex and Paxalgesic, and are used for the symptomatic relief of pain associated with neuralgia, dysmenorrhoea, rheumatism, arthritis, sciatica, lumbago, toothache and other types of nervous or muscular pain; and to reduce fever in common cold and influenza.
- Isotretinoin (Roaccutane) is a synthetic vitamin A compound used for the treatment of recalcitrant cystic acne. It has numerous toxic ocular side-effects which include anterior segment inflammation, dry eye syndrome, contact lens intolerance, altered refraction, photophobia and reduced night vision (Caffery and Josephson, 1988).

Respiratory drugs

Beclomethasone (Becotide) and salbutamol (Ventolin) have been reported occasionally to cause increased sensitivity to contact lenses and solutions (Banes, 1985).

Rifampin or rifampicin

Available as Rifadin and Rimactane, this is a semisynthetic antibiotic, bactericidal to both Gram-positive and some Gram-negative bacteria. Its use is mainly in tuberculosis and ocular chlamydial cases and has been reported to turn soft lenses orange (Lyons, 1979).

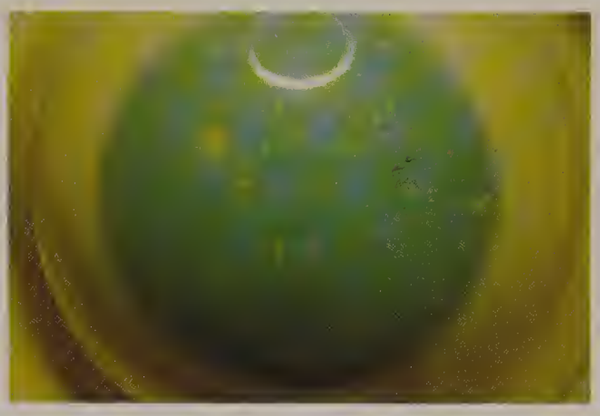


Figure 4.20 Many creams for acne vulgaris contain benzyl peroxide. These and other oxidizing agents, if brought into contact with tinted soft lenses, may cause the patchy bleaching shown above. Information should be sought from individual manufacturers as to the stability of their particular tinting process. (Courtesy of R. Payor)

Skin creams

Some skin creams such as Oxywash for teenage spots and pimples contain benoyl peroxide which may bleach or discolour Cibatint lenses (*Figure 4.20*).

Other hand creams such as Vaseline Intensive Care and Skin Repair may remain on the hands after several washes and, if brought into contact with a hydrogel lens surface, are extremely difficult to remove (*see Figure 18.16*). Liquid soaps not fully rinsed from the hands may produce a similar but lesser effect.

Johnson's Baby Lotion may discolour soft lenses pink if not carefully washed from the hands. Eye make-ups are also likely to discolour hydrogel lenses if misused.

Sulphasalazine

Prescribed as Salazopyrin, this drug is used for rheumatoid arthritis and ulcerative colitis, especially for maintenance therapy following corticosteroid treatment, and also for treatment of active Crohn's disease especially in patients with colonic involvement.

The alkaline urine and also contact lenses may be discoloured orange-yellow (Riley *et al.*, 1985).

Tetracyclines

Available in a wide range of products, such as tetracycline (Achromycin), Mysteclin (tetracycline + nystatin), oxytetracycline (Terramycin), doxycycline (Vibramycin) etc., the tetracycline group has a wide range of antimicrobial activity against Gram-positive and -negative organisms and often to micro-organisms insensitive to other chemotherapy, e.g. rickettsiae, *Chlamydia trachomatis* etc. It is commonly prescribed in bronchitis, sinusitis, prostatitis, teenage acne, blepharitis etc.

Tetracycline is known to discolour teeth brown if used with young children, the teeth fluorescing yellow at first and then, later, permanently brown. This is probably due to a

tetracycline–calcium orthophosphate compound or perhaps an oxidation product. Presumably similar compounds are formed in the tears and contact lenses ultimately discolour yellow-brown.

Current medical trends are to use tetracyclines such as doxycycline which appears not to cause dental (and possibly contact lens) discoloration to the same extent. However, Banes (1985) reported a case of marked photophobia and contact lens sensitivity on a patient taking doxycycline.

Some evidence was put forward to claim an increased sensitivity to thimerosal-preserved solutions in patients taking systemic tetracycline (Crook and Freeman, 1983).

Topical medication and pharmacological effects

Drops used in conjunction with hydrogel lens wear, may cause the following to occur:

- Increase the contact time of the drug. For example corneal anaesthesia is prolonged if a soft lens is reinserted over a cornea anaesthetized for applanation tonometry.

2 Adsorb, concentrate and gradually release certain drugs. The effect of certain cycloplegics, pilocarpine, phenylephrine, idoxuridine, possibly steroids and other high-molecular-weight, water-soluble drugs may be enhanced by the use of a hydrogel delivery system provided they are preservative free or use appropriate preservative systems (*see* Chapters 20.7 and 23). However a minimum 2-hour soak in the appropriate solution is necessary for maximum effect.

In a similar manner, swimming pool chlorine may be concentrated in hydrogel lenses and subsequently released onto the cornea causing tissue damage after a prolonged open-eye swimming session in heavily chlorinated pool water. Nevertheless, protection is afforded to the eye during swimming and adverse effects from the chlorine may be avoided if the lenses are removed straight after swimming and rinsed thoroughly (although the lenses may adhere to the cornea and be difficult to remove). Disinfection is also advisable to minimize any risk of subsequent infection from contaminated pool water. It is safer to avoid contact lens wear when swimming or to wear water-tight swimming goggles. Particular care should also be taken because of the risk of *Acanthamoeba* infection.

The vapour from trichlorethylene can be concentrated in soft lenses with severe adverse ocular effects.

- An exaggerated response may be seen, possibly due to a compromised cornea, in long-term wearers. A mydriatic response has been reported with as little as a 0.125% phenylephrine hydrochloride solution (Krezanoski, 1981).
- Effect of the vehicle used for the medication. Clear vehicles create the least problems. Oleaginous composition or suspensions can lead to discomfort or lens intolerance but fortunately are little used nowadays (Krezanoski, 1981).

Topical medication and pH

Low (acidic) pH therapeutic solutions, e.g. some adrenaline solutions, can cause water loss from hydrogels, shrinkage and steepening. High (alkaline) pH solutions cause the opposite. Methacrylic acid-containing materials are the most prone to this effect (Krczanoski, 1981).

Topical medication and tonicity

Hypertonic solutions such as 10% sodium sulphacetamide or 6–8% pilocarpine hydrochloride can cause lens dehydration and temporary parameter changes if administered to hydrogel lens wearers. High water content lenses are the most prone to this effect (Krezanoski, 1981).

Trandate (labetalol)

Labetalol (Trandate) is an antihypertensive agent exhibiting both α- and β-adrenergic blocking properties. The β-blocking agents in general lower blood pressure by reducing heart rate and contractability. Norwood (1983) observed lens calculi on patients taking labetalol which did not occur when methyldopa (Aldomet) was prescribed as an alternative. Although marked xerophthalmia and keratoconjunctivitis occurred with earlier β-blockers, such as practolol, this has not been observed with labetalol. However, the calculi are probably caused by some subtle interference with or reduction of the tears liquid. Banes (1985) has indeed reported dry eyes in some patients prescribed atenolol (Tenormin) and oxprenolol (Trasicor).

Summary of lens deposits and discoloration

Table 4.2 may serve as a useful practitioner's reference list. Soft lenses are generally referred to unless otherwise stated. It should be emphasized that discoloration is only likely with prolonged use of many of the medications listed.

Solution misuse and incompatibility

The following summarizes some of the more common patient mistakes and misuses of soft lens solutions and serves to emphasize the need for careful patient instruction.

- Tints: Cibatints are reduced or removed by strong oxidants such as chlorine (Softabs or Aerotabs) or sodium perborate (Liprofin). The fading of some tints with time may be exacerbated by the long-term use of hydrogen peroxide disinfection.
- Preservatives and discoloration: thimerosal has been reported as causing grey-black discoloration of soft lenses and containers. Chlorhexidine has been blamed for causing lens yellowing.
- Hydrogen peroxide: proprietary pharmaceutical and supermarket hydrogen peroxides contain stabilizers. Phenacetin, one such product, may cause some lenses to turn pink.

Table 4.2 Summary of lens deposits and discoloration with prolonged use of many of the medications listed

Deposits	
Protein	Usually natural, high lysozyme levels in tears Pseudoprotein following conjunctivitis Giant papillary conjunctivitis Exacerbated by thermal disinfection methods
Lipid	Natural hyper-meibomian secretion High cholesterol diet Low tear potassium levels Regular alcohol drinker Pseudolipid with intensive hand creams and unrinsed liquid soaps Loss of coating with certain RGP materials Acne
Calcium	Natural high tear levels Poor blinkers/dry eyes High oestrogen dose contraceptive pills Calcium phosphate resulting from phosphate buffers in solutions used Use of tap water for rinsing
Calculi	Natural for some individuals Beta-blockers, e.g. labetalol Low system or tear potassium levels Higher oestrogen dose contraceptive pills Poor blinkers/high water contact lenses May be worse after antibiotic therapy (Roth, 1987)
Discoloration	
Grey	Phenazopyridine Adrenaline (epinephrine) Phenylephrine Prolonged thimerosal preservative use Tetrahydrozoline (Visine) Repeated thermal disinfection with same saline Swapping lenses soaked in chlorhexidine/thimerosal to sorbic acid solutions
Brown	Adrenaline (epinephrine) Phenylephrine Nitrofurantoin Tetrahydrozoline Nicotine Tetracycline Boiling in old sorbic acid-preserved solutions Boiling NVP-containing materials Prolonged soaking of high water content ionic lenses in a sorbic acid-preserved solution
Discoloration (*Continued*)	
Reddish-brown	Phenazopyridine Iodine-liberating disinfecting systems used with old or high water content lenses Clofazimine
White	Calcium deposits Boiling in Mirasol
Yellow	Nicotine Tetracyclines Boiling in old sorbic acid-preserved solutions Old lenses in chlorhexidine solutions
Orange	Rifampicin Boiling old or chlorhexidine-soaked lenses in chlorine-releasing solutions Sulphasalazine Fluorescein
Pink	Phenolphthalein Commercial metabisulphite as antioxidant in adrenaline eye drops Some antioxidants in commercially used hydrogen peroxide Johnson's baby lotion Antioxidant used in commercial hydrogen peroxide (phenacetin?)
Red	Rubber stamp ink Rose bengal
Black	Adrenaline (epinephrine) Phenylephrine
Blue	Rubber stamp ink Hair dye
Purple	Heating protein deposits in old sorbic-acid preserved solutions

- Daily soft lens cleaners used as soaking solutions may cause a gummy residue, opaque or discoloured lenses, and ocular irritation.
- Cold disinfection solutions used in thermal units, not thoroughly rinsed and re-used: a gummy residue and lens discoloration may result.
- Enzyme misuse: lenses soaked in papain for longer than 1–2 hours may cause irritation in some wearers on subsequent lens insertion.
- Polyvinyl alcohol-containing solutions mixed with boric acid-containing solutions: a gummy gelatinous precipitate is formed.
- Misuse of thermal unit: repeated use of the same saline has been reported to turn lenses grey to grey-black (Sibley, 1984).
- Use of high-molecular-weight containing solutions, e.g. polyvinyl alcohol in a thermal unit (Sibley, 1984) can cause whitish-coloured gummy residues that can ruin hydrogel lenses.
- Changing preservatives: soaking chlorhexidine–thimer-

osal disinfected lenses in sorbic acid-preserved solutions without purging may cause lenses to discolour grey to black (Sibley, 1984).

- Use of old (expired) solutions may cause discoloration and precipitation (Sibley, 1984).
- Use of old sorbic acid-preserved solutions and deposited lenses. Sorbic acid slowly breaks down with oxidation to form small amounts of aldehydes. The effect is speeded up by low pH, temperature, light, oxygen and trace metal ions. Amine in protein on the lens surface combines with the aldehyde to produce a yellow-brown discoloration (Sibley and Chu, 1984). This can usually be removed by Liprofin or hydrogen peroxide cleaning.
- Sorbic acid concentration: concentrations greater than 0.15% have been reported to turn lenses grey-green if used with heat or hydrogen peroxide (Greco, 1984).
- Heating high water content lenses containing NVP will gradually induce a brown discoloration (Lubert and Caplan, 1984).
- Storage of hydrogels in rigid lens solutions. Marked discomfort can be produced especially if benzalkonium chloride or chlorbutanol-preserved solutions were inadvertently used. Purging and use of a strong oxidizing cleaner, e.g. Liprofin, may remove the preservative.
- The mixing of cationic preservatives such as chlorhexidine, polyquad and dymed, e.g. if present in a surfactant cleaner and inadequately rinsed, with an anionic preservative such as sorbic acid, may neutralize the antimicrobial effect.
- A keratopathy may occur if thimerosal-chlorhexidine preserved solutions are mixed with those containing alkyl triethanol ammonium chloride (Allergan's Hydrocare).
- A similar keratopathy may occur in CAB lens wearers if chlorhexidine–thimerosal solutions are mixed with those containing benzalkonium chloride.
- Lenses soaked in chlorhexidine-preserved solutions and then placed in 3% hydrogen peroxide may turn grey-black due to the precipitation of the oxidized preservative.
- Soaking lenses in sorbic acid which is then mixed with thiosulphate peroxide neutralizer is likely not only to cause eye irritation but also ruin the lenses (Rakow, 1988).
- Temporary use of hydrogen peroxide neutralizer solutions in an AOSept case may gum up the disc (Rakow, 1988).
- Mixing pyruvate and thiosulphate hydrogen peroxide neutralizers in the same container may cause eye irritation.
- Use of Allergan's Ultrazyme (Subtilisin A) tablets with the AOSept system may generate so much pressure from the breakdown of the hydrogen peroxide by the disc and the effervescence of the Ultrazyme that there is a risk of container cracking or explosion (Rakow, 1988).
- A sticky gel may be seen on some RGP lenses when borate-buffered preparations are used in conjunction with those containing polyvinyl alcohol.
- Tear substitutes preserved with chlorbutanol are not compatible with RGP lenses containing polysiloxane and may cause ocular discomfort and changes in lens parameters.
- Surface coated RGP lenses cleaned with 'friction enhanced' surfactant cleaners will have the surface layer removed commonly resulting in ruination of the lens.
- Use of some RGP solutions with the Softperm lens may cause eye irritation or lens ruination.
- Over the counter (OTC) hydrogen peroxide may be as high as 36% when significant ocular and lens damage may result. Even at the 3% level OTC hydrogen peroxide neutralizes at a pH below the ocular threshold level and discomfort will result (Harris *et al.*, 1989b). In addition, the antioxidants used in some commercial brands of OTC hydrogen peroxide may turn lenses permanently pink.
- Some CAB RGP lenses may change in BOZR and become slightly yellow in colour if stored in benzalkonium chloride-preserved solutions.
- Concern has been expressed (Anon, 1996) that Ciba Vision's Saline may reduce the antimicrobial action of Aerotab due to incompatibility of the preservatives used.

With more than 100 contact lens products on the market, dozens of lens materials, thousands of systemic medications and hundreds of topical eye medications and OTC products, the permutations for lens discoloration, lens damage and potential eye damage, possibly serious, require constant vigilance on the part of the contact lens practitioner. As control of contact lens products moves increasingly away from the qualified professional, the legal implications of this new scenario have yet to be defined.

Lens conditioning, tear replacement and similar solutions

Some soft lens wearers experience occasional discomfort or loss of acuity while the lens is in the eye. Assuming that no fitting problems exist, the cause may be partial dehydration of the lens or the build-up of meibomian secretion on the lens surface. To overcome these problems solutions have been developed which clean and rehydrate lenses *in situ* (*see* Appendix C at the end of the book).

Rehydration and lens cleaning *in vivo* may be needed by the extended wear patient on waking. Solutions such as Clerz (Ciba) have been developed for this purpose. Similar products are listed in Appendix C. Clerz is a hypertonic saline combined with a surfactant. The hypertonicity will 'draw out' surface contaminants and possibly temporarily flatten the lens front surface thereby stimulating movement of a possibly dehydrated (and therefore tight-fitting) lens. Such lubricating drops are often needed during the day especially for patients in heated, air-conditioned or windy environments.

Soft lenses are still undergoing continuing development and coupled with this has been the development of related solutions. Practitioners must accept the fact that no

particular solution or technique will be ideal for every patient or lens material. In the same way that careful investigation will indicate the optimum lens material and parameters for a particular patient, the practitioner must equally carefully ensure that the method of disinfection selected is both appropriate to the individual patient's temperament, occupation and available facilities as well as to the lens material to be used.

Similarly, care must be taken in choosing the lens storage case or container. (With asepticizor units the practitioner may have no choice since only the one design of case will fit the unit.) Where a choice is possible, the practitioner should choose a container which conforms to the following ideals.

- A transparent container will allow the quantity of solution to be seen.
- It should be clearly marked 'Left' and 'Right', preferably also colour-coded, possibly with identifying tactile projections.
- The storage solution volume should not be so small that insufficient quantities of preservative are contained (where chemical disinfecting solutions are used). It should be large enough to allow adequate diffusion and dilution of contaminants into the solution. Conversely the container volume should not be so large that excessive quantities of solution are used which may discourage daily changing of the solution because of the cost.
- The container material must be compatible with lens materials and solution constituents.
- The container material must be capable of withstanding regular boiling and have leak-proof caps.
- It should be readily cleanable without inaccessible crevices.
- The container must be inexpensive enough that it can be replaced frequently.

Scleral lens solutions

RGP sealed scleral lenses are usually inserted with unpreserved normal saline (unit dose). A solution of 2% sodium bicarbonate, with 0.2% chlorbutol can be used. It is important to avoid the use of hydrobenzoates, or phenylmercuric nitrate or acetate in a sealed scleral lens solution, as they cause intense irritation to the eye. The lenses can be cleaned and rinsed with RGP solutions and stored dry.

Ophthalmic preparations

Drugs for ophthalmic use can be presented in a variety of ways:

- Multi-dose aqueous eye drops
- Single use aqueous eye drops, e.g. Minims
- Eye ointments
- Paper strips

Unfortunately there is not always a free choice for the practitioner as not all the drugs are available in all dosage forms.

Multi-dose eye drops are amongst the oldest forms of ophthalmic medication and are principally intended for therapeutic use by individual patients and their formulation and presentation are based on this fact. Drugs in aqueous solution are packed into some form of dropper bottle in volumes of between 5 and 15ml, a volume which relates to the likely requirement for one patient for one month using the drops daily. Being an aqueous solution, eye drops are subject to two main potential problems – chemical degradation and loss of sterility. The problems of chemical degradation which can lead to loss of efficacy or adverse reactions (or both), are addressed by:

- the specification of storage conditions;
- the setting of an expiry date for the unopened container;
- the incorporation of adjuvants into the solution such as an anti-oxidant which will reduce the rate of degradation.

The aqueous solution is potentially contaminated by micro-organisms which can be pathogenic to the eye. Suitable preservatives are incorporated into the solution which will deal with the small degree of contamination encountered when patients use the drops on a day-to-day basis. A limit for the use of the drops of one month is also imposed to reduce the dangers of infection. The shelf life of opened bottles must be drastically reduced if the drops are to be used on more than one patient.

Some of the preservatives used in eye drops are incompatible with hydrophilic lenses and drops containing benzalkonium chloride should theoretically not be applied with lenses *in situ*. In practice this has not been found to be a major problem, although, ideally, therapeutic drops should be used prior to or after lens wear where possible.

Single dose drops are a better presentation for optometric practice use. They are packed in small volumes (0.5 ml) and contain no preservative. They are intended for single use. A useful range of agents is available in this dosage form and these are to be recommended.

Eye ointments are mainly in therapeutic dosage forms because of their long duration of action. They are rarely used for diagnostic purposes, atropine eye ointment being the exception. When used therapeutically, a shelf life of one month for opened containers is imposed for sterility considerations.

Preservatives are not effective when incorporated into ointments and every care must be taken to avoid contamination. Single use ointments were introduced to avoid such problems but they are no longer available.

Paper strips are an excellent method for applying minimal amounts of agent and are ideally suited for administering stains such as fluorescein. As the stains are coloured it is easy to visualize the amount of compound that has been delivered to the eye and thus good control can be exercised. As the stain is in dry form, chemical breakdown and

bacterial contamination are potentially much less of a problem than with aqueous eye drops.

The Novel Ophthalmic Delivery System (NODS) was a system that addressed many of the inaccuracies of aqueous eye drops. An accurate dose of active principal was incorporated into a water-soluble polymer film. This film was then placed in the conjunctival sac by means of an applicator. Water from the tear film was taken up by the polymer which released a concentrated solution of the drug into the precorneal film. This method avoided the instillation of a large volume of liquid into the conjunctival sac, half of which is normally lost. Thus all the drug is available for absorption and a greater effect is obtained for a given amount of drug. The more efficient application increases the useful effects and reduces the side-effects. NODS are currently not available.

The following topical preparations are the most commonly used ones in contact lens practice:

- Topical anaesthetics
- Conjunctival decongestants
- Anti-allergic agents
- Staining agents
- Chemotherapeutic agents.

Topical anaesthetics

Topical anaesthetics are used in contact lens practice to produce surface anaesthesia of the cornea and conjunctiva by reducing the sensitivity of their sensory nerve endings. Their mode of action is to reversibly prevent the transmission of nerve impulses along sensory fibres. Motor fibres are only affected by higher concentration.

The ideal requirements of a surface anaesthetic are:

- Rapidity of action
- Adequate depth of anaesthesia
- Short duration
- Non-toxic
- Non-irritant
- No subsidiary actions such as cycloplegia, mydriasis or vasoconstriction
- Stability.

The depth and duration of anaesthesia depends on many factors. The status of the cornea, iris colour, concentration of drug and the number of drops applied are some of the factors that can influence the performance of these agents. Hence, quoted times for onset and duration can be misleading.

All the topical anaesthetics have some effect on the corneal metabolism and increase its permeability to other drugs. Hence, while 0.1% adrenaline instilled into the eye normally causes no mydriatic effect, after the instillation of a topical anaesthetic some dilatation of the pupil may occur. This is a result of increased absorption and not of sympathetic supersensitivity.

Another effect on the cornea which is frequently encountered is desquamation of the superficial layers of the corneal epithelium. Cocaine is the worst offender. The insensibility of the cornea renders it susceptible to accidental damage as the eye's natural defence mechanism is impaired.

The most commonly used topical anaesthetics are amethocaine (also known as tetracaine, pantocain, pontocaine, decicain), oxybuprocaine (benoxinate), proxymetacaine (Ophthaine) and lidocaine (lignocaine). Unlike cocaine, none of the commonly used agents has subsidiary actions like mydriasis and vasoconstriction, and there is no effect on accommodation.

Amethocaine

This agent is used in concentrations of 0.5% and 1% and causes some initial stinging on application, which usually results in a blepharospasm and some reflex tearing. This is short-lived as the anaesthesia takes effect in about 10 seconds. It has no toxic or subsidiary actions, but is more likely to affect the superficial epithelial cells than Ophthaine or benoxinate.

Amethocaine is incompatible with alkalis, bromides, silver salts and oxidizing agents. Solutions should be protected from light.

Proxymetacaine

A 0.5% solution is a very satisfactory, all-round anaesthetic, being non irritating, safe, effective and free from subsidiary actions (Rycroft, 1964). With a single instillation, the onset of anaesthesia occurs in an average of 13 seconds and persists for about 15 minutes (Boozan and Cohen, 1953). Its initial discomfort is considerably less than with amethocaine, and allergic manifestations have occurred only rarely. In comparison with cocaine and dorsacaine (oxybuprocaine), Jervey (1955) found that proxymetacaine seemed to produce the least discomfort. The only problem with proxymetacaine is its stability. Once the bottle has been opened, it must be kept refrigerated (not frozen) between 2 and 8 °C and protected from light. Breakdown of the active principal is evident as a discoloration and must be discarded. Minims of proxymetacaine should also be refrigerated.

Oxybuprocaine (benoxinate)

Like amethocaine, oxybuprocaine is an ester of para-amino-benzoic acid, whereas proxymetacaine is an ester of meta-amino-benzoic acid. It is incompatible with alkalis and silver salts. The onset of anaesthesia is fairly rapid (after about 30 seconds) and the duration of action of a 0.4% solution is about 10–15 minutes. It is much less irritating than amethocaine on initial instillation and causes fewer microscopic changes of the cornea.

Lidocaine (lignocaine)

Lidocaine is an amide-type local anaesthetic which is widely used for surface anaesthesia in general medicine. It

is available as a mixture with fluorescein for use in applanation tonometry.

Topical anaesthetics are used primarily in contact lens practice to anaesthetize the eye prior to the fitting a rigid lens to a very nervous patient or prior to the taking of eye impressions. When used before rigid lens fitting, two drops instilled into the lower fornix is usually sufficient. For eye impression work, usually two or three drops are instilled. The first into the lower conjunctival sac, and the subsequent drops onto the superior limbal region, so allowing the anaesthetic to run gently over the whole cornea. This ensures that the whole cornea is effectively anaesthetized.

One drop can also be instilled into the other eye to inhibit the blink reflex. Regardless of which anaesthetic is used, it is of the utmost importance to ensure that either the corneal sensitivity has returned or that the eye is adequately protected by an eyepad or shade before the patient leaves the practice. The possible hazard of a foreign body becoming embedded in an insensitive cornea must not be overlooked.

Once tearing has subsided following the instillation of a local anaesthetic, lacrimation may be reduced. Therefore to prevent corneal epithelial drying (which may cause a rapid and severe drop in vision), patients should be encouraged to blink frequently until normal sensitivity returns (about 15–20 minutes). Alternatively, an artificial tears solution may be instilled to keep the cornea moist. Eye rubbing should be discouraged as the surface epithelial cells may be damaged or dislodged.

Conjunctival decongestants

The dilatation of the conjunctival blood vessels is a common response to irritation or inflammation. As well as being unsightly and uncomfortable for the patient, dilated vessels can interfere with impression taking. To overcome this problem, dilute solutions of sympathomimetic amines are used as conjunctival decongestants. The drugs most commonly used for this purpose are naphazoline and phenylephrine. These are the same formulations that are found in over-the-counter eye preparations used as eye 'brighteners'. Adrenaline has been used for this purpose but is inherently unstable, being susceptible to attack by atmospheric oxygen, breaking down to a coloured solution. Adrenaline has been superseded by newer, more stable drugs.

Naphazoline

Naphazoline, available as the nitrate or hydrochloride, is a quick acting, powerful and prolonged vasoconstrictor, used as a 0.1% or 0.05% aqueous solution, the latter strength being normally adequate. Although it is not chemically related to adrenaline, it has similar actions to it and has the advantage of being more stable in heat, light and air.

Adverse effects are relatively uncommon and it has no effect on pupil size, amplitude of accommodation or on intraocular pressure. Hurwitz and Thompson (1950), using 0.1% naphazoline hydrochloride, found only a slight mydriatic effect on light coloured irides.

One or two drops instilled into the lower conjunctival sac are adequate and it has a duration of action of about 4 hours. As with all vasoconstrictors, excessive use over long periods, particularly in chronic conditions, is not advised as the blood vessels gradually cease to react to it and reactive hyperaemia will persist.

Vasocon A is a multidose combination of the antihistimine antazoline phosphate (0.5%) with naphazoline hydrochloride (0.05%), preserved with 0.01% benzalkonium chloride.

Phenylephrine

Phenylephrine is routinely used as a mydriatic in concentrations of 2.5% and 10.0%. It is a useful vasoconstrictor in a concentration of 0.125%. Even in these low concentrations a mild mydriatic effect has been experienced. It is used in over-the-counter remedies for the relief of cold symptoms.

Other vasoconstrictors

Xylometazoline and tetrahydrozoline are other sympathomimetics which have been used as topical vasoconstrictors for ophthalmic use. Xylometazoline is combined with an antihistamine (antazoline) in Otrivine Antistin, a preparation which is useful in contact lens practice for dealing with conjunctival injection from an allergic cause.

The mydriasis produced by these agents is very slight and the danger of precipitating closed angle glaucoma is somewhat overstated. As with naphazoline, their long-term indiscriminate use must be questioned. These agents break down to coloured compounds and these can discolour soft contact lenses if they are instilled over a long period with the lenses in.

Anti-allergic agents

The principal agent in this group is sodium cromoglycate, which has been used for many years for the treatment of allergic conjunctivitis. It was originally indicated for the treatment of asthma in the form of inhalers and nasal sprays etc. It produces its effect by stabilizing the membranes of mast cells, thus preventing the release of histamine. It is best used as a prophylactic, being given as a course of treatment. It will not act as an antihistamine and is not effective once the histamine has been released. It is available as a 4% solution, which is now available in the UK as an over-the-counter preparation, and it can be useful to the contact lens practitioner in cases of GPC.

A more recent adjunct in the treatment of allergic eye conditions is iodexemide 0.1% (Alomide) which is an anti-inflammatory agent.

Diagnostic staining agents

Fluorescein

Fluorescein is one of the most useful diagnostic agents for ophthalmic use, producing a brightly coloured tear film in high dilution. It demonstrates areas of damage of the cornea by exhibiting an intense green fluorescence to ultraviolet or blue light. It is used as a means of checking the contact lens fit and detecting corneal abrasions. As it colours the tear film it can be used to demonstrate the drainage (or lack of drainage) of tears through the nasolacrimal duct. A patent nasolacrimal duct is essential if contact lenses are to be fitted. A few minutes after instillation of fluorescein into the conjunctival sac of one eye only, the nose should be blown onto a paper tissue, which is then examined under ultraviolet light. The process can be repeated on the other side once a few more minutes have elapsed.

The official salt is fluorescein sodium BP either as a 1 or 2% solution, or as fluorescein-impregnated paper strips. With the widespread availability of single use units, multi-dose dropper bottles should not be used at all. Fluorescein can provide an excellent culture medium for certain bacteria such as *P. aeruginosa* (Chatoo, 1963; Doris 1964). The impregnated strips have the advantage that they can be stored for a long time, providing they are kept dry. They also deliver smaller amounts of the dye than do drops.

Following instillation of a drop of solution for the detection of abrasions, it is usually advisable to instil a drop of physiological saline to wash away any excess stain from the normal tear film, which might otherwise mask any damaged areas. This is not necessary with the small amount instilled from a paper strip. Such areas, if present, may then be observed with ultraviolet light and a slit-lamp microscope. Excess stain which may have spilled from the eyes should be washed or wiped off before the patient leaves the practice.

Fluorescein sodium (molecular weight 376) has been used routinely for many years in contact lens practice for evaluating the fit of a hard contact lens. However, it is unsuitable for evaluating the fit of a hydrophilic lens because of its absorption and binding to the lens. If fluorescein has been instilled into the eye this should be well irrigated from the eye or there should be a delay of at least 1 hour before a hydrophilic lens is inserted.

A fluorescent water-soluble dye, Flurexon, was described by Refojo *et al.* (1972b) and Refojo *et al.* (1972a). It was a derivative of fluorescein but had a molecular weight of 710 and was absorbed much more slowly than fluorescein. The stain was reversible and washed out of the lens by boiling in saline. Also, solutions of Flurexon were just as vulnerable to contamination as fluorescein (Refojo *et al.* 1972a) hence, single use drops are advocated.

Fluoresoft (Sauflon) is available in 0.5 ml unit doses. The active ingredient is calcein 0.035% with a molecular weight of 622.5.

Rose Bengal

This is a fat-soluble stain, which crosses the membranes of dead cells but not living cells. It is used as 1% solution either in unit or multi-dose dispensers to determine the presence of dried areas of corneal and conjunctival epithelium prior to contact lens fitting, also the influence of facial skin conditions on contact lens tolerance. It is also available in paper strips in some countries. Its action differs from the fluorescein in staining dead or desquamated tissue red when viewed under white light. The presence of excess desquamation is an indication of an abnormal ocular condition or skin disease, either clinical or subclinical. It is very irritating to those eyes which exhibit staining, being better tolerated by eyes without damage.

The conjunctiva and skin are of the same origin; and if the palpebral or bulbar conjunctiva stain red, it is advisable to reject the patient for contact lenses until medical advice on the ocular or facial skin condition has been obtained. Otherwise, the wearing of contact lenses may only aggravate matters. Conditions in which positive staining occur include keratoconjunctivitis sicca (Sjögren's syndrome), seborrhoeic eczema, acne vulgaris and acne rosacea.

A mixed stain of 1% fluorescein and 1% Rose Bengal was suggested by Norn (1964) as serving a useful dual purpose in determining both epithelial lesions and degenerate epithelial cells. However, in practice it is of little use as mucus is stained by both agents. One per cent alcian blue (Norn, 1964) differentially stains the mucus blue, but this stain is not generally available.

Chemotherapeutic agents

There is some controversy as to the usefulness of prophylactic agents. Opponents to their use point out, correctly, that the duration of action is very short. Thus only a short period of protection will be afforded to a damaged eye and practitioners may be lulled into a false sense of security. However, the corneal epithelium is well equipped to deal with the small amounts of damage that are likely to occur during contact lens work. The antibacterial will provide protection at the time when it is needed, i.e. just after damage has occurred. When its effectivity has worn off, normal repair mechanisms will have acted to renew the eyes' normal protection. If the damage is so great that the normal defence mechanisms will be impaired, then medical attention with prolonged antibacterial use will be required.

The most effective of the chemotherapeutic agents are the broad spectrum antibiotics of which two are available to the optometrist in the UK. The sulphonamides, which were formerly the prophylactic agents of choice, have currently fallen from use and very few preparations are now available. They can be disregarded as possible agents for this purpose.

The two antibiotics which are available are chloramphenicol and framycetin, of which the former is the most useful as it has a wider spectrum of activity, being available in single dose units.

Chloramphenicol

Despite the fact that chloramphenicol has been in use for many years, it is still by far the most widely used of the topical antibiotics. It has a wide spectrum of activity being effective against chlamydiae, rickettsiae and spirochaetes as well as numerous species of bacteria including *Corynebacterium* spp., *Escherichia coli, Haemophilus* spp. and *Streptococci.* It is not effective, however, against most strains of *Pseudomonas aeruginosa.* Its spectrum of activity makes it suitable as a treatment for ophthalmia neonatorum and for the secondary infections that often follow trachoma. The antibacterial action of this agent is produced by the inhibition of protein synthesis by interaction with the bacterial ribosomes. It traverses mucous membranes, being markedly fat soluble, and penetrates easily into the cell by a process of facilitated diffusion.

Although resistance can develop by the production of inactivating enzymes by certain strains of bacteria, it is comparatively rare because of the infrequent use of chloramphenicol systemically. Routine systemic use was stopped many years ago because of the incidence of aplastic anaemia producing agranulocytosis, which, although rare, is fatal. The incidence of this adverse effect from topical use is infinitesimal.

Framycetin

Framycetin is one of the neomycins – neomycin B. It is not available in Minims form and in multidose form is preserved with phenylmercuric nitrate (0.002%). Its spectrum of activity is similar to that of neomycin and covers both Gram-positive and Gram-negative bacteria. Susceptible bacteria include *Proteus vulgaris, Escherichia coli* and *Haemophilus influenzae.*

Like all antibiotics, resistance can develop with continued indiscriminate use and this resistance will affect neomycin and other aminoglycoside antibiotics.

Other antibacterial agents

Propamidine isethionate

This useful alternative chemotherapeutic agent is available both as an eye ointment containing 0.15% dibromopropamidine isethionate and as eye drops containing 0.1% propamidine isethionate. The range of activity is against pyogenic cocci and some Gram-negative organisms, *Escherichia coli* and *Proteus vulgaris*: there is also some *in vitro* activity against *P. aeruginosa* and it is effective against *Acanthamoeba.* Propamidine isethionate can cause an allergic reaction in a few patients.

Statutes and government regulations

The UK

The Medicines Act was enacted in the UK in 1968 but the orders relating to the sale and supply of drugs were not made until 1978.

The Medicines Act covers all aspects of the manufacture, testing and sale of medicinal agents and it is proposed to concentrate here on Part III, which specifically deals with the sale and supply of medicinal substances.

The effect of this part of the Act is to divide products into three groups. There is provision for setting up a General Sales List, which contains all those drugs and agents which it is thought can be safely sold to the general public without the supervision of a pharmacist. The General Sales List was published in 1978 and contains some of the pharmaceutical agents used by optometrists, for example, hypromellose. However, in Schedule 6 of the order there is a specific exclusion from the General Sales List of all eye drops and eye ointments.

The other list of drugs is the Prescription Only Medicines (PoM) List which contains those drugs only obtainable on the prescription of a doctor, dentist or veterinary surgeon. As with all this type of legislation, there are exemptions and special cases. However, again, eye drops are singled out as requiring special control. For example, amethocaine hydrochloride is PoM only when injected or applied to the eye.

Substances which appear on neither list are referred to as pharmacy medicines and although available for sale to anyone can only be sold under the supervision of a pharmacist. Thus if an eye drop is not on the PoM list it is automatically a pharmacy medicine (designated as P).

The lists published in 1978 make specific provision for the use of drugs by the optometrist. In the PoM list there is a provision for the registered optometrist to obtain and supply certain drugs. The original list as published has been modified by further statutory controls and some agents have been deleted and some added. The agents listed include mydriatic/cycloplegics, miotics and sulphonamides. There is a separate order allowing the optometrist to obtain but not supply local anaesthetics. Appendix C, at the end of the book, gives details of the drugs and eye drops used in association with contact lens fitting and wearing.

Contact lens solutions and contact lenses were brought under the Medicines Act by an order made in 1976. However, this particular order was mainly concerned with the manufacture and labelling and made no provision for subjecting them to control of sale.

In 1980, several important rules were applied to contact lens solutions which can be summarized as follows. With effect from 1 January 1980 no new solution, not previously on the market, could be sold without a product licence. Existing solutions were given a transitional exemption. Full product licences were issued for most products on 1 July 1983. The product licence ensures that products are fully tested for quality, safety and efficacy, and approved by the Department of Health prior to general release.

On 1 January 1994 the control of sale order was modified to allow wider sale of these products, including allowing the supermarket sale of solutions. Additionally the classification for certain drugs used by the optometrist was modified (*see* Optometrist's Formulary, from the British College of Optometrists, 1994, for the full listing). The licensing standards relating to antimicrobial efficacy were also

altered, enabling hygiene systems also to be licensed in kit form. In such cases, rather than each individual solution being required to pass the microbial challenge tests, the 'system' of cleaning and disinfection is required to demonstrate microbial efficacy. This has led to the licensing of newer multipurpose solutions in the UK market, such as ReNu, Complete and OptiFree (*see* Appendix C).

From 1 January 1995, a further change in the licensing of UK products altered the control for the licensing of contact lens solutions which passed from the Medicines Control Agency to the Medical Devices Agency. After June 1998 all contact lens care products require CE marking, enabling them to be sold in all countries of the European Union. Notified Bodies will examine companies for quality and safety standards to ensure that their products are properly tested.

Other countries

In the USA all new contact lens materials (i.e. other than PMMA) are considered as drugs. Prior to approval by the Food and Drugs Administration (FDA) for general use they are subjected to clinical trials on rabbits and humans, and microbiological, toxicological and allergy tests are carried out with both lenses and solutions as well as tests on the associated use of their respective containers. Thus, several years may elapse between the original application to permit testing of the new lens/solution/system and its final approval. As far as extended wear contact lenses are concerned, the FDA requires the clinical trials to cover a given number of patients using the lenses for daily wear first, for a prescribed period of time. Pachometry, checks of the corneal endothelium, slit-lamp examination of the upper tarsal plate, and other observations are all to be included in the clinical trials, as well as oxygen permeability studies on the lenses and their uptake of solution preservatives. If they pass these stringent daily wear trials they may then be used for similar extended wear trials.

In Japan, the Ministry of Health and Welfare insists on independent testing of contact lens materials, methods of manufacture, and on contact lens solutions. University departments normally carry out the tests over a 3–5-year period which includes clinical trials. At present only a few companies are licensed to produce soft lenses. Even PMMA for hard lenses is subject to testing, and firms wishing to set up as hard lens manufacturers are rigorously controlled. Most contact lens solutions containing mercurial compounds, such as thiomersalate (thimerosal), are banned.

In Australia, contact lens care products are classed as therapeutic goods and as such need to be registered and listed with the TGA (Therapeutic Goods Administration). Products to be accepted for listing need to come from an FDA/BP or GMP approved manufacturing facility.

The TGA audits facilities both local and overseas. This registration or listing takes 2–3 months on new products and normally does not require a full drug evaluation unless the product is for internal use.

In New Zealand solutions require a special submission outlined by the NZ Health Department. This registration process usually takes up to 12 months for new products. At present, contact lenses have no registration process.

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Chapter 5

Practical optics and computer design of contact lenses

Morley W. Ford and Janet Stone

The practical effects of optical differences between contact lenses and spectacles p. 154
Optical considerations of contact lenses on the eye p. 170
Astigmatism of the front surface of the cornea and the effect of the liquid lens p. 171
Power variations as a sequel to other changes p. 173
Toric contact lenses p. 184
Bifocal contact lenses p. 186
Optical changes of the eye caused by contact lenses p. 188
Aspects of contact lens design p. 189
Optical formulae for contact lens work, with examples to illustrate their use p. 198
Examination questions and answers p. 224

This chapter is very little different, in essence, from the previous edition. However, references to tables that appeared as Appendices in previous editions have now been removed (apart from Appendix A which gives spectacle and ocular refraction values for various vertex distances). Instead there are references to sets of formulae on which the tables were based. Appendix A remains, and the formulae have been put in the Formulae section (*see* p. 198) and numbered with Roman numerals from I to XXXXVII.

There are also references to the CD-ROM developed by Tony Hough which accompanies this book. Most people now have access to computers and scientific calculators which have so speeded up the process of calculation that they are frequently quicker to use than tables, and are more accurate.

There are two main aspects to be considered when dealing with the optics of contact lenses – the effects on the wearer of the optical differences from spectacles, and the necessity for the practitioner to understand the components which affect the back vertex power of the contact-lens/liquid-lens system. There is some overlap of these two aspects, but for the sake of convenience they are discussed separately in the first two sections of the chapter. In the second section a set of approximate rules is included, the use of which should permit contact lens practitioners to make quick and reasonably accurate estimates of changes in power caused by altering certain lens parameters. In all sections it is assumed that the reader has an understanding of basic optics and vergence considerations. The Cartesian sign convention is used throughout. For further understanding of the basic principles involved readers are referred to the works of Freeman (1990), Obstfeld (1982), Bennett and Rabbetts (1990), Bennett (1985), Douthwaite (1995) and Tunnacliffe (1993).

It is hoped that the practical approach presented in the first two sections of this chapter will not dissuade readers from the study of more erudite mathematical methods of using schematic eye models to evaluate the optical effects of contact lenses. Readers are particularly encouraged to consider the most realistic schematic eye data suggested by Bennett and Rabbetts (1988) which takes account of up-to-date research into the ocular components of the eye.

The practical effects of optical differences between contact lenses and spectacles

Again, it is convenient to subdivide this section, but it will be apparent to the reader that there is an overlap between the subdivisions. For example, a myope's eyes look bigger without negative spectacle lenses for the same reason that the myope sees objects larger without spectacles – because the minifying effect of the spectacle lenses is removed.

The various differences, and similarities, between contact lenses and spectacles will now be considered.

Cosmetic appearance

Aside from the generally improved appearance achieved by doing away with spectacles, the magnification of the spectacle lenses is also eliminated. An observer therefore sees the eyes looking their normal size – smaller than with spectacles for a hypermetrope and bigger for a myope. Disturbing appearances due to the prismatic effects and surface reflections of spectacle lenses are also removed.

Field of view or field of fixation, and field of vision

The wearer of a pair of centred contact lenses has a field of view equal in size to the field of fixation, i.e. limited only by the extent to which the eyes can move. This normally gives a clear field of view of about 100°.

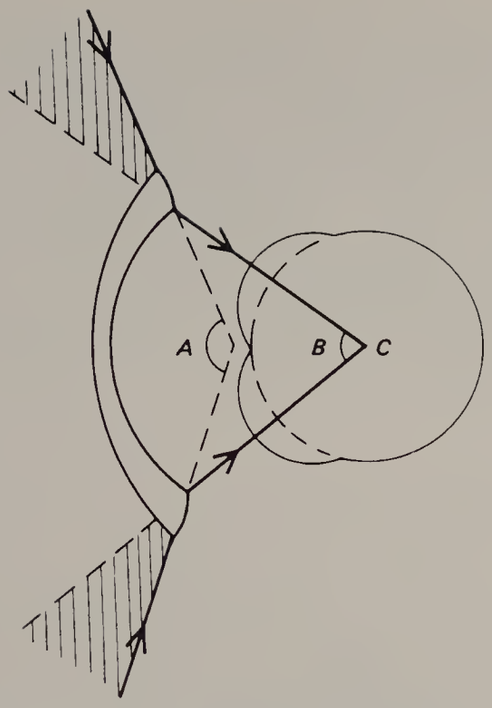


Figure 5.1 Field of view of a myope through a spectacle lens. *A* = actual macular field of view; *B* = apparent macular field of view; *A* > *B*; *C* = centre of rotation of eye. Hatched area is seen double due to prismatic effect (doubling is minimized by the spectacle frame, if present)

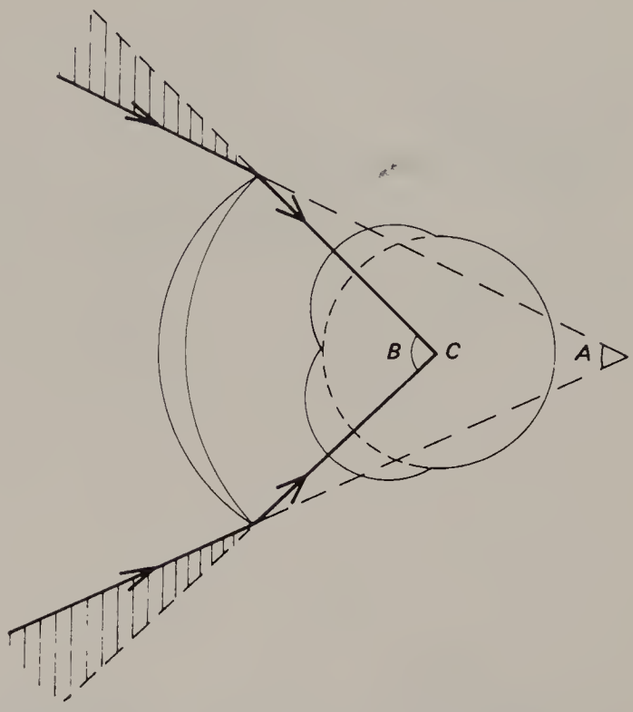


Figure 5.2 Field of view of a hypermetrope through a spectacle lens. *A* = actual macular field of view; *B* = apparent macular field of view; *A* < *B*; *C* = centre of rotation of eye. Blind area due to prismatic effect (and spectacle frame when present) is shown hatched

By comparison, the clear field of view of the spectacle wearer is limited by the size and vertex distance of the spectacle lens and is restricted to an apparent field of about 80° (although blurred vision is possible beyond the limits of the spectacle lens or frame as far as the eyes can rotate). *Figure 5.1* shows that in fact the myopic spectacle wearer has a much larger real field of view than this, depending on the power of the spectacle lens. On the other hand, the hypermetropic spectacle wearer (*Figure 5.2*) has a real field of view smaller than 80°. This means that, on transferring to contact lenses, the myope must move the eyes about more to see the same area of the visual field as seen with spectacles. The reverse applies to the hypermetrope.

The sizes of the real and apparent fields of view through the spectacle lens are easily calculated. The angular subtense of the spectacle lens at the eye's centre of rotation, *C*, gives the apparent macular field of view, *B*. For example, size of spectacle lens, 50 mm; thus, the semi-diameter is 25 mm. Distance from spectacle lens to *C* is 25 mm. Therefore $\frac{1}{2}B = \tan^{-1}(25/25) = 45°$. And thus $B = 90°$.

To obtain the size of the real macular field of view, *A*, requires that the position of the image of *C*, as formed by the spectacle lens, be found. Then *A* is the angular subtense of the spectacle lens at that point. Using the same example as above and reversing the path of the light rays shown in *Figure 5.1*, if the lens has a power of −10.00 D and making use of the usual nomenclature for object and image distances, then: $l = -25$ mm. Therefore, $L = -40.00$ D, $F = -10.00$D; thus, $L' = L + F = -50.00$ D, $l' = 1000/L' = -20$ mm. *C* is thus imaged 20 mm from the spectacle lens, on the same side as *C*. Therefore, $\frac{1}{2}A = \tan^{-1}(25/20) = 51° 20'$. And thus $A = 102° 40'$.

In addition, the prismatic effects of the spectacle lenses cause blind areas in the peripheral visual field of the hypermetrope and areas of doubled vision for the myope, as illustrated in *Figures 5.2* and *5.1* respectively. The blind area experienced by a hypermetrope is enlarged due to the thickness of the spectacle frame. This prismatic effect and the blind area are particularly troublesome to aphakics owing to the high power of the spectacle lenses. Contact lenses afford great relief.

Whereas the average spectacle wearer is accustomed to the presence of a spectacle frame in the peripheral visual field, the contact lens wearer must get used to an effect similar to some entoptic phenomena.

Soft lens wearers and, to a lesser extent, rigid lens wearers experience visual disturbances due to contamination of the lens surfaces by deposits and interruption to the tear film on the front surface of the lens. Such effects may be compared to a dirty spectacle lens, but deposits on a contact lens obscure a proportionately larger area of the pupil because they are situated closer to it than deposits on a spectacle lens; also they remain in the same position relative to the visual axis as the eye moves, whereas the eyes can move to avoid deposits on a spectacle lens.

Wearers of rigid corneal lenses, particularly lenses which are very small and/or which have a large amount of peripheral corneal clearance – possibly only in one meridian

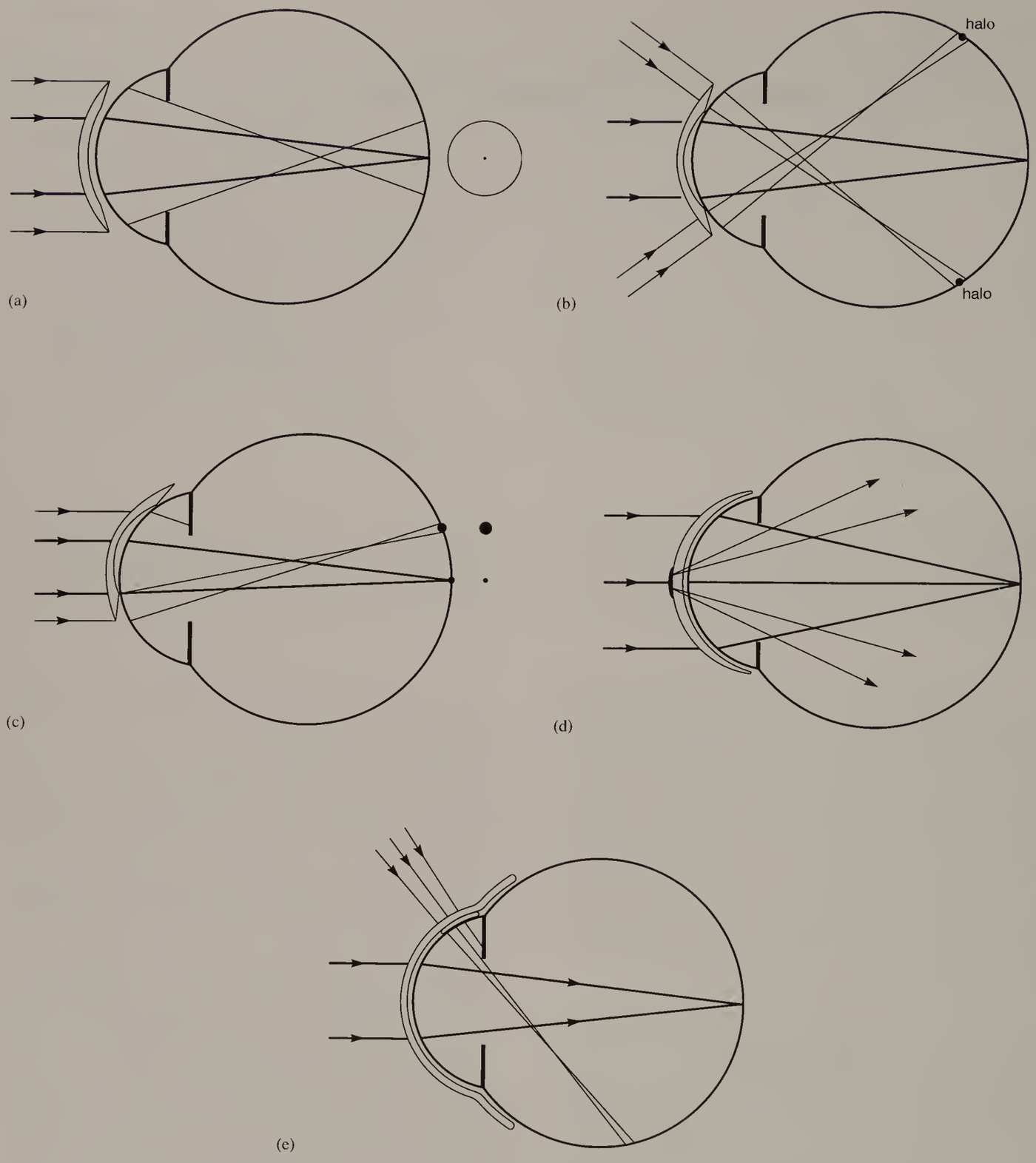


Figure 5.3 Some disturbing optical effects created by contact lenses. For ease of illustration the crystalline lens has been omitted from the diagrams. (*a*) When the pupil is large, refraction through the peripheral zone of a corneal lens and the underlying peripheral band of tears may create a blurred image or flare as indicated on the right-hand side which shows the image of a distant point object. (*b*) A large pupil may also permit the formation of a disturbing peripheral halo due to light entering the eye obliquely and being refracted through the peripheral zone of the contact lens and tear layer. (*c*) With a high riding corneal lens vertical diplopia may be produced, as shown on the right-hand side. In this case it is due to refraction through the lower area of the peripheral zone of the lens and underlying tear layer. Horizontal and oblique displacements of lenses can give rise to corresponding effects. (*d*) Vision may be disturbed by light scattered from deposits on a contact lens (shown here as a soft lens) which gives rise to flare. (*e*) A peripheral halo may be caused by the limbal bubble under a scleral lens. This may also give rise to blurred images, diplopia and flare as shown in (*a*), (*c*) and (*d*), depending on the bubble position and pupil size

due to corneal astigmatism – often experience a halo or partial halo in the peripheral visual field caused by refraction of light through the peripheral zone of the lens, including transitions, and through the surrounding tear film. The wearer of fenestrated scleral lenses experiences a similar effect due to the bubble, which gives rise to unusual reflections and refraction of light. In both cases the effect subsides as the lenses settle and lacrimation decreases. However, a slight effect may always remain, particularly if the pupil is large and the anterior chamber deep (Stone, 1959). *Figure 5.3* illustrates the optical reasons for these effects.

Oblique aberrations

Even best-form spectacle lenses allow objects viewed through their periphery to suffer from the effects of oblique aberrations – these being oblique astigmatism, coma, distortion, transverse chromatic aberration and curvature of field. Contact lenses remain almost centred in all directions of gaze, and any imperfections they impart to the retinal image are therefore kept to a minimum. By contrast, the visual acuity of a person wearing high-powered correcting spectacle lenses may drop slightly when the eyes are rotated to look through the most peripheral zones of the lenses.

The higher the prescription the greater these aberration effects are. Many aphakic spectacle wearers are extremely disturbed by pincushion distortion, and even medium to low hypermetropes wearing large spectacle lenses notice the same effect. Myopes, too, often suffer the disorientation of barrel distortion, and again the larger the lens and the higher the power the more noticeable it is. The relief afforded by contact lenses is then considerable but conversely, returning to spectacles from contact lenses can give rise to disorientation and nausea and may require modification of the spectacle prescription to keep the power as low as possible consistent with adequate visual acuity. Any cylindrical correction needs to be kept to an absolute minimum and possibly removed altogether if visual acuity is not unduly compromised thereby. The size of the spectacle lens should also be kept as small as possible to avoid some of the peripheral distortion. The contact lens practitioner needs to be aware of these optical effects and to be a patient and skilful spectacle lens prescriber.

Prismatic effects

Apart from the prismatic effects of spectacle lenses already mentioned, which affect both the appearance of a person and the field of view, two other factors must be considered. These are the prismatic effects of spectacle lenses during convergence and those due to the anisometropic spectacle correction, when the eyes make version movements.

Convergence

Spectacles optically centred for distance vision but which are used for all distances of gaze differ from contact lenses,

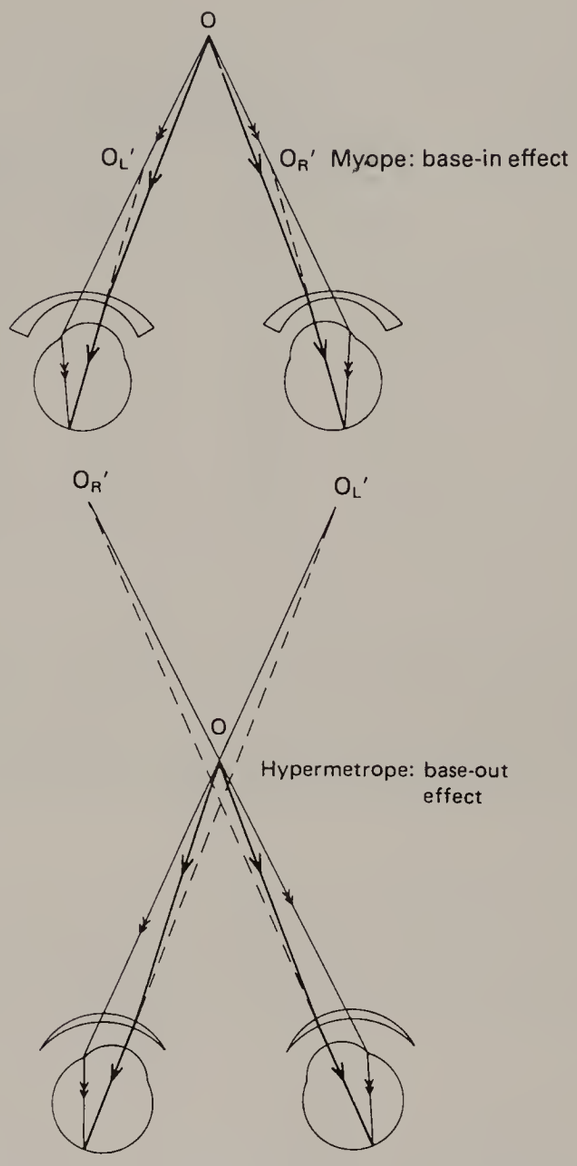


Figure 5.4 Spectacles centred for distance vision give prismatic effects when the eyes converge

which move with the eyes and thus remain centred (or nearly so) for all distances and positions of gaze.

Thus, during near vision, a spectacle-wearing myope experiences a base-in prism effect and a spectacle-wearing hypermetrope a base-out effect, as shown in *Figure 5.4*. Provided that contact lenses remain optically centred, no such prism effect is experienced by the contact lens wearer. Therefore, for a given object distance, the contact-lens-wearing myope exerts more convergence and the hypermetrope less convergence than with spectacles.

Table 5.1 gives the amount of convergence in prism dioptres (Δ) exerted by both eyes in various degrees of ametropia, assuming spectacles centred for a distance CD of 60 mm and worn 27 mm in front of the eyes' centres of rotation, and contact lenses giving an equivalent power, remaining centred for all distances of gaze and worn 15 mm in front of the centres of rotation of the eyes. The method of

Table 5.1 Comparison of convergence with spectacles and contact lenses

Spectacle refraction (D)	*Convergence (Δ) at*			
	0.33 metre from spectacle plane		*0.25 metre from spectacle plane*	
	Spectacles	*Contact lenses*	*Spectacles*	*Contact lenses*
−20	11.11	16.66	14.56	21.66
−15	12.11	16.66	15.87	21.66
−10	13.33	16.66	17.56	21.66
−5	14.80	16.66	19.31	21.66
0	16.66	16.66	21.66	21.66
+5	19.03	16.66	24.67	21.66
+10	22.19	16.66	28.63	21.66
+15	26.64	16.66	34.14	21.66

calculation of the convergence in Δ is as described for the calculation of prismatic effects in anisometropia (*see below* and p. 159). *Table 5.1* is used as a basis for the graph in *Figure 5.5*.

The significance of this difference in convergence must be considered in association with changes in accommodation (*see* Accommodation, p. 168 where it is shown that the ratio between accommodation and convergence remains the same with spectacles and contact lenses). The effect of the change in convergence alone, when transferring from spectacles to contact lenses, is only likely to prove difficult in a myope whose near point of convergence is abnormally remote, when the removal of the base-in prism may be sufficient to disrupt binocular vision at near.

The general effect of transferring from spectacles to contact lenses for near vision, is as if the myope had brought the near task a little closer, as more convergence and accommodation are required, whereas for the hypermetrope the reverse applies and it is as if the working distance had been increased.

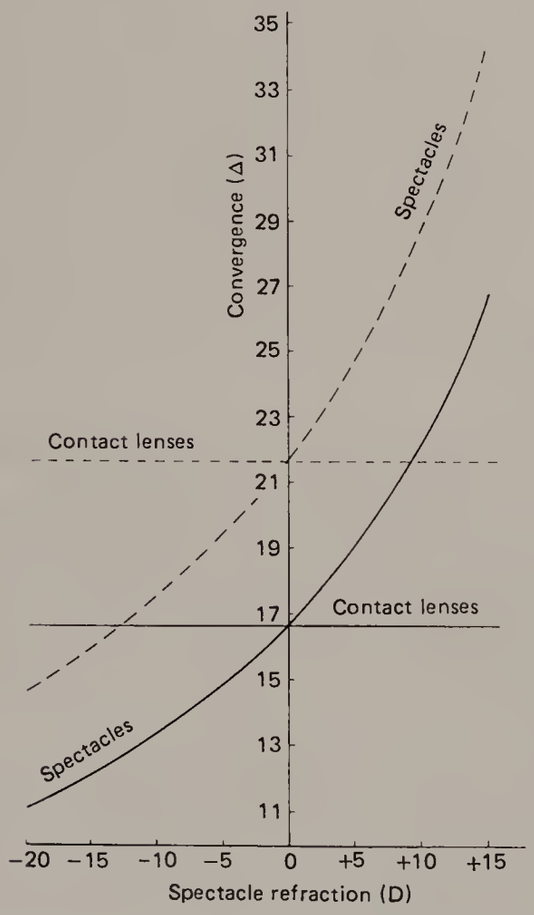


Figure 5.5 Convergence with spectacles and contact lenses. — at 0.25 metre; — at 0.33 metre. (Compare this with *Figure 5.18*)

Anisometropia

Since contact lenses move with the eyes, the visual axes always pass through their optical centres – or very close to them. Thus, differential prismatic effects which can create difficulties for anisometropic spectacle wearers are virtually removed. (The effects of contact lens movement on the eyes are considered in the section on Incorporation of prism, p. 160).

An example will serve to illustrate this:

Spectacle correction: R − 4.00 DS
L + 1.00 DS

Prismatic effect when looking down at an object 10 cm below the horizontal and 25 cm in front of the spectacle plane (assumed to be 25 mm in front of the centres of rotation of the eyes):

R 3.33 Δ, base-down.
L 1.00 Δ, base-up.

Difference between the two eyes in the vertical meridian is over 4 Δ, which is too great for the patient to obtain comfortable binocular single vision. This spectacle correction would therefore necessitate vertical head movements rather than eye movements. *Figure 5.6* illustrates the difference in vertical eye rotation that would be required with this spectacle correction, in use as described, as well as the difference in magnification (*see* Relative spectacle magnification, p. 165).

Calculation of the prismatic effect is simple. The positions and sizes of the images O_R' and O_L' formed by the spectacle lenses are first found (*Figure 5.6*).

Thus, for the right eye, $l = -25$ cm

Therefore, $L = -4$ D

Now $F = -4$ D, and since $L + F = L'$, $L' = -8$ D

Therefore $l' = -12.5$ cm

$$\text{Since } \frac{h'}{h} = \frac{L}{L'},\ h_R' = 10 \times \frac{-4}{-8}\ \text{cm} = 5\ \text{cm}$$

And for the left eye, $l = -25$ cm. Therefore, $L = -4$ D

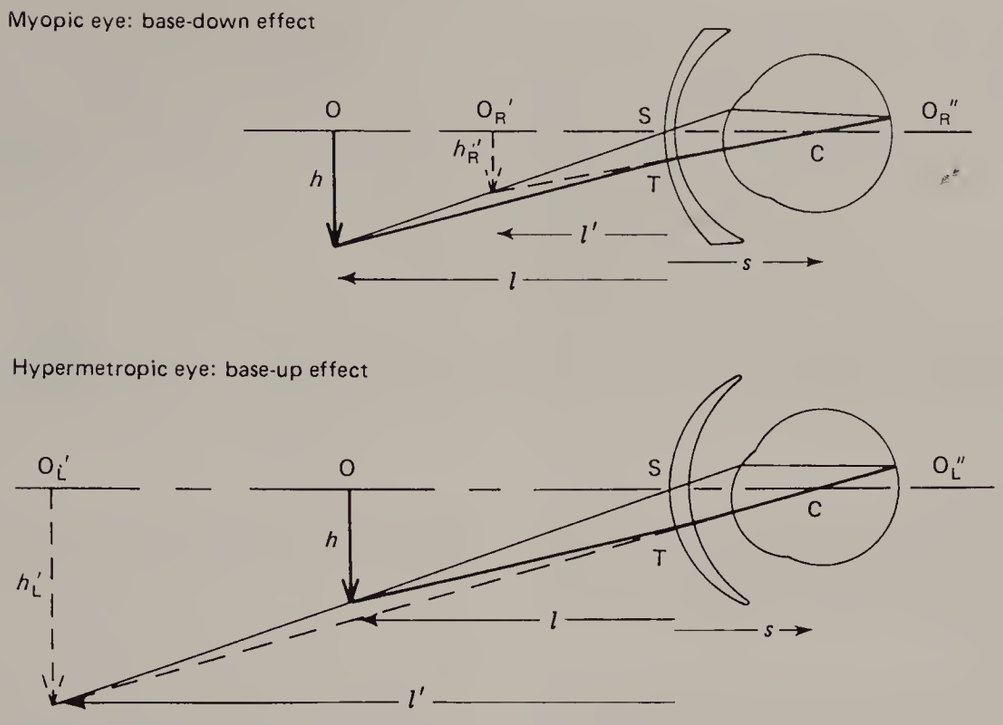


Figure 5.6 Anisometropia: during near vision when wearing spectacles the visual axis of the hypermetropic eye is depressed more than that of the myopic eye. The image seen by the hypermetropic eye is also larger than that seen by the myopic eye. O = object. O_R' and O_L' = images of O formed by the spectacle lenses. O_R'' and O_L'' = retinal images

Now $F = +1$ D, and therefore $L' = -3$ D

Therefore, $l' = -33.33$ cm

and $h_L' = 10 \times \frac{-4}{-3}$ cm $= 13.33$ cm

Then the points (T), at which the two visual axes intersect the spectacle lenses, must be found.

There are for each eye, similar triangles, with apex at C and bases at O′ and ST (the distance s (SC) is assumed to be 25 mm).

Thus for the right eye, $\frac{ST}{h_R'} = \frac{s}{s - l'}$

and $ST = 5 \times \frac{2.5}{15.0} = 0.833$ cm

and for the left eye $\frac{ST}{h_L'} = \frac{2.5}{35.83}$

Thus, $ST = 13.33 \times \frac{2.5}{35.83} = 0.930$ cm

Now, from Prentice's law (*see* p. 160), the prism effect of the right lens is $-4 \times 0.833 = 3.33\ \Delta$ base-down, and that of the left lens is $+1 \times 0.930 = 0.93\ \Delta$ base-up.

As pointed out, this gives over 4 Δ difference between the two eyes, the actual difference being 4.26 Δ.

An alternative way of looking at this is to calculate the actual angles through which each eye rotates downwards, and then find the difference:

Thus, the right eye rotates downwards by an angle of:

$$\tan^{-1}\frac{h_R'}{s - l'} = \tan^{-1}\left(\frac{5}{2.5 - (-12.5)}\right) = \tan^{-1}\left(\frac{5}{15}\right)$$

This is an angle of 500/15 Δ = 33.33 Δ

The left eye rotates downwards by an angle of

$$\tan^{-1}\left(\frac{13.33}{2.5 - (-33.33)}\right) = \tan^{-1}\left(\frac{13.33}{35.83}\right)$$

This is an angle of 1333/35.83 Δ = 37.20 Δ

The difference between the rotation required of the two eyes is thus 3.87 Δ, which as expected, differs a little from the value measured in the spectacle plane, which was 4.26 Δ.

The latter method – of determining the angles through which each eye rotates – is the way in which angular values for convergence are also calculated. An object located on the midline between the two eyes (*see Figure 5.4*) is then considered as an object of height (h) equal to half the interpupillary distance, because this is its distance from the optical axis of the spectacle lens.

Horizontal prismatic differences are more tolerable than vertical differences. In fact, during version movements of the eyes, the anisometropic spectacle wearer learns to make allowance for the increasing prismatic difference as the visual axes intersect points at increasing distances from the optical centres. This habit of allowing for the prismatic difference shows itself as a non-comitant heterophoria which may persist for some time after contact lenses are first worn, and this can at first cause difficulty on lateral rotation of the eyes. From habit, one eye moves more than the other, and objects tend to be seen double until a new extraocular muscle balance is achieved.

Incorporation of prism

Most manufacturers of contact lenses prefer not to incorporate more than 3 Δ into a contact lens, as the thickness difference with such steeply curved surfaces makes more than this amount impracticable, although it can be done on lenses of high power.

Because the prism base always rotates downwards in corneal and soft lenses, and remains down and slightly in, it is impossible to prescribe a horizontal prism satisfactorily. Vertical prism is also limited, therefore, to one lens, and so the maximum vertical prism that may be prescribed is about 3 Δ but this may be rejected due to physical discomfort. Thus potential contact lens wearers requiring horizontal or large vertical prismatic corrections must be prepared to wear spectacles containing the necessary prism in conjunction with their contact lenses.

Sometimes contact lenses provide a better standard of binocular vision than spectacles and the expected prism proves to be either unnecessary or of reduced amount. This is where tolerance trials in contact lenses are most useful, as are tests for uncompensated heterophoria rather than actual heterophoria.

It is still just about possible with scleral lenses to prescribe horizontal and vertical prism to a maximum of 6 Δ, shared between the two eyes. This necessitates great care in fitting the scleral zone of the lens to prevent lens rotation on the eye due to the weight of the prism.

With spectacles, the difficulties of lens rotation do not arise. It is rare for more than 6 Δ to be needed in a correction, and this can easily be prescribed in spectacles.

With contact lenses some unwanted prismatic effect occurs due to movement of the lenses on the eyes. One of the aims of correct fitting is to ensure that this movement is similar for both lenses so that little prismatic difference between the two eyes is experienced.

The prism effect due to such movement is given by:

$P = F \times c$ (Prentice's law)

where

P is prism effect in Δ
F is back vertex power, in D, of contact-lens/liquid-lens system
c is displacement in cm

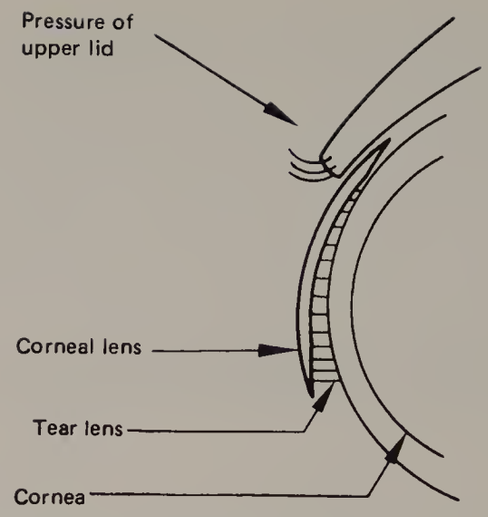


Figure 5.7 Prism base-down liquid lens: this effect is due to tilt of a corneal lens caused by pressure of the upper lid

If the powers of the two lenses are the same and the movement is similar, then no prismatic difference occurs. If the two lens powers are not the same, the amount of movement enables the prismatic difference to be calculated. It is worth noting that, if a person wears a negative-powered contact lens in one eye and a positive-powered lens in the other, to counteract the prismatic effects due to vertical lens movement, the negative lens should move up (prism base-down) as the positive lens moves down (also prism base-down). With corneal lenses, because of the position of the centre of gravity and the action of the lids during blinking (*see* Chapter 10), this desirable opposite movement of positive and negative lenses does frequently occur.

If a lens tilts due to pressure of the upper lid on a corneal lens or to downward lag of a scleral lens, then a certain amount of extra prism base-down is introduced due to the liquid lens, as shown in *Figure 5.7*. Bennett (1985) showed that this may be enough to counteract the prism base-up effect of a high negative scleral lens. Again, this tilt may be ignored as long as it is similar in the two eyes.

Where a contact lens has prism worked on it, then the prism power on the eye is the same as that in air. The liquid lens (unless it contains a prism element of its own due to tilt of the contact lens) has no effect on the prismatic element of the contact lens.

Cylinder effect introduced by prism, slip and tilt

The suggestion that a prism in a contact lens introduces a significant cylindrical element is incorrect. Although the refracted pencil is slightly oblique the amount of cylinder introduced is negligible. For example, taking a lens of BVP +10.00 D, BOZR 7.80 mm and centre thickness 0.40 mm, calculation shows that the cylindrical element introduced is only 0.023 D for a prism of 3 Δ. Expressed as a positive cylinder, the power is along the prism base-apex line and the axis perpendicular to it. Thus, in the example given, if the

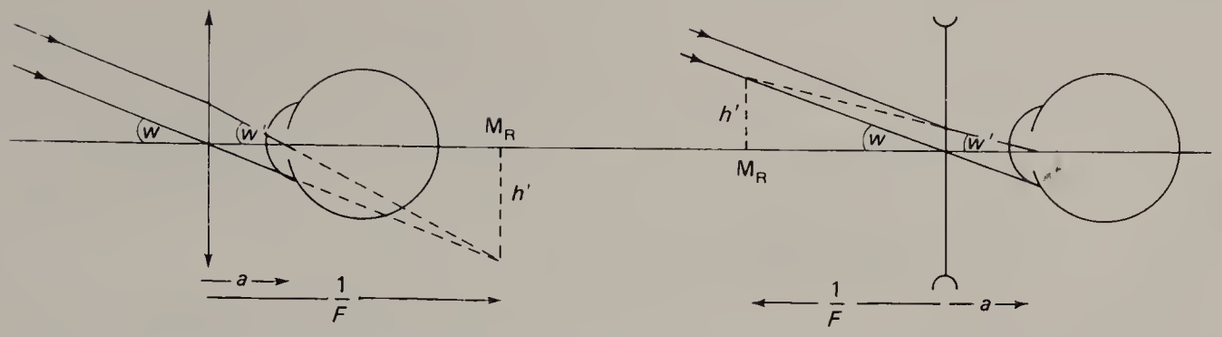


Figure 5.8 Spectacle magnification is w'/w. A distant off-axis object, subtending an angle w at the spectacle lens, is imaged by the lens of power F, in the far-point plane M_R. The image is of size h' and subtends an angle w' at the centre of the entrance pupil, which is situated at a distance of a metres from the spectacle lens. The left-hand diagram shows the situation in hypermetropia, and the right-hand diagram in myopia

prism is base-down along 90, there will be a +0.023 D cylinder axis 180.

Lenses can also tilt by slipping on the eye. If the slipping occurs as a rotation about the centre of curvature (C_2) of the back surface then C_2 will not be displaced, but C_1, the centre of curvature of the front surface, is displaced. Thus, the chief ray is deviated and is no longer normal to the front surface. This introduces a small amount of astigmatism, as shown in the following example. Taking a lens of BVP +12.00 D, BOZR 7.80 mm and centre thickness 0.44 mm, calculation shows that if the lens slips by 2.0 mm then 0.23 D of astigmatism results. The effect increases sharply with increased slip (0.52 D astigmatism with 3.0 mm slip) but only slightly with increasing curvature. The axis of the induced positive cylinder is perpendicular to the direction of slip.

In the case of negative lenses of similar numerical power, the astigmatism induced is less.

Note that in the above examples the effect of the back surface has been neglected as the refractive index change at this surface is small.

Clearly, the induced astigmatism may be increased if the lens actually tilts on the eye as well as slipping. When the whole lens tilts through a small angle the resulting astigmatism can be found approximately by the equation:

$$\text{Cylinder} = F \tan^2 \theta$$

where θ is the angle of tilt and F is the back vertex power of the lens. The cylinder axis is perpendicular to the direction of tilt. Thus, if F = +10.00 D and θ = 5°, the induced cylinder is +0.0765 D. If the direction of tilt is vertical, i.e. about a horizontal axis, then the cylinder axis is horizontal. Such a lens tilted in the vertical about a horizontal axis, due to upper lid pressure on the top of the lens, is shown in *Figure 5.7*. There is also a very small change in the spherical element given approximately by the equation:

$$\text{Sphere} = F\left(1 + \frac{1}{3}\sin^2 \theta\right)$$

Thus, in the same example the sphere is increased to +10.025 D, which is of no significance.

Sarver (1963) studied the effect of contact lens tilt on residual astigmatism and his experimental observations confirmed the above theoretical findings.

Magnification

Any correction, be it a spectacle lens or a contact lens, alters the size of the basic retinal image. (The basic retinal image is taken to be the size in the uncorrected eye assuming blur circles of zero diameter, i.e. 'pinpoint' pupils.) This change in the basic retinal image size is known as 'spectacle' magnification, even when it is the magnification due to contact lenses. In order to make a satisfactory comparison between spectacles and contact lenses, the differences in magnification given by the two forms of correction must be considered for both spherical and toric correcting lenses. This magnification is affected by the form and thickness of the lens.

Spherical lenses

Positive spectacle lenses magnify and negative lenses minify, and this magnification or minification increases with the vertex distance. Only if a corrective lens is worn in the plane of the eye's entrance pupil is unit magnification of the basic retinal image achieved. Thus, a contact lens worn on the cornea approaches as nearly as possible to giving unit magnification. Only an intraocular implant can be fitted closer to the entrance pupil plane. Bennett (1985) showed that spectacle magnification may be expressed as:

$$\frac{1}{1 - aF}$$

where F is the power in dioptres of the correcting lens which is assumed to be infinitely thin, and a is the distance in metres from the correcting lens to the entrance pupil plane. *Figure 5.8* shows how this expression is derived.

The size of the retinal image is proportional to the angular subtense of the object at the entrance pupil. The angular subtense is w' when the spectacle lens is present and w when it is not (a distant object is assumed).

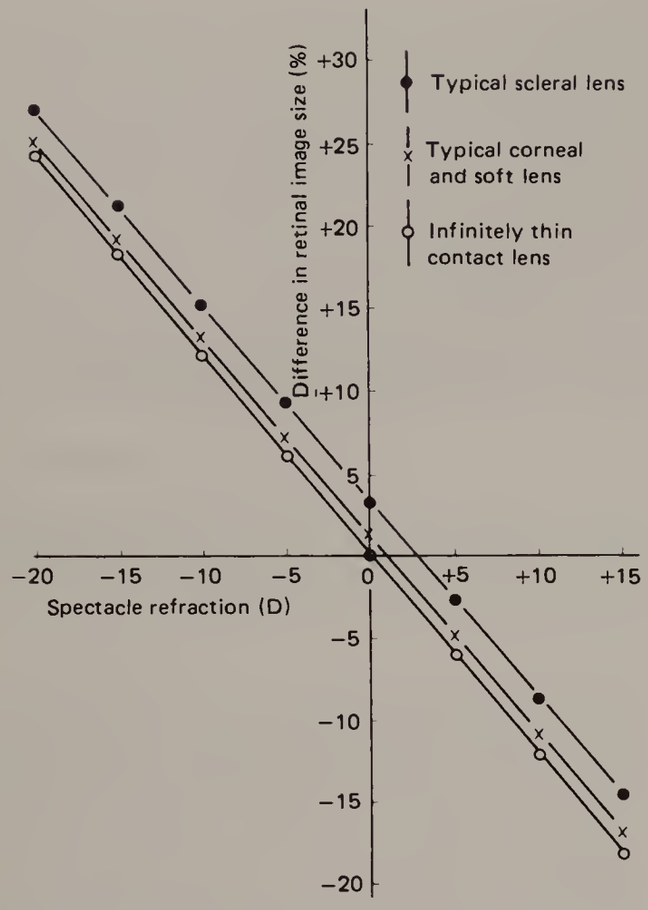


Figure 5.9 Percentage difference in retinal image size: comparison with a thin spectacle lens

$$\text{Now, } w' = \frac{h'}{(1/F) - a} \text{ and } w = \frac{h'}{(1/F)}$$

$$\text{Thus, spectacle magnification } \frac{w'}{w} = \frac{(1/F)}{(1/F) - a} = \frac{1}{1 - aF}$$

Note that when a spectacle lens is present, a is equal to the vertex distance plus approximately 3 mm. With a contact lens a is about 3 mm, this being the approximate distance of the entrance pupil plane from the cornea.

Thus, it can be seen that myopes who change from spectacles to contact lenses see objects larger than before, and hypermetropes see objects smaller than before. This is illustrated by the graph in *Figure 5.9*, which shows the percentage increase or decrease in retinal image size given by theoretically infinitely thin contact lenses as compared with infinitely thin spectacle lenses. This is based on a vertex distance of 12 mm and a distance of 3 mm between anterior cornea and entrance pupil plane. More realistic values are shown for typical aligning corneal lenses, soft lenses and typical scleral lenses, again compared with infinitely thin spectacle lenses. The slope for soft lenses actually falls somewhere between the corneal and scleral lens slopes for positive lenses, depending on thickness and refractive index, and for negative lenses approximates to that of corneal lenses, again depending on thickness and refractive index. (Lenses of low refractive index are normally thicker than their higher refractive index counterparts.)

Myopes can be expected to obtain increased visual acuity in contact lenses but may experience some disorientation when they are first worn owing to the apparent increase in the size of the external world.

Conversely, hypermetropes might expect to have poorer acuity with contact lenses than with spectacles; but since the difference in image size is only of real significance in the higher powers, it is only the high hypermetropes who are affected. Since many of these are aphakic, in the majority of cases they enjoy seeing objects reduced to only slightly larger than their normal size again (except for those with poor visual acuity). The disorientation experienced by an aphakic due to the spectacle magnification is comparable with but far worse than the disorientation felt by a high myope who transfers from spectacles to contact lenses. This is because the high positive spectacle correction causes field restriction and apparent image movement due to prismatic effects and aberrations, whereas a myope's contact lenses do not suffer from these additional defects.

The graph in *Figure 5.10* shows the different values for spectacle magnification given by four types of lenses. Theoretical values are drawn for spectacle lenses (assumed infinitely thin, and worn 12 mm from the cornea) and contact lenses (also assumed infinitely thin, and worn on the cornea, 3 mm in front of the entrance pupil) as well as more realistic values for typical rigid corneal, soft and scleral lenses, taking form and thickness into account. Soft lenses fall close to the values for corneal lenses but there are slight differences due to the lower refractive index of soft lenses, the absence of any tear lens, and small thickness differences. The effects of thickness and refractive index and the tear lens are dealt with more fully under the heading Shape factor on p. 163. The spectacle magnification of an infinitely thin contact lens should be multiplied by this factor to obtain a truer idea of the retinal image size when making comparisons with spectacles. This is borne out in *Figure 5.9*.

Toric lenses

The graph in *Figure 5.10* shows that contact lenses cause less change in size of the basic retinal image than do spectacle lenses.

A toric spectacle lens gives different magnification in different meridians, which produces distortion of the retinal image. This is particularly noticeable where the principal meridians are at oblique axes, as Bennett (1985) pointed out. A square object seen through a toric spectacle lens may look rectangular if the principal meridians are horizontal and vertical, or diagonal like a parallelogram if the principal meridians are oblique. This distortion of shape is minimized with a contact lens because the meridional difference in magnification is reduced, as can be seen from the graph in *Figure 5.10*.

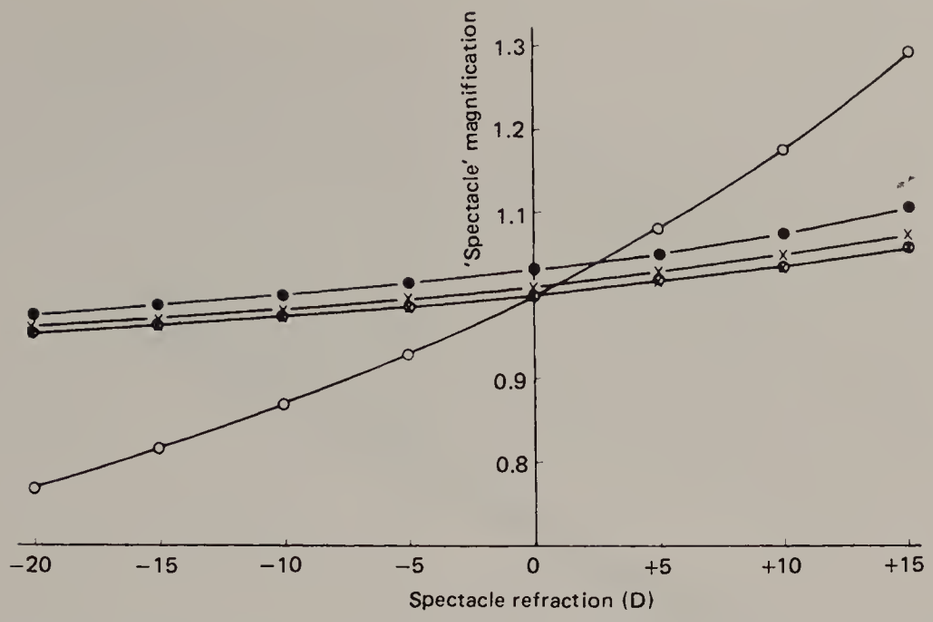


Figure 5.10 Variation of magnification with type and form of correcting lens: —●— typical scleral lens; —×— typical corneal and soft lens; —⊗— 'thin' contact lens; —○— 'thin' spectacle lens

Difficulty may arise when a toric spectacle correction has been worn for many years and a perceptual allowance has been made for the distortion. On transferring to contact lenses which give a less distorted retinal image, the perceived image may appear more distorted until the processes of perception become readjusted to the new situation. The type of effect experienced with spectacles and contact lenses is shown in *Figure 5.11* where the spectacle lens contains a high oblique cylinder.

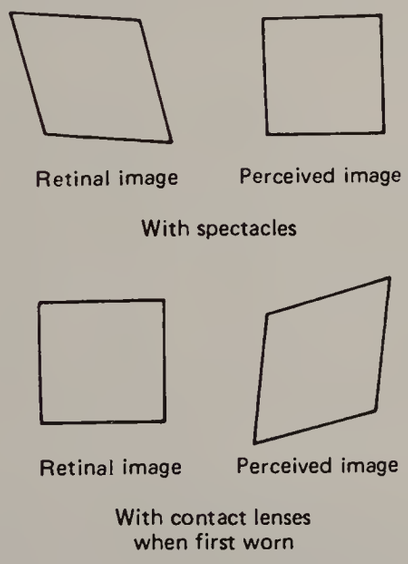


Figure 5.11 Perceptual compensation for retinal image distortion: this is acquired during spectacle wear and continues when contact lenses are first worn

Shape factor

(Note: Unfortunately this term is also applied to the asphericity '*p*' of conic sections, – *see* Chapter 10, pp. 316 and 331, and *Figures 10.4 and 10.5*.)

The magnification of two lenses having the same back vertex power is affected by their front surface power and thickness. Shape factor is the allowance which must be made for the increase in magnification due to the form and thickness of the lens and is given as:

$$\frac{1}{1 - (tF_1/n)}$$

which is the ratio between back vertex power and equivalent power, where

n = refractive index
t = central optic thickness in metres
F_1 = front surface power in dioptres

The values for spectacle magnification for the 'thin' lenses in *Figure 5.10* should therefore be amended to:

$$\frac{1}{1 - aF} \times \frac{1}{1 - (tF_1/n)}$$

if shape factor is to be taken into account. This expression is easily applied to spectacle lenses but a contact lens system comprises a plastic lens and a tear lens in combination. The expression for the shape factor is correspondingly more involved. Bennett (1985) derived an approximate simplified expression for shape factor of a

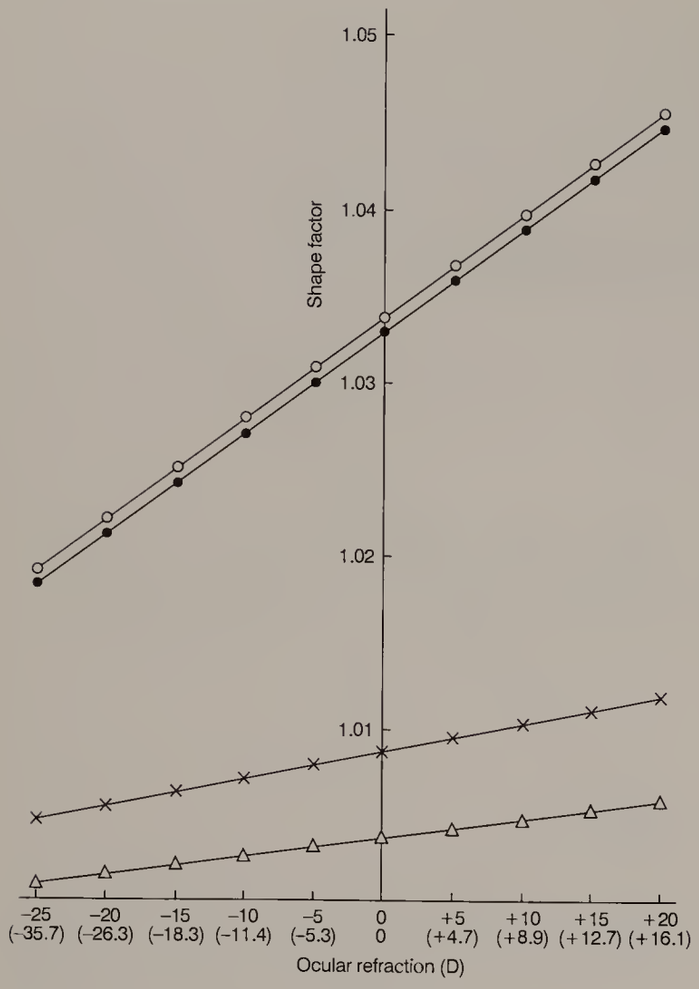


Figure 5.12 Relationship between retinal image sizes, due to shape factor differences, with scleral, corneal and soft lenses. The ocular refraction (D) = back vertex power of contact lens system. The values in parentheses are the spectacle refraction (D). —○— aligned PMMA scleral lens; —●— flat PMMA scleral lens; —×— aligned RGP corneal lens; —△— aligned soft lens (n' = 1.4)

contact lens system, based on values which are normally known. This is:

$$1 + t(K + C) - (t_1/n_1)F_2$$

where

- t = total reduced thickness in metres of plastic lens and liquid lens = $t_1/n_1 + t_2/n_2$
- K = ocular refraction in dioptres
- C^* = keratometer reading in dioptres, where the index of calibration is assumed to equal that of the tear liquid (= 1.336)
- t_1 = thickness of plastic contact lens in metres
- n_1 = refractive index of plastic material of contact lens
- F_2 = interface power in dioptres at the back optic zone surface of the contact lens

This expression was used in calculating values for the graphs in *Figures 5.9, 5.10* and *5.12*. These show that corneal and soft lenses give somewhat smaller retinal images than the corresponding scleral lens, because a scleral lens has a larger shape factor.

Figure 5.12 shows shape factor for soft, corneal and scleral lenses. Soft lenses were assumed to be 0.1 mm thick, corneal lenses 0.2 mm and scleral lenses 0.75 mm, and the liquid lens was taken to be 0.01 mm and 0.1 mm thick in the latter two cases respectively, with zero thickness assumed behind a soft lens. This is a rather broad assumption because negative lenses, especially those of high power, are normally thinner than the values stated, while positive lenses may be considerably thicker. The tear lens behind a corneal lens is assumed to be 0.01 mm thick. However, the values assumed permit sufficient illustration of the effect of thickness on shape factor. Had more accurate thickness values been used, the graphs shown would have been slightly more steeply sloped. A keratometer reading (C)* of +42 D was assumed. This gives a corneal radius of 8 mm. The corneal lenses have the same back optic zone radius as the corneal radius, which is fairly typical. For comparison, values are shown for scleral lenses having the same back optic zone radius. Values are also given for scleral lenses with a back optic zone radius of 8.75 mm. (It is normal for the back optic zone of a scleral lens to be fitted about 0.50–0.75 mm flatter than the keratometer radius value.) It can be seen from the graph that this flattening has little effect on the shape factor as compared with the thickness difference between corneal and scleral lenses. Positive soft lenses are generally a little thicker than positive corneal lenses, but only slightly so, whereas negative soft lenses are often thinner than negative corneal lenses. When on the eye they fit so that the back surface of the lens almost parallels the central cornea. Because they generally have a lower refractive index than rigid corneal lenses the shape factor is slightly less than for corneal lenses.

Values used for the graph in *Figure 5.12* are:

	Soft lens	*Aligned corneal lens*	*Aligned scleral lens*	*Flat scleral lens*
n_1	1.40	1.47	1.49	1.49
n_2	1.336	1.336	1.336	1.336
t_1 (mm)	0.10	0.2	0.75	0.75
t_2 (mm)	0.00	0.01	0.1	0.1
Back optic zone radius (mm)	8.00	8.00	8.00	8.75
F_2 (interface) (D)	−8.00	−16.75	−19.25	−17.60
Corneal radius (mm)	8.00	8.00	8.00	8.00
Keratometer reading (C)*(D)	+42.00	+42.00	+42.00	+42.00

*Although many contact lens practitioners refer to the corneal curvature as measured by keratometry as the 'K' reading, and indeed this applies elsewhere in this book, because in visual optics the letter K is reserved for ocular refraction this chapter adopts the use of 'C' to denote the power of the cornea measured by a keratometer, where there would otherwise be confusion.

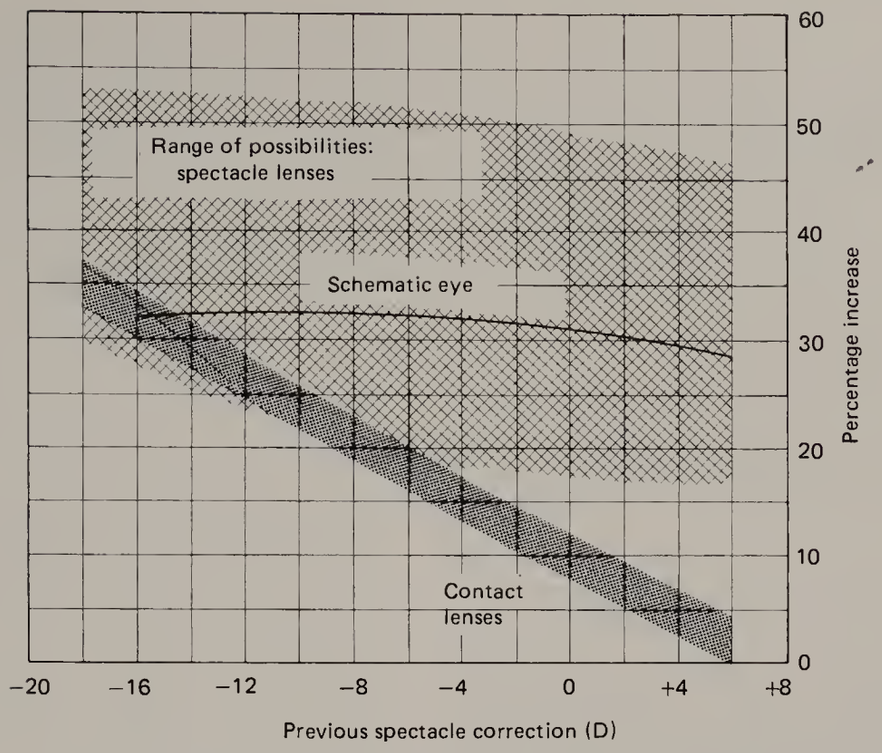


Figure 5.13 Percentage increase in the retinal image size in the aphakic eye corrected by spectacle and contact lenses. The dark band indicates the possible spread of values for contact lenses. As can be seen for eyes which originally had medium to high myopia, there is some overlap of the contact-lens-corrected and spectacle-lens-corrected values, depending on the optical dimensions of the given eye. Thus, some myopes who become aphakic, will not necessarily get a smaller retinal image size with contact lenses as compared to spectacles, as they may still be slightly myopic even though aphakic. (Reproduced by kind permission of A.G. Bennett)

Bennett (1968, 1972) did a considerable amount of work in calculating realistic retinal image sizes in the aphakic eye corrected by spectacle lenses and contact lenses, and in the pre-aphakic eye corrected by spectacles. He not only took into account the shape factor of the two types of correcting lens, but considered the likely variations in axial length and corneal power (*Figure 5.13*). He thereby derived some very useful values for relative spectacle magnification.

Relative spectacle magnification

This is defined as the ratio between the retinal image size in a corrected ametropic eye to that in a standard emmetropic eye. Various formulae have been given to calculate it, depending on whether the difference between the two eyes is axial or refractive. Its main use is in determining whether or not a particular type of correction is likely to improve or disrupt binocular vision, by comparing the two retinal image sizes. However, as Bennett (1985) pointed out, such formulae, although useful, can be misleading because the human emmetropic eye does not always have the same length and power, indeed the range of values found is quite large. A much simpler approach is therefore used in this chapter, based on 'reduced eye' data and values for 'spectacle' magnification to determine retinal image sizes. This more than adequately permits an understanding of the concepts involved.

Where a person has different ocular refractions in the two eyes, the different magnification given by the two spectacles lenses (or contact lenses) may result in poor binocular vision. This is usually due to fusion difficulties resulting from unequal retinal image sizes. (Similar distribution of the retinal receptors in the two eyes is assumed although this may be a false assumption.)

It is common to think of anisometropia as being either axial or refractive. Sorsby *et al.* (1962) showed that most naturally occuring anisometropia is predominantly *axial*, but this is often accompanied by a smaller *refractive* component.

By contrast, one obvious example of *refractive* anisometropia is unilateral aphakia. It is in such cases that contact lenses give greater similarity in retinal image sizes than do spectacle lenses. As can be seen in *Figure 5.10*, a soft or corneal lens for the aphakic eye renders the minimum amount of magnification of the basic retinal image, but in two eyes of the same length only an intraocular implant for the aphakic eye can achieve 'equality' of retinal image sizes.

The diagrams in *Figure 5.14* illustrate how two eyes of the same length and corneal power, one aphakic and the other phakic, have similar basic retinal image sizes. Contact lenses give rise to a minimum change in this basic retinal image size, thereby permitting a good chance of binocular vision which may, however, still be difficult as study of

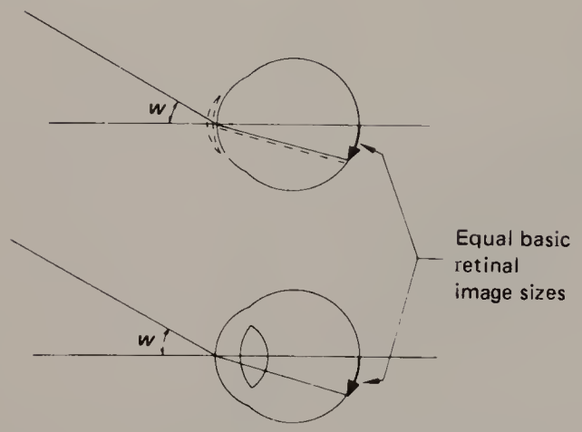


Figure 5.14 Refractive anisometropia: corneal and soft lenses cause minimum change in the basic retinal image size. w = angular subtense of distant object

Figure 5.13 indicates. Retinal image size differences of as little as 1% may give rise to binocular problems in some patients.

Figure 5.15 shows how two eyes of unequal length have unequal basic retinal image sizes. In such cases, contact lenses – which scarcely affect this basic size – are theoretically unsatisfactory if fusion is to be achieved, assuming equally spaced retinal receptors in the two eyes. A spectacle lens worn by the ametropic eye makes the retinal image in that eye closer in size to that of the other eye. Typical of such a case is unilateral myopia. However, the retinal receptor distribution may be different in the two eyes, being more widely spaced in the bigger eye. In practice it is found that axially anisometropic patients achieve better binocular fusion in contact lenses than in spectacles. This was established beyond doubt by Winn *et al.* (1986) who conducted a careful study using ultrasonography to measure axial length and other ocular component thicknesses and depths, and eikonometry to study perceived image sizes. Thus it would appear that all types of anisometropia and antimetropia would be better corrected by contact lenses than by spectacles, if optimum binocular vision is to be achieved.

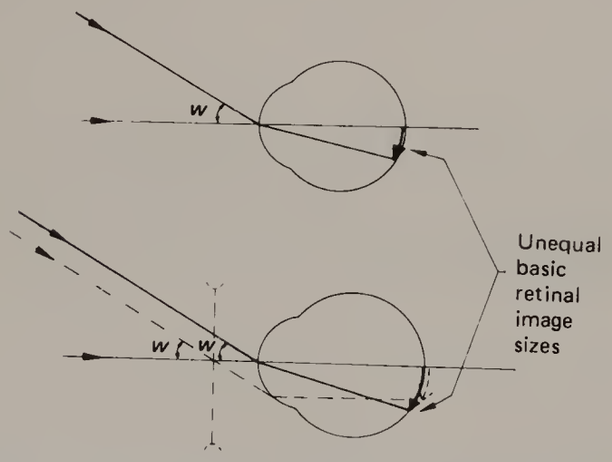


Figure 5.15 Axial anisometropia: a spectacle lens suitably placed before the ametropic eye can give equality of retinal image sizes, but this may not be desirable (*see* text). w = angular subtense of distant object

If it becomes necessary to compare or calculate retinal image sizes, it is simplest to assume a reduced eye as shown in *Figure 5.15*. The reduced eye is assumed to have a refractive index of 4/3 and a single spherical refracting surface of radius 5.55 mm giving it a power of +60 D.

When the error (K) is known to be axial, then the power of the reduced eye (F_e') is assumed as +60 D and its length is k'.

$$\text{Now, } k' = \frac{n'}{K'}, \text{ where } K' = K + F_e'$$

Thus, if the ocular refraction, $K = -10$ D then

$$K' = +50\,\text{D and } k' = \frac{4}{3} \times \frac{1000}{50} = 26.67\,\text{mm}$$

A standard emmetropic eye has an axial length

$$f_e' = \frac{n'}{F_e'} = \frac{4}{3} \times \frac{1000}{60} = 22.22\,\text{mm}$$

When the error is known to be refractive (as in aphakia) then the power of the eye (F_e') is determined from its length (k') and its ocular refraction (K). For example, $K = +12$ D, $k' = 22.22$ mm.

$$\text{Thus, } K' = \frac{4}{3} \times \frac{1000}{22.22} = +60\,\text{D}$$

$$\text{and } F_e' = K' - K = 60 - 12 = +48\,\text{D}$$

As can be seen from *Figure 5.15*, the principal ray determing the basic retinal image size, undergoes refraction at the principal point of the eye according to Snell's law.

Considering this principal ray, prior to refraction the angle subtended at the eye's principal point is w, and after refraction the angle subtended by the basic retinal image is thus w/n'. (All angles are small, and the sine, tangent and angle in radians then all become equal.)

$$\text{But } \frac{w}{n'} = \frac{\text{Basic retinal image size}}{k'}$$

Thus, basic retinal image size = k' (w/n') = w/K' (in metres).

Note the principal ray may already have undergone refraction at a spectacle lens or contact lens, so that w is then equivalent to the w' of *Figure 5.8*. Thus, the spectacle magnification is taken into account in determining the angular subtense at the principal point prior to refraction by the eye. The final retinal image size then becomes

$$\frac{1}{1 - aF} \times \frac{w}{K'} \text{ (in metres)}$$

Table 5.2

	Spectacle correction (D)		*Ratio of basic retinal image sizes in uncorrected eyes (R:L)*	*With spectacle correction*			*With contact lenses*		
				Spectacle magnification		*Difference in retinal damage sizes (%)*	*Spectacle magnification*		*Difference in retinal image sizes (%)*
	R	*L*		*R*	*L*		*R*	*L*	
(1)	+2	+12	60.00:60.00	1.03	1.22	18.29	1.01	1.04	3.75
(2)	−1	−10	51.07:59.01	0.99	0.87	1.98	1.00	0.97	12.87

In the standard emmetropic eye the retinal image size is thus $w \times 60$ metres.

Two examples, shown in *Table 5.2*, will serve to illustrate the differences between axial and refractive anisometropia. The vertex distance is assumed as 12 mm and the distance from cornea to entrance pupil as 3 mm. Shape factor has not been taken into account.

The first example in *Table 5.2* is representative of refractive anisometropia and is a unilateral aphakic having equal basic retinal image sizes in the two eyes because the eyes are similar in length. Thus, the spectacle magnification afforded by both spectacles and contact lenses has a direct effect on the retinal image sizes. With spectacles, the difference in magnification between the two eyes is large and so, therefore, is the percentage difference between retinal image sizes. With contact lenses, it is small. Obviously, the contact lens correction allows the greater chance for binocular vision.

The second example in *Table 5.2* is that of unilateral axial myopia in which the power of both eyes is assumed to be 60 D. Thus, the basic retinal image sizes are proportional to the axial lengths (or inversely proportional to the dioptric lengths as shown in *Table 5.2*). These basic image sizes are then affected by the spectacle magnifications; so that, with spectacles, where the difference in magnification is large there is only a small difference in the retinal image sizes. With contact lenses, the spectacle magnifications are almost the same but the retinal images are very different in size. Here, theoretically, but not in practice (as explained on p. 166), spectacles provide the better chance for binocular vision. The values found in the examples may be checked using the equations given on p. 166 for determining retinal image sizes using standard reduced eye data, the values in *Table 5.2* being correct to two places of decimals.

It should be pointed out that where binocular vision is absolutely impossible the patient is less likely to suffer any asthenopic symptoms. If binocular vision is made possible but difficult, symptoms may occur. This frequently arises with the unilateral aphake. Because of the greater reduction in magnification afforded by corneal and soft lenses, these should allow slightly better binocular vision than sclerals. The aphake also enjoys the other benefits of contact lenses over spectacles – but even so, the symptoms of difficult binocular vision have often caused the unilateral aphake to abandon contact lens wear. Now that intraocular lenses are inserted routinely at the time of cataract extraction this binocular problem has almost disappeared. However, the intraocular implant chosen may prove to be of incorrect power, or the corneal power may be affected by suturing, and some lesser problems of *refractive anisometropia* still occur.

The extremes of purely refractive or purely axial anisometropia, as shown in the examples in *Table 5.2*, are rare. In most anisometropes, contact lenses afford other advantages – such as absence of differential prism – which make their effects on retinal image size worth investigating before they are ruled out entirely. In the authors' experience, the perceptual process which allows fusion of different sized images is more readily adaptable than is the extraocular musculature which has to cope with dissimilar prism effects. In spite of the fact that most anisometropia is mainly axial, contact lenses have been found to be more acceptable than spectacles to many anisometropes and as stated on p. 166 this may well be due to differences in retinal receptor spacing in the two eyes.

Soft lenses, being more stable than corneal lenses, are the better type of lens to use for anisometropia, unless large corneal lenses with very little movement can be satisfactorily fitted. In scleral lenses, the weight of the high positive lens may cause hypophoria and excyclophoria of the aphakic eye (*Figure 5.16*). This is an extreme example.

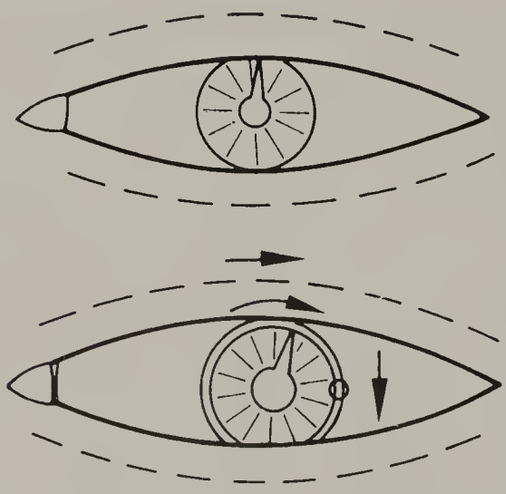


Figure 5.16 The effect of a high positive scleral lens: there is a wider lid aperture and the eye tends to rotate in the directions shown

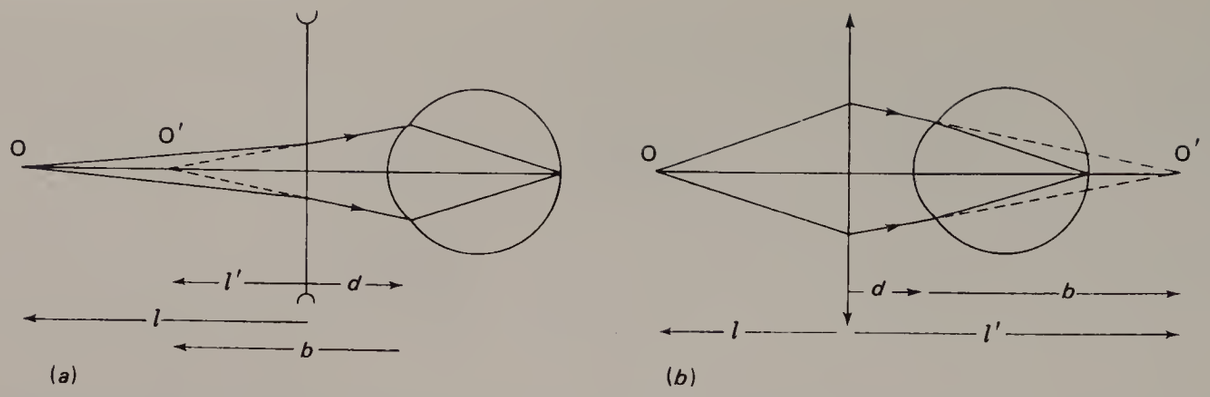


Figure 5.17 Near vision through spectacle lenses. The near object of regard, O, is imaged at O′, which is at a distance, b, from the eye. The object, image and vertex distances from the spectacle lens are l, l', and d respectively. (*a*) Myopia; (*b*) hypermetropia

Accommodation

The accommodation exerted for a given working distance varies, depending on whether spectacles or contact lenses are worn. More accommodation is required by myopes and less by hypermetropes when they transfer from spectacles to contact lenses (*Table 5.3* and the graph in *Figure 5.18*).

In order to calculate the actual amount of accommodation exerted by the eye, known as the ocular accommodation (A), it is necessary to determine the ocular refraction (K) and the distance (b) at which the near object of regard is imaged by the spectacle lens of power F_s. For example, *Figure 5.17a* shows a myope wearing a spectacle lens of −8 D, who reads at a distance (l) 25 cm from the spectacle plane. Thus, the spectacle accommodation (A_s) is 4 D. Now if the spectacle lens is worn 12 mm from the eye, the ocular refraction (K) is −7.30 D (*see* Appendix A and formula I in the Formulae Section on p. 199, where ocular refraction is denoted as F_O instead of K due to the use of the symbol K for Keratometer readings. The accompanying CD-ROM also deals with conversion from spectacle to ocular refraction.)

Table 5.3 Comparison of accommodation with spectacles and contact lenses

Spectacle refraction (D)	*Ocular accommodation (D) at*			
	0.33 metre from spectacle plane		*0.25 metre from spectacle plane*	
	Spectacles	*Contact lenses*	*Spectacles*	*Contact lenses*
−20	1.89	2.90	2.50	3.82
−15	2.09	2.90	2.76	3.82
−10	2.32	2.90	3.06	3.82
−5	2.58	2.90	3.40	3.82
0	2.90	2.90	3.82	3.82
+5	3.27	2.90	4.31	3.82
+10	3.72	2.90	4.89	3.82
+15	4.25	2.90	5.61	3.82

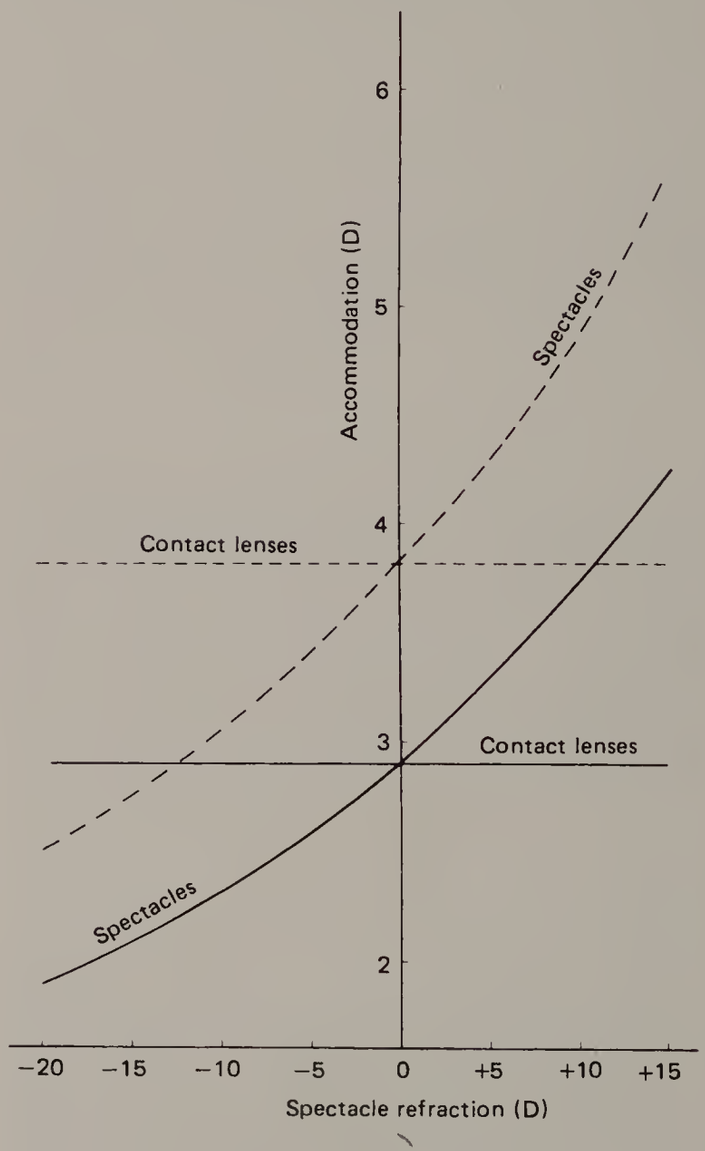


Figure 5.18 Accommodation with spectacles and contact lenses. -- at 0.25 metre; — at 0.33 metre. (Compare this with *Figure 5.5*)

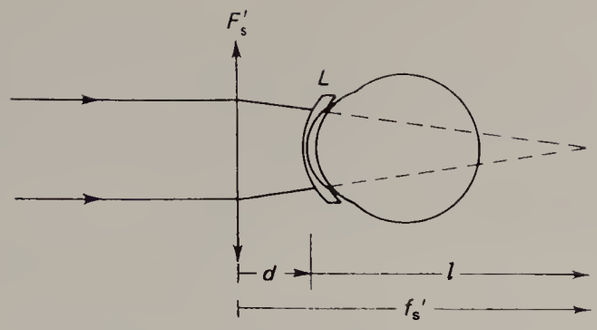


Figure 5.19 Effective power of spectacle lens at contact lens is: $L = 1/l = F_s'/(1 - dF_s')$ (*see* Appendix A and formula I, p. 199)

(The method of calculating ocular refraction from spectacle refraction and vertex distance, d, should be apparent from *Figure 5.19* if K is substituted for L and k for l.)

In *Figure 5.17a* the near object, O, is imaged by the spectacle lens at O′.

Now $l = -25$ cm
Therefore, $L = -4$ D
$F_s = -8$ D
Therefore $L' = -12$ D
Thus, $l' = -8.33$ cm
But $b = l' - d = -8.33 - 1.2 = -9.53$ cm

$$B = \frac{1}{b \text{ (in metres)}}; \text{ so, } B = -10.5 \text{ D}$$

But −7.30 D of this corrects the ocular refraction. The remaining 2.20 D must be overcome by the use of the myope's accommodation, i.e. $A = K - B$.

This demonstrates the effectivity of the spectacle lens in permitting such a myope to use only 2.2 D of accommodation, whereas if a contact lens were worn, the same near object would be 26.2 cm from the eye necessitating 3.82 D of accommodation.

Figure 5.17b shows a similar situation for a hypermetrope. $F_s = +8$ D, $l = -25$ cm and $d = 12$ mm. Thus, $K = +8.85$ D (*see* Appendix A, p. 845 and formula I, p. 199).

Now $L = -4$ D, $F_s = +8$ D
Therefore, $L' = +4$ D and $l' = +25$ cm
But $b = l' - d = +25 - 1.2 = +23.8$ cm
Therefore, $B = +4.2$ D
Since $A = K - B$, $A = +8.85 - 4.2 = +4.65$ D

This demonstrates how the ocular accommodation of a hypermetrope wearing spectacles is in excess of that required if contact lenses are worn. In this example 4.65 D of accommodation is required as compared to 3.82 D in contact lenses.

If a comparison is made of the graphs of convergence in *Figure 5.5* and the graphs of accommodation in *Figure 5.18*, it will be noted that the slopes showing convergence and accommodation with spectacles are the same. They are also the same with contact lenses. As Westheimer (1962) stated, this implies that the accommodation/convergence ratio (A/C ratio) is the same with contact lenses as it is with spectacles. It was also shown by both Stone (1967) and Bennett (A.G., personal communication, 1967) that if contact lenses remain centred for all working distances and a comparison is made with spectacles centred for distance vision, the accommodation/convergence ratio remains approximately the same with both forms of correction, as shown in *Table 5.4*.

The figures for the basis of this table come from *Tables 5.1* and *5.3*. Bennett (A. G. personal communication, 1967) derived an expression for the A/C ratio with spectacles, to that with contact lenses by using binomial approximations. This is based on a theoretical analysis and shows that:

$$\frac{\text{A/C ratio with spectacles}}{\text{A/C ratio with contact lenses}} \doteqdot 1 - F(s - 2d)$$

where

F = spectacle lens power in dioptres
s = distance from spectacle plane to centre of rotation of eye, in metres
d = back vertex distance of spectacle lens in metres

Now, if $d = s/2$ it can be seen that the A/C ratio is the same with both spectacles and contact lenses.

In *Table 5.4*, d was taken as 12 mm and s as 27 mm, which accounts for the slight discrepancies between the values found for the two forms of correction. But as d is always approximately $s/2$, the ratios are always approximately the same.

Changes in accommodation should therefore only cause difficulty in the presbyopic or pre-presbyopic myope, who may have trouble in exerting extra accommodation and convergence when transferring to contact lenses from spectacles.

Table 5.4 Ratio between accommodation and convergence with spectacles and contact lenses

Spectacle refraction (D)	*Ratio of accommodation (D) to convergence (Δ) at*			
	0.33 metre from spectacle plane		*0.25 metre from spectacle plane*	
	Spectacles	*Contact lenses*	*Spectacles*	*Contact lenses*
−20	0.170	0.174	0.172	0.176
−15	0.173	0.174	0.174	0.176
−10	0.174	0.174	0.174	0.176
−5	0.174	0.174	0.176	0.176
0	0.174	0.174	0.176	0.176
+5	0.172	0.174	0.175	0.176
+10	0.168	0.174	0.171	0.176
+15	0.160	0.174	0.164	0.176

Optical considerations of contact lenses on the eye

To understand why a contact lens correction often differs considerably from a spectacle correction, the significance of the following points must be fully understood:

1. The contribution made by the liquid (tears) lens.
2. The effects of radius changes on back vertex power of the contact-lens/liquid-lens system.
3. The differences between total and corneal astigmatism.

This section is intended as a practical guide in determining soft and rigid corneal and scleral lens powers, and it employs the method of specifying back optic zone radii in millimetres rather than in terms of the keratometer reading in dioptres.

To correct fully an eye's refractive error, the back vertex power of the contact-lens/liquid-lens system must equal the ocular refraction (K) – not to be confused with the keratometer reading, also often denoted as 'K'.

In the following considerations, it will be assumed that surface powers are additive provided that their separations are small. This leads to some approximations. It will also be assumed that the back vertex power of a contact lens can be directly added to the vergence of the light reaching it – although this, again, is an approximation, as the following example shows.

Example

Consider a scleral lens with the following characteristics:

Back vertex power (BVP) in air	–12 D
Central optic thickness (t_c)	0.80 mm
Back optic zone radius (BOZR) = (r_o)	8.75 mm
Front optic zone radius (FOZR) = (r_{ao})	11.40 mm
Refractive index (n)	1.49
Refraction with this lens *in situ* (F_s)	+8.00 D
Back vertex distance (d)	12 mm

Reference to *Figure 5.19* shows the following:

Reduced vergences		*Equivalent air distances*
F_s' = +8.00 D	⟶	f_s' = +125 mm
		$-d$ = 12 mm
L = +8.85 D	⟵	l = +113 mm

The effective power of the spectacle lens at the front surface of the scleral lens = L = +8.85 D. If it is assumed that BVP of the scleral lens may be added directly to this, then the BVP of the required scleral lens

= +8.85 D – 12.00 D
= **–3.15 D**

But this is only approximate, as more accurate calculations show:

$$\text{Front surface power, } F_1 = \frac{(n - 1)1000}{r_{ao}}$$

$$= \frac{(1.49 - 1)1000}{11.4}$$

$$= +43 \text{ D}$$

$$\text{Back surface power, } F_2 = \frac{(1 - n)1000}{r_o}$$

$$= \frac{(1 - 1.49)1000}{8.75}$$

$$= -56 \text{ D}$$

$$\text{Reduced thickness, } t/n = \frac{0.8}{1.49}$$

$$= 0.54 \text{ mm}$$

Reduced vergences		*Equivalent air distances*
L_1 = + 8.85 D		
$+F_1$ = +43.00 D		
L_1' = +51.85 D	⟶	+19.29 mm
		$-t/n$ = – 0.54 mm
L_2 = +53.33 D	⟵	+18.75 mm
$+F_2$ = –56.00 D		
L_2 = – 2.67 D	This is the correct BVP of the contact lens required	

It can be seen that the error due to the use of the approximate method is an over-correction of –3.15 D – (–2.70) D = –0.48 D.

Note: Francis (1968) compiled some useful tables which removed most of the hard work from accurate methods of calculation. These have now been superseded by the use of pocket calculators and of suitable computer programs, such as those in the CD-ROM accompanying this book, which speed up calculations.

Nevertheless, approximate methods of calculation are useful to cross-check that formulae and computer programs have been used correctly. In the example above, the error between approximate and exact calculations is 0.48 D. This error would have been less, had the contact lens used for refraction purposes been close to the actual power required. It is also reduced when lenses are thinner and have a lower refractive index. The example above thus shows why a contact lens having an entirely different back vertex power from that required should not be used for refraction.

This example also uses a combination of positive spectacle lens and negative contact lens, which constitutes a Galilean telescope system. This should be avoided, wherever possible, since it gives a higher magnification than that obtained with the final contact lens. Hence, a false assessment of visual acuity may be made, and disappointment will follow when the final contact lens gives poorer vision.

Different aspects of refraction with contact lenses will now be considered.

Ocular refraction

BVP of final contact lens in air
+ BVP of liquid lens in air (liquid lens assumed thin)

= Ocular refraction

Ocular astigmatism

Front surface corneal astigmatism
+ back surface corneal astigmatism
+ crystalline lens astigmatism (referred to the corneal plane)

= Total ocular astigmatism

Note that the front surface of the cornea usually has greater positive power near the vertical meridian, i.e. 'with-the-rule' astigmatism, whereas the other two contributors to total ocular astigmatism normally have 'against-the-rule' astigmatism, the total effect usually being 'with-the-rule', although this decreases with age.

Astigmatism of the front surface of the cornea and the effect of the liquid lens

Refractive index of tears, n_t = 1.336
Refractive index of cornea, n_c = 1.376

When a rigid contact lens with spherical back surface is placed on the eye, the front surface of the liquid lens is spherical because it is formed by the back surface of the contact lens. If the front surface of the cornea is toroidal, then the back surface of the liquid lens is also toroidal, with radii (r) in mm equal to that of the cornea, but having negative power.

The powers in air of the back surface of the liquid lens are given by $F = (1 - 1.336)\ 1000/r$, and the powers of the front surface of the cornea are given by $F = (1.376 - 1)1000/r$. This means that the front surface astigmatism of the cornea is partly neutralized by the back surface astigmatism of the liquid lens. The amount neutralized is thus 336/376, which is almost 90%. This is of importance with toroidal corneas because it is likely that the back surface of the cornea itself will neutralize the remaining 10% of its front surface astigmatism.

Thus, with a rigid, non-flexing, spherical contact lens on the eye, any residual astigmatism found is almost entirely due to the crystalline lens since practically all the corneal astigmatism is corrected, i.e.

Back surface astigmatism of liquid lens
+ front surface astigmatism of cornea
+ back surface astigmatism of cornea

= Zero (approximately)

Keratometry and corneal astigmatism

Keratometers measure front surface corneal radii but give *total* corneal power on the assumption, given above, that the back surface of the cornea has −10% of the power of the front surface.

The true refractive index of the cornea (1.376) is therefore not used to calibrate keratometers. Instead, an index of 1.3375 is usually used (n_k). This allows the instrument to read total corneal power (or approximately 90% of the front surface power).

But n_k and n_t are almost the same (1.3375 and 1.336). Indeed, some keratometers are calibrated for an index of 1.336 or even 1.332. Therefore, the astigmatism measured by the keratometer is almost the same as that corrected by the back surface of the liquid lens. In fact, the use of n_k instead of n_t gives a *power* value which is slightly too high; for a radius of 8 mm the use of n_k gives F_k = 42.19 D and the use of n_t gives F_t = 42.00 D. But astigmatism is the *difference between the two principal powers*, and the error due to the slight difference in the refractive indices is then reduced to an insignificant amount. This is illustrated in the following example of a highly astigmatic cornea.

Example:

Keratometry	8 mm/+42.19 D along 180
(n_k = 1.3375)	7 mm/+48.21 D along 90
Total corneal astigmatism	+ 6.02 DC × 180
Liquid lens back surface	8 mm/−42.00 D along 180
powers (n_t = 1.336)	7 mm/−48.00 D along 90
Liquid lens back surface astigmatism	− 6.00 DC × 180

Even in such an extreme example it can be seen that the amount of total corneal astigmatism uncorrected by the liquid lens is an insignificant amount of +6.02 − 6.00 = +0.02 D. In this context, it is therefore valid to state that all the astigmatism measured by keratometry is corrected by the back surface of the liquid lens (*see* adjacent paragraph).

Residual astigmatism

Since the amount of astigmatism corrected by the back surface of the liquid lens can be measured by keratometry (as shown above), the amount of residual astigmatism with a spherical contact lens may be predicted in advance, although this assumes that the lens is reasonably thick and does not flex (*see* pp. 180–181). If this is so then:

Total ocular astigmatism
− astigmatism measured by keratometry

= Residual astigmatism

Care must be taken when determining the total ocular astigmatism from the spectacle refraction and vertex distance as it is incorrect to calculate the effective change in power of the cylinder alone.

The following is an example showing the correct method of calculating the effective power of a cylinder at the eye:

Spectacle refraction	$-6.00/-1.00 \times 180$
Back vertex distance	12 mm
Spectacle refraction in crossed cylinder form	$-6.00 \times 90/-7.00 \times 180$
Ocular refraction in crossed cylinder form after allowing for vertex distance (*see* Appendix A and formula I, p. 199)	$-5.60 \times 90/-6.46 \times 180$
Ocular refraction	$-5.60/-0.86 \times 180$

This shows that the 1 D cylinder is reduced to 0.86 D due to the associated sphere power, whereas if the sphere power were ignored there would be no significant change in the power of the cylinder – which is demonstrably incorrect. The higher the powers of sphere and cylinder are, the greater is the effect of vertex distance.

Prediction of residual astigmatism allows the effect of this amount of astigmatism to be simulated by the use of a trial cylinder in front of the patient's usual spectacle correction. The sphere power may then be adjusted to obtain the best visual acuity. If this is inadequate, it is obvious that the contact lens must incorporate a cylinder for the correction of the residual astigmatism in order to obtain a satisfactory visual acuity. A suitable lens design may then be selected at the outset of the fitting.

With spherical soft lenses, owing to their replication of corneal astigmatism (*see* p. 179), the residual astigmatism is usually almost the same as the ocular astigmatism and if this is 1 D or more a toric soft lens or a spherical rigid lens may be necessary to obtain adequate visual acuity.

RGP materials vary in the amount of lens flexure that takes place on a toroidal cornea. Also a thin spherical lens that corrects all the corneal astigmatism when first worn, may, after several weeks of wear, alter shape thereby increasing the amount of residual astigmatism. Then, as indicated on pp. 180–181, the lens parameters or material may need to be changed to alter the lens flexure in order to achieve better visual acuity.

Approximate rule (1)

Generally speaking, when rigid non-flexing spherical lenses are to be fitted, if the corneal astigmatism and total ocular astigmatism are both 'with-the-rule' or 'against-the-rule' and the difference between them is less than 0.75 D, this cylinder (which represents the expected residual astigmatism) may be ignored. When spherical soft or RGP lenses are to be fitted, ocular astigmatism of 0.75 D or less may usually be ignored.

Refraction with a contact lens of incorrect back optic zone radius

Fitting sets of corneal lenses, particularly at the extremes of the range, often have back optic zone radii in steps of 0.1 mm or 0.2 mm, so that the lens required to give the best fit may fall between two fitting lenses and the refraction may have to be carried out using a lens of incorrect BOZR.

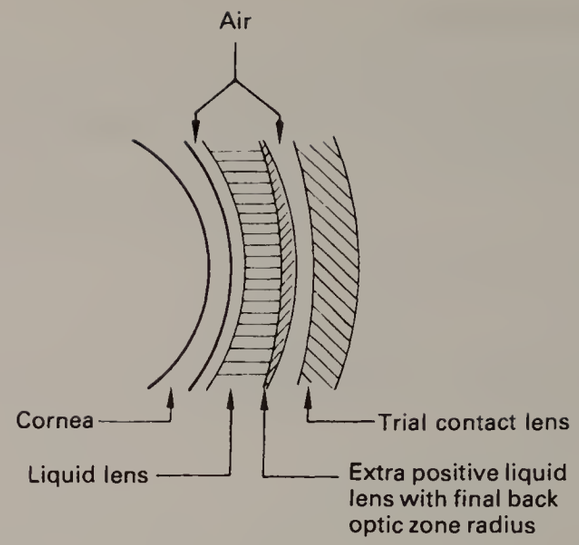


Figure 5.20 Refraction with a trial contact lens: the trial contact lens has too flat a back optic zone radius

A similar situation arises with scleral lenses. Not all trial scleral shells are sighted, and the refraction may have to be done with a lens of incorrect BOZR.

In this case:

Liquid lens power in air
+ trial contact lens BVP in air
+ effective power at the contact lens of the additional spectacle lens

= Ocular refraction

If the BOZR is flatter than that to be ordered, the liquid lens is more negative than it will be with the final contact lens (*Figure 5.20*). The vergence of the light reaching the front surface of the liquid lens must therefore be adjusted to allow for this. Negative power must be added to counteract the extra positive power of the final liquid lens.

When fitting soft lenses, this does not apply because they conform to the central corneal contour so that only if very big radius differences between lens and cornea are used is there any effect on the liquid lens. Even then, this effect is unpredictable as it depends partly on the thickness of the lens, as ultra-thin lenses wrap around the cornea much more than their thicker counterparts; also on the relationship of the back surface of the lens to the peripheral corneal contour, which varies from one eye to another. If the back surface of the lens closely parallels the entire cornea, then the liquid lens will have zero power, but if the lens touches the apex region of the cornea and clears the mid-peripheral region, there is likely to be a small negative-powered liquid lens. Soft lenses fitted with BOZR 1 mm or more flatter than the keratometer readings, may therefore possibly introduce a liquid lens of up to −0.50 D.

Approximate rule (2)

If when fitting rigid corneal or scleral lenses, the BOZR is flatter than that to be ordered, add −0.25 D to the BVP of the contact lens for each 0.05 mm that the BOZR is too flat.

When the BOZR is steeper than that to be ordered, add +0.25 D to the BVP of the contact lens for each 0.05 mm that the BOZR is too steep.

This rule can be shown to be approximately correct by checking on a Heine's scale (*see* Bennett, 1985) or by using radius/power tables for a refractive index of 1.336 (*see* formulae III, p. 199 and V, p. 200 in the Formulae section, or the accompanying CD-ROM).

Examples

(i) A typical corneal lens problem
(ii) A typical scleral lens problem

		(i)	(ii)
BOZR used (mm)		8.10	8.25
BOZR ordered (mm)		8.00	8.50
Change in power (D) of liquid lens front surface in air	from:	+41.48	+40.73
	to:	+42.00	+39.53
	by:	+0.52	−1.20
Contact lens BVP change (D) to counteract this	Accurate method:	−0.52	+1.20
	Approximate method:	−0.50	+1.25
Error of approximate method (D)		+0.02	+0.05

These examples show that the error of the approximate method is sufficiently small to be ignored.

Power variations as a sequel to other changes

Back vertex power and thickness

This section applies particularly to high positive corneal and soft lenses and to scleral lenses.

The vergence of light reaching the eye must be the same with the final lens as when the refraction is done with a trial contact lens. Thus, BVP must be specified on orders for lenses. Sometimes only the front vertex power of the trial contact lens is known. When this is so the laboratory must be given the central optic thickness of the trial lens so that its BVP may be calculated, but it is preferable for practitioners to calculate this for themselves (*see* formula XVIII, p. 204).

Example

BVP of trial scleral lens	+5.62 D
t_c	0.50 mm
BOZR	8.00 mm
FVP	+5.40 D

This illustrates the difference between BVP and FVP for a typical scleral lens.

If the lens were to be ordered on the basis of FVP without t_c being specified, it might be returned from the laboratory as:

FVP	+5.40 D
t_c	0.75 mm
BOZR	8.00 mm
BVP (instead of + 5.62 D)	+5.75 D

There is thus an error in BVP of +0.12 D, and the error increases with thickness and power (*see* formulae VI, p. 200, and XVIII to XXV, p. 204). Special care should therefore be taken when ordering high positive lenses, whether corneal, soft or scleral, although small errors often have to be accepted as being within tolerance especially with high prescriptions (*see* Addendum I, Chapter 12 and *Table 13.2*).

Corneal lenses are usually much thinner than sclerals, even in high positive powers, and the errors due to thickness differences are correspondingly much smaller. However, thickness should be specified with corneal lenses as it affects movement of the lens on the cornea as well as lid sensation and the rigidity of the lens itself (*see* Chapter 10). Where possible, soft lens thickness should also be specified for, in addition to back vertex power considerations, it affects the comfort, the rigidity and the gas transmissibility of the lens. However, it is not always possible to specify centre thickness as so many modern lenses are made to the manufacturers' set parameters by automatic manufacturing methods; but the centre thickness values for various powers are usually supplied with the data published by each manufacturer.

A program for computer calculation enabling the potential oxygen transmission to be assessed for a material of known Dk can be found on the accompanying CD-ROM. Formulae XXXX and XXXXI may also be used (*see* p. 219)

Spherical aberration becomes an important consideration when dealing with steeply curved surfaces, and with a contact lens on the eye the front surface of the lens suffers from positive spherical aberration which may seriously affect the BVP of the lens as it moves on the cornea. For example, a single vision corneal lens fitted as a distance prescription to an aphake can prove adequate in power for some close work. This occurs if the lens becomes displaced off-centre (usually upwards) relative to the pupil when the wearer looks down, and due to spherical aberration the effective power of the lens is increased. Unfortunately, not all spherical aberration effects are so beneficial, and a high positive lens which does not centre well on the cornea may therefore give poorer distance visual acuity than expected, possibly blurring to 6/18 from 6/6 if 1.00 D of positive spherical aberration is introduced.

Figure 5.21 shows that a decentration of 2.5 mm on the eye leads to an addition of +1.7 D for a lens of BVP +12.00 D, centre thickness of 0.35 mm and BOZR of 7.80 mm.

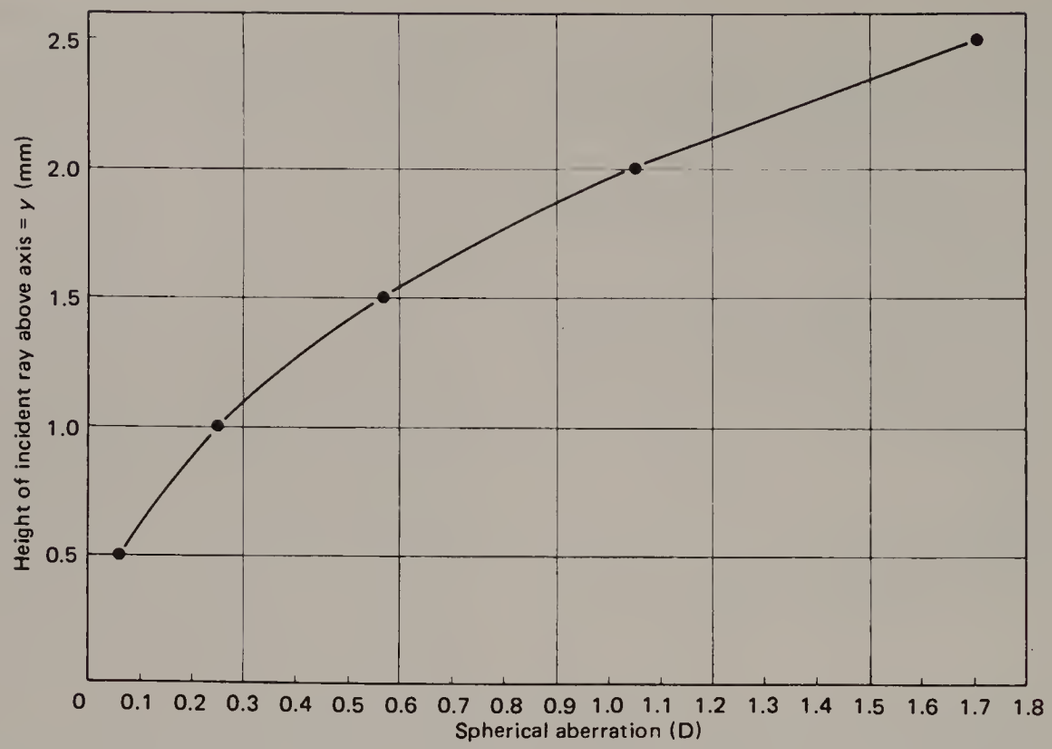


Figure 5.21 Variation of spherical aberration with aperture for a contact lens (n = 1.490) of +12.00 D BVP, BOZR of 7.80 mm and t_c of 0.35 mm. Parallel incident light is assumed

Aspherical front surfaces can reduce these spherical aberration effects, thereby improving visual acuity. Kerns (1974) showed that such lenses permit improved visual acuity in patients with residual astigmatism, possibly reducing the size of the circle of least confusion, due to removal of the spherical aberration effects. The Unilens (formerly known as the CALS lens, but now made by Unilens in Florida), the Nissel EV38, and Pilkington Barnes-Hind Hydrocurve II, for example, have aspheric front surfaces which work on this principle. Aspheric front surfaces are also used to create an 'extended' focus or progressive power as in the Nissel PV200 and PV250, for example (*see Chapter 16*).

Power changes of soft lenses

Before being placed on an eye a soft contact lens is normally in a fully hydrated state in physiological saline solution and the refractive index is at its lowest value. The lens is also at room temperature and its curvature (i.e. its BOZR, or posterior apical radius, PAR, if the back surface is aspherical) and power should be as specified by the manufacturer.

After being placed on the eye several changes occur, all of which affect the power of the lens.

First change – flexure

The centre of the back surface takes up the same curvature as the central cornea, or almost so. This curvature change – so that the back surface of the lens takes up a different curvature on the eye from its curvature when in an unstressed and unsupported state in saline solution – is commonly referred to as flexure. The amount of the resultant power change due to flexure, be it spherical or toroidal, is small for thin lenses, but becomes significant for lenses of high positive power (Fatt and Chaston, 1981).

Various empirical methods of predicting the power change due to this flexure have been suggested, such as assuming that the FOZR changes by the same amount as the BOZR (Baron, 1975), or alternatively that the two surfaces change in the same ratio. Strachan (1973) termed this ratio between the pre-wear and post-wear back optic zone radii, the 'wrap-factor'. The most plausible explanation and theoretical exposition was given by Bennett (1976), who based his argument on the criterion that the volume of the lens remains constant even though its curvature changes. This seems a valid assumption to make. He also assumed that there was no redistribution of lens thickness, that the centre thickness remains unchanged and that the front surface of the lens remains spherical if the cornea is spherical. Bearing these factors in mind he calculated that both positive and negative lenses change power with flexure, by the same amount as concentric lenses (i.e. lenses which have a common centre of curvature for back and front surface radii) change power when they are bent. These changes are summarized in *Table 5.5* which is reproduced by kind permission of A. G. Bennett. He calculated the values from an equation he derived, namely that

Table 5.5 Change in power when a soft lens is moulded by the cornea to a steeper back optic zone radius, refractive index (1.43–1.44) and volume remaining the same

Thickness	*Change † in power (D) for change of back optic zone radius, r_o (mm) (see note*)*						
t (mm)	*9.5*	*9.0*	*8.5*	*8.0*	*7.5*	*7.0*	*6.5*	*6.0*
0.10	–0.03	–0.05	–0.05	–0.07	–0.08	–0.10	–0.12
0.15	–0.06	–0.07	–0.08	–0.09	–0.12	–0.15	–0.18
0.20	–0.07	–0.09	–0.11	–0.13	–0.15	–0.20	–0.24
0.25	–0.10	–0.11	–0.13	–0.16	–0.19	–0.24	–0.30
0.30	–0.12	–0.13	–0.16	–0.19	–0.23	–0.28	–0.36
0.35	–0.13	–0.15	–0.18	–0.22	–0.27	–0.33	–0.41
0.40	–0.14	–0.18	–0.21	–0.25	–0.30	–0.37	–0.47
0.45	–0.16	–0.19	–0.24	–0.28	–0.34	–0.41	–0.53
0.50	–0.19	–0.21	–0.26	–0.31	–0.37	–0.46	–0.58
0.55	–0.20	–0.24	–0.28	–0.33	–0.41	–0.51	–0.63
0.60	–0.21	–0.26	–0.30	–0.37	–0.44	–0.55	–0.68

†The change is invariably an addition of *minus* power and is virtually independent of the back vertex power of the original lens. For every 0.01 increase in refractive index over 1.44 the above figures should be increased by 1.5%

The following example shows the method of use of the table: if a lens of BOZR 9.00 mm and t 0.20 mm is fitted to a cornea of radius 8.00 mm, the power change expected, if n is 1.43, is –0.09 D + –0.11 D = –0.20 D. (The values in all columns between the two appropriate radii are added together to arrive at the power change.)

$$F_v' = -\frac{(n-1)}{n} \times \frac{t}{r_2^2} \quad *$$

which for a value of n of 1.43 gives

$$F_v' = \frac{-300\,t}{r_2^2}$$

where F_v' is back vertex power, t is centre thickness, n is refractive index and r_2 is back optic zone radius.

Thus:

$$\Delta F_v' = -300t\left[\frac{1}{(r_2')^2} - \frac{1}{r_2^2}\right]$$

where r_2' is the radius to which r_2 changes after flexure. Now the refractive index of different soft lenses in their hydrated state varies between 1.36 and 1.46, but even if this variation is allowed for the values in *Table 5.5* would be altered by an insignificant amount and can safely be applied to all materials. (The greatest error introduced would be of the order of 0.10 D for a lens of centre thickness 0.60 mm and a change in r_2 from 6.5 mm to r_2' of 6.0 mm, the value for the change in power for n = 1.36 being –0.68 D and that for n = 1.46 being –0.78 D.) It is interesting that Wichterle (1967), by a completely different method, arrived at a value for $\triangle F_v'$ only 10% different from Bennett's, namely,

$$270\,t\left[\frac{1}{(r_2')^2} - \frac{1}{r_2^2}\right]$$

*This system of calculation was used before the symbols used in the current International Standard were adopted. Formerly the subscript $_1$ was used to denote front surface parameters, for example, r_1; and $_2$ was used for back surface parameters, for example r_2. Now, with the advent of ISO 8321:1991, r_1 has become r_{ao} and r_2 has become r_o. However, for optical calculations subscripts $_1$ and $_2$ are still valid and have been retained here.

Had Bennett assumed a refractive index of 1.37 for soft lens materials instead of 1.43, he and Wichterle would have arrived at exactly the same expression.

Although it could be argued that Bennett's assumptions – that the centre thickness and volume of the lens remain unchanged and the front surface remains spherical if the cornea is spherical – are not absolutely correct, mathematical considerations show that errors introduced by their acceptance are of an insignificant order (Wichterle, 1967; Bennett, 1970, 1976).

Examples showing the effects of such flexure, as described by Bennett (1976), on two specific positive lenses now follow, and *Figures 5.22* and *5.23* illustrate this flexure on a positive and a negative lens respectively.

Example 1

In order to assist calculation a positive lens of knife-edge form is illustrated, but the same arguments can be applied to a lens of any specified edge thickness. A lens has BOZR 9.50 mm, TD 14.50 mm, BVP +6.00 D, n = 1.44. This lens must have t_c 0.616 mm and FOZR 8.599 mm to give a knife edge (Jalie, 1974) (*Figure 5.22*).

The volume of this lens can be calculated, as explained by Bennett (1976), by subtracting the volume of the spherical cap bounded by the back surface from the volume of the spherical cap bounded by the front surface. Now, volume of spherical cap = $\pi/3(3r - s)s^2$ where r = radius and s = sag.

For the unstressed lens defined above, the volumes are thus:

Front spherical cap = 361.113 mm^3
Back spherical cap = 297.379 mm^3
Volume of lens, thus = 63.734 mm^3

If this lens is applied to a spherical cornea of radius 8.00 mm, the semi-diameter, y (7.25 mm) is reduced to some

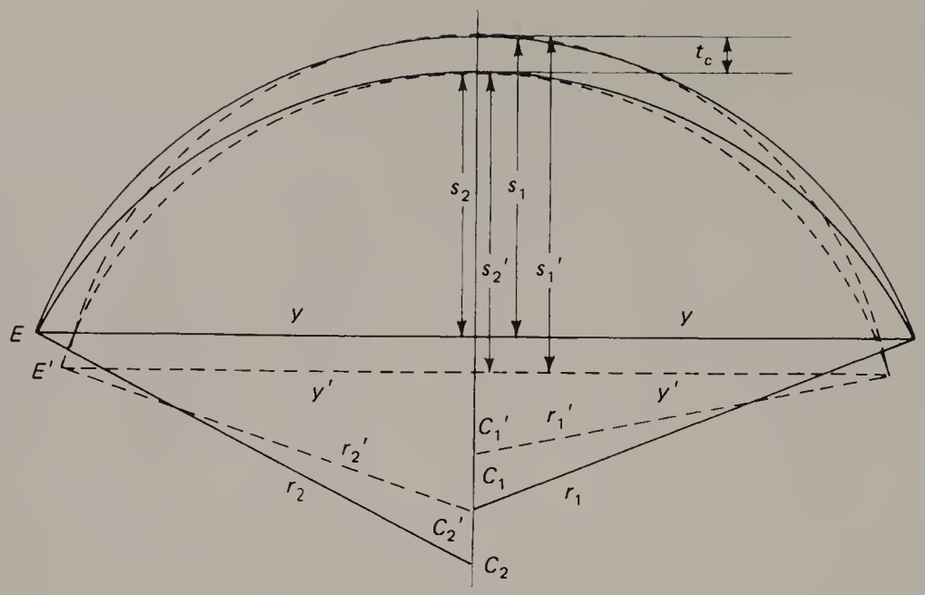


Figure 5.22 Steepening of a positive soft lens with knife edge: solid line before steepening and broken line after steepening. Before steepening: edge E, centres of curvature of front and back surfaces C_1 and C_2 with their radii of curvature r_1 and r_2 and sagitta s_1 and s_2 respectively, and semi-diameter y. After steepening these become: E', C_1', C_2', r_1', r_2', s_1', s_2' and y' respectively. Centre thickness t_c is the same before and after steepening

new value y' and since the BOZR is assumed to equal the corneal radius, the sag s_2' of the new back surface, can be calculated, as therefore can the volume. Because (for a knife-edge lens), $s_1' = s_2' + t_c$ and the semi-diameter y' is common to both front and back surfaces (*Figure 5.22*), the new front surface radius r_1' is readily obtainable from the general expression relating radius to sag and semi-diameter, namely,

$$r = \frac{y^2 + s^2}{2s} \quad (\textit{see} \text{ formula XVII, p. 203})$$

The volume of the new front surface spherical cap can also be readily calculated.

The value of y' must be found iteratively, the correct value being the one which gives the flexed lens the same volume as the unstressed lens. In this example $y' = 6.9$ mm,

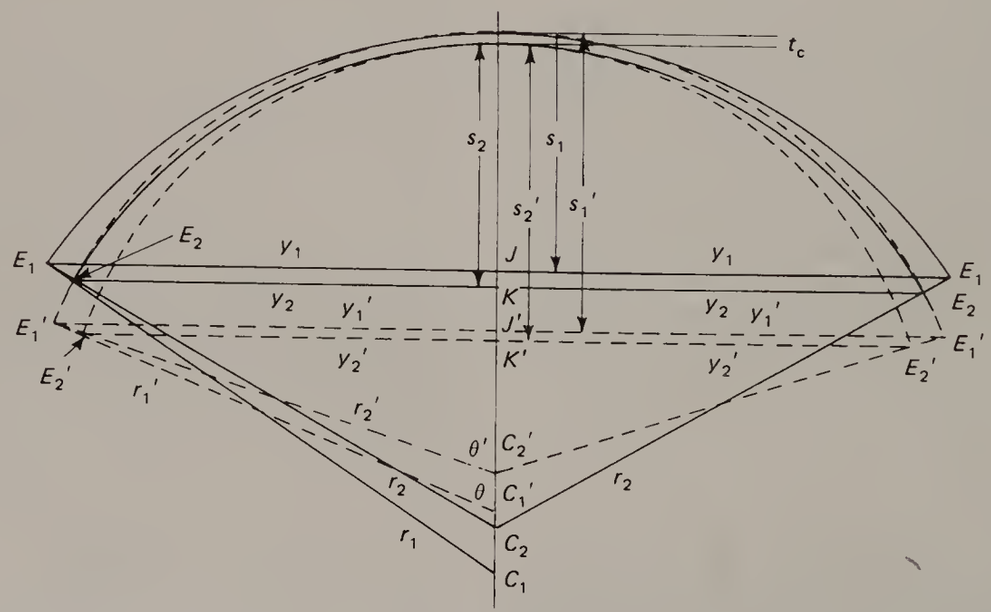


Figure 5.23 Steepening of a negative soft lens: solid line before steepening and broken line after steepening. Before steepening: front and back surface edges E_1 and E_2 with semi-diameters y_1 and y_2 intersecting the primary axis at J and K and subtending an angle θ at C_2. After steepening these become: E_1', E_2', y_1', y_2', J', K', and θ' at C_2' respectively. Other symbols are as in *Figure 5.22*

r_1' = 7.496 mm, BVP = +5.21 D, showing a power change of −0.79 D.

After steepening the volumes become:

Front spherical cap	= 391.951 mm^3
Back spherical cap	= 328.217 mm^3
Flexed lens (= that of unstressed lens)	= 63.734 mm^3

From the above it can be seen that whereas the BOZR has shortened by 1.5 mm (from 9.5 to 8.0 mm) the FOZR has shortened by only 1.103 mm. If both radii had shortened by 1.5 mm the volume of the lens would have increased to:

Front spherical cap	= 460.939 mm^3
Back spherical cap	= 328.217 mm^3
Volume of lens, thus	= 132.722 mm^3(!)

and the centre thickness would have increased to 1.479 mm!

Clearly, if the front surface radius steepened more than the BOZR, both volume and centre thickness would increase to an even more ridiculous extent.

The differential change in radii which does occur can be envisaged by referring to FLOM fitting (*see* Chapter 17) and thinking of the effect on sag when shortening the radius. For a given change of radius the sag is altered more when the radius is steep than when it is flat (*see* formula XI, p. 202).

Because the front surface radius of a positive contact lens is shorter than that of the back surface, the front surface radius must alter substantially less than the back optic zone radius if the volume and thickness of the lens are to remain the same.

The values used in calculating the above example and another example using a steeper cornea are listed below for interest. Linear values are in millimetres, the volumes of the front and back spherical caps, V_1 and V_2 respectively and the volume of the lens, V, are in cubic millimetres. Back vertex powers (BVP) are used throughout. The power changes shown below agree with the findings of Bennett (1976) as shown in *Table 5.5*, which for a fractionally lower thickness value of 0.60 mm and a change of BOZR from 9.5 mm to 8.0 mm gives a power change of:
(−0.21 − 0.26 − 0.30) D = −0.77 D

Parameter	*Unstressed*	*Flexed*	*Change*
t_c	0.616	0.616	Nil
BOZR	9.50	8.00	1.50
y	7.25	6.90	0.35
BVP	+6.00	+5.21	−0.79
r_1	8.599	7.496	1.103
s_1	3.975	4.570	0.595
s_2	3.361	3.954	0.593
V_1	361.113	391.951	30.838
V_2	297.379	328.217	30.838
V	63.734	63.734	Nil

Example 2

BOZR 8.00 mm, TD 12.00 mm, BVP + 10.00 D, n = 1.44, t_c 0.7028 mm, FOZR 6.984 mm.

Parameter	*Unstressed*	*Flexed*	*Change*
t_c	0.7028	0.7028	Nil
BOZR	8.00	7.00	1.00
y	6.00	5.792	0.208
BVP	+10.00	+9.059	−0.941
r_1	6.984	6.333	0.651
s_1	3.409	3.771	0.362
s_2	2.708	3.069	0.361
V_1	213.564	226.862	13.298
V_2	163.565	176.863	13.298
V	49.9989	49.9989	Nil

Negative lenses are treated in much the same way, except that edge thickness must be taken into account, and so it is necessary for the convenience of calculation to make one further assumption. It is assumed that the lens has a conical edge, with the apex of the cone at C_2 (*see Figure 5.23*). The edge E_1E_2 is therefore normal to the back surface and it is assumed that E_1E_2 and its relationship to the back surface remain unchanged after flexure.

The volume of the lens is the volume of the front spherical cap plus the volume of the frustum of the cone bounded by E_1E_2, minus the volume of the back spherical cap. (Volume of frustum of cone = $\pi/3\ (y_1^2 \times JC_2) - (y_2^2 \times KC_2)$ and $\theta = \sin^{-1} y_2/r_2$ (Bennett, 1976).)

Hydrophilic lenses acquire additional positive power if they are flattened. The change of power due to flexure,

$$\triangle F_v' = \frac{-(n-1)}{n} t_c \left[\frac{1}{(r_2')^2} - \frac{1}{r_2^2}\right]$$

(n = refractive index and other symbols are as in *Figure 5.22* and as given on p. 175).

It is evident from the above formula that the change of power due to flexure is dependent on refractive index, centre thickness and the degree of bending and is independent of the original BVP (Bennett, 1976).

Unfortunately, these power changes are not always those found in practice and some of the differences are explicable as outlined in the second and third changes given below. It would appear from the work of Sarver *et al.* (1974) and of Sarver *et al.* (1975) that the spun-cast lenses of Bausch & Lomb, which have an aspherical back surface, may have a different power change due to flexure from lathe-cut lenses. Sarver and his co-workers term the change in power induced by the flexure of the lens and any liquid lens present, the 'supplemental power effect'. Most lathe-cut lenses are fitted with BOZR considerably flatter than the central cornea (*see* Chapter 11) and so flexure induces a negative increase in power or negative supplemental power effect (*Table 5.5*).

It is interesting that Sarver *et al.* (1975) found a zero supplemental power effect with spun-cast lenses of PAR fitted approximately 0.50 mm flatter than the keratometer reading. Indeed, from *Table 5.5* it can be seen that for a centre thickness of less than 0.30 mm and for average PAR little change in power with flexure is to be expected for a change of 0.50 mm. However, Sarver and his co-workers remark that there is a large variation in the supplemental power effects found for a given corneal radius/PAR relationship. They state that lens thickness could be a factor contributing to the variation in supplemental power effects found. This is borne out by Bennett's work (*Table 5.5*) which shows that flexure of thicker lenses induces a greater change of lens power. They also state that peripheral corneal flattening and the shape of the back surface of the lens may be contributory factors. This seems very likely since a lens with an aspherical back surface is likely to flex differently on a given cornea from a lens whose back surface is spherical.

Voerste (1976) also considered that corneal geometry influences lens flexure. He used Hydroflex/m lenses which are lathe-cut but of similar size to Bausch & Lomb lenses, and found a preponderance of zero and low negative (mainly up to −0.50 D) supplemental power effects in a study on over 200 eyes. Only a few eyes had a positive supplemental power effect. This is good clinical evidence in support of Bennett's theoretical work (*Table 5.5*) for the Hydroflex/m lenses are fitted up to 0.4 mm flatter than the mean keratometer reading and would thus steepen on flexure. Also, the lenses used in Voerste's study were all negative lenses and therefore thin – between 0.1 mm and 0.2 mm centre thickness. Voerste also studied 30 eyes fitted with larger lathe-cut lenses (14.5–15.5 mm total diameter) and with these there was a larger negative (mainly up to −0.75 D) supplemental power effect. This again confirms Bennett's theoretical work, for the larger Hydroflex lenses are fitted up to 1.4 mm flatter than the central cornea, thereby steepening more with flexure and so inducing a greater increase in negative power, and possibly also retaining a small negative liquid lens.

Bennett also showed that on toroidal corneas the differential bending of a flatter spherical soft lens so that its back surface steepens to conform to the eye in both meridians, very slightly corrects the corneal astigmatism since there is a greater negative flexure effect along the steeper meridian. However, he showed that the amount of corneal astigmatism which can be corrected in this way is theoretically very small – from 2% to 13% dependent on centre thickness.

Second change – temperature effects

As the temperature of the cornea is 37°C and room temperature is about 20°C there is a change in temperature of the lens when it is put on the eye (Fatt and Chaston, 1980a,b, 1981) which leads to steepening with an accompanying slight increase in the negative power of the lens. (The effects on surface power of small changes in radius are shown in *Table 5.6*.)

Table 5.6 Rate of change of surface power in air, in terms of D/0.10 mm change in radius *r*, for surfaces of various curvatures and various refractive indices

Refractive indices	*dF/dr (D/0.10 mm change) at surface radius of curvature values (mm) of*						
	6.50	*7.00*	*7.50*	*8.00*	*8.50*	*9.00*	*9.50*
1.33	0.781	0.673	0.587	0.516	0.457	0.407	0.366
1.34	0.805	0.694	0.604	0.531	0.471	0.420	0.377
1.35	0.828	0.714	0.622	0.547	0.484	0.432	0.388
1.36	0.852	0.735	0.640	0.562	0.498	0.444	0.399
1.37	0.876	0.755	0.658	0.578	0.512	0.457	0.410
1.38	0.899	0.776	0.676	0.594	0.526	0.469	0.421
1.39	0.923	0.796	0.693	0.609	0.540	0.481	0.432
1.40	0.947	0.816	0.711	0.625	0.554	0.494	0.443
1.41	0.970	0.837	0.729	0.641	0.567	0.506	0.454
1.42	0.994	0.857	0.747	0.656	0.581	0.519	0.465
1.43	1.018	0.878	0.764	0.672	0.595	0.531	0.476
1.44	1.041	0.898	0.782	0.688	0.609	0.543	0.488
1.45	1.065	0.918	0.800	0.703	0.623	0.556	0.499
1.46	1.089	0.939	0.818	0.719	0.637	0.568	0.510
1.47	1.112	0.959	0.836	0.734	0.651	0.580	0.521
1.48	1.136	0.980	0.853	0.750	0.664	0.593	0.532
1.49	1.160	1.000	0.871	0.766	0.678	0.605	0.543
1.50	1.185	1.022	0.890	0.782	0.693	0.618	0.554
1.51	1.209	1.042	0.908	0.798	0.706	0.630	0.565
1.52	1.233	1.063	0.925	0.813	0.720	0.642	0.577
1.53	1.256	1.083	0.943	0.829	0.734	0.655	0.588

Table 5.7 Rate of change of surface power in air (F) for changes in refractive index (n) of 0.01 for various radii of curvature (r)

r (mm)	*dF/dn (D)*	*r (mm)*	*dF/dn (D)*
6.40	1.5625	8.00	1.2500
6.50	1.5385	8.10	1.2346
6.60	1.5152	8.20	1.2195
6.70	1.4925	8.30	1.2048
6.80	1.4706	8.40	1.1905
6.90	1.4493	8.50	1.1765
7.00	1.4286	8.60	1.1628
7.10	1.4084	8.70	1.1494
7.20	1.3699	8.80	1.1236
7.30	1.3889	8.90	1.1369
7.40	1.3514	9.00	1.1111
7.50	1.3333	9.10	1.0989
7.60	1.3158	9.20	1.0870
7.70	1.2987	9.30	1.0753
7.80	1.2821	9.40	1.0638
7.90	1.2658	9.50	1.0526

Third change – evaporation effects

The increase in temperature and the fact that the front surface of the soft lens is exposed to the air which leads to evaporation, means that the water content of the lens decreases slightly when on the eye. This leads to a small increase in refractive index and further steepening of the lens, both of which tend to increase its negative power. (The changes in surface power due to alterations in refractive index are shown in *Table 5.7*.)

Ford (1976) termed this altered state of the lens when on the eye, 'the equilibrated state', which takes into account changes due to flexure, temperature and evaporation. He developed tables and graphs for Sauflon material of 70% water content and for lenses of different thicknesses. These permit the changes in BVP due to equilibration and flexure to be determined from the changes in thickness and BOZR. Thereby a lens of appropriate hydrated BVP can be selected. An example is given of a Sauflon 70 lens of hydrated BVP of −9.25 D and BOZR 9.00 mm being selected for an eye of ocular refraction −10.00 D and keratometer reading 7.50 mm. The hydrated lens thickness of 0.21 mm would decrease to 0.204 mm on equilibration and the BOZR would alter to 8.743 mm. The effects of flexure would contribute −0.30 D, leaving the requirement of an equilibrated BVP of −9.70 D which is obtained by a hydrated BVP of −9.25 D.

Unfortunately, as Ford (1974) also showed, the amount of change in the lens due to evaporation depends on the tear output of the wearer. Thus, greater changes occur in those lenses worn by people with *dry* eyes than in those with *normal* or *excessive* tear output. According to Ford, variations in tear output alone can contribute to differences in power of over 1 D, and he has gone so far as to suggest that in order to determine the equilibrated lens power on the eye soft lens wearers should be put into one of the above three categories according to their tear output. An allowance could then be made for evaporation based on the tear output.

Obviously, then, the determination of the required soft lens power for a given eye is rather imprecise. It depends on whether the lens is lathe-cut or spun-cast (although in general the effects of flexure are similar), on the rate of peripheral corneal flattening, on the tear output of the wearer, on the temperature and evaporation from the lens which in turn may be affected by external atmosphere and temperature as well as the lens material itself and its thickness. This section can therefore give no more than a guide as to what to expect and re-enforces the need to allow soft lenses adequate time to settle before carrying out over-refraction.

The effects on astigmatism of power changes due to soft lens flexure and equilibration

Unlike the rigid hard lens, spherical soft lenses flex to match the corneal contour as already discussed on pp. 174–178. They therefore replicate the front surface corneal toricity on their own front surface. The thickness of the soft lens itself may slightly reduce the amount of toricity transferred, but as almost all soft lenses have a refractive index higher than that of the cornea, the amount of astigmatism transferred to the soft lens front surface is usually about the same as that of the corneal front surface. Different soft lenses have different refractive indices, and the refractive index can vary with the state of hydration at which the soft lens reaches equilibrium on the eye. When fully hydrated most soft lens materials have a refractive index in the region of 1.36–1.46. Thus, the amount of astigmatism transferred to the front surface of the soft lens depends on a number of factors: the type of material and its flexibility, its thickness and its refractive index in the equilibrated state on the eye.

What is more important, is to realize that the astigmatism on the front surface of the soft lens is partly neutralized by the back surface astigmatism of the cornea as well as that at the cornea/soft lens interface, and possibly by crystalline lens astigmatism also. Bennett (1976) showed that any soft lens fitted with its back surface flatter than the cornea very slightly corrects corneal astigmatism (*see* p. 178). As it flexes to match the steeper cornea the soft lens becomes more negative in power, and this increase in negative power is greater along the steeper meridian, hence the slight correction of corneal astigmatism.

It should also be remembered that there is little, if any, liquid lens between a soft lens and the central cornea, and since the soft lens forms almost a glove fit in this region, any tear lens present is usually of zero or very low negative power.

It may be helpful at times to be able to determine the astigmatism of the front surface of a soft lens and how it may alter while *in situ* on the eye. *Table 5.6* can be used to show the amount of astigmatism introduced by the toroidal surface of any lens (soft or hard), provided its radii of

curvature and refractive index are known. It shows the change in surface power in air for a change of radius of 0.10 mm, for refractive indices between 1.33 and 1.53 in steps of 0.01. (Interpolation would permit power changes for even smaller gradations in refractive index than 0.01 to be obtained.)

Because a change of radius of 0.10 mm induces different power changes, depending on whether the curvature of the surface is steep or flat, this is allowed for by taking surface radii in 0.50 mm steps between 6.50 mm and 9.50 mm.

Thus, for example, for a large change in radius, say from 7.00 mm to 8.00 mm, and for a refractive index of 1.45, the figure in the intermediate (r = 7.50 mm) column should be used. So, for a lens of front surface radii 7.00 mm × 8.00 mm the power difference, or astigmatism, is 10 × 0.800 = 8.00 D, which gives an error of only 0.036 D.

If there is only a moderate radius change, as for a surface of radii 7.00 mm × 7.50 mm then (using the same refractive index of 1.45) it is best to average the figures in the two relevant columns to obtain the effect of a 0.10 mm change in radius, i.e. the average of 0.918 and 0.800 is 0.859 D, and for the 0.50 mm difference is 5 × 0.859 = 4.295 D of astigmatism. This gives an error of 0.009 D.

For small radius differences, as for a surface of radii 7.00 mm × 7.20 mm and of refractive index 1.44, then the value in the column applying to the nearest radius should be used; in this case it is 7.00 mm, and thus 0.898 D is the value for a 0.10 mm radius change. So the 0.20 mm difference in surface radii would give 2 × 0.898 = 1.796 D of astigmatism, an error of only 0.05 D.

If the front surface of a soft lens alters curvature while it is on the eye, as for example due to temperature changes or evaporation, then there is a surface power change which may also be obtained from *Table 5.6*. Suppose the front surface of a lens steepens from 9.50 mm to 9.40 mm and the lens is assumed to have a refractive index of 1.43, then its power will change by 0.476 D, and as this is a steepening of a convex surface, the power will become more positive. Changes in toricity of a surface would lead to changes in astigmatism which can be determined from *Table 5.6* in the same way.

However, such radius changes of a soft lens occurring while it is on the eye are often accompanied by changes in refractive index, again due to equilibration factors such as temperature changes and evaporation from the lens. *Table 5.7* shows how the surface power may alter if this occurs. For example, evaporation might lead to a rise in refractive index from 1.39 to 1.40 for a surface of radius 8.50 mm. There is then a resultant power change of 1.1765 D, while a change from 1.39 to 1.41 would lead to twice this amount, i.e. 2.353 D. For a rise in refractive index, there is always an increase in power of the surface, and a drop in refractive index leads to a decrease in surface power.

Note that in *Table 5.7*, as indicated in the above paragraph, the changes in power are linear at any one radius; thus for a radius of 7.50 mm, a change of refractive index of 0.06 would give a surface power change of 6 × 1.3333 = 7.9998 D, and a change of refractive index of 0.006 would give a power change of 0.79998 D.

When these factors of radius and refractive index change with equilibration are considered, it is surprising that the power of soft lenses on the eye remain as constant as they do. Small changes in visual acuity due to alterations in power are therefore both understandable and to be expected. The effects on soft lens power of flexure, dehydration, refractive index changes, temperature and humidity changes, and thickness variations have been investigated by many researchers, among them Andrasko and Schoessler (1980), Bibby (1980), Fatt and Chaston (1980a, b, 1981), Chaston and Fatt (1981) and Port (1982), in addition to others already mentioned. Because 'water content' featured largely in many of their investigations, Brennan, *et al.* (1986) established definitions for hydration changes of soft hydrogel lenses, in an attempt to avoid confusion and to establish just what is meant by 'water uptake' and 'water loss'. Chapters 11 and 13 cover this aspect in further detail.

The effects of flexure on rigid corneal lenses

In the same way that a soft lens flexes to conform to the corneal contour there is a tendency for RGP and very thin PMMA lenses to flex on toroidal corneas, partially replicating the corneal astigmatism. Harris and Chu (1972) found that with PMMA lens centre thicknesses of less than 0.13 mm, the thinner the lens, the more it flexes; the more corneal astigmatism present, the greater is the lens flexure. They found that thin lenses flexed in a predictable manner and induced astigmatism which affected the amount of residual astigmatism. Their results are summarized in *Figure 5.24*. As can be seen this flexure-induced astigmatism can be made use of to benefit the patient. Frequently, as explained on p. 171, if the lens does not flex, all corneal astigmatism is corrected by the liquid lens and any residual astigmatism is due to the crystalline lens. The latter is normally a small to moderate amount of against-the-rule astigmatism. If such is found, and if the cornea has with-the-rule astigmatism, then obviously by fitting a thin lens the induced with-the-rule astigmatism caused by the lens flexure can be used to partially or completely neutralize the against-the-rule residual astigmatism. The standard of visual acuity and quality may thus be improved (*see also* Chapter 14).

Rigid gas permeable lenses may flex considerably on toroidal corneas, some materials being more flexible than others. This flexure can be minimized by fitting the BOZR as flat as possible (Pole, 1983; Stone and Collins, 1984) and by keeping the BOZD as small as possible (Brown *et al.*, 1984) (*see* Chapter 10). Such flexure is similar to that of a thin PMMA lens and may be optically beneficial or, more often, prevent the lens from adequately correcting corneal astigmatism, rather like a spherical soft lens on a toroidal cornea, although the flexure is not as great with an RGP lens as with a soft lens. It may necessitate fitting a compensated bi-toric lens (Douthwaite, 1988).

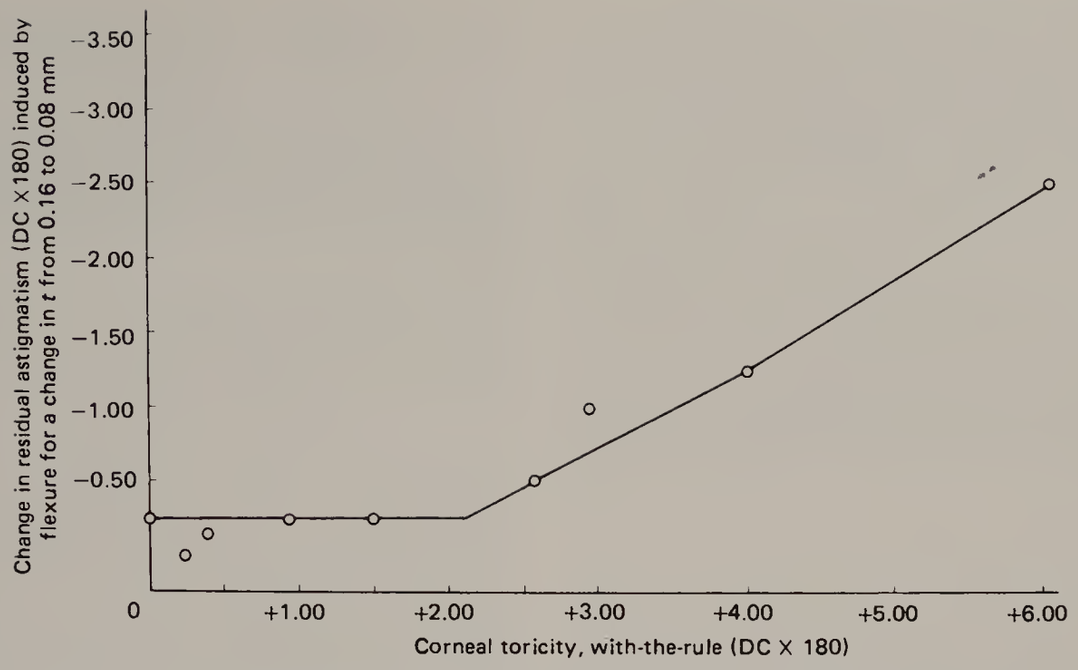


Figure 5.24 The difference in residual astigmatism between that induced by a thick PMMA lens (0.16 mm) and that induced by a thin lens (0.08 mm) for corneas of various toricities. For example, if a patient had −1.25 DC × 90 residual astigmatism with a 0.16 mm thick lens, on a 4.00 D with-the-rule toroidal cornea, then changing the lens to one of 0.08 mm thickness would induce −1.25 DC × 180 of astigmatism due to flexure, thereby eliminating the residual astigmatism. (Reproduced by kind permission of M.G. Harris and C.S. Chu)

Because flexure affects both front and back surfaces of the contact lens, thereby altering the front surface of the liquid lens, the cumulative effect on astigmatism is complex. Provided the radius changes of the lens are known – and the front surface of a lens can be measured on the eye by keratometry – then the power effects can be obtained from *Table 5.6* or from formulae, III, IV and V, p. 199–200. Unfortunately the flexure effect may vary as the lens moves on the eye and, generally speaking, it is best assessed by refractive techniques (both objective and subjective) with the lens *in situ*.

Alteration of the back optic zone radius of scleral contact lenses

Sometimes a lens is supplied which has the correct BVP and is initially a good fit. After being worn for a few weeks, settling takes place and a heavy central corneal touch develops (*see* Chapter 17).

Two possibilities arise: in the first *the back optic zone may be ground out using the same BOZR, thereby reducing central optic thickness.* This is usually done when the limbal clearance is also too small, as demonstrated by the fluorescein picture.

As shown by Swaine (1956), grinding substance out of the back optic zone surface affects the vergence reaching the eye in two ways: the reduction in plastic thickness adds negative power to the BVP of the contact lens, and the increase in liquid thickness adds positive power to the tear lens. The latter may be ignored if the liquid lens is restored to its original satisfactory thickness.

Example:

BVP of PMMA scleral lens	+6.00 D
t_c	0.60 mm
BOZR	8.50 mm
Keratometry: front corneal radius	7.75 mm

This gives central corneal touch after settling, and is ground out to:

t_c	0.40 mm
BOZR	8.50 mm
This gives liquid thickness	0.10 mm

The reduction in thickness of the contact lens adds −0.54 D to its BVP, making the BVP +5.46 D.

The increase in thickness of the liquid lens from zero to 0.10 mm changes the liquid lens power from −3.83 D to −3.72 D, an addition of +0.11 D.

Detailed calculations to obtain these BVP values are as follows. Tracing a pencil of rays 'backwards' through the scleral lens as in *Figure 5.25*. As the BOZR = 8.5 mm

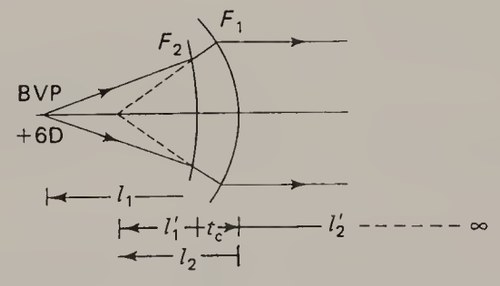


Figure 5.25 A pencil of rays traced 'backwards' through the optic zone of a scleral lens

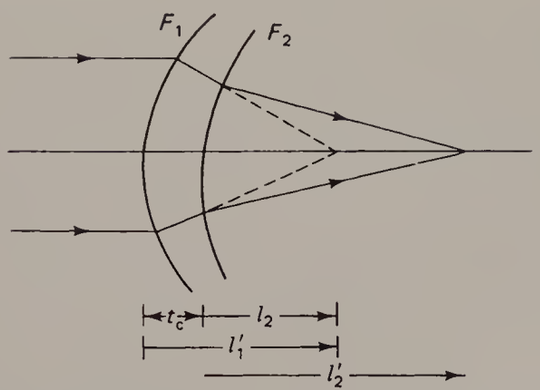


Figure 5.26 A pencil of rays traced 'forwards' through the optic zone of a scleral lens

$$*F_2 = \frac{(1.49 - 1)1000}{-8.5} = -57.65\,\text{D}$$

$$\begin{aligned} L_1 &= -6.00\,\text{D} \; (= -\text{BVP}) \\ +\; F_2 &= -57.65\,\text{D} \\ \underline{L_1' = -63.65\,\text{D}} & \end{aligned}$$

$$l_1' = \frac{1.49 \times 1000}{L_1'} = \frac{1490}{-63.65}\,\text{mm} = -23.41\,\text{mm}$$

$$t_c = 0.60\,\text{mm}$$

$$l_2 = l_1' - t_c = -23.41 - 0.60\,\text{mm} = -24.01\,\text{mm}$$

$$L_2 = \frac{1.49 \times 1000}{l_2} = \frac{1490}{-24.01}\,\text{D} = -62.06\,\text{D}$$

$$L_2' = 0\,\text{D (emergent rays are parallel)}$$

$$F_1 = L_2' - L_2 = +62.06\,\text{D}$$

Now that the front surface power of the lens is known, the effect of grinding out the back surface to give a new thickness, t_c, of 0.4 mm can be determined, and the new BVP ascertained.

Tracing a pencil of rays 'forwards' through the lens as in *Figure 5.26*, $F_1 = +62.06\,\text{D}$ and $F_2 = -57.65\,\text{D}$.

$$\begin{aligned} L_1 &= 0\,\text{D (incident parallel light)} \\ +\; F_1 &= +62.06\,\text{D} \\ \underline{L_1' = +62.06\,\text{D}} & \end{aligned}$$

$$l_1' = \frac{1.49 \times 1000}{L_1'} = \frac{1490}{+62.06}\,\text{mm} = 24.01\,\text{mm}$$

$$t_c = 0.40\,\text{mm}$$

$$l_2 = l_1' - t_c = +23.61\,\text{mm}$$

$$L_2 = \frac{1.49 \times 1000}{l_2} = \frac{1490}{+23.61}\,\text{D} = +63.11\,\text{D}$$

$$\begin{aligned} +\; F_2 &= -57.65\,\text{D} \\ \underline{L_2' = +5.46\,\text{D}} &= \text{BVP of thinner scleral lens, a change of } -0.54\,\text{D} \end{aligned}$$

Note that the above method of calculation, termed the 'step-along' method by W. Swaine, is an alternative to the use of reduced vergences with equivalent air distances and reduced thicknesses, as, for example, the calculations shown on p. 170.

The liquid lens power in air may be found as follows:

Thus, front surface power

$$F_1 = \frac{(1.336 - 1)1000}{+8.5} = +39.53\,\text{D}$$

Its front surface radius is the BOZR of the scleral lens = +8.50 mm

Its back surface radius is the corneal radius found by keratometry = +7.75 mm

Back surface power

$$F_2 = \frac{(1 - 1.336)1000}{+7.75} = -43.36\,\text{D}$$

And for $t = 0$ mm, BVP = $F_1 + F_2 = -3.83\,\text{D}$

After grinding out the back optic zone of the scleral lens, the liquid lens thickness, t, becomes 0.10 mm. The power of the liquid lens in air is then found thus:

An incident parallel beam of light is assumed, so

$$\begin{aligned} L_1 &= 0 \\ +\; F_1 &= +39.53\,\text{D (as before)} \\ \underline{L_1' = +39.53\,\text{D}} & \end{aligned}$$

$$l_1' = \frac{1.336 \times 1000}{L_1'} = \frac{1336}{+39.53}\,\text{mm} = +33.80\,\text{mm}$$

$$t = 0.10\,\text{mm}$$

$$l_2 = l_1' - t = +33.70\,\text{mm}$$

$$L_2 = \frac{1.336 \times 1000}{l_2} = \frac{1336}{+33.70}\,\text{D} = +39.64\,\text{D}$$

$$\begin{aligned} +\; F_2 &= -43.36\,\text{D (as before)} \\ \underline{L_2' = -3.72\,\text{D}} &= \text{BVP, a change of } +0.11\,\text{D} \end{aligned}$$

These calculations may be simplified by the use of formulae III, IV, VI, XX, XXII and XXVII on pp. 200–206, and by the use of the CD-ROM.

When RGP scleral lenses are fitted the effect of the difference in refractive index from PMMA (1.49) may be determined from *Table 5.7*.

*This system of calculation was used before the symbols used in the current International Standard were adopted. Formerly the subscript $_1$ was used to denote front surface parameters, for example, r_1; and $_2$ was used for back surface parameters, for example r_2. Now, with the advent of ISO 8321:1991, r_1 has become r_{ao} and r_2 has become r_o. However, for optical calculations subscripts $_1$ and $_2$ are still valid and have been retained here.

Approximate rule (3)

This applies to PMMA scleral lenses.

Reduction of 0.1 mm plastic thickness adds −0.25 D
Increase of 0.1 mm liquid thickness adds +0.12 D
(Note: for RGP material of refractive index 1.53 a reduction of 0.1 mm in plastic thickness adds −0.30 D; and for a refractive index of 1.40 adds −0.20 D.)

In the example given above, the total effect on the vergence reaching the eye is −0.52 D + 0.11 D = −0.41 D, or if it is assumed that the original liquid thickness is restored by the grind-out, the vergence is changed by −0.52 D as the liquid lens is then unaltered (*see* Chapter 17).

For this reason, as Fletcher (1965) stated, it is wise to order the original scleral lens a little too positive (by +0.25 D to +0.50 D, depending on the visual acuity obtainable). Even if the lens does not settle enough to require grinding out, it is bound to settle a certain amount, thereby reducing the liquid thickness and adding negative power to the liquid lens. A total settling of 0.2 mm is quite normal.

In the second possibility for alteration *the BOZR may be steepened as well as the thickness reduced.* This is usually done when the limbal clearance is more than adequate, as indicated by a large bubble in a fenestrated lens, surrounding the area of corneal touch.

The grinding out has the same effect described in the first possibility, coupled with a further increase in negative power due to the steepened BOZR. The liquid lens is made more positive, but to a lesser extent than the negative increase of the contact lens.

Example:

BVP	+6.00 D
t_c	0.60 mm
BOZR	8.50 mm

This gives heavy central corneal touch and a large limbal bubble; 0.20 mm is to be removed centrally by grinding out, and the BOZR is to be steepened at the same time to 8.25 mm. The final apical corneal clearance required is 0.10 mm.

The effect on the PMMA lens is to reduce the BVP from +6.00 D to +3.73 D, which is:

− 0.54 D due to the thickness reduction (*see above under* first possibility, p. 181)
− 1.75 D due to the radius alteration (*see* formula V, p. 200, n_2 = 1.49, n_1 = 1.00)

− 2.27 D total change in BVP

This is partially offset by the increase in positive power of the liquid lens from −3.83 D to −2.52 D, which is:

+ 0.11 D due to the thickness increase (*see above under* first possibility, p. 181)
+ 1.20 D due to the radius change (*see* formula V, n_2 = 1.336, n_1 = 1.00)

+ 1.31 D total change in liquid lens power

The change in vergence reaching the eye is approximately −1.00 D:

− 2.27 D due to the plastic lens
+ 1.31 D due to the liquid lens

− 0.96 D total change in vergence

The BVP of the contact lens should be changed to correct this amount, i.e. from its new value of +3.73 D by +0.96 D to + 4.69 D. This change must be carried out on the front surface of the lens.

Approximate rule (4)

For each 0.05 mm that the BOZR of a sighted PMMA scleral lens is steepened, +0.12 D must be added to the altered BVP of the plastic lens (by changing the front surface power) in order to keep the BVP of the plastic/liquid system unchanged. For material of refractive index 1.53, this approximate value increases to +0.14 D, and for a refractive index of 1.40 the approximate change in power required for a +0.05 mm steepening of the BOZR is 0.05 D, (*see also Table 5.6*).

Applying the approximate rules to the example given results in the following for material of refractive index 1.49.

Rule (4)

BOZR steepened by 0.25 mm = 5 × 0.05 mm steepening.
Compensation for negative increase at plastic/liquid interface = 5 × +0.12 D = +0.60 D to add to BVP.

Rule (3)

Reduction of plastic thickness by 0.20 mm = 2 × 0.10 mm
Compensation for negative power added = 2 × + 0.25 D = +0.50 D to add to BVP.

Rule (3)

Increase of liquid thickness by 0.10 mm = 1 × 0.10 mm
Compensation for positive power added = 1 × −0.12 D = −0.12 D to add to BVP
Total change to be made to altered BVP by changing front surface power = +0.60 D +0.50 D −0.12 D = +0.98 D

This yields almost the same result as that found by detailed calculation, which gave +0.96 D.

An alternative method of steepening the BOZR is to select the BOZR which will give the extra clearance

required. This is done by deciding how much is to be ground out and over what diameter the BOZR is to be steepened. (This diameter is usually about 8–9 mm to allow adequate coverage of the pupil area.) Then the sagitta of the existing BOZR at this diameter may be determined (*see* formulae XI and XVII, pp. 202 and 203). The substance to be removed is added to this sagitta and gives the sagitta value at the same diameter for the steeper BOZR required. (Nomograms, as compiled by Clark (1970) may be used as an alternative to formulae for determining sagitta values.)

Example:

BOZR	9.00 mm
Diameter	9.00 mm
Sagitta	1.206 mm
Extra clearance	= 0.20 mm
Sagitta of new BOZR	= 1.406 mm
Diameter as before	= 9.00 mm
New BOZR required	= 7.90 mm (*see* formulae XI and XVII).

This method of determining BOZR usually means that there is a considerable alteration over the central area alone which does not always result in a satisfactory fit. Central corneal clearance is achieved but touch may remain at the transition of the old and new back optic zone curves. (On the whole, it is better to steepen the BOZR by a small amount, such as 0.25 mm, after removing most of the substance required using the original BOZR.)

Toric contact lenses (*see* Chapter 14)

Both optical and fitting considerations of toric PMMA corneal lenses have been dealt with in detail by Capelli (1964), Stone (1966) and Westerhout (1969). In summary, it may be said that if the back optic surface of a rigid contact lens is to be made toroidal, the BVP required should be found by refraction either with a lens having the correct toroidal BOZR in place or with a spherical lens having a BOZR equal to the flatter meridian of the toric lens to be ordered. In the latter case, which is not as straightforward as the former, some calculation is necessary in order to determine the BVP of the final toric lens to be ordered. Since the BOZR of one meridian is to be steepened by a known amount when ordering, the calculation is the same as that for a spherical lens where a refraction has been carried out with a trial lens of incorrect BOZR, as outlined on pp. 172 and 173 and summarized in Approximate rule (2). It is a simple matter of allowing for the fact that the liquid lens power in one meridian will be different, with the final lens in place, from the value with the spherical trial lens in place. An allowance for this difference must therefore be made on the contact lens itself, as shown in the following example.

Example:

BOZR of lens to be ordered	7.50 mm along 90 8.30 mm along 180
BOZR of spherical trial lens for refraction	8.30 mm
BVP of spherical trial lens for refraction	−3.00 D
Additional spectacle lens needed	−1.00/+0.50 × 180
BVP of final contact lens along 180 is thus	−3.00 + −1.00 = **−4.00**
BVP of final contact lens along 90 is thus approximately	−3.00 + −1.00 + +0.50 + allowance for radius change, of −4.00 D (*see* Approximate rule (2)) = **−7.50 D** in total.

(When the radius change is as large as this it is more accurate to work out the change in power of the liquid lens, remembering that this change is a change of the front surface of the liquid lens in air – *see* pp. 172 and 173 and *see* formulae III and V, pp. 199 and 200 for a refractive index difference of 1.336 – 1. In this example, this gives a change of −4.32 D, i.e. 0.32 D more than the value given by Approximate rule (2). Thus, the BVP of the final contact lens along 90 should be **−7.82 D**.)

It can now be established whether or not a front toroidal surface will also be necessary on the final toroidal back surface lens. This depends on whether or not the cylinder power of the back surface in air is the same as the required cylinder element of the BVP of the lens in air:

Required BVP of final lens (in air)	−4.00/−3.82 × 180
For a PMMA lens back surface powers (in air) (from formula III for 1.490 – 1)	−65.33 along 90 and −59.04 along 180
Back surface cylinder in air is thus	−6.29 × 180
Front surface cylinder required (ignoring thickness)	−3.82 – (−6.29) × 180 = +2.47 × 180

The computer program on the accompanying CD-ROM may also be used to determine back surface cylinder power in air and if each meridian is treated separately formula III, p. 199 may be used.

The above example is an obvious case where a front surface cylinder is necessary to give good visual acuity. Frequently the front surface cylinder calculated in this way is quite small and the practitioner may prefer to order a lens with a spherical front surface and risk leaving the patient with a small amount of uncorrected (but usually over-corrected) astigmatism. In such a case the cylinder element of the BVP of the final lens to be ordered must be altered by this amount, i.e. the cylinder element of the BVP is then the same as the back surface cylinder in air.

Alternatively the final lens may be ordered stating that it is to have a back toroidal surface only, and giving the back vertex power of the flattest meridian, i.e. the maximum positive or least negative power.

It often helps in considering the optical effects of contact lenses with back toroidal surfaces, to imagine the existence of a very thick tear lens, in the centre of which is sandwiched a perfectly flat layer of air. The surfaces bounding this flat layer of air are therefore of zero power in all meridians, the tears on either side forming two liquid lenses – one whose power depends on the toroidal radii of the back surface of the contact lens, and the other quite separate one whose power depends on the corneal radii. Then the optical effect of the tears on the cornea (which is to neutralize the corneal astigmatism – *see* p. 171) can be considered separately from the plastic/tears interface at the back of the contact lens. If appropriate the two can be added together. Thus, the rear portion of this tear lens corrects the corneal astigmatism, but further astigmatism is introduced by the front portion at the plastic/tears interface (*see* Chapter 14).

Compensated bi-toric or spherical power equivalent bi-toric lenses

These are rigid lenses in which the front toroidal surface in air has an equal and opposite cylindrical power to the back toroidal surface in tears. It thus acts like a spherical lens on the eye, both in terms of power and in that rotation of the lens on the eye does not induce any cylindrical effect (*see* Chapter 14). Such a lens may be required for reasons of comfort or fit, or if a spherical lens flexes on a toroidal cornea.

If, for example, a rigid spherical PMMA lens corrects the astigmatism of an eye, but for physiological (and/or fitting) reasons a gas permeable lens is to be ordered which is likely to flex, thereby inducing unwanted astigmatism, it may be desirable to fit an RGP lens with a toroidal back surface to match the corneal radii. This prevents flexure but introduces astigmatism at the interface of the lens back surface with the liquid lens. The amount of this induced astigmatism is given by

$$\frac{1000\ (n' - n)}{r_F} - \frac{1000\ (n' - n)}{r_S}$$

where n' = refractive index of contact lens
n = refractive index of tears = 1.336
r_F = BOZR along flattest meridian of lens back surface
r_S = BOZR along steepest meridian of lens back surface

To compensate for this astigmatism introduced at the back surface of the lens *in situ*, a front toroidal surface with principal meridians parallel to those of the back surface must be made which, since it is in air, will not be as toroidal as the back surface. The ratio between front and back surface toricity depends on the refractive index of the lens material and is given by

$$\frac{1/(n' - 1)}{1/(n' - 1.336)} = \frac{n' - 1.336}{n' - 1}$$

For PMMA this is

$$\frac{1.49 - 1.336}{1.49 - 1} = 0.314 \text{ or approximately } \tfrac{1}{3}$$

For an RGP material of refractive index 1.45 it is

$$\frac{1.45 - 1.336}{1.45 - 1} = 0.253 \text{ or approximately } \tfrac{1}{4}$$

Thus to provide a spherical effect on the eye, a compensated parallel bi-toric lens has a front surface cylinder which counteracts in the region of a third to a quarter of the back surface cylinder in air, depending on the refractive index of the lens material. This information is useful when checking the lens on a focimeter. Its total cylindrical effect is thus two-thirds to three-quarters of the back surface cylinder in air – the latter being easily obtained from radiuscope readings (*see* Chapter 12) and then by radius/power conversion (*see* formulae III, IV and V, pp. 199 and 200). The CD-ROM also provides this information.

If such lenses are not accurately manufactured with the principal meridians absolutely parallel on front and back surfaces, then not only is the cylinder power of the lens in air different from that expected but the lens will not provide the correct 'spherical equivalent' effect on the eye (Douthwaite, 1988). The resultant cylindrical effect can be calculated by Stokes' construction or by using the CD-ROM program.

Stokes' construction

This is an excellent method of resolving two cylinders F_1 and F_2, with an angle between their axes of α, into an equivalent sphere/cylinder power (*Figure 5.27*).

A parallelogram is constructed with the two sides OA_1 and OA_2 proportional to F_1 and F_2, with the angle between them 2α

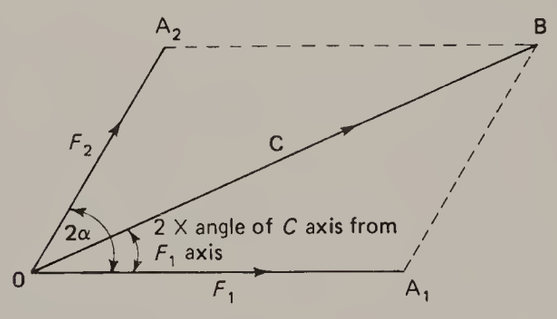


Figure 5.27 Stokes' construction

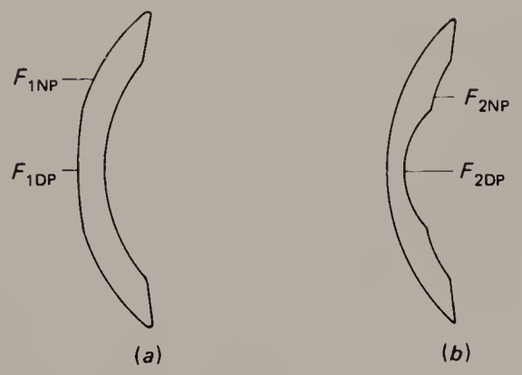


Figure 5.28 Concentric solid bifocal corneal lenses. (*a*) Front surface addition; (*b*) back surface addition

The parallelogram is completed and the resultant OB drawn. This is proportional to the resultant cylinder C. The angle between OB and OA_1 being twice the angle between the axis of C and that of F_1, where

S = equivalent sphere
C = equivalent cylinder
$S = \frac{1}{2}(F_1 + F_2 - C)$

If the power of the cylinder on the front surface does not have the correct ratio to that of the back surface then again it will not be the equivalent of a spherical lens on the eye. This may not be problematical unless the lens rotates when the effect of the swinging cylinder may give rise to a reduction and variation in visual acuity. If the resultant refractive error is constant then Stokes' construction permits the cylinder error of the lens and the misalignment of the lens on the eye to be determined (*see* the computer program on the CD-ROM). These erroneous effects are compounded if the front surface cylinder is both incorrect in power and not parallel to that of the back surface – which may explain the reluctance of some manufacturers to supply such lenses, as they are extremely difficult to manufacture accurately.

Bifocal contact lenses

Like bifocal spectacle lenses, contact lens bifocals are available in both solid and fused types. However, there are also diffractive bifocal contact lenses, both in rigid gas permeable materials as well as soft. The underlying theory has been explained by Freeman and Stone (1987). Although they could be considered as solid bifocals because they are manufactured from one solid piece of material, the optical theory is different from a normal refractive solid bifocal which uses 'refraction' rather than 'diffraction' to achieve the two separate distance and near powers. References to solid bifocals here, are to the conventional refractive variety. Chapter 16 deals with the various designs and methods of fitting of all types of bifocal contact lenses. The basic principles of normal refractive solid and fused bifocals may be understood by considering the concentric solid bifocal with distance portion in the centre and the fused bifocal with the near segment on the back surface. The latter is shown in *Figure 5.29*. An appreciation of the optical principles of these two main types should permit a general understanding of all other designs of bifocal contact lens.

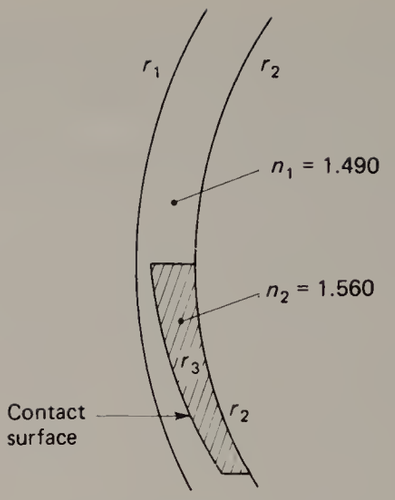


Figure 5.29 Fused bifocal corneal lens: r_1, r_2 and r_3 are the radii of the front, back and contact surfaces respectively; n_1 and n_2 are the refractive indices of the main lens and the near segment

Concentric and flat-top solid bifocals

As *Figure 5.28* shows, these are available with the addition worked on either the front or back optic surface (and, of course, a combination of back and front surface additions could be used). When the addition is on the front surface (a plastic/air interface), the front optic zone has two radii worked on it, the steeper corresponding to the near portion of the lens. Then, provided that the lens is assumed to be infinitely thin, the near addition is equal to the difference between the two front surface powers.

For example, if the near addition to be incorporated in a PMMA lens is +3.00 D and where F_{1DP} and F_{1NP} are the front surface powers of the distance and near portions respectively (*see* footnote, p. 182), then $F_{1NP} = F_{1DP} + 3.00$. Since this is a plastic/air interface the appropriate front optic zone radii may be obtained from formulae III, IV and V, pp. 199 and 200, using $n_2 = 1.49$ and $n_1 = 1.00$.) If, in a particular case, F_{1DP} is calculated to be +58.00 D, this gives a radius, r_{1DP}, of

$$8.45\,\text{mm} = \frac{(1.490 - 1)\ 1000}{58.00}$$

For an addition of +3.00 D, F_{1NP} must therefore be +61.00 D giving a radius of 8.03 mm.

If thickness is to be taken into account, reference to formula VI, p. 200 should be made. In the example just given, if the centre thickness of the distance portion were 0.20 mm and that of the near portion 0.22 mm since L_1 = 0.00 D and F_{1DP} = +58.00 D, L_1' = +58.00 D for the distance portion. It can be seen that 0.20 mm thickness adds 0.46 D

to this power. The reduced vergence reaching the back surface is thus +58.46 D. Similarly, for the near portion, since L_1 = 0.00 D and F_{1NP} = +61.00 D, L'_1 = +61.00 D. 0.22 mm thickness adds 0.55 D to the reduced vergence reaching the back surface. The difference between 0.46 D and 0.55 D is 0.09 D and is small enough to be ignored, but it indicates that F_{1NP} should be reduced by this amount, from +61.00 D to +60.91 D, giving r_{1NP} as 8.04 mm instead of 8.03 mm. This small radius change is not really worth making as will be shown.

In fact, most practitioners agree that there is a tendency for a small negative-powered liquid lens to collect in front of the upper and lower portions of any corneal lens due to the tears rivus along the eyelid margins. The configuration of the front surface of a solid bifocal with front surface addition (*Figure 5.28a*) is such that this tear lens may slightly reduce the front surface positive power at the periphery. If anything, then, it is wise to err on the positive side, and indeed many practitioners increase the addition they have determined, by as much as +1.00 D, to allow for this negative tear lens although its amount is rather variable depending as it does on the patient's tear output and the rate of evaporation in differing atmospheric conditions. Concern over the effect on the addition, of differences in thickness between the distance and near portions, is therefore seen to be unwarranted.

D-shaped segments with the flat top uppermost are also available as solid front surface bifocals, with a junction ridge similar to plastic spectacle lens bifocals of this shape. However, on a contact lens the ridge is polished away centrally. The optical theory is the same as for concentric bifocals. RGP lenses of this type are fairly common (*see* Chapter 16).

When the addition is on the back surface, no allowance for the effect of thickness need even be considered, but the major consideration here is that it is a plastic/tears interface, rather than a plastic/air interface.

In air the power of a PMMA surface depends on

$$\frac{1.490 - 1}{r}$$

whereas in tears it depends on

$$\frac{1.490 - 1.336}{r}$$

This is a factor of 0.49/0.154 or approximately 3.18 for PMMA lenses. (For RGP lenses of, for example, refractive index 1.45, this factor becomes 3.95, and for soft lenses of refractive index of 1.43 the factor becomes 4.57.) Thus, the practitioner and manufacturer must make the back surface radii such that they provide approximately three to four times the addition on the back surface (when measured in air) than is really required, due to the neutralizing effect of the tears (*see* Chapter 16). This point is important to remember when checking such a lens on the focimeter.

Usually this type of bifocal is fitted with a steep BCOZR (r_{2DP}) (*see* footnote, p. 188) and small BCOZD, with the back peripheral optic zone radius (r_{2NP}) providing the near addition and fitted so as to align or be just flatter than the cornea. For example, if BPOZR (r_{2NP}) is 8.50 mm, reference to formula III, p. 199, for 1.336–1.490 shows F_{2NP} to be −18.118 D. (It is negative in power because the medium of higher refractive index has a concave surface.) To give a +3.00 D addition requires that F_{2DP} be −21.118 D and thus r_{2DP}, the BCOZR, is 7.29 mm (from formula IV). Now if this lens were measured in air on a focimeter, the radii of 8.50 mm and 7.29 mm would have surface powers, for 1–1.490, of −57.65 D and −67.22 D respectively (*see* formula III). Thus the near addition measured in air is +9.57 D, which equals the near addition in tears × 3.18 (approximately), as stated above, depending on whether PMMA or some other material of different refractive index is used.

Fused bifocals

Formulae VII to X, p. 200–201 should be consulted in connection with this section. In the formulae the alternative symbols, based on ISO 8321:1991, are used. Thus $r_1 \equiv r_{ao}$, $r_2 \equiv r_o$, $r_3 \equiv r_{BCS}$ or r_{FCS} (depending on whether the fused segment is a back surface or front surface segment) and subscripts for powers F are similarly denoted. It should be apparent that the contact surface, F_{CS}, must have a positive power (F_{BCS}) with a back surface fused segment, *see Figure 5.29*, and a negative power (F_{FCS}) when the segment is on the front surface.

These are very similar to fused bifocal spectacle lenses except that most corneal lenses have the segment on the back surface, and the refractive index of the fused segment is usually 1.56. The optical theory is easily understood if reference is made to *Figure 5.29*. Since the back surface is a negative surface and the segment has the higher refractive index, there is actually a gain in *negative* power at the back surface of

$$\frac{1.560 - 1.490}{r_2}$$

and where r_2 is in millimetres this expression becomes

$$\frac{-70}{r_2}\ \text{D} = -8.75\ \text{D}$$

For example, if the BOZR (r_2) is 8.00 mm then the back surface powers in tears are:

$$F_{2DP} = \frac{(1.336 - 1.490)1000}{8.00}\ \text{D} = -19.25\ \text{D}$$

(*see* formula III, p. 199)

$$F_{2NP} = \frac{(1.336 - 1.560)1000}{8.00}\ \text{D} = -28.00\ \text{D}$$

(*see* formula III)

The difference

$$F_{2NP} - F_{2DP} = -8.75\,D = \frac{-70}{8}\,D$$

(*see above* and formula VII)

It should be emphasized here that the power difference due to the segment is the same whether the power is determined in air or in tears, because the BOZR (r_2), is the same throughout (as distinct from the back surface solid bifocal where $r_{2DP} < r_{2NP}$). This is easily shown using the same value for r_2 as above. The back surface powers in air are

$$F_{2DP} = \frac{(1 - 1.490)1000}{8.00}\,D = -61.25\,D$$

(*see* formula III)

$$F_{2NP} = \frac{(1 - 1.560)1000}{8.00}\,D = -70.00\,D$$

(*see* formula III)

The difference, $F_{2NP} - F_{2DP} = -8.75\,D = \frac{-70}{8}D$

This is exactly the same result as when the back surface powers were determined in tears (*see* p. 187).

Because the back surface addition is the same measured in air as in tears, the addition read on a focimeter is the same as that on the eye.

Since the fused segment gives rise to a gain in negative power on the back surface, it must give rise to a gain in positive power at the contact surface sufficient to overcome the negative gain as well as to provide the near addition, i.e. if the power of the contact surface is F_3 then for the refractive indices already given

$$*F_3 = \text{Addition} - \left(-\frac{70}{r_2}\right) = \text{Addition} + \frac{70}{r_2}$$

Now F_3 (which is convex to the medium of higher refractive index)

$$= \frac{1.560 - 1.490}{r_3}\,D = \frac{70}{r_3}\,D \text{ (where } r_3 \text{ is in mm)}$$

$$\text{And since } F_3 = \text{Addition} + \frac{70}{r_2}$$

$$r_3 = \frac{70}{\text{Add.} + \dfrac{70}{r_2}} \quad (\textit{see} \text{ formula IX})$$

(where the addition is in dioptres, and r_2 and r_3 are in millimetres).

Where the segment is fused on the front surface formulae VIII and X apply (*see* Example 13, p. 201.).

The above example illustrates a PMMA fused bifocal but RGP bifocal lenses are available with similar straight-top segments, such as the Paragon Vision Sciences lens (Paragon Fluoroperm ST), which has a Fluoroperm 60 main lens and is a monocentric no-jump bifocal (*see* Chapter 16).

Optical changes of the eye caused by contact lenses

Contact lenses may bring about curvature, thickness and refractive index changes of the cornea (*see* Chapters 10 and 18). These effects, usually referred to as 'spectacle blur', are more marked after PMMA lens wear, but do occur to a lesser extent when RGP lenses are worn. Rengstorff (1989) has described the changes in detail.

It seems appropriate here to record the work of Carney (1975) who used atmospheres of 100% oxygen tension and zero oxygen tension coupled with PMMA corneal lenses fitted both flat and steep to study curvature and thickness changes induced in the cornea. A summary of his results suggests that all such lenses tend to mould the cornea to their own shape – flat lenses flattening and steep lenses steepening the central cornea. In addition, those lenses which give rise to central corneal oedema cause an unequal change in corneal thickness, it being greatest in the centre which leads to steepening of the corneal front surface. Such steepening leads to an increase in myopia, and flattening to an increase in hypermetropia.

The resulting dioptric change in air, measurable as a change in ocular refraction, is largely masked by the wearing of the contact lens because the corneal change is neutralized by the tears. The ratio:

$$\frac{\text{Dioptric change in air}}{\text{Dioptric change with contact lens in place}}$$

$$= \frac{1.376 - 1.0}{1.376 - 1.336} = \frac{9.4}{1}$$

As can be seen, it is dependent on the refractive index differences of the cornea in air relative to the cornea in tears. Thus, a person who becomes 1 D more myopic due to corneal steepening manifests less than 0.12 D of this while wearing contact lenses.

The wearing of low Dk or PMMA rigid contact lenses tends to cause central corneal oedema and steepening,

*This equation was derived before the symbols used in the current International Standard were adopted. Formerly the subscript $_1$ was used to denote front surface parameters, for example, r_1; and $_2$ was used for back surface parameters, for example r_2. Now, with the advent of ISO 8321:1991, r_1 has become r_{ao} and r_2 has become r_o. However, for optical calculations subscripts $_1$ and $_2$ are still valid and have been retained here with $_3$ used for the intermediate surface.

whilst the removal of the lenses results in central corneal thinning and flattening (Mandell and Polse, 1969; Polse, 1972). The mechanism of this change has been likened by Stone (1973) to the curvature change of a hard negative corneal lens during its hydration/dehydration cycle (Gordon, 1965). The resultant increases and decreases in myopia (and astigmatism) have been well documented by Rengstorff (1989).

It is often not realized that the presence of corneal oedema alone can lead to a small increase in myopia – the lowering of the corneal refractive index due to the imbibition of water actually increases the total power of the cornea, a decrease in index of 0.01 giving rise to a power increase of approximately +0.12 D. This surprising result occurs because the back surface of the cornea has no effect as a negative powered surface once the corneal refractive index drops to that of the aqueous (1.336). Therefore, as the corneal refractive index lowers during oedema, the corneal back surface has less and less neutralizing effect on the front surface power (Rengstorff and Arner, 1971). The small change in corneal thickness brought about by oedema has little effect, on its own, on corneal power. It is the lowering of refractive index and the accompanying curvature change which affects the refractive error.

With soft lens wear the cornea may suffer an increase in thickening due to oedema if a low Dk material is used. This thickening tends to occur over the entire cornea and is not as localized as with a PMMA or low Dk rigid corneal lens, although during soft lens wear the greatest oedema tends to correspond to the thickest part of the lens, i.e. central with positive lenses and more peripheral with negative lenses. Thus the corneal curvature change with soft lens wear may vary from very slight steepening to very slight flattening. The associated change in refractive error is also very small (Mandell, 1975). The oedema which leads to a uniform thickness increase in the cornea and therefore to a small increase in the anterior corneal radius which would decrease myopia, also leads to a drop in refractive index which would increase myopia. Thus, although soft lenses do bring about changes of the cornea, there is little effect on refractive error and therefore little associated 'spectacle blur'.

Prescribing spectacles for contact lens wearers is a topic covered in Chapter 18. The corneal changes just described obviously influence the prescription for such spectacles.

Aspects of contact lens design

The main purpose of this section is to give some guidelines to those contact lens practitioners who wish to design their own lenses. It is hoped that they can then avoid the pitfall of ordering a lens of such thickness that it is impossible to manufacture. While intended primarily for the design of rigid corneal lenses, the principles outlined in this section may be applied to any type of contact lens.

Readers are referred to papers by Campbell (1987) on the calculation of tear volume between lens and cornea, and Young (1988) who gives an overview of computer-assisted contact lens design and also to Creighton's *Contact Lenses Fabrication Tables* (1964).

The CD-ROM and the formulae given on pp. 199–224 should allow users of personal computers and programmable scientific calculators to carry out the following tedious calculations extremely quickly. However, *Figures 5.30–5.36* and the accompanying explanatory text should provide a firm understanding of the principles involved. The use of a computer or programmable scientific calculator permits much more complex lens forms to be considered than the multi-curve spherical design considered in the text here. It is thus possible to cope with aspherical lens surfaces in conjunction with ellipsoidal corneal surfaces of specific asphericity, and to design lenses to give a required central tear layer thickness and a specified corneal clearance at the lens edge, as also discussed in Chapter 10 and on pp. 202–212 of the Formulae section at the end of this chapter. Readers are recommended to study the definitive work of Bennett (1988) on the subject of aspheric and continuous curve contact lenses.

Sagitta of front and back surfaces

(*See* formulae XI and XII for spherical and ellipsoidal surfaces respectively on p. 202.)

It should be obvious from *Figure 5.30* that for both positive and negative lenses the sagitta or sag value, s_{ap}, of the front surface of a lens plus the axial edge thickness, t_{EA} must equal the primary sag (of the back surface), s_p, plus the centre thickness, t_c. Thus $s_{ap} + t_{EA} = s_p + t_c$.

For a positive lens there is a danger of ordering the centre thickness too small to permit adequate edge thickness, and for a negative lens the attempt to keep the edge thickness reasonably small may result in the centre of the lens becoming excessively thin.

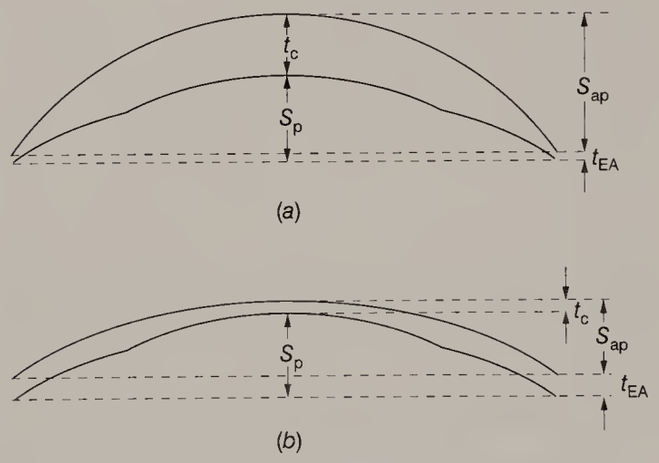


Figure 5.30 $s_{ap} + t_{EA} = s_p + t_c$ (*a*) Positive lens; (*b*) negative lens. (Note: $s_{ap} = s_{ao}$ when the front surface of the lens has one single curve of radius r_{ao}

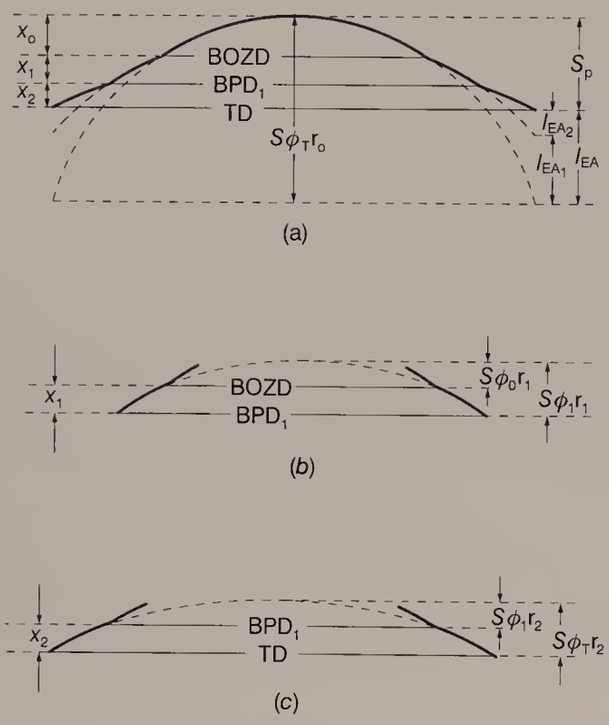


Figure 5.31 Back surface of a lens. (*a*) $s_p = x_0 + x_1 + x_2$; $l_{EA} = s_{\phi_T r_o} - s_p$; $l_{EA} = l_{EA_1} + l_{EA_2}$; (*b*) $x_1 = s_{\phi_1 r_1} - s_{\phi_o r_1}$; (*c*) $x_2 = s_{\phi_T r_2} - s_{\phi_1 r_2}$. (Note: BOZD = ϕ_0, $BPD_1 = \phi_1$, TD = ϕ_T)

The values for s_p and s_{ap} may be found as follows:

Primary sag (S_p) (see formula XXXII, p. 222)

From *Figure 5.31* it can be seen that the primary sag of the back surface of a tri-curve corneal lens is $x_o + x_1 + x_2$ where x_o is the sag of the BOZR at the BOZD = $s_{\phi_o r_o}$.
x_1 and x_2 may be determined by studying *Figure 5.31 b, c*.

Thus, $x_1 = s_{\phi_1 r_1} - s_{\phi_o r_1}$ where $s_{\phi_1 r_1}$ is the sag of BPR_1 at BPD_1 and $s_{\phi_o r_1}$ is the sag of BPR_1 at BOZD. x_2 is determined in exactly the same manner as x_1 (*see Figure 5.31c*).

Thus $x_2 = s_{\phi_T r_2} - s_{\phi_1 r_2}$ where $s_{\phi_T r_2}$ is the sag of BPR_2 at TD (or BPD_2 if the lens has more than three back surface curves) and $s_{\phi_1 r_2}$ is the sag of BPR_2 at BPD_1.

It can be seen, then, that the primary sag of a C3 lens is given by $s_P = x_o + (s_{\phi_1 r_1} - s_{\phi_o r_1}) + (s_{\phi_T r_2} - s_{\phi_1 r_2})$ and for a C4 lens $s_P = x_o + (s_{\phi_1 r_1} - s_{\phi_o r_1}) + (s_{\phi_2 r_2} - s_{\phi_1 r_2}) + (s_{\phi_T r_3} - s_{\phi_2 r_3})$. All the individual sag values may be obtained directly from formula XI (or XII for ellipsoidal surfaces), p. 202, or from the CD-ROM. For example the tri-curve corneal lens C3 8.00: 7.00/9.05: 7.80/10.80: 8.60 has a primary sag, s_P, which can be calculated as follows:

x_o = sag of BOZR of 8.00 mm at BOZD of 7.00 mm

= **0.806 mm**

$x_1 = s_{\phi_1 r_1} - s_{\phi_o r_1}$

Now $s_{\phi_1 r_1}$ = sag of 9.05 mm (BPR_1) at 7.8 mm (BPD_1)

= 0.883 mm

$s_{\phi_o r_1}$ = sag of 9.05 mm (BPR_1) at 7.0 mm (BOZD)

= 0.704 mm

Thus x_1 = 0.883 − 0.704 = **0.179 mm**

$x_2 = s_{\phi_T r_2} - s_{\phi_1 r_2}$

Now $s_{\phi_T r_2}$ = sag of 10.80 mm (BPR_2) at 8.6 mm (TD)

= 0.893 mm

and $s_{\phi_1 r_2}$ = sag of 10.80 mm (BPR_2) at 7.8 mm (BPD_1)

= 0.729 mm

So x_2 = 0.893 − 0.729 = **0.164 mm**

And primary sag $s_P = x_O + x_1 + x_2$

= 0.806 + 0.179 + 0.164

= **1.149 mm**

(Note: Small discrepancies may occur in the third place of decimals due to rounding.)

Axial edge thickness (t_{EA})

When using sagitta-involved methods of designing lenses it is necessary to measure thickness values parallel to the primary axis of the lens, although this involves using axial edge and junction thicknesses, which are terms not used in International Standard ISO 8321:1 (1991) and British Standard 7208: Part 1 (1992). The abbreviation t_{EA} has therefore been used here to denote axial edge thickness, and similarly t_{JA} to denote axial junction thickness, as compared to t_{ER} and t_{JR} which refer to the respective radial measurements.

In order to determine the centre thickness and therefore front surface details, t_{EA} may be chosen as any desired value. It will therefore be taken as 0.15 mm for the purposes of this example.

Front surface sag ($S_{ap} = S_{ao}$ for lenses with a single front surface curve, r_{ao})

Now suppose the lens with the above primary sag value of 1.149 mm is to be made up with F'_v = +2.00 D, using a material having refractive index (n) = 1.47.

First choose an appropriate axial thickness for the edge of the lens (t_{EA}), as indicated above.

Suppose t_{EA} = 0.15 mm. The sagitta of the required front surface (s_{ao}) can be calculated using formula XXXVII (see Formulae section, p. 214), where Q, A and B are 'sub' values required for this formula, and other symbols are as above. (The lens is assumed to be infinitely thin at this stage.)

(In the following calculations the symbol * represents a multiplication sign as now used by computers and calculators.)

Back surface power = F_2 = (1.00 – 1.47)/0.008 m

= **–58.75 D** (from *III*)‡

Front surface power = F_1 'thin' = $F'_v - F_2$

= +2.00 – –58.75 = **+60.75 D**

Focal length of F_1 'thin' (in mm) = f_1 'thin'

= 1000/60.75 D

= **16.461 mm**

$Q = s_P - t_{EA}$ = 1.149 – 0.15 = **0.999 mm**

$A = n*f_1$ *'thin'* $- Q$

= 1.47 * 16.461 – 0.999 = **23.199 mm**

$y = \phi_T/2$ = 8.6/2 = **4.3 mm**

$B = n - 2(n - 1.00)$ = 1.47 – (2 * 0.47)

= 1.47 – 0.94 = **0.53**

Enter the values ***n, A, y*** and ***B*** into formula **XXXVII** to calculate s_{ao}.†

$$s_{ao} = ((n-1)*A - \sqrt{((n-1)^2*A^2 - y^2*n*B)})/B$$

s_{ao} = (0.47*23.199

$- \sqrt{(0.47^2*23.199^2 - 4.3^2*1.47*0.53)})/0.53$

= (10.903 – $\sqrt{(0.221*538.172 - 18.49*0.779)})/0.53$

= (10.903 – $\sqrt{(118.882 - 14.406)})/0.53$

= (10.903 – $\sqrt{(104.477)})/0.53$

= (10.903 – 10.221)/0.53

= 0.682/0.53

= **1.287 mm** (from *XXXVII*)

Anterior optic radius (r_{ao})

$r_{ao} = (y^2 + s_{ao}^2)/(2*s_{ao})$ = (18.49 + 1.655)/2.573

= 20.145/2.573

= **7.829 mm** (from *XVII*)

Centre thickness (t_c)

$t_c = s_{ao} + t_{EA} - s_P$ (*see* p. 189 and *Figure 5.30*)

= 1.287 + 0.15 – 1.149

= **0.288 mm**

Lenticular lenses

If, in the above example, it is felt that the t_c of 0.288 mm is too great, but the t_{EA} of 0.15 mm is desirable, then a lenticular front surface must be designed. It is convenient, although not essential, to make the central lenticular diameter (ϕ_{ao}) the same as the back optic zone diameter (ϕ_o), so let $\phi_{ao} = \phi_o$ = 7.00 mm and, so that the lens will have a parallel carrier zone, let the junction thickness (t_{JA}) = t_{EA} = 0.15 mm.

Calculation of s_{ao} (now $s_{\phi_{ao}r_{ao}}$ for the lenticular front surface, *see Figure 5.32*), r_{ao} and t_c for the central lenticular surface is the same as for the anterior surface of the full aperture lens above except that t_{JA} is used instead of t_{EA} (in this example they are the same) and the primary sag of the *back* surface must be calculated at ϕ_{ao} instead of ϕ_T.

All the values for formula ***XXXVII*** remain the same except ***y*** and ***Q***, and of course, the value ***A*** because it contains ***Q*** (*see* explanation on p. 215).

y now = $\phi_{ao}/2$ = 7.00/2 = **3.5 mm**

Q now = $s_{\phi_{ao}P} - t_{JA}$

As $\phi_{ao} = \phi_o$, $s_{\phi_{ao}P}$ = the sag of the back central optic surface = **0.806 mm** (from above, p. 190).

$t_{JA} = t_{EA}$ = **0.15 mm, so *Q*** now = 0.806 – 0.15

= **0.656 mm**

$A = n*F_1$ 'thin' $- Q$ = 1.47*16.461 – 0.656

= **23.541 mm**

$$s_{ao} = s_{\phi_{ao}r_{ao}} = ((n-1)*A - \sqrt{((n-1)^2*A^2 - y^2*n*B)})/B$$

- - - - ***XXXVII***

$s_{ao} = s_{\phi_{ao}r_{ao}}$ = (0.47*23.541

$- \sqrt{(0.47^2*23.541^2 - 3.5^2*1.47*0.53)})/0.53$

= **0.83 mm** (from ***XXXVII***)

$s_{ao} = s_{\phi_{ao}r_{ao}}$ is used to calculate the lenticular r_{ao}

$r_{ao} = (y^2 + s_{\phi_{ao}r_{ao}}^2)/(2*s_{\phi_{ao}r_{ao}})$ - - - - ***XVII***

r_{ao} = (12.25 + 0.689)/1.661 = **7.792 mm** (from ***XVII***)

and

$t_c = s_{\phi_{ao}r_{ao}} + t_{JA} - s_{\phi_{ao}P}$ (*see* p. 216 and *Figure 5.32*)

= 0.83 + 0.15 – 0.806

= **0.174 mm**

Thus lenticulation has reduced t_c by about 40% from 0.288 mm to 0.174 mm.

† The values shown above have been rounded to three decimal places for clarity on the printed page. However, calculators operate in floating decimal mode, even when the number of decimal places displayed is deliberately limited.

The sags, radii, thicknesses etc. have been calculated to an accuracy of ten decimal places where appropriate. This explanation is given in case a student is puzzled by the slightly different results obtained if the rounded figures are entered into the various formulae.

‡ All figures in **bold** Roman numerals refer to the numbers of the appropriate formulae in the Formulae section which commences on p. 198.

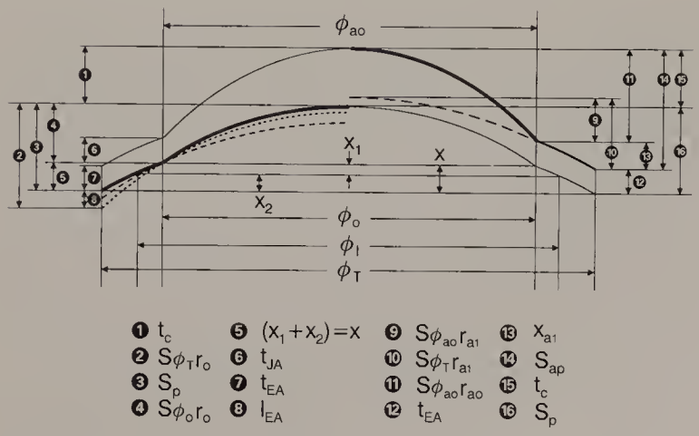


Figure 5.32 Positive lens with reduced optic zone and 'parallel' carrier zone (i.e. axial edge and junction thicknesses are the same) and having the same back and front optic zone diameters. The heavy lines on the left-hand side show the tri-curve back surface with related sag values and thicknesses. On the right-hand side, the heavy lines show the bi-curve front surface and related sag values

Calculation of front peripheral radius (r_{a1})

The lens is to have a 'parallel' carrier (*see below*, Form of the carrier zone), so t_{EA} must = t_{JA}. Therefore the anterior peripheral radius, r_{a1}, must provide the same sag value (x_{a1}) between ϕ_{ao} and ϕ_T as the sag provided by the peripheral geometry of the *back* surface from ϕ_{ao} out to ϕ_T. In this example, this back surface sag is x which = $(x_1 + x_2)$ (*see Figures 5.32* and *5.37* and Formulae section, pp. 216 and 217). This statement is true for any form of back surface.

Using a little lateral thinking then, the data from the back surface may be used to design the front peripheral surface. There are two methods of determining the sag, x, of the back peripheral surface (which determines the value for x_{a1}). In the example being used (for a lens of back surface specification C3 8.00:7.0/9.05:7.8/10.80:8.6)

$x = (x_1 + x_2)$

$= (s_{\phi_1 r_1} - s_{\phi_o r_1}) + (s_{\phi_T r_2} - s_{\phi_1 r_2})$
(*see* p. 190, also *Example 26*, p. 216 and ***XXVIII*** and ***XXXVIII***)

$= (0.8835 - 0.7042) + (0.8929 - 0.7288)$ (sags from ***XI***

$= \mathbf{0.3434\,mm} = x_{a1}$

Alternatively (*see* Formula ***XXIX***) x may be determined if the axial edge lift, l_{EA} is known.

Now $l_{EA} = s_{\phi_T r_o} - s_p$ (*see Figure 5.32*)

and $s_{\phi_T r_o} = 1.254\,mm$ (from ***XI***)

$-s_p = \underline{1.149\,mm}$ (*see above*, Primary sag, p. 190)

Thus $l_{EA} = \underline{0.105\,mm}$

(Axial edge lift is considered in more detail on p. 195 and in formulae ***XXVIII*** to ***XXXII***, as well as in Chapter 10.)

Using formula ***XXIX***, $x_N = s_{\phi_T r_o} - s_{\phi_o r_o} - Dl_{EA}$
(where Dl_{EA} = *D*esired l_{EA})

Thus $x_N = x = x_{a1} = 1.254 - 0.806 - 0.105$
(sags from ***XI***)
$= \mathbf{0.343\,mm}$ (as above)

This enables the anterior peripheral radius to be calculated as follows:

$$r_{a1} = \sqrt{(((y_{\phi_T} - y_o^2 - x_N^2)/(z * x_N))^2 + y_{\phi_T}^2)} \quad \text{- - - - ***XXVIII***}$$

$$= \sqrt{(((4.3^2 - 3.5^2 - 0.343^2)/(2 * 0.343))^2 + 4.3^2)}$$

$= \mathbf{9.913\,mm}^{\dagger}$

Now that r_{a1} is known, confirmation that the carrier zone is indeed parallel-surfaced may be established by showing that $t_{EA} = t_{JA}$ (which has been chosen to be 0.15 mm). This necessitates determining the primary sag s_{ap} of the *anterior* surface.

$s_{ap} = s_{\phi_{ao} r_{ao}} + (s_{\phi_T r_{a1}} - s_{\phi_{ao} r_{a1}})$ (*see Figure 5.32*)

$= 0.830 + (0.981 - 0.638)$

$= \mathbf{1.173\,mm}^{\dagger}$

Figures 5.30 and *5.32* show that

$t_{EA} = s_p + t_c - s_{ap}$

Thus

$t_{EA} = 1.149 + 0.174 - 1.173 = \mathbf{0.15\,mm} = t_{JA}$

For negative and positive carrier zones and for lenses in which ϕ_{ao} differs from ϕ_o *see* Formulae section, pp. 216–219.

Form of the carrier zone

It is of interest here to review the significance of the relationship between axial edge thickness, t_{EA}, and axial junction thickness, t_{JA}, at the edge of the lenticular zone. The form of the carrier zone of a lenticular lens affects the position which the lens takes up on the eye. A lens is said to have a negative carrier zone when its edge thickness is greater than the junction thickness and a positive carrier zone when the reverse applies, the thickness relationship being similar to that of negative and positive lenses. Lenses having negative and parallel surfaced carrier zones have been found to provide better attachment of the lens to the upper eyelid than positive carrier zones, which encourage the lens to drop. Lenses which move with the upper eyelid are less likely to stick to the cornea, they give better tears exchange, and are less likely to give rise to corneal oedema or drying than lenses which drop and remain low on the cornea. It is therefore desirable for the edge thickness to be equal to or greater than the junction thickness in order to provide a parallel surfaced or negative zone, respectively (*see* Chapter 10).

† See footnote on p. 191.

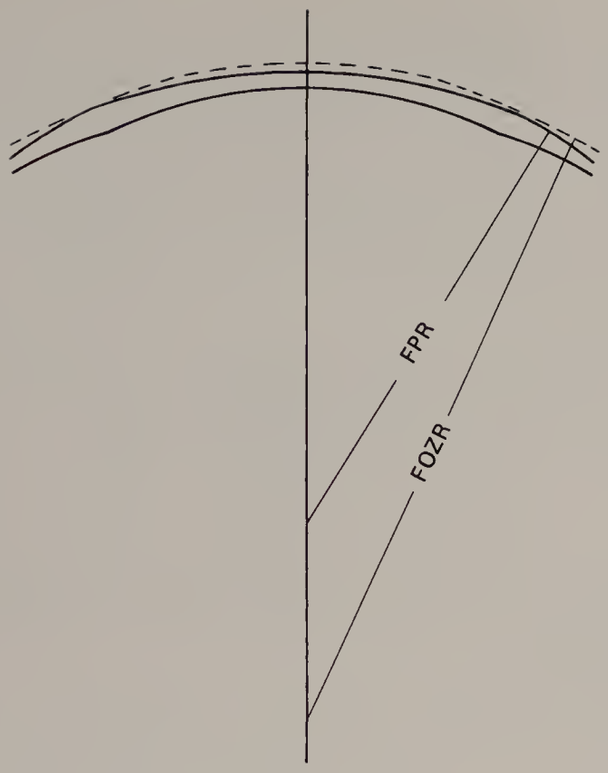


Figure 5.33 Lenticular negative lens

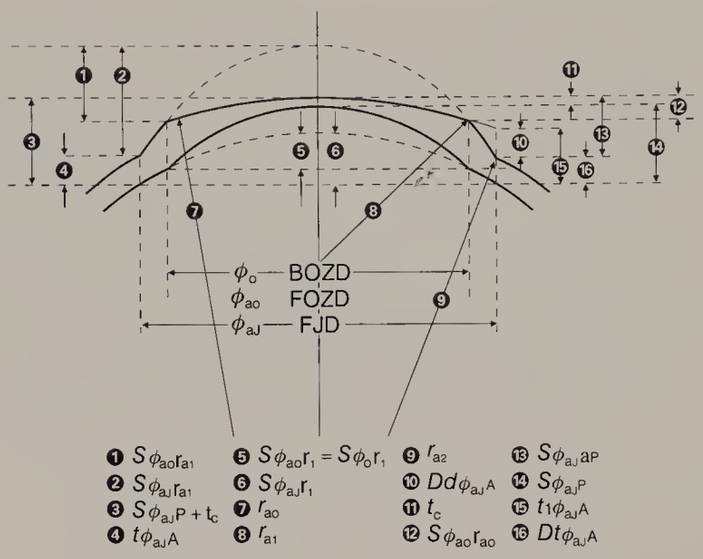


Figure 5.34 Negative lenticular lens with front junction radius (r_{a1}). The diagram shows all the parameters needed for calculation of r_{a1} to give a desired axial junction thickness at the anterior junction diameter. (Axial junction thickness symbols are $t_{\phi_{aJ}A}$ or t_{JA} and $Dt_{\phi_{aJ}A}$ – the desired axial junction thickness, *see text*, p. 194. Note: $Dt_{\phi_{aJ}A}$, the desired axial junction thickness, equals the original axial junction thickness, $t_{1\phi_{aJ}A}$, less the desired axial drop, $Dd_{\phi_{aJ}A}$, as shown on the right hand side of the diagram)

Negative lenses

Because these lenses do not suffer from excessive centre thickness problems, the approach to determining front surface radii is somewhat different from positive lenses.

For full aperture lenses *see* Formulae section, pp. 212–216, formulae XXXV to XXXVII.

If excessive edge thickness becomes a problem a reduced optic design can be employed (*see Figure 5.33*). A front peripheral radius (r_{a1}) can be calculated for the carrier zone which will give the desired edge thickness (*see* 'calculation of front peripheral radius' for the +2.00 lens above and Formulae section, p. 216).

With negative lenses of high power, a desirable edge thickness frequently results in the lens having a positive carrier zone because the edge thickness is less than the junction thickness. This positive carrier zone encourages the lens to drop whereas it may be more desirable for the lens to attach to the upper lid. Since 'lid attachment' is more likely to be achieved with a negative or parallel surfaced carrier zone some way must be found of reducing the junction thickness. By creating a ***F***ront ***J***unction ***R***adius (which becomes r_{a1}) the junction thickness may be reduced so that it is equal to or less than the edge thickness, the carrier zone thereby becoming parallel surfaced or negative, respectively. Such an *FJR* (now r_{a1}) and front peripheral radius (now r_{a2}) are shown in *Figure 5.34*.

Occasionally, with very high powered negative lenses a front junction radius (r_{a1}) is necessary anyway to join r_{ao} to r_{a2}. From *Figure 5.34* it can be seen that the front junction radius (r_{a1}) is a shorter radius than either r_{ao} or r_{a2}.

Example (using the same back surface specification)

The **C3** lens **8.00:7.00/9.05:7.80/10.80:8.60** is to be made with F'_v = **–10.00 D**, t_c = **0.1 mm** (= **0.0001 m**), and, in this example, with ϕ_{ao} equal to ϕ_o. The material chosen is **Paraperm O_2**, refractive index (n) = 1.48.

The power of the front surface (F_1) can be found by tracing light backwards through the lens, in the direction shown in *Figure 5.25* on p. 181.

$$\text{The power of the back surface } (F_2) = \frac{n-1}{r_o}$$

$$= \frac{1.48 - 1*10^3}{-8.00} = \frac{480}{-8} = \textbf{–60.00 D} \text{ (from } \textit{III}\text{)}$$

(r_o has a –ve sign because it is measured from surface to centre of curvature which is now in the *opposite* direction to that in which the light is travelling).

$$L'_1 = F_2 - F'_v = -60.00\,\text{D} - -10.00\,\text{D} = \textbf{–50.00 D}$$

$$L_2 = L'_1/(1 - t_c/n*L'_1)$$

$$= -50.00/(1 - 0.0001/1.48* - 50.00)$$

$$= \textbf{–49.83 D} \text{ (from } \textit{XXII}\text{)}$$

Light must emerge parallel from F_1 therefore F_1 = **+49.83 D**

$$r_{ao} = \frac{1.48 - 1*10^3}{F_1} = \frac{480}{49.83} = \textbf{9.63 mm} \text{ (from } \textit{IV}\text{)}$$

[For calculators:

(combining formulae ***IV*** and a modified version of ***XXIII***)

$r_{ao} = (1-n)*10^3/(((1-n)*10^3/r_o - F'_v)^{-1} - t_c/n/10^3)^{-1}$ - - - - ***XXXV*** (r_o and t_c in mm)

$r_{ao} = (1-1.48)*10^3/(((1-1.48)*10^3/8.0 - -10.00)^{-1} - 0.1/1.48/10^3)^{-1}$ = **9.63 mm**]

The sagitta, s_{ap} of the front surface at ϕ_T

$= 9.63 - \sqrt{(9.63^2 - 4.3^2)}$ = **1.013 mm** (from ***XI***)

$t_{EA} = s_p + t_c - s_{ap}$ (*see Figure 5.30*, p. 189).

If the lens is made in full aperture form

t_{EA} = 1.149 + 0.1 − 1.013 = **0.236 mm**

which, despite the choice of a relatively high refractive index, is thicker than is desirable.

Axial thickness at ϕ_o, $t_{\phi_o A}$

$= s_{\phi_o r_o} + t_c - s_{\phi_o r_{ao}}$

$= 0.806 + 0.1 - (9.63 - \sqrt{(9.63^2 - 3.5^2)})$

$= 0.806 + 0.1 - 0.659$

= **0.247 mm**

($t_{EA} < t_{\phi_o A}$ because of the substance removed to create the back surface peripheral curves thus giving a slightly 'positive' form of peripheral zone).

If substance is removed from the periphery of the front surface to reduce t_{EA} from 0.236 mm to say 0.15 mm, the positive carrier effect, unfortunately, will be augmented. To maintain a parallel or negative carrier requires a front junction radius to be calculated, and this is simplified by introducing the concept of edge *drop D*, as distinct from edge *lift*. In formula ***XXIX***, $x_N = (s_{\phi_G r_{N-1}} - s_{\phi_{G-1} r_{N-1}} - Dl_{EAN})$ (*see* Formulae section, p. 206. This can be modified to $x_N = (s_{\phi_G r_{N-1}} - s_{\phi_{G-1} r_{N-1}} + Dl_{EAN})$ - - - - ***XXIX***(*D*), to produce a value x_N which, when used with formula ***XXVIII***, will yield a ***F***ront ***J***unction ***R***adius to create a stipulated ***A***xial (***E***dge) ***drop*** (d_{EA}), as opposed to ***A***xial (***E***dge) ***l***ift (l_{EA}) at a ***G***iven diameter. In this example let the ***G***iven diameter be a chosen ***a***nterior ***J***unction ***d***iameter (ϕ_{aJ}), say 7.60 mm, and $\phi_{G-1} = \phi_{ao}$ = 7.00 mm.

As this axial drop is not specifically at the edge of the lens in this calculation, the symbol $Dd_{\phi_{aJ}A}$ will be used:

$Dd_{\phi_{aJ}A} = t_{\phi_{aJ}A} - Dt_{\phi_{aJ}A}$ (*see Figure 5.34*)

Where

$Dd_{\phi_{aJ}A}$ = ***D***esired ***A***xial (***E***dge) ***drop*** at the ***J***unction ***d***iameter

$t_{1\phi_{aJ}A}$ = ***A***xial ***t***hickness at the proposed ***a***nterior ***J***unction ***d***iameter **before** the junction radius is incorporated.

$t_{1\phi_{aJ}A} = s_{\phi_{aJ}P} + t_c - s_{\phi_{aJ}r_{ao}}$

$s_{\phi_{aJ}P}$ = ***P***rimary ***s***ag at the proposed ***a***nterior ***J***unction ***d***iameter.

$s_{\phi_{aJ}r_{ao}}$ = ***s***ag of r_{ao} at the proposed ***a***nterior ***J***unction ***d***iameter.

$Dt_{\phi_{aJ}A}$ = ***D***esired ***A***xial ***t***hickness at the proposed ***a***nterior ***J***unction ***d***iameter.

t_c = ***c***entre ***t***hickness.

$s_{\phi_{aJ}P} = s_{\phi_o r_o} + s_{\phi_{aJ} r_1} - s_{\phi_o r_1}$ =

0.806 + 0.836 − 0.704 = 0.938 mm (sags from ***XI***)

+ t_c = 0.100 mm

Total sag at ϕ_{aJ} = $s_{T\phi_{aJ}}$ = 1.038 mm

− $s_{\phi_{aJ}r_{ao}}$ = 0.781 mm (from ***XI***)

Thus, $t_{1\phi_{aJ}A}$ = 0.257 mm

− $Dt_{\phi_{aJ}A}$ = 0.150 mm

Thus, $Dd_{\phi_{aJ}A}$ = 0.107 mm

which is the ***D***esired ***A***xial (***E***dgc) drop at the ***J***unction diameter.

[For calculators:

$$Dd_{\phi_{aJ}A} = r_o - \sqrt{(r_o^2 - y_o^2)} + (r_1 - \sqrt{(r_1^2 - y_{aJ}^2)}) - (r_1 - \sqrt{(r_1^2 - y_o^2)}) + t_c - (r_{ao} - \sqrt{(r_{ao}^2 - y_{aJ}^2)}) - Dt_{\phi_{aJ}A}$$

where

y_o = ***b***ack ***o***ptic zone ***d***iameter/2.
y_{aJ} = ***a***nterior ***J***unction ***d***iameter/2
Other symbols as above.

$Dd_{\phi_{aJ}A}$ = 0.806 + 0.836 − 0.704 + 0.1 − 0.781 − 0.15

= **0.107 mm** (sags from ***XI***)]

Now, to determine front junction radius, r_{a1}:

$x = s_{\phi_{aJ}r_{ao}} - s_{\phi_{ao}r_{ao}} + Dd_{\phi_{aJ}A}$ = 0.781 − 0.659 + 0.107

= **0.229 mm** (from ***XXIX***(*D*) above)

$r_{a1} = \sqrt{(((y_{aJ}^2 - y_{aO}^2 - x^2)/(2*x))^2 + y_{aJ}^2)}$ - - - - from ***XXVIII***

Thus,

$r_{a1} = \sqrt{(((3.8^2 - 3.5^2 - 0.229^2)/(2*0.229))^2 + 3.8^2)}$

r_{a1} = **6.011 mm**

6.011 mm is considered to be fairly steep, although acceptable, for r_{a1}. If the calculated figure for r_{a1} is less than 5.5 mm, r_{a1} should be recalculated increasing the proposed ϕ_{aJ} in 0.1 mm steps to obtain a more reasonable value.

As a general guide there is little advantage in using a junction radius greater than 8.5 mm unless ϕ_T (TD) is greater than 10.00 mm.

Confirmation of the correct axial junction thickness required is as follows:

$t_{\phi_{aJ}A}$ = ***A***xial ***t***hickness at ***a***nterior ***J***unction ***d***iameter.

$t_{\phi_{aJ}A} = s_{\phi_{aJ}P} + t_c - s_{\phi_{aJ}P} = s_{T\phi_{aJ}} - s_{\phi_{aJ}P}$

Where

$s_{\phi_{aJaP}}$ = ***P***rimary ***s***ag of ***a***nterior surface at ***a***nterior ***J***unction ***d***iameter.

$s_{\phi_{aJaP}} = s_{\phi_{ao}r_{ao}} + s_{\phi_{aJ}r_{A1}} - s_{\phi_o r_{a1}}$

$= 0.659 + 1.353 - 1.124$

$= 0.888$ mm (sags from ***XI***; other symbols as above).

Now,

$s_{\phi_{aJP}} + t_c = s_{T\phi_{aJ}} = 1.038$ mm (from above p. 194)

$- s_{\phi_{aJaP}} = 0.888$ mm (from above)

$= t_{\phi_{aJ}A} =$ **0.150 mm**

[For calculators:

$$t_{\phi_{aJ}A} = r_o - \sqrt{(r_o^2 - y_o^2)} + (r_1 - \sqrt{(r_1^2 - y_{aJ}^2)}) - (r_1 - \sqrt{(r_1^2 - y_o^2)}) + t_c - ((r_{ao} - \sqrt{(r_{ao}^2 - y_{ao}^2)}) + (r_{a1} - \sqrt{(r_{a1}^2 - y_{aJ}^2)}) - (r_{a1} - \sqrt{(r_{a1}^2 - y_{ao}^2)}))$$

(Symbols as above)

$t_{\phi_{aJ}A} = 0.806 + 0.836 - 0.704 + 0.1 - (0.659 + 1.353 - 1.124) =$ **0.150 mm**]

To create a parallel surfaced carrier, r_{a2} must provide the same sag, x_{a2}, as provided by the ***back*** surface peripheral curves ***from*** ϕ_{aJ} ***out to*** ϕ_T (sag x).

The value for the back surface sag from ϕ_{aJ} to ϕ_T, in this case,

$= s_{\phi_1 r_1} - s_{\phi_{aJ}r_1} + s_{\phi_T r_2} - s_{\phi_1 r_2} = 0.211$ mm

Alternatively it may be found by determining the edge lift between ϕ_{aJ} and ϕ_T, Dl_{EA}, and using this in formula ***XXIX*** as follows:

$Dl_{EA} = l_{EA}$ from ϕ_{aJ} out to ϕ_T = Total $l_{EA} - l_{EA}$ at ϕ_{aJ}

$Dl_{EA} = 0.105$ {from above, p. 192} $- (s_{\phi_{aJ}r_o} - s_{\phi_{aJP}})$

$Dl_{EA} = 0.105 - ((8.0 - \sqrt{(8.0^2 - 3.8^2)}) - 0.938$ {from above, p. 194}

$Dl_{EA} = 0.105 - (0.960 - 0.938) = 0.105 - 0.022$

$=$ **0.083 mm**

Thus $x = s_{\phi_T r_o} - s_{\phi_{aJ}r_o} - Dl_{EA}$ (from ***XXIX***, *see* p. 206)

$= 1.254 - 0.96 - 0.083$

$x = 0.211$ mm (from ***XXIX***)

Thus $x_{a2} = x = 0.211$ mm

and

$r_{a2} = \sqrt{(((y_{\phi_T}^2 - y_{\phi_{aJ}}^2 - x^2)/(2*x))^2 + y_{\phi_T}^2)}$ (from ***XXVIII***, *see* p. 206)

$r_{a2} = \sqrt{(((4.3^2 - 3.8^2 - 0.211^2)/(2*0.211))^2 + 4.3^2)}$

$r_{a2} =$ **10.42 mm** (from ***XXVIII***)

To confirm that this radius gives the required edge thickness may be shown as follows:

Establish the primary sag of the anterior surface (s_{ap})

$s_{ap} = s_{\phi_{ao}r_{ao}} + s_{\phi_{aJ}r_{a1}} - s_{\phi_{aO}r_{a1}} + s_{\phi_T r_{a2}} - s_{\phi_{aJ}r_{a2}}$

$= 0.659 + 1.354 - 1.124 + 0.929 - 0.718$ (sags from ***XI***)

$=$ **1.099 mm**

Then

$t_{EA} = s_p + t_c - s_{ap} = 1.149 + 0.1 - 1.099$

$=$ **0.150 mm** $= t_{\phi_{aJ}A}$

Tears layer thickness

The BOZD and BOZR of a lens may be chosen to give a required central clearance between lens and cornea. This is known as the apical tears layer thickness or TLT (*see Figure 10.13*). It is the difference in sag value between the primary sag of the lens at the contact diameter, usually the BOZD, and the sag of the cornea at the contact diameter. In contact lens designs the BOZD values used are too large to assume that the corneal cross-section is an arc of a circle at this diameter, so that the corneal contour must either be measured (*see* Chapter 6) or assumed. More detail is given in Chapter 10, pp. 314–317 and 330–333. Formulae XI to XVII on pp. 202–204 show how the sagitta of spherical (***XI***) and ellipsoidal (***XII***) surfaces are derived; how the apical radius of the cornea can be obtained for a specific keratometer reading and known asphericity (***XIII*** and ***XV***) taking into account the mire separation of the keratometer used (***XIV***). Formula XVI then makes use of this information to obtain TLT and formula XVII shows how the BOZR of a lens may be changed to give a required alteration to TLT. Values for TLT range from 0.01 mm to 0.02 mm and are specified in microns (0.001 mm).

Axial edge lift and axial edge clearance

Another aspect of lens design is to create peripheral curves which will give a desired axial edge lift (*see* Chapter 10 and the CD-ROM). If a specific axial edge clearance (AEC) is required, the peripheral corneal contour must be assumed or measured (*see* Chapters 6 and 10) as for TLT (*above*). Then a lens of suitable axial edge lift is designed to give the necessary clearance at the total diameter of the lens. Suitable use of sag formulae is required. (*See also* p. 222 and *Figure 5.40*)

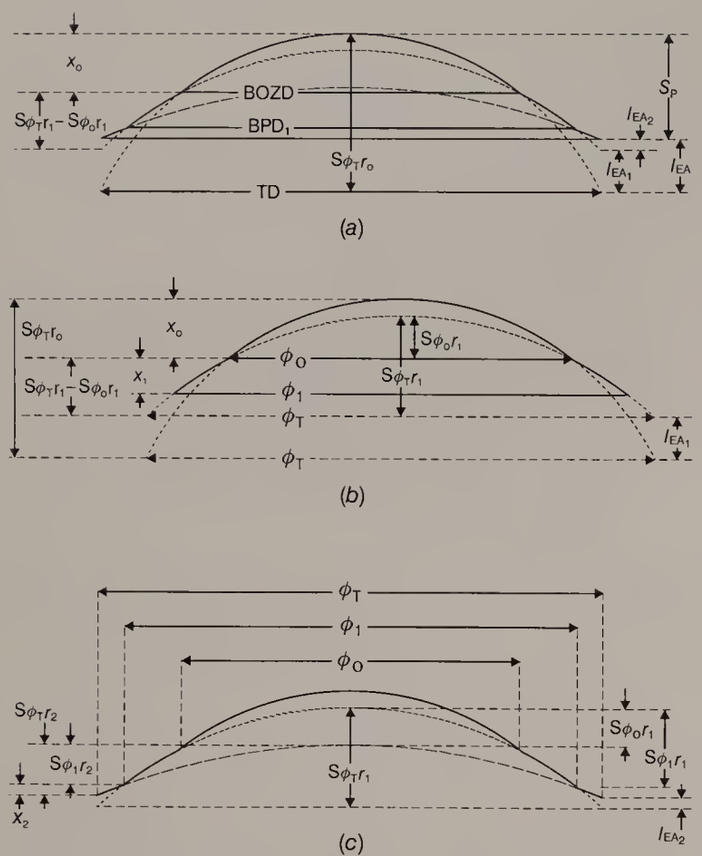


Figure 5.35 (*a*) Axial edge lift $l_{EA} = l_{EA1} + l_{EA2} = s_{\phi_T r_o} - s_p$; (*b*) $l_{EA1} = s_{\phi_T r_o} - (x_o + s_{\phi_T r_1} - s_{\phi_o r_1})$; (*c*) $l_{EA2} = s_{\phi_T r_1} - s_{\phi_1 r_1} - x_2$ and $x_2 = s_{\phi_T r_2} - s_{\phi_1 r_2}$. (Note: BOZD = ϕ_o, $BPD_1 = \phi_1$, TD = ϕ_T)

Axial edge lift, l_{EA}, is then calculated in the following manner:

From *Figure 5.35a* it is seen that for a tri-curve lens, the axial edge lift $l_{EA} = s_{\phi_T r_o} - s_p$ where s_p is the primary sag and equals $x_o + x_1 + x_2$ (*see Figure 5.31a*). If the two peripheral curves are to contribute equally to the edge lift then l_{EA_1} must be equal to l_{EA_2} where $l_{EA_1} + l_{EA_2} = l_{EA}$.

For example, a lens has a BOZR of 8.00 mm. The BOZD is 7.00 mm, BPD_1 is 7.80 mm and TD is 8.60 mm. An axial edge lift of 0.12 mm is required, of which 0.06 mm is to be contributed by BPR_1, and 0.06 mm by BPR_2. The values for BPR_1 and BPR_2 to give the necessary edge lift are determined as follows:

BPR_1

From *Figure 5.35b* it can be seen that the lens is treated first as if it were a bi-curve lens with BPR_1 extending out to the TD.

Then $l_{EA_1} = s_{\phi_T r_o} - (x_0 + s_{\phi_T r_1} - s_{\phi_o r_1})$

From above, $s_{\phi_T r_o} = l_{EA_1} + x_0 + s_{\phi_T r_1} - s_{\phi_o r_1}$

and so $s_{\phi_T r_1} - s_{\phi_o r_1} = s_{\phi_T r_o} - x_0 - l_{EA_1}$

Then using formula XI, p. 201, for the determination of sag values, and formula XXIX (pp. 194 and 206) to determine the sag value, x_N, of the peripheral curve BPR_1 between BOZD and TD, which is $s_{\phi_T r_1} - s_{\phi_o r_1}$, gives:

$s_{\phi_T r_o}$ = sag of 8.00 mm (BOZR) at 8.60 mm (TD)
= 1.254 mm

x_0 = sag of 8.00 mm (BOZR) at 7.00 mm (BOZD)
= 0.806 mm

and

$s_{\phi_T r1} = s_{\phi_T r_o} - x_0 - l_{EA}$, = 1.254 − 0.806 − 0.06
= **0.388 mm** = x_N in formula ***XXIX***

Having determined x_N, BPR_1 may be obtained from formula XXVIII where

y_{ϕ_G} = 4.3 mm (= TD/2)
$y_{\phi_{N-1}}$ = 3.5 mm (= BOZD/2)
x_N = 0.388 mm ($= s_{\phi_T r_1} - s_{\phi_o r_1}$)

Thus $r_N = r_1$ = **8.95 mm** ($= BPR_1$)

BPR_2

In the same way, a value for BPR_2 may be calculated which will yield a value of 0.06 mm for l_{EA_2}.

From *Figure 5.35c*, $l_{EA_2} = s_{\phi_T r_1} - s_{\phi_1 r_1} - x_2$ where $s_{\phi_T r_1}$ is the sag of BPR_1 at TD, $s_{\phi_1 r_1}$ is the sag of BPR_1 at BPD_1 and x_2 is now $s_{\phi_T r_2} - s_{\phi_1 r_2}$ (*see Figure 5.35c*). $s_{\phi_T r_2}$ is the sag of BPR_2 at TD, and $s_{\phi_1 r_2}$ is the sag of BPR_2 at BPD_1.

Thus $x_2 = s_{\phi_T r_1} - s_{\phi_1 r_1} - l_{EA_2}$

Again, using formulae XI and XXIX for the determination of the various sag values; for this portion of the peripheral zone, x_N in formula XXIX is x_2.

Thus $s_{\phi_T r_1}$ = sag of 9.00 mm (BPR_1) at 8.60 mm (TD)
= 1.094 mm

$s_{\phi_1 r_1}$ = sag of 9.00 mm (BPR_1) at 7.80 mm (BPD_1)
= 0.889 mm

l_{EA_2} = 0.06 mm

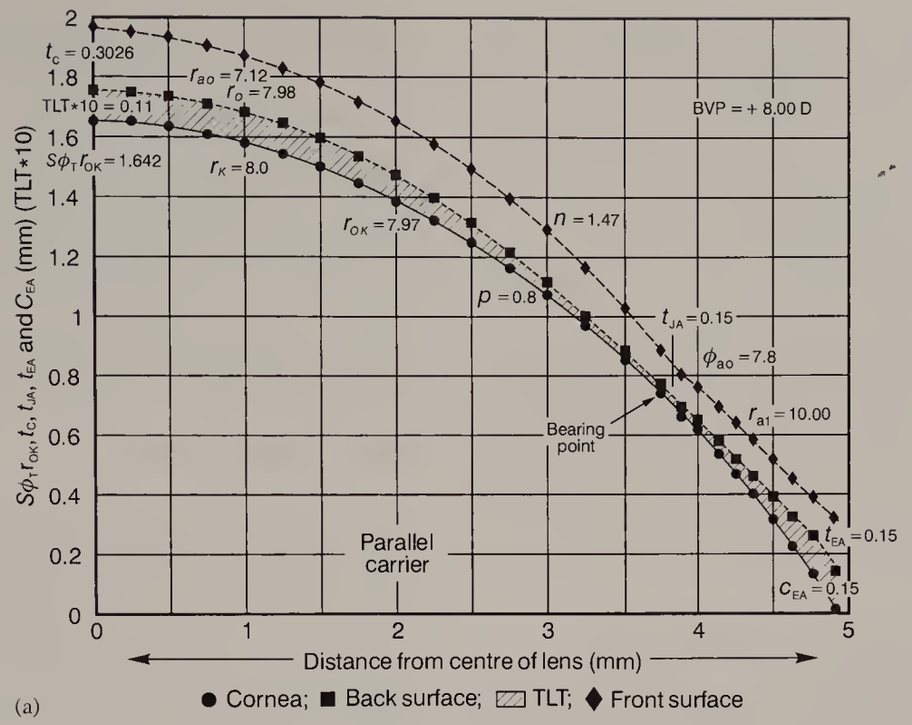
Since $x_2 = s_{\phi_T r_1} - s_{\phi_1 r_1} - l_{EA_2}$ then $x_2 = x_N$
= 1.094 − 0.889 − 0.06
= **0.146 mm**†

Using Formula XXVIII again allows BPR_2 to be obtained where

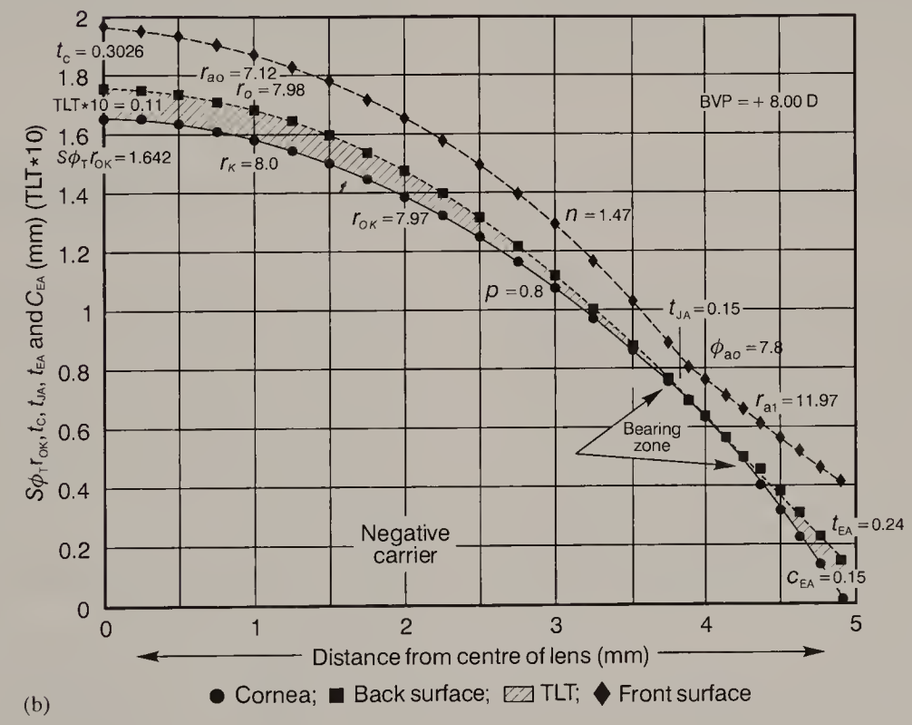
y_{ϕ_G} = 4.3 mm (= TD/2)
y_{N-1} = 3.9 mm ($= BPD_1/2$)
x_N = 0.146 mm ($= x_2$)

Thus $r_N = r_2$ = **11.96 mm** ($= BPR_2$)

† See footnote on p. 191.



(a)



(b)

Figure 5.36 (*a*) Cross-section of half a C3 spherical lenticular lens on a cornea having a spherical keratometer radius of 8.00 mm and a '*p*' value of 0.8. The lens back surface is of orthodox design giving 0.011 mm apical clearance (TLT) and 0.15 mm axial edge clearance (C_{EA}). The lens contacts the cornea at the transition between r_o and r_1. BVP = +8.00 D and the lens is depicted in lenticular form with $\phi_{ao} = \phi_o + 0.3$ mm and the carrier is parallel surfaced, ie. $t_{EA} = t_{JA}$. The horizontal axis shows distance from the lens centre and the vertical axis shows sags and thickness values: t_c, TLT (×10), t_{JA}, t_{EA}, c_{EA} and $s_{\Phi_T r_{OK}}$. Values for r_{aO} of 7.12 mm, r_o of 7.98 mm and r_K of 8.00 mm (r_{OK} = 7.97 mm) are shown. (*b*) Here r_1 and r_2 have been changed so that the surface of r_1 is parallel to the cornea creating a bearing **zone** and r_2 is increased to give the same c_{EA} (0.15 mm). The lens has a negative surfaced carrier, $t_{EA} > t_{JA}$. Primary sag (s_p) and all other parameters are the same as in (*a*). s_p = 1.5012 mm for both lenses. In the 'y' scale of the graphs (0 to 2.0 mm) the **TLT** (0.011 mm) would be barely thicker than a line so **the central tears layer only** is shown expanded by a factor of 10 for clarity, and does not therefore show the true relationship between the back optic surface and the cornea. All other parameters and measurements are to scale including c_{EA}

Therefore the two peripheral curves necessary to give a total axial edge lift of 0.12 mm are **8.95 mm** for $\mathbf{BPR_1}$ and (to the nearest 0.05 mm) **11.95 mm** for $\mathbf{BPR_2}$.

The detailed calculations and the effect on axial edge lift of rounding the values for the radii to the nearest 0.01 mm (or indeed any value, such as 0.05 mm) are dealt with in the Formulae section on pp. 207–211.

Formula XXX shows how the desired axial edge lift to be achieved from any one peripheral curve may be determined to arrive at a well-balanced peripheral zone. The total axial edge lift required must be known as well as the TD of the lens, and the diameter (ϕ_c) at which the lens contacts the cornea – usually ϕ_c = BOZD = ϕ_o.

Formula XXXI, p. 207, is a sag difference formula to give axial edge lift when peripheral radii have been given 'rounded' values. This enables the practitioner to decide if the error in axial edge lift introduced by 'rounding' is acceptable.

Axial edge lift calculation of existing lenses

Formula XXXII (p. 208) may be used for this. It is another sag difference formula to allow calculation of the axial (edge) lift value of each peripheral curve at its own outer diameter, rather than at the edge of the lens. The totals of these axial lift values are equal to the total axial edge lift of the lens. Any lens of known back surface specification may thus have its axial edge lift determined by this method.

Details of fitting sets with constant axial edge lift are given in Chapter 10 (*see Tables 10.2* and *10.5*).

Modification of peripheral radii to alter edge lift

Formula XXXII can also be used with XXVIIIA and XXIXA (adaptations of formulae XXVIII and XXIX) to determine new peripheral radii in order to alter the axial edge lift of an existing lens. For those practitioners who modify their own lenses, this can be very useful in deciding on the curvature of the polishing tools to use. It is also helpful if a new lens is to be ordered to give increased or reduced edge clearance.

Drawing lenses to scale

Another way to design lenses is to draw them to scale at ×40 full size as recommended by Mackie (1973), who described the method in detail. Graph paper, 56 × 38 cm, a drawing board and beam compass (preferably 50 cm long) are essential, as well as a contact lens slide rule or tables, or an electronic calculator. Some manufacturers have employed this method but computer programs such as those on the accompanying CD-ROM, and the formulae on pp. 199–224 now make such drawing unnecessary. *Figure 5.36* shows how computer graphics may be used to draw lenses to scale, with the scale being magnified vertically to show thicknesses and clearances more obviously, with extra magnification of the central tears layer.

Optical formulae for contact lens work with examples to illustrate their use

It is hoped that the formulae incorporated here will help to simplify and to speed up optical calculations which occur in the contact lens field. The principles involved are well covered elsewhere (Francis, 1968; Bennett, 1985), and are therefore not dealt with in detail here.

All the formulae used to calculate the tables which were printed as Appendices A to D in the previous edition of this book appear below with worked examples. Many new formulae have been added. All formulae are presented in orthodox notation and also, using the arithmetic hierarchy recognized by most scientific calculators and computers, in a form which may be useful for those who have (especially programmable) pocket calculators.

In the worked examples the results have been rounded to a few decimal places where appropriate for clarity.

Appendix A has been retained at the end of the book and is a table showing the effective power of spectacle lenses at various distances from the back surface of the spectacle lens. Thus, it can be seen from the table that a lens of back vertex power +7.00 D has an effective power of +7.76 D, in a plane 13 mm from the back surface of the lens, while the effective power of a –7.00 D lens at the same vertex distance is –6.41 D. From this table, then, can be obtained very quickly the effective power of a trial spectacle lens at the eye. A comprehensive table of this sort can be useful in other ways, such as comparing spectacle and ocular refraction, in assessing the correction of astigmatism in near vision and in the determination of spectacle and ocular accommodation (*see* p. 168). Included on the CD-ROM is a program for obtaining the effective spectacle power.

Many of the following equations and those used in the computer programs printed previously as Appendix E are on the accompanying CD-ROM.

A system for 'constructing' the symbols used to indicate, define or describe values relating to a contact lens and/or the cornea is employed throughout this section. The system is based on (***and is an extension of***) that used in the International Standard ISO 8321: 1991 which has been adopted as the British Standard BS 7208: 1992.

A symbol **normally** has three parts which represent, in sequence, the answers to the questions ***What*** is it?, ***Where*** is it?, and ***Which*** is it?. For example $\boldsymbol{r_{ao}}$ is the symbol used to indicate the ***r***adius of the ***a***nterior ***o***ptic surface.

As with all good rules there is an exception, which is also taken from the 'Standard' system. The most frequently used

contact lens specifications are those of the back surface so the 'middle' part of the symbol, ***Where*** is it?, is omitted when referring to a back surface zone. r_o and r_2 for example represent respectively the back central optic radius (or apical radius for an aspheric surface) and the second back peripheral radius.

Back surface data other than zones require a full symbol. For example $s_{\phi_o r_1}$ indicates the *s*agitta at the back central *o*ptic diameter (ϕ_o) of the first back peripheral *r*adius (r_1).

Other examples are $s_{\phi_T r_{a1}}$ which is the *s*agitta at ***T***otal diameter (ϕ_T) of the first ***a***nterior peripheral *r*adius (r_{a1}) (i.e. the anterior radius of the carrier portion of a lenticular lens); l_{EA} is the ***l***ift at the ***E***dge of a lens and it is ***A***xial, (as opposed to ***R***adial – l_{ER}). Note: Capital subscript A = axial; lower case subscript a = anterior.

Some of the symbols appear strange at first but become familiar quite quickly with use and the system has the advantage that if the significance of a symbol is forgotten a knowledge of the rules enables the meaning to be construed or a new symbol to be constructed.

All the formulae used for spherical lenses can be used for toric lenses if each principle meridian is treated separately as though it were spherical.

In all cases powers (F) are in dioptres (D).

All distances are in metres (m), millimetres (mm = $m/10^3$), or microns (μm = $m/10^6$) as indicated.

Spectacle and ocular refraction

*Formulae **I** and **II***

$$\text{Ocular refraction} = F_o = \frac{F'_s}{1 - dF'_s} \text{ - - - - } I$$

$$\text{Spectacle Rx} = F'_s = \frac{F_o}{1 + dF_o} \text{ - - - - } II$$

Where F'_s = BVP of spectacle lens (D), F_o = Ocular Rx(D), d = BVD (m).

Formula ***I*** is the ***basic*** form of the 'Effectivity' equation, *see* p. 169, *Figure 5.19* and formula ***XXII***, p. 202.

For calculators:

$$F_o = F'_s/(1 - d*F'_s) \text{ - - - - } I$$

$$F'_s = F_o/(1 + d*F_o) \text{ - - - - } II$$

In the example on p. 170 (*Example 1* for this text) the 12 mm BVD must be divided by 1000 to preserve scale when using equation ***I*** (or ***II***).

Thus $12\,mm/10^3 = 0.012\,m$

Example 1

$F_o = 8.00/(1 - 12/10^3*8.00) =$ **+8.85 D** (from ***I***)

Other examples (*Examples 2 & 3*) are:

For F'_s – 12.50 D at 9 mm BVD;

$F_o = -12.5/(1 - 0.009*-12.5) =$ **–11.24 D** (from ***I***)

For F_o +18.00 D;

F'_s at 10 mm BVD = $18/(1 + 0.01*18)$

= **+15.25 D** (from ***II***)

Radius and surface power

*Formulae **III** and **IV***

$$\text{Surface power} = F = \frac{n_2 - n_1}{r} \text{ - - - - } III$$

$$\text{Radius} = r = \frac{n_2 - n_1}{F} \text{ - - - - } IV$$

Where r = surface radius in **metres**; n_1 = refractive index of 1st medium; n_2 = refractive index of 2nd medium.

Because radius is normally in mm, r can **either** be divided by 10^3 to convert it to metres ***or*** the numerator multiplied by 10^3 so that r can remain in mm.

For calculators:

$$F = (n_2 - n_1)/(r(\text{mm})/10^3)$$

OR

$$F = (n_2 - n_1)*10^3/r(\text{mm}) \text{ - - - - } III$$

$$r(\text{mm}) = (n_2 - n_1)*10^3/F \text{ - - - - } IV$$

Examples 4, 5, 6 & 7

A lens has FOZR = r_{ao} = 8.00 mm, BOZR = r_o = 7.90 mm, Refractive index = n = 1.47

Front surface power in air = $(1.47 - 1.00)/(8.00/10^3)$

= $0.47/0.008$

= **+58.75 D** (from ***III***)

Back surface power in air = $(1.00 - 1.47)/(7.90/10^3)$

= $-0.47/0.0079$

= **–59.49 D** (from ***III***)

Lens–tears interface power = $(1.336 - 1.47)*10^3/7.90$

= $-134/7.90$

= **–16.96 D** (From ***III***)

Front surface radius = $(1.47 - 1.00)*10^3/+58.75$

= $470/+58.75$

= **+8.00 mm** (from ***IV***)

Change in surface power (δF) when radius (r_1) is changed to new radius (r_2) for given refractive index differences

Formula V

This calculation is based on formula ***III*** (used twice)

Change in Surface Power = δF

$$= \frac{n_2 - n_1}{r_2} - \frac{n_2 - n_1}{r_1} \text{ - - - - } V$$

(radii in metres)

For calculators:

$$\delta F = (n_2 - n_1)/(r_2(\text{mm})/10^3) - (n_2 - n_1)/(r_1(\text{mm})/10^3) \text{ - - - - } V$$

Examples 8, 9 & 10

A lens has FOZR = r_{ao} = 8.20 mm, BOZR = r_o = 7.95 mm, refractive index = 1.473

If r_{ao} is changed from 8.20 (r_1) to 7.70 (r_2):

$$\delta F = (1.473 - 1.00)/(7.70/10^3) - (1.473 - 1.00)*10^3/8.20$$

$$= \mathbf{+3.75\,D} \text{ (from } V)$$

If r_o is changed from 7.95 (r_1) to 7.80 (r_2):

$$\delta F \text{ in air} = (1.00 - 1.473)/(7.80/10^3) - (1.00 - 1.473)/(7.95/10^3)$$

$$= \mathbf{-1.14\,D} \text{ (from } V)$$

$$\delta F \text{ in tears} = (1.336 - 1.473)*10^3/7.80 - (1.336 - 1.473)*10^3/7.95$$

$$= \mathbf{-0.33\,D} \text{ (from } V)$$

Change in reduced vergence (δRV) due to thickness for a given initial vergence and refractive index

Formula VI

$$\delta RV = L_2 - L_1'$$

$$= \frac{1}{\left[\frac{1}{L_1'} - \frac{t_c/10^3}{n}\right]} - L_1' \text{ - - - - } VI$$

For calculators:

$$\delta RV = (L_1'^{-1} - t_c/10^3/n)^{-1} - L_1' \text{ - - - - } VI$$

Where L_1' = initial vergence of light (after refraction at the **first** surface); L_2 = the changed vergence of light after travelling through a given thickness; t_c = centre thickness (in mm); n = refractive index.

This type of calculation is based on the concept of reduced thickness and equivalent air distances (*see* p. 170). If the initial vergence is L_1', the changed reduced vergence due to thickness = L_2 as shown in that part of the calculation which leads from L_1' (+51.85 D) to L_2 (+53.33D).

Scale must be preserved. 1/51.85 D = 0.01929 metres, which in the text on p. 170 has been multiplied by 10^3 to convert it to mm so that t_c/n could be expressed in mm. Also 1/18.75 mm = 0.05333 which, multiplied by 10^3 = 53.33 D.

Alternatively, t_c could be divided by 10^3 to convert it (and therefore t_c/n) to metres thereby allowing the use of the reciprocals.

The **change** = $\delta RV = L_2 - L_1'$

$$= 53.33 - 51.85 = \mathbf{+1.48\,D} \text{ (from } VI)$$

Example 11

L_1' = 62.00 D, t_c = 0.4 mm, refractive index = 1.47

$$\delta RV = (62.00^{-1} - 0.4/1.47/10^3)^{-1} - 62.00$$

$$= \mathbf{+1.06\,D} \text{ (from } VI)$$

An example similar to the above appears on p. 182 as part of an illustration of the 'step-along' method of doing the same calculation.

The change in vergence due to thickness, or an increase in thickness, is always +ve (or less –ve) and a decrease in thickness will always produce a –ve (or less +ve) change in vergence except when L_1' is plano, in which case there is no change in vergence due to thickness. Care must be taken when light is traced 'backwards' through a lens, (i.e. if the lens is reversed as in *Figure 5.25* on p. 181), as the radius of the back (concave) surface is treated as a –ve value.

Difference in surface power (dF) of a fused bifocal lens when, for a given radius the refractive index changes from the main lens to the near segment

Formula VII (*see* p. 187–188)

Surface power of segment differs from that of the main lens by

$$dF = \frac{n_N - n_D}{r} \text{ - - - - } VII$$

Where n_N = refractive index of near segment, n_D = index of distance portion, r = surface radius in metres.

Most fused bifocal corneal lenses have the segment on the back surface (*see Figure 5.29* on p. 186). Because r_o is a concave surface common to both distance and near portions and the near segment has a higher refractive index than the distance portion, the power of the back surface of the near segment is more –ve than that of the distance portion. The change in surface power is proportional to the difference in refractive indices and dependent on r_o.

Note: ***For equation VII only*** the sign of the radius (denominator) departs from the normal sign convention. If the surface is concave to the higher refractive index the radius is entered as a negative value and for a surface which is convex to the higher index the radius is regarded as a positive value. The use of this device enables equation ***VII*** to be used in the calculation of surface power differences for both back and front surface fused bifocals.

For calculators: the ***external*** surface power of the seg differs (***dF***) from that of the main lens (d_BF back surface seg, d_FF front surface seg) by:

$$dF = (n_N - n_D) * 10^3 / \pm r_o(\text{mm})$$

OR

$$dF = (n_N - n_D) / (\pm r_o(\text{mm}) / 10^3) \text{ - - - - } \textit{VII}$$

Example 12

A bifocal corneal lens has a seg fused into the back surface, the refractive index of the main lens = 1.49, the index of the seg = 1.56 and r_o = 8.00 mm (*see* p. 188).

$$d_BF = (1.56 - 1.49) * 10^3 / -8.00$$
$$= 0.07 * 10^3 / -8.00$$
$$= 70 / -8.00$$
$$= \mathbf{-8.75\,D} \text{ (from } \textit{VII})$$

Example 13

For a front surface seg using the same refractive indices and FOZR = r_{ao} = 8.20 mm.

$$d_FF = (1.56 - 1.49) / (8.2 / 10^3)$$
$$= 0.07 / 0.0082$$
$$= \mathbf{+8.54\,D} \text{ (from } \textit{VII})$$

Contact surface powers and radii for fused bifocal lenses of various optic zone radii and near additions

*Formulae **VIII**, **IX** and **X***

$$F_{CS} = \text{Add} - (d_BF \text{ or } d_FF) \text{ - - - - } \textit{VIII} \quad (dF \text{ is obtained from } \textit{VII})$$

$$r_{BCS} = \frac{(n_2 - n_1)}{F_{BCS}} \text{ - - - - } \textit{IX} \qquad \left[r_{BCS}(\text{in mm}) = \frac{(n_N - n_D) * 10^3}{F_{BCS}} \right]$$

$$r_{FCS} = \frac{(n_2 - n_1)}{F_{FCS}} \text{ - - - - } \textit{X} \qquad \left[r_{FCS}(\text{in mm}) = \frac{(n_D - n_N) * 10^3}{F_{FCS}} \right]$$

To differentiate between back and front surface additions the contact surface is denoted $_{BCS}$ and $_{FCS}$ appropriately.

Where $_{CS}$ = Contact surface, ***F*** = Power, ***dF*** = Difference in power, ***r*** = Radius, **Add** = Reading addition, n_1 and n_2 are the refractive indices of the 1st and 2nd media. Thus for a back surface addition (*see Figure 5.29*) $n_1 = n_D$ and $n_2 = n_N$, and vice versa for a front surface addition (*see **VII***).

For calculators:

$$F_{CS} = \text{Add} - (d_BF \text{ or } d_FF) \text{ - - - - } \textit{VIII} \quad (dF \text{ is obtained from } \textit{VII})$$

$$r_{BCS} = (n_N - n_D) * 10^3 / F_{CS} \text{ - - - - } \textit{IX} \qquad (r_{BCS} \text{ in mm})$$

$$r_{FCS} = (n_D - n_N) * 10^3 / F_{CS} \text{ - - - - } \textit{X} \qquad (r_{FCS} \text{ in mm})$$

If in *Example 12* (a back surface fused bifocal) the required near addition (Add) is +3.00 D, the contact surface between the lens and the segment must have enough +ve power to provide the required Add ***AND*** to neutralize the unwanted –ve power d_BF at the back surface of the seg (= –8.75 D, from ***VII***).

To achieve this the contact surface (cs) must be convex to the higher index and its power, F_{BCS}, must be +3.00 D – –8.75 D = **+ 11.75 D** (from ***VIII***).

$$r_{BCS} = \frac{(1.56 - 1.49) * 10^3}{+11.75} = \frac{70}{+11.75}$$

$$= \mathbf{5.96\,mm} \text{ (from } \textit{IX})$$

Where r_{BCS} = the contact surface radius (back seg) and F_{BCS} = its power.

In *Example 13* (a front surface fused bifocal) d_FF = +8.54 D (from ***VII***).

If the required near Add is +2.00 D the contact surface must be concave to the higher index and its –ve power must neutralize the **unwanted part** of the +ve power on the front surface of the seg.

$$F_{FCS} = +2.00 - 8.54 = \mathbf{-6.54\,D} \text{ (from } \textit{VIII})$$

$$r_{FCS} = \frac{(1.49 - 1.56) * 10^3}{-6.54} = \frac{-70}{-6.54}$$

$$= \mathbf{10.70\,mm} \text{ (from } \textit{X})$$

Where r_{FCS} = the contact surface radius (front seg) and F_{FCS} = its power.

Sagitta calculations

Formulae XI and XII

For a spherical surface or one principal meridian of a toroidal surface

$$s = r - \sqrt{r^2 - y^2} \text{ - - - - } XI$$

For calculators:

$$s = r - \sqrt{(r^2 - (\phi/2)^2)} \text{ - - - - } XI$$

Where s = sagitta, r = radius, ϕ = diameter, $y = \phi/2$

Primary sag,

$$s_P = s_{\phi_O r_O} + s_{\phi_1 r_1} - s_{\phi_O r_1} + \ldots\ldots s_{\phi_N r_N} - s_{\phi_{N-1} r_N};$$

which involves *XI* used repeatedly (also *see* p. 190 and *Figures 5.30 and 5.31*).

For the **prolate** (flattening) curve of an ellipse:

$$s_K = \frac{r_{OK}}{p} - \sqrt{\left[\frac{r_{OK}}{p}\right]^2 - \frac{y^2}{p}} \text{ - - - - } XII$$

For calculators:

$$s_K = r_{OK}/p - \sqrt{((r_{OK}/p)^2 - y^2/p)} \text{ - - - - } XII$$

Where $p = 1 - e^2$ (e = eccentricity); s_K and r_{OK} are used respectively to differentiate between the sagitta and apical radius of an '**ellipsoidal**' cornea (or lens) and those of a **spherical** lens or cornea when s and r_o and r_{oks} are used; other symbols as above. For details of corneal contour and its measurement, *see* Chapter 6, and Chapter 10, p. 314–317.

For worked examples *see* Calculation of tear layer thickness (TLT) below, pp. 202–204 and pp. 209–212, and for information on fitting techniques using desired TLT values, *see* Chapter 10 from p. 330 on.

Calculation of Apical Radius of Cornea (r_{OK}) from 'K' reading (r_K) in mm (for the *PROLATE* (flattening) curve of an ellipse); determination of keratometer mire image diameter (ϕ_{MI}) and reflecting power (FK_R) of the cornea

Formulae XIII, XIV and XV

$$r_{OK} = \sqrt{r_K{}^2 - (1 - p)y_{MI}{}^2} \text{ - - - - } XIII$$

(r_{OK}, r_K and y_{MI} in mm)

For calculators:

$$r_{OK} = \sqrt{(r_K{}^2 - (1 - p)*y_{MI}{}^2)} \text{ - - - - } XIII$$

Where r_K = keratometer radius; $y_{MI} = \phi/2$ of mire image; other symbols as above.

The diameter of the mire image (ϕ_{MI}) is taken to be the ϕ of the annulus around the corneal apex (or more correctly around the visual axis) which is measured by the keratometer (*see* pp. 232–236 and *Figure 6.1*).

The image sizes, produced by reflection in corneas of various radii, of the mires of several different keratometers were determined by Mandell (1962) and Lehmann (1967) and their findings are still valid (Sheridan, 1989). In keratometers with fixed mires ϕ_{MI} increases in proportion to corneal radius, but the reverse applies with moveable mire keratometers. There is a significant difference in ϕ_{MI} between different instruments, varying from 2.0 to 3.5 mm for corneal radii of 7.00 mm, and 2.6 to 3.8 mm for radii of 9.25 mm.

ϕ_{MI} created by any keratometer can be calculated from

$$\phi_{MI} \approx \frac{r_K/2 * \phi_M}{d} \text{ - - - - } XIV$$

For calculators:

$$\phi_{MI} \approx (r_K/2 * \phi_M)/d \text{ - - - - } XIV$$

Where $\phi_M = \phi$ of a fixed mire, or the separation between movable mires: d = distance between the **mire plane** and the **mire image**, (ϕ_M and d in mm).

The mire image, formed at distance d from the mire plane, is slightly in front of the focal point of the cornea, distance x in *Figure 6.1* but as explained on p. 232 negligible error is introduced by accepting these two distances as being the same. x (or d) ≈ mire plane to corneal apex + $r_K/2$.

The **reflecting** power of the cornea = FK_R

$$= \frac{1000}{(-r_K/2)} \text{ - - - - } XV \ (-r_K \text{ in mm})$$

For calculators:

$$FK_R = 1000/(-r_K/2) \text{ - - - - } XV$$

$$\text{Average } FK_R = \frac{1000}{(-7.9/2)} \approx \mathbf{-253\,D} \text{ (from } XV)$$

The mire image is minified by a factor of about 22 to 1 so in the absence of any data concerning the mire size or distance, the use of equation *XIII* with an assumed average ϕ_{MI} of 3.00 mm will allow a more precise calculation of TLT than is obtained by using r_K as a basis for determining corneal sag: 3.10 mm is said to be the ϕ_{MI} created in an average cornea by a Bausch & Lomb keratometer.

Calculation of Tear Layer Thickness (TLT)

Formula XVI

Example 14

A spherical corneal lens of $r_O = 7.80$ mm and $\phi_O = 8.00$ mm is placed on a cornea having a 'p' value of 0.80 for which an unknown (but impeccable) keratometer has indicated a radius of 7.85 mm and no astigmatism. What will be the

TLT? The mire image diameter, ϕ_{MI}, is assumed to be 3.00 mm.

(1) Calculate sagitta of lens at ϕ_O;

$$s_{\phi_O r_O} = 7.80 - \sqrt{(7.80)^2 - (8/2)^2)}$$
$$= 7.80 - \sqrt{(60.84 - 16)}$$
$$= 7.80 - \sqrt{(44.84)}$$
$$= 7.80 - 6.696$$
$$= \mathbf{1.104\,mm} \text{ (from } \textit{XI})$$

(2) Calculate apical radius of cornea;

$$r_{OK} = \sqrt{(7.85^2 - (1 - 0.8) * 1.5^2)}$$
$$= \sqrt{(61.6225 - 0.2 * 2.25)}$$
$$= \sqrt{(61.6225 - 0.45)}$$
$$= \sqrt{(61.1725)}$$
$$= \mathbf{7.82\,mm} \text{ (from } \textit{XIII})$$

(3) Calculate sagitta of cornea at ϕ_O;

$$s_{\phi_O r_{OK}} = 7.82/0.8 - \sqrt{((7.82/0.8)^2 - 4^2/0.8)}$$
$$= 9.775 - \sqrt{(9.775^2 - 16/0.8)}$$
$$= 9.775 - \sqrt{(95.55 - 20)}$$
$$= 9.775 - 8.692$$
$$= \mathbf{1.083\,mm} \text{ (from } \textit{XII})$$

$$\mathbf{TLT} = s_{\phi_C P} - s_{\phi_C r_{OK}} \text{ - - - - } \textit{XVI}$$

Where $s_{\phi_C P}$ = primary sag of lens at the ϕ at which the back surface of the lens **C**ontacts the cornea (ϕ_C). This is *usually* ϕ_O if there is apical clearance, but *see Example 23*.

$s_{\phi_C r_{OK}}$ = sag of cornea at the contact diameter, (ϕ_O in the present case).

TLT = 1.104 mm − 1.083 mm = **0.021 mm** (from ***XVI***)

(0.021 mm = 21 microns (μm).

If the above calculation gives a −ve value for TLT it indicates that there is central touch and the TLT represents **Axial 'Edge' Clearance** (at ϕ_O in this case).

To calculate the TLT created by a lens when the junction between r_O and r_1 is not the bearing surface or for an aspheric lens *see Example 23* and p. 212.

The sag of the cornea at ϕ_O using r_K (7.85) instead of r_{OK} (7.82) in *Example 14* is 1.078 mm, which gives the TLT as 26 μm, an error of ≈ 24%.

A central TLT of 21 μm is considered excessive today, about half that value (when calculated using r_{OK}) being preferred for rigid gas permeable lenses.

Calculation of Radius (*r*) from Sagitta (*s*) and Semi-diameter (*y*), and new BOZR (r_{ON}) required to change TLT by a specified amount (δ)

*Formula **XVII***

$$r = \frac{y^2 + s^2}{2s} \text{ - - - - } \textit{XVII}$$

For calculators;

$$r = (y^2 + s^2)/(2 * s) \text{ - - - - } \textit{XVII}$$

Formula ***XVII***, which is a rearrangement of the 'sag' formula ***XI***, will yield the radius of any spherical surface, given the sagitta (*s*) and the semi-diameter (*y*)

Example 15

The BCOD, ϕ_O, of a contact lens is 7.50 mm (y = 3.75 mm) and its sagitta (s) is 0.94 mm. What is its radius?

$$r_O = (3.75^2 + 0.94^2)/(2 * 0.94)$$
$$= (14.0625 + 0.8836)/1.88$$
$$= \mathbf{7.95\,mm} \text{ (from } \textit{XVII})$$

The value of s is modified in ***XVII*** below to give the radius required to change TLT.

For calculators:

$$r_{ON} = ((\phi_O/2)^2 + (s \pm \delta)^2)/(2 * (s \pm \delta)) \text{ - - - - } \textit{XVII}$$

Where

r_{ON} = New BOZR (r_O) required to alter TLT by a specified amount;
ϕ_O = diameter of Back Central Optic Zone (BCOZ);
y = $\phi_O/2$;
s = sag of BCOZ at the present radius;
δ = the desired change in TLT.

Example 16

We require the TLT in *Example 14* to be reduced by 10 μm, thus δ = −0.01 mm, and the desired TLT is

0.021 mm − 0.01 mm = 0.011 mm = 11 μm

s_{ϕ_O} = **1.104 mm** (from ***XI***) − *see Example 14(1)*

$$r_{ON} = ((8.00/2)^2 + (1.104 - 0.01)^2)/(2 * (1.104 - 0.01))$$
$$= (4^2 + 1.094^2)/(2 * 1.094)$$
$$= (16 + 1.1968)/2.188$$
$$= 17.1968/2.188$$
$$= \mathbf{7.86\,mm} \text{ (from } \textit{XVII})$$

sag of 7.86 mm at

$\phi 8.00\,\text{mm} = 1.0939$ (from ***XI***)

$-s_{\phi_O r_{OK}} = \underline{1.083}$ (from ***XII***) (*see Example 14(3)*)

TLT = 0.0109 mm = 10.9 μm ≈ 11 μm as required.

The merit of ordering radii to an accuracy of 0.01 mm is discussed on p. 210.

Back and front vertex powers for various centre thicknesses and BCOZ radii

*Formulae **XVIII**, **XIX**, **XX**, **XXI**, **XXII**, **XXIII**, **XXIV*** and ***XXV***

BOZR (r_O), refractive index (n) and centre thickness (t_C) must be known in order to find back vertex power (F'_V) given front vertex power (F_V) or to find F_V given F'_V

The relationship between F_V and F'_V can be seen from the formulae:

$$F'_V = F_V\left[\frac{1-(t_C/n)F_2}{1-(t_C/n)F_1}\right] \text{ - - - - } \textbf{\textit{XVIII}}$$

$$F_V = F'_V\left[\frac{1-(t_C/n)F_1}{1-(t_C/n)F_2}\right] \text{ - - - - } \textbf{\textit{XIX}}$$

Where t_C = centre thickness in **metres**, n = refractive index, F_1 = the power of the convex surface, F_2 = the power of the concave surface.

In either case it is necessary to find the powers of both surfaces. For the power of F_1 *see* pp. 181 and 182 *Figures 5.25 and 5.26*, Formula ***XXIII*** and **Step 1** below. The power of F_2 is found from formula ***III***. (The wording on pp. 181 and 182 relates to a scleral lens but the mathematics are the same for corneal lenses.)

$L_1' = L_1 + F_1$ when determining BVP (F'_V)

$L_1' = L_1 + F_2$ when determining FVP (F_V)

Where L_1 = vergence of incident light.

= zero when calculating vertex powers.

Thus for determining BVP, $L_1' = F_1$ and for determining FVP, $L_1' = F_2$

L_2 = the vergence of light incident on the second surface (calculated from ***XXIV***).

Once the power of the convex surface (F_1) is known, (*see **XXIII*** below):

$$F'_V = L_2 + F_2 = \frac{L_1'}{1-(t_C/n)L_1'} + F_2 \text{ - - - - } \textbf{\textit{XX}}$$

(Also *see **XXVII***, p. 206)

For calculators:

$$F'_V = L_1'/(1 - t_C/n*L_1') + F_2 \text{ - - - - } \textbf{\textit{XX}}$$

(Note: F_1 may be substituted for L_1' in formula ***XX***, *see above*)

$$F_V = L_2 + F_1 = \frac{L_1'}{1-(t_C/n)L_1'} + F_1 \text{ - - - - } \textbf{\textit{XXI}}$$

(Also *see **XXVI***, p. 206)

For calculators:

$$F_V = L_1'/(1 - t_C/n*L_1') + F_1 \text{ - - - - } \textbf{\textit{XXI}}$$

(Note: F_2 may be substituted for L_1' in formula ***XXI***, *see above*)

(t_C in metres for ***XX*** and ***XXI***)

Formula ***XX*** will yield F'_V if calculated on the basis that parallel light is incident on the convex (first) surface F_1. (F_2 is the concave (second) surface.)

Formula ***XXI*** yields F_V if parallel light is incident on the concave surface.

The calculation is simplified if reduced thickness is used, as on p. 170, allowing the use of reciprocals and, especially if using a calculator, a further simplification is gained by expressing r_O and t_C in metres (mm/1000).

Example 17 To find front vertex power (F_V)

A lens has r_O = 7.90 mm (0.0079 m), n = 1.47, t_C = 0.4 mm (0.0004 m), F'_V = +6.00 D. What is the front vertex power F_V?

Step 1 is to find the power of the convex surface (F_1 in *Figure 5.25*). The 'step-along' method can be employed, following the ray diagram in *Figure 5.25* but using reduced thickness (t_C/n) and effectivity (*see **XXII*** below).

L_1 = Vergence of incident light (the lens is reversed in *Figure 5.25* so L_1 = **−6.00 D** and the **first** surface (concave) is F_2; the second surface (convex) is F_1).

F_2 = Power of 1st surface

$= (1.47 - 1.00)/(7.90/10^3)$

= **−59.49 D** (from ***III***)

(When the lens is reversed as in *Figure 5.25* r_O is given a −ve sign because it is measured *from* the surface *to* the centre of curvature, i.e. in the *opposite* direction to which the light is now travelling).

Lens is reversed so

$$L_1 = -F'_V;$$

$$L_1' = F_2 - F'_V = -59.49 - 6.00 = \textbf{−65.49 D}$$

$$L_2 = \frac{L_1'}{1-(t_C/n)L_1'} \text{ - - - - } \textbf{\textit{XXII}}$$

$$L_2 = \frac{-65.49}{1 - (0.0004/1.47)*-65.49}$$

$$= \mathbf{-64.35\,D} \text{ (from } \textit{XXII})$$

In ***XXII***, formula ***I*** has been modified to use t_C/n (in metres) instead of ***d***, but it is essentially the same 'effectivity' equation.

For calculators:

$$L_2 = L_1'/(1 - t_C/n*L_1') \text{ - - - - } \textit{XXII}$$

$$L_2 = -65.49/(1 - 0.0004/1.47*-65.49)$$

$$= -65.49/1.0178$$

$$= \mathbf{-64.35\,D} \text{ (from } \textit{XXII})$$

Light (L_2') emerging from the second surface is parallel so the vergence of $L_2' = \mathbf{0\,D}$ (*see Figure 5.25*).

$L_2' = L_2 + F_1$ therefore:

$$F_1 = L_2' - L_2 = 0 - L_2 = 0 - -64.35 = \mathbf{+64.35\,D}$$

The individual steps above can be combined into one formula, ***XXIII***, which is a mathematical expression of the 'step-along' method:

$$L_1' = F_2 - F'_V$$

$$\text{Power of } F_1 = 0 - L_2 = 0 - \frac{1}{\left[\frac{1}{L_1'} - \frac{t_C}{n}\right]} \text{ - - - - } \textit{XXIII}$$

For calculators:

$$F_1 = 0 - (((n_2 - n_1)/-r_O - F'_V)^{-1} - t_C/n)^{-1} \text{ - - - - } \textit{XXIII}$$

(r_O and t_C in metres)

$$F_1 = 0 - (((1.47 - 1.00)/-0.0079 - 6.00)^{-1} - 0.0004/1.47)^{-1}$$

$$= \mathbf{+64.35\,D} \text{ (from } \textit{XXIII})$$

Step 2. Now that F_1 is known (from ***XXIII***), if *parallel* light is incident on the back surface in the direction shown in *Figure 5.25*, $L_1 = 0\,D$

$$L_1' = F_2 = \mathbf{-59.49\,D} \text{ (from } \textit{III})$$

L_2 is calculated from ***XXII*** and $F_V = L_2' = L_2 + F_1$

$$L_2 = \frac{-59.49}{1 - (0.0004/1.47)*-59.49} = \mathbf{-58.55\,D} \text{ (from } \textit{XXII})$$

$$F_V = L_2' = L_2 + F_1$$

$$= -58.55 + 64.35 \text{ (from } \textit{XXII} \text{ and } \textit{XXIII})$$

$$= \mathbf{+5.80\,D}$$

For calculators:

$$F_V = F_2/(1 - t_C/n*F_2) + F_1. \text{ - - - - } \textit{XXI}$$

(Where $L_1 = 0$ then $L_1' = F_2$)

$$F_V = -59.49/(1 - 0.0004/1.47*-59.49) + 64.35$$

$$= -58.54 + 64.35$$

$$= \mathbf{+5.81\,D} \text{ (from } \textit{XXI})$$

The discrepancy of 0.01 D is due to the use in the calculation of values which have been rounded to two decimal places for clarity.

The discrepancy does not occur if the computer is allowed to operate in its normal floating decimal mode (*see **XXV*** below).

L_2 may also be found by the 'step-along' method. If parallel light is incident on the concave surface as in **step 2** above, then $L_1' = F_2 = \mathbf{-59.49\,D}$ (from ***III***).

L_2 = ***Reduced*** vergence of light incident on 2nd surface

$$= \frac{1}{\left[\frac{1}{F_2} - \frac{t_C}{n}\right]} \text{ - - - - } \textit{XXIV}$$

For calculators:

$$L_2 = (((n_2 - n_1)/-r_O)^{-1} - t_C/n)^{-1} \text{ - - - - } \textit{XXIV}$$

(r_O and t_C in metres)

$$L_2 = (((1.47 - 1.00)/-0.0079)^{-1} - 0.0004/1.47)^{-1}$$

$$= \mathbf{-58.55\,D} \text{ (from } \textit{XXIV})$$

$$F_V = L_2' = L_2 + F_1$$

$$F_V = \frac{1}{\left[\frac{1}{F_2} - \frac{t_C}{n}\right]} + F_1 \text{ - - - - } \textit{XXV}$$

For calculators:

$$F_V = (((n_2 - n_1)/-r_O)^{-1} - t_C/n)^{-1} + F_1 \text{ - - - - } \textit{XXV}$$

(r_O and t_C in metres)

Example 17

$$F_V = (((1.47 - 1.00)/-0.0079)^{-1} - 0.0004/1.47)^{-1} + 64.35$$

$$= \mathbf{+5.80\,D} \text{ (from } \textit{XXV})$$

Example 18 To find back vertex power (F'_V)

Given $r_O = 8.00$ mm (0.008 m), $t_C = 0.20$ mm (0.0002 m), $n = 1.473$ and $F_V = -9.86\,D$

Step 1. To find the power of the front surface: **parallel** light is incident on the 'reversed' lens as in ***Step 2***, *Example 17*, above. F_2 is the power of the back surface and r_O is –ve. F_1 is the power of the front surface.

$$L_1' = L_1 + F_2, \quad L_1 = 0 \text{ therefore } L_1' = F_2$$

$$L_1' = F_2 = \frac{0.473}{-0.008} = \mathbf{-59.13\,D} \text{ (from } \textit{III}\text{)}$$

$$L_2 = \frac{-59.13}{1 - (0.0002/1.473) * -59.13}$$

$$= \mathbf{-58.66\,D} \text{ (from } \textit{XXII}\text{)}$$

L_2 should emerge (L_2') after refraction at F_1 with vergence = F_V = −9.86 D.

$$L_2' = F_V = L_2 + F_1 \text{ therefore}$$

$$F_1 = F_V - L_2$$

$$F_1 = -9.86 - -58.66 = \mathbf{+48.80\,D}$$

Step 2. Now that the power of the **front** surface (F_1) is known F'_V can be found if a pencil of parallel incident rays is traced '**forwards**' through the lens as in *Figure 5.26* on p. 182.

$$L_1' = L_1 + F_1, L_1 = 0 \text{ therefore } L_1' = F_1 = \mathbf{+48.80\,D}$$

L_2 is calculated from ***XXII***

$$L_2 = \frac{48.80}{1 - (0.0002/1.473) * 48.80} = \mathbf{+49.13\,D} \text{ (from } \textit{XXII}\text{)}$$

And

$$F'_V = L_2 + F_2 = 49.13 + -59.13 = \mathbf{-10.00\,D}$$

Rapid calculation of F_V and F'_V having established three values

*Formulae **XXVI** and **XXVII***

Most scientific and all programmable calculators have many memories. The use of three memories can simplify the above calculations significantly.

Example 17, For calculators:

To find F_V given r_O = 7.90 mm, n = 1.47, t_C = 0.4 mm, F'_V = +6.00 D

(1) Calculate $F_2 = (n_2 - n_1)/r_O(\text{m}) = (1.00 - 1.47)/(0.0079)$ = **−59.49 D** (from ***III***). Store F_2 in memory no. 1 (named m_1)

(2) Calculate **reduced** $t_C = t_C(\text{m})/n$ = 0.0004/1.47 = **0.00027211**. Store t_C/n in m_2.

(3) Calculate $F_1 = 0 - L_2 = 0 - (m_1 - F'_V)/(1 - m_2 * (m_1 - F'_V))$ = **+64.35 D** (L_2 from ***XXII***). Store F_1 in m_3.

$F_V = m_1/(1 - m_2 * m_1) + m_3$ - - - - ***XXVI*** (equivalent to ***XXI***)

= **+5.80 D**

Similarly formula ***XIX*** may be expressed as

$$F_V = F'_V * (1 - m_2 * m_3)/(1 - m_2 * m_1)$$

Example 18, For calculators:

To find F'_V given r_O = 8.00 mm, n = 1.473, t_C = 0.2 mm, F_V = −9.86 D

(1) Calculate $F_2 = (n_2 - n_1)/r_O(\text{m}) = (1.00 - 1.473)/0.008$ = **−59.13 D** (from ***III***). Store F_2 in memory no. 1 (named m_1)

(2) Calculate **reduced** $t_C = t_C(\text{m})/n$ = 0.0002/1.473 = **0.0001358**. Store t_C/n in m_2.

(3) Calculate $F_1 = F_V - L_2 = -9.86 - m_1/(1 - m_2 * m_1)$ = **+48.80 D** (L_2 from ***XXII***). Store F_1 in m_3.

$F'_V = m_3/(1 - m_2 * m_3) + m_1$ - - - - ***XXVII*** (equivalent to ***XX***)

= **−10.00 D**

Similarly formula ***XVIII*** may be expressed as

$$F'_V = F_V * (1 - m_2 * m_1)/(1 - m_2 * m_3)$$

Calculation of Peripheral Radii to create a stipulated axial edge lift (l_{EA})

*Formulae **XXVIII, XXIX, XXX, XXXI** and **XXXII***

(Note: The term 'axial edge lift' appears to imply that the measurement is made at the edge of the lens, but it may be made at the edge of any specified zone.)

The radius (r) required so that any spherical peripheral surface (N), of sag value x_N, will create a **D**esired **A**xial **E**dge **l**ift (Dl_{EA}) at a **G**iven diameter (ϕ_G) can be calculated from

$$r_N = \sqrt{\left[\frac{y_{\phi_G}^2 - y_{\phi_{N-1}}^2 - x_N^2}{2 * x_N}\right]^2 + y_{\phi_G}^2} \text{ - - - - } \textit{XXVIII}$$

where $y_{\phi_G} = \frac{\text{Given } \phi}{2}$; $y_{N-1} = \frac{\text{inner } \phi \text{ of surface N}}{2}$

(where ϕ = Diameter).

$$x_N = (s_{\phi_G r_{N-1}} - s_{\phi_{N-1} r_{N-1}} - Dl_{EAN}) \text{ - - - - } \textit{XXIX}$$

(sags from ***XI***)

(ϕ_G must have the same value in both ***XXVIII*** & ***XXIX*** and must be >= ϕ_N).

Where $S_{\phi_G r_{N-1}}$ = sagitta at ϕ_G of r_{N-1} = radius of surface inside (central to) r_N; ϕ_{N-1} = inner ϕ of surface N; Dl_{EAN} = **A**xial **E**dge **L**ift **D**esired from r_N. x_N is the sag value of the portion of surface (N) involved.

Example 19

The C3 lens described on p. 196, 8.00:7.00/?.??:7.80/?.??:8.60 is to have **total** $l_{EA} = 0.12$ mm (*see* also *Figure 5.35* on p. 196).

Most modern rigid multicurve corneal lenses are designed so that the edge lift increases progressively from the diameter at which the back surface of the lens contacts the cornea (ϕ_C) to the total diameter (ϕ_T). For a given increase in peripheral diameter the sag increases less as the peripheral radius is increased, so a fairly well-balanced lens is created if the total edge lift is apportioned in ratio to the peripheral band widths between ϕ_C and ϕ_T, as on p. 196. The back peripheral radii so produced are usually reasonable but can, of course, be modified if this is thought to be necessary.

The l_{EA} share for any peripheral diameter (ϕ_N) can be stated mathematically:

$$Dl_{EA_N} = \frac{\text{Total } l_{EA} * (\phi_N - \phi_{N-1})}{\phi_T - \phi_C} \text{ - - - - } XXX$$

(all values in mm)

For calculators:

$$Dl_{EAN} = \text{Total } l_{EA} * (\phi_N - \phi_{N-1})/(\phi_T - \phi_C) \text{ - - - - } XXX$$

In *Example 19*, $\phi_C = \phi_O$ and the diameter difference, 0.8 mm (peripheral band width, 0.4 mm), is the same for r_1 and r_2.

$$Dl_{EA_1} = 0.12*(7.8-7)/(8.6-7)$$
$$= 0.12*0.8/1.6$$
$$= 0.096/1.6$$
$$= \mathbf{0.06\ mm} \text{ (from } XXX)$$

$$Dl_{EA_2} = 0.12*(8.6-7.8)/(8.6-7)$$
$$= 0.12*0.8/1.6$$
$$= 0.096/1.6$$
$$= \mathbf{0.06\ mm} \text{ (from } XXX)$$

For calculators:

$$r_N = \sqrt{(((y_T{}^2 - y_{N-1}{}^2 - x_N{}^2)/(2*x_N))^2 + y_T{}^2)} \text{ - - - - } XXVIII$$

$$r_1 = \sqrt{(((y_T{}^2 - y_O{}^2 - x_1{}^2)/(2*x_1))^2 = y_T{}^2)}$$

Where

$$x_1 = (s_{\phi_T r_O} - s_{\phi_O r_O} - Dl_{EAN})$$
$$= (1.25389 - 0.80625 - 0.06)$$
$$= \mathbf{0.38764} \text{ (from } XXIX)$$

$$r_1 = \sqrt{(((4.3^2 - 3.5^2 - 0.38764^2)/(2*0.38764))^2 + 4.3^2)}$$
$$= \sqrt{(((18.49 - 12.25 - 0.15026)/0.77528)^2 + 18.49)}$$
$$= \sqrt{((6.08974/0.77528)^2 + 18.49)}$$
$$r_1 = \sqrt{(7.85489^2 + 18.49)}$$
$$= \sqrt{(61.69931 + 18.49)}$$
$$= \sqrt{80.18931}$$
$$r_1 = \mathbf{8.9548484\ mm} \text{ (from } XXVIII)$$

If the calculated value of r_N is 'Rounded' (r_{NR}) to a standard value (e.g. 0.05 mm) the **A**xial **E**dge **l**ift produced by r_{NR}, l_{EA_N}, (relative to r_{N-1}) can be found from;

$$l_{EA_N} = s_{\phi_T r_{N-1}} - s_{\phi_{N-1} r_{N-1}} - (s_{\phi_T r_{NR}} - s_{\phi_{N-1} r_{NR}})$$
$$\text{- - - - } XXXI \text{ (sags from } XI)$$

The difference between Dl_{EA_N} and l_{EA_N} can then be added algebraically to $Dl_{EA_{N+1}}$ (the next peripheral surface out from N), when calculating the value of x_{N+1}

If r_1 is rounded to 8.95 mm (r_{1R}):

$$l_{EA_1} = 1.25389 - 0.80625 - (1.10064 - 0.71274)$$
$$= \mathbf{0.05974\ mm} \text{ (from } XXXI)$$

the **error** $= Dl_{EA_1} - l_{EA_1} = 0.06 - 0.05974 = \mathbf{0.00026\ mm}$

a very small error, but for the sake of the example, Dl_{EA_2} (0.06 mm) is **M**odified to $Dl_{EA_{2M}} = \mathbf{0.06026\ mm}$ to compensate for the error introduced by rounding r_1.

$x_2 = (s_{\phi_T r_{1R}} - s_{\phi_1 r_{1R}} - Dl_{EA_{2M}}$; where $Dl_{EA_{2M}} = Dl_{EA_2} + (Dl_{EA_1} - l_{EA1})$ to take account of the error due to the rounding of r_1.

$$x_2 = (1.10064 - 0.89441 - 0.06026)$$
$$= \mathbf{0.14597\ mm} \text{ (from } XXIX)$$

$$r_2 = \sqrt{(((y_T{}^2 - y_1{}^2 - x_2{}^2)/(2*x_2))^2 + y_T{}^2)}$$

Where y_1 = (inner ϕ of r_2)/2 = (outer ϕ of r_1)/2

$$r_2 = \sqrt{(((4.3^2 - 3.9^2 - 0.14597^2)/(2*0.14597))^2 + 4.3^2}$$
$$r_2 = \sqrt{(((18.49 - 15.21 - 0.02131)/0.29193)^2 + 18.49)}$$

which resolves to **11.96234 mm** (from *XXVIII*)

If r_2 is **R**ounded to 11.95 mm (r_{2R})

$$l_{EA_2} = s_{\phi_T r_{1R}} - s_{\phi_1 r_{1R}} - (s_{\phi_T r_{2R}} - s_{\phi_1 r_{2R}})$$
$$= 1.10064 - 0.89441 - (0.80045 - 0.65432)$$
$$= \mathbf{0.0601\ mm} \text{ (from } XXXI)$$

Total $l_{EA} = l_{EA_1} + l_{EA_2} = 0.05974 + 0.0601$
$= \mathbf{0.11984\ mm}$. Error = 0.00016 mm (0.16 μm)

The final specification for *Example 19* is 8.00:7.00/8.95:7.80/11.95:8.60.

In *Example 19* the peripheral radii were calculated on the basis that they were produced to ϕ_T ($\phi_T = \phi_G$ for *XXVIII* and *XXIX* in this case) and that **at ϕ_T** the l_{EA} created by each peripheral radius would be 0.06 mm **relative to the preceding radius produced to** ϕ_T.

In the finished lens r_1 extends only from ϕ_O to ϕ_1 and l_{EA} is normally stated **relative to r_O**. The l_{EA} contributed by r_1 and r_2 individually at their respective outer diameters is given by:

$$l_{EA_{Ni}} = s_{\phi_N r_O} - s_{\phi_{N-1} r_O} - (s_{\phi_N r_N} - s_{\phi_{N-1} r_N}) \text{ - - - - } \textit{XXXII}$$

(sags from *XI*)

$l_{EA_{Ni}}$ = the individual l_{EA} contribution of r_N (**relative to r_O**) in the final lens.

and

$$l_{EA_{1i}} = s_{\phi_1 r_O} - s_{\phi_O r_O} - (s_{\phi_1 r_{1R}} - s_{\phi_O r_{1R}})$$
$$= 1.015016 - 0.806253 - (0.894412 - 0.712737)$$
$$= \mathbf{0.027089\ mm}$$

$$l_{EA_{2i}} = s_{\phi_T r_O} - s_{\phi_1 r_O} - (s_{\phi_T r_{2R}} - s_{\phi_1 r_{2R}})$$
$$= 1.25389 - 1.015016 - (0.800448 - 0.654315)$$
$$= \mathbf{0.092741\ mm}$$

Total l_{EA} (as above) = **0.119829 mm** (from *XXXII*)

Calculation of new peripheral radius to alter axial edge lift by a given amount

Formulae XXVIIIA, XXIXA and XXXII

Formulae *XXVIII* and *XXIX* can be modified so that they yield a spherical peripheral radius (r_N) which will create a new Dl_{EA_N} **relative to** r_O at ϕ_N. This is achieved by using ϕ_N as ϕ_G in both formulae and, because the l_{EA} created by r_N is to be calculated relative to r_O, r_O is used instead of r_{N-1} in *XXIXA*

In *Example 20*, r_O is r_{N-1} but r_O would be used instead of r_{N-1} in *XXIXA* when calculating a new radius for any other peripheral band.

$$r_N = \sqrt{\left[\frac{y_{\phi_N}^2 - y_{\phi_{N-1}}^2 - x_N^2}{2 * x_N}\right]^2 + y_{\phi_N}^2} \text{ - - - - } \textit{XXVIIIA}$$

For calculators:

$$r_N = \sqrt{(((y_{\phi_N}^2 - y_{\phi_{N-1}}^2 - x_N^2)/(2 * x_N))^2 + y_{\phi_N}^2)}$$
$$\text{- - - - } \textit{XXVIIIA}$$

$$x_N = (s_{\phi_N r_N} - s_{\phi_{N-1} r_O} - Dl_{EA_N}) \text{ - - - - } \textit{XXIXA}$$

(sags from *XI*)

(symbols as before)

Example 20

If it was decided to flatten r_{1R} of the lens in *Example 19* to increase its l_{EA1i} contribution from 0.0271 to say 0.03 mm, the outer and inner diameters of the peripheral surface r_1 (ϕ_1 and ϕ_O respectively) would be used for y_{ϕ_N} and $y_{\phi_{N-1}}$ in *XXVIIIA* and for ϕ_N and ϕ_{N-1} in *XXIXA*.

Also in formula *XXIXA*, $Dl_{EA} = 0.03$ is used (where 0.06 was used previously) because the formula is now dealing with r_1 produced to ϕ_1 (as opposed to ϕ_T).

$$\textbf{New } r_1 = \sqrt{(((y_{\phi_1}^2 - y_{\phi_O}^2 - x_1^2)/(2 * x_1))^2 + y_{\phi_1}^2)}$$

Where $x_1 = s_{\phi_1 r_O} - s_{\phi_O r_O} - Dl_{EA_1}$

$x_1 = 1.015016 - 0.806253 - 0.03$

$= \mathbf{0.178763\ mm}$ (from *XXIXA*)

$$\textbf{New } r_1 = \sqrt{(((3.9^2 - 3.5^2 - 0.178763^2)/(2 * 0.178763))^2 + 3.9^2)}$$

$= \mathbf{9.070930856\ mm}$ (from *XXVIIIA*)

This **New r_1**, if polished on to an existing lens, would increase ϕ_1 (the diameter of r_1) from 7.80 to 7.812 mm and increase l_{EA_1} from 0.0271 to 0.03048 mm which is a little more than was required.

The surplus l_{EA_1} is due to the increase in ϕ_1. This causes an unwanted reduction in the **width** of r_2 from 0.40 to 0.39394 mm reducing l_{EA_2} from 0.09274 to 0.09145 mm. The total l_{EA} = 0.1219 mm which is a little less than expected.

The width of r_2 could be restored using a tool of radius r_2 (11.95 mm) until ϕ_1 became 7.80 mm again. If the edge thickness was insufficient to allow this correction it must either be accepted that l_{EA} = 0.1219 mm or the lens must be remade.

If the new r_1 is rounded to 9.07 mm **and** ϕ_1 is restored to 7.80 mm, $l_{EA_{1i}}$ would be 0.02997 mm (from *XXXII*) which, with $l_{EA_{2i}}$ (above) gives **Total l_{EA} = 0.1227 mm**.

If ϕ_1 is not restored to 7.80 mm the effect of flattening r_1 on the total l_{EA} would be reduced because the reduction in the contribution of r_2 due to the narrowing of its band width would detract from the increased l_{EA} from r_1.

If r_1 is rounded to 9.05 mm (and ϕ_1 = 7.80 mm)

$l_{EA_{1i}}$ = 0.0295 mm. **Total** l_{EA} = 0.12224 mm

The quantities in the above example are quite small because both ϕ_T and the proposed modification are relatively small. The increase in total l_{EA} due to changing r_1 from 8.95 to 9.07 mm is 2.5%. The values become more significant for greater modifications and/or larger lenses but the principle is demonstrated.

Calculation of peripheral radii to create a stipulated axial edge clearance (C_{EA})

Formulae XXVIII, XXIX, XXX, XXXIII and XXXIV

In order to calculate peripheral radii which will create a stipulated **A**xial **E**dge **C**learance (C_{EA}) either the facility to measure the contour of the cornea must be available or a corneal model must be adopted. It is widely accepted that

the average cornea approximates most closely to the surface created when the ***Prolate*** curve of an ellipse is rotated about its major axis and an analysis of the findings of most researchers indicates that the average '***p***' value is in the order of 0.8, with a 'normal range' varying from 0.9 (less flat periphery) to 0.7 (flatter periphery). Cases have been reported (rarely) of corneas having a periphery which is steeper than the central region, with p values greater than 1.0 (or rotation of the ***Oblate*** curve of an ellipse about the minor axis). The following formulae are equally valid for either type of cornea provided that the p value is known.

To create a stipulated C_{EA} at a specified diameter, ϕ_N, the l_{EA} of the lens over the peripheral zone between the contact diameter (ϕ_C) and ϕ_N must be equal to the sagitta of the cornea over the same peripheral zone + the **D**esired Axial Edge **C**learance (DC_{EA}).

$$Dl_{EA} = s_{\phi_N r_{OK}} - s_{\phi_C r_{OK}} + DC_{EA} \text{ (at } \phi_N) \text{ - - - - } \textit{XXXIII}$$

The procedure for calculating peripheral radii which will create a desired C_{EA} is similar to that used with formulae ***XXVIII*** and ***XXIX*** on page 206, differing only in the derivation of the value 'x' for the ***first*** peripheral surface *outside* (wider than) ϕ_C. Formula ***XXIX*** is modified to

$$x_N = s_{\phi_T r_{OK}} - s_{\phi_{N-1} r_{OK}} - DC_{EA_N} \text{ - - - - } \textit{XXIXB}$$

because axial *Clearance* is relative to the sagitta created by the radius of the cornea, (which changes with diameter depending on the '***p***' value), not to that created by the adjacent back surface radius central to r_N. x_N represents an element of 'corneal sag' reduced by an element of C_{EA}.

Any subsequent peripheral radii are calculated using formulae ***XXVIII*** and ***XXIX*** unmodified, (*see* page 206 and *Example 21* below).

Formula ***XXX***, which was used previously to apportion the share of the total l_{EA} for each peripheral band, can be used to apportion the total C_{EA}. The 'C_{EA} share' for each band can be used in formula ***XXIX*** instead of the 'l_{EA} share'.

Example 21

C5 ?.??:7.50 / ?.??:8.10 / ?.??:8.70 / ?.??:9.30 / ?.??:9.80

A cornea having a p value of 0.8 for which a Bausch and Lomb keratometer has indicated a spherical radius of 8.00 mm (r_K) is to be fitted with a C5 RGP corneal lens designed to create a tear layer **0.011** mm deep at the corneal apex and a total axial edge clearance (C_{EA}) of **100 microns** (μm) = **0.1 mm**. In this example (and most commonly), ϕ_O is chosen to be the contact diameter (ϕ_C).

The C5 lens specification with unknown radii has diameters as shown above. ϕ_O and ϕ_T have been chosen to take account of the patient's pupil diameter (4.5 mm in average indoor lighting), Horizontal Visible Iris Diameter (HVID) 13.50 mm, lower lid margin at the lower limbus and vertical palpebral aperture 9.0 mm between lids of normal tension.

First convert the '***K***' reading (r_K) to corneal apical radius (r_{OK}) using formula ***XIII*** *see* page 202. ϕ_{Mi} is assumed to be 3.10 mm for the Bausch & Lomb keratometer and an average cornea.

$$r_{OK} = \sqrt{(8^2 - (1 - 0.8) * 1.55^2)}$$
$$= \sqrt{(64 - 0.2 * 2.4025)}$$
$$= \sqrt{(63.5195)}$$
$$= \mathbf{7.9699\ mm} \text{ (from } \textit{XIII})$$

To create a tears layer (**TLT**) **11 μm** thick,

$$s_{\phi_C r_O} \text{ must } = s_{\phi_C r_{OK}} + 0.011 \text{ mm}$$

$$s_{\phi_C r_{OK}} = 7.9699/0.8 - \sqrt{((7.9699/0.8)^2 - 3.75^2/0.8)}$$
$$= \mathbf{0.9252\ mm} \text{ (from } \textit{XII})$$

Thus $s_{\phi_C r_O} = 0.9252 + 0.011 = \mathbf{0.9362\ mm}$

$$r_O = (0.9362^2 + 3.75^2)/(2 * 0.9362)$$
$$= 14.9389/1.8224$$
$$= \mathbf{7.9786\ mm} \text{ (from } \textit{XVII})$$

$$DC_{EA} \text{ share for } r_1 = \frac{\text{Total } C_{EA} * (\phi_1 - \phi_O)}{\phi_T - \phi_C}$$
$$= \frac{0.100 * (8.1 - 7.5)}{9.8 - 7.5}$$
$$= \frac{0.100 * 0.6}{2.3} = \frac{0.06}{2.3}$$
$$DC_{EA_1} = \mathbf{0.0261\ mm} \text{ (from } \textit{XXX})$$

Since $\phi_2 - \phi_1$ and $\phi_3 - \phi_2 = 0.6$ mm (as $\phi_1 - \phi_O$),

$$DC_{EA_2} \text{ and } DC_{EA_3} = \mathbf{0.0261\ mm} \text{ (as } DC_{EA_1}).$$

$$DC_{EA} \text{ share for } r_4 = \frac{0.100 * (9.8 - 9.3)}{9.8 - 7.5}$$
$$DC_{EA_4} = \mathbf{0.0217\ mm} \text{ (from } \textit{XXX})$$

The sag formula for an ellipse (***XII***) must be used for corneal sag values involving r_{OK}, whereas formula ***XI*** is used for spherical surface sag values.

$$x_1 = s_{\phi_T r_{OK}} - s_{\phi_O r_{OK}} - DC_{EA_1} = 1.6415 - 0.9252 - 0.0261$$
$$= \mathbf{0.6902}\dagger \mathbf{\ mm} \text{ (from } \textit{XXIXB})$$

†Very small discrepancies may occur in the calculated values here and in the following pages, depending on the number of decimal places used. This applies even when 'floating decimal mode' is used in a calculator or computer, as instruments vary in the number of decimal places they employ.

$$r_1 = \sqrt{(((y_{\phi_T}{}^2 - y_{\phi_O}{}^2 - x_1{}^2)/(2 * x_1))^2 + y_{\phi_T}{}^2)}$$

$$r_1 = \sqrt{(((4.9^2 - 3.75^2 - 0.6902^2)/(2 * 0.6902))^2 + 4.9^2)}$$

$$r_1 = \sqrt{(((24.01 - 14.0625 - 0.4764)/(1.3804))^2 + 24.01)}$$

$$r_1 = \sqrt{((9.4711/1.3804)^2 + 24.01)} = \sqrt{(6.8611^2 + 24.01)}$$

$$r_1 = \sqrt{(47.0751 + 24.01)} = \sqrt{(71.0851)}$$

$$= \mathbf{8.4312\ mm}\ (\text{from } \textit{XXVIII})$$

$$x_2 = s_{\phi_T r_1} - s_{\phi_1 r_1} - DC_{EA_2} = 1.5701 - 1.0364 - 0.0261$$

$$= \mathbf{0.5075}\dagger\ \mathbf{mm}\ (\text{from } \textit{XXIX})$$

$$r_2 = \sqrt{(((y_{\phi_T}{}^2 - y_{\phi_1}{}^2 - x_2{}^2)/(2 * x_2))^2 + y_{\phi_T}{}^2)}$$

$$r_2 = \sqrt{(((4.9^2 - 4.05^2 - 0.5075^2)/(2 * 0.5075))^2 + 4.9^2)}$$

$$= \mathbf{8.7429}\dagger\ \mathbf{mm}\ (\text{from } \textit{XXVIII})$$

$$x_3 = s_{\phi_T r_2} - s_{\phi_2 r_2} - DC_{EA_3} = 1.5022 - 1.1590 - 0.0261$$

$$= \mathbf{0.3171\ mm}\ (\text{from } \textit{XXIX})$$

$$r_3 = \sqrt{(((y_{\phi_T}{}^2 - y_{\phi_2}{}^2 - x_3{}^2)/(2 * x_3))^2 + y_{\phi_T}{}^2)}$$

$$r_3 = \sqrt{(((4.9^2 - 4.35^2 - 0.3171^2)/(2 * 0.3171))^2 + 4.9^2)}$$

$$= \mathbf{9.2656}\dagger\ \mathbf{mm}\ (\text{from } \textit{XXVIII})$$

$$x_4 = s_{\phi_T r_3} - s_{\phi_3 r_3} - DC_{EA_4} = 1.4017 - 1.2513 - 0.0217$$

$$= \mathbf{0.1287\ mm}\ (\text{from } \textit{XXIX})$$

$$r_4 = \sqrt{(((y_{\phi_T}{}^2 - y_{\phi_3}{}^2 - x_4{}^2)/(2 * x_4))^2 + y_{\phi_T}{}^2)}$$

$$r_4 = \sqrt{(((4.9^2 - 4.65^2 - 0.1287^2)/(2 * 0.1287))^2 + 4.9^2)}$$

$$= \mathbf{10.4357\ mm}\ (\text{from } \textit{XXVIII})$$

It is proposed that radii should be rounded to the nearest 0.01 mm, *see* below.

The final specification is thus

C5 7.98:7.5 / 8.43:8.1 / 8.74:8.7 / 9.27:9.3 / 10.44:9.8

With radii rounded to 0.01 mm and using Douthwaite's (1995) formula, C_{EA} may be found as follows:

$$C_{EA} = s_{\phi_T r_{OK}} + \mathbf{TLT} - s_P \text{ - - - - } \textit{XXXIV}\ (\text{for } s_p \textit{ see pp. 189 and 222})$$

$$= 1.6415 + 0.0108 - 1.5524 = \mathbf{0.0999\ mm}$$

The small discrepancy (0.1 µm) is due to rounding the radii to 0.01 mm and limiting the calculation to 4 decimal places.

The radii in *Example 21* have been rounded to the nearest 0.01 mm rather than the traditional 0.05 mm because the extremely large tolerances contained in ISO 8321–1991 and BS 7208–1992, (±0.05 mm for r_O and ±0.1 mm for peripheral radii), allow significant departure from the intended lens parameters. If r_O is rounded from 7.9786 mm to **7.98** mm **TLT** is reduced from 11.0 µm to 10.8 µm as shown above (from ***XVI***). Rounding all the radii to the ***nearest*** 0.05 mm gives the specification:

C5 8.00:7.5 / 8.45:8.1 / 8.75:8.7 / 9.25:9.3 / 10.45:9.8

TLT is reduced from 10.8 µm to 8.17 µm (from ***XVI***). r_2 and r_4 are each increased by 0.01 mm. r_1 is increased by 0.02 mm but r_3 is ***decreased*** by 0.02 mm and these therefore ***tend*** to cancel each other out. Thus the net flattening of the peripheral radii due to rounding in this case is in the order of 0.02 mm which increases C_{EA} minimally from 99.9 µm to 100.5 µm (from ***XXXIV***)†.

However 'Standard' tolerances allow a manufacturer to supply the above lens in the form:

C5 8.05:7.5 / 8.55:8.1 / 8.85:8.7 / 9.35:9.3 / 10.55:9.8

which reduces **TLT** from 8.17 µm to 1.61 µm and C_{EA} is increased from 100.5 µm to 109.06 µm.

To degrade the accuracy by gross rounding before ordering adds unnecessarily to the errors permitted by the 'Standard' tolerances and the total inaccuracy is compounded if every radius is so rounded.

Example 22

A C4 lens will now be designed to give the same DC_{EA} (100 µm) on the same eye. r_O, ϕ_O and ϕ_T are the same:

C4 7.98:7.5 / ?.??:8.0 / ?.??:8.8 / ?.??:9.8

$$DC_{EA_1} = \frac{0.1 * (8.0 - 7.5)}{9.8 - 7.5} = \frac{0.1 * 0.5}{2.3} = \frac{0.05}{2.3}$$

$$= \mathbf{0.0217\ mm}\ (\text{from } \textit{XXX})$$

$$DC_{EA_2} = \frac{0.1 * (8.8 - 8.0)}{9.8 - 7.5} = \frac{0.1 * 0.8}{2.3} = \frac{0.08}{2.3}$$

$$= \mathbf{0.0348\ mm}\ (\text{from } \textit{XXX})$$

$$DC_{EA_3} = \frac{0.1 * (9.8 - 8.8)}{9.8 - 7.5} = \frac{0.1 * 1.0}{2.3} = \frac{0.1}{2.3}$$

$$= \mathbf{0.0435\ mm}\ (\text{from } \textit{XXX})$$

$$x_1 = s_{\phi_T r_{OK}} - s_{\phi_O r_{OK}} - DC_{EA_1} = 1.6415 - 0.9252 - 0.0217$$

$$= \mathbf{0.6946\ mm}\ (\text{from } \textit{XXIX}\mathbf{B})$$

$$r_1 = \sqrt{(((y_{\phi_T}{}^2 - y_{\phi_O}{}^2 - x_1{}^2)/(2 * x_1))^2 + y_{\phi_T}{}^2)}$$

$$r_1 = \sqrt{(((4.9^2 - 3.75^2 - 0.6946^2)/(2 * 0.6946))^2 + 4.9^2)}$$

$$= \mathbf{8.3919\ mm}\ (\text{from } \textit{XXVIII})$$

†see Footnote to page 209.

$x_2 = s_{\phi_T r_1} - s_{\phi_1 r_1} - DC_{EA_2} = 1.5791 - 1.0146 - 0.0348$

$= \mathbf{0.5297\ mm}$ (from ***XXIX***)

$r_2 = \sqrt{(((y_{\phi_T}{}^2 - y_{\phi_1}{}^2 - x_2{}^2)/(2 * x_2))^2 + y_{\phi_T}{}^2)}$

$r_2 = \sqrt{(((4.9^2 - 4.00^2 - 0.5297^2)/(2 * 0.5297))^2 + 4.9^2)}$

$= \mathbf{8.7890\ mm}$ (from ***XXVIII***)

$x_3 = s_{\phi_T r_2} - s_{\phi_2 r_2} - DC_{EA_3} = 1.4927 - 1.1807 - 0.0435$

$= \mathbf{0.2685\ mm}$ (from ***XXIX***)

$r_3 = \sqrt{(((y_{\phi_T}{}^2 - y_{\phi_2}{}^2 - x_3{}^2)/(2 * x_3))^2 + y_{\phi_T}{}^2)}$

$r_3 = \sqrt{(((4.9^2 - 4.40^2 - 0.2685^2)/(2 * 0.2685))^2 + 4.9^2)}$

$= \mathbf{9.8333\ mm}$ (from ***XXVIII***)

The specification of the lens in *Example 22*, (with radii rounded to 0.01 mm) is:

C4 7.98:7.5 / 8.39:8.0 / 8.79:8.8 / 9.83:9.8

Then $C_{EA} = s_{\phi_T r_{OK}} + \mathbf{TLT} - s_P$ (for s_p *see* pp. 189 and 222)

$= \mathbf{1.6415 + 0.0108 - 1.5524}$ (TLT from ***XVI***)

$= \mathbf{0.0999\ mm}$ ($\approx$ 0.1 mm), (from ***XXXIV***)†

'Standard' tolerances allow the above lens to be supplied in the form C4 8.03:7.5 / 8.49:8.0 / 8.89:8.8 / 9.93:9.8 This would reduce TLT to **0.0042 mm**, an error of 61.8%, from the desired 0.011 mm.

If all the calculated radii are rounded to 0.05 mm the lens becomes C4 8.00:7.5 / 8.40:8.0 / 8.80:8.8 / 9.85:9.8 which allows the lens to be supplied as

C4 8.05:7.5 / 8.50:8.0 / 8.90:8.8 / 9.95:9.8

TLT is then reduced to **0.0016 mm**, (error of 85.4%) and C_{EA} = **0.1097 mm**, (error = 9.7% from the desired 0.1 mm).

The change in TLT indicated above is the 'worst case' result due to rounding and permitted tolerance for r_O. The error in C_{EA} could be significantly greater than that indicated above in the 'worst case' – if all three peripheral radii needed to be increased by 0.024 mm to round them to 0.05 mm.

A further degradation of the intended specification may be introduced due to the remarkable tolerances permitted for diameters; ± 0.2 mm for optic and peripheral zones and ± 0.1 mm for total diameter.

C4 8.05:7.3 / 8.50:7.8 / 8.90:8.6 / 9.95:9.7 could be supplied ***within tolerance!*** TLT virtually disappears and is reduced to 0.00089 mm, (error 92%) and C_{EA} is increased to 0.1144 mm, (error of 14.4%). The 'worst case' error for C_{EA} could be more than this for the reasons explained above.

Collectively these sources of error probably account for why two lenses, purporting to be of the same specification, can look and behave quite differently on the eye.

†see Footnote to page 209.

Although these 'worst case' results are possible (and permissible under International and British standards) it is extremely unlikely that the deviation of every variable parameter would be in the 'wrong' direction and at the maximum tolerance, however it is clearly disadvantageous and unnecessary to 'round' calculated values to more than 0.01 mm before ordering.

Most modern lathes can be set to 0.005 mm (some to 0.0005 mm) so it is relatively easy for manufacturers to set their lathes to 0.01 mm. Some lathes are now so accurate that the surfaces they produce do not need to be polished but even if polishing is necessary it is no more difficult for a manufacturer to produce a radius to within ± 0.05 mm of 7.98 mm than to within ± 0.05 mm of 8.0 mm.

It has long been accepted practice to design multi-curve lenses so that the bearing surface is the transition between r_O and r_1. This is normally blended to improve comfort by reducing the sharpness of the transition (*See Figure 10.6*).

For lenses having two or more peripheral curves (and when the eccentricity of the cornea is known) the authors favour a design in which the surface created by r_1 is parallel to the cornea and is the main bearing surface.

Example 23

The C4 lens above will now be re-designed (for the same eye) so that r_1 is parallel to the cornea and the desired C_{EA} (0.1 mm) is provided by r_2 and r_3.

C_{EA}, r_O, ϕ_O and ϕ_T are the same. The band width for r_1 is increased to provide a greater bearing surface area although this, as with all other diameters, is optional.

C4 7.98:7.5 / ???:8.5 / ???:9.3 / ???:9.8 shows the predetermined and unknown parameters.

If r_1 is to align with the cornea the sag created by the surface of r_1 must equal the sag of the cornea over the band ϕ_O to ϕ_1, which is the value of x_N required for formula ***XXVIIIA***, (used instead of formula ***XXVIII*** in this case as we are dealing with a single peripheral band).

Formula ***XXIXB*** is modified to ***XXIXC*** which calculates a single band of corneal sag and the DC_{EA} term is omitted as no C_{EA} is required from this surface.

$x_N = s_{\phi_1 r_{OK}} - s_{\phi_O r_{OK}} = 1.2062 - 0.9252$

$= \mathbf{0.281\ mm}$ (from ***XXIXC***)

$r_N = \sqrt{(((y_{\phi_N}{}^2 - y_{\phi_{N-1}}{}^2 - x_N{}^2)/(2 * x_N))^2 + y_{\phi_N}{}^2)}$

$r_1 = \sqrt{(((4.25^2 - 3.75^2 - 0.281^2)/(2 * 0.281))^2 + 4.25^2)}$

$= \mathbf{8.1695\ mm}$ (from ***XXVIIIA***). Round to 8.17 mm.

Because r_1 is in alignment with the cornea ϕ_1 is the 'effective' contact diameter (ϕ_c); i.e., the diameter from which edge clearance begins.

The desired C_{EA} (0.1 mm) is shared between r_2 and r_3 using formula ***XXX***.

$$DC_{EA_2} = \frac{0.1 * (9.3 - 8.5)}{9.8 - 8.5} = \frac{0.1 * 0.8}{1.3} = \frac{0.08}{1.3}$$

$$= \mathbf{0.0615\,mm} \text{ (from } \textit{XXX}\text{)}$$

$$DC_{EA_3} = \frac{0.1 * (9.8 - 9.3)}{9.8 - 8.5} = \frac{0.1 * 0.5}{1.3} = \frac{0.05}{1.3}$$

$$= \mathbf{0.0385\,mm} \text{ (from } \textit{XXX}\text{)}$$

$$x_2 = s_{\phi_T r_{OK}} - s_{\phi_1 r_{OK}} - DC_{EA_2} = 1.6415 - 1.2062 - 0.0615$$

$$= \mathbf{0.3738\,mm} \text{ (from } \textit{XXIXB}\text{)}$$

$$r_2 = \sqrt{(((y_{\phi_T}{}^2 - y_{\phi_1}{}^2 - x_2{}^2)/(2 * x_2))^2 + y_{\phi_T}{}^2)}$$

$$r_2 = \sqrt{(((4.9^2 - 4.25^2 - 0.3738^2)/(2 * 0.3738))^2 + 4.9^2)}$$

$$= \mathbf{9.1847\,mm} \text{ (from } \textit{XXVIII}\text{). Round to 9.18 mm.}$$

$$x_3 = s_{\phi_T r_2} - s_{\phi_2 r_2} - DC_{EA_3} = 1.4171 - 1.2648 - 0.0385$$

$$= \mathbf{0.1138\,mm} \text{ (from } \textit{XXIX}\text{)}$$

$$r_3 = \sqrt{(((y_{\phi_T}{}^2 - y_{\phi_2}{}^2 - x_3{}^2)/(2 * x_3))^2 + y_{\phi_T}{}^2)}$$

$$r_3 = \sqrt{(((4.9^2 - 4.65^2 - 0.1138^2)/(2 * 0.1138))^2 + 4.9^2)}$$

$$= \mathbf{11.5264\,mm} \text{ (from } \textit{XXVIII}\text{). Round to 11.53 mm.}$$

Thus the lens to order (radii rounded to 0.01 mm) is:

C4 7.98:7.5 / 8.17:8.5 / 9.18:9.3 / 11.53:9.8

The following calculation will confirm that the desired edge clearance (0.10 mm) is provided by r_2 and r_3. In this case the effective ϕ_C is ϕ_1 so the edge ***clearance*** created between ϕ_C and ϕ_T = the ***sagitta*** of the ***cornea*** from ϕ_1 to ϕ_T minus the ***sagitta*** of the back surface of the ***lens*** from ϕ_1 to ϕ_T.

Sagitta of cornea (ϕ_1 to ϕ_T) $= s_{\phi_T r_{OK}} - s_{\phi_1 r_{OK}}$

$= 1.6415 - 1.2062$

$= \mathbf{0.4353\,mm}$ (sags from ***XII***)

Sagitta of back surface of lens (ϕ_1 to ϕ_T) =

$$s_{\phi_2 r_2} - s_{\phi_1 r_2} + s_{\phi_T r_3} - s_{\phi_2 r_3}$$

$$= 1.2648 - 1.0431 + 1.0930 - 0.9792$$

$$= \mathbf{0.3355} \text{ (sags from } \textit{XI}\text{)}$$

$$C_{EA} = 0.4353 - 0.3355 = \mathbf{0.0998\,mm}$$

The small discrepancy (0.2 μm) is due to the rounding of calculated values.

The contact diameter (ϕ_C) of *any* contact lens on a given cornea is the *widest* back surface diameter at which the primary sag of the lens ($s_{\phi_w P}$) is => the sag of the cornea at the same diameter.

In *Example 23*, r_1 was calculated to produce a surface parallel to the cornea, or as nearly parallel as a spherical surface with its radius rounded to the nearest 0.01 mm can be to an ellipsoidal surface.

Although ϕ_1 was taken to be the 'effective' ϕ_C for the purpose of calculating r_2 and r_3, either ϕ_O or ϕ_1 can be used in formula ***XVI*** to calculate TLT because the surface of r_1 is parallel to the cornea (or very nearly so).

Using r_O = **7.98** mm, r_1 = **8.17** mm, r_{OK} = **7.97** mm (all radii have been rounded to 0.01 mm):

TLT for ϕ_O $= s_{\phi_O r_O} - s_{\phi_O r_{OK}}$

$= 0.9360 - 0.9252$

$= \mathbf{0.0108\,mm}$ (from ***XVI***, ***XI*** and ***XII***)

TLT for ϕ_1 $= s_{\phi_1 P} - s_{\phi_1 r_{OK}}$

$= s_{\phi_O r_O} + s_{\phi_1 r_1} - s_{\phi_O r_1} - s_{\phi_1 r_{OK}}$

$= 0.9360 + 1.1924 - 0.9115 - 1.2062$

$= \mathbf{0.0107\,mm}$ (from ***XVI***, ***XI*** and ***XII***)

The similarity of these two results† (within 0.1 μm) indicates that r_1 aligns fairly closely with the cornea.

Calculation of anterior optic radius (r_{ao}) when Centre Thickness (t_C) is known (or chosen), given spherical r_O, refractive index (n) and BVP (F'_v)

Formula XXXV

An appropriate centre thickness (t_C) is usually chosen when designing minus lenses. t_C can be chosen empirically for plus lenses but may have to be modified by trial and error to achieve an acceptable t_{EA} (or t_{JA} for lenticular lenses), but see formula ***XXXVII*** below. It is assumed that the lens is in air.

$$r_{ao} \text{ (in m)} = \frac{(n_2 - n_1)}{-L_2} \text{ (from modified } \textit{IV}\text{)}$$

$$= (1 - n)/(-L_2) \text{ in air}$$

The lens is reversed to calculate L_2 and, unless F'_v is plano, ***XXIV*** is modified so that $L_1' = F_2 - F'_v$ because the light incident on F_2 is not parallel.

$$L_2 \text{ (vergence of light incident on } F_1) = \frac{1}{\left[\frac{1}{F_2 - F'_v} - \frac{t_C}{n}\right]}$$

(from modified ***XXIV***) (t_C in m)

†see Footnote to page 209.

Combining modified expressions ***IV*** and ***XXIV***:

$$r_{ao} = \frac{(1-n)}{\left[\frac{1}{F_2 - F'_v} - \frac{t_C}{n}\right]^{-1}} \text{ - - - - } XXXV \ (t_C \text{ in m})$$

The lens is reversed (as in *Figure 5.25*, p. 181) to calculate r_{ao}, and r_o is given a –ve sign.

[Care must be taken with $(n_2 - n_1)$. Bearing in mind that the lens is reversed, the modified formula ***IV*** and the first part of the 'calculator' version of ***XXXI*** are concerned with light which will emerge **from** F_1 therefore $(n_2 - n_1) = (1 - n)$; where n = the refractive index of the lens. The middle part of the calculator formula ***XXXV*** deals with light **entering** F_2 so $(n_2 - n_1) = (n - 1)$].

For calculators:

$$r_{ao} \text{ (in metres)} = (1-n)/(((n-1)/\{-r_o\} - F'_v)^{-1} - t_C/n)^{-1}$$

- - - - ***XXXV***

The 'curly' brackets enclosing $\{-r_o\}$ have no effect on the working of formula ***XXXV*** and are simply to highlight the fact that r_o is given a –ve sign because it is measured in the opposite direction to the incident light.

Example 24

A C3 lens having the back surface 8.00:7.70/8.85:8.20/10.30:9.20 and refractive index (n) 1.47, is to have BVP –5.00 D. If t_c is made 0.15 mm what will be the radius of the front surface (r_{ao})? For t_{EA} *see Example 24* below.

r_o = 8.00 mm, entered as –0.008 metres; t_c should also be in metres.

$$r_{ao} \text{ (in m)} = (1.00 - 1.47)*/(((1.47 - 1.00)/ -0.008 - -5.00)^{-1} - 0.00015/1.47)^{-1}$$

and

$$r_{ao} \text{ (in mm)} = -470/((0.47/-0.008 - -5.00)^{-1} - 0.000102041)^{-1}$$
$$= -470/(-53.75^{-1} - 0.000102041)^{-1}$$
$$= -470/(-0.018604651 - 0.000102041)^{-1}$$
$$= -470/-0.018706692^{-1}$$
$$= -470/-53.45680578$$
$$= \mathbf{8.79\ mm} \text{ (from } XXXV)$$

For *Example 17*, t_c = **0.4 mm** was chosen empirically; r_o = **7.9 mm**; n = **1.47**; F'_v = **+6.00 D**

$$r_{ao} \text{ (in mm)} = (1.00 - 1.47)*10^3/(((1.47 - 1.00)/ -0.0079 - 6.00)^{-1} - 0.0004/1.47)^{-1}$$
$$= -4.70/((0.47/-0.008 - 6.00)^{-1} - 0.000272109)^{-1}$$
$$= -4.70/-64.3469$$
$$= \mathbf{7.304\ mm}$$

Alternative method of calculation of anterior optic radius (r_{ao}) when centre thickness (t_C) is known (or chosen), given r_o, refractive index (n), and BVP (F'_v)

Formula XXXVI

An alternative approach to the calculation of r_{ao} is to add a correcting value to the radius of the 'thin lens' front surface. The correcting value is part of a formula derived by Bennett (1985) for afocal lenses, adapted here for powered lenses. t_c must still be chosen empirically for **plus** lenses when using formula ***XXXVI*** but see formula ***XXXVII*** below.

$$\text{Bennett's value} = \frac{(n_2 - n_1)*t_c}{n_2}$$
$$= (n-1)*t_c/n \text{ for a lens of refractive index } n, \text{ in air.}$$

(where n_2 is the refractive index of the lens and n_1 is air).

This represents the amount by which the radius of the 'thick lens' front surface **exceeds** that of its 'thin lens' front surface equivalent, so it is added to the 'thin lens' front surface radius.

The 'thin lens' ***power*** of the front surface:

$$F_1 \text{ 'thin'} = F'_v - F_2$$

The power of the back (concave) surface:

$$F_2 = \frac{n_2 - n_1}{r_o} \text{ (from } III)$$
$$= \frac{1-n}{r_o} \text{ (}see\text{ below)}$$

Care must be taken when calculating F_2; n_2 = air and n_1 = the lens. Elsewhere in this calculation $n_2 - n_1$ relates to the front surface when n_2 = the lens and n_1 = air (*see* below).

$$r_{ao} \textbf{ 'thin'} \text{ (in mm)} = \frac{(n_2 - n_1)*10^3}{F_1 \text{ 'thin'}} \text{ (from modified } IV)$$
$$= \frac{(n-1)*10^3}{F'_v - \left[\frac{1-n}{r_o}\right]} \ (r_o \text{ in metres})$$

$$r_{ao}\ \textbf{'thick'}\ (\text{in mm}) = \frac{(n-1)*10^3}{F'_V - \left[\frac{1-n}{r_o}\right]} + \frac{(n-1)*t_c}{n} \quad \text{- - - - } \textit{XXXVI}$$

For calculators:

$$r_{ao}\,(\text{in mm}) = (n-1)*10^3/(F'_V - (1-n)/r_o) + (n-1)*t_c/n \text{ - - - - } \textit{XXXVI}$$

The lens in *Example 17* has r_o = 7.90 mm (0.0079 m); n = 1.47; t_c = 0.4 mm; F'_V = +6.00 D

r_{ao} = (1.47 − 1.00)*10^3/(6.00 − (1.00 − 1.47)/0.0079)
+ (1.47 − 1.00)*0.4/1.47
= 470/(6.00 − (−59.49)) + 0.188/1.47
= 470/65.49 + 0.1289
= 7.176668 + 0.1289
= **7.304559 mm** (≈ 7.305) (from *XXXVI*)

The lens in *Example 18* has r_o = 8.00 mm (0.008 m); n = 1.473; t_c = 0.2 mm; F'_V = −10.00 D

r_{ao} = (1.473 − 1.00)*10^3/(−10.00 − (1.00 − 1.473)/(0.008)
+ (1.473 − 1.00)*0.2/1.473
= 473/(−10.00 − (−59.125)) + 0.0946/1.473
= 473/49.125 + 0.064222675
= 9.6284987 + 0.064223
= **9.6927 mm** (≈ 9.69) (from *XXXVI*)

Calculation of axial edge thickness (t_{EA})

$t_{EA} + s_{ao} = s_P + t_c$ for full aperture lenses.

Where s_{ao} = sagitta of r_{ao}, at ϕ_T for full aperture lenses; s_P = primary sag (*see* pp. 189 and 190 and *Figures 5.30 and 5.31*; sags from *XI*)

$t_{EA} + s_{ao} = s_{\phi_{ao}P}$ (s_P at ϕ_{ao}) + t_c, for positive lenticulars (*see* p. 190 and *Figure 5.32*)

If the lens in *Example 17*, p. 204, has the back surface:

C3 7.90:7.70 / 8.70:8.20 / 9.80:9.20

$s_P = s_{\phi_o r_o} + s_{\phi_1 r_1} - s_{\phi_o r_1} + s_{\phi_T r_2} - s_{\phi_1 r_2}$
= **1.3779 mm** (see p. 190 and *Figure 5.31*)

t_c = **0.4 mm**

$s_{ao} = s_{\phi_T r_{ao}}$ = **1.6305 mm**
(from r_{ao} = 7.304 and ϕ_T = 9.20, *see* above and *XI*)

$t_{EA} = s_P + t_c - s_{ao}$ = 1.3779 + 0.4 − 1.6305
= **0.1474 mm** (*see* p. 189 and *Figure 5.30*)

The back surface of the lens in *Example 18* is:

C3 8.00:7.70/8.85:8.20/10.30:9.20

$t_{EA} = s_P + t_c - s_{ao}$ = 1.3461 + 0.2 − 1.161
= **0.385 mm** (calculated as for *Example 17*).

The front surface of this lens would probably be lenticulated to give t_{EA} = 0.15 mm

For the lens in *Example 24*:

C3 8.00:7.70/8.85:8.20/ 10.30:9.20

$t_{EA} = s_P + t_c - s_{ao}$ = 1.3461 + 0.15 − 1.2997
= **0.196 mm** (calculated as above).

Calculation of anterior optic radius (r_{ao}) and (t_c) for plus lenses, given F'_V, refractive index (n) and back surface specification

Formula XXXVII

The calculation of r_{ao} is more complicated if t_C is not known, which is often the case for plus lenses. An appropriate t_{EA} is normally chosen for full aperture plus lenses (t_{JA} for lenticular lenses). The centre thickness (t_c) so produced is then calculated from $t_c = s_{ao} + t_{EA} - s_P$ (see p. 189 and *Figure 5.30*).

First the sagitta of the required front surface (s_{ao}) must be found. F_2 is calculated from *III*, then, assuming the lens to be infinitely thin, the value of F_1 (F_1 'thin') = $F'_V - F_2$. The focal length of F_1 'thin' = f_1 'thin' = $1/F_1$ 'thin'. This establishes the position of the second principal focus of the front surface relative to the back vertex. f_1 'thin' is then modified to maintain this relationship taking account of the change in vergence due to the thickness of the finished lens, i.e. t_{EA} (or t_{JA}) + the t_c imposed by the refractive index. This is achieved using a modified version of a formula published by Jalie (1974): s_{ao} =

$$\frac{(n-1)\left(n\left[\frac{10^3}{F'_V - \left[\frac{1-n}{r_o}\right]}\right] - (s_P - t_{EA})\right)}{n-2(n-1)} - \sqrt{\frac{(n-1)^2\left(n\left[\frac{10^3}{F'_V - \left[\frac{1-n}{r_o}\right]}\right] - (s_P - t_{EA})\right)^2 - \left[\frac{\phi_T}{2}\right]^2 n(n-2(n-1))}{n-2(n-1)}}$$

The formula in this form is for full aperture lenses, symbols as above.

For lenticular lenses t_{EA} would be replaced by t_{JA} and ϕ_T by ϕ_{ao}, also, s_P would be calculated at ϕ_{ao} instead of ϕ_T.

Although this looks formidable two of the 'groups' which appear twice and some of the other values can be pre-calculated thus simplifying the formula.

Since $1 - n/r_o = F_2$ and F_1 'thin' $= F'_V - F_2$,

$$\left[\frac{10^3}{F'_V - \left[\frac{1-n}{r_o}\right]}\right] = f_1 \text{ 'thin' (in mm)}$$

The 'group' $(n*f_1$ 'thin' $- (s_P - t_{EA}))$ appears twice in the formula. If $s_P - t_{EA}$ ($s_{\phi_{ao}P} - t_{JA}$ for lenticular) is named 'Q'; $(n*f_1$ 'thin' $- Q)$ could be termed 'A'.

$s_P = s_{\phi_O r_O} + s_{\phi_1 r_1} - s_{\phi_O r_1} + \cdots s_{\phi_N r_N} - s_{\phi_{N-1} r_N}$
(see ***XI*** also p. 190, *Figure 5.31*).

$n - 2(n-1)$ also appears twice. Call this 'B'

$y = \phi_T/2$ *(or* $\phi_{ao}/2$, if lenticular).

The formula now becomes:

$$s_{ao} = \frac{(n-1)A - \sqrt{(n-1)^2A^2 - (y^2nB)}}{B} \text{ - - - - } \textit{XXXVII}$$

Which looks much more agreeable!

For calculators:

$$s_{ao} = ((n-1)*A - \sqrt{((n-1)^2*A^2 - y^2*n*B)})/B$$
$$\text{- - - - } \textit{XXXVII}$$

Example 25

The C3 lens from p. 190 is used here 8.00:7.00/9.05:7.80/10.80:8.60 but with refractive index 1.47 and BVP +8.00 D. If t_{EA} is made 0.15 mm what will be the radius of the front surface (r_{ao}) and the centre thickness (t_c)?

A corneal lens with BVP +8.00 D would normally be made in lenticular form but it will be designed first as a full aperture lens to show the method and also to illustrate later the reduction in t_c achieved by using the lenticular form.

First the pre-calculations:

$F_2 = (1.00 - 1.47)/0.008 = \mathbf{-58.75\ D}$ (from ***III***)

F_1 **'thin'** $= F'_V - F_2 = +8.00 - -58.75 = \mathbf{+66.75\ D}$

f_1 **'thin'** (mm) $= 1000/F_1$ 'thin' $= 1000/66.75$
$= \mathbf{14.9813\ mm}$

$Q = s_P - t_{EA} = 1.1497 - 0.15 = \mathbf{0.9997\ mm}$
(for s_P *see* p. 190 and *Figures 5.30 and 5.31*.)

$A = n*f_1$ 'thin' (mm) $- Q$
$= 1.147*14.9813 - 0.9997 = \mathbf{21.0228\ mm}$

$y = \phi_T/2 = 8.6/2 = \mathbf{4.3\ mm}$

$B = n - 2*(n-1) = 1.47 - (2*0.47) = \mathbf{0.53}$

Enter the sub-values '***A***' '***y***' and '***B***' into formula ***XXXVII***

$s_{ao} = (0.47*21.0228$
$- \sqrt{(0.47^2*21.0228^2 - 4.3^2*1.47*0.53)})/0.53$
$= (9.8807 -$
$\sqrt{(0.2209*441.9581 - 18.49*1.47*0.53)})/0.53$
$= (9.8807 - \sqrt{(83.2230)})/0.53$
$= (9.8807 - 9.1227)/0.53 = 0.7580/0.53$
$= \mathbf{1.4302\ mm}$ (from ***XXXVII***)

$r_{ao} = (y^2 + s^2)/(2*s) = (4.3^2 + 1.4302^2)/(2*1.4302)$
$= (18.49 + 2.0455)/2.8604 = 20.5355/2.8604$
$= \mathbf{7.1792\ mm}$ (from ***XVII***)

$t_c = s_{ao} + t_{EA} - s_P = 1.4302 + 0.15 - 1.1497$
$= \mathbf{0.4305\ mm}$ (*see* p. 191).

Using these values which are correct to 4 decimal places, F'_V checks as + **7.9966 D**. Using 'floating decimal mode' for the calculations, F'_V checks as exactly **+8.00 D**.

A lenticular front surface will reduce t_c, thereby reducing weight and increasing the oxygen transmissibility of the lens, but will also require a slightly steeper r_{ao} to converge the light in the shorter distance (reduced t_c) to give the same BVP.

The sequence of calculations to find the new r_{ao} and t_c is the same as for the full aperture lens except that ϕ_{ao} and t_{JA} must now be chosen instead of ϕ_T and t_{EA}. Also the primary sag of the ***back*** surface must be calculated for ϕ_{ao} ($s_{\phi_{ao}P}$) instead of ϕ_T.

Surprisingly axial junction thickness varies very little (usually 0.15 to 0.18 mm) over a wide range of lens parameters and RGP materials. If t_{JA} is more than 0.18 mm the advantage of a reduced t_c and the usefulness of a negative carrier portion are lost, as the maximum t_{EA} advised is 0.24 mm. When t_{JA} is less than 0.15 mm increased flexure occurs and the lens is in danger of splitting round the junction.

Although traditionally we refer to ***AXIAL*** junction thickness the physical strength of the junction depends on the shortest cross-section, which is rarely represented by t_{JA}. The accurate calculation of the thinnest cross-section of the junction is mathematically very complex, involving a protracted iterative procedure. The critical minimum thickness for RGP materials is in the region of 0.13 mm.

It is difficult to justify the iterative procedure for 'long hand' calculations when a very good approximation of the thinnest cross-section, which is 7 times more accurate (or better) than the ±0.02 mm tolerance allowed for thickness in ISO 8321–1: 1991 and BS 7208–1: 1992, may be deduced trigonometrically (*see* formula ***XXXIX*** below).

$$s_{ao} = ((n-1)*A - \sqrt{((n-1)^2*A^2 - y^2*n*B)})/B \quad \text{- - - - } \textit{XXXVII}$$

$$s_{ao} = (0.47*21.3016 - \sqrt{(0.47^2*21.3016^2 - 3.65^2*1.47*0.53)})/0.53$$

$$= \mathbf{1.0048\ mm} \text{ (from } \textit{XXXVII})$$

Calculation of anterior surface specification and t_C for plus lenses in lenticular form, given F'_V, refractive index (n) and back surface specification

*Formulae **XVII**, **XXVIII**, **XXIX**, **XXXVII** and **XXXVIII***

Example 26

The front surface of the lens in *Example 25* will now be re-designed in lenticular form with a negative surfaced carrier portion. Ideally the anterior optic diameter (ϕ_{ao}) of any lenticular lens should be greater than ϕ_o to avoid 'designed in' junction flare caused by light, having passed through the anterior optic surface, converging within the thickness of the lens to a diameter less than ϕ_o. Worst case calculations using r_o = 6.25 mm and F'_V = +18.00 D indicate that if ϕ_{ao} exceeds ϕ_o by 0.08 mm or more no flare will emanate from this cause.

The tolerance allowed in ISO 8321–1:1991 and BS 7208–1:1992 for optic and peripheral diameters is ± 0.2 mm so the front surface will be designed with ϕ_{ao} 0.3 mm greater than ϕ_o on the grounds that a lens produced within tolerance will not create junction flare, and no detrimental effect will be caused (other than a very slight increase in t_c) if ϕ_{ao} is 0.5 mm greater than ϕ_o.

All the values for formula ***XXXVII*** remain the same except y and Q, and of course, the value A because it contains Q.

The anterior optic diameter, $\boldsymbol{\phi_{ao}} = \phi_o + 0.3 = \mathbf{7.3\ mm}$

$$y = \phi_{ao}/2 = 7.3/2 = \mathbf{3.65\ mm}$$

$$Q = s_{\phi_{ao}P} - t_{JA}$$

When $\phi_{ao} > \phi_o$ then:

$$s_{\phi_{ao}P} = s_{\phi_o r_o} + s_{\phi_{ao} r_1} - s_{\phi_o r_1}$$

$$= 0.8063 + 0.7687 - 0.7042$$

$$= \mathbf{0.8708\ mm} \text{ (sags from } \textit{XI})$$

(for s_P *see* p. 190 and *Figure 5.31*)

t_{JA} is chosen to be **0.15 mm**, so Q now = 0.8708 – 0.15

$$= \mathbf{0.7208\ mm}$$

$$A = (n*f_1 \text{ 'thin'} - Q) = 1.47*14.9813 - 0.7208$$

$$= \mathbf{21.3017\ mm}$$

$$B = n - 2*(n-1) = 1.47 - (2*0.47)$$

$$= \mathbf{0.53} \text{ (as in } \textit{Example 25})$$

This new s_{ao} is used to calculate the lenticular r_{ao}.

$$r_{ao} = (y^2 + s_{ao}^2)/(2*s_{ao}) \quad \text{- - - - } \textit{XVII}$$

$$r_{ao} = (13.3225 + 1.0096)/2.0096$$

$$= \mathbf{7.1320\ mm} \text{ (from } \textit{XVII})$$

(Note: The value given for r_{ao} has been determined by using 'floating decimal mode' for the calculations.)

$$t_C = s_{ao} + t_{JA} - s_{\phi_{ao}P} \text{ (}\textit{see}\text{ p. 214).}$$

$$= 1.0048 + 0.15 - 0.8708 \text{ (from above).}$$

$$= \mathbf{0.2840\ mm}$$

Thus lenticulation has reduced t_c by about 34% from 0.4305 mm to 0.2840 mm.

Calculation of front peripheral radius (r_{a1}).
(Also applies to negative lenses)

The lens in *Example 26* is to have a 'negative' carrier so t_{EA} must be greater than t_{JA}. The anterior peripheral radius (r_{a1}) must therefore provide a *smaller* sag, x_{a1}, between ϕ_{ao} and ϕ_T than is provided by the peripheral geometry of the ***back*** surface ***from*** ϕ_{ao} ***out to*** ϕ_T (*see Figure* 5.37(a) (right hand side of diagram).

Had a 'positive' carrier been required (needed only rarely, for example in the case of a patient with proptosed eyes wearing a full aperture –ve lens which attaches to the upper lid), t_{EA} must be less than t_{JA}, r_{a1} being required to provide a *greater* sag, x_{a1}, than is provided by the ***back*** surface ***from*** ϕ_{ao} ***out to*** ϕ_T.

The amount by which t_{EA} differs from t_{JA} is a matter of choice. The maximum t_{EA} advised is 0.24 mm, which will be used in the present example.

For a 'parallel' carrier x_{a1} in *Figure 5.32* would = x (*also see* p. 191).

For the negative carrier in this example, since t_{JA} = 0.15 mm, r_{a1} must provide 0.24 – 0.15 = 0.09 mm *less* sag than is provided by the ***back*** surface from $\boldsymbol{\phi_{ao}}$ ***to*** $\boldsymbol{\phi_T}$, therefore in *Figure 5.37(a)* (right hand side of Figure)

$$x_{a1} = x - 0.09\ \text{mm}.$$

Because $\phi_{ao} > \phi_o$, x includes only *part* of the sag contributed by the surface of r_1 and *all* of the sag contributed by the surface of r_2.

$$x = s_{\phi_T r_2} - s_{\phi_1 r_2} + (s_{\phi_1 r_1} - s_{\phi_{ao} r_1}).$$

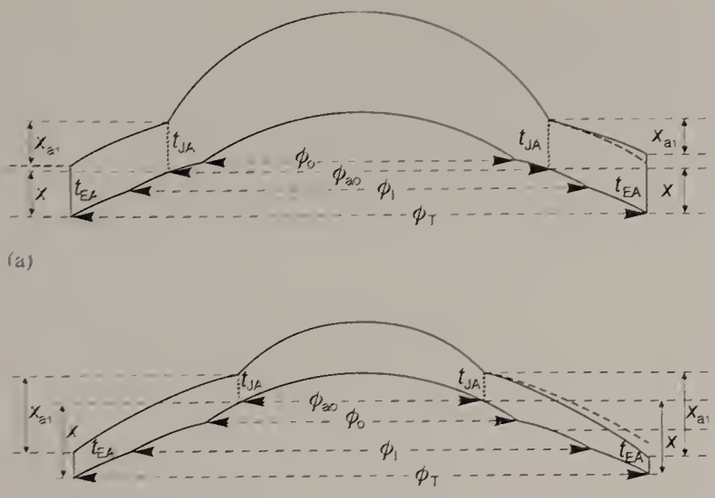


Figure 5.37 *(a)* Positive lenticular lens with tri-curve back surface and $\phi_{ao} > \phi_o$. Left hand side of figure shows a parallel carrier zone with $t_{JA} = t_{EA}$ and $x_{a1} = x$. Right-hand side of figure shows a negative carrier zone with $t_{JA} < t_{EA}$ and $x_{a1} < x$. *(b)* Positive lenticular lens with tri-curve back surface and $\phi_{ao} < \phi_o$. Left-hand side of figure shows a parallel carrier zone with $t_{JA} = t_{EA}$ and $x_{a1} = x$. Right-hand side of figure shows a positive carrier zone with $t_{JA} > t_{EA}$ and $x_{a1} > x$

Since x_{a1} is $(Dt_{EA} - t_{JA})$ less than x,

$$x_{a1} = s_{\phi_T r_2} - s_{\phi_1 r_2} + (s_{\phi_1 r_1} - s_{\phi_{ao} r_1}) - (Dt_{EA} - t_{JA})$$

(*see* ***XXXVIII*** in adjacent column)

For calculators:

$$x_{a1} = 10.8 - \sqrt{(10.8^2 - 4.3^2)} - (10.8^2 - \sqrt{(10.8^2 - 3.9^2)}) + (9.05 - \sqrt{(9.05^2 - 3.9^2)}) - (9.05 - \sqrt{(9.05^2 - 3.65^2)}) - (0.24 - 0.15)$$

$$x_{a1} = 0.8929 - 0.7288 + 0.8835 - 0.7687 - 0.09 \quad \text{(sags from } XI\text{)}$$

$$= \mathbf{0.18896\ mm}$$

Thus,

$$r_{a1} = \sqrt{(((y_{\phi_T}{}^2 - y_{ao}{}^2 - x_{a1}{}^2)/(2 * x_{a1}))^2 + y_{\phi_T}{}^2)} \quad \text{----} \ \textit{XXVIII}$$

$$r_{a1} = \sqrt{(((4.3^2 - 3.65^2 - 0.18896^2)/(2 * 0.18896))^2 + 4.3^2)}$$

$$= \mathbf{14.2438\ mm}$$

The following calculation shows that this value for r_{a1} provides the desired value for t_{EA} of 0.24 mm.

The Primary Sag of the ***anterior*** surface.

$$s_{ap} = s_{\phi_{ao} r_{ao}} + (s_{\phi_T r_{a1}} - s_{\phi_{ao} r_{a1}})$$

$$= 1.0048 + (0.6646 - 0.4756) = 1.0048 + 0.189$$

$$= \mathbf{1.19376\ mm}$$

$$t_{EA} = s_P + t_C - s_{ap}$$

$$= 1.149 + 0.2843 - 1.19376$$

$$= \mathbf{0.2395\ mm}\ (\approx 0.24\ \text{mm}).$$

The small discrepancy in t_{EA} (0.5 μm) is due to the use of rounded values, for in floating decimal mode s_P = 1.149690443 which gives t_{EA} = 0.2402 mm.

Figure 5.37 (a) (right hand side) depicts a lenticular lens with a –ve carrier and $\phi_{ao} > \phi_o$. In *Figure 5.37 (b) (left hand side)* the lens has a parallel carrier and $\phi_{ao} < \phi_o$. On p. 191 a lens with $\phi_{ao} = \phi_o$ is calculated with a parallel carrier and the use of a lens with a +ve carrier is described above. The following general formula applies to all three types of carrier and any combination of ϕ_{ao} and ϕ_o.

$$s_{ac} = (s_{\phi_1 r_N} - s_{\phi_{T-1} r_N}) + (s_{\phi_{T-1} r_{N-1}} - s_{\phi_{T-2} r_{N-1}}) + \cdots (s_{\phi_o r_o} - s_{\phi_{ao} P}) - (Dt_{EA} - t_{JA})^*$$

---- ***XXXVIII***

where s_{ac} is the sag of the anterior surface of the carrier portion ***and is the value*** x_{a1} for formula ***XXVIII*** (p. 206):

r_N is the radius of the outermost back surface zone.
r_{N-1} is the radius of the next back surface zone 'inside' (central to) r_N.
ϕ_T = Total diameter.
ϕ_{T-1} and ϕ_{T-2} represent respectively the diameter of the zone central to ϕ_T and the diameter of the zone two zones in from ϕ_T.
$s_{\phi_{aop}}$** is the Primary Sag at ϕ_{ao}**.

If s_P is known $x_{a1} = s_{ac} = x - (Dt_{EA} - t_{JA})^*$

Where

if ϕ_{ao}** = ϕ_o, $x = s_P - s_{\phi_o r_o}$ *(see Figures 5.32, 5.37(a, b)).*
if ϕ_{ao}** < ϕ_o, $x = s_P - s_{\phi_{ao} r_o}$**.
if ϕ_{ao}** > ϕ_o, $x = s_P - (s_{\phi_o r_o} + s_{\phi_{ao} r_1}{}^{**} - s_{\phi_o r_1})$

* In all cases, if the carrier is to be parallel surfaced, the $-(Dt_{EA} - t_{JA})$ term can be omitted as $Dt_{EA} - t_{JA} = 0$.

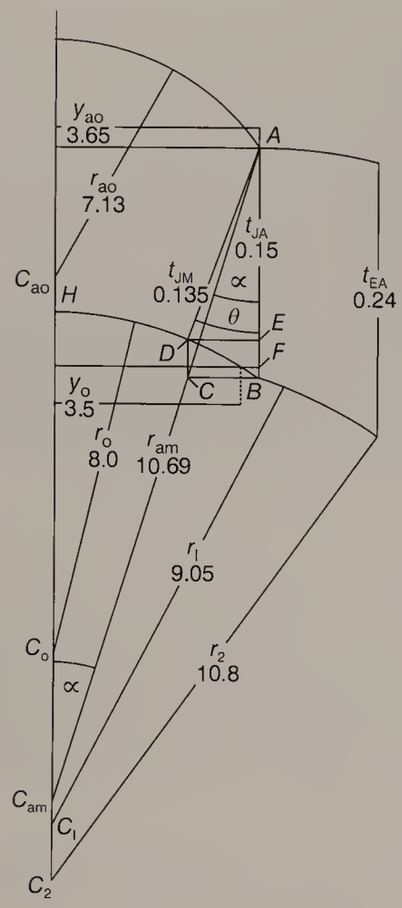
** In all cases, if the lens has a Junction radius, the term ϕ_{ao} is replaced by ϕ_{aJ} (the diameter of the anterior Junction, *see Figure 5.34*).

Approximation of minimum junction thickness of lenticular lenses calculated from Junction of r_{ao} and r_{a1}, (or r_{a1} and r_{a2} if the lens has a front junction radius)

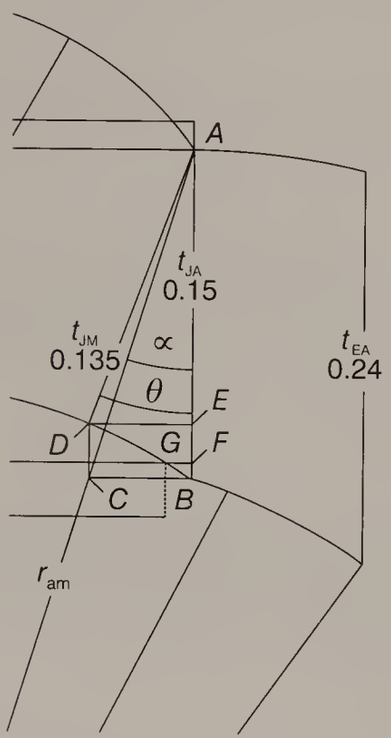
Formula XXXIX

Example 27

The lens in *Example 26* and the +2.00 D and –10.00 D lenticular lenses designed on pp. 190 to 193 all have an *Axial* Junction thickness (t_{JA}) of 0.15 mm and will be used



(a)



(b)

Figure 5.38 (*a*) Exaggerated detail of the positive lenticular lens with negative carrier shown on the right hand side of Figure 5.37(a): *see* Example 27, p. 217. (*b*) The junction area and negative carrier only to illustrate the difference between t_{JA} and the ***Minimum* Junction thickness** (t_{JM}).

Calculation of the minimum cross-section† from the junction of r_{ao} and r_{al} to the back surface of a lens involves an iterative process which does not lend itself well to 'long hand' calculation. The following trigonometrical approach gives an approximation of t_{JM} which is within 0.003 mm (or better) of the true t_{JM}.

In *Figures 5.38 (a) and (b)* t_{JM} is represented by the distance *AD*. The Figures are not to scale. $\angle\alpha$ has been widened and the vertical scale expanded to show more clearly the values used in the calculations.

The arithmetic **m**ean of the **a**nterior surface **r**adii,

$$r_{am} = (r_{ao} + r_{al} + \ldots + r_{aN})/N+1$$

In *Example 26*

$$r_{am} = (r_{ao} + r_{al})/2 = (7.1320 + 14.2438)/2$$
$$= \mathbf{10.6879\ mm}$$

$$y_{ao}\dagger = \phi_{ao}/2 = 7.3/2 = \mathbf{3.65\ mm}$$

$$\angle\alpha = \angle CAB = \angle AC_{am}H = \sin^{-1} y_{ao}/r_{am}\dagger$$
$$= \sin^{-1} 3.65/10.6879$$
$$= \mathbf{19.96875711°}$$

(where **$\sin^{-1}$ = the inverse sin**, not the reciprocal, and where $\angle AC_{am}H = \angle CAB$ as they are alternate angles; C_{am} = centre of curvature of r_{am})

$$BC = t_{JA} * \tan\alpha = 0.15 * 0.363352828$$
$$= \mathbf{0.054502924\ mm = DE}$$

***DC* (in this case)†**

$$= s_{\phi_{ao} r_1} - s_{\phi_{(ao\ \ 2*BC)} r_1}$$

$$= r_1 - \sqrt{(r_1^2 - y_{ao}^2)} - (r_1 - \sqrt{(r_1^2 - (y_{ao} - BC)^2)})$$

$$= 9.05 - \sqrt{(9.05^2 - 3.65^2)}$$
$$- (9.05 - \sqrt{(9.05 - (3.65 - 0.054502924)^2)})$$

$$= 0.768695755 - 0.74488707$$

$$= \mathbf{0.023808685\ mm}$$

$$AE = t_{JA} - DC = 0.15 - 0.023808685$$
$$= \mathbf{0.126191315\ mm}$$

$$\theta = \angle DAE = \tan^{-1} DE/AE = \tan^{-1} BC/AE$$
$$= \tan^{-1} 0.054502924/0.126191315$$
$$= \tan^{-1} 0.431907093$$
$$= \mathbf{23.35985833°}$$

† *See Explanatory Note* on p. 219.

$AD = AE/\cos\theta = \mathbf{0.137458418\,mm} = t_{JM}$ (approx.)

True t_{JM} = 0.137458368 mm
(computed accurately to 9 decimal places).

Error = +0.000000050 mm

Using pre-calculations;

$$t_{JM}\text{ (approx)} = AD = \frac{t_{JA} - DC}{\cos(\tan^{-1}((t_{JA} * \tan\alpha)/(t_{JA} - DC)))} \qquad \text{- - - - } XXXIX$$

For calculators:

$$t_{JM}\text{ (approx)} = AD = (t_{JA} - DC)/(\cos(\tan^{-1}((t_{JA} * \tan\alpha)/(t_{JA} - DC)))) \qquad \text{- - - - } XXXIX$$

For the +2.00 D lenticular lens on page 191,

r_{am} = 8.8525 mm, ϕ_o = 7.00 mm, r_o = 8.00 mm

For the −10.00 D reduced optic lens, page 193,

r_{am} = 8.687 mm, ϕ_{aJ} = 7.60 mm, r_1 = 9.05 mm

For the +2.00 D lens

Calculated as above AD = 0.1353376 mm

True t_{JM} = 0.13514746 mm

Error = +0.00019014 mm

For the −10.00 D lens

AD = 0.137577591 mm

True t_{JM} = 0.136352202 mm

Error = +0.001225389 mm

Explanatory Note

Where a negative lens with a front junction radius is used, the value t_{JA} is measured at ϕ_{aJ} and this diameter is used instead of ϕ_{ao} when calculating $\angle\alpha$.

Thus, in the example just quoted, of the −10.00 D reduced optic lens

$\angle\alpha = \sin^{-1} y_{aJ}/r_{am}$

Now $y_{aJ} = \phi_{aJ}/2 = 7.6/2 = 3.8$ mm

and $r_{am} = (r_{ao} + r_{a1} + r_{a2})/3$

$= (9.63 + 6.011 + 10.42)/3 = 8.687$ mm

Thus $\angle\alpha = \sin^{-1} 3.8/8.687 = 25.94035403°$

These are the values used in calculating AD in that particular case.

In *Figures 5.38 (a) and (b)*, which are based on the lens in *Example 26*, the distance BC is shown to extend from the surface of r_1 into the area of r_o. This is because the $\angle\alpha$ and the vertical scale have been increased to make the values used in the calculation clearer, particularly the difference between $\angle\alpha$ and $\angle\theta$. The lens in *Example 26* has ϕ_o = 7.0 mm and ϕ_{ao} = 7.3 mm. BC = 0.054502924 mm (from above) therefore, because $2 * BC < 7.3$ mm − 7.0 mm, BC is contained wholly in the surface area of r_1, as in condition (2) below.

There are three conditions to consider when calculating DC 'long hand':

(1) if $\phi_{ao} = < \phi_o$ only r_o is involved and
$DC = s_{\phi_{ao} r_o} - s_{\phi_{(ao-2*BC)} r_o}$

(2) if $\phi_{ao} > \phi_o$ by $2 * BC$ or more, only r_1 is involved,
$DC = s_{\phi_{ao} r_1} - s_{\phi_{(ao-2*BC)} r_1}$

(3) if $\phi_{ao} > \phi_o$ by less than $2 * BC$, both r_o and r_1 are involved and $DC = s_{\phi_{ao} P} - s_{\phi_{(ao-2*BC)} P}$

Calculation of harmonic mean thickness (t_{HM})

Formulae XXXX and XXXXI

The oxygen permeability of a plastic material is independent of thickness. A statement of this property is normally given as a **Dk** value where D is the diffusion coefficient and k is the solubility of oxygen. The transmissibility of a material *is* dependent mainly on thickness and is given as Dk/L where L is the thickness (t). Since most lenses vary in t the **A**rithmetic **M**ean (**AM**) of a number of thicknesses (t_{AM}), calculated at varying diameters across the lens has been used for the value L.

$$t_{AM} = \frac{(t_1 + t_2 + \cdots t_N)}{N}$$

Sammons (1981) stated that the flow of gas through a substance is related to the reciprocal of the thickness ($1/t$) so the arithmetic mean of the reciprocals of the various thicknesses is required

$$= \frac{(1/t_1 + 1/t_2 + \cdots 1/t_N)}{N}$$

and, because this calculation results in a 'mean reciprocal', the reciprocal of this value

$$\frac{N}{(1/t_1 + 1/t_2 + \cdots 1/t_N)}$$

is the 'effective' or **H**armonic **M**ean **T**hickness (t_{HM}).

Thus, t_{HM} is the reciprocal of the **AM** of the sum of the reciprocals of a series of thicknesses.

For example, the **AM** of 1 + 2 + 3 + 4 + 5 = 15/5 = 3.

The **HM** = 5/(1/1 + 1/2 + 1/3 + 1/4 + 1/5) = 5/2.283333

= 2.189781

t_{HM} is always less than t_{AM}. Therefore, since the L in Dk/L has been based traditionally on t_{AM}, more oxygen has been supplied through contact lenses to corneas than had been supposed.

When calculating the t_{HM} of a lens the smaller the intervals between successive calculations the more accurate the result, especially towards the periphery. There are other factors which affect the flow of oxygen through a lens such as the boundary effect, temperature and the oxygen tension on each side of the lens. Also, other gases must pass through a lens to maintain ocular health but these considerations are dealt with in Chapter 3.

There are four ways to measure the thickness of a contact lens: axially, radially normal to the back surface, radially normal to the front surface and the true thickness (measured by calipers or calculated), which is the shortest distance between the two surfaces at a given diameter. Axial thickness is easier to calculate involving simple sag relationships. True thickness is, of course, more accurate but involves iterative calculations except in the special case where r_{ao} exceeds r_o by exactly t_c, which occurs in some low minus lenses. For example a lens having r_o = 7.9 mm, t_c = 0.2 mm, refractive index, n = 1.47, and F'_V −1.00 D, will have r_{ao} = 8.1 mm (from ***XXXV***). In these circumstances, because r_{ao} and r_o have a common centre of curvature, the radial thickness (t_R), normal to either the front or the back surface = t_c = true thickness at any diameter.

True thickness may be calculated using iteration, but this is not practicable for 'long hand' calculations.

Radial thickness, normal to either surface, is more accurate than axial thickness. The back surface of a contact lens is usually more compound (or complex) than the front so radial thickness normal to the front surface would seem to be the best compromise.

Figure 5.39, which is based on the lens in *Example 25* (although not to scale), depicts a C3 lens and shows some of the parameters used to calculate t_{HM}. Sadly, in the absence of a computer program, there is no alternative to repeated calculation.

Examination of *Figure 5.39* shows that for a given change in diameter (ϕ) there is more change in t_R peripherally than near the primary axis. A reasonably accurate t_{HM} will be obtained if, starting with t_c (where y_O = 0), y_O is then increased in 0.5 mm steps up to ϕ_O (y_O = 3.5 mm), 0.2 mm steps to ϕ_I (y_I = 3.9 mm), then 0.1 mm steps from ϕ_I to ϕ_T. (Note this procedure continues only to ϕ_T at the ***front*** surface, *see below* and *Figure 5.39*.)

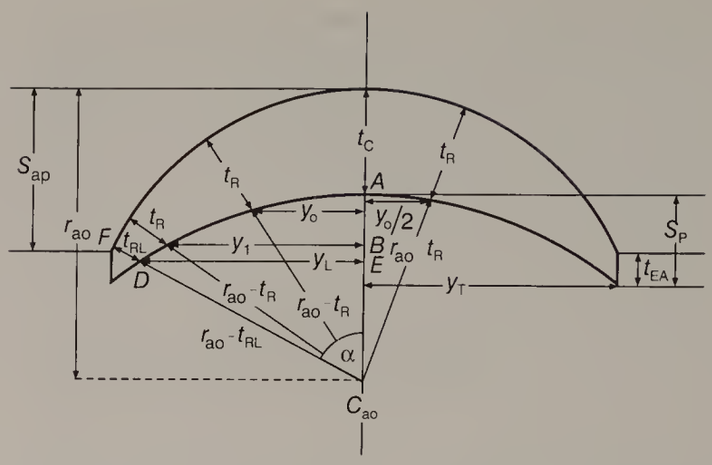


Figure 5.39 Determination of harmonic mean thickness of a lens when the thickness, t_R, is measured radial to the front surface

$$t_{HM} = \frac{N}{(1/t_c + 1/t_{R_2} + - - - - 1/t_{R_N}0} - - - - \textit{XXXX}$$

$$t_{R_N} = r_{ao} - \sqrt{((r_{ao} - t_c - s_{\phi_N P})^2 + y_N^2)} - - - - \textit{XXXXI}$$

Where $s_{\phi_N P}$ is the **P**rimary **S**ag at the diameter being calculated and $y_N = \phi_N/2$.

In the following example, based on the lens in *Example 25*, every parameter has been calculated in floating decimal mode, but only shown to four places of decimals here. This explains small discrepancies between these figures and those elsewhere in the text, for example on p. 190 and 191.

The lens in *Example 25*, C3 8.0:7.0/9.05:7.8/10.8:8.6 has r_{ao} = 7.1789 mm and t_c = 0.4306 mm (calculated using floating decimal mode, which gives very slightly different values from those on p. 215)

$$t_{R_1} = t_c = \mathbf{0.4306\ mm}$$

which is axial and radial to both surfaces, (y_O = 0)

t_{R_1} and its reciprocal 2.3223 and the radial thicknesses and reciprocals of subsequent calculations are reproduced in *Table 5.8* below, accurate to 9 places of decimals.

When using formula ***XXXXI***, $r_{ao} - t_c$ is a constant for all the calculations of t_R for a given lens and can therefore be pre-calculated. r_{ao} is marked $r_{ao'_O}$ to signify that it has been reduced by a constant (t_c) on this occasion, for diameters within ϕ_o. ϕ_N is chosen (and changed for each subsequent calculation) therefore y_O is known. $s_{\phi_N P}$ must be calculated for each chosen diameter, using formula ***XI***, or formula ***XII*** for lenses with elliptical back surfaces. For diameters from 0 to ϕ_o (y values from 0 to 3.5), $s_{\phi_N P}$ is simply the sag of r_o at ϕ_N.

Table 5.8 Radial thicknesses (t_R) normal to r_{ao}, and their reciprocals

	No.	$y = \phi/2$	t_R	$1/t_R$
ϕ_0	1	0.0	0.430598624	2.322348341
	2	0.5	0.427698157	2.338097520
	3	1.0	0.418969984	2.386805831
	4	1.5	0.404332078	2.473214605
	5	2.0	0.383641796	2.606598163
	6	2.5	0.356686053	2.803585927
	7	3.0	0.323165463	3.094390067
	8	3.5	0.282669579	3.537699399
ϕ_1	9	3.7	0.252507353	3.960280717
	10	3.9	0.220466176	4.535843173
ϕ_2	11	4.0	0.196176630	5.097447122
	12	4.1	0.171260910	5.839044058
	13	4.2	0.145717037	6.862615502
	Totals		4.013889840	47.857970428
			$t_{AM} = 0.308760757$	$t_{HM} = 0.271637094$
			$t_{AM} = \frac{4.013889840}{13}$	$t_{HM} = \frac{13}{47.857970428}$

The radial thicknesses were calculated in floating decimal mode so that they could be compared with the minimum thickness at each diameter, calculated accurately by a computer program. The comparison showed that the radial thicknesses above (normal to the anterior surface) and those of a number of other contact lenses, including lenticular designs, exceeded the minimum thickness by 0.000003 mm or less, which has no clinical significance.

$$r_{ao'_O} = r_{ao} - t_c = 7.1789 - 0.4306 = \mathbf{6.7483\ mm}$$

(precalculation)

For $y = 0.5$,

$$s_{\phi_N P} = 8 - \sqrt{(8^2 - 0.5^2)}$$

$$= 8 - \sqrt{64 - 0.25)} = 8 - \sqrt{(63.75)}$$

$$= 8 - 7.9844 = \mathbf{0.0156\ mm}$$

(pre-calculation from ***XI***)

$$t_{R_2} = 7.1789 - \sqrt{((6.7483 - 0.0156)^2 + 0.25)}$$

$$= 7.1789 - \sqrt{(6.7327^2 + 0.25)}$$

$$= 7.1789 - \sqrt{(45.3292 + 0.25)}$$

$$= 7.1789 - \sqrt{(45.5792)} = 7.1789 - 6.7512$$

$t_{R_2} = \mathbf{0.4277}$ mm (from ***XXXXI***) $(1/t_{R_2} = 2.3381)$

t_{R_3} (calculated as above except y = 1.0)

$= \mathbf{0.4190\ mm}\ (1/t_{R_3} = 2.3868)$

t_{R_4} (where y = 1.5) $= \mathbf{0.4043\ mm}\ (1/t_{R_4} = 2.4732)$

For t_{R_5} to t_{R_8} *see Table 5.8*

For y values > 3.5 ($\phi > \phi_O$), $r_{ao'_O}$ and the $s_{\phi_N P}$ term in formula ***XXXXI*** can be modified to simplify the repetitive calculation.

For diameters contained within the band width of r_1 (in this case y values > 3.5 to $y = 3.9$),

$$s_{\phi_N P} = s_{\phi_O r_O} + s_{\phi_N r_1} - s_{\phi_O r_1}.$$

$s_{\phi_O r_O}$ is a constant and can therefore be subtracted from $r_{ao'_O}$ to update its value to $r_{ao'_1}$ to calculate thicknesses in the band width of r_1, leaving only $s_{\phi_N r_1} - s_{\phi_O r_1}$ to evaluate.

$s_{\phi_O r_1}$ is also a constant for this band width, so need only be evaluated once, leaving $s_{\phi_N r_1}$ to be recalculated for each increment of ϕ_N.

Thus r_{ao_2} changes to r_{ao_1} as follows

$$r_{ao_1}' = r_{ao'_O} - s_{\phi_O r_O}$$

$$= 6.7483 - (8 - \sqrt{(8^2 - 3.5^2)}) = 6.7483 - 0.8063$$

$r_{ao'_1} = \mathbf{5.9420\ mm}$ (pre-calculation, sags from ***XI***)

$s_{\phi_O r_1} = 9.05 - \sqrt{(9.05^2 - 3.5^2)} = \mathbf{0.7042\ mm}$

(pre-calculation, sags from ***XI***)

For $y > 3.5$ to 3.9,

$$t_{R_N} = r_{ao} - \sqrt{((r_{ao'_1} - (s_{\phi_N r_1} - s_{\phi_O r_1}))^2 + (\phi_N/2)^2)}$$

$$t_{R_9} = 7.1789 -$$

$$\sqrt{((5.9420 - ((9.05 - \sqrt{(9.05^2 - 3.7^2)}) - 0.7042))^2 + 3.7^2)}$$

$$= 7.1789 - \sqrt{((5.9420 - (0.7909 - 0.7042))^2 + 3.7^2)}$$

$$= 7.1789 - \sqrt{((5.9420 - 0.0867)^2 + 3.7^2)}$$

$$= 7.1789 - \sqrt{(5.8553^2 + 3.7^2)}$$

$$t_{R_9} = 7.1789 - \sqrt{(34.2845 + 13.69)} = \mathbf{0.2525\ mm}$$

(from ***XXXXI***) $(1/t_{R_9} = 3.9603)$

$t_{R_{10}}$ (calculated as above except $y = 3.9$)

$= \mathbf{0.2205\ mm}\ (1/t_{R_{10}} = 4.5358)$

For diameters contained within the band width of r_2 (in this case y values > 3.9),

$$s_{\phi_N P} = s_{\phi_O r_O} + s_{\phi_1 r_1} - s_{\phi_O r_1} + s_{\phi_N r_2} - s_{\phi_1 r_2}$$

The sag created by $r_1 = (s_{\phi_1 r_1} - s_{\phi_O r_1})$ is a constant and must be subtracted from $r_{ao'_1}$ to update its value to $r_{ao'_2}$ to calculate thicknesses in the band width of r_2, leaving only $s_{\phi_N r_2} - s_{\phi_1 r_2}$ to evaluate.

$s_{\phi_1 r_2}$ is also a constant for this band width so need only be evaluated once, leaving $s_{\phi_N r_2}$ to be recalculated for each increment of ϕ_N.

Thus

$$r_{ao'_2} = r_{ao'_1} - (s_{\phi_1 r_1} - s_{\phi_O r_1})$$
$$= 5.9420 - 0.1793$$

$r_{ao'_2}$ = **5.7627 mm** (pre-calculation, sags from ***XI***)

$$s_{\phi_1 r_2} = 10.8 - \sqrt{10.8^2 - 3.9^2)}$$
$$= \mathbf{0.7288\ mm}\ \text{(pre-calculation from } \textit{XI})$$

For $y > 3.9$,

$$t_{R_N} = r_{ao} - \sqrt{((r_{ao'_2} - (s_{\phi_N r_2} - s_{\phi_1 r_2}))^2 + (\phi_N/2)^2)}$$

$$t_{R_{11}} = 7.1789 - \sqrt{((5.7627 - ((10.8 - \sqrt{(10.8^2 - 4^2)}) - 0.7288))^2 + 4^2}$$
$$= 7.1789 - \sqrt{((5.7627 - (0.7681 - 0.7288))^2 + 4^2)}$$

$t_{R_{11}}$ = **0.1962 mm** (from ***XXXXI***) ($1/t_{R_{11}}$ = 5.0974)

For $t_{R_{12}}$ ($y = 4.1$) and $t_{R_{13}}$ ($y = 4.2$) calculated as above (*see Table 5.8*).

It is not possible in this calculation to increase y to y_T (4.3). Examination of *Figure 5.39* will show that to do so would place the point *F* off the lens. It is necessary (and acceptable) to **L**imit the increase in y to a value equal to or ***just*** less than y_L. The limiting value of y (y_L) is that which places the point *F* at the edge of the anterior surface (ϕ_T). This condition can be recognized (near the end of the calculation) as follows. In the triangle *BFC* in *Figure 5.39*, $\angle\alpha = \sin^{-1} y_T/r_{ao} = \sin^{-1} 4.3/7.1789 =$ **36.7969°**.

Because triangles *BFC* and *EDC* are similar triangles any radial thickness (t_R) should be disregarded if $\sin^{-1} y/(r_{ao} - t_R) >$ **36.7969°**. For this value of $\angle\alpha$, $y = y_L$.

$t_{R_{13}}$ = 0.1457 mm, therefore ***DC*** (in *Figure 5.39*)
= 7.1789 – 0.1457 = 7.0332 mm

$\angle\alpha = \sin^{-1} 4.2/7.0332 = 36.6676°$

which is only just less than the limiting angle of 36.7969°.

Clearly any significant increase in y would put the point *F* beyond the edge of the lens.

Calculation of axial and radial edge lift of a specified lens

Formulae XXXXII and XXXXIII

The calculation of both axial and radial edge lifts depend upon Pythagoras' theorem ($CE^2 = BC^2 + BE^2$ in *Figure 5.40*).

Axial edge lift (l_{EA}) is defined as the amount by which the sag of the back central optic zone radius (r_o) of a lens, calculated for a stipulated diameter (ϕ_N), exceeds the **P**rimary **S**ag (s_P) of the lens at the same diameter $l_{EA} = s_{\phi_N r_O} - s_{\phi_N P}$

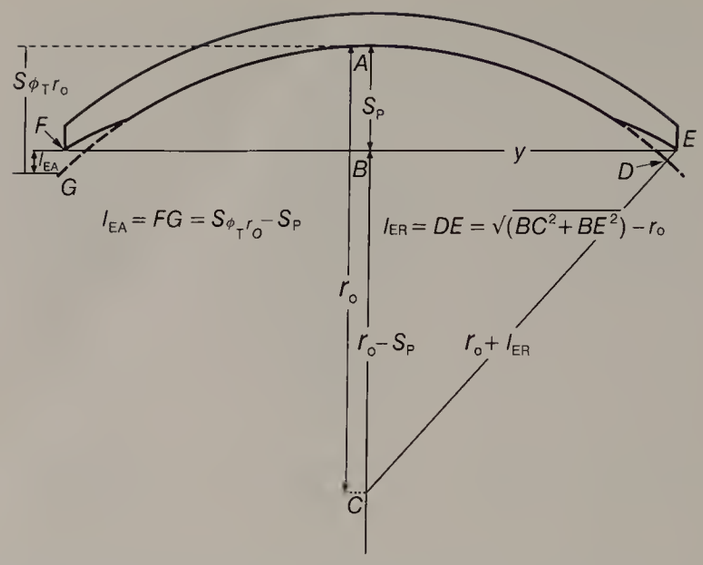


Figure 5.40 Dimensions necessary for conversion of axial edge lift, l_{EA}, to radial edge lift, l_{ER}, and vice versa

where $s_P = s_{\phi_O r_O} + s_{\phi_1 r_1} - s_{\phi_O r_1} + s_{\phi_2 r_2} - s_{\phi_1 r_2} + \cdots s_{\phi_N r_N} - s_{\phi_{N-1} r_N}$ - - - - ***XXXXII***

ϕ_{N-1} = the diameter of the zone central to zone N.

Sags (s) are found from Formula ***XI***.

Pages 189 to 198 give a detailed analysis of various lens sagitta values. *Figures 5.30*, *5.31* and *5.40* should also be consulted.

Radial edge lift (l_{ER}) is defined as the amount by which the distance between the centre of curvature of r_O and a point on the back surface of the lens at a stipulated diameter (*CE* in *Figure 5.40*) exceeds r_O (*DE* in *Figure 5.40*).

$l_{ER} = \sqrt{(BC^2 + BE^2)} - r_O$; where $BC = r_O - s_P$;

$BE = y$ = the chosen diameter/2

$l_{ER} = \sqrt{((r_O - s_P)^2 + y^2)} - r_O$ - - - - ***XXXXIII***

Example 28

For the C4 lens from *Example 23*:

7.98:7.5/8.18:8.5/9.16:9.3/11.65:9.8

$$s_{\phi_T r_O} = 7.98 - \sqrt{(7.98^2 - 4.9^2)}$$
$$= 7.98 - \sqrt{(63.6804 - 24.01)}$$
$$= 7.98 - \sqrt{(39.6704)} = 7.98 - 6.2984$$

$s_{\phi_T r_O}$ = **1.6816 mm** (from *XI*)

$s_P = 7.98 - \sqrt{(7.98^2 - 3.75^2)}$

$+ ((8.18 - \sqrt{(8.18^2 - 4.25^2)})$

$- (8.18 - \sqrt{(8.18^2 - 3.75^2)}))$

$+ ((9.16 - \sqrt{(9.16^2 - 4.65^2)})$

$- (9.16 - \sqrt{(9.16^2 - 4.25^2)}))$

$+ ((11.65 - \sqrt{(11.65^2 - 4.9^2)})$

$- (11.65 - \sqrt{(11.65^2 - 4.65^2)}))$

$= 0.936 + (1.1907 - 0.9102) + (1.268 - 1.0456)$

$+ (1.0806 - 0.9682)$

(The brackets in the line above are not essential and are included for clarity only)

$= 0.936 + 0.2805 + 0.2224 + 0.1124 = 1.5513$

s_P = **1.5513 mm** (from *XXXXII*)

$l_{EA} = s_{\phi_T r_O} - s_P = 1.6816 - 1.5513 = 0.1303$

l_{EA} = **0.1303 mm**

$l_{ER} = \sqrt{((r_O - s_P)^2 + y^2)} - r_O$

$= \sqrt{((7.98 - 1.5513)^2 + 4.9^2)} - 7.98$

$= \sqrt{(6.4287^2 + 4.9^2)} - 7.98$

$= \sqrt{(41.3282 + 24.01)} - 7.98$

$= \sqrt{(65.3382)} - 7.98 = 8.0832 - 7.98$

$=$ **0.1032 mm** (from *XXXXIII*)

Conversion of axial to radial and radial to axial edge lifts

Formulae XXXXIV, XXXXV, XXXXVI and XXXXVII

Conversion of axial to radial and radial to axial edge lifts is enabled by transposing the above formulae

$$l_{ER} = \sqrt{r_O^2 + l_{EA}^2 + ((2l_{EA})\sqrt{(r_O^2 - y^2)})} - r_O \quad \text{- - - - } \textit{XXXXIV}$$

For calculators:

$$l_{ER} = \sqrt{r_O^2 + l_{EA}^2 + 2*l_{EA}*\sqrt{(r_O^2 - y^2)}} - r_O \quad \text{- - - - } \textit{XXXXIV}$$

Example 29 Using the C4 lens from Example 23

$l_{ER} = \sqrt{(7.98^2 + 0.1303^2 + 2*0.1303*\sqrt{(7.98^2 - 4.9^2)})} - 7.98$

$= \sqrt{(63.6804 + 0.017 + 0.2606*\sqrt{(63.6804 - 24.01)})} - 7.98$

$= \sqrt{(63.6974 + 0.2606*\sqrt{(39.6704)})} - 7.98$

$= \sqrt{(63.6974 + 0.2606*6.2984)} - 7.98$

$= \sqrt{(63.6974 + 1.6414)} - 7.98$

$= \sqrt{(65.3388)} - 7.98 = 8.0832 - 7.98 = 0.1032$

l_{ER} = **0.1032 mm** (from *XXXXIV*)

An approximate conversion of axial to radial edge lift may be obtained from:

$$l_{ER} \approx l_{EA}*(1 - (\phi^2/(8*r_O^2))) \text{ - - - - } \textit{XXXXV}$$

For calculators:

$$l_{ER} \approx l_{EA}*(1 - \phi^2/(8*r_O^2)) \text{ - - - - } \textit{XXXXV}$$

where ϕ = Total diameter

$l_{ER} \approx 0.1303*(1 - 9.8^2/(8*7.98^2))$

$= 0.1303*(1 - 96.04/(8*63.6804))$

$= 0.1303*(1 - 96.04/509.4432)$

$= 0.1303*(1 - 0.1855)$

$= 0.1303*0.8115 \approx$ **0.1057 mm** (from *XXXV*)

Accurate value = 0.1032 mm

$$l_{EA} = \sqrt{((r_O + l_{ER})^2 - y^2)} - \sqrt{(r_O^2 - y^2)} \text{ - - - - } \textit{XXXXVI}$$

$l_{EA} = \sqrt{((7.98 + 0.1032)^2 - 4.9^2)} - \sqrt{(7.98^2 - 4.9^2)}$

$= \sqrt{(65.3381 - 24.01)} - \sqrt{(63.6804 - 24.01)}$

$= \sqrt{(41.3281)} - \sqrt{(39.6704)}$

$l_{EA} = 6.4287 - 6.2984 =$ **0.1303 mm** (from *XXXXVI*)

An approximate conversion of radial to axial edge lift may be obtained from:

$$l_{EA} \approx l_{ER}*(1 + (\phi^2/(8*r_O^2))) \text{ - - - - } \textit{XXXXVII}$$

For calculators:

$$l_{EA} \approx l_{ER} * (1 + \phi^2/(8 * r_O^2)) \text{ - - - - } \textit{XXXXVII}$$

where ϕ = Total diameter

$$l_{EA} = 0.1302 * (1 + 9.8^2/(8 * 7.98^2))$$

$$= 0.1032 * (1 + 96.04/(8 * 63.6804))$$

$$= 0.1302 * (1 + 96.04/509.4432)$$

$$= 0.1032 * (1 + 0.1885)$$

$$= 0.1032 * 1.1885 \approx \mathbf{0.1227\ mm} \text{ (from } \textit{XXXXVII}\text{)}$$

Accurate value = 0.1303 mm

Examination questions and answers

The following questions have all been taken from past papers in visual optics of the Advanced Contact Lens Examination for the Diploma in Contact Lens Practice, set by the British College of Optometrists (formerly the British Optical Association) and are reproduced by their kind permission. The date of the questions and their answers are given in brackets after each question. Only the numerical type of questions have been included. Terminology has been brought up-to-date. It is hoped that these will be helpful to those people preparing for such examinations.

(1) For the practitioner one of the greatest problems in verifying the characteristics of a corneal lens is that of back surface peripheral radii of curvature. Discuss methods that have been used to verify these radii and the limitations of such methods.

The following corneal lens has been ordered from a laboratory:

C2. 7.80: 6.50/8.00: 9.50/–6.00 D (refractive index 1.490).

On checking the following values were obtained:

Centre thickness	0.10 mm
Back vertex power	–6.00 D
BOZR	7.80 mm
Back vertex power of peripheral zone	–5.00 D
Thickness at centre of peripheral zone	0.20 mm

Does the peripheral radius of curvature conform to specification?
(*July, 1970; No – 7.90 mm;* see *Chapter 12*)

(2) A patient with the following refractive details is to be fitted with minimum clearance scleral lenses in order to provide a satisfactory level of vision binocularly. Calculate the necessary back vertex powers of the lenses if the back optic zone radii of the contact lenses are R and L 8.30 mm.

RX R + 4.00/–2.00 × 180
Vertex distance 15 mm
L + 5.00

Keratometer readings R and L
7.64 mm along 90°
8.00 mm along 180°
(*January, 1971; R + 5.78/–0.22 × 180 say +5.75 DS. L + 6.93/+1.98 × 180, say +7.00 with +2.00 DC × 180 on front surface,* see *pp. 171–172*)

(3) A patient is fitted with an air cell underwater scleral contact lens. Calculate the radius of curvature of the front optic zone surface of the scleral component from the following details:

RE Spectacle *Rx*
+5.00/–2.00 axis 180
Vertex distance 15 mm

Keratometry:
7.80 mm along 90°: 8.20 mm along 180°

BOZR 8.60 mm: centre thickness 0.4 mm: refractive index 1.490
(*July, 1971: 7.76 mm assuming contact lens BVP of +7.25 D* see *Formula XXIII, p. 205 and pp. 170–172*)

(4) Discuss the relative merits and usefulness of the following instruments for checking contact lenses: keratometer, radiuscope, focimeter and slit lamp.

A focimeter may be used to check the BOZR of a corneal lens if a lens of known characteristics is available. Given a lens of known characteristics (BOZR 8.2 mm, BVP +6.00 D) calculate the BOZR of an unknown lens given the following details:

BVP of known and unknown lens +4.00 D
BVP of known and unknown lens +3.00 D with water (n = 1.336) between lenses.
Centre thickness of unknown lens 0.2 mm, lens material refractive index 1.49
(*January, 1972; 7.68 mm;* see *Chapter 12*)

(5) A young emmetropic patient has an alternating esotropia of 15°, and uses the RE for distance and the LE for near (assumed as 25 cm from the spectacle plane). Following an accident his macular areas

undergo degenerative changes and his accommodation is considerably reduced. He requires a telescopic aid for the RE and a 'microscope' aid for the LE. Corneal lenses are to be used for the eyepieces and spectacles worn at a vertex distance of 16 mm for the objectives of these aids. As his corneas are identical, two similar corneal lenses are made up, of BOZR 7.50 mm and FOZR 12.00 mm. (Assume an infinitely thin contact lens of refractive index 1.5.) If the LE continues to use the same working distance, what back vertex powers must the two spectacle lenses have and what magnification would they afford?
(*July, 1973; RE +17.86 D, ×1.40; LE +21.86 D, ×1.40*; see *p. 839*)

(6) A soft contact lens, when fully hydrated, has a back optic zone radius of 8.00 mm, a refractive index of 1.35, centre thickness of 0.30 mm and back vertex power of −3.00 D.

It is allowed to become partially dehydrated and its refractive index goes up to 1.40. Calculate the change in back vertex power on the basis of the refractive index change alone.

What other factors associated with dehydration would also contribute to a change in BVP?
(*January, 1975; −0.40 D: curvature and thickness changes*; see *pp. 174–179*)

(7) A fused bifocal corneal lens has a segment of refractive index 1.58 in the lower part of the back optic zone and coming into contact with the tear layer of refractive index 1.336. The lens has a back optic zone radius of 7.00 mm. The main part of the lens has a refractive index of 1.49. Calculate the interface radius necessary to give the lens a near addition, on the eye, of +3.00 D. (Assume thin lens theory.)

Explain what different factors would be taken into consideration in determining the interface radius, had the segment been on the front surface.
(*January, 1975; 5.67 mm; Surface power is positive, not negative, and in air, not tears*; see *Formulae VII–X and Examples 12 and 13, pp. 200–201*).

(8) An aphakic eye has a spectacle refraction of +13.50 D at a vertex distance of 12 mm. The corneal radius is 7.90 mm. Assuming a refractive index of tears of 1.333 and a keratometer, aqueous and vitreous index of 1.336, calculate:

(*a*) the axial length of the eye;
(*b*) the back vertex power of a corneal lens of BOZR 7.80 that corrects the eye;
(*c*) compare the spectacle magnification given by the two forms of correction, assuming also an apparent depth of anterior chamber of 3.0 mm and shape factors of 1.094 and 1.026 for the spectacle and contact lenses.

(*June, 1985; 22.78 mm; +15.57 D; ×1.372: ×1.078*; see *pp. 161–167*)

(9) (*a*) Define induced astigmatism.
(*b*) An astigmatic eye has a spectacle refraction of −6.00/−3.75 × 170 at a vertex distance of 15 mm. The K readings are 7.95 along 180 by 7.35 along 90. A toric corneal lens of BOZR 7.90 × 7.40 is fitted and assumed to orientate along the corneal meridians. Assuming an index of 1.490 for the lens, 1.333 for tears and keratometer:
(i) what back vertex power is required in the two meridians?
(ii) what compensating cylinder has to be worked on the front surface of the lens to obtain an accurate correction (ignoring lens thickness)?

(*June, 1985; (a) Any astigmatism created in the contact lens and/or tears lens when a contact lens is worn; for example at the plastic/tears interface of a back toroidal optic surface of an RGP lens. (b) Assuming corneal meridians can be treated as parallel to those of spectacle refraction: BVP of contact lens −6.10/−2.89 × 180. Front surface cylinder +1.35 × 180* see *pp. 184–186.* and Chapter 14).

(10) If the apparent central thickness of the optical section of the cornea produced by a slit beam is 0.42 mm, what would be its true central thickness?

Assume: refractive index of cornea = 1.376
anterior corneal surface radius = 7.8

Should the cornea become oedematous, what changes would be produced in the relationship between true and apparent thickness?
(*October, 1987; 0.566 mm*; see *Figure 6.14*,

use $\frac{n}{t} + \frac{1 - n}{r} = \frac{1}{t'}$

where $t' = -0.42/1000$ m and $r = -7.8/1000$ m. This is treating the back surface of the cornea as the object for the front surface, the apparent central thickness being the image distance in air; increase in true thickness with oedema, slight reduction in refractive index and slight change in anterior corneal radius lead to small reduction in ratio between real and apparent thickness)

(11) (*a*) Define residual and induced astigmatism.
(*b*) A patient with refraction Plano/−2.50 × 180 has K readings of 8.00 m180 by 7.50 m90. Using approximations, what, if any, is the remaining astigmatism when a rigid corneal lens is placed on the eye of BOZR:
(i) 7.85 spherical;
(ii) 8.00 × 7.50;
(iii) 7.90 × 7.60.
(*c*) If the patient in (*b*) is fitted with a back toroidal surface soft lens of HEMA, calculate the required radius in the steep meridian if the radius in the flat meridian is 8.5. Assume a refractive index of 1.43 in the hydrated state.

(*d*) A patient wearing rigid lenses of specification R BOZR 7.7 mm, BVP −6.00 D and L 7.9 mm, −5.50 D respectively inserts the lenses on the wrong eyes. What is the induced error for each eye, assuming a perfect correction when worn normally?

(*December, 1986; (a) Residual astigmatism is the astigmatism remaining uncorrected when a contact lens is worn; induced astigmatism*, see *Question 9(a); (b) none; +1.28 × 180; +0.77 × 180; (c) 8.1 mm; (d) R −0.61 D, L +0.61 D needing lenses of equal and opposite power to correct it*; see *pp. 184–186 and Chapter 14*).

(12) Discuss some of the possible uses of contact lenses in the management of low visual acuity.

A contact lens/spectacle combination is used to provide magnification for distance vision, in the form of a Galilean telescope. If the spectacle lens has a power of +20.00 D, and the lens separation is 14 mm, what will be the power required for the contact lens, and what will be the magnification of the system? (Assume that the lenses are thin, neglect effects of lens form.)

(*October, 1986; to provide a satisfactory optical front surface to the eye in the case of corneal irregularities; to give greater magnification than spectacles for high myopes; to form the eyepiece of a Galilean telescopic system to give magnification; to occlude an eye giving distorted images; −27.78 D; × 1.67* see *p. 839*)

(13) Following cataract extraction, a previously emmetropic eye has a spectacle prescription of +11.00/+1.50 × 180 (back vertex distance 10 mm), and K readings 7.80 m90; 8.05 m180.

(*a*) Assuming that a rigid contact lens were to be fitted in alignment with the flattest K, calculate accurately the FOZR for a lens with a centre thickness 0.5 mm (assume n = 1.495).

(*b*) Calculate the spectacle magnification when such a lens is worn: to what level would this improve a VA of 6/9 obtained with a spectacle magnification of unity?

(*February, 1986; (a) 6.87 mm assuming astigmatism corrected by liquid lens. In fact +0.59 DC × 180 remains uncorrected. (b) Spectacle lens ×1.17, VA 6/7.7; contact lens ×1.04, VA 6/8.7 (assuming entrance pupil 3 mm from cornea*) (see *formula XXIII, p. 205, and p. 166*)

(14) Discuss the optics of bifocal contact lenses.

A solid bifocal contact lens is required with a +3.00 D addition, on a PMMA lens having a mean refractive index of 1.491. If the BOZR is 7.80 mm and the FOR is 8.00 mm, calculate the radius of curvature required for the segment, assuming:

(*a*) that the segment is on the rear surface of the lens;

(*b*) that the segment is on the front surface of the lens.

(Assume tear film mean refractive index 1.336.)

(*February, 1987; (a) 9.19 mm; (b) 7.63 mm*; see *pp. 186–187*)

(15) Discuss the magnifications of retinal image produced by correcting aphakia with:

(*a*) Spectacle lens
(*b*) Scleral contact lens
(*c*) Corneal contact lens
(*d*) Intraocular lens

If an intraocular lens is to be implanted 5 mm from the anterior corneal surface, calculate its power (in aqueous) to produce emmetropia.

Length of eye = 23.5 mm
Mean Anterior Corneal Surface Power = 43.0 D

(*February, 1988; (a)–(d)* see *pp. 165–167; +20.98 D ≏ +21.00 D*)

(16) A patient has K readings of R 8.00 @ 90, 7.75 @ 180 and L 7.95 @ 90, 7.80 @ 180. Calculate:

(*a*) the residual astigmatism with a rigid contact lens: BOZR 7.90:

(*b*) the residual astigmatism with a soft contact lens; assuming that:

(i) his spectacle Rx is R + 2.00/−1.25 × 90, L + 2.00/−0.75 × 90

(ii) his spectacle Rx is R + 1.00/−0.25 × 90, L + 1.00

The normal indices of refraction may be assumed.

What general conclusions can you draw from this about the selection of contact lens type in cases of ocular astigmatism?

(*February, 1988; (a)* see *pp. 170–173; (i) R + 0.10 × 90 ≏ zero, L + 0.07 × 90 ≏ zero; (ii) R + 1.10 × 90, L + 0.82 × 90*; (*b*) Assuming the soft contact lens is spherical (see *p. 172*) *(i) R − 1.25 × 90, L − 0.75 × 90; (ii) R − 0.25 × 90, L Zero. Optically significant ocular astigmatism requires correction with a toric soft lens, a spherical rigid lens when corneal and ocular astigmatism are similar, otherwise a toric rigid lens*)

(17) (*a*) A cornea whose anterior radius of curvature is 7.80 mm appears to have an opacity 0.10 mm from its anterior surface when viewed through this surface. Assuming the refractive index of the cornea to be 1.376, calculate its real depth.

(*b*) What are the accepted values for the thickness of the normal cornea and its limits of normal variation?

(*October, 1988; (a) 0.138 mm*; see *Question 10; (b) 0.5 mm ± 0.05 mm centrally; 0.75 mm ± 0.15 mm limbally*)

(18) (*a*) Discuss the design of contact lenses using *diffractive* optics.

(*b*) A front surface solid PMMA bifocal contact lens is required with a centre thickness of 0.3 mm. Assuming that the BOZR is 7.15 mm, and that the required lens prescription in air is +5.25 D with a +2.00 D Add (measured as BVPs), calculate the front optic radii of the lens.

(*October, 1988; (a) Simultaneous vision bifocals with near addition proportional to the number of diffraction rings* – see *Chapters 12 and 16*; (b) 6.74 mm – distance, 6.56 mm – near, see *pp. 186–187;)*

(19) (*a*) Describe how the sagitta system may be used in the verification of hydrophilic contact lenses.

(*b*) If a contact lens has a sagittal height of 2.5 mm over an aperture of 12 mm what is the radius of curvature of its back surface? Assume that the back surface is a single spherical curve.

(*February, 1989; (a)* see *Chapter 13 and Figure 13.11; (b) 8.45 mm*; see *formula XVII, p. 203)*

(20) (*a*) A patient with K readings 7.70 @ 180, 7.90 @ 90 and spectacle refraction –4.25/+1.25 × 90 at BVD 15 mm, is fitted with an afocal PMMA trial lens in alignment with the flattest K reading. Calculate:

(i) the residual astigmatism;

(ii) the FOZR of the required lens, assuming it to have the same BOZR as the trial lens, and a centre thickness of 0.30 mm.

(*b*) A patient with K readings 7.60 @ 180, 7.95 @ 90 and spectacle refraction +3.00/+3.00 × 90 at BVD 15 mm, is fitted with an aligning toric PMMA lens. Calculate:

(i) the induced residual astigmatism;

(ii) the likely astigmatic element of the over-refraction.

Normal indices of refraction may be assumed.

(*February, 1989; (a) (i) + 2.25 D × 90; (ii) 7.52 mm along 90, 7.78 mm along 180*; (*b*) *(i) –0.89 D × 90; (ii) + 4.51 D × 90 at the eye*; see *pp. 171–172 and 184–185, and Chapter 14*)

(21) (*a*) Discuss the use of aspheric surfaces in single vision contact lenses.

(*b*) A rigid contact lens has an aspheric rear surface of conic form, based on the equation:

$$y^2 = 2rx - px^2$$

If the back optic zone radius of the contact lens and the keratometry reading of the eye are both 8.00 mm, what will be the axial edge lift of a 9.00 mm diameter lens with a rear surface p value of 0.7 on a spherical cornea?

(*October, 1989; (a)* see *p. 174 and Chapters 10, 11, 16 and 20: (b) 0.0409 mm, the difference between x and the sagitta of radius 8 mm at diameter 9 mm;* see *formulae XII and XI, p. 202*)

(22) (*a*) Differentiate between residual astigmatism and induced residual astigmatism.

(*b*) A patient has K readings of 8.10 along 180, 7.55 along 90, and an ocular refraction of –1.00/–3.50 × 180. Calculate:

(i) the over-refraction if an afocal spherical corneal lens of BOZR 7.9 is fitted;

(ii) the astigmatic element of the over-refraction if an aligning toric PMMA lens is fitted.

Indicate whether either of the terms residual astigmatism or induced residual astigmatism are appropriate to the answers in (a) and (b) above.

(*October, 1989; (a)* see *Questions 9 and 11; (b) (i) Approximate method: –2.00/–0.75 × 180, accurate method; –2.05/–0.48 × 180. Astigmatism is residual; (ii) Assuming only the back surface of the PMMA lens is toroidal: +0.91 D × 180. Astigmatism is induced residual*; see *pp. 171–172 and 184*)

(23) A hypermetrope, +5.00 D spectacle prescription (R&L) at 10 mm from the cornea, is fitted with contact lenses. Calculate the accommodation and convergence required to view a near object at 250 mm from the spectacle plane:

(*a*) Wearing spectacles

(*b*) Wearing contact lenses

Assume that the spectacle plane is 25 mm from the centre of rotation and the distance PD is 70 mm. Illustrate your answer with diagrams and discuss the significance of your results.

(*February, 1990; (a) +4.25 D, 28.72 Δ, (b) +3.85 D, 25.45Δ*, see *pp. 157–159 and 168–169. Contact lenses alleviate accommodation and convergence for hypermetropes*)

(24) (*a*) A solid bifocal is required with an addition of +3.00 D on the rear surface of a PMMA lens having a back optic zone radius of 8.00 mm. Calculate the radius required to give the correct addition, and the power of the addition in air.

(*b*) Discuss the tolerances that are given for bifocal power in BS 7208: Part 1: 1989 'Specification for rigid contact lenses'.

(*February, 1990*; (*a*) *Assuming tears of refractive index 1.336, 9.48 mm and +9.56 D*; see *formulae III, IV and V pp. 199–200;* (*b*) see *Chapter 12, Addendum II, but the British Standard quoted in the question is no longer applicable. It has been replaced by BS7208: Part 1: 1992 or ISO 8321–1: 1991 where bifocal powers are not specifically mentioned*

(25) An eye has the following ocular refraction: –2.50/–3.50 × 10. The keratometry readings for this eye are: 8.00 along 10, 7.40 along 100.

You use a spherical back surface fitting set and conclude that you have achieved alignment along the 10 degree meridian with the following lens: C3 8.00:7.00/8.50:8.40/10.00:9.00 BVP –1.50.

The over-refraction with this lens in place is –1.00 D (no cylinder is required in the trial frame) and the visual acuity is 6/4.

In the interest of ocular comfort you decide to order a lens with a toric back surface having BOZRs of 8.00 along 10 and 7.50 along 100.

(*a*) Calculate the BVP required for this toric lens. Do not use approximate rules.
(*b*) If the contact lens produced for the wearer was manufactured with a central thickness of 0.3 mm, what is the radius of curvature of the front surface of the lens along the 10 degree meridian (PMMA material)?
(*c*) What is the axial edge lift at diameter 9.00 mm (ignoring the effect of any edge finishing) along the 10 degree meridian?

(*February, 1990; (a) – 2.50/–2.80 × 10 (but cylinder is – 2.89 × 10 if calculated on the basis of the ocular refraction*; see *formula 1, p. 199); (b) 8.44 mm (BVP –2.50 D along 10);* see *formulae XXIII and IV, pp. 205 and 199); (c) 0.0783 mm,* see *Figure 5.31 and formula XXXXII and Example 28 on p. 222*)

(26) A patient has a visual acuity of 6/24 but requires an acuity of 6/12 to perform his job which involves distance vision. His ocular refraction is –3.00 D. He is fitted with a –50.00 D soft lens as the eyepiece of a Galilean telescope system.

(*a*) What is the BVP of the spectacle lens objective and at what vertex distance must this lens be placed? What is the ocular accommodation required with this unit when observing letters half a metre from the plane of the objective?
(*b*) The vertex distance that you have calculated is obviously too large for practical purposes. Describe what can be done to decrease the vertex distance whilst maintaining the magnification. What advantages and disadvantages does this produce compared to the system described above? (Use numerical examples where appropriate.)

(*February, 1990; (a) +23.5 D at 21.28 mm, 7.36 D* see *p. 839 (b) Increase contact lens and spectacle lens powers: neater but heavier*)

(27) (*a*) How would you verify the BOZR of a rigid lens and a hydrogel lens using the keratometer?
(*b*) Describe how you would verify the back vertex powers of a diffractive bifocal lens.
(*c*) A soft lens (n = 1.435) mounted in a wet cell containing saline (n = 1.334) is measured using a projection focimeter. The lens measures –0.75 D. Calculate the back vertex power of the lens in air.

(*October, 1990 (a) Rigid lens on horizontal mount, front surface in water, with 45° mirror above. Soft lens in saline cell, similarly, but instrument to be re-calibrated using test plates of known radii in saline cell*, see *Figures 12.6, 12.7 and 13.7b; (b) Near addition – count the number of diffraction rings on the lens. Distance BVP – Measure maximum positive back vertex power in air on focimeter (image to be blue in colour) and deduct twice the near addition*, see *Chapter 12, p. 423 (c) –3.23 D,* see *Chapter 13*)

(28) (*a*) Discuss fully the advantages and disadvantages of fitting the aphakic eye with a contact lens rather than a spectacle lens, taking into account all relevant factors of the patient's history (assuming that an intra-ocular lens has not been implanted).
(*b*) If an aphakic patient has a spectacle prescription of: +14.50/+2.50 × 175, at BVD 10 mm, = 6/9, calculate accurately the change in spectacle magnification and new visual acuity that will result if a contact lens is fitted. To what extent will the type of lens fitted affect the result?

(*October, 1990; (a)* see *pp. 154–169 (b) reduction of spectacle magnification by 14% along 175 and 17% along 85; new VA = 6/10.5 to 6/10.8 ≏ 6/12*; see *pp. 161–165 for effects of lens type*)

(29) (*a*) Calculate the accommodation required by a myope with a –8.00 D spectacle prescription (back vertex distance = 15 mm) to view an object 40 cm from the spectacle plane whilst wearing: (i) spectacles and (ii) contact lenses.
(*b*) Calculate the same values for a +8.00 D hyperope.
(*c*) Discuss the clinical implications of your findings.
(*d*) List any other optical differences between contact lenses and spectacles.

(*February, 1991: (a) (i) 1.93 D; (ii) 2.41 D*, see *pp. 168–169: (b) (i) 3.10 D; (ii) 2.41 D*, see *pp. 168–169; (c) Myopes have to exert more accommodation in contact lenses than spectacles and so become presbyopic earlier. The reverse applies to hypermetropes; (d)* see *pp. 154–169*

(30) (*a*) Discuss the use of the doubling principle in keratometry.
(*b*) The BOZR of a soft lens placed in saline (n = 1.334) measures 6.58 mm. Calculate the true BOZR.
(*c*) What factors limit the accuracy and precision of this lens measuring technique?
(*d*) Suggest a method of verifying the aspheric back surface of a contact lens.

(*February, 1991; (a)* see *Chapter 6; (b) 8.78 mm;* see *p. 438; (c) Mainly lens flexibility and temperature; (d) Assuming an ellipse, measure sag and obtain p value from formula:*

$$p = \frac{2rs - y^2}{s^2}$$

where s = sag; r = radius; y = semi-diameter

(31) (*a*) Explain the circumstances in which it would be necessary to fit a bitoric PMMA lens.

(*b*) A patient has K readings: R 7.75 @ 180, 8.25 @ 90 and L 7.60 @ 180, 8.15 @ 90, and the spectacle prescription is: R –1.00/–3.50 × 90 and L –1.50/–4.00 × 90 at back vertex distance 10 mm.

Assuming that the patient is to be fitted with aligning, toric PMMA lenses, calculate for each lens:

(i) the induced residual astigmatism;

(ii) the FOZR required, assuming a centre thickness of 0.6 mm. Normal indices of refraction may be assumed.

(*February, 1991; (a) when back toroidal surface needed to obtain a good fit induces unacceptably high induced residual astigmatism; (b) (i) Induced by back of contact lens: R –1.20 × 90, L –1.36 × 90, requiring correction of opposite power, but as crystalline lens astigmatism is: R –0.70 × 90, L –0.75 × 90, the total residual astigmatism needs correction by R +0.50 × 90, L +0.61 × 90; (ii) R along 90, 8.19 mm; along 180, 8.12 mm ≏ 8.15 mm, L along 90, 8.16 mm; along 180, 8.07 mm ≏ 8.11 mm*; see *pp. 171–172 and 184–186*)

(32) (*a*) Define fully and differentiate between residual astigmatism and induced residual astigmatism.

(*b*) During a contact lens fitting an over-refraction is performed while the patient is wearing rigid corneal lenses as follows: R BOZR 7.75, BVP –2.00 D and L BOZR 7.50, BVP –2.00 D. The refractive result is: R +1.00 D and L +0.05 D.

The patient's K readings are R 7.85 and L 7.65. If it is intended to fit the lenses in alignment with the cornea, calculate the BVP required for each lens.

(*February, 1992; (a)* see *Question 22; residual astigmatism is usually taken to be that remaining when a spherical rigid lens is worn and assumed not to flex on the eye; induced residual astigmatism is usually regarded as that created at the back surface of a toroidal contact lens because its refractive index is different from the cornea and/or tears; (b) R –0.45 D, L –1.07 D*, see *pp. 171–173*)

(33) A low vision patient with a +3.00 D ocular refraction has a distance visual acuity of 6/36 but requires 6/24 for certain tasks. The patient is to be fitted with a –30.00 D soft contact lens as the eyepiece of a Galilean telescope system.

(*a*) What magnification is required from the system?

(*b*) What spectacle lens power and back vertex distance would be required to achieve this magnification?

(*c*) Discuss the optical limitations of such a system.

(*February, 1992; (a)* $1.5 \times = \left(\frac{6}{24} \div \frac{6}{36}\right)$; *(b) + 22 D at 15.15 mm*, see *p. 839; (c) Mainly restricted field of view*)

(34) (*a*) Discuss the use of the keratometer for the measurement of soft contact lens back optic zone radii (BOZR). Explain the limitations of this technique.

(*b*) What would you expect rigid lenses with BOZR of 7.00 and 7.80 mm to measure using a keratometer?

(*c*) A toric soft lens (n = 1.435) has a back vertex power in air of: Plano/–3.25 × 180. What would you expect the lens to measure when mounted in a wet cell filled with saline (n = 1.334).

(*d*) Discuss the optical and visual implications of wearing aspheric contact lenses.

(*February, 1992; (a)* see *Question 27 and Chapter 13; (b) Approximately 6.98 mm and 7.77 mm*, see *Chapter 12; (c) Plano/–0.75 × 180*, see *p. 438; (d) Thinner lenses, reduction of spherical aberration, or increase to give progressive power effect*; see *Question 21*)

(35) (*a*) Describe briefly *four* methods of stabilizing the orientation of a soft toric contact lens.

(*b*) A soft toric trial lens of BOZR 8.70 mm is fitted to an eye with K readings 8.40 along 180, 7.90 along 90 and ocular refraction of –5.25/–2.50 × 180. The trial lens has a BVP of –5.00 D, central thickness of 0.30 mm and refractive index 1.444. The over-refraction is Plano/–2.25 × 180. Calculate:

(i) the flexure induced change in power of the trial lens, and

(ii) the BVP and FOZR of the lens to be ordered.

(*October, 1992; (a)* see *Chapter 14; (b) (i) An increase in power of – 0.09/–0.62 × 180* see *Table 5.5, p. 175; (ii) BVP – 5.00/–2.25 × 180, FOZR 9.74 mm along 180, 10.23 mm along 90;* see *formulae XXII and XXIII, and IV on pp. 199 and 204*)

(36) (*a*) Differentiate between axial edge lift (AEL) and axial edge clearance (AEC), and explain their significance in contact lens practice.

(*b*) Show from first principles how axial edge lift may be calculated.

(*b*) Calculate the axial edge lift for the following lenses:

(i) C2 7.9:6.50/8.40:9.00

(ii) C3 7.30:7.0/8.30:9.00/10.50:10.00

(*February, 1993; (a) AEL refers to distance from lens edge at back surface to BOZR continued to this diameter, i.e. a lens parameter; AEC refers to distance from lens edge to cornea; both measurements are made parallel to the primary axis of the lens; (b)* see

Figures 5.31 and 5.40, and formula XXXXII on p. 222
(c) (i) 0.0546 mm; (ii) 0.2819 mm)

(37) (*a*) Discuss the principles of keratometry, illustrating your answer with diagrams.
(*b*) A keratometer has a mire separation of 200 mm. If the keratometer has a working distance of 192 mm from the cornea, calculate the position of mire reflections on an 8.0 mm spherical cornea. Is it better to have the mires close together or widely separated?
(*October, 1993; (a)* see *Chapter 6; (b) 4.01 mm,* see *Figure 6.1. Close together to measure apical radius. Widely separated if a 'mean' radius of central area of cornea is required*)

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Chapter 6

Clinical instrumentation in contact lens practice

Keith H. Edwards

Keratometry p. 232
Topographical keratoscopy p. 236
Slit lamp biomicroscopy p. 240
Pachometry p. 244
Summary p. 245

It is the duty of the contact lens practitioner to ensure that a prospective contact lens wearer is suitable for lens wear, is fitted with the most appropriate and well-fitting lens and that subsequent corneal and ocular response is monitored adequately. To achieve this, careful preliminary assessment and continual monitoring during wear are essential.

For most practitioners, the keratometer and slit-lamp biomicroscope are the two primary tools used to meet these objectives. Together with instrument accessories and the appropriate grading scales for recording results, they provide invaluable, ongoing information on the wearer's response to contact lenses. More recently, video keratoscopes are being used increasingly in contact lens practice.

Keratometry

The keratometer is used to provide an indication of the corneal curvature. It provides a measurement of the radius of curvature of the 'corneal cap' (*see* Chapter 10) by using the surface as a convex mirror. At a fixed viewing distance, an object of known size will be imaged so that the image size is a function of the radius of curvature of the reflecting surface. *Figure 6.1* shows the derivation of the radius of curvature from the known object size and the measured image size using the principle of similar triangles.

If this principle is to be applied to the keratometer, it will be necessary to provide a means of assessing the working

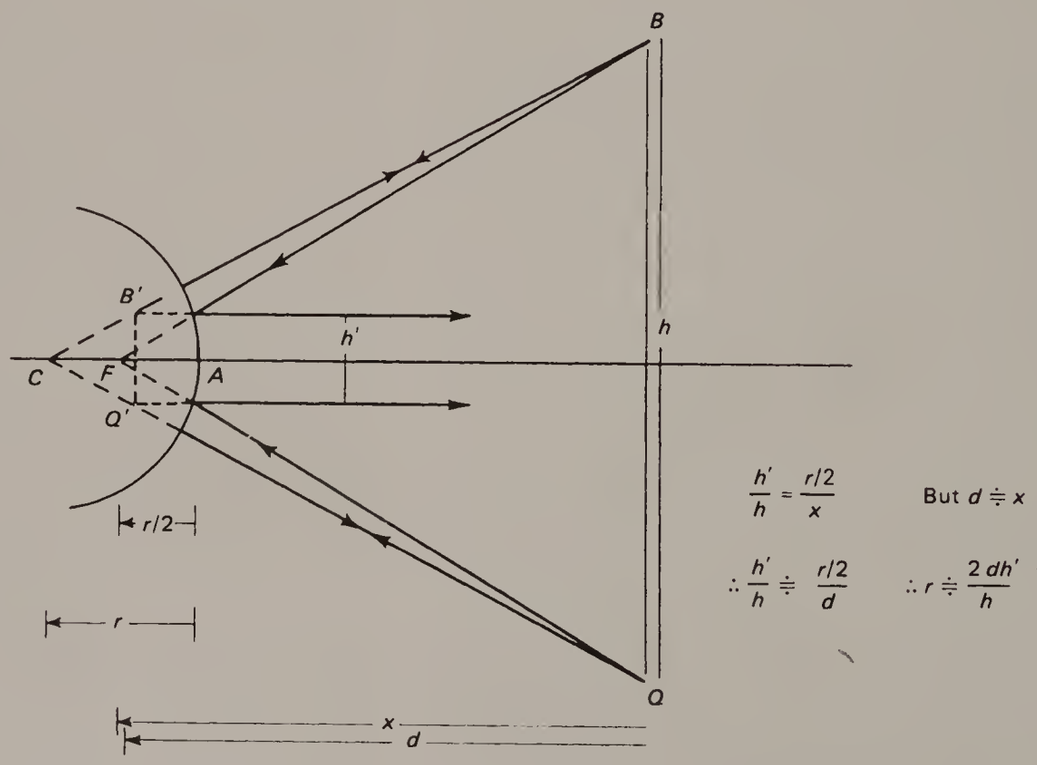


Figure 6.1 Optical principle of keratometry

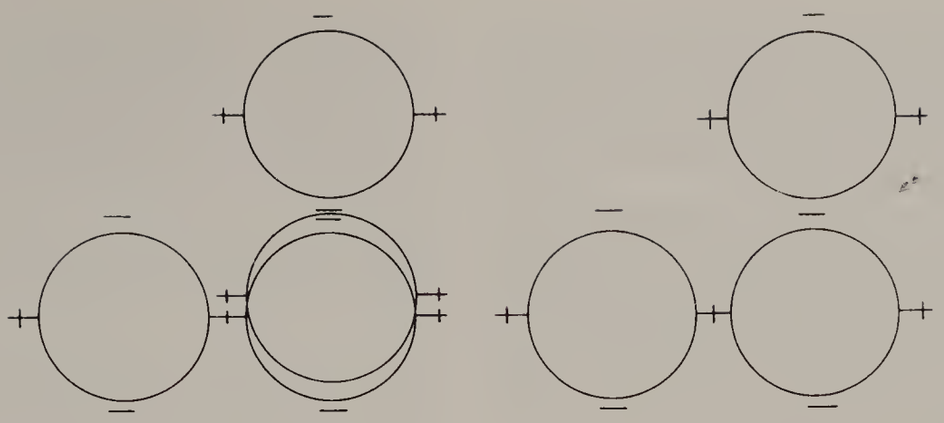


Figure 6.2 The Bausch & Lomb keratometer mires. When not set at the correct working distance a Scheiner disc creates a doubled image of the mires in the eyepiece

distance (d) during measurement and to provide a precise method of measuring the image size. The working distance is usually monitored through a Scheiner disc or similar system. This produces a doubled image of the object in the eyepiece unless the instrument is used at the exact working distance required by the instrument design *(Figure 6.2)*

Doubling systems

The eye is constantly in motion, moving even during apparently steady fixation, and it is therefore difficult to measure the size of an image reflected by the cornea directly. However, if an image is passed through a prism *(Figure 6.3)* or a doubly-refractive crystal to produce two images of the object, the image size can be judged by aligning the base of one image with the top of the other. At this point the image will have been displaced by its exact height. During eye movements, as both images move together, the alignment process will be unaffected. This is the principle of doubling and can be achieved in two ways.

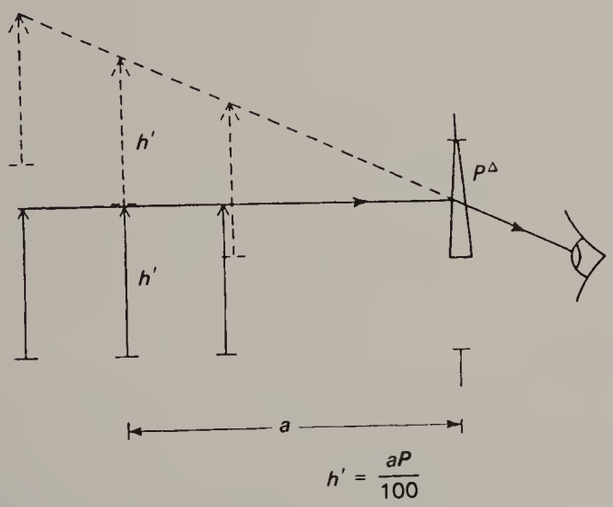


Figure 6.3 The principle of doubling used to measure image height

Fixed doubling

In a fixed doubling system, a pre-determined amount of doubling is produced by the system and the object mire is moved until the image produced is of the pre-determined height. Since the working distance and the image size are known and the object size is measured by the position of the object mire, the radius of curvature can be determined from the formula shown in *Figure 6.1* and is read directly from the scale. This type of keratometer is recognizable by its movable mires (e.g. Javal–Schiötz or Haag Streit).

Variable doubling

In a variable doubling system, the object is set to a predetermined size and the doubling system is varied until the image is displaced through its exact height. The working distance and the object size are known while the image size can be determined from the amount of doubling created during measurement. From this information the radius of curvature can be determined as before, and is read directly from the scale. Variable doubling instruments can be recognized by their fixed mires (e.g. Bausch & Lomb).

Mire type

A number of different mire designs are available which have individual benefits and disadvantages. The essential requirements are that they must all provide a means by which to determine the principal meridians of a toric cornea and must provide a precise method of alignment to permit repeatable measures of curvature.

Bausch & Lomb mires

These are circular mires used in a variable doubling system where the object mire is fixed. The image is doubled in two directions at right-angles to each other which provides a means of measuring the two principal corneal meridians

simultaneously. As a result, this type of instrument is referred to as a one-position instrument. The mire type is shown in *Figure 6.2*. Axis orientation is achieved by rotating the mires until the horizontal limbs of the mires are co-incident. The instrument is then adjusted until the two parts of the mire are superimposed.

The circular Bausch & Lomb mire is used in a number of instruments and is useful for rapid assessment of curvature, being a one-position instrument. However, if the principal corneal meridians are not exactly at right-angles, it is necessary to assess and record each meridian separately, locating the axis of each meridian individually. The circular mire readily demonstrates any corneal distortion and is useful in assessing soft lens fit and flexure of RGP lenses *in situ* by reflection of the mire on the front surface of the lens while in the eye (over-keratometry) (*see also* Chapter 10).

Zeiss mires

The Zeiss mire incorporates an open and closed cross where orientation is determined by arranging the horizontal limb of the closed cross mire centrally within the horizontal limb of the open cross (*Figure 6.4*). Alignment for measuring curvature is achieved when the vertical limb of the closed cross is central within the vertical limb of the open cross. Since each principal meridian of the cornea must be assessed separately, this type of keratometer is known as a two-position instrument. The Zeiss mire, or modern variations of it, can provide high levels of precision because of the mire size and the high levels of vernier acuity exhibited by the human eye. However, given the limitations of keratometers (*see below* Keratoscopy) this precision may not be a significant benefit.

Javal–Schiötz mires

These mires are used in both fixed doubling and variable doubling instruments and represent a two-position instrument format. One mire is a rectangular block while the other is a stepped mire. Orientation is achieved by coincidence of the central line of the two mires. Alignment for measuring curvature is achieved when the two edges of the mire are abutted. The mires are usually of two different colours so that any overlapping of the mires produces a change in mire colour. The stepped mire allows a rapid estimation of corneal astigmatism. Once the mires are aligned in one meridian and the mires are then rotated through 90° to the other meridian, any overlap of the mires can be assessed against the steps in the mire, each step representing one dioptre of astigmatism (*Figure 6.5*). Overlapping will only occur when the second meridian measured is steeper than the first. According to Shephard (1989) the Javal–Schiötz mire is useful for estimating corneal curvature in keratoconus where other mires may present difficulties in achieving a result.

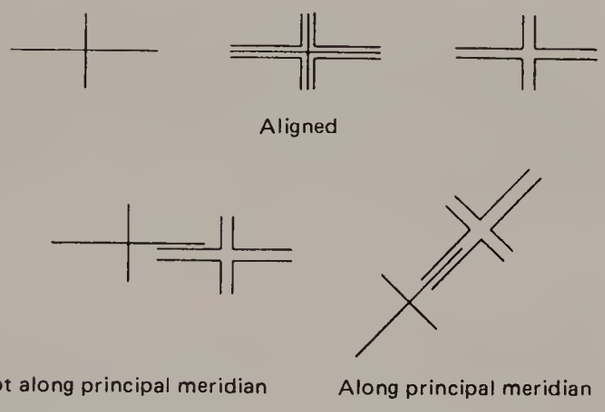


Figure 6.4 The Zeiss mire

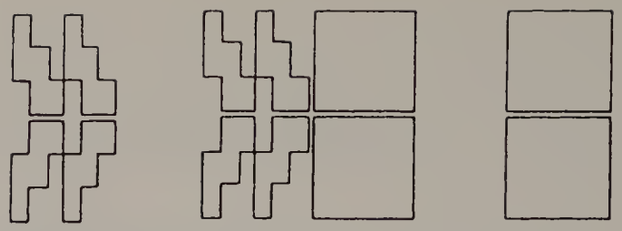


Figure 6.5 The Javal–Schiötz mire. The steps on the second mire represent 1 dioptre intervals of astigmatism

Sources of error in keratometry

There are two types of error that can be associated with the use of the keratometer; those which are a feature of the instrument design and are outside the control of the operator, and those which are operator-induced.

The accuracy of keratometry is influenced by calibration using paraxial theory. Emsley (1960, 1963) and Bennett (1966) showed that the paraxial ray theory used to derive the relationship between image and object size and curvature is too simplistic. This is demonstrated in the need to correct measurements of concave surfaces obtained with a keratometer (e.g. a contact lens BOZR). Paraxial ray theory does not differentiate between concave and convex surfaces and provides no correction factor, while Bennett (1966) demonstrated that the discrepancy found can be related to the differences in aberration between convex and concave surfaces.

Figure 6.1 shows that in the approximate formula used to derive radius of curvature, the working distance d is equated with the separation of object and focal point, x. While this undoubtedly introduces an error it can be shown that this is of a very small order (Emsley, 1955), being 0.10 D or 0.02 mm for the Bausch & Lomb instrument. Collimation overcomes the small discrepancy and also prevents working distance errors from detracting from the accuracy of measurement.

Errors can also arise because assumptions have to made about the relationship between the central corneal point (or keratometric pole) and the peripheral areas from which the mire images are reflected. In calibration it is assumed that the peripheral points and the pole all have the same spherical radius. If this is not the case then the readings will

be erroneous. The wider the separation of the reflecting areas of the cornea (which is a function of both the instrument design and the radius of curvature of the cornea being measured), the greater is the likelihood of error.

Operator-induced errors usually derive either from inadequate centration of the instrument or from using incorrect working distances. If there is no symmetry between the keratometric pole and the peripheral reflecting areas caused by poor centration, the assumptions of equal spherical shape between the pole and reflecting positions is invalid. Incorrect working distances can be employed through failure to focus the eyepiece or from proximal convergence. Discrepancies due to eyepiece focusing errors may not be large but detract from overall precision and accuracy (Rabbetts, 1977).

Applications of keratometry

Keratometry is used in contact lens practice in a number of ways.

Preliminary assessment

In addition to the obvious role of providing baseline data on corneal curvature, the keratometer, either in modified or conventional form, can be used to assess the non-invasive tear break-up time (Hirji *et al.*, 1989). Since the quality and stability of the reflected image of a keratometer mire is dependent on the tear film in which it is reflected on the corneal surface, debris in the tear film or a rapid break-up in the tear film will be seen as disruption to the quality of the mire images. If the time taken between a blink and the first sign of the mire image distorting is determined, this will be equivalent to a non-invasive tear break-up time. While there are some disadvantages caused by the limited area of tear film involved in the assessment, it is a simple test requiring no additional equipment (*see below* Precorneal tear film analysis).

Lens fitting

Most keratometers are calibrated with a refractive index of 1.3375 to give total corneal power and thereby the amount of corneal astigmatism can easily be assessed prior to lens fitting (*see* Chapter 5). This gives a useful indication of what type of lens will be suitable. Keratometry guides the selection of the first trial lens, particularly with rigid lenses. With soft lenses, where the central corneal curvature is a poor guide to overall corneal shape, the keratometer still provides a starting point and can also be used to assess the fitting characteristics (*see* Chapter 11). In either case, keratometry provides good baseline data which permits comparison of subsequent results during after-care. It has been suggested that keratometry can be used as the basis for the empirical fitting of RGP lenses (Edwards, 1982) without the need for trial lens assessment although the effects of lens thickness and the interaction with lids will not be predictable.

Lens selection can also be assisted by comparing corneal astigmatism, as measured by keratometry, with the spectacle astigmatism. Such comparisons help predict whether rigid or soft lenses are likely to give a better visual result and whether a toric lens might be necessary (*see* Chapters 10 and 11).

Modern RGP lenses are prone to flexure when fitted to astigmatic corneas (Stone and Collins, 1984) and where this is thought to be compromising visual performance, keratometry over the lens will confirm the extent to which this is occurring. A spherical rigid lens will have a spherical front surface and therefore the over-keratometry should be spherical. If the lens is flexing, the over-keratometry will give a toric result. It should be remembered that the instrument is not calibrated for the refractive index of contact lens materials and so conversions may be needed to provide accurate dioptric assessments of induced astigmatism. (For formula *see* Chapter 5. Also Appendix B, and the CD-ROM supplied with this book.)

After-care

Contact lens-induced changes to the cornea can often be detected through keratometry. Oedema, if central and localized, will be evident from the steepening of the corneal curvature. A flat fitting contact lens will often produce a distorted image of the keratometry mire from the cornea although there is not universal agreement that flat fitting lenses flatten the cornea (Bier, 1957; Rengstorff, 1965a,b; Spurrett, 1973). However, much of this work was conducted with PMMA lenses where the outcome was inevitably complicated by the corneal response to the hypoxic conditions created by this material. More recent studies using topographical measurements suggest that lens position may be most relevant in determining the degree and nature of distortion (Wilson *et al.*, 1990). Corneal moulding can result from a spherical lens fitted to a toric cornea and will be evident from a reduction in measured corneal astigmatism as well as mire distortion and spectacle blur.

The precision of keratometry should be considered if repeated readings over time are to be compared. Care must be taken as a difference can occur between observers (due to proximal accommodation), between instruments (because of the varying mire separations referred to above) and due to diurnal variation in corneal shape (Reynolds, 1959).

Contact lens measurement

Keratometers provide a simple and readily available method for verifying rigid contact lenses. The lens can either be supported in a holder mounted directly in front of the instrument or held in a container at right-angles to the instrument when a mirror is used to obtain the necessary image (*see Figure 12.6*). Due to the aberrations discussed above, conversion of the results obtained is necessary to allow for the measurement of a concave rather than a convex surface. Tables are obtainable from a number of keratometer manufacturers for this purpose although for

most of the BOZRs encountered in contact lens work, it is sufficient to add 0.03 mm to the reading given by the instrument.

Extending the range of measurement

In certain cases, it may be necessary to measure a cornea or contact lens beyond the normal range for which the instrument is calibrated. This may occur in keratoconus or with post-refractive surgery cases. The range of the instrument can be extended using additional trial lenses held over the measurement system to change the working distance. Plus-powered auxiliary lenses will permit the measurement of steeper radii, while minus powers will permit the measurement of flatter radii. To obtain the radius of a surface measured in this way, recalibration of the instrument is required using steel balls of known and validated radius. A calibration graph can then be drawn, plotting measured value against real value. This graph can be used to convert measured values to corrected values and may be used for each occasion on which the same auxiliary lens is used.

Topographical keratoscopy

Keratometry offers a reasonably accurate indication of central corneal curvature based on the assumption that the cornea is a spherical surface. However corneal shape is generally considered to be more complex, approximating an evolute (*see* Chapter 10), and may be most easily represented as an ellipse where the periphery of the cornea flattens compared to the centre. (In fact there is wide variation between individuals although the average cornea conforms to this description; Guillon *et al.*, 1986.)

Due to this peripheral flattening, keratometry is not a particularly useful guide to the overall corneal shape and may be misleading where contact lens fitting involves significant coverage of the peripheral cornea. In an attempt to overcome the limitations of keratometry in this respect, numerous attempts have been made to assess the peripheral as well as central corneal curvature.

Topographical keratometers

In its simplest form, corneal topography can be assessed using off-axis keratometry. To enhance accuracy of assessment and the ability to obtain measurements of the extreme periphery of the cornea, small mire separations are preferable. Using adaptations of conventional keratometers that allow fixation to be moved through predetermined angular distances from the central fixation point, some measure of peripheral flattening (eccentricity) can be made. For example, Wilms and Rabbetts (1977) showed how simple modification of the Rodenstock keratometer provided an easy method of obtaining peripheral measurements of radius on either side of fixation in the two principal meridians of a given cornea. A simple relationship then exists between all the values obtained and is given in *Equation 6.1*.

An alternative, computer-derived approach was demonstrated by Lam and Douthwaite (1994) using a modified Bausch & Lomb keratometer. The use of eccentric fixation positions also led to the development of lens fitting systems where the choice of lens can be linked to the eccentricity of the cornea determined from the keratometry (Douthwaite, 1991; Lam, 1993). The method of off-axis keratometry was re-emphasized by Caroline (1994).

Equation 6.1 Derivation of eccentricity from peripheral keratometry (after Wilms and Rabbetts, 1977)

If $$r_s = \frac{(R_{s_1} + \Delta r_0) + (R_{s_2} + \Delta r_0)}{2}$$

then $$e = \sqrt{4\left(1 - \left(\frac{r_{0_1}}{r_s}\right)^2\right)}$$

Where: e = numerical eceentricity of cornea
r_{0_1} = central radius in steep meridian
Δr_0 = difference in radius between steep and flat meridian
R_{s_1} = peripheral measurement 30° temporal or superior of fixation on steep meridian
R_{s_2} = peripheral measurement 30° nasal or inferior of fixation on steep meridian

For the flat meridian the formula is modified so that Δr_0 is subtracted from the peripheral radii to give r_s.

Some special topographical keratometers have been described and in some cases only a single mire was used (Bonnet, 1964). This had the advantage of limiting the reflecting area to a minimum, making the measurement more accurate. To enable a measurement to be made, a different doubling system was used which permits one end of the mire to be aligned with the other.

Whenever off-axis keratometry is used, the resulting data must be treated with caution since the principle of keratometry makes the assumption of symmetrical positioning of mires about the centre of a rotationally symmetrical surface. In off-axis keratometry, this requirement is not met, although the information obtained may be adequate to permit reasonable assumptions about corneal shape.

Automated systems

With the advent of computerized systems, the computations necessary to describe corneal topography can be achieved more readily. The Humphrey Auto Keratometer assesses corneal contour along the horizontal meridian by using off-axis fixation and has been described by Rabbetts (1985). Other automated instruments have been described by Port (1985, 1987). These may give central corneal curvature, an

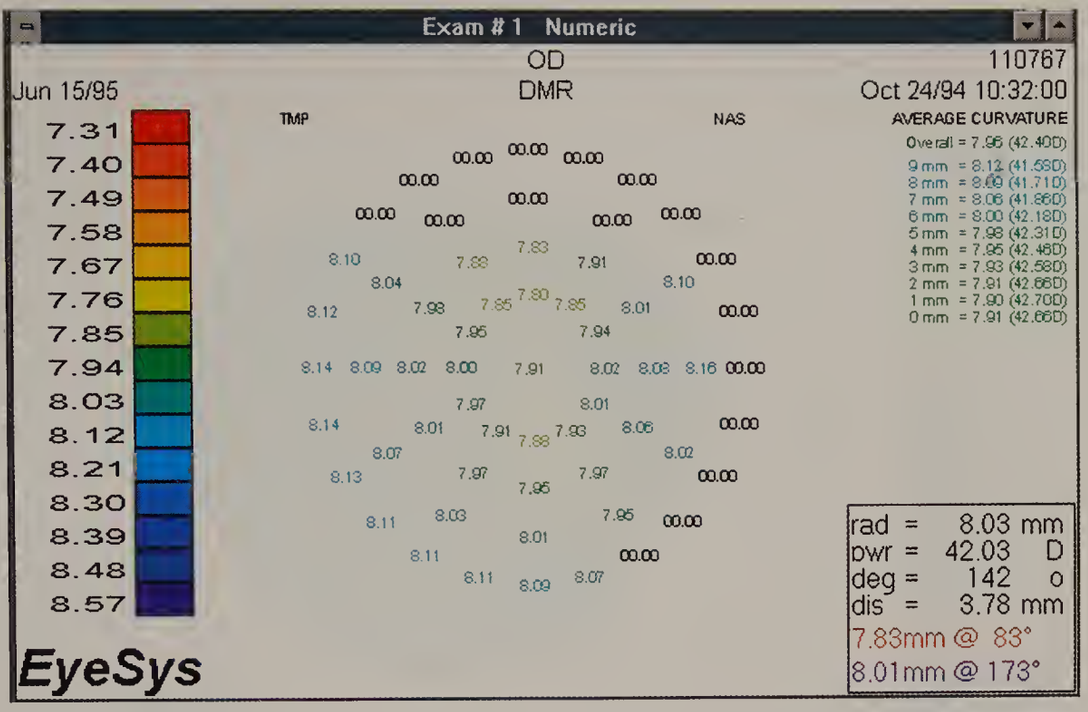


Figure 6.6 EyeSys plot of corneal shape utilizing radius values for all points plotted. Each radius value is also colour coded. (Courtesy of D.M. Ruston)

indication of the degree of peripheral flattening (eccentricity) (*see* Chapter 10) and in some cases, an estimate of how closely the measured shape conforms to the mathematical model of eccentricity used.

The use of photographic techniques was exemplified in the Photo-Electric Keratoscope (PEK) used by Bibby to produce assessments of corneal curvature which could then form the basis of lens designs for individual corneas (Bibby, 1976). This system produced a Polaroid photographic negative of a number of concentric rings reflected on the corneal surface. Analysis of the separation of the rings could then provide an assessment of image size (and therefore equivalent radius) at each point on each ring. The data was used to compute corneal topography for the two principal meridians from which a corneal contact lens could be designed giving pre-determined central and peripheral clearances. However, the image analysis and subsequent lens design was carried out at a laboratory which incurred delay between imaging the cornea on film and obtaining the results of the analysis. The results were also influenced by the quality and focus of the photographic images.

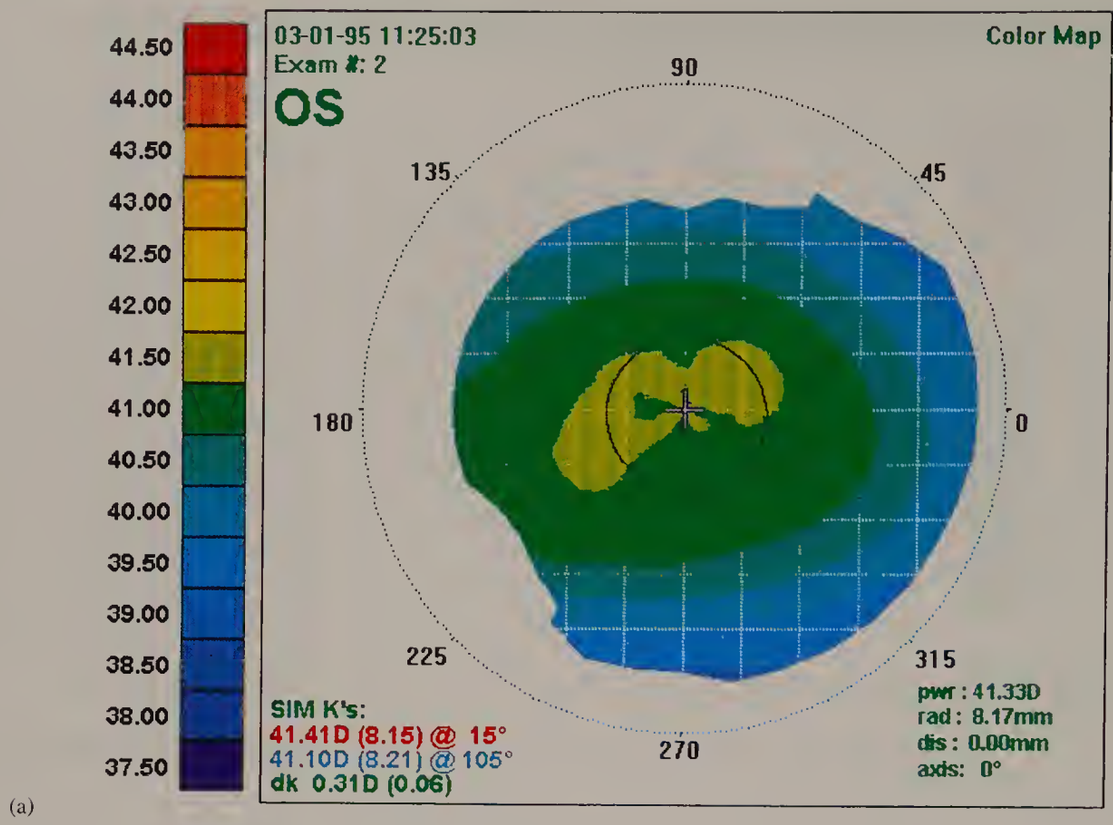
More recently, video-capture techniques linked to personal computers have resulted in systems that can produce immediate on-screen images of the mires reflected in the cornea and instant analysis of the data to provide both point by point curvature maps or overall contour maps of the corneal shape. The computations are based on image size and semi-chord diameter as described in keratometry but the assessment is of a number of points across the corneal surface. Typically, a 10 mm diameter is assessed but this may be limited by shadows created by anatomical features such as nose, brows and lashes which obstruct the imaging process. The number of rings used and therefore the number of data points created, varies between instruments as does the working distance and brightness of the image. However, comparisons between instruments suggest that each has relative advantages and disadvantages in aspects of design and precision (Stevenson, 1992; Antalis *et al.*, 1993) with no one instrument overcoming all the limitations.

Data analysis

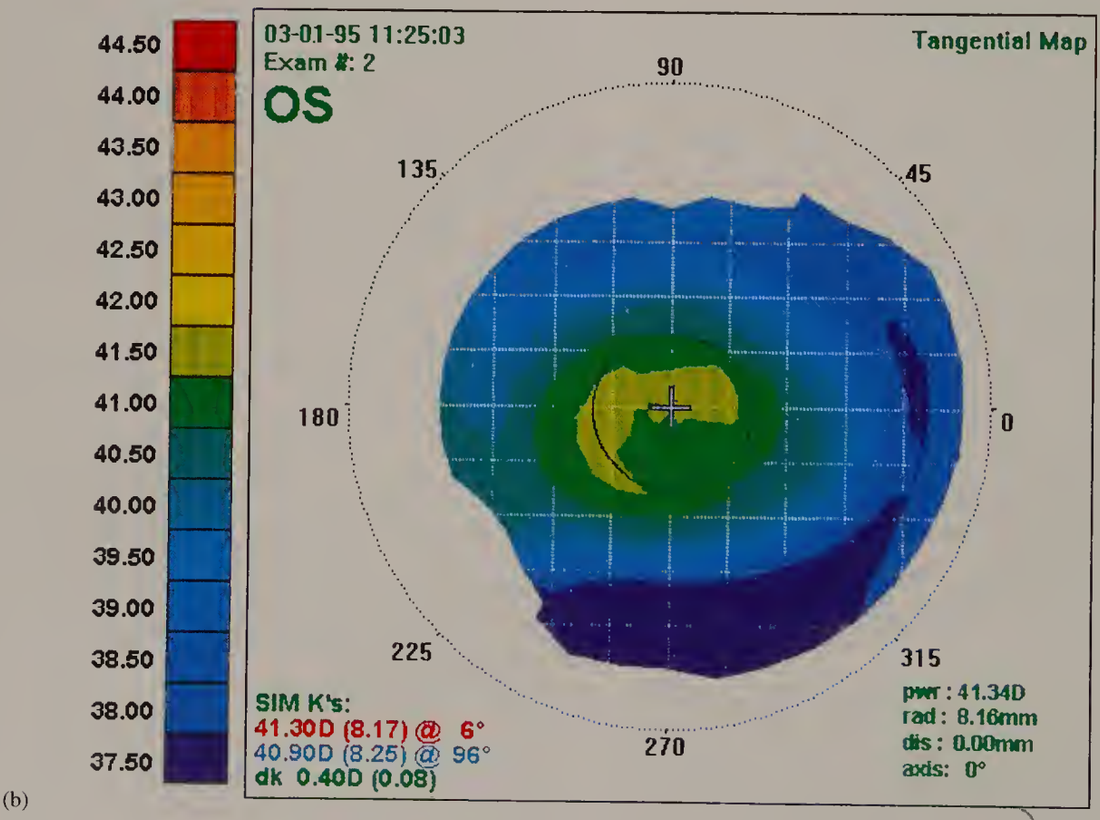
Different analysis of the video images can be used to produce a variety of information about the corneal surface being imaged.

Under normal circumstances, the cornea is assessed as a refractive surface and the assessment revolves around dioptric power or radius of curvature. For individual lens design, point by point radius values measure the changes in shape over the corneal surface (*Figure 6.6*). Contour maps (*Figure 6.7a*) which show areas of equal corneal curvature are useful in indicating corneal distortion since they highlight the position, degree and extent of the changes.

To correlate with keratometry, the videokeratoscopes usually provide keratometric data derived from the innermost rings whose semi-cord diameters most nearly equate with conventional keratometers. To determine true apical radius and a measure of the corneal p value ($1 - e^2$: where e is eccentricity, *see* Chapter 10, p. 316) Douthwaite (1995) indicated that where the square of the radius r is plotted against the square of the semi-chord diameter d, then the



(a)



(b)

Figure 6.7 (*a*) EyeSys contour map. Here iso-dioptric lines and areas are mapped using a colour code. This presentation makes it easier to gain an overall impression of corneal shape. (*b*) The tangential map of the same eye illustrating how the peripheral power gradient is most affected by the method of calculation. (Courtesy of Tinsley Medical Instruments)

intercept of the best straight line through the data points will indicate the square of the apical radius while the slope of the line will give the value of p.

Where corneal surface elevation is of more interest than refractive performance (e.g. in pathological corneal conditions), the corneal sagittal data can be analysed against a reference surface which is usually either a flat plane or a reference sphere. While both give good analyses, differences between meridia are less apparent when using a flat plane as the reference surface, since elevation in this case is a measure of the total sag of the cornea at each point. Small differences in sag between corneal meridia will be insignificant compared to the total sag of the surface (*see* Chapter 5). With a reference sphere, the overall sag differences between cornea and reference surface are smaller and therefore small differences between corneal meridia are more readily apparent.

One further complication arises when considering the validity of the radius and refractive power data derived for the cornea. Sagittal power values are derived from paraxial theory, assume rotational symmetry of the surface and predict that all rays will be focused on the axis of symmetry. However given the asphericity of the cornea, the fact that the optical properties are being evaluated outside the area considered to be 'paraxial' and a possible loss of rotational symmetry, the sagittal power approach may be an oversimplification. The use of tangential power allows the impact of peripheral aberrations to be evaluated, for example in the more accurate location of a cone apex or in viewing the 'knee' at the edge of a photo-ablated zone. Equally the tangential plot will give a better comeal *shape* when comparing the plot to the observed fluorescein pattern. In particular the obliquity of rays striking the cornea away from the centre will result in oblique astigmatism, producing separate tangential and sagittal images. Fowler and Dave (1994) reviewed the principles involved and have shown by ray tracing, that for rays 2.02 mm and 3.90 mm from the corneal axis, differences of 2 D and 10.3 D respectively occur, between sagittal and tangential ray tracing approaches. They suggest that these differences may be due to spherical aberration. Salmon and Horner (1994) showed that when surface elevation, axial curvature, tangential (instantaneous) curvature and ray-trace focal powers are compared, there are significant differences in the maps produced with instantaneous curvature most sensitive to surface asymmetry and the ray-trace focal power map giving a reasonable estimate of the corneal optics. *Figure 6.7(b)* shows the tangential map for the same eye as *Figure 6.7(a)*. Klein and Mandell (1994) showed a simple relationship between tangential and sagittal radius where the axial power is the average of the tangential powers from the axis to the point being measured.

Despite these various complications in interpreting the print-out data when making comparative assessments with keratometric data, it is the conventional sagittal radius that might be most appropriate since Bennett and Rabbetts (1991) showed that it is sagittal and not tangential radius that is measured by keratometry.

In addition to the theoretical, analytical aspects of inaccuracy, there are other sources of error in both application and data analysis. At its most basic, all keratographic instruments fail to image the two principal meridia of a toric cornea in the same plane. As a result, image analysis may prove difficult and, although modern instruments allow on-screen adjustment of the points being assessed, this is still little more than trial and error. Alignment errors can adversely affect the accuracy of these systems although the magnitude may be limited if the working distance is sufficiently long (Nieves and Applegate, 1992). More consistent and significant errors occur because centration of the image occurs about the visual axis which may not coincide with the geometric axis of the cornea, usually resulting in nasal displacement of the mire image. This will create measurement error, affecting nasal readings more than temporal ones and inducing errors in calculating the peripheral curvature of aspheric surfaces (McCarey *et al.*, 1992).

In spite of these inherent errors, videokeratoscopes are being constantly improved and prove to be useful tools in the fitting and monitoring of corneas and contact lenses (*see* Chapter 10 for operating instructions).

Applications of videokeratographic images

The applications of the plots produced by new topographical instruments are being developed all the time.

They may be of particular value in irregular corneas such as keratoconus or post-refractive surgery cases. The exact location of the cone in keratoconus and the relationship with the peripheral, unaffected cornea may assist in predicting fitting difficulties as well as centration problems (*see Figure 20.1.1*). After photo-refractive keratectomy (PRK) the diameter of the ablated zone and the shape of the transitional zone may be useful in predicting fitting parameters for a rigid lens (*see Figure 20.4.5*). In fact, the use of topographical plots both before and after surgery is becoming obligatory for PRK surgeons.

Most instruments are supplied with lens design software so that simple multicurve and aspheric lenses can be designed based on the topographical data and the expected fluorescein picture can be superimposed over the map on the video screen (*Figure 6.8*). These programs may also permit investigation of the effects of decentration and lens tilt. Several instruments have software which permit the fitting of a full range of different manufacturer's lenses to the on-screen topographical map by accessing a database of lens specifications (*see* Chapter 10).

Where detail is required to obtain the precise fits necessary for orthokeratology (see Chapter 19), videokeratographs can be of great assistance in providing information from which to compute BOZR and intermediate curves.

After fitting patients with rigid lenses, the greater detail provided from topographical maps may help to identify any corneal distortion at an early stage. With soft lenses,

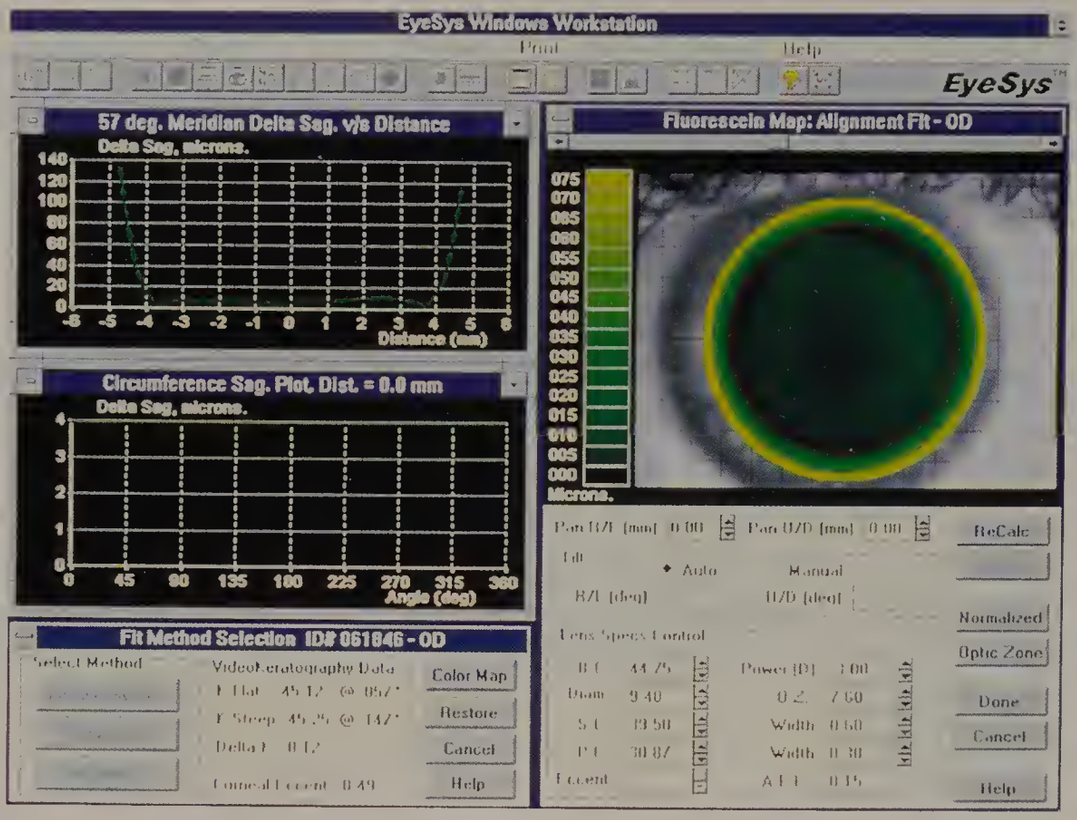


Figure 6.8 Simulated fluorescein pattern produced by contact lens fitting program of EyeSys computerized video keratoscope. Lens can be moved over corneal surface vertically and horizontally and the pattern recalculated. Suggested lens parameters can be modified by the practitioner and effects on fitting patterns observed. The displays to the left show tear layer thickness profiles along a specified meridian (*top*) or diameter (*bottom*). (Courtesy of D.M. Ruston)

topographical plots of the front surface can be used to show surface distortion of older lenses (for example where there is an unexplained loss of acuity) and even in the identification of aspheric back or front surface lenses.

Alternative approaches to corneal contour

Despite the limitations of the videokeratographic instruments, they nevertheless provide useful additional information either to supplement or to replace keratometry and which may form the basis of detailed corneal shape assessment and suitable contact lens designs.

An alternative approach of producing contour mapping of the cornea by profile photography was described in 1966 (Collignon-Brach *et al.*, 1966) and has recently undergone a resurgence of interest due to the advances in personal computer and video-imaging capacity (Caroline, 1994). This technique can provide exact profile imagery of the cornea using a slit lamp beam and is generally unaffected by the anatomical restrictions that limit videokeratographic techniques. An overall profile map can be created by the compilation of a series of individual sections across the cornea into a single picture which can then be analysed. This technique has a particular advantage where there are local anatomical anomalies such as pterygia. A variation of this technique using vertical planes of light imaged on the cornea and then mathematically evaluated has been described by de Cunha and Woodward (1993) for assessing corneal topography in kerataconus. At least one commercially available instrument, the Orbscan (Orbtech, Salt Lake City), now uses this technique to measure both the anterior and posterior corneal topography as well as corneal thickness.

Slit lamp biomicroscopy (*see also* Chapter 8)

Careful observation and monitoring of the ocular response to contact lens wear is the prerequisite to successful contact lens fitting. The slit lamp biomicroscope is the main tool used in this process, providing a detailed view of the ocular structures at high magnification.

The principal components of the slit lamp are an illumination system that provides a focused slit image of light with well-defined borders and a microscope with high resolution providing magnifications typically between 10 and 60 times. Both systems can be moved around a common centre of rotation so that there is a common point of focus which is constant as the system is moved over the curved surfaces of the eye.

Illumination system

In order to assess changes in media that would normally be optically transparent, it is necessary to have a light source with clearly defined edges. This will ensure that there is no diffusion of light away from the point of focus unless there is any irregularity in the media through which the light is passing. In the slit lamp, this requirement is achieved by utilizing an optical system which projects an image of a mechanical slit aperture on to the surface being examined. The slit aperture is machined to have sharply defined edges and can be varied in height and width.

The slit illumination can be augmented by the use of coloured, neutral density and, sometimes, dichroic filters which may be interposed in the illumination system. The coincident focus of illuminating and observation systems can be uncoupled so that special methods of illumination can be employed (*see below*). To provide a photographic facility, a flash tube may be fitted so that it is coincident with the lamp of the illuminating system. This will provide a flash source focused and imaged in exactly the same plane as the normal system illumination (*see* Chapter 7).

Observation system

The observation system of the slit lamp comprises a microscope with either converging or parallel eyepieces. The latter type is finding increasing popularity since it permits a turret of objectives allowing a greater range of magnification without the need to change eyepieces. Eyepiece reticules can be used for measuring purposes although calibration will be necessary for each magnification used. Special eyepieces with doubling prisms may be required for techniques such as pachometry.

Slit lamp techniques

In order to gain as much information from the use of the slit lamp microscope as possible, it is necessary to use the instrument correctly.

To gain maximum overlap of the field of view and area of illumination, the instrument has coincident centres of rotation for both observation and illumination systems. This will ensure that the slit image is produced in the same plane as the focus of the microscope and that the slit image is centred in the field of view. To maintain this situation, it is important that the eyepieces are correctly focused for each individual using the instrument. Where there is an error of eyepiece focus the planes of focus and rotation will no longer be coincident and this will lead to the slit appearing decentred in the field of view, especially at higher magnifications. 'Uncoupling' or offsetting the illumination system with regard to the observation system, is necessary for certain types of viewing such as sclerotic scatter (*see below*). This is achieved by physical rotation of the illumination system about a horizontal or vertical plane.

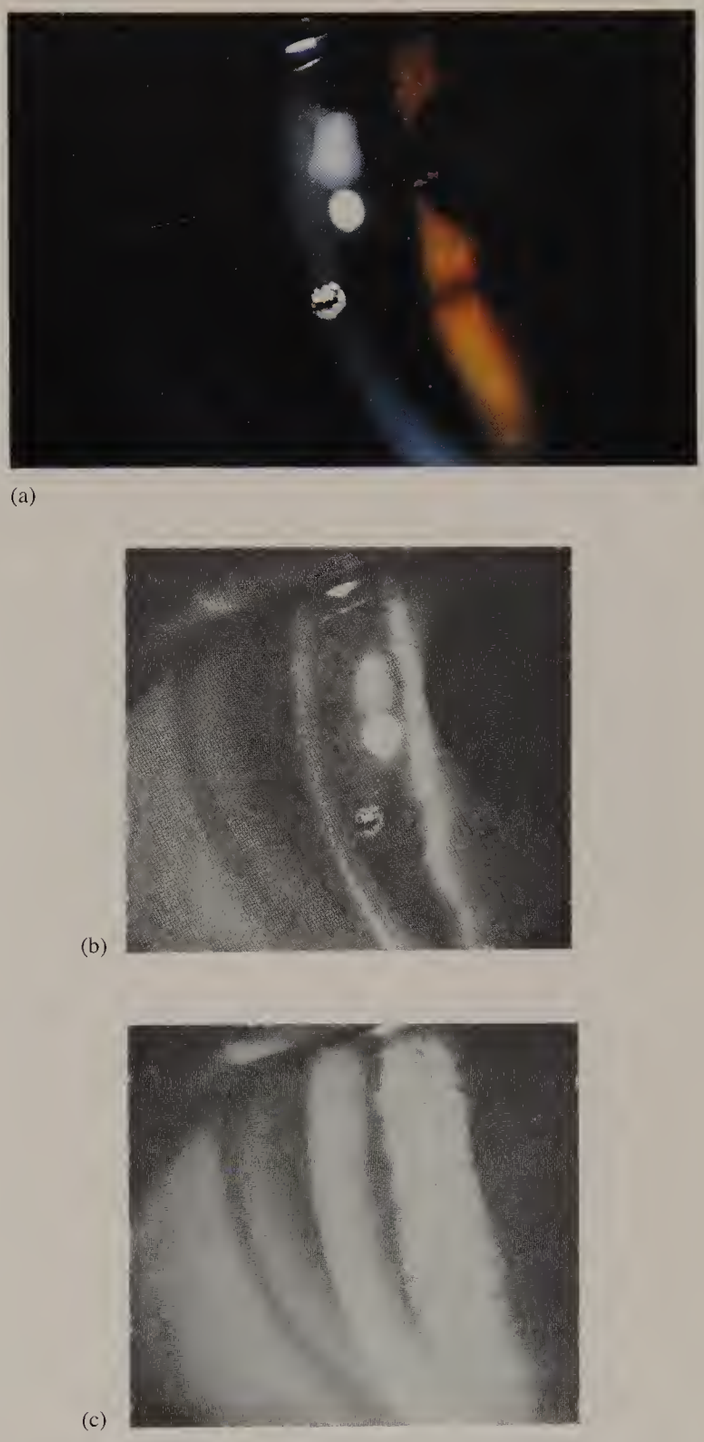


Figure 6.9 Different methods of illumination: (*a*) direct illumination; (*b*) indirect illumination; (*c*) retro-illumination. (Figures (*b*) and (*c*) are reproduced from Edwards, K. and Llewellyn, R. (eds), *Optometry*. London: Butterworths, 1988, with permission)

There are a number of different methods of illumination which can be isolated and described individually (Stockwell and Stone, 1988; Morris and Stone, 1992): some of these are shown in *Figure 6.9*. However, routine slit lamp examination rarely requires the isolation of these separate techniques. Since the field of view of the observation system is

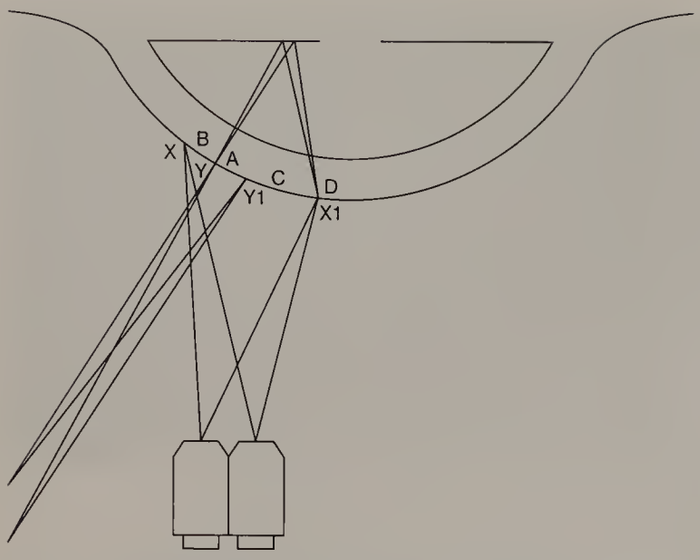


Figure 6.10 Methods of illumination as seen during routine slit lamp examination. The field of view of the observation system (microscope) X–X1 is larger than the area illuminated by the illumination system (slit beam) Y–Y1. Object A is seen by direct illumination and will appear as a dark object in the brightly illuminated slit. Object B is seen, at the same time, by indirect illumination and will appear as a brightly lit object in a dark field of view. Object C will be visible against the light reflected from the iris (direct retro-illumination) and will be seen as a dark object against a light background. Object D will be seen to one side of the light reflected from the iris and will be seen in indirect retro-illumination as a light object against a dark background. All these methods of illumination are seen at the same time within the field of view of the microscope

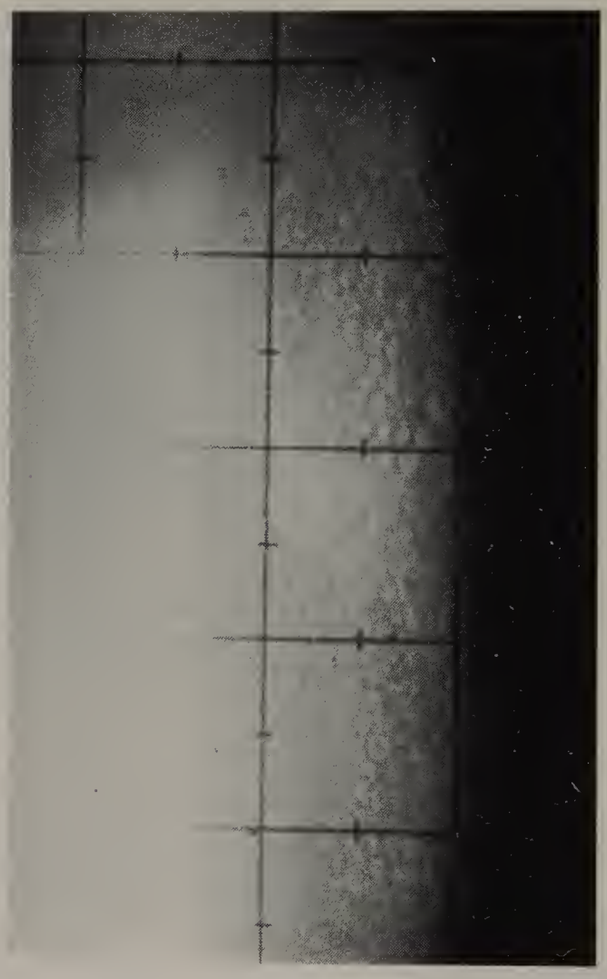


Figure 6.11 Endothelium seen by specular reflection (photographically magnified)

always larger than the area illuminated by the slit, several types of illumination will be evident at any one time. Scanning of the structures by moving both illumination and observation system across the surfaces under examination will allow objects of interest to pass from one method of illumination to another. It is the change in appearance of the objects as they are illuminated in different ways that makes them readily visible. In *Figure 6.10* the field of view and area of illumination are shown. The legend describes how different objects are seen within the field of view. As soon as the illumination system is moved sideways, objects move from **direct** to **indirect** illumination (and *vice versa*) and the observer will be aware of objects changing from light to dark or dark to light within the field of view.

Specular reflection occurs when the angle of illumination and observation are equal about the normal to the surface. Even this technique, which is used to view the endothelium, needs no special set-up, other than high-powered magnification, unless a specific point of interest is to be examined. The conventional examination technique is to scan the whole cornea in three sweeps with the illumination system moved laterally so that it is always on the same side of the mid-line as the part of the cornea under examination (Stockwell and Stone, 1988). Under these conditions there will always be two points in each sweep at which specular reflection becomes visible. In following this technique it is possible to sample the endothelium (*Figure 6.11*) at six points during every corneal examination without deviating from the normal routine and without setting up a special illumination method.

The only illumination techniques that require specific set-up are those requiring uncoupling of the illumination and observation systems. **Sclerotic scatter**, used to check for rigid lens-induced oedema, requires the light to be displaced to the limbus while the microscope remains focused on the central cornea. In some instances, the magnification system can be ignored and the result of sclerotic scatter viewed with the naked eye. Light incident on the limbus travels through the cornea by total internal reflection and will only be visible within the cornea if there is an irregularity or opacity which causes light to scatter outwards (*Figure 6.12*).

In focused **retro-illumination** the slit is focused on the iris while the microscope remains focused on the cornea. However retro-illumination is not dependent on the light source being focused on the iris since even out-of-focus light reaching the iris will be reflected back and provide a source for retro-illumination (*Figure 6.9c*).

When using some accessories such as gonioscopy lenses, it may be beneficial to move the slit about a vertical axis to permit better focus and field of view.

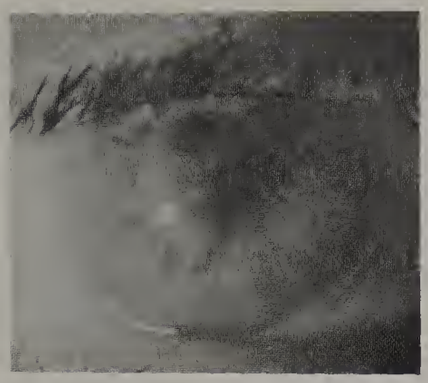


Figure 6.12 Central opacity as seen by sclerotic scatter. (Reproduced from Edwards, K. and Llewellyn, R. (eds), *Optometry*. London: Butterworths, 1988, with permission)

For measurements of blood vessels, opacities, etc., the slit width or length scale on the slit lamp can be used. The slit can be turned through up to 90° in order to take measurements at the appropriate angle. Alternatively, a reticule can be incorporated into one of the eyepieces.

Applications

The application of slit lamp techniques requires regular use of the instrument and considerable practice. *Table 6.1* indicates some typical conditions and the preferred methods of illumination to render them most visible. Slit width, the angle between observation and illumination system and magnification are continuously varied to obtain the best view. The table gives a suggested starting point. As indicated above, there is usually no need to set up a particular method of illumination during the examination process, but a knowledge of how the various changes show up most readily will assist in the interpretation of signs as seen through the microscope.

Grading scales

In order to make sensible clinical decisions based on slit lamp microscope findings over a period of time, it is important to be able to make valid comparisons of information recorded at different appointments. This becomes increasingly important when more than one clinician is likely to see the same patient. Grading scales are a valuable tool in trying to record clinical findings on a simple numerical scale with distinct and identifiable criteria. In a study of the repeatability of grading scales, Lloyd (1992) found that there was some variation between observers in allocating a grade to conditions shown on a slide. The discrepancies increased if the number of grading intervals was increased. However, there was no disagreement about when conditions required clinical intervention, discontinuation of lens wear or referral for medical opinion. While grading scales can be more complex (Mandell, 1986), a more simple scale used widely in FDA and UK domestic trials is shown in *Table 6.2*, where the description relates to specific clinical criteria and has been endorsed by Woods (1989). An illustrated Grading Scale produced by the CCLRU in Australia is shown in Appendix D at the end of this book.

Table 6.1 Application of slit lamp techniques to ocular examination

Area/abnormality to be observed	*Magnification*	*Illumination method*	*Slit width*	*Filter accessory*
Lids and general view of external eye	Low–medium	Diffuse	Wide	Diffuser
Lashes	Medium	Direct focal	Medium to wide	None
Localized oedema	Low	Sclerotic scatter	Medium	Uncoupled system
Corneal opacities/defects	Medium–high	Direct focal Indirect focal	Medium to narrow	None
Depth of opacity/defect within cornea	Medium–High	Direct focal	Narrow	None. Wide separation between illuminating and observation system
Microcysts	High	Indirect	Narrow	None
Striae	High	Indirect	Medium to narrow	None
Neovascular changes/ghost vessels	Medium–high	Indirect retro	Medium to narrow	None. Green filter may help if there is blood flow
Endothelium	High	Specular reflection	Medium	None
Dystrophies	Low Medium	Direct retro Direct focal	Wide Medium	Neutral density? None
Fluorescein staining	Low–medium	Direct focal or diffuse	Wide	Blue filter in illumination system. Yellow filter in observation system

Table 6.2 Grading scale applicable to all structures

Grade	*Finding*
0	Absent
1	Trace
2	Minimal
3	Moderate
4	Severe

Grade 0–1 require no action; grade 2 usually requires no action. Grade 3 requires amendment to lens fit, type or wearing schedule while grade 4 usually requires cessation of wear and may require medical intervention. Consistent application of grading allows progress of a condition to be monitored accurately. Changes such as vascular infiltration may require measurement with a suitable reticule.

Accessories

The slit lamp biomicroscope can be adapted to provide additional information about corneal structure and function.

Filters

All modern slit lamps come fitted with a range of coloured filters and often a diffusing filter as well.

A diffuser can be used when general examination is required without the need for a focused slit beam (*see Table 6.1*). It can be used for examination of the external eye and adnexa and for assessment of a contact lens fit under white light.

A blue filter in the illumination system can be used in conjunction with fluorescein to assess corneal damage or the fitting of rigid lenses. The excitor filter will cause fluorescein dye to fluoresce and the addition of a yellow barrier filter in the observation system will enhance the contrast and maximize the visibility of the fluorescence (Pearson, 1984, 1986).

Neutral density filters may aid patient comfort where a full aperture slit is required but the resulting light levels are uncomfortable.

Red-free filters may be used to enhance contrast between blood vessels and the cornea and sclera to render vascularization and hyperaemia more visible.

Occasionally dichroic filters are available and may be used to permit transmission of visible light while restricting transmission of heat.

Pachometry (pachymetry)

In response to physiological compromise the normal hydration of the cornea can be upset, resulting in swelling (*see* Chapter 2), while in conditions such as keratoconus there will progressive thinning of the central cornea. Pachometry provides a method by which corneal thickness can be measured.

In its simplest form, this can be achieved using the slit lamp to provide a thin section of the central cornea, which



Figure 6.13 Appearance of slit section at end-point of measurement (Stone, 1974). Note vertical bisection of first Purkinje image, I, ensuring a vertically centred corneal measurement

can be viewed through a doubling system. A variable prism introduced into half the field will permit the displacement of one half of the corneal image with respect to the other. If the image of the cornea is displaced so that the endothelium of one image aligns with the epithelium of the second, the apparent thickness is equal to the amount of displacement (*Figure 6.13*). Apparent thickness can be converted to real thickness by using a nominal refractive index for the corneal tissue.

If a narrow slit beam is directed normally at the corneal surface, the apparent thickness of the cornea can be found by measuring the optical section seen through the microscope (*Figure 6.14*). This method of optical pachometry has limitations due to the need for accurate alignment of the slit lamp beam both horizontally and vertically on the cornea and the need for the beam to be imaged normally to the corneal surface. Failure to obtain accurate alignment will lead to errors and poor precision of measurement.

Ultrasonic pachometry offers an alternative approach without the need to use the slit lamp. At each major corneal interface, an echo will be evident on an ultrasound trace. Once calibrated, the distance between the epithelial and endothelial echoes will provide a measure of corneal thickness and modern instruments give a digital read-out. (For a review of the use of ultrasound in optometry *see*

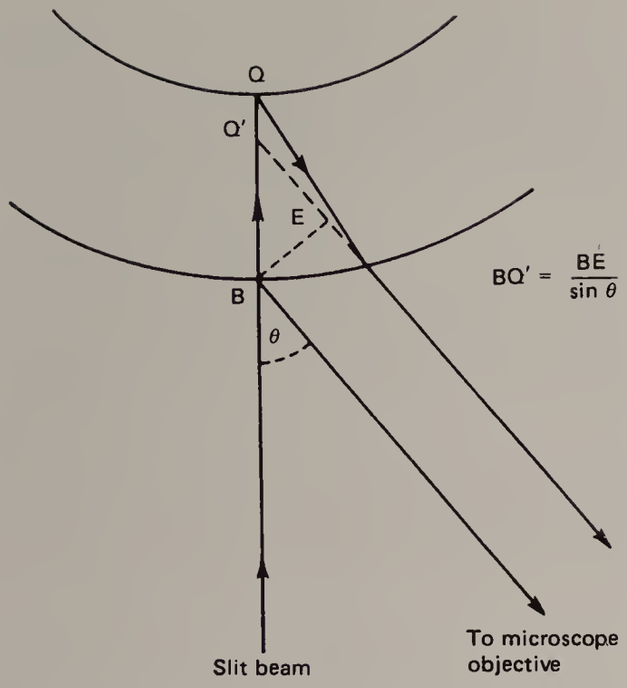


Figure 6.14 Optical principle of pachometry

Storey, 1988.) While there are potential errors in this method due to the need to use appropriate ultrasound velocity for the tissue being measured, Ling *et al.* (1986) found good correlation between ultrasonic and optical pachometry.

While pachometry continues to be a useful research tool for monitoring the physiological performance of lenses, it may have further clinical uses in the assessment of those who have undergone photorefractive surgery, with the concomitant changes in corneal thickness that accompany this procedure. It may also be used in the detection and monitoring of keratoconus.

Corneal sensitivity

Aesthesiometers have been used to assess corneal sensitivity and its variation with contact lens wear (Millodot, 1976, 1978). Comprising nylon filaments which can be brought into contact with the cornea with a known force, some slit lamps facilitate attachments of this type. This permits touch thresholds to be established, by using the microscope to assess when contact with the cornea is made, and the threshold level recorded when the subject indicates awareness of contact as the filament length is varied. Shorter filament lengths will apply greater force at contact.

This technique is not a common clinical tool in general practice.

Pre-corneal tear film analysis

When assessing the suitability of patients for contact lens wear, quality, quantity and stability of the pre-corneal tear film are of great significance (*see* Chapter 8, p. 269). One instrument that permits an enhanced assessment of this aspect of ocular physiology with the slit lamp, is the Tearscope (*see Figure 8.1a–c*). Described by Guillon (1984), this comprises a small hand-held, diffusing hemisphere internally lit by a cold cathode tube to prevent undue heat causing tear evaporation. It is held concave side towards the eye and the image which is reflected in the cornea is viewed with the slit lamp objective through a sight-hole in the middle of the sphere. A number of different patterns can be seen in the tear film which can be related to different thicknesses of the tear film components, in particular the lipid layer (*see* Chapter 8, Precorneal film). From this the suitability for contact lens wear can be predicted. In addition there is a facility to measure the non-invasive tear break-up time with a built-in stopwatch and the instrument can also be used to assess pre-lens tear film quality and break-up time if used while a contact lens is being worn.

Summary

Current instrumentation permits the contact lens practitioner to assess corneal structure and function in ways that will assist in maximizing success for contact lens patients. Careful recording of results and the use of appropriate grading scales will ensure that meaningful comparisons can be made between visits.

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Chapter 7

External eye photography

David Campbell-Burns

The camera p. 248
The lens p. 248
The film p. 250
Illumination p. 251
Ultraviolet photography p. 253
Slit lamp photography p. 254
Exposure p. 256
Fundus cameras p. 256
Photokeratoscopy p. 256
Photography of the corneal endothelium p. 256

It is not intended, in a book of this nature, to attempt to cover the whole field of ocular photography, let alone the realm of medical photography. Neither is it felt necessary, in a publication intended for such a specialized readership, to include the usual glossary of optical definitions and terms. The purpose of this chapter is to provide those basic data which will enable practitioners to employ routine photography in their contact lens work. The bibliography gives references for further study. The aim must be a speedy and accurate recording of features of clinical interest, such results to be obtained with the minimum of disturbance to the practitioner's routine and the least possible inconvenience and discomfort to the patient. Apart from more specialized work with photo slit lamps, the hand-held camera is the preferred system as stands, head rests, bellows and other such items can impede the swift and convenient use of the camera. The copy stand, bellows and transillumination stage have their place in the high-magnification photography of, for example, lens defects, but all of the clinical work described here can be undertaken with the camera and hand-held flash gun.

Many practitioners feel that their most valuable photographic record is that of the external eye, life-size, taken before fitting is commenced (*Figure 7.1*). Features such as lid position and conjunctival vascularization can be clearly recorded for future reference. The colour photographs in this book are a splendid example of the usefulness of external eye photography for record purposes.



Figure 7.1 The external eye photographed at 1:1 magnification on the negative and utilizing the technique shown in *Figure 7.4*. The photographs in *Figures 7.7* and *7.8* were also taken in the same way

The camera

By far the most suitable type of camera is the single lens reflex, normally referred to as an SLR (*Figure 7.2*). The particular advantage of this type is the complete absence of parallax, so important in close-up work. All modern SLRs have automatic diaphragm control which permits framing and focusing to be done with the lens at full aperture. The diaphragm is then automatically stopped down to the chosen aperture just before the shutter releases. It is rare to find an SLR camera where the lens is not interchangeable. This facility permits the use of macro lenses, extension tubes, bellows and lenses of different focal lengths, all important in close-up photography. Examples of such accessories are shown in *Figure 7.3*. The focusing screen fitted as standard equipment to most cameras has a circular central micro-prism surrounded by ground glass and/or a Fresnel lens to improve edge brightness. Although this arrangement is excellent for general photography, it is generally accepted that a plain ground glass or fine Fresnel screen is better when using macro and long-focus lenses. Some higher quality cameras, such as Nikon, Leica, Minolta and Contax, feature interchangeable screens allowing a flexible approach. Another important, though rarely considered, factor is that the photographer should find the camera comfortable to hold (*Figure 7.4*). This does not necessarily mean the smallest and lightest, as someone with large hands may find small cameras difficult to operate. Zeiss, for example, retained the design consultancy at Porsche to develop the body and control layout of the Contax for near-perfect ergonomic efficiency with an 'average' user. The practitioner should try holding and using the complete equipment, i.e. the camera fitted with the flash gun and close-up equipment of choice, with one hand, as the other will be required for steadying against the patient's brow or manipulating the lids.

Virtually all current camera systems are capable of meeting all or most of the above requirements; the smallest and lightest are probably the Pentax and Olympus, the largest and heaviest the Leica and Nikon. The most widely used systems are Nikon, Canon and Minolta.

It is necessary to warn against the ordering of eyepiece correction lenses by direct reference to the user's spectacle prescription; most cameras do not have the viewing screen image at infinity, but have a built-in 'refractive error' of their own. The best way to ensure accurate correction is to interpose trial lenses between the eye and the viewfinder until the best result is found. (A few cameras have eyepiece corrections built-in.)

A new method of 'data capture' is the use of digital technology. Cameras such as the Kodak Professional DCS Series (developed in conjunction with Canon and Nikon), provide variable resolution digital images which can be stored internally then downloaded directly to a computer. Advantages include the ability to incorporate the images into DTP (data-transfer programs) using industry standard file formats, and the production of unlimited perfect copies using printers such as the Kodak Digital Image Processor with no immediate or long-term loss of quality. Unfortunately the cost of this technology is currently very high and powerful computer systems (typically with 64MB of system memory and large capacity hard disks) are needed for the image manipulation. The Canon ION and LogiTech Foto-Man cameras have some of this capability at lower performance levels.

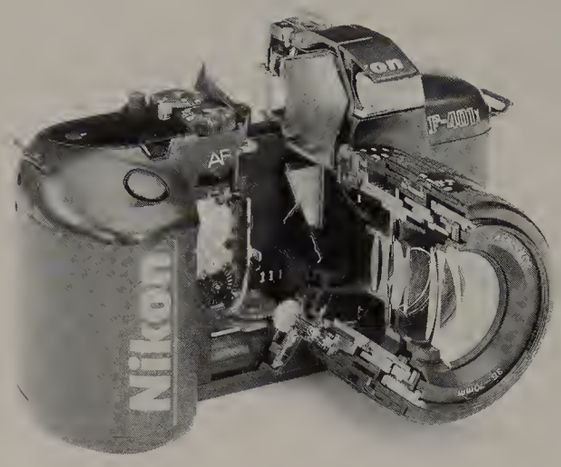


Figure 7.2 Section through a single lens reflex camera. The 45° mirror, allowing through-the-lens viewing, can be seen. This springs out of the way when the shutter is released. (Reproduced by kind permission of Yashica)

The lens

SLR cameras used to be fitted with a so-called 'standard' lens of 50 mm focal length and f2 aperture but, with the advent of lightweight, zoom lenses of much improved quality, a variable focal length lens of 35–70 mm and f3.5 aperture has become the norm. Despite the enormous popularity of these lenses, they do not deliver the quality required for critical macro applications. Although some have a macro facility, the image quality at this setting is unlikely to be up to the required standard and a specially designed macro lens should be employed.

Perhaps the best known is the Micro-Nikkor series from Nikon although most manufacturers have suitable models in their range. These lenses may have a slightly longer focal length than normal (for example 55 mm), and are computed to give best results at much closer range than standard lenses. They allow a slightly longer working distance thereby lessening illumination problems and may also be used quite satisfactorily for general photography. The Micro-Nikkor 55 mm lens, for example, focuses from infinity down to 1:2 (half life-size) without interruption and, with the addition of an automatic extension tube, right down to 1:1. The latest 60 mm f2.8 auto-focus version of this

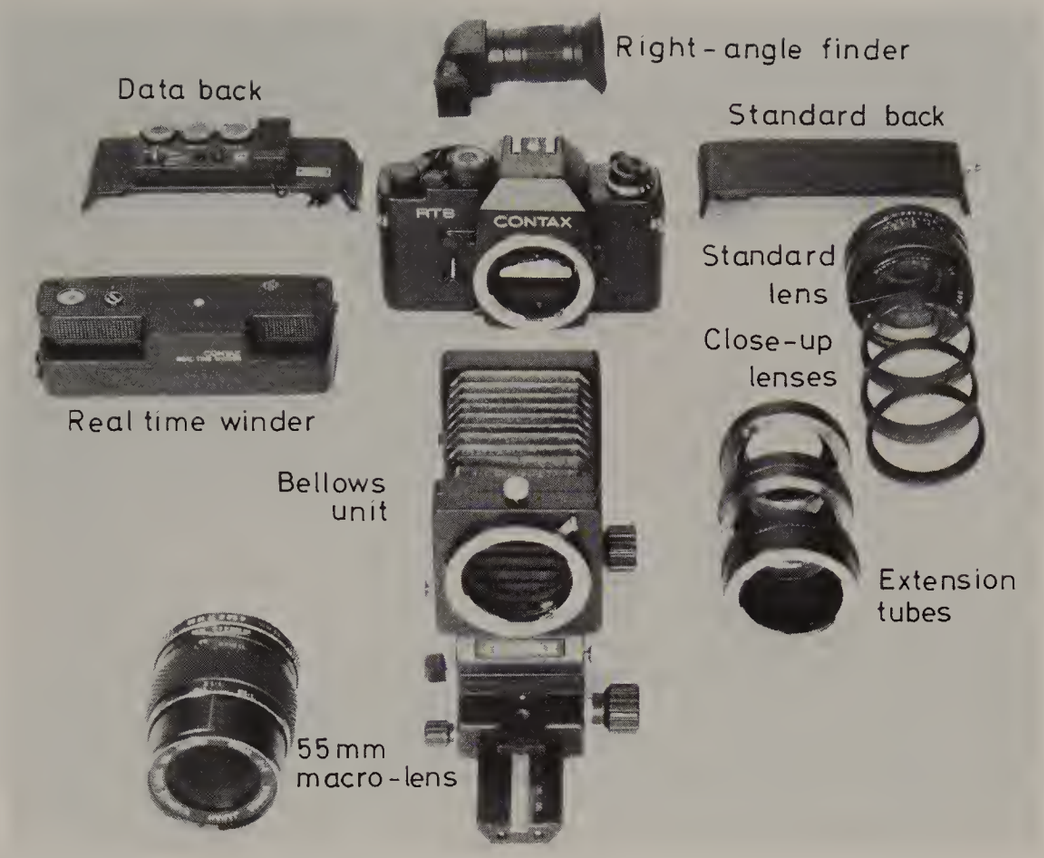


Figure 7.3 Accessories for macro-photography using the Contax system

superb optic (*see Figure 7.4*) can focus directly from infinity to life-size without the need for additional extension tubes. It may be found preferable to use a lens of 'normal' focal length for ocular photography because the working distance enables the photographer to steady himself against the patient's brow with the fingertips of the left hand (if normally right-handed) while the thumb is rested on the lens mount (*Figure 7.4*). Although macro lenses are available in longer focal lengths (e.g. 100 mm), the longer working distance may make this technique more difficult. There is no advantage in using either longer or shorter focal length lenses, insofar as depth of field is concerned, as this is a function of magnification and aperture, and independent of focal length. Autofocus lenses will rarely select the required zone for sharpest focus and this feature should be switched off, the lens set manually to the required magnification and the working distance adjusted to suit.

Nikon manufactures a special purpose lens for clinical photography called the Medical-Nikkor with a 120 mm focal length and f4 aperture. A built-in ring light flash gives shadow-free illumination with automatic control of exposure and the reproduction ratio can be imprinted on the film.



Figure 7.4 Single lens reflex system in use, showing one hand steadying the camera against the patient's face and the other hand holding the camera with forefinger ready to operate the shutter release

Close-up (supplementary) lenses

Although normally available in powers of +1.00 to +4.00 D, for closer work adequate results have been obtained with lenses of up to +12.00 D. These lenses should, of course, be anti-reflection coated. Maximizing depth of field will require the use of very small apertures which will, in turn, control the aberrations resulting from the use of such powerful supplementary lenses making this a viable alternative to true macro lenses where cost is the major consideration.

Table 7.1 Increase in magnification with extension: Macro-Takumar 50 mm f_4 lens with distance scale at 0.234 m

Magnification	*Tubes used*	*Area to be photographed (mm)*	*Film-to-subject distance (mm)*	*Exposure factor*[a]
0.50	Not used	48 × 72	234	× 2.3
0.73	1 (12 mm)	33 × 49	213	× 3.2
0.86	2 (19 mm)	28 × 42	209	× 3.7
1.00	3 (26 mm)	24 × 36	208	× 4.3

[a]Exposure factor – increase exposure by this amount.

Extension tubes

Extension tubes are fitted between the lens and the camera body. As they contain no optical elements they do not directly affect the optical performance of the lens, except that the lens may be operating in a magnification range for which it was not designed. Tubes are normally sold in sets of three and may be used either singly or in combination to give the required magnification (*Table 7.1*).

Bellows

Bellows are, in effect, continuously variable extension tubes but are less convenient to hand-hold and are best used on a tripod or copy-stand. More expensive versions retain fully automatic diaphragm control.

The film

The choice of films can be considered in two ways. (1) Are slides or prints required? (2) Should the film be fast or slow? Colour film is assumed to be a necessity. If more than one camera body is available it is simple enough to have different films in each but, for most of us, this would be impossibly expensive. The fundamental dilemma is that fluorescein/UV work would ideally employ a faster film than that which gives best results for general external eye photography (*see below*).

This dilemma is entirely overcome with the new APS (Advanced Photo System) developed by Kodak and Fuji and supported by all major manufacturers. This system employs a new, smaller film cassette and offers a choice of print and slide formats. Top of the range models, such as the Vectis S1 from Minolta, are fully specified SLR cameras with interchangeable lenses, sophisticated metering systems and the added advantage of mid-roll film changing. Different types and speeds of film can, therefore, be used in the same camera body according to the requirements of the subject matter. The cameras will be smaller and lighter than existing 35 mm models.

Another advantage is the ability to display results on a TV or computer monitor by means of a special scanning unit. It is thus possible to archive photographic data without the need for transfer to Photo CD.

Another innovation with enormous implications for the storage and recall of large numbers of images is the Photo CD technology jointly developed by Kodak in the USA and Phillips in Holland. Negative or transparency originals are transferred to a special CD disc and 'played back' via a one or five-disc machine (which also plays audio CDs), on a standard colour television set. Each disc stores up to 100 images which may also be accessed, and modified, by a computer using a CD-ROM drive. Patient records on a practice computer system can now simultaneously access both clinical and photographic data. The Photo CD system is 'multi-session', meaning that any number of frames, up to the 100 image capacity of a single disc, can be added at any one time. While sharpness is marginally less than that of a projected slide, it is better than that of a standard television image and much more convenient to store, recall and display. Any number of hard copies can be made, for example to accompany referral letters, with the distinct advantage that there will be little or no degradation of the image with the passage of time. Standard CD storage systems can be used to archive the discs.

Prints

Although prints may be more convenient, slides (transparencies) are cheaper and yield much better contrast range and detail. If, however, prints are preferred, suitable negative films are Kodacolor Gold, Agfacolor or Fujicolor Super G (ASA 100–200). There may well be more marked variations between the standard of processing of one laboratory compared with another, than between the performances of different films, although Kodak has introduced Ektar colour negative films and a special processing service to give the highest possible standards short of individual professional attention. The availability of high speed (400–800 ASA) negative films such as Fuji fine grain SG800 has made high quality UV prints a possibility. Even faster films, up to and beyond 1000 ASA are made but the grain penalty makes them unacceptable for critical work. Processing variations make the use of prints for the colour matching of cosmetic (prosthetic) lenses rather unreliable and, for best results, one should keep to the same brand of transparency film, standardize illumination and experiment with colour temperature filtration until a satisfactory result is achieved. For critical applications, such as research projects requiring absolute standardization, it will be necessary to re-assess each production batch of film stock.

Instant films

A number of new introductions from Polaroid have dramatically improved the range of options in this inter-



Figure 7.5 Acmel Macro clinical camera



Figure 7.6 Photography using Acmel system with ring flash showing centrally

esting technology. We have, for many years, had instant film attachments for microscopes, slit lamps and medium format cameras together with a limited range of 35 mm films but the advantage of immediate access to the results had to be set against a significantly higher cost and lower definition.

The Lester Dine camera from the USA has been available in Europe for some time but, although usable for external eye photography, is primarily intended for dental work.

Early in 1994 Polaroid introduced a close-up attachment for the Image camera which gives a half-life-size photograph on normal Polaroid colour film without the need for viewfinder focusing. The camera employs a non-contact method of focusing whereby two light beams are projected onto the subject, when they coincide the image is in focus and the exposure made. A special grid film is available for identifying and locating features of interest. Advantages are relatively low cost, simplicity and good image quality but the low magnification limits its usefulness to the contact lens practitioner.

Much more versatile (and much more expensive) is the Polaroid Acmel Macro clinical camera system (*Figure 7.5*). Magnification is varied from 0.25X to 3X by fitting various attachments to the front of the instrument and focusing is on the same coincidence principle as the Image accessory; in fact this camera does not normally have a viewfinder fitted. Results are the best of the instant systems (*Figure 7.6*), but still not as good as quality prints from 35 mm negatives.

The Polaroid Macro 5 SLR camera has all the Acmel features but the various lens systems are built-in and an appropriate magnification selected by means of a dial. Focusing is with a reflex viewing system or 'ranging' lights as described above. An ultraviolet photographic attachment is available with the camera.

Another instrument in the Polaroid range is the MicroSLR Microscope Camera, an attachment for microscopes or, indeed any eyepiece instrument, which gives 'instant image' capability with the minimum of physical alteration to the host equipment. Exposure control is automatic with manual override to allow for subject variation. The MicroSLR produces 3×4″ B&W or colour prints on 331/339 film. Results on a slit lamp have been found to be disappointing, however, due to a too high magnification range and extended exposure times.

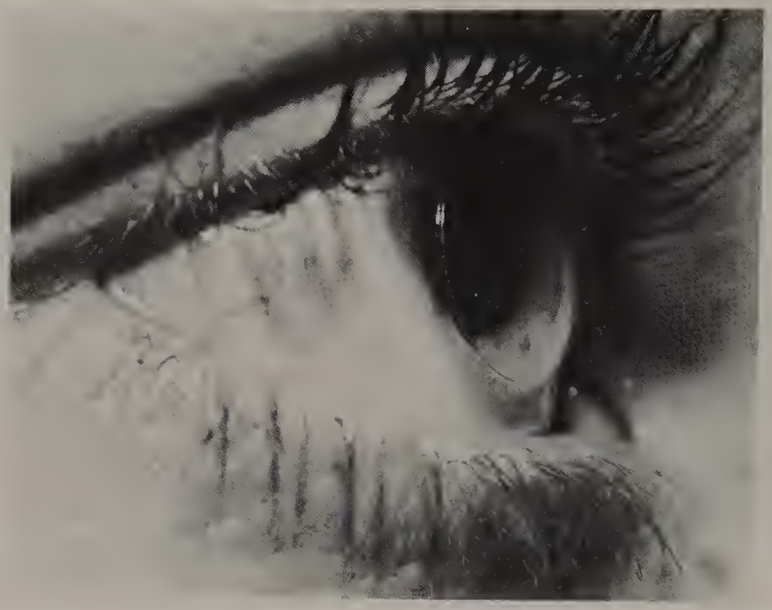
Transparencies

For general clinical photography, Kodachrome 25 is widely considered to give the best combination of sharpness, colour quality and processing reliability. Fujichrome, Ektachrome Elite, Agfacolor CT100, Fuji Sensia 200 and Kodachrome 64 can also be recommended. Where extra film speed is called for, Ektachrome 200 is a most versatile material as it can, by varying its development times, be rated at speeds from its normal ASA 200 up to ASA 800 or 1600. Naturally, quality suffers when the film is 'pushed' to this degree, but very acceptable results are obtained by rating it one stop faster, i.e. up to ASA 800.

Fuji offers a service which provides for slides and prints from one film. Any Fujichrome, or E6 compatible, slide film can be processed and returned together with 6 × 4 inch (15 × 10 cm) prints of excellent quality. This service is of great benefit to the lecturer who may wish to put the print in the patient's record and keep the slides for lectures. (Some of the materials or services discussed above may not be available in every country.)

Illumination

The modern compact electronic flash gun combines all the requirements for a light source in clinical photography. It is light in weight, powerful, has balanced, consistent light



(a)



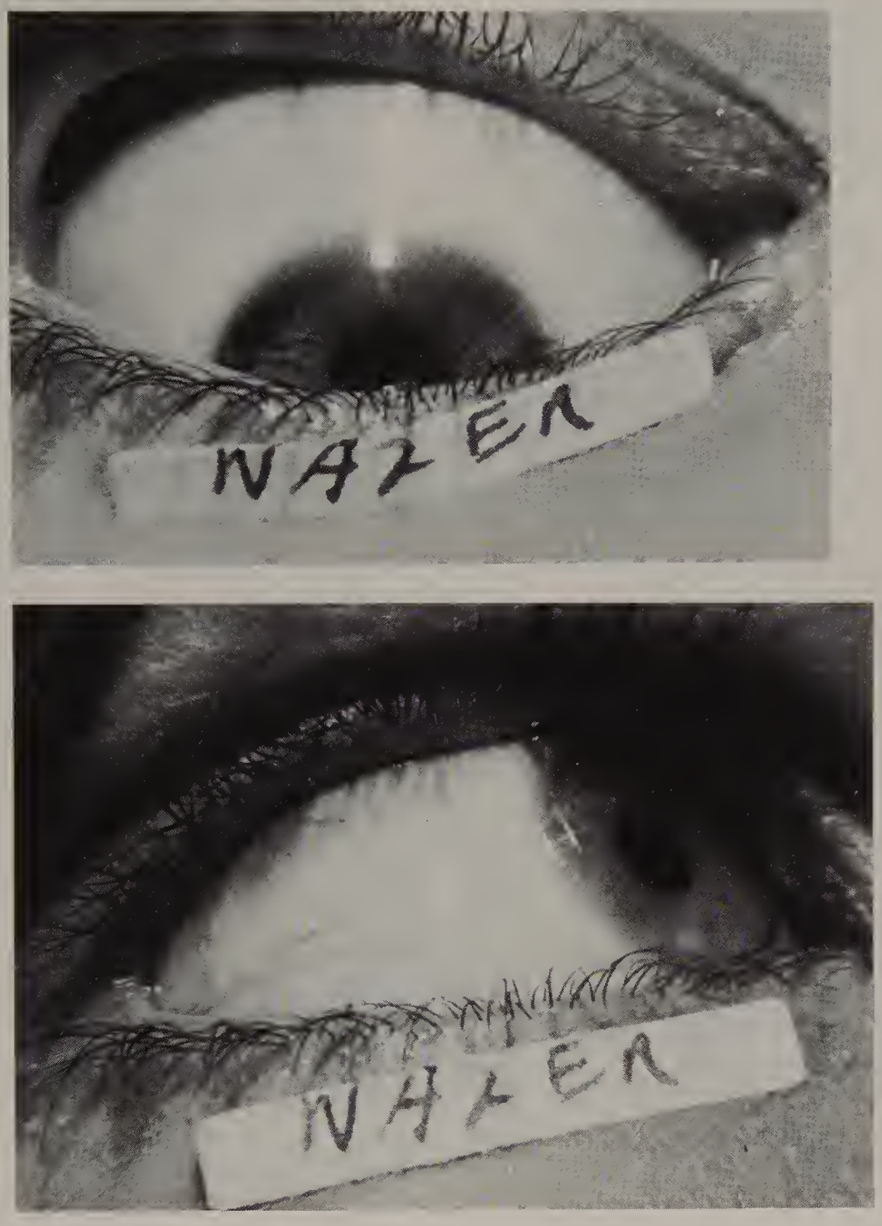
(b)

Figure 7.7 Photographs showing the position taken up by a corneal lens: (*a*) from the side; (*b*) from in front. Notable also is the lower lid position and in (*b*) the shadow cast on the iris by the edge of the lens

output and is cheap to buy and run. The flash duration is very short, typically less than 1/10000th of a second, eliminating any danger of subject movement. The flash gun should, ideally, have a light source with a small aperture as this will produce a correspondingly small reflex when photographing highly reflective subjects such as the cornea. (One suitable gun is the Braun CT15). The Medical Nikkor is a complete lens/flash unit with variable magnification ranges while Minolta and Nikon offer special flash units for clinical work which are fitted to the front of the macro-lens. These provide completely automatic exposure together with control of the illumination via four tiny flash tubes plus focusing lights which extinguish before exposure.

Technique

The flash gun is best fitted to a tilting 'hot-shoe' flash adaptor and both mounted on the camera accessory shoe. It must be remembered that some adaptors may render the 'hot shoe' (direct contact) feature inoperative, so that the flash unit must be connected to the camera's x-synchronization contact (if present). The flash gun is then tilted downwards in order to point directly at the subject; if this angle is carefully adjusted it is possible to produce evenly illuminated photographs as close as life-size (i.e.1:1; *see Figures 7.1, 7.7, 7.8*). Although in theory the ring flash seems more suitable, in practice it produces a most inconvenient reflex right in the centre of the photograph which may obscure



(a)

(b)

Figure 7.8 Photographs showing the positioning of a soft lens on the eye: (*a*) with gaze depressed and upper lid raised; (*b*) looking nasally

areas of clinical interest (*see Figure 7.6*). The light output of the smallest flash units has been found to be quite adequate even with slow films such as Kodachrome 25, producing excellent results at apertures as small as f16. Larger flash guns, useful in ultraviolet photography, are of no help in normal colour work as they are too powerful. Many camera lenses cannot cope with the extra illumination as they do not stop down further than f16, although the majority of specialized macro lenses will stop down to f32.

Most SLR cameras must be set to a speed of around 1/125th of a second or slower as their focal plane shutters will otherwise produce partially exposed frames. For best results the camera handbook should be consulted. It is of no advantage to set the shutter speed at a value slower than that required for flash photography, because the result may well show blurring due to the effect of the ambient illumination, even though the flash duration is so short. The lighting used for focusing must be very carefully controlled; if it is too dim it is impossible to see properly to focus and, if too bright, particularly with ultraviolet work, the colour rendering is affected.

Ultraviolet photography

The recording of corneal staining or of the fit of a rigid contact lens requires some adaptation to the above technique (*see* Chapter 10 for examples). It is most convenient

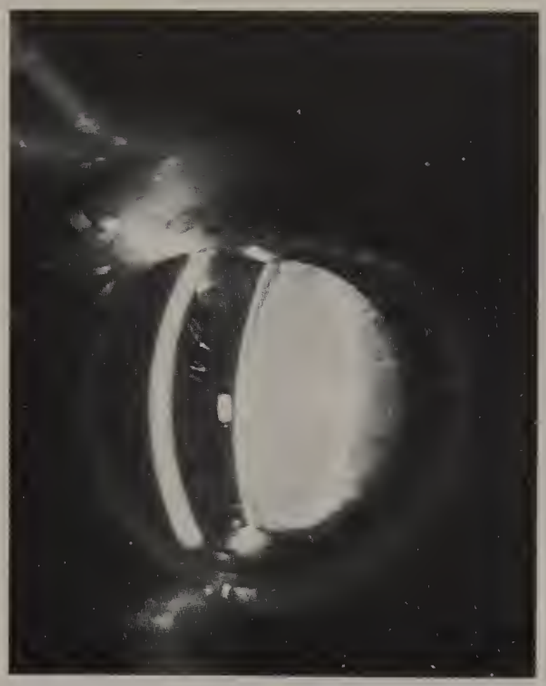


Figure 7.9 Section of cornea and crystalline lens taken with a Zeiss (Oberkochen) photo slit lamp

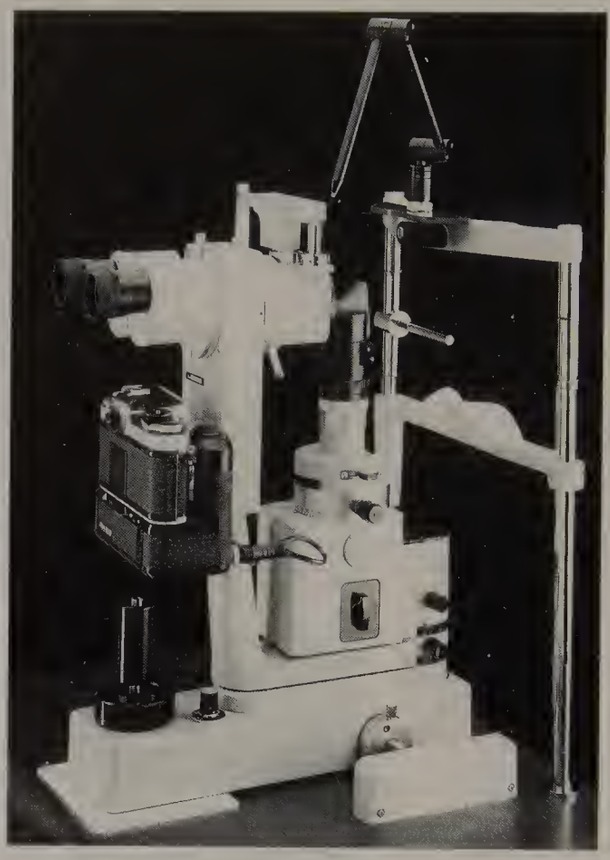


Figure 7.10 The Nikon Zoom–Photo Slit Lamp Microscope FS–2. (Reproduced by kind permission of Nikon)

if a second camera body is available, permanently loaded with a faster film for example, Ektachrome 200 or 400, or Kodacolor 400 (*see* The film *above*). With only one camera body it is inevitable that it is loaded with the wrong film when required! A small electronic flash gun, fitted with a blue Kodak Wratten 47B Gelatine emitter filter, should be mounted, as before, on a tilting flash shoe and angled downward. In order to enhance the blue/yellow–green contrast of the photograph a pale yellow (×2) discriminator filter must be fitted over the camera lens.

Slit lamp photography

If photographs of the external eye are all that is required, the results obtained with a conventional camera system are superior (and very much cheaper) to those obtained with a photo slit lamp. When slit section photographs are called for, such as that in *Figure 7.9*, there is no substitute for a specially designed photo slit lamp such as those from Zeiss or Nikon (*Figure 7.10*).

The introduction by Zeiss (Oberkochen), in the mid-1960s, of a photo slit lamp with an integrated electronic flash system, marked a turning point in ophthalmic photodocumentation. Together with the availability of much improved colour emulsions, this instrument made possible the production of very high quality records with a minimum of operator skill. The main practical advantage was the ease with which the clinician could instantly record features of interest. Later developments include stereoscopic attachments, cine and TV/video recording and now, digital imaging. Two systems were eventually offered by Zeiss: one used a camera body mounted above, and photographing between, the microscope objectives of the slit lamp and another employed a beam-splitter between the body of the instrument and the eyepieces. The latter system achieved a true 'WYSIWYG' (what you see is what you get) result. The electronic flash discharge tube was neatly integrated into the lamp-housing and fired by a button on the joystick.

Later developments have included fibre-optic fill-in illumination (Gambs and Nikon), motorized film transport, simultaneous 'third-party' viewing, camera data backs and zoom lenses (Nikon). All illumination and viewing techniques employed in routine slit lamp examination may be used in biophotomicroscopy. Desirable features to look for when choosing an instrument include ease of use, one-handed operation, simplicity of exposure adjustment and the provision of fill-in illumination for external eye photography.

Suitable instruments are available from Nikon, Zeiss, Topcon and Takagi.

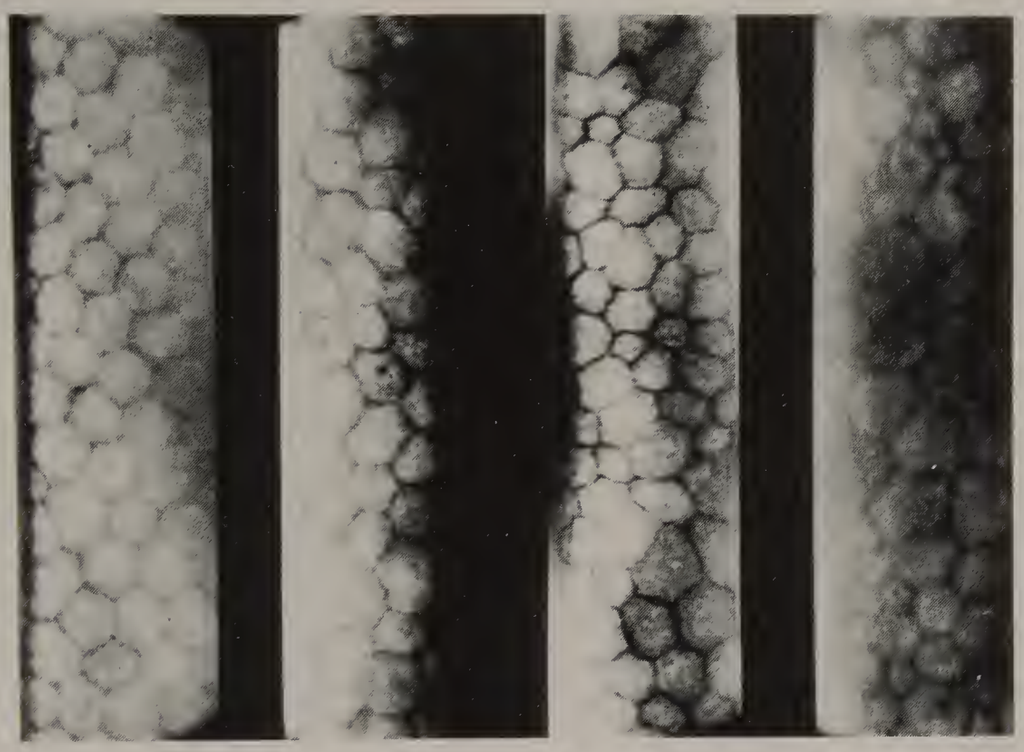


Figure 7.11 Corneal endothelium photographed by the Holden–Zantos technique showing normal central corneal endothelium (grade 0) on the left and various grades of endothelial polymegathism (variations in cell size) – grades 2, 3 and 4 – as indicated by the coefficient of variation given below each grade. (Reproduced by kind permission of Bausch & Lomb) (*See also* Appendix D: Grading scales)

Slit lamp photography is now regularly used in digital imaging systems (or data capture mentioned earlier). The slit lamp usually needs a beam splitter to direct light into the camera, although in some instruments a small camera is used within one of the eyepieces. This does, however, restrict the observer's view monocularly.

The picture from the slit lamp is fed via a video camera into a capture card within the computer, where image manipulation (brightening, darkening, enhancing etc.) can take place. These images can then be stored in various different ways. One way is to incorporate the image into the patient's record card (in a similar way to that done by computer videokeratoscopes, *see Figure 10.16*). One such system is the Topcon IMAGEnet system with fundus camera.

Exposure

Although it is theoretically possible to calculate the correct exposure from the flash factor and the film speed, in practice the result is usually unreliable due to the very short distances involved. A much simpler method is to make an 'exposure gradient' test. The chosen film/flash gun/magnification combination is used to produce a series of test exposures from maximum to minimum apertures of the lens used. When the slides (or prints) are returned from processing they should be viewed by whichever method will subsequently be employed, i.e. projection, viewer or light box for slides, and the exposure of the best slide (or print) chosen. It is sometimes possible to refine this result still further by selecting an intermediate aperture, although not all lenses have 'click' settings at half-stop intervals. This information should then be recorded on a label stuck to the camera or flash gun (for example, K25/1:1/f16). This will, of course, have to be repeated for different film/filter combinations, although it has been found that moderate changes in magnification, for example, between 3:1 and 1:1.5, make little difference. The reason for this is that the inverse square law relating to the increase in illumination versus the extra exposure required with greater extension, cancel each other out. Typical exposure data are given in *Table 7.2*.

Table 7.2 Typical exposure data

	Film		
	K25[a]	*E200*[b]	*E400*[c]
Magnification	1:1	1:2	1:2
Lens (mm)	50	50	50
Filter (camera)	None	2 × yellow	2 × yellow
Filter (flash)	None	47B	47B
Flashgun	–	Vivitar 121	–
Aperture	*f*16	*f*2.8	*f*5.6

[a]K25 is Kodachrome 25, i.e. film speed ASA 25.
[b]E200 is Ektachrome 200, i.e. film speed ASA 200.
[c]E400 is Ektachrome 400, i.e. film speed ASA 400.
All three films are made by Kodak.

Fundus cameras

Besides the equipment already described, fundus cameras, such as those from Zeiss and Canon, may also be used for external eye photography, yielding high quality transparencies or Polaroid prints. Magnification can be varied from about twice life-size (2:1) down to one-third life-size (1:3).

Photokeratoscopy

This is a technique for photographing the regularity of the corneal front surface or the front surface of a soft contact lens by means of Placido disk type rings. Systems such as the EyeSys and TMS make use of computers to process and analyse the images (see Chapter 6). Examples can be seen in *Figures 10.23, 10.24, 11.6, 11.9* and *11.14* and *Figure 15.14*. The technique is also used for measuring the corneal contour and corneal lenses can then be designed by computer from this information (see Chapters 5, 6 and 10).

Photography of the corneal endothelium

Holden *et al.* (1978) described a technique for endothelial and high magnification slit lamp photography where a 35 mm camera, preferably motorized, is mounted behind one of the eyepieces of a slit lamp by means of a special support. The endothelial zone is viewed through the viewfinder and the photograph (*Figure 7.11 and see Figure 15.12*) taken by means of a cable release to avoid camera shake.

An entirely different approach is employed by Pocklington in the Keeler Widefield Specular Microscope. This specially designed instrument uses a contact cone together with a motorized focusing system to cover an area of 1 mm^2 and produces an image which fills the 35 mm format (36 × 24 mm). The floating cone movement of 5 mm employs a known degree of applanation with an independent, internal mechanism adjusting the focus. In addition to the standard 35 mm camera body, a Polaroid back or video camera can be used. A normal photographic magnification would be ×30 (viewed at ×120), with variation between ×22 and ×50 being provided for.

The Konan Robo non-contact specular microscope introduces a high level of automation to photography of the corneal endothelium enabling even inexperienced operators to obtain good results. Features include a wide field of view, built-in software for analysis of cell density and the ability to photograph paracentral areas. Konan also offer the SP5500 Specular Microscope for more demanding research purposes.

Chapter 23 (p. 818) gives details of the Eisner Contact Glass used with the Haag–Streit photo slit lamp for corneal endothelial photography.

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Chapter 8

Assessment of patient suitability for contact lenses

Janet Stone

Indications and contraindications for contact lens wearing p. 258
Psychological influences p. 258
Pathological, anatomical and physiological factors p. 261
Personal and external factors p. 274

Since the early editions of this book were published contact lenses have become a popular form of visual correction and their fitting in private practice has become largely soft lens orientated. However, there has been a renewal of interest in corneal lens fitting with the advent of more and more rigid gas permeable (RGP) materials of increasing oxygen permeability and better wetting characteristics – many now permitting extended wear. Scleral lens fitting is time-consuming and therefore costly, compared to soft and corneal lenses, and they are now rarely considered as a practical option by most contact lens practitioners. Scleral lens fitting is now almost entirely confined to hospital departments where these lenses are used for eyes with pathological or abnormal conditions unsuited to soft or corneal lenses, although gas permeable materials have improved their success rate (*see* Chapters 17 and 20). Additional special uses of scleral lenses are covered in Chapter 23. The hybrid lens available with rigid gas permeable optic zone and hydrophilic soft periphery (the Softperm lens made by Wesley-Jessen) as well as the flexible gas-permeable lenses (*see* Chapter 10) has reduced the need for scleral lenses for certain abnormal conditions.

The advent of disposable and frequent replacement soft lenses of various water contents and tints, including toric soft lenses, has also extended the scope of contact lenses to cater for different patient requirements. The daily disposable lens has extended the range yet further.

The increasing price and complexity of spectacle lenses has led to a reduction in the cost differential between the two modes of visual correction, so that many more people now consider contact lenses as their main form of optical correction. Also, contact lenses are often requested for specific limited use and need to be interchangeable with spectacles, so that the contact lens practitioner not only has to assess patient suitability for contact lenses in general, but also the best form of lens and material to satisfy these more sophisticated requirements. This has led to a broadening in the factors to consider when assessing patients for contact lens fitting. Limitations still exist in the types of lenses available as well as in the suitability of the prospective wearers. Careful selection benefits both the patient and the practitioner by avoiding time wasted in attempting to fit unsuitable patients or in fitting patients with unsuitable lenses.

As far as ocular contour is concerned, it is now possible to fit any eye with a contact lens – but successful wearing depends on patient motivation and absence of contra-indications. Patient selection depends on recognition of these factors by the practitioner.

Certain pathological and abnormal conditions of the eye and adnexa are a definite *indication* for contact lenses for example, keratoconus.

Indications and contraindications for contact lens wearing

These may be considered broadly under three headings: psychological influences, pathological, anatomical and physiological factors, and personal and external factors. Some overlap between the three is inevitable.

Such factors are also useful to consider during after-care or continuing care of contact lens wearers (*see* Chapter 18). Because some of the predictive tests, such as tears break-up time, are still being refined and studied their results should be taken into account during assessment for contact lens wear but it would be unwise to reject a patient on the grounds of failure of one such test alone.

Psychological influences

A small study in 1987 by Nelson and West indicated that extroverted, well-adjusted, stable people were more likely to successfully adapt to contact lenses than anxious,

introverted people. Practitioners need to keep this in mind when pointing out the following factors to their patients who should be made aware of the essential differences between the fitting and wearing of spectacles and of contact lenses. This is necessary to avoid subsequent disillusionment on the part of the patient. From the legal standpoint, it is as well to issue the patient with a printed booklet in which certain general facts about contact lenses are emphasized. This is also helpful because many patients are not fully attentive at the initial interview and may forget what is said by the practitioner, who may omit to mention or emphasize certain points.

In the United Kingdom this aspect has been considered so important that the Department of Health – a government body – has produced a leaflet (CL1) which it is suggested practitioners ask their new patients to sign. They are asked to sign to confirm that they:

(a) have been given a full explanation of the different types of contact lenses appropriate for them and the benefits and risks of each type of lens;
(b) are aware that contact lens wear carries the risk of eye infection and its associated complications;
(c) understand the instructions for cleaning and looking after their lenses which have been demonstrated to them, and that they know that careful adherence to these instructions will reduce the risk of infection;
(d) have been instructed on a wearing schedule for their lenses;
(e) understand what to do if they have problems with their contact lenses, both during and outside normal office hours;
(f) have had the importance of continuing care and regular check-ups explained to them.

The Department of Health suggests that the patient retains one copy of this 'Patient Acknowledgement Form' and another copy is kept with their contact lens record notes.

Prior to embarking on the actual fitting of contact lenses, the practitioner should draw the patient's attention to the following special aspects of contact lens fitting and wear, so that the patient has the opportunity to reject them before being placed under any obligation.

Time taken for fitting

Since this varies from patient to patient, and depends on the skill of the practitioner and the type of lens to be fitted, it is up to each practitioner to say how long the entire fitting is likely to take. Including tuition of lens handling some 2–3 hours may be needed with the practitioner and/or optometric assistant. Numerous visits to the practitioner may be necessary and, if the fitting proves complicated, a longer time may be involved.

Tolerance trials add to the time spent by both patient and practitioner. Some practitioners like to arrange for a 2-week trial of contact lenses. Four hours is about the desirable minimum length for a tolerance trial. If fitting extended or continuous wear lenses, it is advisable to arrange a 24-hour tolerance trial commencing early in the day, and to see the patient again at the end of the day, as well as the following morning after the lenses have been worn all night. All this may add another hour of 'chair' time to the fitting, and if more than one tolerance trial is necessary the time spent with the patient during fitting may be extended and the patient involved for much longer. Tolerance trials are discussed further in Chapter 9 and in those chapters devoted to lens fitting.

Fitting children with contact lenses can be very time-consuming and parents should be advised of this. The special considerations for paediatric fitting are dealt with in Chapter 20.5. It is especially important with children that they be dealt with in an unhurried but reassuringly firm fashion. If under the age of 12 years, ideally the child should be fitted in the presence of one of the parents, both to give the child reassurance and to demonstrate lens handling to the parent who may subsequently be required to insert and remove the lenses, particularly if the child is under the age of 7 years. At the first visit, besides the preliminary examination and measurements, it may be enough just to insert one lens and leave proper fitting for a further visit. Several hours practice are often needed for a child to perfect insertion and removal techniques, a few short visits being better than one long one, although children who are well-motivated and those whose parents wear contact lenses may accomplish insertion and removal very quickly, and can be less troublesome and time-consuming than adults.

Patients should also be made aware of the need for continuing clinical care involving time spent at regular after-care check-ups.

Initial discomfort – physical and visual

Patients used to wearing spectacles are sometimes totally unprepared for the initial difficulties with contact lenses and should be warned of the likelihood of corneal and lid sensation, photophobia, flare, after-wear blur with spectacles, and so on, as appropriate. These difficulties are much less noticeable with soft lenses but may still occur as may fluctuations of vision during wear due to variations in hydration, deposits on the surfaces or deformation of the surface by lid pressure and rotation of lenses during blinking and eye movements.

Gradual wearing procedure

The advisability of building up wearing time slowly, particularly with corneal lenses, is well recognized. Patients must be made fully aware of this, otherwise they may think that changing to contact lenses is as simple as changing their spectacle prescription. Extended wear lenses do not usually require a build-up time, but these lenses are not fitted so often, and when they are prescribed, several appointments are necessary in the first few weeks of wear.

Special storage

Owing to the properties of the plastics material from which they are made, contact lenses must be handled and stored carefully. Because of their wetting and hydration properties and the danger of transferring harmful organisms on to the eye, they must be kept in sterile conditions and certain solutions must be employed during handling and storage. This aspect is of extreme importance (*see* Chapter 4), and patients must be informed early on which types of solution are suitable for their lenses and which ones may come into contact with the eye.

Only daily disposable lenses do not require the use of regular cleaning and soaking solutions. Even with these lenses, sterile saline and/or re-wetting drops may be necessary.

Extra hygiene

Many of the problems associated with contact lens wear result from failure to keep the lenses properly clean and/or disinfected, probably because these are time-consuming and costly procedures. Patients who start off by carrying out these procedures adequately do not always maintain them, whereas in fact the older the lenses become the more the surfaces deteriorate with natural wear and tear, and the more likely they are to become soiled. Thus, rigorous cleaning is important throughout the lens life. By contrast spectacle wearers may spend one minute or less each day cleaning their spectacles.

During handling of contact lenses the hands should be kept clean and free of grease and nicotine. Contamination of the lenses with face or eye make-up preparations must also be avoided, and special make-up creams may be necessary (Cordrey, 1972). Eye cosmetics are known to be a source of potentially serious infection (Bruch, 1973; Wilson *et al.*, 1973), and cases of conjunctival-embedded pigment from mascara and eye-liner causing long-term discomfort and excessive lacrimation have been reported by Stewart (1973), Davis *et al.* (1992) and Pesudovs and Phillips (1992). It is helpful to issue patients with a leaflet explaining the safest methods of using eye and other make-up with contact lenses, such as that issued and regularly updated (Pearson, 1994, personal communication) by the Department of Optometry and Visual Science, The City University, London, which was originally based on articles by McConnell (1967) and Gustafson (1967). Chapter 9 also deals with this aspect of eye and lens care (*see* p. 308).

Patients should also examine their lenses daily to avoid wearing badly scratched, cracked or chipped lenses. These aspects add to the 'nuisance value' of the lenses and patients who are not prepared to take the necessary time and trouble to keep their lenses clean should preferably not be fitted. This is particularly so with soft lenses, which are more easily contaminated than hard lenses, but rigid gas permeable (RGP) lenses also attract deposits and require meticulous cleaning (*see* Chapter 4). Cleaning and disinfecting regimes unfortunately add to the time and cost of lens maintenance.

Stringent after-care at regular intervals

Abrasions of the cornea are easily caused by contact lenses, usually due to foreign bodies beneath them, or adherent deposits, but occasionally due to trauma from the edge of a rigid lens during insertion or removal before these techniques have been mastered. Finger nails also sometimes damage the eye during these procedures. Usually the ensuing discomfort is minimal, but patients have been known to reject lens wear as a result.

As corneal sensitivity is lowered during (especially PMMA) contact lens wear (Boberg-Ans, 1955; Millodot, 1976), these symptoms may go unnoticed and patients should be warned in advance of the slight additional risk. Provided they understand the need for after-care and the possibility of minor emergencies arising, patients rarely forego contact lens wear for this reason. However, it is important that they realize that examination of the eyes and lenses at intervals of no greater than 1 year is advisable all the time that contact lenses are worn, so that the practitioner may detect any changes which may have taken place and advise them accordingly. This routine after-care check is, of necessity, longer and more detailed than that given to a normal spectacle wearer. Some patients require more frequent after-care checks because of recurrent symptoms or pathology. Also, if continuous or extended wear lenses are fitted, more frequent after-care checks should be made.

Need for and cost of insurance

Corneal lenses are easily lost, soft lenses less so, and scleral lenses hardly ever. All contact lenses are easily damaged but particularly ultrathin and high water content soft lenses. Loss or damage is most likely to occur during the initial wearing period before complete adaptation to the lenses takes place, and before facility of handling has been mastered. It is therefore essential for patients to insure lenses for their replacement value plus the estimated cost of the practitioner's fee at the time of replacement. The insurance premium may be as much as 20% of the original fee plus the cost of the lenses. This is the normal rate for soft lenses, although usually it is about 5–10% for rigid lenses. Disposable lenses do not need insurance. Some of the lens manufacturers run insurance or replacement schemes of their own, which can be helpful to both patient and practitioner, but practitioners should be aware of the legal implications of being involved in these schemes.

Lack of protection from foreign bodies

Spectacle wearers who transfer to contact lenses always, at first, miss the protection afforded by their spectacles and should be warned of initial troubles in windy and dusty atmospheres. *Figures 10.20* and *18.34* show the effect of foreign bodies on the cornea. Soft and scleral lenses provide more protection from foreign bodies than rigid corneal lenses – the degree of protection being related to the size of the lens, its edge clearance, and the glove fit of soft lenses.

Cost of lenses, examination fees and accessories

Conscientious practitioners usually include up to 1 year of after-care in the initial fitting fee, which must therefore be adequate to cover the practitioner for the time likely to be spent with the average patient during that time. It is only fair to warn patients of other costs they are likely to incur, such as the costs of solutions and accessories, and even travelling expenses. Also soft lenses may require cleaning by the practitioner from time to time (*see* Chapter 4) and rigid lenses similarly may need polishing. Many practitioners run after-care or service schemes for which appropriate annual charges are made.

Fear of lenses

Another barrier that has to be overcome is the patient's fear of having anything put on the eye. Patient handling is dealt with in Chapter 9, and it is sufficient here to say that a practitioner who inspires confidence is usually able to help a patient overcome this fear very quickly. Children (and the parents who accompany them) often require a very special approach.

Apart from these possible 'psychological' disadvantages, there are many definite indications for contact lenses which have a psychological background, as will be seen from the following.

Safety

Fear of damage to the eyes from possible broken spectacles in sports such as football, rugby and cricket is removed. There are many cases of contact lenses having afforded definite protection to the eyes, where otherwise a blow to the eye might have resulted in both external and internal ocular damage (Rengstorff and Black, 1974). However, special safety spectacles or goggles for sports use provide even greater protection and should be worn over contact lenses.

Security and clarity of vision

A feeling of safety is engendered by wearing contact lenses as opposed to spectacles when worn for certain sports such as horse riding, cycling (especially in the rain), shooting in rough country, skiing and bob-sleighing. The removal of the nuisance value of spectacles which steam up when playing, for example, badminton, tennis, squash and table tennis, is a distinct advantage; also, spectacles become coated with spray when sailing. Again, safety spectacles or goggles designed to avoid steaming up may be a viable alternative or addition to contact lenses.

Cosmetic reasons

Intense dislike of spectacles, particularly if very thick lenses are worn, has often meant that contact lenses bring about a marked cosmetic improvement. This can and does result in a beneficial personality change from introvert to extrovert. To some patients spectacles are an advertisement of a personal disability which is relieved by wearing contact lenses.

Restoration of normal appearance

Similar psychological benefits have been afforded to people (especially children) with disfigured eyes which are fitted with prosthetic lenses to give a normal appearance; for example, in albinism, aniridia, microphthalmos or an ugly eye due to injury or disease. *Figures 20.5.10* and *20.6.1* to *20.6.18* show such examples.

Children

Unfortunately, children who wear spectacles still occasionally suffer taunts from their classmates. If children are very keen to wear contact lenses they usually adapt very readily and thereby avoid such problems.

However, it is definitely not desirable to force children to wear contact lenses because of some whim on the part of the parents. To a child, the fitting of contact lenses (*see* Chapter 20.5) can be a traumatic experience and if it is carried out entirely against the will of the child it can lead to considerable upset and possible long-lasting psychological disturbance to the child.

Pathological, anatomical and physiological factors

Some patients are selected for contact lens wear because no other form of visual correction is as good or even suitable. Others may be rejected due to the presence of an abnormal anatomical feature or because of the existence of a pathological condition.

Cases where contact lenses are indicated for pathological reasons

In these cases patients are frequently referred to the contact lens practitioner by their medical adviser. If not, before fitting is undertaken, medical cooperation should be sought (*see* Chapter 9). Chapters 17 and 20.7 deal in detail with fitting these cases. A few points are considered here.

Non-tolerance of spectacles

Occasionally, spectacles are not tolerated owing to trauma, skin disease, allergies, nervous troubles or even absence of one or both external ears. Contact lenses may then be suitable, but some skin diseases may be made worse by their wear and appropriate medical advice should be sought if indicated. Epidermolysis bullosa, a rare inherited skin disease, in which blisters appear at sites of mechanical trauma, makes both spectacle wear and contact lens wear hazardous, but Rubinstein (1984) reported success using

high water content (extended wear) soft lenses on a daily wear basis.

People who 'cannot bear' spectacles may well not be able to put up with the trials and tribulations of getting used to contact lenses and should not be led to believe that they are essential when a lighter-weight non-allergic, spectacle frame may be all that is required. However, because soft lenses are so easy to adapt to, they may be a great help in such cases if the patient is otherwise suitable.

Partial sight

Young people with partial sight are sometimes helped by wearing a telescopic aid to give magnification. A contact lens can form the eyepiece of such a system, with a spectacle lens as the objective (*see* Chapter 23). Generally, corneal lenses perform least well because their mobility makes them a poorer eyepiece for such a system, than is afforded by a more stable soft or scleral lens. While, in theory, such systems can be used to assist any person with low visual acuity, in practice the system only works in rare instances. Elderly people find it extremely difficult to adapt to the contact lenses as well as to the magnification of the telescopic type system.

Pathological defects found during the examination of the eye for contact lenses

If any previously unsuspected pathological condition is found during the course of the preliminary examination, or if the history reveals the existence of a pathological condition, contact lenses should not be fitted until medical advice has been sought. Both general and ocular conditions indicating referral will be considered below.

General conditions

General debility Tolerance of contact lenses is likely to be poor unless the general health is good.

Diabetes Unless the refraction is stable, contact lenses are not practicable. The low rate of epithelial healing is an additional disadvantage. Soft lenses can be fitted but extended wear soft lenses should be avoided if at all possible due to the increased risk of corneal neovascularization. Where the diabetes is poorly controlled there are also many other attendant risks (Rubinstein, 1987), including lowered corneal sensitivity and being prone to the development of bacterial and fungal infections. Rigid gas permeable corneal lenses are more commonly fitted due to the lower risk of infection, but care should be taken to avoid '3 and 9 o'clock' corneal desiccation with its attendant risks.

Skaff *et al.* (1995) showed that thick soft lenses appear to cause less swelling of the corneas of insulin-dependent diabetics than occurs in normal healthy subjects of corresponding age. However, the corneas of the diabetic subjects were thicker (and therefore probably oedematous) to start with. They cite much of the research work, relative to contact lens wear, that has been done on the eyes of diabetic patients and feel that modern contact lenses are not contraindicated in younger well-controlled insulin-dependent diabetics.

Hyperthyroidism The disturbed metabolism which results in exophthalmos and lack of blinking can make contact lens wear difficult as there is liable to be an insufficient tear flow to the cornea, with all its related problems.

Chronic catarrh and sinusitis The risk of ocular infection is increased if corneal abrasions from contact lenses occur. The associated mucus in the tears also causes visual problems and deposits on the lens surfaces.

In scleral lens wearers strings of mucus may collect between the back optic surface and the cornea. Frequently the nasolacrimal drainage channels become blocked, leading to epiphora which is exacerbated by contact lens wear.

Herpes simplex of the mouth There is a danger of corneal infection from 'cold sores' when contact lenses are worn. Contact lenses should not be licked. Even so, the virus may be transferred by hand from the mouth to the eye, leading to dendritic ulcers which are likely to recur if contact lens wear is not discontinued. Sometimes the improvement in visual acuity provided by a contact lens following such corneal ulceration is felt to be worth the risk of this recurrence, but contact lens wear should only be resumed on medical advice. Rigid gas permeable corneal lenses are the lens of first choice.

Skin conditions and allergic reactions Ocular allergies can involve the cornea, conjunctiva (both bulbar and palpebral), limbus and eyelids (skin and margins). An excellent summary of the mechanisms involved, their diagnosis and management has been given by Jennings (1990). As far as contact lenses are concerned there is a very slight risk of some patients being hypersensitive to certain plastics (or the residual monomer therein), but there is a greater risk of hypersensitivity or delayed hypersensitivity to the preservatives used in some contact lens solutions, as well as to deposits which form on the lens surface during wear. Careful questioning about allergies is advisable before fitting (Larke, 1985) and the upper tarsal conjunctiva should be studied for any signs of papillary conjunctivitis likely to be of allergic origin.

Atopic individuals are said to be five times more likely to be contact lens intolerant than non-atopic wearers, and should reduce contact lens wearing time during periods of seasonal allergy (Kari and Haahtela, 1992).

Backman and Bolte (1974) showed that desensitization treatment for chronic allergic conjunctivitis, although lengthy, is successful in most cases and useful for contact lens patients. However, the Committee on Safety of Medicines in the UK reported (1986) a disturbing number of deaths from anaphylaxis during such treatment for allergies

and it is therefore now undertaken much less frequently. If there is serious concern that a patient may react to a contact lens material or a solution preservative whose use cannot be avoided, then the patient should be referred for a patch test to be carried out. Wilson (as reported by Rengstorff, 1986) stated that patch testing is positive where a *hypersensitivity* reaction (a gradual build-up of signs and symptoms which is slow to resolve) is likely or has previously occurred. Conversely, patch testing is negative if there has been a *toxic* reaction where the onset and resolution of signs and symptoms are both rapid. To avoid any risk of reaction, materials of known purity should be used, such as the clinical quality (CQ) PMMA or CAB, and for soft and gas permeable hard materials only those subjected to stringent toxicity tests such as those necessary to meet the requirements of the Food and Drugs Administration (FDA) in the USA. Strict hygiene, to avoid the formation of deposits on the lenses, should be observed and, for soft lenses, disinfection systems which avoid the use of preservatives should be employed, and all cleaning solutions containing preservatives should be thoroughly rinsed off using sterile non-preserved saline. For all rigid lenses soaking and wetting solutions which contain the minimum number and quantity of preservatives should be selected and, if need be, rinsed off the lenses prior to their insertion on the eye. Cleaning with non-ionic surfactants is desirable to reduce the risk of any binding of preservatives to the lens surfaces, whatever the material. Regular use of protein-removing systems should be initiated from the outset of wear, provided always that the protein remover is itself thoroughly cleaned and rinsed off the lenses, as patients sometimes react to the enzymes used. Chapter 4 covers these aspects in greater detail.

Where there are infections of the eye or its adnexa, soft lenses should not be fitted except under medical supervision, because the lens material is liable to become contaminated, with the risk of extending the infection.

Norn (1964), Mackie (1967) and others have shown that instillation into the conjunctival sac of one drop of 1% Rose Bengal will show up desquamated conjunctival and corneal epithelium and mucus, indicative of active or subclinical conditions likely to be irritated by contact lenses (*see Figure 18.48*). Typical of such conditions are the following, in which very special care should be taken during the fitting, with prolonged tolerance trials – despite which the contact lenses may have to be abandoned if the skin condition worsens or the eye becomes involved.

Atopic eczema This is associated with asthma and hay fever. When contact lenses are fitted, they may cause an urticarial reaction. This should be minimized with soft lenses but the lens surfaces may degrade rapidly due to excessive protein deposits. If rigid lenses are fitted a low wetting angle material is desirable and this aspect may be more important than oxygen permeability. The fluoropolymers (*see* Chapter 3), besides having a high Dk value, also in theory, wet well. They are therefore to be recommended as the current best RGP materials for such patients. However, careful temperature-controlled manufacture is necessary to ensure good surface wetting. Poor manufacturing practice, such as excess polishing creating a high temperature, can spoil the surface wetting properties. PMMA lenses are rarely fitted now, but the material has good wetting properties and some PMMA materials were developed to enhance the surface wetting characteristics. There are some patients for whom PMMA may still be the best material, provided that a suitable fit is selected to ensure an ample oxygen supply to the cornea via the tears flow behind the lens. Moulded CAB (cellulose acetate butyrate) lenses, such as Ciba Vision's Persecon E lenses, also have good wetting properties and encourage the minimum of deposit formation. Again, because of the low oxygen permeability of CAB the lens fit must ensure good tears flow to maintain corneal endothelial integrity. Lid irritation from the lens edge should be avoided by fitting with minimum peripheral clearance and as large a lens as is practicable, with thin (0.12 mm radial edge thickness) and well rounded edges.

Keratoconjunctivitis sicca (Sjögren's syndrome) This is associated with rheumatoid arthritis; there is a lack of tear secretion (*see Figure 18.49*), and filamentary keratitis is common. The lens of choice is now the high Dk rigid corneal lens used with artificial tears supplements, and, if necessary, occlusion of the puncta with plugs (O'Callaghan and Phillips, 1994). Silicone rubber lenses may also be successful. Soft lenses are not recommended unless there is a lot of discomfort and should then only be fitted with great care, together with saline solution or artificial tear drops instilled at regular intervals throughout the day. Even so, the lenses may dehydrate and be unwearable. Sealed scleral or channelled rigid gas permeable lenses used with a suitable artificial tear solution (*see* Chapters 4 and 17) also prove satisfactory and are a good way of protecting the cornea.

Xerophthalmia (vitamin A deficiency), congenital ichthyosis (dry skin) and sarcoidosis The approach to these three conditions is the same as that to keratoconjunctivitis sicca. Success is possible with all options but more likely with high Dk RGP corneal lenses or silicone rubber lenses.

Voke (1986) reported a case of keratomalacia – the corneal manifestation of xerophthalmia – in a vegan (an extreme vegetarian) whose diet lacked vitamin A and carotenoids. It would therefore seem wise to question all dry-eyed patients about possible dietary causes of their symptoms (*see* Diet, p. 276). Artificial tear drops containing vitamin A are available and may be very beneficial (*see* Chapter 4 and Appendix C).

Several other skin conditions, such as the following, may flare up when contact lenses are worn.

Seborrhoeic eczema This manifests itself as dandruff, blepharitis (*see Figures 18.18* and *18.49*) and otitis externa. Only corneal lenses fitted to give rise to minimal lid

irritation are really suitable but occasionally scleral lenses are advisable. Contact lenses are contraindicated in the presence of blepharitis (*see* p. 268), but if this can be resolved soft lenses cause less irritation to the eye and lids than any other type of lens. However, the patient should be advised to discontinue soft lens wear during recurrences of the condition because of the risk of associated staphylococcal keratoconjunctivitis (Catania, 1987). An effective treatment for blepharitis (Mackie *et al.*, 1977) is a half-dose of tetracycline, taken orally: 250 mg twice daily for 6 weeks. This must not be taken in milk, which inactivates it. It may be prescribed by arrangement with the patient's general medical practitioner, but should not be given to young children or pregnant women as it can cause side-effects such as discoloration of growing teeth.

Acne vulgaris This occurs around the age of puberty, is not markedly aggravated by contact lens wear, but greasing and frothing of the tears may prevent satisfactory wear of any type of lens. Prolonged tolerance trials are useful to establish whether or not this is likely to occur. Wetting and soaking solutions containing polyvinyl alcohol minimize greasing of hard lenses. Corneal lenses fitted within the palpebral aperture give fairly good results because there is no massaging effect on the lids to increase the output of sebum. Soft lenses may be satisfactory but rapid deterioration of the lens surfaces is liable to occur due to contamination by sebum from the eyelids (*see* Lid Hygiene, p. 632 and *Figure 18.17*).

Acne rosacea This is accentuated as the foreign body reaction to contact lenses increases the blood vessel dilatation of the skin of the face and conjunctiva. Punctate keratitis is associated with the condition and may be exacerbated by contact lens wear. In the absence of keratitis, soft lenses – preferably high water content, used on a daily wear basis – or RGP corneal lenses may be tolerated, otherwise, if contact lenses are essential, scleral lenses, fitted to avoid any corneal touch, may succeed.

Epidermolysis bullosa As already mentioned under Non-tolerance of spectacles (p. 261), this may necessitate the correction of any refractive error with high water content soft lenses used for daily wear. Other types of lens are likely to exacerbate the effects of the condition on the eye (Rubinstein, 1984) which range from mild blepharitis and conjunctivitis to pronounced vesicle formation over the anterior eye depending on the severity of the condition.

Psoriasis This is not directly aggravated by the wearing of contact lenses, but the generally associated nervous disposition may lead to a worsening of the condition during the initial period of adaptation to contact lenses. For this reason soft lenses are likely to perform best.

Other indications of general or ocular pathology These should be referred for medical advice whether or not they are specific contra-indications to contact lens wear.

Ocular examination

A number of different techniques must be employed to examine the eyes for suitability for contact lenses. Norn (1974) compiled an exhaustive list of techniques used in the external examination of the eye, with an excellent description of each technique. Some of these techniques, routinely used in the examination of the eye prior to the fitting of contact lenses, will now be mentioned in more detail. Reference should also be made to Chapter 6 for a description of some of the equipment used. Any evidence of pathology found should indicate the need for referral.

Slit-lamp examination in ocular conditions

The anterior segment of the eye and its adnexa should be examined. Magnification of ×20 is recommended for routine use, with ×40 for examination of detail. Fluorescein should be instilled and, if necessary, the excess removed by irrigation to prevent masking of small stained areas by fluorescein in the tear film. Rose Bengal 1% may also usefully be instilled. The use of these stains is discussed further on p. 265.

Normal signs, using a broad beam from the side

The eye should be viewed from in front, and white light, red-free illumination and blue light (cobalt filter) should be used.

Cornea and limbus Dust particles and eye make-up particles are apparent in the tear film and move with blinking. The amount of debris in the tear film is an indicator of the amount of deposit formation likely to occur on contact lenses, and the patient can be forewarned. The cornea appears to have a granular structure owing to the presence of cell bodies. Several very fine nerve fibres may extend across to the centre of the cornea. Limbal blood vessel loops normally encroach into the cornea about 0.25 mm, and a little more than this at the upper limbus. The radial arrangement of myelinated nerve fibres around the limbus should show that the myelin ceases about 1 mm in from the limbus. Aqueous veins (usually in the horizontal meridian) may be seen. A ring or crescent of more opaque corneal tissue separated from the limbus by a narrow, normally transparent, band is frequently seen. It is normally associated with advancing age and is then known as arcus senilis, but may be seen from the early teens onwards and is usually situated near the upper and lower limbus, and consists of cholesterol deposits. In the under-35 age group, and even up to the age of 50, particularly if xanthelasma is also present, it may be indicative of the condition known as FHC (familial hypercholesterolaemia) associated with heart disease (Winder, 1981; Cantle, 1988). All such patients should be referred for measurement of blood cholesterol levels and medical advice.

Posterior embryotoxin may be evident as a semi-opaque, linear structure, about the width of a blood vessel, situated at the posterior corneal surface, near the limbus, and usually

in the horizontal meridian where it runs parallel to the limbus (Becker, 1972). It appears to be more common than is indicated in textbooks of ophthalmology. Usually the termination of the endothelium at the anterior chamber angle is not visible except by gonioscopy when it is known as Schwalbe's line, but if tags of endothelium extend into the anterior chamber or the endothelium is raised at that point, then it becomes visible by normal direct illumination with the slit lamp. Its significance, when visible like this, is that the anterior chamber angle is likely to become blocked more easily (*see* Chapter 23); hence, care should be exercised when fitting soft or scleral lenses to avoid corneal oedema near the limbus, and the IOP should be regularly checked and compared with pre-fitting values. The rest of the endothelium should be carefully scanned to rule out the presence of any abnormalities or striate lines, which might later, subsequent to soft lens wear, be attributed to corneal oedema (*see* Chapter 18).

Bulbar conjunctiva and sclera Conjunctival blood vessels appear to move with respect to the deeper scleral vessels during blinking and eye movements. Most conjunctival blood vessels are normally almost empty and the transparency of the conjunctiva is apparent with the slit lamp. McMonnies and Chapman-Davies (1987) produced a reference scale for assessment of conjunctival hyperaemia due to contact lenses. Prior to fitting it is good practice to note the grade of hyperaemia which exists (*see Figure 18.11* and Appendix D).

The presence of pigment, mainly near the limbus region, is normal in Asians and Negroes, but not in white-skinned races. With age, fat is deposited in the conjunctiva within the region of the palpebral aperture and appears as thickened yellow irregularities. These are pingueculae which are also associated with exposure to hot, dry atmospheres and UV radiation. They are thus found in many people who lead an outdoor life, particularly in hot, dry countries when the pingueculae may progress to become pterygia. Prediger and Edmonson (1993) detail the stategies to be adopted for successful contact lens wear in the presence of these conditions. The incidence of pingueculae also increases with age, as does the irregularity of the conjunctiva and its looseness at the limbus.

While these findings are normal, irregularities of the conjunctiva such as those described, may encourage xerosis of the conjunctiva during corneal and soft lens wear and contribute to limbal desiccation of the corneal epithelium at the 3 and 9 o'clock positions during corneal lens wear. It is thought that these irregularities, combined with the presence of the lens, prevent the upper eyelid from massaging the mucoid layer into the surface conjunctival and corneal epithelium which normally permits these tissues to remain wetted.

Plica semilunaris and caruncle Fine hairs are normally visible on the caruncle. The blood vessels should not appear unduly engorged. Both tissues should appear smooth and not granular.

Iris and pupil Small pigment deposits of normal chromatophores and xanthophores are frequently visible, as are pupillary remnants arising from the region of the collarette. The pupil shape and reactions should be checked.

Anterior lens surface Epicapsular pigment stars, often associated with pupillary remnants, may be seen. The 'orange peel' effect of the anterior capsular epithelium should be visible.

Lid margins By slightly everting the lids, their margins may be seen under magnification. Any abnormalities, such as blocking of the orifices of the meibomian glands, can be detected and appropriate action taken. Small marginal cysts, which disappear after a few days, are often visible. They give rise to discomfort when corneal lenses are worn. Slight pressure just above or below the lid margins should result in a clear fluid being expressed.

Normal signs, using a narrow beam from in front

The microscope should be moved round to one side.

Cornea When normal, this transparent tissue shows as slightly granular in cross-section, with a brighter reflex from both the front surface (lacrimal layer and epithelium) and back surface (endothelium). With age, a few pigment spots become deposited on the back surface of the cornea due to disintegration of the iris pigment epithelium. Corneal guttatae (or Hassall–Henle endothelial warts) appear in old age. If large numbers of guttatae are present, care must be taken to ensure that high Dk lens materials are used, as guttatae can be an early sign of corneal decompensation, or Fuchs' dystrophy.

Anterior chamber This should appear optically empty except for normal pupillary remnants and, with age, a few pigment granules. Its depth can be assessed and the chamber angle estimated (van Herick *et al.*, 1969). It is important to rule out those patients with shallow anterior chamber angles if soft lenses, which may cause corneal oedema, are to be fitted, for in soft lens wear the cornea is thought to swell backwards slightly, into the anterior chamber. In this connection, it is wise to carry out gonioscopy or to refer for medical advice before fitting any patient in whom the depth of the chamber at the limbus appears to be equal to or less than a quarter of the thickness of the cornea, as seen by optical section. (The microscope should be used from directly in front of the patient with the narrow slit beam at 60° to one side.) Such narrow angles are potentially capable of closure.

Staining

Several stains may be employed to detect abnormality of which fluorescein is the most common.

Fluorescein A drop of 1 or 2% sterile sodium fluorescein solution should be instilled into the conjunctival sac or

applied from a sterile impregnated paper strip moistened with sterile saline solution. The excess may be rinsed out with sterile physiological saline solution if necessary. The cornea may be examined under magnification with suitable cobalt blue filter or long wavelength ultraviolet light. (Short wavelength ultraviolet rays are dangerous.) This is then followed by slit-lamp examination using × 20 magnification. Any staining of the cornea prior to contact lens fitting, except if caused by a foreign body (the prior presence of which may usually be elucidated by questioning the patient) is abnormal, although Norn (1970) states that a few punctate dots of stain, increasing in number with age, are normal in about 20% of the population. Extensive staining indicates the probable need for referral. (Following an illness or head cold, the corneal permeability is increased and the cornea absorbs some fluorescein; but this gives only a slight green haze, unlike the bright green stain of an abraded area. When the corneal permeability is grossly increased, some fluorescein may enter the anterior chamber.)

The patency of the puncta and lacrimal drainage channels may be demonstrated by asking the patient to blow his or her nose on to a paper tissue, which should stain green. Each side should be checked separately. It is unwise to proceed with fitting contact lenses if the nasolacrimal passages are blocked, for the conjunctival sac is less likely to be sterile. Also the presence of contact lenses, causing excess tear production, is bound to lead to epiphora in such a case. The use of decongestant eye and/or nasal drops or, if necessary, irrigation of the nasolacrimal passages, to clear them is indicated. Blockage is common in catarrh and hay fever sufferers, and in those with dry eyes when the passages may become blocked with epithelial debris. This may be advantageous for dry-eyed patients permitting those tears which are produced to be retained on the eye. Where contact lens fitting is essential, but the nasolacrimal drainage channels remain blocked, fitting should proceed with extra care and the patient be given special advice about risks of eye infections.

Rose Bengal The instillation of a drop of 1% solution should not cause any marked corneal or conjunctival staining (*see Figure 18.48*). Such staining is best sought using red-free illumination and low magnification with the slit-lamp microscope (*see Figure 18.10*). If found it indicates that the tear output may be reduced or an abnormal skin condition may exist and contact lens fitting should be undertaken with caution. The mucus strip along the lid margins normally stains red and thus becomes apparent. It often detaches from the lid margin during contact lens wear and if it adheres to the lens or floats in the precorneal film it may interfere with vision. (Rose Bengal, which stings when instilled, particularly in dry and susceptible eyes, should be instilled after the use of fluorescein. Otherwise it may cause the appearance of punctate staining with fluorescein.)

Alcian blue and trypan blue Kemmettmüller (1962) and Norn (1964) described the use of these dyes for the detection of abnormality. Since their action is liable to be prolonged, their use in normal contact lens practice is not appropriate.

Sensitivity

An anaesthetic cornea is an abnormal cornea. Before contact lenses are fitted to an eye with an insensitive cornea, medical advice should be obtained. Great care is needed in fitting such an eye as abrasions caused by poorly fitting lenses do not give rise to the normal symptoms of discomfort. Injury to the eye and infections may occur without the wearer's realization. For this reason soft lenses are the most appropriate in such cases, provided that strict hygiene is observed. People with insensitive corneas readily accept contact lenses and it is essential to give them careful advice concerning wearing schedules and after-care, and to warn them of the dangers of ignoring this advice. Sensitivity may be quickly checked by gently holding the lids apart and touching a wisp of sterile cotton wool on to the cornea from one side, so that its approach is not seen by the patient. Touching the lashes should be avoided. A normal blink reflex response should result from both apical and limbal touch. More refined methods whereby measurements of sensitivity can be obtained are useful if there is any doubt as to whether or not sensitivity is normal. Suitable instruments are the aesthesiometer and sensitometer, and air puff methods are also available (*see* Chapter 2). Schirmer and Mellor (1961) showed that reduced sensitivity is to be expected following cataract extraction in the sector of the cornea corresponding to the incision. Lowered sensitivity also follows corneal grafting as well as interstitial keratitis and past ulceration of the cornea, and following rigid and soft contact lens wear, with recovery in both cases being rapid (Millodot, 1976).

Pachometry

The use of the slit lamp to observe the thickness of the cornea is aided by the use of a pachometer (pachymeter) or other doubling device for actual measurement of corneal thickness (*see* Chapter 6). A very thin or irregular cornea, as in keratoconus, indicates the need for referral prior to fitting. As a thickened cornea is an indication of oedema, it is desirable to measure corneal thickness prior to contact lens fitting, as a reference for future measurements. It is also useful to know the normal values found in pachometry – the apparent central thickness of the majority of normal corneas falls between 0.50 mm and 0.60 mm.

Classic keratometry

This allows measurement of the curvature of the anterior surface of the central cornea, most radii falling within the range 7.2–8.6 mm. Radii outside this range may indicate abnormalities such as keratoconus (steep radii) and megalocornea (large cornea with possibly flat radii), Marfan's syndrome or cornea plana (flat radii)

The amount of corneal astigmatism present is also measured. A very toric cornea may give rise to difficulties

in fitting, and it is as well to anticipate these in order to warn the patient of extra time required. A big difference between ocular and corneal astigmatism should lead the practitioner to expect a large amount of residual astigmatism with a rigid spherical lens, probably requiring a cylindrical correction (*see* Chapters 5 and 14). Again, this should indicate a more lengthy fitting procedure, and adequate warning can be given to the patient at an early stage. Toric soft lenses are indicated where the ocular astigmatism is sufficient to require correction to achieve adequate visual acuity at both distance and near, and where rigid lenses are unsuitable. If keratometry shows that the anterior corneal surface is highly toroidal, then a soft lens with a back toroidal surface may be indicated (*see* Chapter 14).

The keratometer also reveals surface irregularities of the central cornea, some so small as to be invisible with the slit lamp. Any irregularity should be further investigated prior to fitting.

Corneal analysis

The contour of almost the entire front surface of the cornea may be studied by computerized corneal analysis (*see* Chapters 6 and 10). Not only is this useful when fitting contact lenses to normal corneas so that the amount of peripheral corneal flattening can be determined to give a numerical value of the eccentricity, but it is also useful for cases where the peripheral topography of the cornea is irregular. The development of surgical techniques of altering refractive error such as radial keratotomy, and refractive keratectomy where an excimer laser is used (*see* Chapter 20.4) have led to the peripheral cornea becoming steeper than the central cornea, a situation also created by orthokeratology (*see* Chapter 19). Although these various techniques aim to eliminate refractive errors, it is often still necessary to correct any residual refractive error with a contact lens, or in orthokeratology to wear a rigid gas permeable lens overnight, and so it has become even more imperative to have a knowledge of the entire corneal contour (Sanders and Koch, 1992).

The current instruments for corneal analysis are known as video-keratoscopes (Mandell, 1992), such as the Eye-Sys Corneal Topography system and the TMS (Topographic Modeling System). These have evolved from the original simple Placido disc and Klein keratoscope via the first topographical keratometer (Bonnet and Cochet, 1962) which enabled the radii of curvature of the peripheral cornea to be measured and thus the rate of flattening from apex to periphery to be determined. Standard keratometers were also adapted by means of attachments, to obtain similar measurements. However, the Placido disc (a flat disc composed of alternate black and white concentric rings with a central viewing lens) and the similar internally illuminated Klein keratoscope are principally used to detect irregularities of the corneal front surface. Thus any distortion of shape or continuity in the appearance of the rings reflected from the cornea indicates a surface defect; for example the rings appear oval by reflection from a highly astigmatic cornea and the central rings may appear crowded and displaced when reflected from a keratoconic cornea. It became desirable to photograph these irregularities for record purposes and photokeratoscopes were developed. It then seemed logical to produce one instrument both to record irregularities as well as to permit measurements and Wesley-Jessen developed the PEK (Photo-Electric Keratoscope) system (Bibby, 1976) in which photographs of the corneal reflections were analysed, and from this analysis contact lens specifications were derived.

Tear output

A normal tear output and precorneal film (*see* page 269) are essential for comfortable, trouble-free contact lens wear. When the tears are not normal in output, or the constituents are not in the normal proportions, problems such as greasing and deposit formation on the lenses occur. The eyes and lenses may dry leading to desiccation and infection, and the upper palpebral conjunctiva may suffer an allergic response leading to deposit formation on lenses.

Both insufficient and excessive tear output can indicate that there is some abnormality of the lacrimal or conjunctival glands or of their nerve supply, and many diseases causing discomfort of the eye give rise to excess tears (Phelps-Brown, 1987). Tear output is also affected by diet and by certain drugs (*see* pp. 135–136 *and also* p. 276). To fit corneal lenses to a dry cornea could be harmful, whereas excessive tears would prevent a corneal lens being worn satisfactorily. If the excess is due to a disease process, then any type of contact lens is contra-indicated and the abnormality should be medically investigated before fitting. It should be borne in mind that soft lenses may alter curvature considerably on dry eyes and can only be fitted if saline solution or artificial tears are repeatedly instilled.

Various tests are available for measuring tear output, the quality of the tears and precorneal film, and the rate of drying or thinning of the tears. Tomlinson (1992) has described and summarized these, and given a useful overview of the anatomy, physiology and chemistry of the tears and tear film. A common test for the measurement of tear output is described by Schirmer (*see* Chapter 2), but because the test papers may irritate the eye, unless they are extremely carefully applied, the test is really only adequate for the detection of gross abnormality. Nevertheless, it is very useful in revealing those very dry eyes in which even the irritation from the Schirmer test paper fails to produce any tears. It therefore can be useful before fitting any type of contact lens. Patel *et al.* (1987) and Cho and Yap (1993) carried out detailed studies of its reliability and intersubject variability, which confirm these comments.

Norn's test (Norn, 1965), although rarely used, is more accurate than Schirmer's, for it involves judging the dilution of the tears in the lacrimal rivus over the central part of the lower lid exactly 5 minutes after 10 µl of a mixture of 1% Rose Bengal and 1% fluorescein is instilled into the lower

fornix. Using the slit lamp a comparison is made with known dilutions of the mixture in capillary tubes. Ford (1974) interpreted Norn's work very carefully, and predicted the amount of refractive change likely to take place due to dehydration of soft lenses on the eye, on the basis of the tear output measured by this test.

Another useful clinically simple test is the phenol-red thread (PRT) test developed by Hamano *et al.* (1983) whereby a phenol-impregnated cotton thread is used in place of a Schirmer test paper. Only a 15 second test time is necessary and the thread is less irritant than paper. Little and Bruce (1994) showed it to be a reliable and repeatable test, and for caucasian subjects they state that tear secretion is low if less than 11 mm of the thread is wetted in 15 seconds, borderline if less than 16 mm is wetted, with 21 mm representing normal.

The break-up time (BUT test) of the precorneal film should also be carried out (*see under* Precorneal film).

Further slit-lamp examination of the eye

Abnormalities of the sclera and bulbar conjunctiva Abnormalities, such as pterygia or old operation scars, may make contact lenses difficult to fit and may be irritated by the presence of the lens. When large corneal lenses which bump into the limbus region are worn, any loose conjunctival tissue becomes easily injected, inviting new blood vessel growth.

Pingueculae are apt to be irritated by any sort of contact lens and it is only fair to warn patients of the conjunctival hyperaemia which is likely to detract from their cosmetic appearance when contact lenses are worn. With corneal lenses this is usually due to the development of 3 and 9 o'clock drying of the cornea (*see* pp. 345 and 648. Also *Figures 18.29* and *18.30*). Care should be taken when fitting any type of contact lens to an eye having any form of limbal nodule, or elevation or pre-existing pannus.

Lids The lids should be everted. If abnormal or excessive concretions or other elevations are seen, the patient should be referred for treatment before fitting, although contact lenses may make the eye more comfortable in the presence of multiple concretions by protecting the cornea from them. The upper palpebral conjunctiva comes into contact with almost the entire front surface of a contact lens during blinking and lid closure, while the lower lid barely covers the lower part of a soft contact lens. Particular attention should therefore be given to the everted upper eyelid. Follicles, and papillae (when blood vessels are present in the raised area) are normal nasally and temporally and along the sulcus but not overlying the tarsal plate which should be smooth (Larke, 1985). If encountered on the tarsal plate, they are suggestive of allergy, such as vernal conjunctivitis, and contact lens fitting should only proceed with caution. Due attention should be paid to hygiene and minimizing any possible irritants, such as surface deposits or poorly formed lens edges, or the preservatives of solutions etc.

If ectropion, entropion and/or trichiasis are evident, contact lenses are advisable to protect the cornea as described in Chapter 20.7. Incomplete lid closure (usually due to lagophthalmos following seventh nerve paralysis) again indicates the need for a protective contact lens.

Special scleral lenses can be fitted where there is ptosis of the upper lid (*see* Chapter 17). The right and left eyelids should always be compared and any slight tendency to ptosis noted in order to differentiate it later from possible contact-lens-induced ptosis such as that reported by Levy and Stamper (1992) and by Vanden Bosch and Lemij (1992). The cases they describe followed wear of rigid lenses, some on one eye only, but it can also occur with soft lens wear when one eyelid swells and droops in association with contact-lens-induced papillary conjunctivitis.

Blepharospasm, if it is persistent, can be a nuisance to corneal lens wearers as considerable discomfort ensues. In such cases scleral lenses may help. Soft lenses may be satisfactory but the excessive lid pressure usually distorts the lens. In any case the cause of the blepharospasm should be investigated before fitting. It should be borne in mind that those people who are somewhat apprehensive about wearing contact lenses may exhibit an unusual amount of blepharospasm at an initial interview, simply due to nervousness, and this subsequently disappears.

Contact lenses should preferably not be fitted in the presence of blepharitis (*see* p. 264) as there is a risk of corneal infection. Corneal lenses also give rise to discomfort and lid soreness where blepharitis is present or where the lid margins are highly sensitive. (Lid margin sensitivity may be checked with a wisp of cotton wool or an aesthesiometer.) Recurrent styes are a contraindication, so are any lid margin growths. Where there is absence of lashes – a sign of eczema and/or alopecia – fitting should proceed with great care: the patient (and practitioner) may have difficulty in gripping the lids during insertion and removal of lenses.

Parasites may be encountered among the eyelashes. These include *Demodex folliculorum* (Coston, 1967) which breeds in the eyelash follicles, and even canine lice have been found (Londer, 1987). Removal of the former may be effected with a cotton bud soaked in alcohol applied very carefully to the lashes, and Londer reports clearing canine lice with Lacrilube (Allergan) ointment. Parasite infestation gives the appearance of blepharitis and should similarly be cleared before contact lenses are fitted.

The depth of the fornices should be checked before fitting as past injury or surgery may restrict the limits of the conjunctival sac, making soft and scleral lenses either unsuitable or difficult to fit. Conversely, in certain inflammatory conditions such as the Stevens–Johnson syndrome and ocular pemphigus, scleral lenses or rings may be necessary to maintain the depth of the fornices and prevent the adherence of palpebral and bulbar conjunctiva (*see* Chapters 17 and 20.7).

Palpebral aperture size and lid tightness These may limit the size of lens fitted. A small palpebral aperture and tight lids may indicate choice of a small lens, whereas large

palpebral apertures and loose lids may make larger lenses more appropriate. This is not only true for physical reasons of fitting but physiologically also, for small lid apertures lead to a greater temperature increase behind the contact lens (Hill and Leighton, 1965) and therefore to a reduction in the efficiency of the tear pump, i.e. the amount of oxygen supplied to the cornea via the tears (Fink *et al.*, 1990). The temperature increase raises the metabolic rate, which, if it cannot be met by sufficient oxygen, leads to corneal oedema. Thus, unless a highly oxygen permeable lens is fitted, the smaller the area of eye covered by the lens, the better.

An excessive temperature rise leads to evaporation of tears and the formation of salt deposits at the canthi. If this occurs at a tolerance trial with rigid corneal lenses it may simply be due to the foreign body sensation leading to partial eyelid closure to achieve comfort; but proceeding with caution is indicated, preferably using small, medium to high water content soft lenses, if the prescription allows. These are least likely to upset corneal metabolism.

The presence of foam at the outer canthus is fairly normal (Norn, 1963), but foam along the lower lid margin may be associated with instability of the tear film due to reduced meibomian secretion (Larke, 1985). Its production is increased by blinking and the presence of foreign bodies such as contact lenses. The production of excessive mucus during a tolerance trial is also a contraindication to fitting, as is excessive meibomian activity (*see Figure 18.17*), which may give rise to subsequent greasing problems.

Lacrimal gland This should be checked for normality – for size, position and colour. If it is large and prominent and scleral lenses are to be fitted, the temporal portion of the lens must be made sufficiently thin to slide under the gland without bumping it.

Precorneal film (*See* Tear output *above*) A number of qualitative tests may be used to-assess the normality of the precorneal film prior to fitting contact lenses. These have been described by McDonald (1969), Josephson (1983, 1986), Mengher *et al.* (1985), Patel *et al.* (1985), Guillon (1986a), Tomlinson (1992) and Loveridge (1993), and their relevance to contact lens fitting elaborated by Hill (1973) as well as the above-named researchers.

The wettability of the tear layer is a function of the mucoid layer, and its efficiency may be judged by observing through the biomicroscope the reflection of an ordinary movable lamp in the lacrimal rivus or prism at the lower lid margin (*see Figure 9.1*). This prism has three zones: an upper convex one against the lower cornea, a middle concave one at the centre of the rivus, and another convex one at the limit of the tear layer on the rear of the lower lid. As the lamp is slowly moved up and down, three smoothly moving bright reflections should be seen in the prism – the upper and lower ones giving a 'with' movement and the centre an 'against' movement. It may be necessary to ask the patient to look downwards to see all three, but if all or parts of these reflections are missing, the wettability of the tears is abnormal.

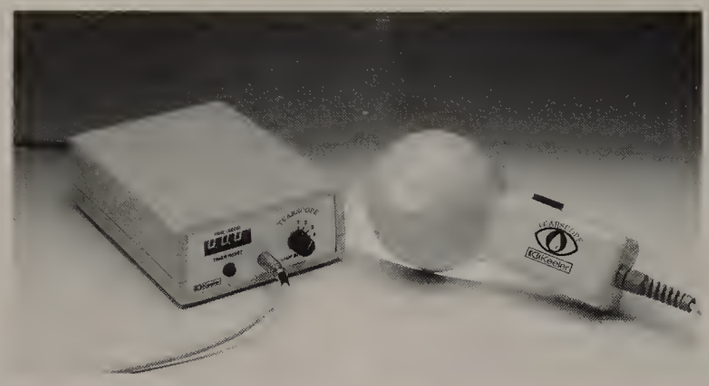
The quality of the surface lipid (oily) layer which controls the rate of evaporation of the aqueous layer behind it, can be judged by looking in the same way at the corneal surface reflection of the lamp. The patient should blink normally about once every 4 seconds, and the reflection of the lamp should remain bright. If streaks of interference colours appear, the tear layer is too thin (or there is too great an evaporation rate) (McDonald, 1969). If the reflection is irregular and pocked, the surface is very dry.

Guillon (1986a) has described a more refined technique for observation of the lipid layer of the preocular tear film (POTF) and the development of an instrument for use with the biomicroscope at low magnification. The instrument, the Tearscope, consists of an internally illuminated white hemispherical cup which is reflected at the tear surface as a circular white area of about 1 cm diameter, against which the lipid layer of the POTF may be viewed at low magnification (*see Figure 8.1*).

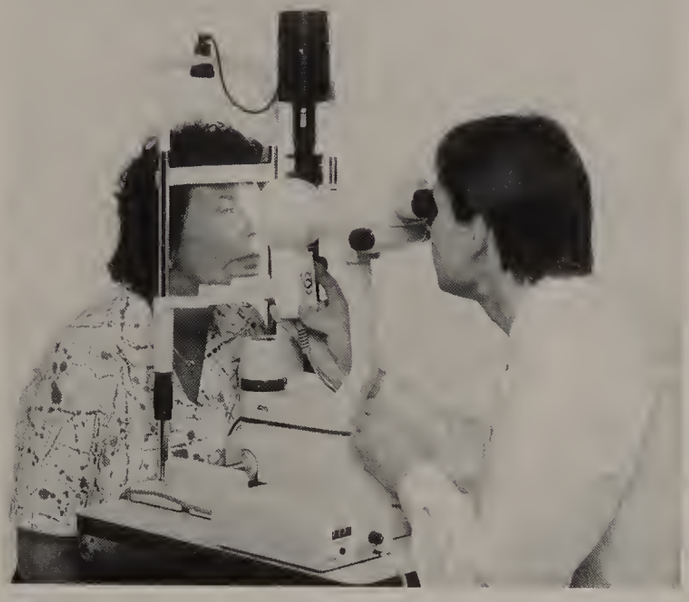
Guillon established that there are five basic patterns which the lipid layer forms: a *marmoreal pattern* of a grey mottled appearance occurring in about 60% of patients where the lipid layer varies between 13 and 70 nm giving rise to a marbled effect; a *contaminated marmoreal pattern* due to contamination by mucus strands or cell debris, as for example after eye rubbing, but which occurs naturally in some 10% of patients indicating an unstable tear film, and the likelihood of surface drying and deposits if contact lenses are worn; an *amorphous pattern* seen in 15% of patients where the lipid layer is between 70 and 90 nm thick and of blue-grey colour, indicating a stable POTF, and a good tolerance to contact lenses, but possibly slightly more lipid deposits on soft lenses; a wavy *flow pattern* where the lipid layer consists of different poor-mixing lipids with thickness varying from 10 to 90 nm and occurring in about 10% of patients, very few of whom have problems related to their tears; and finally a *colour fringe pattern* showing different interference colours with the eyes wide open, and occurring in 5% of cases, indicating a much thicker lipid layer from 86 to 170 nm often contaminated by mucus strands. The latter appearance is often associated with excess meibomian secretion (*see Figure 18.17*) and chronic blepharitis (*see Figure 18.18*), and such patients have problems with contact lenses, particularly soft ones which dry out and attract deposit formation.

Sometimes these patterns occur in combination, and a combination of amorphous and colour fringe patterns where the colours are first order yellow, brown and blue (lipid thicknesses of 90, 140 and 170 nm, respectively). This is regarded by Guillon as highly favourable to contact lens wear.

A test of viscosity may be made by watching the movement of bubbles or debris in the lower tear prism. Surface particles should move more slowly than deeper ones. If the movement is simultaneous and rapid, insufficient viscosity is indicated and not enough tears will be retained on the eye. Simultaneous but slow movement indicates tears which are too viscous, and contact lenses would tend to become greasy and dirty if worn.



(a)



(b)



(c)

Figure 8.1 The Tearscope – a diffuse hemispherical light source with central viewing aperture used in combination with the microscope of a slit lamp, for observation of the tear film. It was developed by J-P. Guillon and M. Guillon (Guillon and Guillon, 1988, 1993) and is produced by Keeler Ltd, by whose kind permission these illustrations are reproduced. (*a*) The instrument showing the central viewing aperture. (*b*) The instrument in use for observation of a patient's tear film, a magnified view being obtained by the microscope of the slit lamp. (*c*) The appearance of the Pre-Lens Tear Film (PLTF) on the front surface of a rigid gas permeable lens. Bright well-spaced fringes can be seen which denote a thin aqueous phase with no superficial lipid layer

Other phenomena described by McDonald (1969), indicating tears which are too viscous, are the 'pleated drape' and 'rolled scum' phenomena. (These appear to correspond to Guillon's flow and colour fringe patterns, respectively.) The former is seen by reflection of a lamp in the upper tear prism at the start of each blink, when waves, like pleats, form interference colours which close together as the lid goes up. The 'rolled scum' effect is left on the lower third of the cornea after each blink, where the two lids have parted and left an oily deposit. This is visible with a wide slit beam and is more noticeable after a high cholesterol intake. It is therefore felt that tear chemistry may be related to diet (Lowther *et al.*, 1970; Young and Hill, 1973).

Normal phenomena are the 'crumple' effect seen with a broad vertical slit at about 15° to the microscope axis, when the surface oil molecules undergo lateral pressure from the lids at the start of each blink and cause a diffuse (instead of uniform) reflection rather like wet silk; the epithelial drying effect, or non-invasive break-up time (NIBUT, *see* below) when the tear layer can be seen to evaporate after about 20 seconds without blinking which causes a reduction in acuity; and the epithelial touch effect, when a foreign body such as an eyelash or a bubble under a contact lens forms a furrow in the epithelium. In the latter case, after the foreign body is washed away, the furrow – visible by its oily margins – gradually widens for up to 5 minutes and then

slowly narrows as the normal tear layer reforms. Such furrows retain fluorescein and, in the case of contact lens wearers, are called dimples. The speed with which the furrow disappears may well be a measure of epithelial fragility. *Figures 18.6, 18.7* and *20.1.12* show dimples and furrows under a corneal lens.

Another test of the epithelial drying effect was described by Polse (1975). He stated that a deficiency of mucus production results in corneal dry spots which show up when the tear film is seen to break up into droplets. The test is known as the BUT (break-up-time) test. It is seen most easily by applying fluorescein below the cornea and observing with the slit lamp, using blue light and the largest possible circular aperture to illuminate the entire cornea. The patient is instructed to make one complete blink and then hold the eyes wide open. In caucasians, dry spots, which show up as black areas within the fluorescein-covered corneal surface, usually only appear if the lids are held apart for 20 seconds or more after a complete blink, whereas they appear within 10 seconds after a complete blink in certain pathological and dry-eye conditions and in orientals (*see Figure 8.1c*) and if there is a mucus deficiency (Lemp *et al.*, 1970, 1971; Koetting, 1976). Polse stated that the appearance of such abnormal dry spots on the cornea is a contraindication to successful contact lens fitting, and this was confirmed by Koetting who showed a correlation between the surface contamination/coating of hydrophilic lenses and a low tear film break up-time, and by Andres *et al.* (1987) who found a definite relationship between reduced BUT and intolerance to contact lenses. They found 15% of 200 patients had dry eyes (BUT of 7.5 seconds or less) and 24% were borderline (BUT of 10 seconds). However, Vanley *et al.* (1977) cast doubts on the usefulness of the BUT test as they found considerable variation in individual eyes from one patient visit to the next. Before rejecting a patient for contact lenses on the grounds of poor tear output, several different tests should be carried out and repeated at intervals in order to obtain a true picture. Even then, rather than reject the patient altogether it is probably better to try a different type of lens such as a rigid gas permeable corneal lens.

Guillon (1986b) stated that instillation of fluorescein upsets stability of the tear film and that it is preferable to observe the lipid layer using his own low magnification technique, described above, to record the non-invasive break-up time (NIBUT). Ideally this should be 20 seconds or more for successful contact lens wear and certainly not less than 10 seconds.

The other non-invasive tests are: the Tear Thinning Time (TTT), when, following a few blinks, the time taken for the keratometer mire images to become distorted or out-of-focus in any way while the eye remains open, is recorded (Patel *et al.*, 1988; Patel and Farrell, 1989); and similar tests for NIBUT using grid patterns reflected in the tear film such as the Mengher grid (Mengher *et al.*, 1985) and the Loveridge grid – a modified Klein keratoscope (Loveridge, 1993) (*see Figures 8.2* and *11.8b*).



(a)



(b)

Figure 8.2 The Loveridge Grid – a hand-held internally illuminated grid pattern with central viewing lens used to observe the precorneal tear film (Loveridge, 1993). (Reproduced by kind permission of R. Loveridge and Evans Instruments)

Many of these tests and phenomena may be observed with contact lenses in place. The tear prism at the temporal edge of the lens may be used for checking wettability and viscosity, and the lens surface for rate of evaporation, although the surface of a contact lens dries more quickly than the surface of the cornea. Guillon (1986a,b) related the lipid layer patterns of the POTF to those of the prelens tear film (PLTF), the latter depending on the lens material and its wettability, and discussed both in connection with the anterior surface drying time (ASDT) of various contact lenses.

Because of the importance of the tears and precorneal tear film to the success of contact lens wear, numerous studies have been undertaken using all these various tests. Many are still on-going. A study by Brown *et al.* (1993) suggested that the tear film, in general, is not as sensitive to disruption

from lid-rubbing and lid-lifting as had been thought, except in certain individual cases. Whether this leads to another possible predictive indicator to the success of contact lens wear remains to be seen. Cho and Brown (1993) have shown that Hong Kong Chinese have acceptably shorter NIBUT (mean 7.6 seconds) than Hong Kong caucasians (mean 10.8 seconds), yet another indication that no single test alone should rule out contact lens wear.

Lowther *et al.* (1971) also found that a normally wetted bulbar conjunctiva which appears smooth may become dry and irregular following corneal lens wear, due to the mechanical effect of the lids being held off the conjunctiva (especially in the 3 and 9 o'clock positions) by the lens edge, so that the conjunctiva is not properly wetted. This can occur when the tear chemistry is normal, so that the remedy is one of lens design (such as thinner edges and/or less peripheral clearance) rather than patient rejection (*see also Chapters 10* and *18*).

Puncta Their presence and apposition to the globe should be checked. Abnormalities which result in poor tear drainage contraindicate contact lens wear.

Punctum plugs are sometimes used for dry-eyed patients, to prevent tears drainage, thereby retaining what little tears there are, on the eye. Tomlinson and Giesbrecht (1993) suggested that reduced tear production with age is at least partially offset by reduced drainage facility, probably caused by some obstruction, as they found no change in evaporation rate of the tear film with age.

Pupil size and reactions Reactions should be normal. Large pupils create difficulties for some corneal lens wearers, particularly motorists who do a lot of night driving, when considerable flare around headlights may be noticed if the optic zone is smaller than the pupil size. Also, wearers of most types of bifocal contact lenses may suffer flare and monocular diplopia if pupils are large. The deeper the anterior chamber the larger should be the optic zone of the lens for a given pupil diameter (Stone, 1959). The transition between the optic zone and the peripheral zone should be made as gradual as possible to minimize flare. Non-spherical surfaces such as ellipsoidal, or those with continuous curves (*see* Chapter 10) minimize these flare effects with large pupils. The maximum pupil size is readily judged by ultraviolet illumination in a dark room when the fluorescence of the crystalline lens shows up the pupil size. Fortunately, modern rigid gas permeable lenses are fitted with large back optic zones and total diameters, and with minimum peripheral corneal clearance, all of which has helped to reduce flare effects. Soft lenses, apart from bifocals and varifocals which can cause flare, should give rise to fewer such problems, but a lot depends on the state of the surface and whether or not it is clean.

Iris Normality should be established. Special lenses may be fitted if the iris is wholly or partially absent, to occlude the unwanted iris apertures. This can result in a considerable improvement in vision. Soft, corneal or scleral lenses may be used depending on the severity of the condition (*see* Chapter 20.6).

Exophthalmos or enophthalmos Abnormalities such as Horner's syndrome should be looked for and pathological conditions ruled out. Soft or corneal lenses are cosmetically better for exophthalmos, although the latter may have to be fitted slightly steep in order to be retained on the cornea. In exophthalmos there is a risk of reduced tear flow behind the lens. For enophthalmos, scleral lenses may improve the cosmesis, but it is rare that they would be fitted for this reason alone. If fitted, they need to be made small to facilitate insertion and removal, which is difficult for these patients with any type of lens.

Ophthalmoscopy

This is carried out to check the media and fundi to establish absence of abnormalities. Any persistent disturbance of the normal red fundus reflex – for example, due to lid pressure on the cornea – should be noted in case it is later mistaken for the after-effects of contact lens wear.

Visual fields

These should be checked if there are any doubts about their normality. In general, contact lenses have a beneficial effect on the visual field as compared to spectacles (*see* Chapter 5). Aphakics, in particular, benefit by losing the ring scotoma caused by high positive spectacle lenses and the surrounding frame.

Tonometry

This is usually carried out if raised intraocular tension is suspected, and routinely in the over-40 age group. Because of the possible risk of some contact lenses increasing intraocular tension by pressure on the anterior ciliary veins, or in the case of soft lens wear when corneal oedema could result in a narrowing of the anterior chamber angle, it is wisest to carry out tonometry both before and after fitting, whenever there is the slightest suspicion of high intraocular pressure.

Non-contact tonometry obviates the need for any local anaesthetic drops or fluorescein dye to be instilled, making routine tonometry straightforward during contact lens fitting and after-care.

Visual acuity and refraction

A consideration of the optical effects of contact lenses (*see* Chapter 5) shows that, in theory, contact lenses should give a better visual acuity than spectacles as there are no oblique aberrations or distortion with contact lenses. However, contact lenses frequently suffer from surface contamination which leads to reduced visual acuity and veiling glare. Also soft lenses may alter power whilst on the eye, and rigid lenses may flex (*see* pp. 174–181). Contact lenses of very

high positive power, as used for correction of aphakia and high hypermetropia, have such steeply curved front surfaces that the slightest movement of the lens on the eye may effect a power change due to spherical aberration, and therefore spectacles may give a better visual acuity than contact lenses in such cases. Also the back vertex distance of the spectacle lens from the eye gives an increase in retinal image size which improves visual acuity. Unfortunately the better visual acuity with spectacles may not be compatible with good binocular vision, and the weight of the spectacle lenses may be unacceptable.

Myopes In myopes, contact lenses give bigger retinal images than spectacles, in proportion to the strength of the correction. This can lead to initial disorientation with contact lenses but should give better visual acuity. More ocular accommodation is needed, and the convergence required is greater than with spectacles, owing to the absence of the prism base-in effect. Thus, myopes tend to experience near-vision difficulties not encountered with spectacles, although the accommodation–convergence relationship should remain the same (Stone, 1967). They also have to move their eyes about more. From the point of view of others, the myope's eyes look bigger in contact lenses, as the reduced magnification of spectacles has been removed. All these effects are proportional to the power of the lenses.

High myopia A definite improvement of visual acuity is usually obtained with contact lenses, although this may be partially offset by difficulties with convergence and accommodation (*see* Chapter 5). Here, consideration must be given to the looseness of the lids and to the state of exophthalmos. Ultrathin soft lenses, unless otherwise contraindicated, are ideal, although there are still occasional problems of high positioning with small lenses, due to lid traction, and if a lenticular or large lens is used the upper lid may push the lens downwards due to pressure on the thick transition between the lenticular and carrier zones. Thick edges on corneal lenses make these difficult to tolerate by myopes with tight lids. Also, the thick edge of a high negative corneal lens is often gripped by the upper lid, and corneal lenses may therefore ride so high on the cornea as to cause drying of the lower cornea and visual disturbance due to the peripheral zone or even the edge of the lens intersecting the pupil area. However, lens constructions are available (*see* p. 193 and *Figures 5.33* and *5.34*) which overcome these difficulties (Mandell, 1974), but the problem then becomes one of manufacture rather than fitting (*see* Chapters 10 and 21). Hybrid lenses are not available, as yet, in sufficient back optic radii or high negative powers to meet all requirements.

A compromise of spectacles plus contact lenses, each correcting part of the myopia – the contact lenses the major part – with spectacles to correct the residue as well as any astigmatism and/or presbyopic addition, has proved a useful approach in some cases.

Hypermetropes In hypermetropes, the effects of contact lenses are the opposite to those for myopes. Smaller retinal images are obtained than with spectacles, and the eyes look smaller than in spectacles. Accommodation needed is less, convergence required is reduced and the eyes have to move less than with spectacles.

Astigmats Spectacle wearers learn to compensate for the distortion of the retinal image afforded by an astigmatic spectacle correction. This compensation by the brain is continued when contact lenses are first worn, and it gives rise to a false experience of distortion which usually soon disappears. A comparison of ocular astigmatism with that measured by the keratometer allows prediction of the approximate amount of residual astigmatism with a rigid spherical contact lens. A suitable lens construction may be chosen in advance if residual astigmatism is likely to cause a reduction in visual acuity. If soft lenses are being considered, ocular astigmatism greater than 1D suggests that a toric lens is necessary. Where ocular astigmatism is negligible but corneal astigmatism is present, which neutralizes any crystalline lens astigmatism, soft lenses are optically ideal, provided the corneal astigmatism is not so great as to disrupt the fit.

Anisometropes Although Sorsby *et al.* (1962) showed that most naturally occurring anisometropia is of axial origin and theoretically, in such cases, the retinal image sizes in the two eyes are more likely to be of similar size if a spectacle correction is used rather than contact lenses (*see* Chapter 5), in practice this does not necessarily work to the patient's advantage. Contrary to expectations, contact lenses often give rise to better binocular vision than spectacles (Winn *et al.*, 1986) and the binocular fusion difficulties associated with unequal retinal image sizes are not encountered. The only reasonable explanation for this is that each retina has the same number of light receptor units, and that in the longer eye these receptor units are more widely spaced than in the shorter eye, as might be expected during the growth process. Thus the bigger retinal image in the longer eye is thought to cover the same number of receptor units as the smaller retinal image in the shorter eye, which then gives rise to the ideal situation for binocular fusion.

In the over-60 age group crystalline lens changes occur, which are often greater in one eye and may lead to a myopic shift of refraction and to a state of refractive anisometropia, for which contact lenses are ideal (*see* Chapter 5). Difficulties then arise, however, if the refractive error is changing fairly fast, necessitating contact lens power changes every few months. Even so, if disposable or frequent replacement soft lenses are used, this may be less expensive for the patient than frequent changes of spectacle lens, and definitely gives better and more comfortable binocular vision.

As a general guide, contact lenses are likely to be optically satisfactory for all young anisometropes and refractive anisometropes, but where a spectacle correction affords good binocular vision in high anisometropia and has

done so for many years, then contact lenses may well be ruled out as aniseikonia is likely to occur.

Even if the anisometropia is known to be refractive, if spectacles give satisfactory binocular vision, contact lenses may induce a state of pseudoaniseikonia owing to the relative difference between the two eyes of the change in retinal image size. An investigation of the binocular state in spectacles and in suitably powered trial contact lenses is therefore advisable before proceeding to supply final lenses. This is worthwhile because a number of successful cases have been reported (F.A.B. Hodd, 1970, personal communication; Winn *et al.*, 1986). Where the eye with the higher refractive error is also amblyopic the author has often found that contact lens wear slowly improves the visual acuity in that eye. Part-time occlusion of the other eye, while very fine visual tasks are undertaken, has been found to help.

Binocular vision

It may be found that non-comitant heterophorias are recorded at first with contact lenses, as the brain still continues to compensate for the ocular movements made with the anisometropic spectacle correction.

Monocular aphakia is an example in which a contact lens correction may give binocular vision where spectacles will not. However, a contact lens is worn some distance in front of the entrance pupil of the eye and it is by no means certain that contact lenses will give satisfactory binocular vision in this condition because of the residual aniseikonia. The patient may well prefer monocular vision to the asthenopic symptoms of disturbed binocularity.

Heterotropias In general, contact lenses perform as well as spectacles in the treatment and correction of squints. Very often, all that is required to correct a squint is a full correction determined with the aid of a cycloplegic. However, this may mean the patient wearing a heavy and/or unsightly pair of spectacle lenses which tend to be abandoned to the detriment of the squint. In such cases contact lenses are invaluable.

A combination of spectacles and contact lenses permits variations in negative additions for exotropes to be made in the spectacle lenses and, where bifocals would be prescribed for either esotropia or exotropia, contact lenses can be worn for general purposes with additional spectacles to be worn for close work. Difficulties arise where there is a residual high heterophoria requiring prismatic correction or where there is a vertical element needing prism to correct it (*see below*). As most patients requiring refractive corrections for heterotropias are children, soft lenses are particularly useful as they are quicker to adapt to and cause less discomfort in fitting. Also, if they are to be used in combination with spectacles, the latter can be used to provide any necessary cylindrical or prism correction.

High heterophorias These are difficult to prescribe for, using contact lenses, as only about 4 Δ can be satisfactorily incorporated into a contact lens. Only with scleral lenses can the prism base be put in any direction, as long as the scleral zone is a good fit and the lens does not rotate. This allows a maximum of 6 Δ difference between the two eyes. However, with soft and corneal lenses, the base always rotates downwards, which limits any prismatic correction to 4 Δ base-down. In fact, 2 Δ is a more reasonable figure as all the prism must be put on one lens. Discomfort is likely with a very thick lower edge; also the prism base usually takes up a slightly nasal position due to lid action.

Myopes often require less prism in contact lenses than in spectacles, presumably because the bigger retinal image size with contact lenses affords a better binocular lock. However, the mobility of the retinal image, in corneal lens wear, may necessitate greater prism. There is no general rule, but the minimum prism to eliminate any fixation disparity and/or symptoms should be prescribed.

Amblyopia Care must be taken to see that any improved visual acuity given by contact lenses does not give rise to insuperable diplopia. As visual acuity improves, orthoptic exercises may be needed to help consolidate binocular vision.

Eye movements Pareses of extraocular muscles give rise to diplopia with contact lenses as with spectacles. As already stated, contact lenses can affect the amount of eye movement required because they remove the prismatic effects of spectacle lenses, so that both version and vergence movements may be affected.

Aniseikonia A combination of spectacles and contact lenses can be used to create size differences to relieve symptoms due to aniseikonia. The principles are those of a Galilean telescope system, similar to the type used as an aid to the partially sighted (*see* Chapter 23).

Uniocularity Contact lenses are a hazard – even if only a very slight one – and it may be in the best interest of a uniocular person, or one with intractable amblyopia in one eye, not to fit contact lenses unless this considerably improves vision as compared with spectacles, or is otherwise necessary. In any case the patient should be warned of the risk, however small. If spectacles are prescribed these should have plastics or toughened lenses.

Personal and external factors

Age and gender

Incentive, enthusiasm and handling ability are generally better in younger people, although there are remarkable exceptions. Presbyopic contact lens wearers need to use spectacles for near work unless the mono-vision system is used or bifocal contact lenses are fitted – and even when it is possible to fit these, they have certain limitations in use (*see* Chapter 16).

Andres *et al.* (1987) found the tear film BUT insignificantly greater (i.e. better) in men than in women, but they did find a significant reduction in BUT with age. Corneal sensitivity also reduces with age (Millodot, 1977) and in women it is affected by the menstrual cycle reducing considerably during the premenstruum and menstruation (Millodot and Lamont, 1974; Guttridge, 1994). However, in the latter case the possibly beneficial effect on contact lens wear from the slight loss of sensitivity may be offset by other changes (*see below*). Riss *et al.* (1982) did not confirm a premenstrual loss of corneal sensitivity when using an electromagnetic aesthesiometer on three normal subjects, and as Millodot and Lamont used a Cochet–Bonnet aesthesiometer the results may depend on the type of instrument used.

The eyelid tissue slackens with age making, for example, the support of a prism-ballasted bifocal corneal lens more difficult, and other tissue changes associated with ageing lead to less efficient tear drainage from the conjunctival sac. In some people these changes are beneficial to contact lens wear and in others detrimental. Each case must be assessed on an individual basis.

Women undergoing the menopause may experience difficulties with their lenses. Xerosis sometimes occurs during the menopause. Occasionally hormonal changes lead to psychological disturbances and consequent loss of motivation to wear contact lenses. Such changes are most likely to take place at the time of a pregnancy or during the menopause. Pregnancy also frequently disturbs contact lens wearing, presumably due to metabolic changes in the cornea (Imafidon *et al.*, 1993). The change in hormone balance alters the water content of all tissues, including the cornea and lids – which may result in a corneal thickness or curvature change and a consequent alteration in lens fit. The fit of corneal lenses can become dramatically tighter, with very little peripheral clearance where plenty existed before and, if modifications are made to alleviate the ensuing discomfort, the lenses can be made wearable again until the termination of the pregnancy. The cornea then returns to its original state and the modified lenses become loose and uncomfortable, and must either be made smaller or replaced. In this respect soft lenses cause different problems from rigid lenses, as tear output is often reduced during periods of water retention and this, coupled with corneal curvature and thickness changes, can make even soft lens wearing difficult.

Similar effects have been recorded in women taking oral contraceptives (Koetting, 1966), although improvements in these drugs have now reduced the effects to a minimal amount. Difficulties in wearing contact lenses associated with premenstrual tension have also been reported (K. Dalton, 1970, personal communication).

Farrell (1976) showed that a reduction in tear output with associated drop in lysozyme and relative increase in globulin-type protein is to be expected when women first take the oral contraceptive pill, or change to another type, or cease to take it. The increased corneal oedema, reduced lacrimal secretion and increased mucus and lipid content of the tear film may last a few weeks but gradually subside. In a contact lens wearer, though, they may be sufficient to cause difficulty or even abandonment of contact lenses in a very few cases.

In Guttridge's (1994) survey, all the ocular changes associated with the menstrual cycle are discussed, most of which may affect contact lens wear to a greater or lesser extent as all the ocular tissues and adnexa may be involved.

Skin, hair and eye colouring Millodot (1975) showed that, in general, those people with blue eyes and fair skins have more sensitive corneas than others, although there may be considerable variations and exceptions to this rule. Most contact lens practitioners find that auburn-haired patients with fair freckled skin are particularly sensitive to hard and rigid gas permeable lenses. For these people, if appropriate, soft lenses may be the contact lens of first choice.

Ability to handle lenses

Contact lenses should not be supplied unless they can be handled properly by the patient. A light (neutral) handling tint may help. In cases such as aphakia, a spectacle frame can be supplied, glazed to a suitable prescription on one side only, the other 'eye' being left empty and the lower rim removed. The first contact lens is then inserted through the empty 'eye' of the frame, which enables the patient to see it with the other eye. The frame is then removed as the patient is able to see the second contact lens with the first in place.

People, such as the elderly, with very clumsy or shaky hands, may be better fitted with extended wear lenses (soft, rigid gas permeable or silicone rubber) provided they are otherwise suitable. A relation or someone close to the patient should, if possible, be taught the various insertion and removal techniques and be given all the necessary information, so that the lenses may be removed and cleaned periodically (*see* Chapters 4 and 9).

Some soft lenses are much easier to handle than others, the thin and ultrathin ones being most difficult. Ghormley (1988) suggested that very young patients, athletes, men with large hands and others who have handling difficulties be fitted with standard thickness lenses, i.e. centre thickness 0.10 mm for negative lenses, provided that these do not lead to an adverse corneal response during the wearing period.

Working and living conditions

Contact lenses can be difficult to wear in a number of conditions: dusty and smoky atmospheres, hot or cold temperatures, windy weather, and dry or humid atmospheres. An example is that of an aircraft cabin in which the humidity is usually low, and travellers then notice difficulty with their soft lenses due to dehydration. By contrast, hot, humid conditions do not seem to affect soft lenses (Fatt and Rocher, 1994). People working in rarefied atmospheres or at high altitudes may suffer corneal oedema due to lack of oxygen.

Soft lenses are absolutely contraindicated for people coming into contact with any noxious fumes such as workers in the chemical industry.

In poor light conditions, the pupil may dilate to a greater size than the optic zone of a corneal lens so that diplopia (ghost images) or peripheral blur is seen. A large lens with large BOZD or a design which avoids transitions minimizes this problem (*see* Chapter 10).

If excessive light is likely, a tint may be necessary although tinted spectacles worn over the contact lenses may be more practical. Choice of tint must depend on the absorption required and the colour rendering. A neutral tint is preferable for most purposes because, as Fletcher and Nisted (1963) showed, some tints can be dangerous if used under a monochromatic illumination the wavelength of which is not transmitted by the tint. The effects of tints on dark adaptation should also be remembered. Some countries have a legal limit on the maximum light absorption permissible for night driving.

UV-inhibiting lenses

For the aphakic eye ultraviolet-inhibiting tints are advisable. Manufacturers can supply details of the transmission curves of tinted corneal and soft lenses. These are important for the eye is also at risk from ultraviolet radiations:

UV-A – 315–400 nm
UV-B – 280–315 nm
UV-C – 100–280 nm

(There is some overlap of wavelength between the three types of ultraviolet radiation.) According to Pitts (reported by Kerr, 1987), those people particularly at risk are: all aphakics and many pseudophakics; cataract patients suffering glare due to lenticular scatter; patients taking photosensitizing drugs such as sulphonamides, tetracyclines and oral contraceptives; patients spending long hours in bright sunlight, as for example, when sunbathing, skiing or mountaineering; patients suffering from pingueculae, pterygia and macular degeneration; and finally workers in vocations which expose them to large amounts of UV-B, such as welders, electronics workers and graphic artists.

Fortunately, where required for patients at risk, contact lenses are available which absorb ultraviolet radiations below about 400 nm. All types of lens material are available – soft, rigid gas permeable and PMMA (Pearson, 1984, 1985, 1986). Although these may be more expensive than their non-ultraviolet absorbing counterparts, patients needing them are well advised to be fitted. Chapters 11 and 23 include further details of ultraviolet-absorbing contact lenses.

Occasionally in very sensitive individuals, and particularly in the early stages of wear, certain head postures and eye movements are rather uncomfortable for wearers of rigid lenses. Looking up continually, as for example when playing snooker, and making rapid lateral eye movements, as in copy typing, may cause irritation and injection. Continually looking down, as when doing close work all day, so that the palpebral aperture size is reduced may lead to corneal oedema in certain contact lens wearers as explained on p. 269.

Patients and practitioners alike have become aware that some RGP lenses, as well as developing surface cracking (*see Figure 18.32* and Chapter 10), at times seem to fracture spontaneously. Silk (1987, 1988) attributed this to electrical effects such as static build-up on the lenses, which may affect the polarity of the material and its surfaces. Some people are more static sensitive than others, and many man-made fibres encourage the build-up of static charges. This may, in extreme cases, explain epithelial damage by such lenses. Silk found the effects to be worse in cold dry conditions rather than wet or humid ones. Thus people wearing clothing made of synthetic fibres or walking on carpets of synthetic material or even playing football on synthetic pitches, may experience more problems with their RGP lenses than at other times. These problems include greater surface deposition, proneness to fracture in the eye, surface cracking and removal of surface epithelial cells.

Drugs

Drug taking can influence metabolism, which in turn may influence contact lens wear. Tolerance trials extended over 4 weeks if necessary (as, for example, in the case of women under hormone treatment) may be advisable before prescribing contact lenses for some patients, as the corneal curvature, especially peripherally, may alter quite dramatically. The effects of oral contraceptives on tear output and corneal oedema have been dealt with under the heading of Age and gender. Other steroid drugs may have similar effects.

Thyroxine treatment has been reported to cause intolerance to contact lenses (Marsh, 1975). Mackie *et al.* (1977) showed that β-adrenergic blocking drugs used for certain heart conditions and as anti-hypertensives may reduce tears output and alter lysozyme concentration. Contact lenses may therefore be contraindicated for patients on prolonged courses of beta-blockers. Diuretics have a similar effect (Bergman *et al.*, 1985).

Drugs used in the treatment of allergies, and tricyclic antidepressants have also been found to cause dry eyes (*see* Chapter 4).

It is wise to check on the side-effects of any regular medication taken by a patient. Those reported to cause a dry mouth are also likely to cause dry eyes. Reference to the Data Sheet Compendium produced annually by the Association of the British Pharmaceutical Industry (ABPI), or similar publication, is recommended.

Diet

As indicated on p. 263 under Xerophthalmia and on p. 269 under Precorneal film, diet can affect the state of the eye and in particular the quality of the tears and their output.

A high cholesterol diet, as well as obesity, have been shown to have an association with increased levels of cholesterol in the tears (Terry and Hill, 1975; Hill and Terry, 1976), while Lane (1985), who carried out hair analysis on

patients with contact lens greasing problems as well as on dry-eyed patients, and compared them with a control group, showed a huge deficiency in potassium and sodium in those with coated lenses. Dietary changes to increase folic acid, ascorbic acid, vitamin B_6 and potassium and to decrease sugar intake (which otherwise reduces potassium in the body), were successful within one month in treating those with coated lenses, and many of the dry-eyed patients improved after several months.

Shreeve (1982) in a study of dry-eyed patients discussed the role of specific prostaglandins – prostaglandin E_1 (PGE_1) being necessary for adequate tear output. The chemicals in the body necessary for the formation of PGE_1 require the availability of insulin, zinc, magnesium, ascorbic acid (vitamin C), pyridoxine (vitamin B_6) niacin (a B vitamin sometimes referred to as B_3) and the essential fatty acid *cis*-linoleic acid found in evening primrose oil and other vegetable oils. The formation of PGE_1 can be blocked by deficiencies of these and by excesses of *trans*-fatty acids, saturated fats, cholesterol, excess alcohol intake, ageing, diabetes, viruses, chemical carcinogens and ionizing radiations. Of interest may be the fact that *trans*-fatty acids are formed when *cis*-linoleic acids, found in corn, sunflower and safflower oils, are heated to a high temperature and otherwise treated to make them acceptable for cooking purposes!

There are probably many other dietary implications, as yet unknown, which may help or hinder contact lens wear and normal ocular function.

Habits

Hygiene is essential in the handling of contact lenses. Eye rubbing should be discouraged, and preferably both active and passive smoking avoided as soft lenses may become discoloured, and nicotine on the fingers can cause eye irritation if transferred via contact lenses (*see* Chapter 4).

Hobbies

Although most RGP corneal lenses can be fitted to give minimum peripheral clearance and are therefore more difficult to dislodge as compared to PMMA hard lenses, they are still less stable than soft or scleral lenses. Soft lenses have therefore become the lens of choice for virtually all sports and have been worn satisfactorily on mountaineering expeditions at high altitude, and by swimmers in chlorinated pools (*see* Chapter 23). There is less risk of them being washed out during swimming than a corneal lens. However, in order to avoid such infection as *Acanthamoeba*, patients should be advised, where possible, to use swimming goggles.

The Sports Council in the United Kingdom does not issue specific advice about contact lens wear, nor does the Sports Vision Association. The regulating authority of each particular sport must be consulted regarding permission to wear contact lenses for professional sports. There are written regulations given for motor racing by the RAC (*see below*). Further general advice is available in *Sports Vision* (Loran, 1995).

For those who need contact lenses for the stage and films, arc lights make photophobia a difficulty. Various tints are available, as are lenses having artificial iris patterns. For effect purposes, contact lenses in the form of cosmetic or prosthetic lenses can be used to alter the appearance and colour of the eyes (*see* Chapter 20.6 and *Figure 23.43*).

If contact lenses are required for only occasional wear, as for social events, soft lenses are by far the best lens to fit. With rigid corneal lenses difficulties are likely to be encountered as a satisfactory tolerance must always be built up beforehand. Daily wear disposable soft lenses are ideal for occasional wearers.

Special occupations

In the UK there are certain restrictions regarding the wearing of contact lenses while driving, or piloting an aircraft, as well as serving in the armed forces or police, and in certain other occupations. Similar restrictions may apply in other countries and regulations regarding the use of contact lenses are normally available from the appropriate vehicle or driver/pilot licensing authority in that country or from the prospective employer. In Australia, according to the Australian Optometrical Association, most of the regulations regarding vision standards are set by State authorities, and so they vary across the country. In the UK up-to-date information is published in their Members' Handbook by the AOP (Association of Optometrists). At the time of writing the following regulations apply in the UK.

Drivers

Since 1983, the wearing of contact lenses has been permissible for all classes of driver including heavy goods vehicle and public service vehicle drivers provided the other visual standards are satisfied. For motorists the minimum visual standards are: VA with corrective lenses, if needed, of at least 0.4 (6/15) in the better eye and 0.2 (6/30) in the worse eye and 0.5 (6/12) binocularly; muscle balance within 2 Δ vertically and 6 Δ horizontally; a horizontal visual field of 120° minimum using a 3 mm white target at 1/3 metre, with a minimum vertical visual field of 20° above and below the horizontal; and an absence of diplopia.

For heavy goods and public service vehicle drivers, new applicants for licences must have a corrected VA of at least 6/9 in the better eye and 6/12 in the worse eye and an uncorrected vision of 3/60 in each eye separately. When renewing a licence first held before 1983, the corrected VA should be 6/12 in the better eye and 6/36 in the worse eye. If cataracts have been removed from one or both eyes then these drivers are only permitted a licence if intraocular lenses have been successfully implanted. Since 1991 monocular vision has become a bar to driving this type of vehicle, as has a pathological visual field defect associated with a loss of normal binocular vision.

The standards of vision laid down by the RAC (Royal Automobile Club) to hold a racing licence in the UK are published yearly in the RAC Yearbook. As far as contact lenses are concerned PMMA or RGP lenses are barred. Soft lenses are permitted but the contact lens practitioner must provide an annual certificate giving visual acuity in soft lenses and unaided vision for each eye. Although rigid lenses are barred a new applicant for a licence who is already a successful rigid lens wearer is likely to be granted approval to wear them and be given a licence on application to the Medical Committee. The current vision requirements are normal binocular vision with full visual fields, normal eye movements and normal stereoscopic vision, and colour vision adequate to distinguish the appropriate 3 ft square flags in red and green. Corrected vision of 6/9 or better in each eye with spectacles or contact lenses, and unaided vision of 6/36 or better in each eye is required, but if unaided vision is worse than this a Medical Committee may allow an existing racing driver to continue depending on his past racing experience.

A most useful publication is *Medical Aspects of Fitness to Drive*, published by the Medical Commission on Accident Prevention (35–43 Lincoln's Inn Fields, London, WC2A 3PN), fourth edition edited by J.F. Taylor, in 1995.

Civil pilots

The wearing of contact lenses is permitted by civil pilots in the UK subject to certain conditions, full details of which are available from the Medical Department of the Civil Aviation Authority (CAA), but broadly the lenses must have been worn constantly and successfully for over 8 hours a day for at least one month. A pair of ordinary spectacles must be carried at all times while exercising the privileges of a licence. Bifocal contact lenses are not permitted. If needed for near vision only half-eye type reading spectacles are permitted. Varifocals and full reading lenses are barred. Radial keratotomy and excimer laser surgery are not recommended for aircrew. To wear contact lenses a medical certificate endorsing approval for their use must be obtained following a report from an ophthalmologist or an approved contact lens practitioner. This must give details of field of vision, unaided vision, corrected VA with spectacles and contact lenses as well as the prescription of each, and confirmation that the contact lenses have been worn for the required length of time.

In Australia, the Civil Aviation Authority requires that pilots (private and commercial) and other aircrew members, who use contact lenses to meet the appropriate visual acuity standards, must be able to wear their lenses for twice the projected length of flight time or duty time without deterioration in visual acuity or comfort and, if they use rigid lenses, they must be able to achieve 6/9 acuity binocularly with spectacles immediately after removal of their contact lenses. The CAA in Australia recommends contact lenses as the preferred form of correction for myopia greater than 7 dioptres.

Police

Most but not all police forces in the UK accept contact lens wearers. Either the AOP or individual Police Authorities should be consulted about their wear and the eyesight standards required.

In Australia, police officers are generally permitted to wear contact lenses. Recently, some applicants have been permitted to enter police forces, despite the fact that they did not meet the unaided acuity standards, when they were able to demonstrate that they were successful contact lens wearers, because the probability of a lens being dislodged while on duty was felt to be extremely low, and that any blow which dislodged a contact lens would almost certainly be incapacitating regardless of the contact lens.

Prison officers

Provided the visual standards can be met, contact lenses are permitted subject to the wearer being able to defend himself and positively identify an assailant should the lenses become displaced.

Railway employees

Train drivers are not allowed to wear contact lenses, nor are workers on the running lines permitted to wear them except in special circumstances and with medical approval.

Fire service

Fire fighters are not permitted to wear contact lenses (or spectacles) in the UK or in Australia.

Defence forces

The Australian Defence Force vision standards, apart from the Royal Australian Navy, do not mention contact lenses, although they list a range of positions which require the ability to perform duties without spectacles, many of which, such as firemen, would probably preclude contact lens wear. In the UK the situation is as follows.

Royal Air Force personnel The Medical Board of the Royal Air Force decides on each individual's fitness and although there are no specific regulations about contact lenses, the RAF's Consultant Adviser in Ophthalmology usually makes the decision as to whether or not they may be worn in particular circumstances.

Royal Navy personnel There is no general restriction to the wearing of contact lenses to improve visual efficiency provided that the required visual standards are met. This also now applies on Australian Royal Navy warships where officers are to be tested annually.

Merchant Navy personnel Although not part of the Defence Forces, Merchant Navy regulations are included

here for comparison with those of the Royal Navy. Apart from those in the 'Deck Department' where no visual aids of any kind are permitted, contact lenses are allowed provided satisfactory visual standards are achieved and spare contact lenses or spectacles are available when on duty.

New entrants to the Merchant Navy or fishing industry are not allowed to wear any artificial aids to vision during the sight test and must not have had any treatment, designed to improve their form vision temporarily, undertaken shortly before the test. This would preclude the use of orthokeratological techniques to improve unaided vision.

Army personnel The Army Medical Board judges each candidate's fitness on merit and there are no specific regulations about contact lens wear.

Sufficient has now been said about indications, contraindications and selection of patients and contact lenses, as well as the factors to be considered in the choice of the best type of lens to fit. The reader must realize that both frustration and satisfaction are to be the lot of the contact lens practitioner at different times and with different patients.

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Chapter 9

Patient management and instruction

K.W. Atkinson and M.J.A. Port

Introduction p. 282
Routine examination p. 284
General ocular examination p. 284
Insertion and removal of rigid lenses p. 286
Insertion and removal of scleral lenses p. 290
Insertion and removal of soft lenses p. 291
Insertion and removal of composite (Softperm) lenses p. 293
Reactions to the first lens p. 294
Refraction with contact lenses p. 295
Ordering p. 296
Selecting a care system p. 297
Dispensing contact lenses p. 297
After-care p. 299
Fitting children's contact lenses p. 300

Addenda:
1 Instructions to the patient on the care and handling of soft contact lenses p. 300
2 Instructions on chemical disinfection routines p. 302
3 Instructions on hydrogen peroxide routines p. 303
4 Instructions on Optimeyes, Softab and Aerotab soft lens disinfection routines p. 304
5 Instructions to the patient on the care and handling of disposable lenses p. 305
6 Instructions to patients wearing rigid gas permeable contact lenses p. 306
7 More information for contact lens wearers p. 308
8 Instructions for patients with monovision lenses p. 309
9 Instructions for orthokeratology patients p. 310

Introduction

Patient management is the bringing together of a number of skills in contact lens practice. It involves building a rapport with the patient so that he or she has confidence in the practitioner's ability. It also requires good communication with the patient. The practitioner needs to listen to the patient's concerns, and in turn be able to communicate well in order to inform the patient completely about contact lenses.

The topics involved in this include the following:

- Patient information and indoctrination
- Patient selection and preparation for contact lens wear
- Selection of appropriate lens type and material
- Insertion and removal of contact lenses
- Establishment of a 'good fit' and accurate over-refraction
- Selection of appropriate lens care and maintenance system
- Ordering and verifying of contact lenses
- Dispensing contact lenses
- Complete after-care

Discussion with a prospective contact lens wearer should include the following topics:

- Comparison of contact lenses and spectacles
- Differences between the various lens designs
- Discussion of planned replacement versus conventional lenses and comparative costs
- Care systems and follow-up
- The part of the contact lens wearer in ensuring their success and in minimizing any risks involved

Having either written or video material for prospective wearers is useful, and will help reinforce the verbal information given (see Addenda at end of chapter).

Some of the psychological factors likely to influence a patient have already been mentioned in Chapter 8. Many of these are worth repeating because the way in which a patient is managed is as important as pure technical ability and can make the difference between success and failure.

It is necessary for the patient to have confidence in the practitioner, in order that the patient who commences lens wear continues with contact lenses in spite of occasional difficulties, and accurately follows all the instructions.

Simple terms should be used in explanations. Before examining a patient's eyes, it is wise to discuss the characteristics of the types of contact lenses. It is important to correct any mistaken ideas the patient has acquired. The practitioner should beware of making extravagant claims which may lead to loss of patient confidence or even legal proceedings if they are not met. A full explanation and discussion must cover any points on which the patient may require information.

There may be interest in refractive surgery as an alternative to contact lens wear. The practitioner should be familiar with the pros and cons of these procedures for different refractive states. Good visual performance after such procedures is critical to certain occupations and such phenomena as poor contrast sensitivity should be explained.

The reasons given by the patient for wanting contact lenses are important and as long as these are addressed, a successful outcome can usually be achieved, assuming the practitioner is competent enough to deal with any fitting difficulties. Patients most commonly want lenses for cosmetic reasons and for sports, but the type of lens fitted needs to be selected on the basis of intelligence, dexterity, environment and motivation as well as the patient's needs.

A demonstration may be useful. Even though contact lenses are in wide usage, many people are still unsure of size and flexibility, for example. The practitioner might consider a demonstration on his own eyes before fitting the patient's eyes. If lens insertion and removal can be shown to be smooth, simple and painless, confidence in the practitioner is enhanced and at the same time the patient's apprehension is reduced regarding their ability to tolerate contact lenses.

Discussion tends to relax patients; they are normally tense and worried at the first visit. This discussion should include the advantages and disadvantages of contact lenses together with a brief résumé of adaptive difficulties. Their reasons for using different types of contact lens can be given. It is important to anticipate a particular patient's visual expectations wherever possible.

Soft lenses may give a reduced visual quality even though Snellen acuity is good (Applegate and Masof, 1975). Visual degradation may be caused by surface drying, surface distortion and surface deposits. The use of contrast sensitivity tests or low contrast charts may give more information than just the Snellen acuity (Woodhouse, 1987).

The practitioner should explain how much time is involved in fitting and what it entails. The patient should be informed of the annual cost of wearing contact lenses. This normally consists of a fee for after-care, the cost of replacing lenses, and the cost of maintaining the prescribed hygiene regimen. Also regular after-care visits after the initial supervised period will be necessary, for which a fee is normally charged. These may be carried out at 9- or 12-month intervals, and more frequently for extended wear lenses.

It would be unethical to promote contact lenses merely on the cost of lenses alone. The costs of hygiene are significant and if the wearer attempts to reduce these without knowing the consequences, practitioners are to blame.

Collins and Carney (1986) found that only 25% of patients within their sample were truly compliant with practitioner instructions. They further found that a worsening ocular response to contact lenses was correlated to non-compliance with hygiene regimens. Radford *et al.* (1993) found 45% were reasonably compliant. They found that reinstruction raised the compliance level to 85% which demonstrates that regular revision of contact lens hygiene procedures is important.

A major advantage of practitioners' supplying lenses is that the patient should be prompted as to when their last after-care check occurred and the need for the next one. There is probably a global trend for lenses to be supplied from non-professional sources because of lower prices and competition. If this trend continues there is an increasing need to educate patients about their own reponsibilities in having regular checks of eye health. In fact there is some evidence (Port, 1991) that both the level of practitioners' contact lens education and generic information in the media affect the contact lens wearer's appreciation of risks and responsibilities.

Most patients wish to know how long their lenses are going to last. With careful handling, cleaning and storage, PMMA lenses might last from 5 to 15 years but are now rarely fitted. With rigid gas permeable (RGP) lenses a typical life of 2–3 years may be expected. The polymers are softer and scratch or distort more easily and this may adversely affect comfort, performance and optical quality. One to two years for a soft lens is probably about the longest useful life. Taking loss or breakage into account, there may be little difference between the average life of an RGP and a soft lens, but the use of planned/frequent replacement and disposable lenses has created a revolution in contact lens practice. Planned/frequent replacement lenses are replaced at a maximum of every 3 months. Disposable lenses are currently soft lenses which are worn on a daily or extended wear basis and have a life of 1 day to 12 weeks depending on the type of lens. Lenses replaced on a regular basis will be less coated with protein leading to fewer episodes of inflammatory or antigenic response and a lower risk of infection.

Long-term contact lens wearers have a tendency to extract all the life possible from a lens and will often wear their coated and damaged lenses for an extended period of time, putting up with irritation, red eyes and reduced tolerance before ordering a replacement.

Although extended wear (EW) lenses have received much publicity, their usage has now declined because of their greater risk of infection (Schein *et al.*, 1989). In certain situations and occupations EW lenses are still used, e.g. military personnel, medical personnel on long duty shifts and the elderly who cannot manage the insertion and removal of lenses or cannot comprehend the hygiene regimes. The use of lenses during sleep is possible with certain RGP lenses and as these materials have higher gas permeability than hydrogels, they can meet the cornea's oxygen demands better during sleep. Also, tear pump action can clear debris and metabolic waste from beneath the lens as soon as the eye opens and blinking occurs. Benjamin (1991) suggests that the adverse longer-term changes to the cornea are less when compared to hydrogel lenses in EW (*see also* Chapter 15).

Prolonged or flexi-wear can mean that lenses are worn occasionally during sleep but not on a regular basis. Lenses can be prescribed to have this potential.

Disposable lenses are often presented as needing less effort with care systems, but the risk of infection remains and abbreviated care systems may encourage poorer hygiene and greater risks of keratitis (Tomlinson, 1992). The lenses are inexpensive to replace and the wearer will also benefit from having spare sets of lenses to replace lost or damaged ones. Although some disposable lenses have been marketed as being safer for extended wear, none of the soft lens materials currently available has sufficient gas transmissibility to be safe for long-term overnight wear for all patients (*see* Chapter 15). Lenses in the 'disposable' category are replaced monthly, fortnightly, weekly, or daily.

Routine examination

Routine examination helps to determine the limitations that the patient may impose on the possibility of successful contact lens wear. It also helps to determine which type of lens will be most suitable. The patient's history is most important and should cover all the contraindications mentioned in Chapter 8, with particular reference to general systemic conditions, systemic medication, allergies, previous ocular pathology and general ocular history (squint, amblyopia, eye operations and diseases).

The refractive condition of the patient should be considered as follows:

- Degree and type of ametropia, and whether or not corrected. Differences between the corneal astigmatism and the spectacle astigmatism are worth noting (*see* Chapters 5 and 14).
- Length of time spectacles have been worn. The patient may feel incomplete without spectacles if these have been worn for a considerable number of years. Conversely, the ability to see clearly without spectacles may be a strong motive.
- Whether the prescription is worn continually or only intermittently. A patient who wears a spectacle correction intermittently may not have sufficient motivation to persevere with contact lenses.
- The best visual acuity with the spectacle correction worn, the best visual acuity obtainable and whether or not the patient has been fully corrected previously.
- Correction required for vocation or leisure activity. It may well be, for example, that a gardener or rugby player will not need the good acuity of a graphic designer.
- The need of a correction for near vision. Motivation may be lessened when the patient realizes that a near correction is still necessary with contact lenses, be this in the form of bifocal contact lenses (*see* Chapter 16) or supplementary reading spectacles. Myopes find that presbyopia appears slightly earlier if they are wearing contact lenses rather than spectacles (*see* Chapter 5).
- Tints – rigid and soft lenses are available in a wide range of tints. The purpose may be to aid location of the lens, to counteract photophobia, to change the colour of the iris, or to provide protection. The last case is particularly important for aphakic eyes. Without a crystalline lens, the retina receives a much higher level of ultraviolet light and adverse effects of this have been reported (Wittenberg, 1986). A contact lens for aphakia should therefore incorporate some tint that absorbs ultraviolet wavelengths (*see* Chapter 8). Soft lenses normally have their tinted portion the same size as the iris. The tinted portion may surround a clear pupil area if it is needed purely for cosmetic reasons.

If the patient knows other contact lens wearers, their success or failure may affect the patient's attitude and it may be worthwhile to mention individual variations in contact lens tolerance; for example, hours worn, degree of adaptation, lens comfort.

General ocular examination

Some parts of this examination assume added importance in contact lens work, but the following is a guide to the necessary tests (Chapter 8 gives an expansion of this information).

- External examination.
- Motility.
- Measurement of heterophorias at distance and at near. (Vertical prism can be included in all lenses but horizontal prisms can only be incorporated in scleral lenses and then only up to 3△ in each lens.) Cover test for squint; speed of recovery of heterophoria; measurement of near point of convergence; fixation disparity tests.
- Visual acuity with spectacles.
- Ophthalmoscopy.
- Retinoscopy: a swirling movement may be indicative of keratoconus, but it is also seen just after removal of PMMA lenses in some patients. A rigid lens which has bound onto the cornea after overnight wear produces a characteristic retinoscopy reflex.
- Refraction – if the best acuity obtainable with trial lenses, of one or both eyes, is worse than 6/6, the practitioner should endeavour to find a reason for this. Checking with a pinhole disc may be useful.
- Measurement of intraocular pressures and visual fields as necessary.

External ocular characteristics related to contact lenses

General considerations

- Vertical and horizontal measurement of palpebral apertures.
- Vertical and horizontal visible iris diameters.
- Pupil diameters in average illumination and the maximum diameter in low illumination. It is most convenient to do this with a hand-held ultraviolet lamp. The fluorescence of the crystalline lens seen thus makes

comparison with a pupil gauge easier. Pupil diameter is particularly important when rigid lenses are to be fitted where the BOZD should be larger than the pupil diameter under scotopic conditions. It is also important in bifocal lenses with discrete optic zones. The efficacy of these zones can vary considerably under different luminance conditions as the pupil varies in size.

- Any irregularity of the pupil shape and any difference in size between the two eyes.
- The profile of the cornea should be observed against the lower lid margin for Munson's sign (this is visible in moderate to advanced cases of keratoconus when the ectatic cornea distorts the outline of the lower lid margin, although this should not be relied on as a diagnostic sign). The anterior chamber depth, the central corneal radius and the nature of the limbal junction may be estimated at the same time.
- The size of the globes should be noted, i.e. large or small, and the general shape of the sclera.
- Lid tension, texture and thickness.
- Conjunctival texture, thickness and vascularity. Abnormalities are recorded; for example, pingueculae, limbal injection, blebs. It is important to examine the upper and lower lids using a slit lamp. Lid margins and palpebral conjunctivas should be examined for signs of meibomianitis and meibomian gland dysfunction (*see Figure 18.17*). The upper lids should be everted and the lower lids pulled down to examine the palpebral conjunctival surfaces for colour (hyperaemia) and surface texture. The distribution, size and appearance of conjunctival follicles should be noted and recorded, and related to the general history of allergic response.

As with other aspects of the slit-lamp examination (limbus, oedema, vascularization, staining, bulbar injection etc.), it is useful to have a ranking (grading) system. For example, palpebral conjunctival colour:

0 = normal
1 = mild hyperaemia
2 = moderate hyperaemia
3 = severe hyperaemia

The patient record might show 1/3, indicating grade 1 on a scale of 0 to 3. Typical grading scales are shown in Appendix D at the end of this book.

Other considerations

- It is useful to make a drawing of the upper and lower lid positions relative to the cornea. The importance of this together with other lid characteristics should not be underestimated especially when the centration and performance of rigid lenses is being considered.
- Corneal sensitivity can be established grossly using a wisp of tissue. Correct use of a corneal aesthesiometer will give more accurate information. An instrument designed by Cochet and Bonnet (1961) or Draeger (1984) is the technique usually employed.

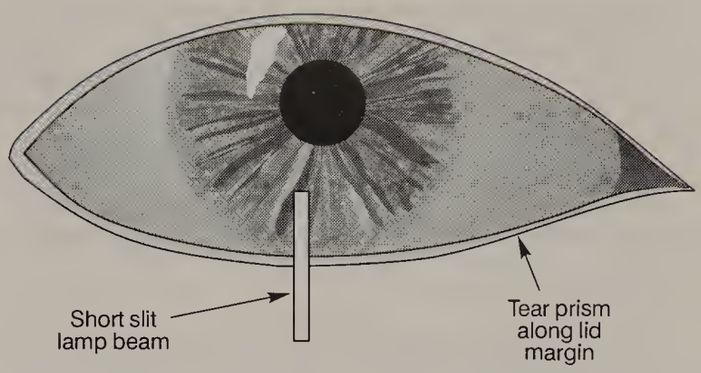


Figure 9.1 Determination of the height of the central inferior tear prism using a short slit-lamp beam of a known width for comparison

- Keratometry (*see* Chapter 6).
- A thorough slit lamp examination (*see* Chapters 6 and 8). Where possible this should include pachometry, to measure at least the central corneal thickness (Stone, 1974). The pachometer should be properly calibrated and a mean of three readings is more useful than a single reading. The practitioner should be aware of the effect of menstrual and diurnal variations in corneal thickness (Fujita, 1980; Guttridge, 1994).
- A Placido disc, Klein keratoscope or corneal topographic mapping device should be used if prior examination has led the practitioner to suspect the presence of keratoconus or corneal irregularity. Keratometry, slit-lamp examination, refraction, visual acuity and pachometry also give clues.
- Assessment of tear output and volume. Significant departures from the norm can be detected using a thread test (Hamano *et al.*, 1982) or with Schirmer paper strips. The figures given by Zappia (1972) are fairly typical but variation is wide (Schapiro and Merin, 1979).

  Paper strips with transparent covers helps minimize evaporation from the strip and they are therefore more efficient than the original design.

  A large percentage of the tear volume is held in the tear prism which interfaces the lid margins and globe. Careful inspection of this prism gives an indication of tear volume (*see Figure 18.47*). Look for thinned areas of the prism, especially on the temporal portions. A simple way of measuring the height of the tear prism (which should be 0.25 mm in height, (Port and Asaria, 1990) is to adjust the beam of the slit lamp to a known width, e.g. 0.25 or 0.5 mm, and compare the width of the focused beam to the height of the tear prism (*Figure 9.1*). Care should be taken to use a short beam as a normal long beam will allow light to enter the cornea and this will stimulate tear production.
- Tear film integrity is assessed. The non-invasive break-up time (NIBUT) should be checked first (*see* Chapter 8) as the use of fluorescein produces an abnormal tear film (Mengher *et al.*, 1985).

  Using a slit lamp, fluorescein and blue light, the fluorescein break-up time (BUT) is then assessed. The

patient is told to blink normally once or twice and then to stop blinking and not to blink during the test. The number of seconds is noted until dry spots appear in the tear film (*see Figure 18.28c*). Lemp *et al.* (1970a,b) found that a BUT of less than 10 seconds was critical although in oriental patients such a BUT is normal. The BUT remains the most readily available tear film stability test and has been shown to be both sensitive and specific in dry eye conditions.

- Fluorescein should be instilled in all cases and Rose Bengal where dry eye or topical skin conditions suggest that more information is necessary.
- Photography of the external eye with both white light and ultraviolet light may be helpful (*see* Chapter 7).

Not all the above tests are necessary for every patient, although it may be valuable to carry them all out. The practitioner must be very careful to examine the eyes for active or passive pathological conditions before proceeding to place a contact lens on the eye.

If the history or oeular examination yields evidence that an active pathological process is present, then the patient should be referred to their doctor or ophthalmologist as appropriate. If the patient is receiving treatment for a general condition it may be prudent to contact the general medical practitioner concerned to discuss the advisability of fitting contact lenses. In the case of a passive condition, careful notes and diagrams should be entered on the patient's record card. Such conditions may not preclude successful contact lens wear, but the patient should be made aware of their presence.

If, for example, an early case of endothelial dystrophy had been discovered and it is decided not to proceed with fitting, it would be wise to inform the patient and provide a covering note to this effect. The practitioner should obviously keep a copy for his or her own protection. This same patient might well consult someone else with a view to having contact lenses fitted. Such a subtle condition could well be overlooked and contact lenses might be supplied to the detriment of the patient's cornea, unless the patient has already been told why he was rejected for contact lenses. Where conditions exist that are 'abnormal' but may not fit precisely into an 'active' or 'passive' category, the opinion of an ophthalmologist should be sought, who may also be able to give opinions as to whether such conditions would be aggravated by the wearing of contact lenses.

Because changes in the eyes, seen at a later date, may be blamed on contact lens wear, it is of paramount importance that accurate records are kept, both of the initial observations and at every subsequent appointment. Having completed the discussion and evaluation it is necessary to decide whether to proceed with fitting, bearing in mind the contraindications which might have been discovered.

If the decision is to proceed with contact lens fitting, the practitioner must determine whether to fit soft, rigid or some other design of lens. The choice between lens types is not always easy. Many patients will demand soft lenses on the basis of comfort but may not appreciate the disadvantages. Although new wearers do usually find rigid lenses cause greater lens awareness, those who have previously worn soft lenses can often change to RGP lenses without difficulty. Practical problems such as environmental conditions may have an influence on lens choice. Those needing lenses to be held very securely in the eye e.g. in some sports, are better served with soft types, as are those who wish to use lenses on an occasional basis (Benjamin, 1991).

Insertion of the first lens

The method of lens insertion and removal by the practitioner and by the patient are very similar – although, of course, the patient may occupy a different position, either sitting or reclining backwards when a lens is being inserted by a practitioner, and leaning over some flat surface or looking into a mirror when inserting their own lenses. The methods described in this chapter are only some of those which can be used, and variations can be left to the ingenuity of the individual.

It is better, where possible, to use finger methods as these are less likely to cause trauma and, when it comes to handling lenses, confidence is more easily achieved when a minimum of artificial aids is necessary. If a suction holder is the only means of lens removal, the patient will bc in a dilemma if it is lost. For this reason suction holders should only be supplied for removing lenses from the cornea as a last resort after all other methods have been attempted, and where necessary a spare should always be supplied.

Patients with enophthalmic eyes and loose lids may have to rely on a suction holder for lens removal. The safe and hygienic storage of the suction holder must be emphasized to users.

Insertion and removal of rigid lenses

Finger method of insertion

The lens is placed on the forefinger of one hand. The second finger of this hand is used to hold the bottom lid down and also to steady the inserting hand. The other hand is used to hold up the top lid and, while some fixation point is regarded with the other eye, the lens is gently placed on to the cornea. If the lids are held apart for a moment after the lens has been placed on the cornea, then the lens is less likely to be dislodged on the first strong blink. The patient should then look down. Best lid control is obtained if the lids are held near or underneath the lashes (*Figure 9.2*).

By the practitioner

Standing beside the patient, ideally the practitioner should work on the same side as the eye being fitted for best lens control. It needs a little practice to becomc equally adept with either hand, but the ease of doing it this way makes practice worth while.

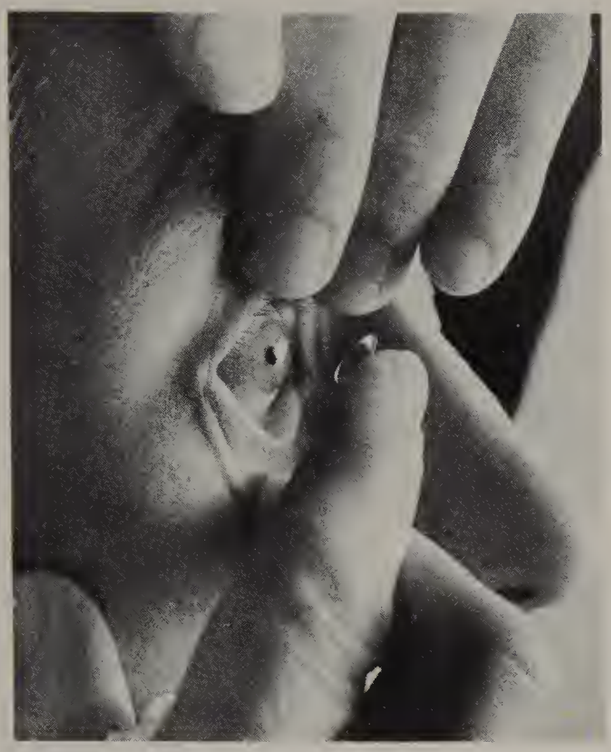


Figure 9.2 Insertion of a corneal lens

The patient's head should be upright with the back of the head against the headrest of the chair.

The patient is instructed to look at a suitable object so that the line of sight is depressed, and the lens is gently placed on to the upper part of the cornea and allowed to move into place before the lids are released.

The patient's head should remain in the same position after the lids have been released. Looking up and around tend to be initially uncomfortable.

By the patient

This may be done over a horizontally placed mirror. Fixation is maintained by the eye which is not receiving the lens. This reduces the avoidance reflex causing eye deviation, if the lens is watched as it approaches the cornea. When the lens insertion technique has been mastered efficiently with the mirror the patient should try to insert the lens without the mirror. The eye receiving the lens then has to fixate the lens or, better still, looks directly ahead so that the cornea remains centred within the palpebral aperature.

Many patients prefer to learn this way as it can be more difficult to see the eye receiving the lens in a mirror. Also a mirror is not always to hand in an emergency.

Some patients prefer to use a vertical mirror. They should be warned that the lens is more likely to slip off the finger and get lost with this method.

The patient learning to insert corneal lenses has to remember a number of points and they are not always coordinated immediately. Four main points are worth underlining when instructing the patient:

1 Keep a very firm grip on the lid margins; some patients find it better to raise the upper lid from underneath the eyelashes.
2 Only let the lids go when the lens is definitely felt to have settled on the cornea.
3 Keep both eyes open during insertion as this helps relax the eyelids.
4 Keep fixation stationary until both lids have been gently released.

Insertion by the suction holder method

It is safer, if possible, to use a hollow suction holder as it is easier to release the suction once the lens is in place.

Instead of being placed on the forefinger, the lens is lightly pressed on the end of a moistened suction holder and transferred from this to the eye by the technique set out above. This is a less satisfactory method than placing the lens on the forefinger as it is more likely to cause damage when inexpertly used and generally causes a larger avoidance eye movement. It also relies on the patient always having a suction holder to hand.

Variations of the suction holder technique are sometimes employed and usually incorporate a fixation target such as a light seen through the hollow suction holder handle. High hyperopes, presbyopes and aphakes may have to resort to such methods of lens insertion if they cannot see to manipulate the lens at short distances. They may also find it useful to have a spectacle frame, glazed on one side only with a prescription for near work. The lower part of the front on the other side is removed from the frame and the first contact lens is inserted through the empty half of the frame. It should then be possible to see to insert the second lens.

One-handed insertion

This method is occasionally necessary when a patient has only one hand which can be used. In this case, the lids are held apart with the first and third fingers while the second finger is used to place the lens on the eye. Some patients can inhibit the blink reflex so well that they only need hold the bottom lid down with the middle finger and place the lens on the cornea with the forefinger.

Insertion technique variations

Patients often develop ingenious and sometimes awkward-looking methods for inserting and removing contact lenses. As long as the method is unlikely to damage their eyes or lenses there is no reason for change.

Removal of rigid lenses

All methods which use the fingers and lids have a common underlying principle. This should be understood by the practitioner and explained to the patient.

- The lens is held in position by capillary attraction.
- To break down this attraction air must be introduced between the cornea and the back of the lens.
- To achieve this the edge of one or both lids has to lift the edge of the lens. When attempting this, if the top lid slips over the lens it will now hold the lens in place. Should this occur, there is no point in pulling the lids further and harder – one has to start again and ensure that the lid margins stay on the lens edge.
- Any technique which results in the lid margins coming away from the globe is likely to fail.

By the practitioner

One finger is placed on the upper lid immediately above the centre of the lens and the finger or thumb of the other hand placed on the lower lid below it. The lids are pulled slightly apart and then the fingers and thumbs are gently pressed on to the eye and towards each other, lifting the lens away from the eye.

By the patient

With the cornea central in the palpebral aperture, the lids are opened as wide as possible. To keep the lids taut the patient should keep their eyebrows raised and stare wide all the time until the lens is expelled. The forefinger, middle finger or thumb is placed at the outer canthus. The lids are then pulled outwards in the direction of the top of the ear so that both lids are tensioned equally at the top and bottom of the lens. An extra pull with the finger or a strong blink will then lift the lens off the eye as shown in *Figure 9.3*. Some patients find that a slight head turn to position the cornea just in the nasal part of the aperture is a useful posture to adopt prior to starting the removal technique. As the lens comes off the cornea it may drop, in which case it can be caught with a free hand. Alternatively it may stick on the lashes. In this case the patient closes the eyes and then removes the lens with the fingers.

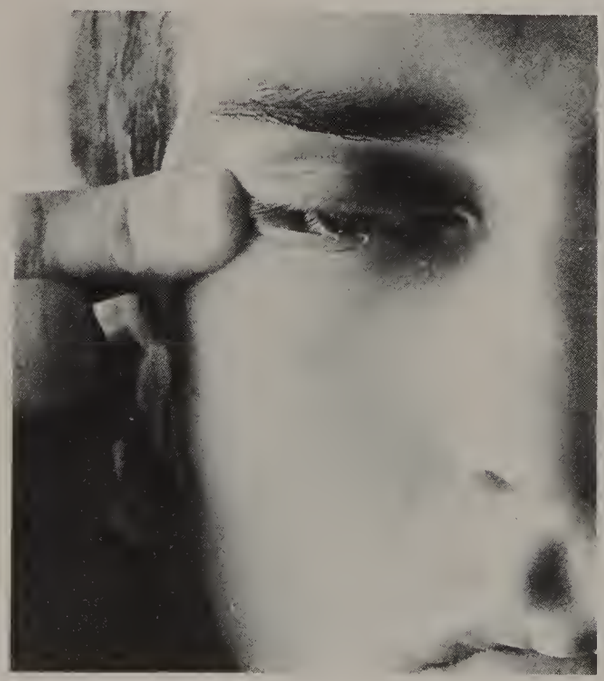


Figure 9.3 Lid removal of a corneal lens using one finger



Figure 9.4 Lid removal of a corneal lens using two fingers

'Scissors' method of removal

Using one hand

The cornea is again positioned centrally or slightly nasally in the palpebral aperture. The middle finger is placed on the upper lid margin and the third finger on the lower lid margin as shown in *Figure 9.4*. The two fingers can control the upper and lower lids independently. It is important that the margins are in contact with the globe; an 'ectropion' lid posture cannot result in successful lens removal. When correctly positioned, the lids are pulled towards the ear as described above.

Using two hands

The forefingers of each hand are positioned on the top and bottom lids as shown in *Figure 9.5* and *9.6*. The method is essentially the same as in using one hand only.

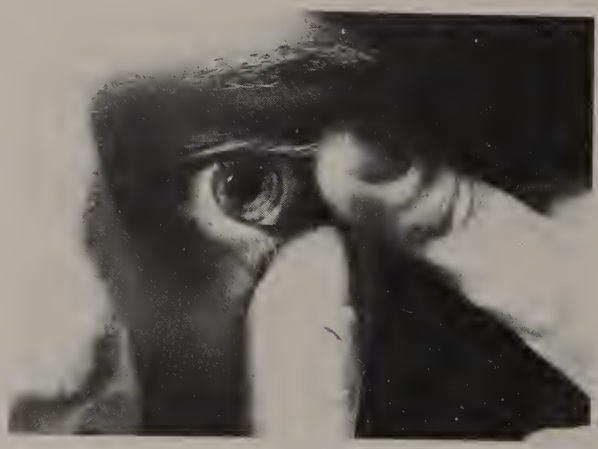


Figure 9.5 Lid removal of a corneal lens using one finger of each hand



Figure 9.6 Later stage of removal – the lens is just coming away from the cornea. Temporal movement of the lens is almost inevitable

The scissors method is normally used when the conventional method is inadequate, the usual reason for failure being the top lid descending over the lens while the pulling action occurs. Before trying the scissors method it may be worth positioning the single finger more on the top lid rather than exactly at the outer canthus.

A variation of this method is similar to that used by the practitioner placing the fingers on the lid margins just above and below the highest and lowest parts of the lens. The lid margins are then used to lift off either the superior or inferior edge of the lens. Care should be taken not to use too much force and cause discomfort.

Suction holder removal of lens

The lids are held apart in the same way as that used for inserting a lens. With the top lid held up by the free hand and the lower lid held down by the hand using the moistened suction holder, the thumb and forefinger hold the suction holder bulb, which is squeezed before the flat end is pressed gently against the lens. Alternatively the lids can be held apart using the forefinger and thumb of one hand while the suction holder is held in the other hand. When the pressure on the bulb is released, the lens is sucked on to the holder and can be removed from the eye.

Sometimes a small twist as the lens comes off the cornea helps to break the suction between lens and cornea (*Figure 9.7*). This method is often useful when dealing with a tense patient.

A large amount of suction is not required in most cases. A common fault is not placing the cup end of the suction holder central and parallel to the lens. Patients having to use this method as a last resort usually have narrow apertures and/or enophthalmic eyes.

Before any repeated attempts are made at lens removal by this method, the patient should be instructed to check that the lens is still on the cornea in order to prevent possible corneal insult by the suction holder. The normal way is to ask the patient to close or cover the other eye. If the vision is still good then the contact lens is still in place.



Figure 9.7 Using a suction holder to remove a corneal lens

With all the above methods of lens removal, the practitioner must be willing and able to help the patient by demonstrating on their own eyes. It is also useful to remove a lens from the patient's eye to demonstrate a particular aspect; for example, the force used by the fingers when pulling the lids.

When using the fingers in conjunction with a mirror the practitioner must emphasize that pulling on the lids after the top lid has passed over the lens edge can have no effect except to keep the lens in and make the eye sore. Similarly, it is difficult to remove a corneal lens if there is excessive lacrimation. Tears should be allowed to subside before attempting removal. The lid margins can then grip and pass under the lens edges more effectively.

Lens on the bulbar conjunctiva

Some corneal lens wearers habitually place the lens on to the conjunctiva and then centre it. Occasionally, the practitioner may place the lens on to the conjunctiva of a nervous patient and then move it carefully on to the cornea. More frequently a corneal lens locates itself on the conjunctiva from faulty insertion or removal technique. The patient must be able to find the lens if this happens, and it must be emphasized that the lens cannot get lost behind the eye. The position of the lens can usually be located because it can be felt as the eye moves, except when in the upper fornix. To expose the lens maximally, it is usually easier to use a vertical mirror. The patient can expose various sections of the bulbar conjunctiva by

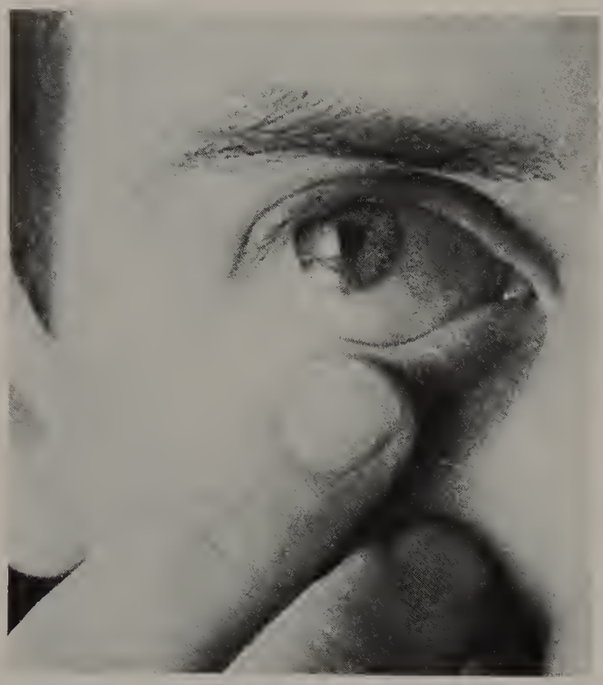


Figure 9.8 Centring a corneal lens with the lower lid

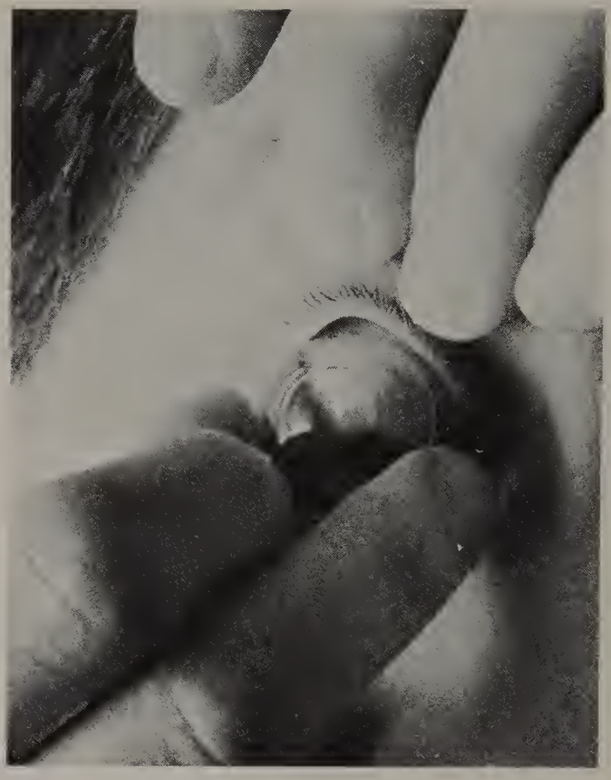


Figure 9.9 Inserting a scleral lens

appropriate head movements; for example, tilting the head down and looking up, if the lens is displaced downwards. Pulling the lids away from the globe can also help in the search for a misplaced lens. Having found the lens it can be recentred on to the cornea by using the lid margin to push the lens into the required position or back on to the cornea.

Figure 9.8 shows a lens being moved from the lower conjunctival sac towards the cornea. The lid is pulled down as necessary, so that the margin is beyond the furthest edge of the lens. Then, using one finger or two to prevent the lens moving sideways, the lid margin is used to push the lens back on to the cornea. It is useful to press down gently on the edge of the lens furthest from the cornea to lift the lens edge closest to the cornea and minimize the risk of abrasion when the lens is centred. From the patient's point of view the lens is most easily centred when it is on the upper or lower sectors of the conjunctiva. It is often simpler to move the lens into one of these areas before attempting to centre it. Again, the lid margin can be used to move the lens across the conjunctiva to the desired area. When using the lower lid to manipulate the lens, it is best to tell the patient to hold the upper eyelid up, out of the way.

Alternatively, the lens can sometimes be located by closing the eye and feeling through the lids with one or two fingers. The lens may be centred by forming the fingertips of one hand into a circle and, with the eye still closed, massaging through the lids to centralize the lens. This is a haphazard approach and is often unsuccessful. It can be useful if the lens has moved into the superior fornix where it may be occluded by the orbital margin.

If the lens displaces during lens removal, it is advisable to recentre it before further attempting removal.

Insertion and removal of scleral lenses

Insertion

The insertion methods are the same whether done by the practitioner or by the patient. The lens is best inserted into the superior fornix. With the eye looking down, the upper lid is lifted by the opposite hand. The lens is grasped at or slightly below its horizontal meridian on each side by the thumb and second finger (*Figure 9.9*). If the lens is fenestrated, then the fenestration should be orientated before the lens is inserted on to the eye. The first finger is positioned against the lower front optic zone and serves to support the lens. The top edge of the lens is gently touched on to the superior portion of the bulbar conjunctiva and allowed to follow the contour of the eye into the superior fornix. While it is held in this position by the fingers, the forefinger of the other hand is used to manipulate the top lid down over the lens, which holds the lens in position. The patient then looks up and the lower lid is simultaneously pulled down so that the lower portion of the lens moves on to the inferior bulbar conjunctiva and the lens is then in position. During this procedure, blinking or closing the eyes must be resisted as a really hard blink may trap the lower lid under the lower edge of the lens and it is then necessary to pull the lid free so that it moves comfortably over the lens.

Sealed RGP scleral lens wearers need to insert the lens with the optic zone filled with saline. This is feasible with all scleral lens types. In this instance the lens is held and inserted horizontally.

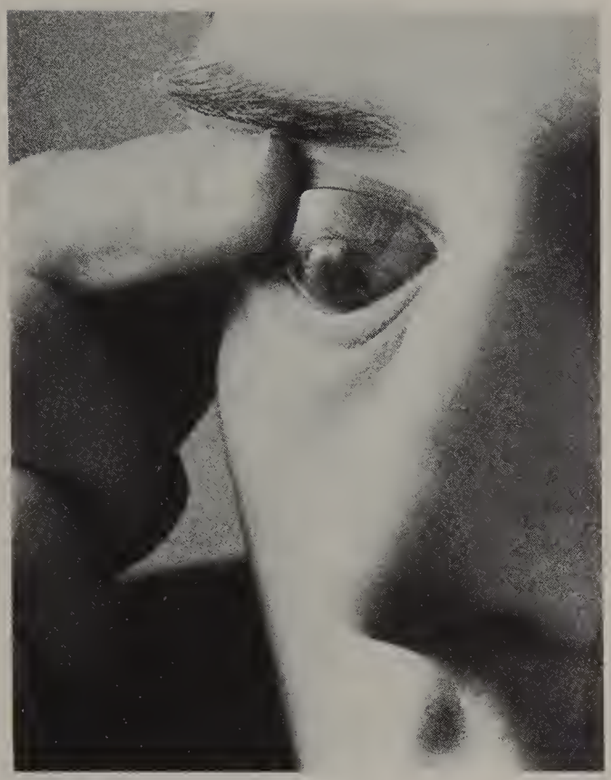


Figure 9.10 Lid removal of a scleral lens



Figure 9.11 Inserting a soft lens

Removal

Removal is accomplished by looking downwards, which exposes the upper edge of the lens when the upper lid is raised. The tip of the forefinger is used to hold the top lid at its nasal margin close against the eye above the lens, and pulling it taut up across the superior aspect of the eye causes the lid margin to move under the top edge of the lens and lever it away from the eye. By looking upwards and pulling the lower lid away from the eye, the lens is finally expelled (*Figure 9.10*).

Alternatively, a small suction holder placed on to the superior scleral zone of the lens may be used to pull the top of the lens away from the eye if the lid method is not successful. A slight twist of the suction holder helps to break any suction between lens and eye.

Care should be taken to supervise patients habitually using the lid removal method to make sure that a fingernail is not used to lever the top of the lens from the eye as this could lead to trauma and possibly infection.

Insertion and removal of soft lenses

Insertion

Often a soft lens can be inserted exactly as described above for the insertion of rigid lenses, i.e. by placing directly on to the cornea either at the superior aspect with the patient looking down, or centrally with the patient looking straight ahead Because of its greater size and flexibility, the interpalpebral gap must be larger than the lens diameter and the lids must be gripped at the margins and held well apart to make insertion easy (*Figures 9.11, 9.12* and *9.13*).

When the initial lenses are being inserted, patient comfort can be enhanced by having the patient look away and placing the lens on to the temporal side of the cornea or pressing it on to the temporal conjunctiva. The lens can be centred by having the patient look into it or by pushing the lens gently on centre either with the lids or with a finger as shown in *Figure 9.14*. Transfer from the finger on to the eye is easy if the lens has dried out a little and excess moisture



Figure 9.12 Inserting a soft lens with the head horizontal

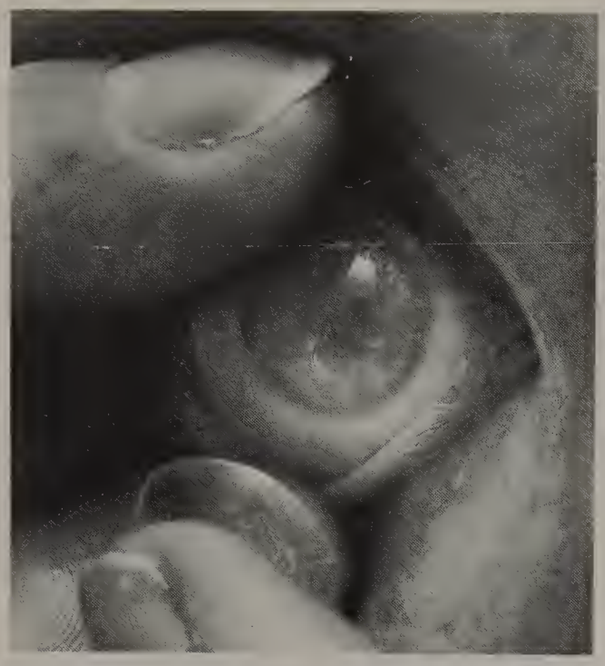


Figure 9.13 Holding the lids apart with the same hand and inserting a soft lens

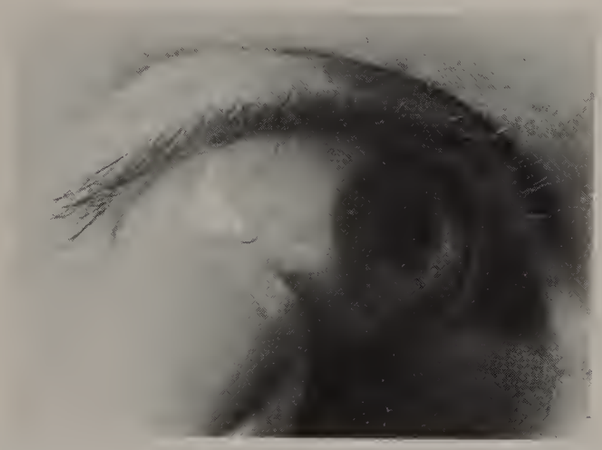


Figure 9.14 A soft lens being moved from the temporal conjunctiva to the cornea



Figure 9.15 A soft lens correct side uppermost



Figure 9.16 The same lens inside out

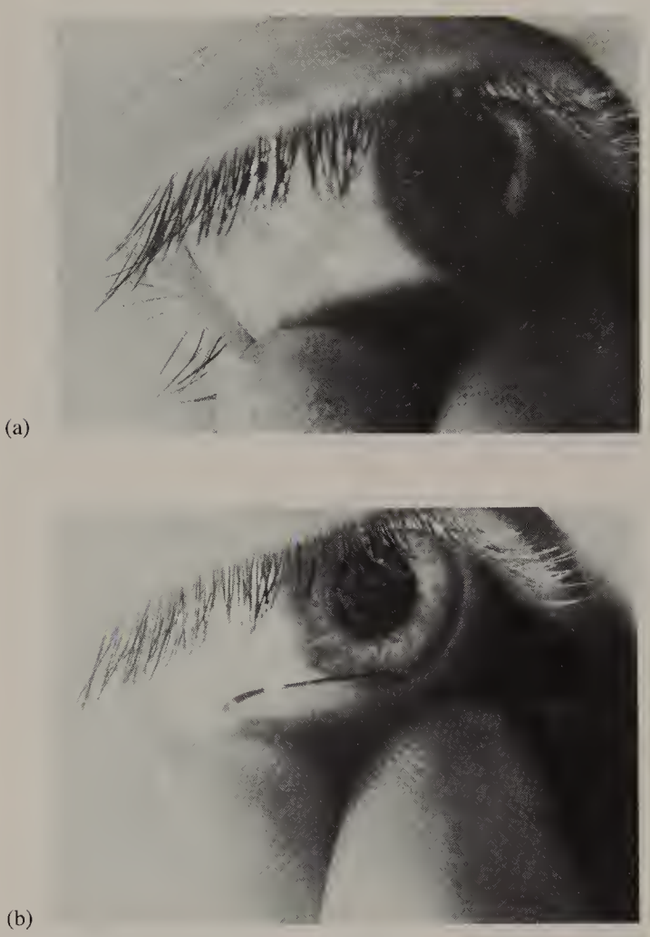
is removed, either by transferring it from one forefinger to the other or by dabbing the moisture pool at the base of the lens with a tissue. Care should be taken not to introduce foreign material on to the lens in the process of drying it. A slightly dry thin lens will actually be taken up from the finger to the eye by the attraction of the tears on the eye's surface, so that the lens need only be touched gently against the eye – the tear layer completing the transfer. If a lens is placed on to the eye inside out it will move excessively and give poor vision and discomfort. *Figures 9.15* and *9.16* show a lens the correct way round, and the same lens inside out. With very thin lenses the difference is not so obvious. A further check can be made by folding the lens inwards gently between thumb and forefinger. If the edges move inwards the lens is the right way round, if they bend outwards it is inside out. Discomfort can also be caused by a foreign body being trapped between the lens and the eye. Using the tip of one finger to slide the lens either temporally or inferiorly off the cornea and on to the bulbar conjunctiva and then back on centre will often remove the source of irritation (*Figure 9.17*).



Figure 9.17 A soft lens pulled onto the conjunctiva to remove a foreign body



Figure 9.18 Pinching a soft lens directly off the cornea



(a)

(b)

Figure 9.19 Pinching lens between finger and thumb of one hand to remove the lens from the lower fornix

Removal

The method chosen to remove the soft lens will depend on dexterity, lid and palpebral characteristics as well as factors such as the size of lens, lens thickness and lens material.

The pinch method is easiest, especially with a nervous patient. The lens is pinched off either from the central position as shown in *Figure 9.18* or pulled either inferiorly (*Figure 9.19*) or temporally with the tip of the forefinger and then pinched between the fleshy parts of forefinger and thumb.

The scissors method can be attempted if the patient is unable to touch their eye with their fingers. It is carried out by placing the fingers directly at the lid margins above and below the lens and pulling the lids first apart then pushing them tightly on to the eye and then together to squeeze the lens out through the lid gap. *Figure 9.20* shows this sequence.

Artificial aids such as suction holders are not recommended but if used at all should first be modified so that in fact no suction can be exerted. The suction holder is used as a wedge, being forced under the lens edge and then away from the eye to break the lens cohesion to the eye.

On removal, a thin lens can become rolled or stuck together. Care needs to be taken to prevent lens damage when separating the lens. The pinch method of removal is more likely to cause the edges of a lens to become stuck together on removal. Instillation of saline into the eye prior to removal or wetting the fingers with saline prior to pinching can help. However, it is easier to pinch a lens off the eye with dry fingers.

A rolled or stuck lens can sometimes be separated by gently rolling it between the fingers as shown in *Figure 9.21* or on the palm of the hand having wetted it with saline or cleaning solution which is more viscous. Soaking in warm saline or heating in saline or distilled water is sometimes needed for a lens that is difficult to separate.

Insertion and removal of composite (Softperm) lenses

Some non-standard soft lenses, for example high powered lenses, non-standard torics or composite lenses such as Softperm, which are relatively thick and heavy, tend to fall off or down the forefinger before the lens can be inserted.

Insertion

Holding the lens near the opposing edges similarly to a pinch movement gives more control. Alternatively, resting the lens on a suction holder which has been designed or modified to not attach to the lens, and then transferring it off the suction holder on to the cornea or conjunctiva can provide easy insertion.

Removal

The lids are held apart and the lens is pinched toward the bottom of the lens so that the flexible skirt is buckled and the adhesion of the lens to the eye reduced. Continue to pull the lens away from the eye while holding the lower skirt. Dry fingers are essential for this.

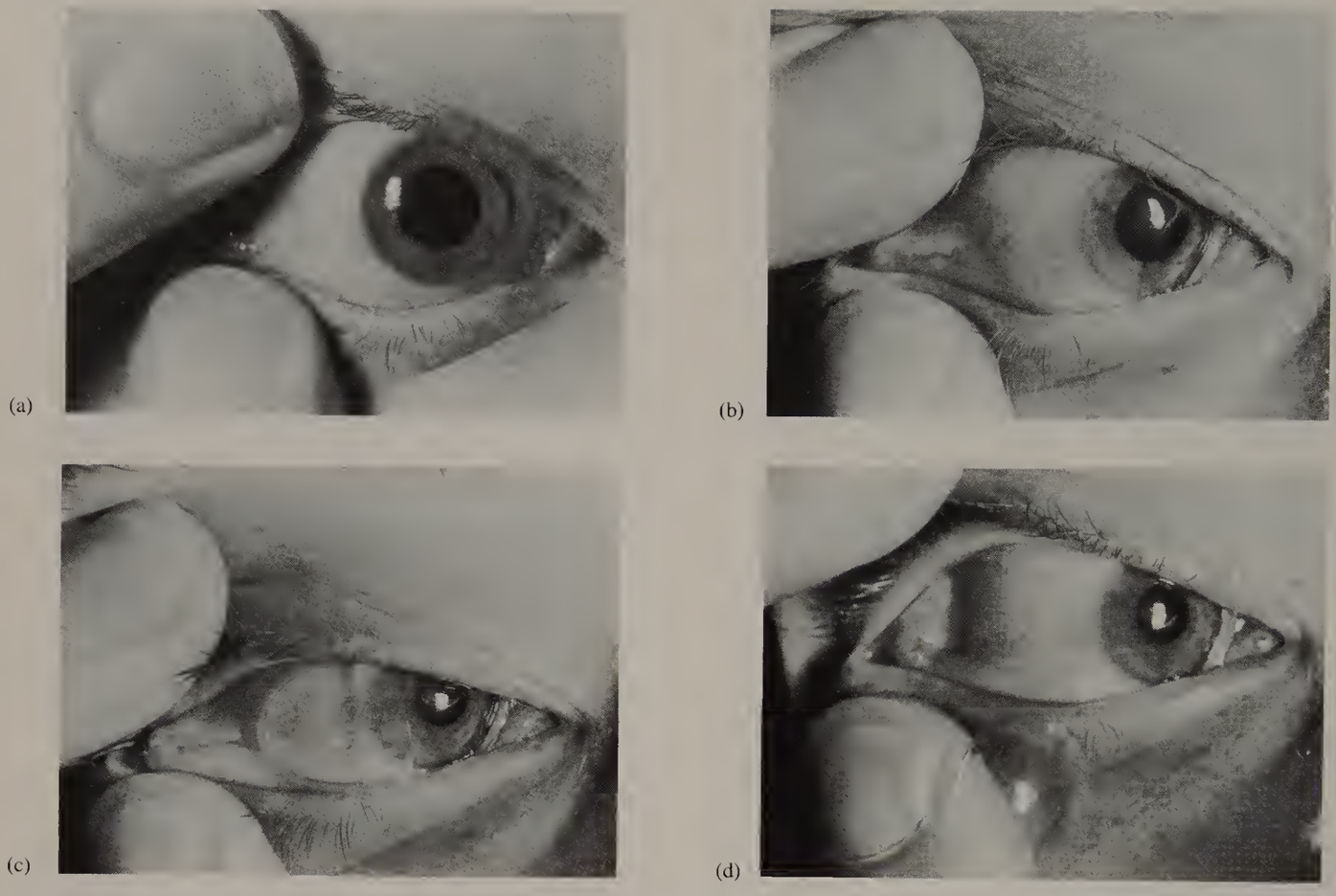


Figure 9.20 Removal sequence of a soft lens using one finger of each hand

Silicone rubber lenses

These are inserted in the same way as rigid lenses and can be removed in a similar fashion, although they are more likely to need a suction holder for removal.



Figure 9.21 Rolling a lens to unstick it

Reactions to the first lens

Cleanliness is vital in all aspects of contact lens practice. The patient should be made aware of this both by modelling behaviour on the practitioner's own example, as well as by instruction and demonstration.

The patient must be prepared physically and psychologically for the insertion of the first lens. It should be stated that some initial discomfort (use of the word 'pain' is deprecated) and lacrimation is quite normal. It should be explained that these initial symptoms usually subside quickly and the lens becomes more tolerable. Most patients admit that the first lens feels much better than expected and there is no harm in telling a new patient this before the lens is inserted.

Patient management

Before insertion, rigid lenses need to be rubbed with an appropriate surfactant and thoroughly rinsed in sterile saline. A pressure can or jet stream bottle provides a faster flow and better rinsing compared with rinsing in a bowl of saline. A sterile soft lens may be inserted directly or rubbed

with sterile saline. A really clean lens is more comfortable and settles more quickly as well as giving better visual results when over-refraction is carried out.

A soothing explanation of what is taking place helps to calm the patient. It should be treated as a matter of course if the lens should fall before being inserted, or if the first attempt is not successful. It is essential not to panic at any stage.

There may well be some irritation for the first minute or two. The new patient has no experience in deciding what may be the cause of this irritation. The practitioner should bear in mind such factors as pH and tonicity of solutions, and foreign bodies. A small piece of dust or mucous behind the lens can be very irritating.

Removing the lens, cleaning it appropriately and re-inserting it can often give a dramatic improvement. With a soft lens it is often sufficient to move the lens on to the conjunctiva for a few seconds and then centre it back on the cornea (*see Figure 9.17*). Patients should always sit comfortably with head supported, and be given a tissue to wipe away any overflow of tears. They should be advised to keep looking down for the first few minutes after the lenses are inserted.

Excess lacrimation, blepharospasm, engorgement of conjunctival vessels or extreme sensitivity may contraindicate the use of contact lenses if these symptoms do not subside in a reasonable time. These symptoms may also indicate a foreign body or a dirty, damaged or poorly fitting lens and these possibilities need to be examined.

Unless a scleral lens is fitting very poorly, the patient does not experience much discomfort relative to that felt with a corneal lens.

With a corneal lens most of the sensation comes from the top lid moving over the lens edge, because the lid margins are very sensitive. The lids being somewhat tense will cause some pressure effects on the lens. These points can easily be demonstrated by the practitioner moving the lids well away from the lens; the patient then finds that the sensation virtually disappears. If the lens is too large there may be localized sensation at the edges. It is often reported that the eye feels full and hot.

Assuming no foreign bodies and a reasonable fit, the symptoms from a rigid lens soon pass. The patient should be told this will occur. Most people react favourably to soft lenses. There is significantly less reaction than with a rigid lens and, although the reaction of the patient is of consequence, the practitioner must not choose a lens type on this basis alone. Other relevant factors must be taken into account before this important decision is taken. Thin soft lenses will settle quickly, thicker soft lenses more slowly. Lenses that need to position on the eye, for example toric soft or bifocal lenses, will need more time as lens movement and position will be affected by excess tears and increased lid tension. After assessing all aspects of the fit and carrying out an over-refraction the lens can be removed. Excess lacrimation and renewed tension at this prospect often make removal difficult. It is essential, therefore, that the practitioner is proficient at this. He or she should be proficient at several methods, and be able to vary them according to the circumstances so that the lens is quickly removed with minimum discomfort.

A patient who sweats profusely, sways about in the chair, complains of a 'stuffy atmosphere', or turns pale, may be in the first stages of fainting or vomiting. It is useful to be prepared for this after the insertion of the first lens. If in doubt, the patient should be asked if they feel well, and if necessary their head should be placed between their knees. The patient should not be left alone in this state as they may fall from the chair and injure themselves. The contact lens should be removed as soon as practicable and the patient given adequate time to recover. It is usually of no use to continue the fitting as the patient may faint again if another lens is inserted. It is useful to be able to obtain assistance easily in any emergency so that a glass of water or smelling salts can be handed to the patient. The presence of another person is desirable for the practitioner's own protection and will be reassuring to the patient.

The basic fitting methods for rigid lenses, soft lenses and scleral lenses are dealt with in Chapter 10, 11 and 17.

Refraction with contact lenses

Rigid lenses

Excess lacrimation can make patient observations difficult. A satisfactory end-point in subjective refraction is not always easy. If the lens does not centre well or the patient blinks excessively then refraction is variable. The duochrome chart may help. The maximum positive power acceptable should be given and the Humphriss balancing technique is useful in helping to keep accommodation relaxed.

Although in most cases only a spherical correction is necessary, the astigmatism with a contact lens in place should still be measured. This may be done most easily with a retinoscope. The methods and criteria for correcting residual astigmatism are set out in Chapter 14.

It is generally found that up to 0.75 D of astigmatism may be left uncorrected without reducing visual acuity, although individual acceptance varies.

It is important to check for any heterophoria when the patient has a lens in each eye. The spectacle correction gives a clue as to whether correcting prism may have to be incorporated. If horizontal prism is needed it may be necessary to terminate the contact lens fitting at this stage.

It may be useful to order the power of the lens +0.25 D more than the power deduced from the refraction. The excess lacrimation with the trial lens provides a temporary increase in negative power and the discomfort of a contact lens can cause the patient to accommodate slightly. In addition, it is easier to add negative power to a rigid lens than positive power.

Soft lenses

Many of the points mentioned above in relationship to rigid lenses also apply to soft lenses. It is important to remember that neither the practitioner nor the soft lens laboratory can satisfactorily modify the power of finished lenses.

A trial lens with power and other parameters as close as possible to the patient's intended prescription is helpful, as well as behaving more nearly like the final lens.

Most corneal astigmatism is transmitted by a soft lens. Residual astigmatism may be less or more than expected (*see* Chapters 5 and 14). It should be measured, recorded and its effects anticipated in every case.

Lenses should be well settled before a refraction is performed. Five minutes wear is a minimum before a final assessment is made (Brennan *et al.*, 1994). If vision cannot be improved to an acceptable level it is a contra-indication to supplying contact lenses. Poor lens fit, excess tearing, excessive movement, uncorrected astigmatism and off-axis astigmatic corrections will all contribute to poor vision. Contrast sensitivity tests or reduced contrast letter charts may be used to assess quality of vision, but such a chart is not essential and as long as a careful over-refraction is carried out, an accurate visual end-point can usually be achieved. However, with a very teary or tense patient this may not be possible until the first aftercare appointment.

Refining the refractive end-point can be done at the first after-care check by exchanging the lenses using a lens from the practitioner's own inventory or one of the variety of exchange plans that can be arranged with the laboratory.

Assessment of suitability for contact lens wear

At some stage a decision to continue with contact lens wear needs to be made and this should be discussed with the patient.

A few potential contact lens wearers will give up quite early on; some for comfort reasons, but more often because of difficulties with insertion or removal. Some people are never able to overcome their fear of putting a contact lens in their eye. Poor vision, for example with toric or bifocal contact lenses, may discourage patients from continuing. An alternative lens may restore their confidence. Others may give up because of the expense of replacement lenses or solutions, but this should be avoided by giving them sufficient information prior to commencing lens wear.

Practitioners also need to decide whether the patient should be advised to cease lens wear. Long-term wearers may need to stop lens wear after developing problems. Those with marginal dry eye or ocular problems caused by contact lenses may need to discontinue lens wear. These patients need careful counselling and the practitioner's decision should be fully explained, bearing in mind that the patient's long-term welfare is the paramount consideration. However, a refitted lens, a different material or lens type, or a reduced wearing time may help a patient to retain their lenses.

Those who refuse to follow instructions, for example over wearing time, contact lens and case hygiene, or replacing lenses at recommended intervals, need written statements as to the risk they are taking and what the contact lens practitioner suggests as an alternative.

Lens handling by the patient

During the initial examination, some practitioners like to give patients some experience in inserting and removing lenses themselves. This can help the patient's confidence in their ability to wear and handle lenses. Whether this is done depends on the time available, but it is useful to have some idea of the patient's ability to handle lenses before proceeding further. Inability to insert and remove lenses is as important a contra-indication to contact lens wear as any of the others. However, with a very tense patient, further instruction may solve any difficulty of lens handling, and the use of an eyebath between consultations may aid relaxation. It has been found useful with those having difficulty, to instruct them to spend a few minutes daily practising the techniques of lens placement and removal without actually touching the eye.

This not only helps them to relax, but it also gives them confidence in handling their eyes and lids, so that by the time they collect their lenses, they are usually adept at controlling their eyelids and eye movements.

Ordering

The practitioner has now amassed the information needed to decide if the lenses are to be ordered and, if so, the necessary specification. The practitioner must be sure that the patient stands a reasonable chance of successfully adapting to contact lenses and wishes to continue. If the patient is likely to have any particular difficulty, then they should be told of this before the practitioner continues. If the patient still desires lenses and there are no disqualifying contra-indications, an informed consent form should be signed (Harris, 1994) and the lenses issued either from inventory stock on that day or an appointment can be made to dispense the finished lenses.

Before the patient leaves, a careful examination of the cornea is essential. Antimicrobial eye drops may be administered if any abrasions are present.

Delivery of contact lenses

Before the lenses are collected they should be checked and replaced, rejected or modified if they are not accu-

rate. They should then be assessed in the patient's eyes for adequate fit and acuity. Unless there are major problems at this stage any refitting decisions should be left until the first after-care appointment when adaptive problems have hopefully been overcome.

Handling instructions are given when the lenses are issued and can be revised at after-care appointments.

Selecting a care system (*see* Chapter 4)

Factors to consider include:

- **Lens materials used**
  - ionic or non-ionic soft lens material
  - low or high water content
  - rigid lens material used
  - expected life of the lens
- **Care system characteristics**
  - efficacy
  - availability
  - cost
  - potential to trigger allergic responses
- **Patient characteristics**
  - personality, level of personal hygiene and likelihood of following instructions
  - history of allergy and observed allergic responses, e.g. follicles and papillae
  - patient history, e.g. previous exposure and reactions to contact lens care systems; previous systems used and abused in the past

How care systems are used needs to be examined at after-care appointments, especially after the initial period. Contact lens wearers will omit steps, substitute solutions for reasons of cost or availability or from the recommendations of other contact lens wearers.

Case hygiene

Poor contact lens case hygiene contributes to an increased risk of infection (Donzis *et al.*, 1987; *see also* Chapter 4). Contact lens wearers should be instructed to clean their lens case regularly, ideally by scrubbing it with a special brush and contact lens cleaning solutions (and rinsing it carefully), and to disinfect regularly by boiling it in water in a microwave or pan. For cases not suitable for boiling, air-drying the open case over the period of non-use may be substituted. Running hot water over the case is a poor alternative.

Cases should be replaced regularly, suggestions varying from having a new case with every new bottle of storage solution to every three or six months. Some manufacturers now supply a lens case with their three month supply of solutions.

At the annual after-care visit it is a good idea to hand over a whole new kit. This will have a complete variety of solutions as well as a new case and instructions, and should reinforce the patient's understanding of the need for good contact lens hygiene. Instructing the patient to promise to throw the old case away also reinforces the idea. Having a new kit will also update the patient on improved care systems as they become available.

Dispensing contact lenses

This is a crucial time for a new contact lens wearer. They are about to start wearing contact lenses, putting them into and removing them from their eyes, wearing a different form of visual aid on a regular basis, and keeping and caring for the lenses in such a way that the care system maintains the lenses and the health of the eyes. The care and completeness of the dispensing appointment sets the stage for the style of care the patient will exert themselves when wearing lenses.

Sloppy demonstrations suggest that hygiene is unimportant, when everything should point to the need for a rigorous system. Contact lens wearers will often modify their care system with time, and mostly in the direction of less, rather than more care.

The contact lens wearer assumes some of the responsibility for the long-term success of contact lens wearing and needs careful training and complete instructions for them to be confident of their own skills and abilities and to understand their part.

The patient expects:

- training and instruction in the successful use of their lenses and the care system;
- advice on normal adaptive symptoms;
- a source of contact to deal with problems, emergencies and adverse responses;
- long-term supervision to ensure ocular health.

The contact lens practitioner expects:

- the wearer to comply with the instructions given and to use the care system appropriately.

Remember *cost* and *complexity* work against *compliance* with lens care systems.

The new wearer needs:

- Boosting of self-confidence with instruction on lens insertion and removal.
- Instruction in the proper care and storage of the lenses, use of solutions and case hygiene; strict instructions on the need to follow carefully the care system regimes and advice against changing any part of the system without reference to the practitioner.
- A schedule of adaptation.
- Warning of adaptive symptoms and how to deal with them.
- Advice on what to do in an emergency and how to obtain professional assistance in cases of difficulty.

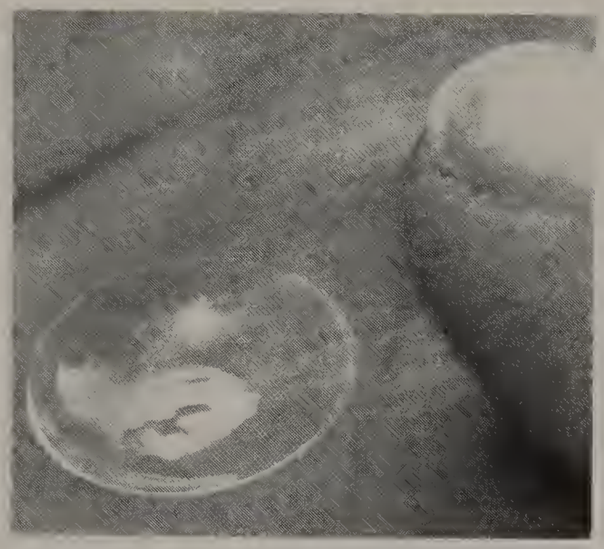


Figure 9.22 Rubbing a soft lens in the palm of the hand to clean it

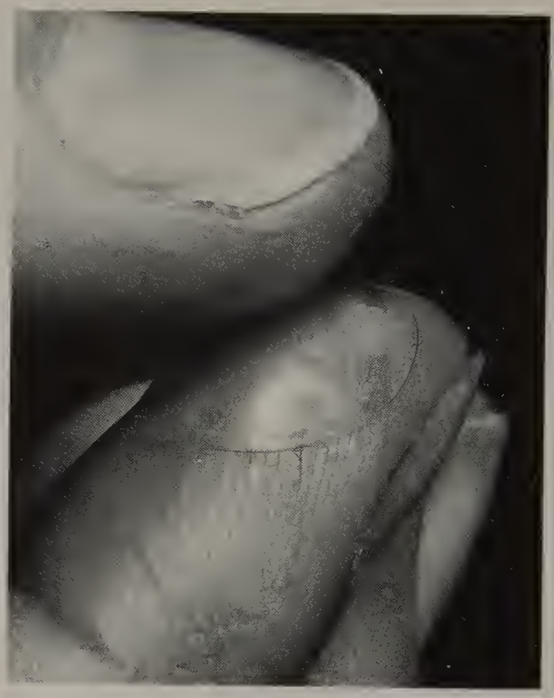


Figure 9.23 Rubbing a soft lens with thumb and forefinger to clean it

Instruction on handling lenses

A great deal of information is imparted at this occasion and it useful to have the instructions, either printed or as a video, which can be given to the patient for future reference (*see* Addenda). These instructions should cover handling, insertion and removal of lenses, and the routine for use of the care system. This is reassuring from the patient's point of view, as it provides an available source of information and guidance. It is also a source of protection for practitioners, should they forget to mention anything, and it is desirable from a legal standpoint. The handling techniques to be used by the patient are described earlier in this chapter.

Cleaning contact lenses on removal

Hygiene is vital and should be modelled on practitioner behaviour. Hand washing before handling the lenses or eyelids both for insertion and removal, and when cleaning the lenses is essential. Not only can bacteria, for example, be transferred, but a variety of other hand contaminants can also be damaging to contact lenses, for example hand-lotions and make-up. Care and cleaning of the contact lens container is also necessary. All contact lenses need to be cleaned with a surfactant cleaner on removal. They should either be rubbed in a circular or linear motion in the palm of the hand (*Figure 9.22*) with the forefinger or the little finger of the other hand, or else supported the end of the forefinger or thumb (*Figure 9.23*), and rubbed with surfactant for about 15 seconds.

Surfactants should be well rinsed off as the residue can be irritating to the eye or damaging to the lens surfaces. A sterile saline rinse should be used. Prior to removal and cleaning, the lens container should have been prepared, opened and filled with a fresh quantity of the appropriate solution. The cleaned and rinsed lens is then transferred to the container, taking care that it is completely in the body of the container and in the appropriate solution. The container is then closed. Care systems are discussed in Chapter 4.

Lens contamination

Patients should be warned of the dangers of contaminating contact lenses. The risks of transferring substances from the hands has already been alluded to but one should not forget the airborne source of contamination. Aerosol sprays such as furniture polishes, hair spray and deodorants can all cause surface contamination which is almost impossible to remove. Poor vision and reduced surface wetting can result in reduced lens performance. In city streets, air-bound particles can become embedded in the lens surfaces. Similar problems can arise in industrial situations where there are small particles and gases in the air which might cause problems.

Wearing schedules

Adaptation to contact lenses is usually necessary and the daily wearing time is therefore gradually increased. Wearing schedules can be variable and the schedule should provide for the fastest passage possible through to maximum daily wear, provided that the patient is physically and visually comfortable in the process. There is no advantage in slow adaptation if proper safeguards are met. With soft lenses, the comfort problems are reduced and a start of 4–6 hours per day with an increase of 1–2 hours daily is typical. Sensitive eyes and lenses with thicker edges, for example prism ballasted torics, may need a slower schedule. Thin, soft

lenses are more comfortable and the physiological stress is reduced so it is safe to start with 8–10 hours if the lenses are comfortable.

RGP lens wearers could be started at 4 or 6 hours depending on lid sensitivity and confidence, and add 1 hour extra daily. Schedules should all be given with the proviso that wearing time can be held at the same level for some days, or built up more slowly if there are problems. It should be stressed that the lens wear should not be continued if there is persistent discomfort.

Example routine for dispensing contact lenses

Try approaching the process as 'A Day in the Life of a Contact Lens Wearer', that is, something like their expected daily routine.

If the lenses have been inserted to check comfort and acuity they should be removed and put into the lens case. Remember to take care with hydrogen peroxide systems that need neutralizing before the lens can be worn.

Wash your hands

- Remove the lenses from the case
- Check if the lens is inside-out
- Insert the lenses
- Show how to check that the lens is on the eye and centred on the cornea
- Deal with the debris trapped at insertion
- Empty and rinse the case
- Talk about adaptive symptoms
- Remove the lenses
- Discuss unrolling a stuck lens
- Clean the lens on removal
- Rinse the surfactant from the lens
- Place into the case
- Instruct on overnight disinfection
- Go through the instruction material with your patient
- Provide a contact number if more advice is needed or in case of any emergency, or just for wearer reassurance
- Make an appointment for the first after-care
- Provide continuing confidence and care and show that the practitioner is interested in the long-term care of lens wear
- **Be positive, be caring, take care**

The Addenda included at the end of this chapter give examples of the instructions that should be included in patient handouts. These are meant to be issued in a presentation appropriate to the type of lenses, for example, a soft lens wearer would be given the general soft lens wear sheet, plus the sheet appropriate to their care system plus information for all contact lens wearers.

The Addenda include appropriate instructions on the following topics:

1. The care and handling of soft contact lenses
2. Chemical care systems
3. Hydrogen peroxide care systems
4. Optimeyes, Softab and Aerotab soft lens disinfection
5. Disposable lenses
6. The care and handling of rigid lenses
7. More information for contact lens wearers
8. Monovision
9. Instructions for orthokeratology patients

The Addenda are based on material used by A.J. Phillips in his practice.

After-care

The routine after-care examination is similar for soft and rigid lenses and can be considered under the following headings:

- Patient responses:
  - confidence and ease of lens handling and wearing;
  - comfort, lens awareness;
  - perceptual adjustment to a new prescription.
- Practitioner observations:
  - Is the fit satisfactory, i.e. does the lens still centre and provide adequate pupil or corneal cover?
  - Is the back vertex power and the visual acuity obtained still satisfactory?
- Lens responses – as comfort increases alterations in tear flow and blinking may alter lens performance.
- Physiological responses:
  - corneal epithelial and endothelial changes, stromal swelling with striae and folding in Descemet's membrane;
  - changes in the tears with alterations in volume and tear composition;
  - changes in the lid margins or palpebral conjunctiva;
  - alterations in limbal vasculature and conjunctival vessels.

Post-wear changes are discussed in more detail in Chapter 18.

Early difficulties

Many early problems are possible; some are adaptive and will diminish with time, others need to be dealt with speedily to maintain patient confidence. Some patients present problems which need simple reassurance that everything is normal, and gentle pressure to resume their wearing schedule. Some problems may be impossible to solve if, for example, an incorrect decision on patient suitability has been made whilst others need to be dealt with by the practitioner at subsequent after-care visits. Those people who are not confident or who are poorly motivated will find numerous problems, which, as soon as they are solved are replaced by new ones. Sources of difficulty are often in the areas covered at delivery and provide some

feedback as to the effectiveness of the methods used and the quality of instruction. Early problems can include:

- Difficulties with insertion and removal of lenses
- Displaced lenses
- Lost lenses
- Soft lenses stuck together
- Soft lenses inside out or difficulty in the detection of lenses inside out
- Difficulties distinguishing right and left
- Handling and cleaning difficulties
- Poor vision
- Variable vision
- Perceptual – adaptive problems
- Discomfort on insertion
- Variable discomfort depending on the environment
- Discomfort after lenses are removed
- Sensitivity to solutions or lens material
- Unsatisfactory or incompatible cleaning and care systems
- Glare
- Self-consciousness

Fitting children's contact lenses

There is nothing particularly unusual about children's eyes. Teenagers are usually very good patients if they are well motivated. Maturing earlier, girls usually have a more responsible attitude towards contact lenses than boys of the same age. If the parents are paying for the lenses good communication and cooperation with them is essential, and a financial contribution from the individual also assists their motivation.

Fitting children under the age of 10 years requires a specialized approach. Chapter 20.5 provides information on paediatric contact lenses.

Acknowledgements

The authors are indebted to Roger Taylor for *Figures 9.2, 9.3* and *9.7–9.10*, Geoff Woodward for *Figures 9.4–9.6, 9.12, 9.21, 9.22* and to Godfrey Boehnke for *Figures 9.11* and *9.13–9.20*.

Addendum 1

Instructions to the patient on the care and handling of soft contact lenses

Soft (hydrophilic) lenses are designed to cover the entire cornea and overlap on to the white of the eye. As the lenses are made of a thin and flexible material, it is essential that they are handled with great care. Further, as the lenses contain a percentage of fluid, daily disinfection and cleaning of lenses is most important. Lenses which are not cleaned regularly can cause eye infections or ulceration.

Lens care products fulfil various functions. Not all are appropriate to every contact lens wearer so it is important that the lens care regime given by the practitioner is fully understood. Your contact lens practitioner may change the regime if the need arises. The regime should not be changed by yourself or on the advice of other lay people. The main categories of care products are as follows:

1 **Cleaning solutions** (surfactant cleaners)
These are probably the most important part of a regime as they are used to clean off deposits, debris and micro-organisms from the surfaces of the lens after wear. Their use makes the second step in the regime (disinfection) more efficient.
2 **Disinfectants**
These stop organisms multiplying to a level which could be dangerous.
3 **Neutralizers**
These are used in conjunction with specific disinfecting solutions to render the disinfectant harmless to the eye. You will be advised if a neutralizer is necessary.
4 **Enzymatic cleaners**
These are used on an intermittent, but regular, basis to remove some lens deposits not removed by surfactant cleaners.
5 **Rinsing solutions**
These are used to rinse off residues of surfactant cleaners, enzyme cleaners and disinfectants from the lens surfaces. In some cases the disinfecting solution itself may be used as a rinsing solution.
6 **Re-wetting solutions** (comfort drops)
These are slightly viscous solutions instilled directly into the eye to minimize lenses drying out. They can also be used to improve comfort and lubrication.
7 **Multipurpose solutions**
These are solutions which are used for more than one purpose e.g. Renu, Optifree, Complete. Subsequent sheets will explain the product recommended for you in greater detail.

Lens insertion

To prevent the right and left lenses being interchanged accidentally, they should be removed from their soaking container and inserted one at a time. The following procedure is carried out for the right eye (and reversed for the left) after ensuring that the lens is not inside out.

Before placing the lens on the eye, always ensure that it has not accidentally become turned inside out. There are two simple methods of checking that this is not the case.

- Place the lens on the tip of the forefinger, concave side upwards, and hold it up to a light or window. Look at the shape of the lens from the side in silhouette. If the lens is the correct way round the edges will point up vertically like a cup. If the lens is inside out the edges will turn slightly outwards.
- Balance the lens on the tips if the thumb and forefinger, concave side upwards. Gently fold the lens where the edges should turn inwards. Also, some lenses are marked or engraved and this can be checked to ensure it is the right way round.

1. Support the lens on the top of the forefinger (or middle finger) of the right hand. Work over a large, smooth flat surface if possible. A mirror may be helpful at first. Allow thin lenses to dry out for a few seconds.
2. Bring the left hand down over the forehead, look right down and grasp the upper right lid firmly with the middle finger(s). Now look straight ahead (at your eye in the mirror).
3. Pull down the lower lid with the middle finger (or fourth finger) of the right hand, keeping the lens away from the eye.
4. Bend the head well forward over the mirror or the flat surface, and holding the lids well apart gently place the lens on the cornea. Obviously the distance between the lids must be greater than the lens diameter and lashes must be well out of the way. Place the lens into the eye.
5. Slowly release both lids.

There may be very slight irritation for the first minute or so. In the case of marked irritation, a particle of dust or fluff may have become trapped behind the lens. It should be removed, rinsed with sterile saline or storage solution, and re-inserted. Sometimes a small foreign body behind the lens can be removed by moving the lens on to the white of the eye (the side nearest the ear is most convenient while looking towards the nose), massaging it there for a few seconds and then sliding it back on to the cornea.

Lens removal

Method 1

(a) Hold the upper and lower lids apart as described under Lens insertion. This time the mirror may be used in either a vertical or horizontal position.
(b) Turn the head so that you are looking across your nose into the mirror that is, for the right eye, turn your head to the right so that your are then looking to the left to see in the mirror.
(c) Using the index finger slide the lens off the cornea, towards the ear, on to the white of the eye. Keep hold of the upper lid but take away the right hand and turn so that the side of the thumb and forefinger are facing the eye.
(d) Keeping the head position constant, hold the lids at the corner of the eye apart with the side of the thumb and forefinger and gently pinch the lens off the eye with the thumb and forefinger.

Method 2

Bend the chin into the neck so that you look upwards to see the eye in the mirror. Slide the lens below the cornea and pinch off using the thumb and forefinger (or middle finger) as before. If you have longer fingernails, deep set eyes or a smaller than average distance between the lids, Methods 1 and 2 may prove difficult.

Method 3

(a) Raise the eyebrows and keep staring wide.
(b) Use one finger of each hand. Put one finger-tip on the edge of the top lid and the other on the edge of the bottom lid. Both lids should be held out about halfway along.
(c) Pull lids towards the ear and keep the edges of the lids in close contact with the white of the eye.
(d) look towards your nose at the same time as (c). The lens should be expelled from the eye.

Wearing schedule

Unless otherwise advised, start at 4 to 6 hours on the first day and increase by 1 to 2 hours each day if it is comfortable to do so. Endeavour to wear your lenses every day during the adaptation period. The lenses may need changing in both fitting and focus as they settle.

General notes

1. Always wash your hands thoroughly before handling your lenses to ensure they are free from all traces of creams, make-up, nicotine etc. Dry them on a lint-free, well-washed towel.
2. If your lenses accidentally dry out (become smaller and lose their flexibility) handle them with extreme care. Preferably drop saline solution on to them and let them soften for half an hour before touching them. Place them loosely in the container and soak in saline or storage solution for at least 2 hours. Ideally, they should then be re-disinfected by your usual method before wear. NEVER PUT A PARTLY DRY LENS ONTO AN EYE.
3. As most lenses are not marked right and left, great care must be taken not to mix them up.
4. There is little chance of dust getting beneath a lens during wear. See under Lens Insertion in case this happens. If discomfort persists, consult your contact lens practitioner or doctor.
5. There is little risk of lens loss from the eye, even when swimming, though they may be displaced on the white of the eye if the eyes are rubbed. Swimming goggles should, if possible, be worn.

6. Take great care to keep the eyes closed when using aerosol or other sprays. Remember that the droplets may persist in the room for several minutes. Such foreign chemicals may again cause subsequent irritation and often ruin the lens permanently.
7. If the lens is irritating your eye and you suspect that it may be contaminated with make-up etc., clean the lens very carefully. If discomfort persists, stop wearing the lens and get in touch with your practitioner.
8. Unless your lenses are designed for extended wear, NEVER SLEEP IN YOUR LENSES for more than very short periods of time. If you should forget, however, check immediately on wakening to see if the lenses will move on the eyes. If they do not move readily do not attempt to remove them. Place several drops of saline solution in the eyes every few minutes and try moving them again. If, after several applications, the lenses will still not move you must consult your contact lens practitioner.
9. If, after placing a lens on the eye, you do not see clearly through it, massage the closed lid gently to centre the lens and express any air bubbles from beneath it. If vision is still not clear, check if you have put in the wrong lens or if the lens is inside out.
10. You may wish to insure your lenses. Acquiring a spare pair of lenses is often sensible and these are supplied at a reduced cost.
11. The lenses should not be worn if you are using medicated eye drops of any sort without checking with your practitioner first.
12. Put a note in your wallet or purse that you are a soft contact lens wearer and that in the event of an accident the lenses should be removed within a few hours.
13. After-care check-ups will be advised at periodic intervals until complete integrity of the eyes has been ascertained. Further appointments at longer intervals, about once a year, are essential to ensure that no abnormal corneal changes are taking place, as often these may cause you no symptoms. If you are in doubt about the state of your eyes or lenses, always seek advice.
14. Always wear your lenses for your appointment unless advised otherwise and bring your spectacles and lens container to every after-care appointment.
15. Keep your lens container clean by rinsing it after inserting the lenses and leaving it open to dry. Disinfect the open c ›e in boiling water every week (check that your container is suitable for this) cleaning it every month with a special toothbrush and lens cleaning solution. Replace it at least every 6 months to avoid build up of bacteria on the surfaces. Some solutions manufacturers now supply a fresh container with every three-month pack of solutions.

Enzyme cleaning

In spite of daily cleaning the porous nature of the lens material will still enable deposits to build up on the surface. Research has shown that the longer deposits remain on soft lenses the more difficult they become to remove. The following method should be carried out at least fortnightly in addition to use of the daily cleaner to minimize deposits building up on the lens surface.

1. One tablet (e.g. Hydrocare, Polyzym, or Sensitive Eyes Cleaning Tablets) should be put in each plastic vial with unpreserved saline.
2. The lenses are then removed from the eyes, cleaned with daily cleaner in the usual way, and rinsed thoroughly. They are then put in their respective vials and left for the recommended time, typically 1–2 hours.
3. The lenses should then be removed from the vials, cleaned very thoroughly with saline to remove enzyme by-products, and rinsed.
4. They should then be disinfected.

Addendum 2

Instructions on chemical disinfection routines

The following schedule should be adhered to in looking after your lenses.

Daily lens cleaning

Lens cleaning is essential to maintain lens wearing comfort and to prevent a drop in the standard of vision. Many cleaners are available, such as Omnicare Cleaner, Miraflow, Sorbiclean, Sensitive Eyes Daily Cleaner, Polyclens II, Opticlean.

Remove the lens from the eye and place it in the palm of the hand, concave side upwards. Put a drop of cleaning fluid on to the lens. The lens is then massaged around the palm of the hand, using the first or little finger of the other hand for 10 seconds. Repeat on the other side. Alternatively place the lens on the index finger concave side downwards. Apply the cleaner and rub it over the surface for 10 seconds, repeating for the other side. Afterwards rinse throughly with saline.

Disinfection

After cleaning the lenses fill the container with your disinfection solution. Use only solutions intended for soft

(hydrophilic) lenses. Under no circumstances should lenses be stored in water, or contact lens solution designed for hard lenses. Immerse the lenses in the solution for a minimum of 4 hours. Take the lenses directly from the solution and insert them in your eyes. For daily wear lenses the solution should be changed each day, and for extended wear lenses each time prior to use.

Enzyme cleaning (see Addendum 1)

Summary

Daily routine:

- Remove, clean and rinse, overnight disinfection in storage solution, insert.

Weekly routine:

- Remove, clean and rinse, enzyme clean, clean and rinse, disinfect, insert.

InstaCare

This product is listed separately as its use is slightly different from most other products.

InstaCare Starting Solution is both a cleaner and disinfecting system. The components of the solutions rapidly kill micro-organisms in 10–20 seconds as well as cleaning the lens surface. It is *essential* therefore that the Starting Solution is used for *at least that length of time on each lens.*

InstaCare Finishing is a lightly preserved saline solution designed to maintain lens sterility *after* the cleaning/disinfection procedure. The lens can be safety inserted into the eye from the solution.

Enzyme tablets (other than Hydrocare tablets) may also be dissolved into the Finishing Solution. If Hydrocare tablets are used, these should be dissolved in preserved saline. Ultrazyme tablets should not be used with this product.

All-in-one solutions

These are also available to clean and disinfect lenses. These solutions have a cleaner incorporated in them so there may be no need for a separate cleaner.

It is still important to clean and rinse the lenses with the one solution before storing them overnight in the same solution.

Addendum 3

Instructions on hydrogen peroxide routines

There are now three specific ways of using hydrogen peroxide systems. These are becoming increasingly popular since the method both disinfects and mildly cleans lenses. Please use the system that has been specifically recommended for you. The following schedule should be used to look after your lenses.

Daily lens cleaning (see Addendum 2)

Hydrogen peroxide systems

AOSept

This is a one-step system requiring a catalytic disc at the bottom of the container to neutralize the hydrogen peroxide.

Immerse the lenses in solution for a minimum of 4 hours, then remove and put directly into your eyes. If there is any stinging rinse the lens with an aerosol or preserved saline. The neutralization disc needs to be changed every 3 months or 100 usages. As the catalytic disc wears out the lenses will sting on insertion.

Oxysept

The lenses are immersed in hydrogen peroxide (Oxysept 1) for a minimum of 20 minutes or overnight.

The container lid and lens basket is removed and the hydrogen peroxide emptied out. This is then replaced with Oxysept 2, either from the bottle or unit dose – according to recommendation. After being left in Oxysept 2 for a minimum of 20 minutes the lenses can be inserted directly from the solution.

The Mirasept 1 and 2, Consept 1 and 2, HP1 and 2 and Ciba 10:10 are used in an identical manner to the Oxysept system.

Omnicare and Oxysept One-Step

The lenses are stored in Omnicare or Oxysept overnight. A neutralizing tablet is placed in the container at the same time as the lenses. This dissolves over the first hour and neutralizes the hydrogen peroxide.

Enzyme cleaning (*see* Addendum 1)

This should be carried out weekly or at least once a fortnight.

Method 1 (Ultrazyme, Polyzym, Sensitive Eyes Effervescent Cleaning Tablets)

1. One tablet should be put in each plastic vial with unpreserved saline.
2. The lenses are then removed from the eyes, cleaned with daily cleaner in the usual way, and rinsed thoroughly. They are then put in their respective vials and left for the recommended time, typically 1–2 hours.
3. The lenses should then be removed from the vials, cleaned very thoroughly to remove enzyme by-products, and rinsed with saline.
4. The lenses should then be disinfected.

Method 2 (Ultrazyme, Optifree Enzymatic Cleaner)

1 The lenses are cleaned and rinsed in the normal way and placed in the container of hydrogen peroxide.
2 An Ultrazyme tablet is added to the hydrogen peroxide. The container lid is replaced and the lenses left for combined disinfection and cleaning overnight.
3 The lenses should again be thoroughly cleaned and rinsed with preserved or aerosol saline to remove enzyme by-products and the lenses inserted.

Summary

Oxysept, Consept 1 and 2

Daily routine:

- Remove, clean and rinse, hydrogen peroxide, neutralize next morning, insert.

Weekly routine:

- Remove, clean and rinse, hydrogen peroxide/enzyme, neutralize, clean and rinse, insert.

AOSept and Oxysept One-Step (Omnicare)

Daily routine:

- Remove, clean and rinse, hydrogen peroxide (add Oxysept One-Step (Omnicare) tablet), insert next morning

Weekly routine:

- Remove, clean and rinse, hydrogen peroxide/enzyme (add Oxysept One-Step (Omnicare) tablet), clean and rinse, insert.

Addendum 4

Instructions on Optimeyes, Softab and Aerotab soft lens disinfection routines

Optimeyes, Softabs and Aerotabs are methods that release lens disinfectants when tablets are dissolved in solution. If one product is unavailable or if you are sensitive to one of them then the other may be substituted, but ***remember***

Optimeyes are dissolved in TAP WATER
Softabs and Aerotabs are dissolved in SALINE

Daily lens cleaning (see Addendum 2)

Optimeyes system

This method releases chemicals to neutralize additives in tap water, salt to convert the water to normal saline, and a disinfecting agent, chlorhexidine.

The lenses should be cleaned as described above and then rinsed with saline and placed in the lens container. Depending upon the container design ensure that the lenses are placed centrally on the dome so that the basket cover does not damage the lens on closure.

The container is then filled to the fill-line with fresh rising mains *tap water* and one Optimeyes tablet added. This is then left overnight. The next morning take the lenses directly from the solution and put them in your eyes. However, if any rinsing is necessary use only aerosol or preserved saline.

The manufacturers claim that no enzyme treatment (see below) is necessary with this product. This has proven true for some but not all wearers. To ensure a good life for your lenses it is advisable that this is still done at least once a month or as advised by your practitioner in your own case.

Finally, ***never*** put your lenses in tap water alone without an Optimeyes tablet, and always use rising mains tap water.

Softab or Aerotab system

This method utilizes a low-level chlorine release system to disinfect the lenses. It has the advantages of being simple to use, inexpensive and because the chlorine has evaporated from the solution by the next morning, there are no preservatives introduced into the eye which can occasionally cause sensitivity problems on lens insertion.

The lenses should be cleaned in the normal way and rinsed with saline. Each lens should then be placed separately on the dome on each side of the lid septum taking care:

(a) to ensure the correct lens is placed on each side.
(b) that when the lid is snapped shut it will not cut into the lens.

The container is then filled to the fill line with fresh, sterile *unpreserved saline* and one Softab added. This is then left overnight. The next morning take the lenses directly from the solution and put them in your eyes. However if any rinsing is necessary use only aerosol or preserved saline.

The lens container can be used to allow one enzyme tablet (see below) to clean both lenses at the same time (prior to Softab disinfection).

Enzyme cleaning (see Addenda 1 and 3)

Summary

Daily Optimeyes routine:

- Remove, clean and rinse, overnight disinfection in rising mains tap water *plus* one Optimeyes tablet, insert.

Daily Softab/Aerotab routine:

- Remove, clean and rinse, overnight disinfection in unpreserved saline plus one Softab/Aerotab tablet, insert.

Weekly routine:

- Remove, clean and rinse, enzyme clean, clean and rinse, disinfect with Optimeyes/Softab/Aerotab, insert.

Addendum 5

Instructions to the patient on the care and handling of disposable lenses

Most disposable lenses are worn on a daily wear basis, removed and disinfected every night, and discarded after 2–12 weeks, depending on the lens type.

You will be told of the most appropriate replacement period for your lenses.

For those patients who wear daily disposable lenses, lens cleaning is not necessary. Simply wash your hands and follow the instructions for Lens Packaging (*see below*). **Never** rewear your daily disposable lenses the following day.

The main uses of disposable lenses are:

1 For those who want as near hassle-free wear as possible, i.e. freedom from enzyme cleaning, no worries about lost, damaged or deteriorating lenses etc.
2 For those who are particularly prone to rapid deposit build-up on lenses.
3 For those who have developed an allergy (GPC) to their own denatured protein on lenses.
4 For those who require lenses intermittently such as for certain sports, bush walking etc.
5 As normal extended wear lenses.

Daily routine

Here is your daily routine.

- *On removing* the lenses from your eyes, clean them with your recommended cleaner, e.g. B & L Contact Lens Cleaner, Optifree Cleaner, Omnicare Cleaner, Polyclens II, by rubbing back and forward in the palm of your hand.
- Rub both sides for at least 10 seconds each.
- Rinse the rubbed lenses with Multi Purpose Solution, Optifree, Complete or preserved or aerosol saline etc. to remove the cleaner.
- Put the lenses into the case in the correct side to identify right and left lenses and fill the case with your soaking solutions such as Multi Purpose Solution, Optifree, Complete.

Before *inserting* the lens, check that it is not inside out and it looks free of debris on the surface. If the lens is dropped or looks dirty, or gets dry and inflexible, then rinse it with Multi Purpose Solution, Optifree, Complete, preserved or aerosol saline, etc.

Insert the lens and check it is on centre and free of wrinkles. If the vision is improved in that eye, then the lens must be on centre.

In case of *discomfort* on insertion, slide the lens down with your forefinger so it is completely on the white part of the eye to get the 'bit' out and then slide it back on centre. If the discomfort persists take the lens out and rub it with Multi Purpose Solution, Complete, Optifree and insert it again.

Summary

Clean with B & L Cleaner, Omnicare Cleaner or Optifree Cleaner etc.
Rinse with Multi Purpose Solution, Complete, or Optifree etc.
Store the lenses in Multi Purpose Solution, Complete or Optifree, etc.

Lens packaging

Lenses are stored individually. To remove a lens:

1. Place the lens package on a flat surface, holding the container firmly.
2. Gently pull back the label where indicated, and follow through the directions of the arrow.
3. Carefully remove the lens from the solution by sliding the lens up the ramp of the lens packaging.

Addendum 6

Instructions to patients wearing rigid gas permeable contact lenses

Rigid gas permeable (RGP) lenses combine the optical advantages of hard lenses with the speed of adaption and other physiological advantages of soft lenses. Although RGP lenses appear superficially the same as conventional hard lenses you ***must*** adhere to the following instructions or permanent damage to the eye or lens may result.

Handling the lenses

1. Hands must be clean and free of creams and nicotine. All traces of soap must be rinsed off. Avoid contamination of the lenses with perfumes. When using hair lacquer keep the eyes closed until the air has cleared.
2. Whilst handling the lenses, always work over a smooth, soft surface such as a paper handkerchief spread over a table. This avoids scratching or losing a lens on the floor.
3. If a lens is dropped, do not move until the lens is located. Always lift a dropped lens by wetting a fingertip or suction holder and gently touch the surface. Lenses must not be slid across table surfaces.
4. Never wipe your lenses with a handkerchief or other material. When wiping is necessary, use only the softest of paper tissues.
5. To avoid distorting the lenses, never leave them near heat and handle very gently. Avoid holding the lenses by the edges.
6. Fingernails should be cleaned and kept reasonably short to avoid scratching the eyes or contact lenses.

Hygiene and lens storage

Absolute cleanliness is essential in the handling and storage of contact lenses. In order to prevent dirt or any harmful organisms being transferred to the eye, the following rules must be observed.

1. The lenses should be stored in a disinfecting solution intended for contact lens use. Whilst any soft lens solution is adequate, solutions intended specifically for RGP lenses usually improve lens wettability and comfort the next day, e.g. Boston or B&L Conditioning Solutions, Soaclens, Total etc. You will be advised if a specific solution or cleaner is necessary for your particular lens material.
2. The case should be emptied and fresh solution should be used each day. The level of soaking solution should be maintained in the container so that each lens is completely immersed in the solution. At least once a week the container should be emptied out, gently scrubbed clean with a soft brush and mild soap, and thoroughly rinsed with running tap water. Final rinsing should be carried out with the storage solution being currently used. The case should then be left open to 'air dry'.
3. The lenses must ***never*** be stored dry as this may allow the growth of bacteria and may affect the curvature of the lens and the wetting ability of its surface.
4. The lenses may normally be inserted direct from the storage solution. This helps the surface wet more easily and forms a protective cushion in the event of a lens being inserted too quickly. If you find that you are sensitive to the storage solution, then this may be rinsed off with *preserved* or aerosol saline and you should discuss a change of solution with your practitioner.
5. On removal of your lenses, clean with the recommended cleaner, e.g. LC65, B&L Concentrated Cleaner, Polyclens etc., and rinse off with saline before replacing the lenses in their container. If working over a hand basin, be sure to put the plug in.
6. *Never* lick your lenses, as harmful organisms can be transferred from the mouth to the eye.
7. Keep hair clean and free of dandruff as this may lead to eye discomfort with contact lenses.
8. Examine the lenses regularly for scratches and chips and to ensure that each lens is being worn in the correct eye. One or both lenses may be engraved with dots (one dot for right and two for the left) or R and L to identify them. Some RGP lenses may also be marked with a code to identify the lens material, e.g. POL for Polycon material.

Enzyme cleaning

Although the lenses should be cleaned every day with a liquid cleaner they may still build up a thin or patchy layer of hardened protein on the surface over a period of time (in a similar way to plaque on your teeth). The following procedure should be carried out at least once a month or when advised to do so.

Clean the lenses in the normal way. Place them in the two transparent enzyme containers and fill up to the fill line with saline. Leave for 1–2 hours. Re-clean with the liquid cleaner and rinse to remove all traces of enzyme and protein by-products. Soak overnight to disinfect in the usual way.

All protein-removing or enzyme tablets are suitable, e.g. Hydrocare Tablets, Polyzym, Amiclair etc., except for Ultrazyme, which is intended for use in hydrogen peroxide. The instructions on most enzyme tablet packets are written for soft lens wearers and can be largely ignored.

Insertion of lenses

Place a wetted lens on the tip of the forefinger of one hand, where it will be retained. Look downwards and, using two

fingers of the other hand, hold the upper lid and eyelashes well up clear of the cornea. Now use the middle finger of the hand holding the lens to pull down the lower lid by the very edge. Keep the head and eyes pointing in the same direction and place the lens gently onto the cornea. Remove the forefinger, release the lower lid and finally the upper lid. The whole procedure is repeated for the other eye. The very tip of the second finger may be used as an alternative, with the third finger holding down the lid, if any difficulty is experienced using the forefinger.

If the lens slips on to the white of the eye, it may be replaced by lifting one lid beyond the lens and pushing it back on to the cornea with the lid margin, using a finger on either side of the lens as a guide. A mirror will aid lens location, and this should be held to one side so that the eye is looking in the *opposite* direction from where the lens is positioned. Alternatively, a suction holder may be used if one is available.

If you cannot remove it from the white of the eye *Do not panic*, it is quite all right to leave it there, overnight if necessary, until you can obtain assistance. It cannot disappear behind the back of the eye as a fold of tissue prevents this. Nevertheless, in the case of an apparent lost lens, remember to check that it has not moved well under the lids.

Check that the lens is on centre by checking your vision once the lens is inserted.

Removal

Although the first method below is the simplest and most commonly used, you are strongly advised to practise the first three techniques so that should one not work, an alternative method can be used.

1. Again, work over a table and hold the free hand cupped to catch the lens. Bend the head slightly and open the eyes as wide as possible, so that both lids are beyond the edges of the lens. Stare straight in front of you and place a finger at the outer edge, separating the lids. Pull the lids towards the direction of the top of the ear and give a single blink, when the lens should be ejected from the eye. At first it may stick to the lashes, from where it is easily removed. A quick glance in the opposite direction to the pull of the fingers at the same instant as the blink may aid lens ejection.
2. The second method is to place the forefinger of each hand on the very edge of the upper and lower lid at the inner corner of the eye. Each lid is then slowly stretched around the lens and then together. Working over a mirror may be helpful at first, though this should be discarded as soon as possible as it may not be available in an emergency. This also applies to the use of a suction holder as suggested in the fourth method of removal described below and a suction holder should not be used except where there is any initial difficulty with either of the above methods.
3. Look straight ahead into a mirror. Place the forefinger of one hand on the upper lid above the lens and the forefinger of the other hand on the lower lid below the lens. Pull the lids slightly apart to reveal the whole of the lens. Gently press the lids on to the eye and move the fingers towards each other. The lens should come away the from the eye and be removed by the two fingers.
4. Using a suction holder. This method will only be suggested to you if you are unable to remove the lens by any other method. The free hand should hold the upper lid away from the lens. Squeeze the bulb of the moistened suction holder firmly and place the end gently against the dome of the lens. Release the pressure on the bulb and slowly withdraw both holder and lens. Always check the lens is in place before attempting to use a suction holder by covering the other eye and ensuring that you still have clear vision in the eye from which the lens is to be removed.

Care of the eyes

1. Insert or remove the lenses gently and slowly to avoid scratching the eyes.
2. In the event of a foreign body becoming trapped behind the lens, the following procedure should be carried out. If initial blinking does not move the particle, look downwards and hold the upper lid away from the eye for a few seconds. Repeat several times if necessary. If the particle is still present, remove the lens, clean and replace. The lens must *not* be left on the eye if there is a foreign body beneath it. If there is any discomfort when the lens is removed, the lens should not be re-inserted until the following day. If the discomfort persists the following day, report to your practitioner as soon as possible or to any suitable hospital Accident and Emergency Department.
3. Always seek advice if:
   (a) your eyes remain red or painful during or after wear
   (b) you continually see coloured haloes around lights or if your vision becomes misty
   (c) you notice white spots on the cornea which do not move on blinking.

   If in doubt, leave the lenses out and seek professional advice immediately.
4. Always report for an examination of your eyes and lenses when advised, at least once a year after the first 12 months. This is *essential* to ensure full integrity of the protective outer layer of the cornea. Always wear your lenses to your appointment unless they are very uncomfortable or you are advised otherwise.
5. Do not wear your lenses if you are ill or have a bad cold, or at least reduce your wearing period. Female patients may occasionally experience slight lens discomfort during the menstrual period, and possibly in the first month or two of taking the contraceptive pill or in the later stages of pregnancy. Advice should be requested where necessary.

Normal symptoms

Some symptoms, such as the following, are *normal* during the adaption period and should not cause anxiety.

1. Excessive blinking and watering of the eyes.
2. Discomfort in bright lights, high wind, dusty atmosphere and on looking upwards. Use sunglasses if helpful.
3. Discomfort when reading and in a stuffy or dry atmosphere. Avoid both where possible in the first few weeks during lens wear.
4. Comfort is greater out of doors than indoors.
5. Moments of blurred vision and temporary double vision.
6. Slight blurred vision with spectacles after wearing contact lenses. This should last a few minutes only and may not be noticeable. Report anything more noticeable than this and particularly any obvious difference between the two eyes (allow for a possibly outdated spectacles prescription).
7. Displacement of lenses on the eye – usually due to poor insertion or removal.
8. Annoying reflections from lights due to the increased lens movement present over the first few weeks.
9. Headaches and tension in the face and forehead. Often found where the wearer is not relaxing the muscles in the forehead.

Wearing programme

The speed of adaption varies greatly from individual to individual. The following gives a good guide, though it may be necessary to adapt more slowly or quickly depending on individual tolerance.

On the first day, wear the lenses for 2–4 hours depending on comfort, and increase by 1–2 hours after that until maximum tolerance is achieved. Wear your lenses every day. This is very important during the adaption period.

Never wear your lenses longer than the recommended period no matter how comfortable they may be. Severe discomfort may be experienced several hours after lens removal if there has been gross over-wear. If the lenses have been left out for several days, for example, due to illness, re-adapt over several days. In cases of prolonged illness, special advice should be requested.

Slight discomfort of both lenses towards the end of the wearing schedule may be ignored, but the lenses should be removed if there is any marked discomfort of one or both lenses. If any discomfort occurs every day, mention this to your practitioner, as occasionally a small modification to the lens becomes necessary as it settles on the eye.

Never leave your lenses in all night. You may rub the eyes during sleep and have sore eyes on waking. Also the presence of the lens reduces normal oxygen supply to the cornea. However, special RGP lens materials are available that allow occasional or more regular sleeping in lenses.

Do not drive with contact lenses in until you are fully adapted to them and have comfortable vision. This is particularly so at night when you may notice haloes or streamers around lights. Remember to keep a pair of spectacles in the car in case of an emergency such as losing a lens or getting something in your eye. These spectacles should be ones that provide good vision – do not rely on a old pair. Cyclists and motor cyclists should wear protective goggles or glasses. In daytime, sunglasses can give protection from both light and dust, but *never* wear tinted glasses at night or at dusk as the tint could then cause you to miss seeing poorly lit cars and pedestrians.

Where possible, wear your lenses outdoors at first and try to do something which will take your mind off your lenses. For instance, do not sit watching television or read a book.

Make a note in your wallet or purse that in the event of an accident your contact lenses should be removed.

When you report for your first examination, usually after 2–4 weeks, *you must be wearing your lenses* and have been wearing them for the maximum period of tolerance that you have achieved; that is, if you have achieved a wearing time of 6 hours, then you should have been wearing your lenses for this time where possible when you come for your appointment.

Addendum 7

More information for contact lens wearers

Before handling your lenses and touching your eyes, careful hand washing will reduce the risk of introducing anything that might damage the lens or hurt your eye.

Here are some basic rules.

- **The working area** For lens insertion and make-up application choose a well-lit, safe area where the lens can easily be seen if dropped.
- **Handling lenses** Concentration on hygiene is essential. Before touching lenses, fingertips must be clean and free from oil, make-up etc. Washing with a pure scent-free soap, e.g. glycerine soap, is ideal to ensure no harmful residue transfers to the lens. Use lint-free towels to dry your hands. Creams can remain on the hands even after several washes and then can be transferred to lenses causing unclear vision. Skin cleanser, oil removers and strongly perfumed deodorants and hair gels need to be washed off carefully before handling lenses.

- **Hand care** Overlong nails will interfere with successful handling of lenses and care must be taken to avoid damage through split nails or rough fingertips. Keep hands away from the eyes when freshly applied enamel is wet.
- **Atomisers and sprays** It is always preferable to use hairspray, deodorant or fragrance sprays *before* inserting the lens. Otherwise close the eyes during use and move out of the area as soon as possible.
- **Cottonwool** When used in the eye area, cottonwool must always be dampened to prevent fibres catching on the lashes and entering the eyes.
- **Moisturizer** If a moisturizer is needed around the eyes, a very light product such as an emulsion or oil should be used. It must not be applied too close to the eyes or on the eye lid as it will very easily transfer to the lenses causing blurred vision. However, by applying near the eyes the normal muscle action of the lids will spread the moisturizer to the surrounding area.

Make-up: some general points

During the first month when your eyes are adapting to lenses, it is best to keep the eye make-up to a minimum, and if the eyes water excessively, then it is best avoided for a time. Streaky mascara defeats the object of the exercise!

Remember eye make-up should be applied *after* lenses have been inserted because you can then see what you are doing and there is less risk of smearing the lenses or smudging make-up. The best cosmetics to use arc those which are non-greasy, water-soluble and less likely to irritate the eyes and delicate surrounding skin. Hypo-allergenic, unperfumed beauty products are the best choice for lens wearers, but even with these, skin reactions can occasionally occur. Lenses should also be removed before removing make-up. This is not applicable of course to wearers of extended-wear lenses who should be particularly careful in their choice and application of eye cosmetics. Eye make-up should be removed *before* general facial make-up as it is generally thicker and may get rubbed into the surrounding skin pores. Removing facial make-up afterwards should therefore prevent this.

If make-up gets in the eye it is best removed using a preserved or sterile saline eye bath rather than Murine or Optrex etc.

All creams, lotions and fluids may become contaminated. For this reason it is best to use a small range of make-up products and discard them after 6 months rather than using a larger range and keeping them for several years. Similarly, make-up sponges should be rinsed after use and allowed to dry to prevent them becoming a source of contamination.

Some more specific points are:

- **Foundation**: Is best not applied too near the eye or on the eye lids for the same reason. Ideally it should be shaded to fade out towards the eye lids.
- **Fluid eyeshadows**: These are ideal for lens wearers providing they are oil-free because oil 'creeps'. Powder eye shadow can also be worn but the applicator should be moistened before use to prevent loose particles falling into the eye, which is extremely uncomfortable. A water-based (for easy removal) cream eye shadow is best but these may be more difficult to obtain. Loose pearlizing agents should not be used.
- **Eye pencils and eyeliners**: Should be used *outside* the line of lashes. This prevents particles falling off the delicate inner edge of the eye lid into the eye and lodging behind the lens. Using eyeliners on the inner lid margins can occasionally cause infections. Avoid the twin extremes of:
  (a) Too hard pencils that may score the lid and also dislodge a lens.
  (b) Too soft a Kohl-type pencil that can become greasy in hot weather.
- **Mascaras**: A water *resistant*, i.e. non-waterproof, type is better than a waterproof one. Waterproof mascaras are difficult to remove from the lens and undue rubbing may be necessary to remove them from the eyelid, thereby irritating the lid area.
- **Lash building mascaras**: Those containing tiny filaments are not recommended for lens wearers as the fibres often drop into the eye with painful results.
- **Products to remove eye cosmetics**: It is preferable to use a non-greasy preparation with a pH (acid–alkali level) matched to that of the tears so that if any runs into the eye it will not sting. Moisturising and removal *creams* are preferable to lotions which can more easily get into the eye.

Addendum 8

Instructions for patients with monovision lenses

Monovision is the term used to describe the situation where one eye is focused for distance objects and the other for near objects. Although this may sound strange it is a situation that often occurs naturally where a person has one short-sighted eye and thereby eliminates the need for reading spectacles. Even for the person with two equal eyes the brain commonly uses one eye at a time. In monovision we simply make use of this mental facility and train the brain to subconsciously alternate use of the eye when changing from near to far viewing. It should be emphasized that monovision does *not* produce the visual loss experienced by shutting one eye. Full fields of vision are retained and significantly less loss of depth perception

occurs than experienced, for example, by a person with a 'lazy eye'. The following notes are to help you get used to monovision.

1. Most monovision wearers adjust to the new situation fairly quickly, i.e. 1–2 weeks, or not at all. If by the end of this period you are still unhappy or very conscious of the blur from one eye then monovision is not for you.
2. Over the first two weeks you will be aware of the slight blur from one eye. This is usually a slight nuisance but is not usually too disconcerting. Relax and try to ignore it. This usually passes until the awareness disappears. Do *not* go around closing one eye!
3. In spite of the fairly high success rate (around 75%) not everyone can tolerate monovision. Please do not get upset by this – there are usually alternatives.
4. Do *not* drive in the monovision mode for at least the first week or two and, in any case, not until you feel entirely safe to do so. Do not drive for the first few occasions at dusk, night time, or in poor visibility.
5. If you feel unsafe driving, even though monovision is otherwise working well, then opt for either a third contact lens corrected for distance vision (e.g. to use for long-distance driving) or supplementary glasses to convert the reading powered contact lens to distance vision. These may also be light sensitive (photochromic) lenses to double as sunspectacles on bright days.
6. A similar situation to (5) applies if problems are experienced for close work.
7. Where possible have a good light on reading matter and let your practitioner know if the best reading focus position is not correct for your visual needs.

Addendum 9

Instructions for orthokeratology patients (*see* Chapter 19)

The wearing schedule and frequency of review is extremely important in the successful control of myopia by orthokeratology. Orthokeratology is intended to produce a change in corneal shape which means, of course, that the lens fitting will change. Failure to follow instructions may mean that temporary corneal distortion may result from an incorrect lens fitting and which can necessitate restarting the whole procedure. Please therefore read the following instructions carefully.

It should be emphasized from the outset that there is a wide range of both corneal shape and rigidity. Some wearers eyes will change significantly slower or faster than others. In some cases ocular rigidity may allow almost no change in corneal shape and you will be advised not to proceed further.

Adaption

If you have previously worn RGP lenses you can go straight to all-day wear provided the lenses are comfortable. If you have not worn RGP lenses before, start at 4–6 hours wearing time, provided this is tolerable, and increase by 2 hours a day. The aim is to achieve all-waking-hours wear as soon as possible. During the adaption period your myopia will be slightly reduced for a short period after lens wear. This means that your current spectacle correction will be temporarily too strong. You may prefer to wait a little while, therefore, before reverting to spectacles. Alternatively, you may be given temporary spectacles or disposable contact lenses.

After the first few days you will be swapped to the second pair of lenses. At each exchange, wear the previous pair of lenses for the first few hours and then swap to the new pair. It is important that you label each pair to avoid confusion e.g. Pair 1, Pair 2 etc.

The second pair is typically worn for 2–4 weeks following the same procedure. Subsequent lenses are usually worn for 1 month before exchange.

It should be stressed again that the speed and degree of change is highly individual. Sometimes it is necessary to go back one or two steps or try different lens designs.

Retainer wear

At some point further change in corneal shape will cease. This may be intentional i.e., at the point where your myopia is fully eliminated. If all your myopia *cannot* be eliminated the final lens becomes your 'retainer' and is worn all waking hours as a normal contact lens. Whilst this is not the ideal end result it does mean that when lenses are not worn, e.g., night-time or for sport, then vision may be much more useful and acceptable.

If your myopia has been eliminated you will be put on to a retainer that will maintain the new corneal shape. Sometimes the last lens used for myopia reduction will become the retainer lens. Typically the retainer lens is worn day and night for approximately 1 month, the lens being removed 1 night a week to rest the cornea. Generally the longer the retainer is worn at this stage the longer the myopia reduction is maintained.

It is important that you be examined when you first start extended wear to ensure that this is acceptable to the eye. You will be examined again at the end of the month with the lenses having been removed one hour after waking.

At this point the retainer lens may be redesigned and you may be asked to go through a further period of stabilization. If the results are good you will now go on to long-term retainer wear.

Long-term retainer wear

The degree of retainer wear is highly individual. Some patients need to wear retainer lenses part of each day, some every night, and others only every second or third night.

Retainer wear should be reduced from full extended wear over the next week or two until the minimum amount of wear is found to give good vision the rest of the day.

Optimal daytime vision is often found if the lenses are left in for the first $\frac{1}{2}$–1 hour after waking. If vision is degrading slightly by evening, the retainer lenses can be re-inserted.

Night therapy

For those with lower errors it is possible to go straight to night therapy. This gives a fast and easy way of arriving at myopia correction.

The lenses can be worn on the first night after you receive them, inserted just before going to sleep. On waking, take note of comfort and vision when the lenses are in, so that you can inform your practitioner of these important factors.

You *must* be reviewed on that *first* morning, wearing your lenses, to ensure that the lens fit is optimal for overnight wear. This visit should be booked when receiving the lenses, and if necessary you should delay beginning the wear of the lenses if an appointment is not available the next day. At that visit, your vision and the lens fit will be assessed, after which the lenses will be removed, and the eyes examined to determine the amount of change which has been achieved. If vision is adequate, the lenses are left out from that time, and reinserted during the later part of the day only if acuity starts to decline. The lenses are again worn to bed on the second and subsequent nights, until the next review (usually 7 days later).

The eyes should be checked *every* morning on waking to ensure that the lenses are not 'bound' or stuck to the cornea. If this should occur, they should be moved using the edge of the lower lid, and left for another 30–60 minutes before being removed.

During the first few visits, we will be able to determine a suitable wearing schedule that gives minimum time with lens wear for good unaided vision. You will continue to be reviewed and gradually the wearing time is decreased to a level which gives the desired reduction in myopia.

Lost lenses

Lenses used during the corneal reshaping therapy period must be returned when finished with.

In the event of a lost lens the cornea will tend to return to its original shape. In this situation we may be able to loan a lens. Alternatively we will retain your previous lens which can be used during the period whilst a replacement is obtained.

Once successful long-term retainer wear is reached you are strongly advised to obtain a spare pair of retainer lenses.

After-care

As with any contact lens wear it is vital to ensure the health and integrity of the cornea at all stages. Over the first year many visits are involved. After the initial therapy an examination twice a year is considered essential to ensure ongoing safety of the eyes and good vision.

In an emergency

If you are concerned as to the safety of your eyes contact your practitioner as soon as possible.

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Chapter 10

Rigid gas permeable corneal lens fitting

A. J. Phillips

Introduction p. 313
Basic requirements p. 314
Corneal contour p. 314
Mathematical models of corneal curvature p. 316
Terms relating to corneal lenses p. 317
Forces affecting the lens on the eye p. 317
Fluorescein patterns p. 319
The general principles of rigid lens fitting p. 321
A brief historical review p. 321
RGP lens materials p. 323
Material and design classification p. 328
Lens fitting designs p. 328
Contact lens fitting with the EyeSys p. 335
Fitting routine of RGP lenses p. 339
Lens care and maintenance p. 347
Refitting the former PMMA wearer p. 348
Fitting sets p. 349
Ordering p. 350
The written prescription p. 354
The final lens p. 354
Identification of RGP materials p. 354
Summary p. 355

Introduction

With the advent of inexpensive, easy-to-fit hydrophilic lenses, some practitioners have abandoned or see little need to learn the art of rigid gas permeable (RGP) fitting. There are, in fact, many reasons why practitioners attempting to do contact lens practice with any degree of seriousness should have a detailed knowledge of RGP lens fitting.

- Former polymethyl methacrylate (PMMA) and RGP wearers all need re-fitting at some stage.
- Some patients will specifically request an RGP lens, e.g. because a spouse has them.
- Some patients will get better visual acuity with RGPs, e.g. astigmats and especially irregular astigmats. In particular, low levels of astigmatism are often left uncorrected in hydrophilic lenses but are corrected by the tear lens with an RGP fit. Build-up of deposits on soft lenses is a further reason for the poor acuity sometimes found with these lenses.
- Some conditions can *only* be fitted with RGPs, e.g. keratoconus, traumatized corneas, post-grafts, etc.
- RGP lenses may be easier for some patients to handle, e.g. those with narrow interpalpebral apertures, enophthalmics etc.
- At the time of writing RGP lenses can be provided with significantly better oxygen transmissibility and better retro-lens tear flow than the best hydrophilic lens, making them more suitable for higher prescriptions, i.e. cases requiring thicker lenses; and also corneas with borderline acceptable physiology, e.g. traumatized corneas, etc.
- For the same reason as the previous point, RGP lenses are safer for extended or flexi-wear than hydrophilic lenses
- From the above, RGP lenses may provide a better, and sometimes the only, alternative to hydrophilic lenses in some clinical situations, e.g. giant or contact lens-induced papillary conjunctivitis (GPC) (CLPC), superior epithelial arcuate lesions (SEALS) (*see* Chapter 18) or in certain other cases such as marginal dry eyes.
- RGP lenses generally show better deposit resistance than hydrophilic lenses and are therefore easier to maintain and may last longer.
- Because of greater deposit resistance, greater resistance to breakage, and lower solution costs, RGP lenses are more economic for the patient.
- RGP lenses can be modified in power and in their peripheral curves and total diameter (TD). The power may be changed by up to +/–0.75 D, the peripheral radii can be flattened to increase the edge lift, the edges can be re-shaped or repolished, the TD can be reduced, and the front surface repolished if highly abraded. These again add to the economy and life of RGP lenses. The inability to modify hydrophilic lenses means that they are unsuitable for patients whose prescriptions are changing rapidly, e.g. young myopes or certain cataract cases.
- Patients who are generally non-compliant with instructions for cleaning and disinfectant procedures, or whose lifestyle is such that they are unlikely to devote sufficient time to lens maintenance, should be encouraged to wear RGP lenses. Compliance is easier, quicker and RGP lenses carry a significantly reduced contamination risk.
- The inherent ability of hydrophilic lenses to absorb and concentrate substances into the lens matrix means that they may be unsuitable for some patients using long-term preserved topical medication such as steroids or glaucoma drugs. Although this has not been found to be a problem in the large majority of cases, if drug absorption is suspected the patient should be refitted with RGP lenses.

- In certain specialized areas, such as orthokeratology, a high degree of knowledge and experience with RGP lens fittings is a prerequisite.

Basic requirements

The student new to contact lens practice is often confused by the multitude of different lens materials and fitting techniques available, each claiming its own special advantages. The basic requirements of a well-fitting contact lens are often forgotten and should be stressed from the outset. These are simply:

- Maintenance of corneal integrity (including integrity of the related ocular and extraocular tissues).
- Maintenance of normal tear flow behind and over the lens.
- Adequate vision.
- Patient comfort.
- Invisibility.

It follows, therefore, that the best fitting technique or lens construction to use in any one particular instance is the one which most readily satisfies these criteria. For many patients, several different techniques may all perform adequately; in others, the use of a specific technique may give improved results.

The ideal corneal lens material should have a high degree of the following properties:

- Oxygen permeability.
- Surface wettability.
- Low surface reactivity.
- Dimensional stability.
- Flexure resistance and recovery.
- Surface hardness.
- Machining and polishing capability.
- Fracture resistance.
- Material and quality control, i.e. different batches of the material should have the same chemical and physical characteristics and should behave in an identical manner during the lens fabrication process.
- Wide range of tints and depths of tint.

With the exception of oxygen permeability, polymethyl methacrylate (PMMA) satisfies all these requirements to a good or acceptable degree. Indeed the manufacturers of rigid gas permeable (RGP) materials have been forced to sacrifice several of the other material considerations in order to gain oxygen permeability. Because PMMA lenses are still fitted, particularly in certain parts of the world, and because the advent of new materials may lead to the development of less flexible materials which may simulate the properties of PMMA, the fitting of both PMMA and RGP materials will be dealt with in this chapter, although the use of gas permeable materials is now almost universal. Manufacturers have gradually improved both oxygen permeability and minimized the trade-offs of the original RGP materials. Some disadvantages do still exist and these will be discussed later. A brief discussion of the history of hard lens fitting and development will be made since some PMMA patients will still occasionally be seen and also because the development of modern RGP lenses has historically followed from the many years of clinical experience with PMMA lenses.

Corneal contour

In the fitting of corneal lenses, a knowledge of the corneal contour is essential. To review the enormous volume of research on this single topic would be impossible in this chapter. Nevertheless, for fitting purposes, a basic knowledge will suffice.

In the late 1940s and early 1950s the main instrument available for measurement of corneal curvature was the keratometer. This gave an accurate value for the central corneal curvature, but a single curve lens made to this curvature and a total diameter of 9.0–10.0 mm showed a fluorescein picture (see p. 319) of central and peripheral touch with intermediate corneal clearance (*Figure 10.1*).

Observations such as this led Bier (1956) to conceive the idea of a triple zone cornea (*Figure 10.2*). Bier believed there to be a central, regular and positively curved zone; outside this a less curved or *relatively* negative zone; and beyond this a further zone of steeper curvature. From this general idea arose the concept of a 'corneal cap'. This commonly used term in contact lens practice was meant to indicate the central, regular corneal area. Bier stated that in the average case the corneal cap was decentred 0.2–0.6 mm nasally and 0.2 mm superiorly.

Modifications to the keratometer confirmed the peripheral flattening of the cornea but representations of this flattening were often incorrectly shown, as in *Figure 10.3*. The centre of curvature for the central region lies at C_1 and at C_2 for the peripheral portion. The construction so produced, supported the concept of a central corneal cap, a secondary negative zone and tertiary positive zone.

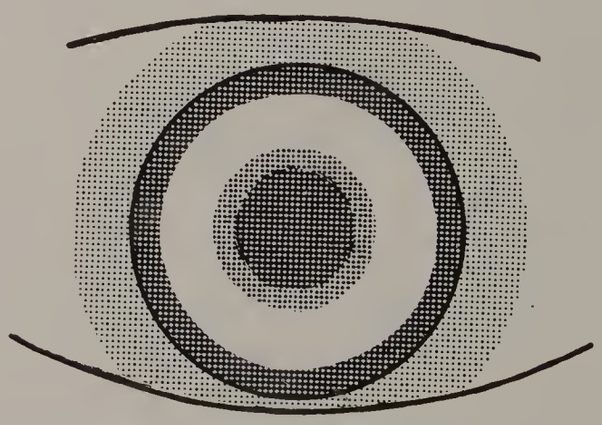


Figure 10.1 Fluorescein picture obtained when fitting a mono-curve corneal lens of approximately the same curvature as the central cornea. Shading within the lens circumference indicates corneal bearing and the unshaded ring indicates corneal clearance

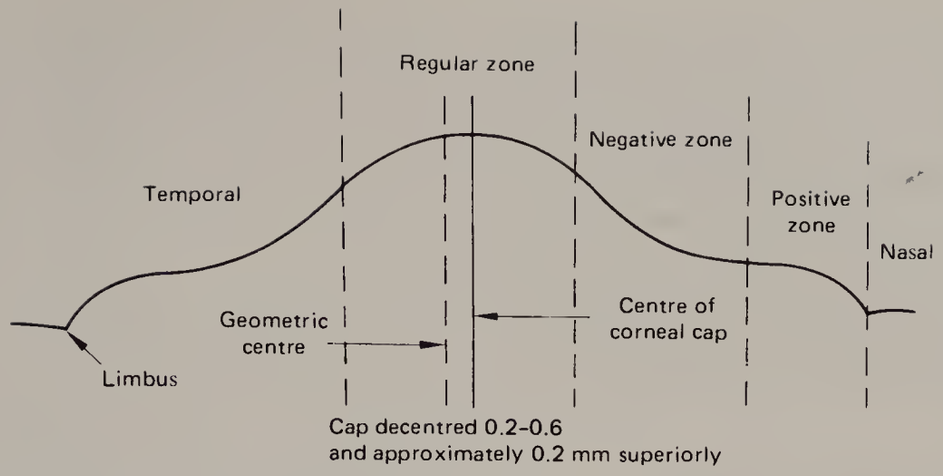


Figure 10.2 Diagrammatic representation of the corneal contour. (After Bier, 1956)

The introduction of more accurate methods of assessing corneal contour – such as single mire keratometry, photokeratoscopy and computerized corneal topography – have shown that the cornea has a constantly varying radius of curvature; also the centre of curvature is constantly changing to a new position, the centres of curvature forming a locus of points which extends from the centre of curvature of the central point to an off-axis position. The locus of centres of curvature for a constantly varying curve is known as an *evolute*. The general appearance of a corneal evolute is shown in *Figure 10.4*.

It is now possible to see why the original single curve lens made to the same curvature as the central keratometer reading gave the fluorescein picture shown in *Figure 10.1*, and how this led to the concept of a triple zone corneal configuration as described by Bier. However, although the concept of a 'corneal cap' is not strictly correct, for clinical purposes it is often convenient to assume that one does exist, for the following reasons:

- The flattening close to the centre of the cornea is so small that the central region may be assumed close to spherical, in each principal meridian, for clinical purposes.
- The keratometer reading obtained for fitting purposes is not the curvature value at the geometric centre of the cornea but of two points some 1.2–1.8 mm each side of the centre (*see* Chapter 6). For a typical back optic zone diameter (BOZD, *see* p. 317) of 6.00–7.00 mm, the keratometer reading is therefore approximately the mean value of the curvature at the geometric centre* and that at the edge of the back optic zone. A curvature value is therefore obtained which should closely approach the cornea over this diameter.

*Arias (1960) pointed out that, since the visual and geometric centres of the cornea do not normally coincide, when the patient fixates the keratometer target, he is looking along the visual axis and a slightly flat value of central curvature is obtained. The curvature at the geometric centre may be 0.02–0.05 mm steeper than the keratometer reading. This was confirmed for emmetropes by Sheridan (1970), although in myopes the visual axis appears to pass through the steepest part of the cornea.

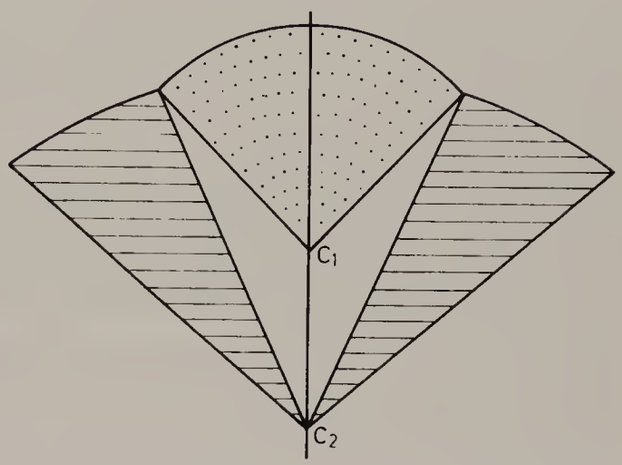


Figure 10.3 Incorrect representation of peripheral corneal flattening as measured by a keratometer

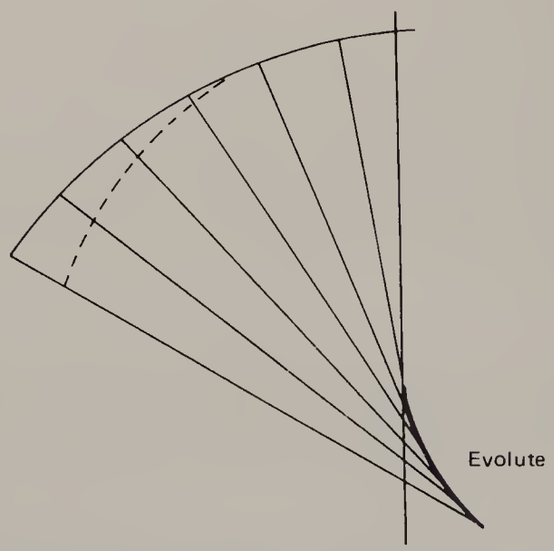


Figure 10.4 General appearance of a corneal evolute

- Where it is attempted to align too large a central area of the cornea with one single curve of a lens, the peripheral corneal flattening shows a circle of non-alignment of the fluorescein pattern in the midperiphery of the curve, similar to that shown in *Figure 10.1*. Earlier writers on corneal lens fitting claimed that this was because the back optic zone diameter was larger than the corneal cap, and they recommended that a smaller BOZD be used. While it has been shown that the corneal cap is a misconception, the clinical remedy of improving the area of alignment by reduction of the BOZD still holds good as an attempt to align a spherical contact lens with a non-spherical cornea.

Mathematical models of corneal curvature

The use of computers has enabled the design, in recent years, of sophisticated lenses which more accurately reflect the true shape of the cornea. For their design, mathematical models of the corneal curvature are necessary for the appropriate calculations to be made.

Conic sections, i.e. the curves exposed when sections are taken through a cone, produce a suitable clinical model for the cornea (Bibby, 1976). The notation given by Bennett (1966) is generally accepted and is shown in *Figure 10.5*.

The prolate curve represents the flattening and the oblate the steepening parts of the ellipse.

Bennett, taking the origin of the coordinates at the apex of the cornea, gives the relationship between the x and y values for any point on the curve as:

$$y^2 = 2r_o x - px^2$$

where r_o is the radius of curvature at the apex of the curve and p is the 'shape' factor.* The 'shape' factor indicates the level of asphericity, i.e. the departure of the actual curve from the apical radius, and takes the following values:

Hyperbola, $p < 0$
Parabola, $p = 0$
Prolate (flattening) ellipse $0 < p < 1$
Sphere $p = 1$
Oblate (steepening) ellipse $p > 1$

Another term often used to define the corneal asphericity is the eccentricity (e) which is equal to cos α/cos β in *Figure 10.5*. It is applicable to all the conic sections and there is a relationship between 'shape' factor and eccentricity (*see also* p. 331)

$$p = 1 - e^2$$

Guillon *et al.* (1986) showed that the majority of corneas approximate to a prolate ellipse with a typical 'shape' factor of 0.85 ($e = 0.39$). However, a large variation was found even within the normal population with some corneas

*Not to be confused with the usual optometrically accepted meaning for the term 'shape' factor which is one of the components of spectacle magnification, and which also applies to contact lenses (*see* Chapter 5).

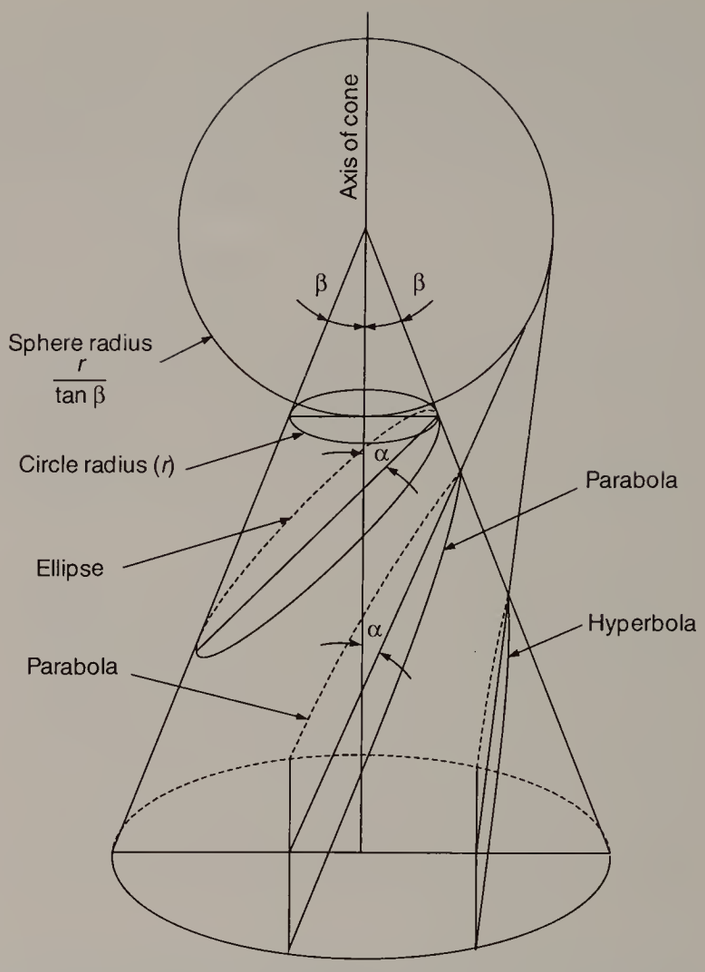


Figure 10.5 Mathematical representation and notation for conic sections. Circle, P = 1; ellipse, 0<P<1 and P>1; parabola, P = 0; hyperbola, P<0

remaining unchanged in curvature towards the periphery whilst a small number even steepened at the periphery (range 0.21–1.20). A high correlation was found between 'shape' factors of the flat and steep meridians of individual patients indicating that, for the majority of eyes, the central and peripheral astigmatism is similar. Again, large individual variations were sometimes found confirming the clinical impression when, in occasional cases, the astigmatic fluorescein patterns (*see below*) observed under the lens are different at the centre and periphery. Such factors need to be borne in mind in the designing of fitting sets and serve to stress the fact that each patient must be treated as an individual.

Barr (1984) gave an average corneal shape factor of 0.75 ($e = 0.50$), Brungardt (1984) of 0.77 ($e = 0.48$), and Guillon *et al.* (1983) of 0.83 ($e = 0.41$), with extremes of 0.70 and 0.88.

Douthwaite and Sheridan (1989) found the majority of their subjects possessed a p value above 0.8, i.e. their corneas displayed relatively little flattening with eccentricity. Only 10% of their group possessed a p value at or below 0.7. This explains why many prospective contact lens wearers can be fitted with a lens having a back optic zone

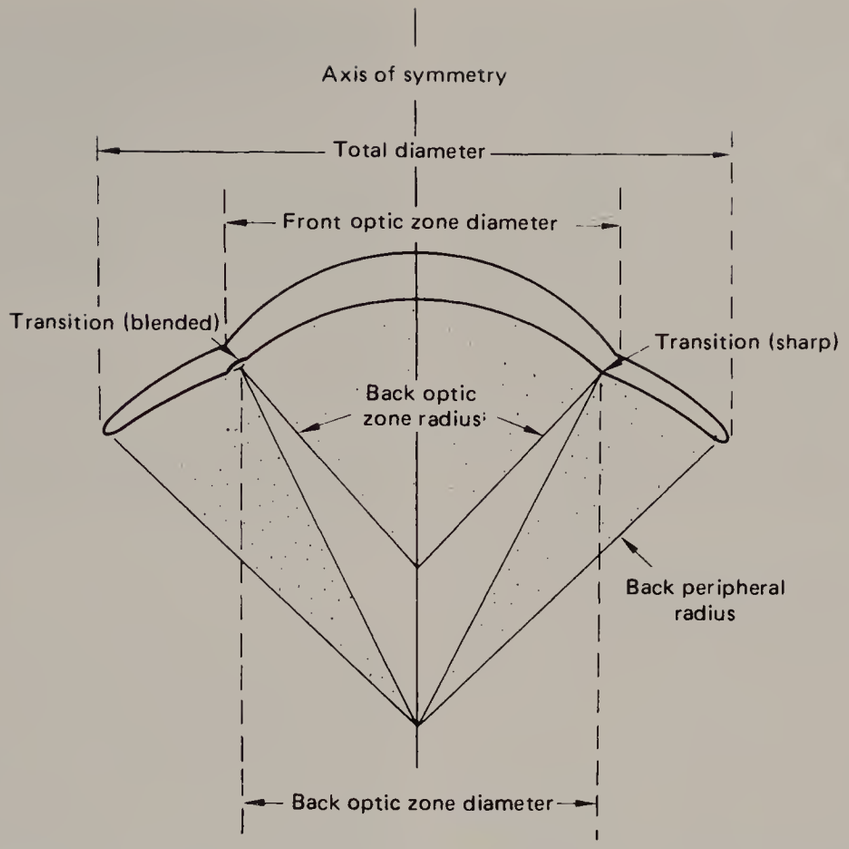


Figure 10.6 Diagrammatic representation of corneal lens dimensions as recommended by the International Standards Organisation

radius (BOZR) similar to the standard keratometry readings. However, every contact lens practitioner will recall encountering patients where this convenient state of affairs does not appear to occur. In these latter cases the subsequent fitting time may be prolonged by the presence of a low p value which goes undetected in the normal initial examination.

According to Burek (1987), Wesley–Jessen refer to e^2 as the 'shape' factor or SF. Thus

$$SF = 1 - p = e^2$$

Because the term 'shape' factor may therefore be misunderstood, it seems best to adopt Bennett's (1988) suggestion of referring to the general term 'asphericity' and denoting it by p, e or e^2.

Terms relating to corneal lenses

Detailed terminology relating to corneal lenses is summarized in the Glossary of terms at the beginning of the book. For ease of reference the major terms are summarized in *Figure 10.6*. The reader is strongly advised to obtain a full copy of ISO standard 8320–1991.*

*A new ISO standard is in the course of preparation at the time of writing.

Forces affecting the lens on the eye

For a correctly fitting lens, a balance is necessary between those forces acting to hold the lens against the cornea and those acting to move the lens or eject it from the eye. The most important of these forces are reviewed as follows.

Capillary attraction

The force of attraction between the lens and the cornea varies inversely with the distance between the two surfaces (Wray, 1963). In other words, the more nearly a lens surface matches the corneal contour the greater is the force of attraction. If the lens curvature is made slightly flatter than that of the cornea, the capillary attraction is lessened and the lens moves more easily. Because the cornea is not spherical, it should be impossible to achieve exact alignment with a spherical corneal lens. However, because the cornea is compressible, lenses which closely approximate the corneal curvature can 'mould' the cornea to the shape of the lens and appear as a good alignment fitting. With lenses fitted steeper than the corneal curvature, although capillary attraction is lessened, the compressibility of the cornea allows the edge of the lens to press into the cornea during blinking, and lens movement is reduced by reason of the suction effect so produced.

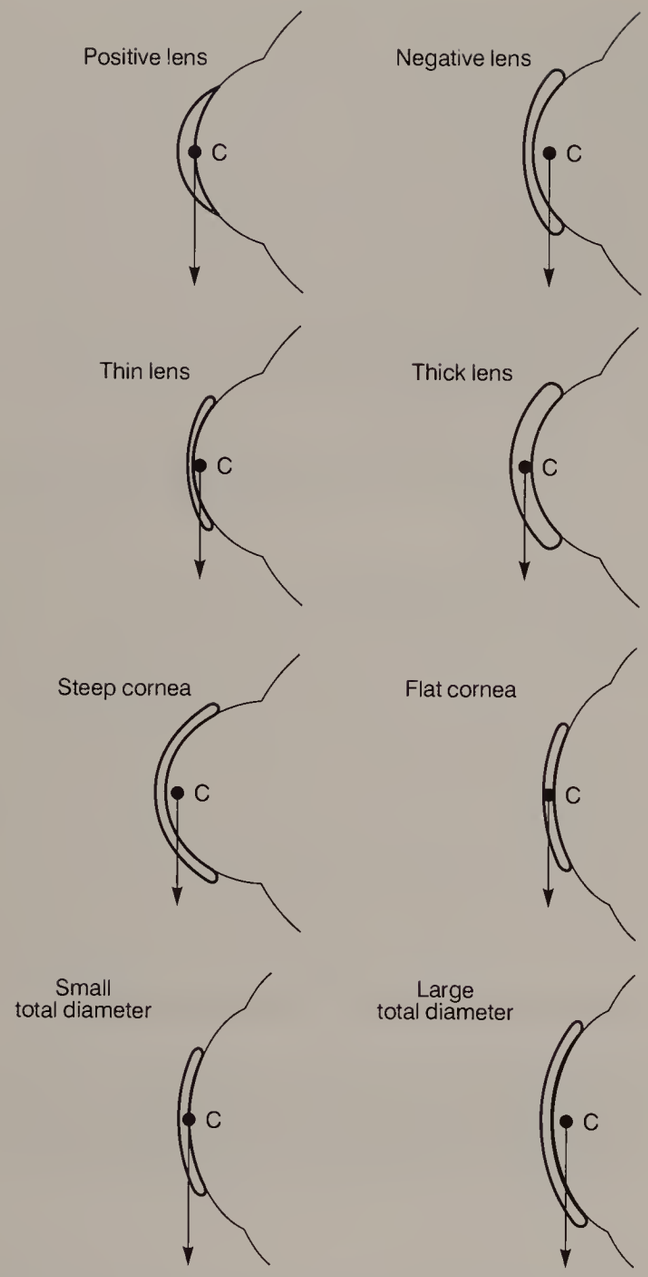


Figure 10.7 Diagrammatic representation of the centre of gravity (C) with lenses of differing power, thickness, BOZR and TD

In practice, while it is desirable to achieve a reasonable area of corneal alignment with the lens to prevent corneal insult, a lens which *exactly* conforms to the corneal contour over the *whole* of its surface cannot be comfortably tolerated. In this instance the capillary attraction would be so great that lens movement would be minimal and adequate tear circulation beneath the lens would be prevented.

Gravity

The effects of gravity on the lens are most easily envisaged by the use of the concept of the centre of gravity. This has the property that the object acts as though all of its weight were concentrated at that one point. For a corneal lens, the position of the centre of gravity is near the back surface or actually behind the lens. The further the centre of gravity moves behind the lens the greater the areas of support above the centre of gravity. As the centre of gravity moves towards the front surface of the lens, there is less support for the lens and it tends to drop or 'lag' more readily under the effect of gravity.

The position of the centre of gravity is affected by the lens total diameter, back vertex power, thickness and BOZR (*Figure 10.7*). Thus, the effects of gravity are lessened for lenses with negative powers, minimal centre thickness, steep corneal curvature and larger total diameter (TD).

Carney and Hill (1987) summarized the relative effects of various changes in lens parameters and the effect that these have on the movement of the lens centre of gravity. These are shown in *Table 10.1*.

This shows the markedly superior effects achieved by total diameter changes in comparison to other design changes.

As an example, if a practitioner wishes to stabilize a –3.00 D lens of 9.00 mm TD, 7.40 mm BOZD, and 7.80 mm BOZR, the following options are realistically available:

(a) increase the diameters in steps of 0.1 mm, each step shifting the centre of gravity back into the eye by 0.018 mm;
(b) steepen the BOZR in steps of 0.05 mm, each step shifting the centre of gravity back into the eye by 0.004 mm.

Although these calculations consider just one of the factors affecting on-eye performance they do give some indication of the design features to be aware of, and their relative importance, in the assessment and correction of that performance.

The lens mass will also be affected by the specific gravity of the material used. Table 10.3 (*see* p. 324) shows the range of specific gravities in some current RGP materials. In a

Table 10.1 The effect of lens parameter changes in shifting centre of gravity to enhance lens stability.*

	Centre of gravity change/ parameter change	*Relative effect*
Negative lenses		
Total diameter	0.018 mm/0.1 mm	× 4.5
Back central radius	0.004 mm/0.05 mm	× 1
Centre thickness	0.006 mm/0.01 mm	× 1.5
Positive lenses		
Total diameter	0.014 mm/0.1 mm	× 7
Back central radius	0.004 mm/0.05 mm	× 2
Centre thickness	0.002 mm/0.01 mm	× 1

*Derived from the altered centre of gravity resulting from the smallest parameter change of clinical relevance. The change in centre of gravity is based on the total parameter ranges encompassed in the figures; the exact values will vary slightly depending on position within those ranges.

Source: After Carney and Hill, 1987

study on a small group of wearers exhibiting poor lens centration, Quinn and Carney (1992) found no major effect by changing to materials of differing specific gravity but made the following recommendations:

- If a patient consistently exhibits a high-riding lens, material changes to manipulate specific gravity will probably not significantly improve centration. However, re-fabricating a lens in a thinner design may provide some benefit.
- If a patient consistently exhibits a low-riding lens, selection of a low specific gravity lens and/or thinning the lens should prove beneficial.

In conclusion, it is thus apparent that changes in lens thickness, total diameter and power are those parameter changes most likely to affect lens position on the eye.

Tear meniscus

The existence of tear meniscus under the edge of a corneal lens is essential for its centration (Mackie *et al.*, 1970; Mackie, 1973). For any given lens, the greater the circumference of the meniscus, the better the lens centration. If the peripheral curve is too close to the cornea the tears meniscus will be ineffective in holding the lens on the eye and reduce tear interchange. If the clearance is too great the meniscus will be inverted and will reduce the adhesion causing possible 3 and 9 o'clock staining (see later) or bubbles under the edge. Although used infrequently nowadays owing to the use of oxygen permeable materials, fenestration holes, which permit the formation of a tear meniscus between lens and cornea, also therefore aid in lens centration as they add to the effective 'length' of the tear meniscus between lens and cornea.

Lid force and position

Many corneal lenses ride in such a position that the upper lid covers a small portion of the lens. The lens is thus held between the cornea and lid. This force contributes to but is not necessary for holding the lens on the eye.

In many cases, the lower lid is sufficiently high for the lens to rest on it between blinks.

Frictional forces

Another factor that keeps the lens stationary on the eye is the frictional force. This is largely due to the viscosity of the precorneal film. If the precorneal layer is thin, friction may also occur directly between the surface of the lens and the corneal epithelium.

Variations in the viscosity of the precorneal film affect the frictional forces and so affect the position of the lens on the cornea. Thus, the foreign body reaction produced by a lens when first worn, or by a lens with a misshapen or damaged edge, causes an increase in lacrimal production. This serous liquid is less viscous than the normal precorneal liquid and lowers its frictional effect, allowing greater lens movement. Since the precorneal film thickness is also increased, the capillary attraction is lessened and, again, lens movement is increased.

Fluorescein patterns

Fluorescein patterns (*see Figures 10.8 and 10.18–10.25*) are obtained when one drop of 2% sodium fluorescein is instilled in the lower fornix or on to the bulbar conjunctiva above the lens in order to give colour to the tears. The lens fit is then viewed under ultraviolet light, which renders the tears fluorescent. A different pattern is obtained as the lens moves upwards and downwards following each blink and as the fluorescein gradually drains from behind the lens. It is thus a dynamic picture and not easily represented pictorially.

The fluorescein picture is dependent both on the tear flow and on the fit of the lens. Initially a few moments should be allowed for excess fluorescein to drain from the front surface of the lens, enabling the retro-lens picture to be seen. However, excess tearing may rapidly wash all fluorescein from behind the lens leaving the 'black' appearance of an aligning zone or lens. Conversely lack of blinking or tearing may leave fluorescein on the lens front surface thereby mimicking fluorescein trapped under the back optic zone (BOZ) of a steep fitting lens.

In the case of a tight fitting lens, i.e. one where the BOZ transition or lens edge dig slightly into the cornea thereby preventing retro-lens tear flow, fluorescein cannot enter behind the lens. Tight fitting lenses will generally not move on normal blinking. In this case digital manipulation of the lens using the lid margin will allow lens movement and the influx of fluorescein under the lens. This is diagnostic of a tight fitting lens, or occasionally a very dry eye (*see also* Lens adhesion phenomenon, p. 345). On the other hand a lens that moves too much after a blink may either be too flat (loose) or simpy be causing excess tearing.

The experienced practitioner can quickly judge the degree of alignment (where the appearance is almost black) or the degree of clearance from the cornea (where fluorescence occurs). With experience the subtle appearance of very slight central clearance or the minutely tight edge will be recognized. On the astigmatic cornea (*see Figure 10.21*) the difference in the degree of fluorescence between the two principal meridians can easily be seen.

Some modern RGP materials contain UV absorbers for ocular protection purposes. These are particularly useful for aphakes who have lost the UV absorbing value of their crystalline lens; for children whose crystalline lenses have little natural UV absorbing properties; or for those working outdoors much of the time. However, the fluorescein pattern of these lenses cannot, of course, be viewed with a normal hand UV (e.g. Burton) lamp. In these cases the cobalt blue filter of a slit lamp used at low magnification should be used, or a white light hand lamp with a Wratten No. 47 filter over the light emitter and a Wratten No. 12 filter over the viewing aperture.

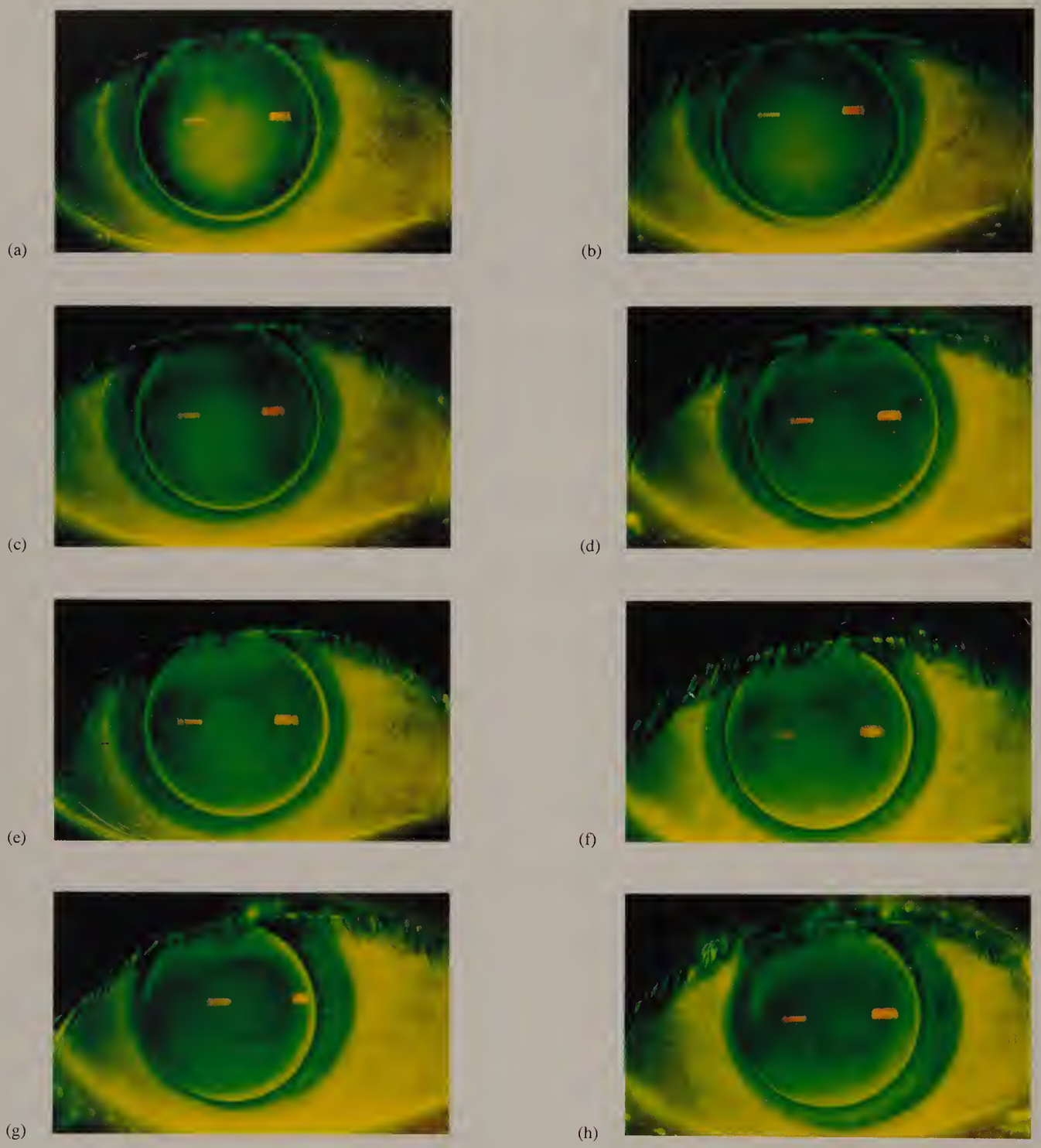


Figure 10.8 This series of pictures shows lenses of various BOZR on the same eye, *K* readings 7.90 at 180°, 7.70 at 90°. The lens TD is 9.60 mm, and BOZD 7.5 mm. The horizontal visible iris diameter is 11.50 mm. (Courtesy of The Cornea and Contact Lens Research Unit, Sydney). (*a*) BOZR 7.65 mm: the central fit is grossly steep with accumulation of fluorescein under the whole back optic zone. (*b, c*) BOZRs 7.70 and 7.75 mm, respectively: the steep central fit is still obvious with the depth and intensity of fluorescence reducing as the fitting approaches corneal alignment. (*d*) BOZR 7.80 mm: the BOZR is still slightly steeper than the flattest horizontal corneal meridian and the slight fluorescence centrally can just be seen. There is more peripheral clearance in the vertical meridian. (*e*) BOZR 7.85 mm: the BOZR is now in good compromise alignment over most of its area. Lack of fluorescence from the tear film over the back optic zone is apparent. (*f*) BOZR 7.90 mm: by assessment of the fluorescein pattern the lens still appears in good alignment with the cornea. A BOZR of 7.85 and 7.90 mm may indeed give a good fit but it is extremely difficult to judge a very slightly flat fit that could possibly result from the 7.90 mm BOZR, although the peripheral clearance is now greater. (*g*) BOZR 8.00 mm: a slightly flat fitting lens is now apparent. The lens cannot balance on the corneal apex and so tilts to (in this instance) the temporal cornea so that central and temporal contact become apparent. (*h*) BOZR 8.05 mm: a definite flat fitting lens can now be seen rocking from the apex to the temporal corneal zone

The general principles of rigid lens fitting

In the simplest form these may be listed as follows.

- An RGP lens should be fitted to provide as large an area of corneal alignment as possible in order to spread the weight of the lens and pressure of the lid against the lens and also to minimize lens-induced trauma through localized pressure, e.g. from a sharp transition or too steep a BOZR.
- The back surface peripheral curve(s) should be flat enough to prevent lens indentation on movement to the flatter corneal periphery, but should not show such excess edge clearance that it would cause lid margin or perilimbal irritation. In addition the peripheral back surface configuration should encourage good retro-lens tear flow.
- The BOZD should be large enough to prevent flare from the peripheral curves when the pupil is dilated at night. However, too large a BOZD will prevent adequate alignment of this typically spherical curve over the aspheric corneal shape.
- The design of the lens should be such as to allow normal corneal physiological function. This will involve choice of a material with an adequate Dk for the eye in question; lens thickness to optimize transmissibility but not so thin that the lens warps, distorts, or is easily fractured; and a lens back surface design that encourages good retro-lens tear flow and no pressure points on the cornea.
- The lens edge should be thin enough and correctly shaped for comfort, but not so thin that it effectively becomes sharp or may chip.
- The lens TD should be large enough to encompass the chosen BOZD; allow adequate width for the peripheral curve configuration; be large enough for minimal lid irritation and to assist good centration. However, too large a TD may reduce retro-lens tear flow; increase lens mass; and possibly allow limbal 'bumping' on lateral eye movements.

Bearing the above in mind, it is now relevant to look at a short historical review to see the development of modern lens fitting.

A brief historical review

The move from scleral to corneal lenses was enormous and could only have come about due to the development of the then new acrylic plastic material. Tuohy (1953) is credited with fitting the first 11.00 mm diameter monocurve corneal 'microlens' in 1948 (*see* Chapter 1). Early experimentation showed that it was impossible to fit this single back curve to the same value as the keratometer reading so that the microlens was generally fitted 0.3 mm flatter than the central corneal curvature (Dickinson, 1954). Nevertheless, this still resulted in lenses which showed heavy central bearing, excessive lens movement, alteration in corneal curvature, and usually eventual corneal insult and lens rejection.

With the early improvements in understanding corneal shape mentioned at the beginning of this chapter, Bier (1957a,b) suggested producing a lens with two back surface curves, the peripheral curve being flatter than the central BOZR. It was found that with a BOZD of 6.00–7.50 mm good corneal alignment could be obtained if the BOZR had the same value as given by the keratometer reading. In order to maintain oxygen flow under the BOZ the secondary curve had to be fitted flat (0.4–0.8 mm flatter than the BOZR) and had a typical TD of 8.50–10.00 mm. A typical construction was:

BOZR:6.50/(BOZR + 0.50):9.50

Although it is still possible to fit patients with this 'contour' design, success by today's standards was limited to only a very few patients. In order to obtain a healthy cornea a PMMA lens needed to be very free and mobile and this design in most cases would cause difficulties with stability of vision or flare from lights. Improvements on this design were made by introducing a 12.25 mm edge curve usually 0.20 mm wide in order to help tear interchange (the Modified Contour Technique). A typical lens would be:

BOZR:6.50/(BOZR +0.50):9.10/12.25:9.50

Again, most successful cases from a comfort point of view did not obtain the same degree of success with vision because of lens mobility. By the late 1960s, however, enough was understood about the shape of the cornea and the main stumbling block to success, corneal oedema. Lenses during this period were usually fitted with a small degree of apical clearance, the BOZD being between 7.00 and 7.50 mm, occasionally going up to 8.00 mm, a small secondary area aligning the cornea, and flatter final peripheral curves to give enough clearance to allow adequate tear exchange and to avoid tightening on the cornea as the lens rode up onto flatter parts of the cornea (*see Figure 10.20*). Typical designs were:

BOZR:7.00/(BOZR + 0.50):8.00/10.00:8.50/12.25:9.00

or

BOZR:7.50/(BOZR + 0.80):8.00/10.50:9.00

Because of variations in blending during manufacture and the difficulty in assessing the accuracy of the peripheral curves, it would often be necessary to spend some considerable time within the practice attending to the degree of blend between the curves and to the edge shape.

A further development on hard lens design came when Stone (1975) showed that by choosing secondary and tertiary curves with a fixed difference from the BOZR the axial edge lift (*see* p. 330) of a lens reduced as the radius flattened. For example:

7.20:7.00/7.70:8.00/9.40:8.50/11.90:9.00
7.80:7.00/8.30:8.00/10.00:8.50/12.50:9.00
8.40:7.00/8.90:8.00/10.60:8.50/13.10:9.00

These gave an axial edge lift of 0.172 mm for the 7.20 mm BOZR, 0.140 mm (7.80 mm) and 0.117 mm (8.40 mm) respectively.

Table 10.2 Lenses of constant axial edge lift design

Total diameter 8.60 mm. Constant axial edge lift 0.12 mm (Stone)
7.20:7.00/8.10:7.80/ 9.50:8.60
7.80:7.00/9.00:7.80/10.90:8.60
8.40:7.00/9.90:7.80/12.75:8.60
Total diameter 9.00 mm. Constant axial edge lift 0.15 mm (Stone)
7.20:7.00/7.70:7.80/ 8.80:8.60/10.40:9.00
7.80:7.00/8.75:7.80/10.10:8.60/11.30:9.00
8.40:7.00/9.60:7.80/11.60:8.60/12.60:9.00
Total diameter 9.50 mm. Constant axial edge lift 0.175 mm (Rabbetts)
7.20:7.50/8.00:8.50/ 8.80:9.00/ 9.50:9.50
7.80:7.50/8.90:8.50/10.00:9.00/11.15:9.50
8.40:7.50/9.65:8.50/11.35:9.00/13.00:9.50

Stone considered that this caused problems with lenses showing too much edge clearance on steeper corneas and too little on flat ones. In order to offset this problem she suggested that the secondary and tertiary curve radii should be chosen so that the axial lift at all points along the lens was constant. These lenses are now accepted as being of constant axial edge lift design (CAEL) and are discussed later in more detail. In the late 1970s a whole range of these lenses were designed although in most cases the BOZD was between 7.00 and 8.00 mm, the total diameters between 8.50 and 9.50 mm and the edge lifts between 0.120 and 0.175 mm. *Table 10.2* shows typical examples of three fitting sets designed by Stone (1975) and Rabbetts (1976).

By this time many of the restrictions with PMMA lenses were recognized. Most important were oedema, 3 and 9 o'clock staining, spectacle blur following contact lens removal, inconsistent spectacle refraction with lowered acuity, reduced wearing times and flare.

As far as design was concerned it was not possible to get the BOZD small enough to reduce the stagnation of tears without causing visual problems, or large enough without causing oedema. Lenses often had to be fully blended to increase movement, the edge had to be very flat which caused lid irritation and/or 3 and 9 o'clock staining. Also a great deal of time had to be spent on modification, each new lens often requiring meticulous attention to detail. In many cases spectacle blur and unstable refraction were sacrificed for comfort. As long as the patient was able to wear lenses all day without recourse to glasses, and emergency overwear treatment was avoided, they were deemed a success. This era gradually gave way to soft lenses which were initially more comfortable, did not cause spectacle blur and gave the possibility of extended wear. Solution allergies, corneal vascularization due to low grade chronic oedema, GPC, continual replacements, expensive care systems and the gradual understanding that even high water content lenses were not going to transmit enough oxygen for truly safe extended wear in a large percentage of the population, meant that after a number of years in the wilderness rigid lenses were reborn (Atkinson, 1987).



Figure 10.9 Central corneal clouding or oedema such as that seen following the wear of a tight fitting PMMA corneal lens. This gives rise to hazy or smoky vision known as veiling or Sattler's veil, Fick's phenomenon or simple veil (*see also* Figure 20.1.16) (Courtesy of B. Czigler)

Summary of disadvantages of PMMA lenses and hydrophilic lenses

Although PMMA corneal lenses were fitted in large numbers over a period of 30 years, certain disadvantages became apparent in a significant proportion of patients. These can now be summarized as follows.

- Corneal oedema (as central corneal clouding or disc oedema, and hypoxic intracellular epithelial oedema (*see Figure 10.9*).
- Induced refractive and corneal curvature changes (*see* Chapters 5 and 18).
- Corneal staining.
- Prolonged adaptation period for many individuals.
- Flare in low levels of illumination.
- Discomfort in dusty surroundings.
- Poor tolerance in adverse environments.
- Ease of lens loss.
- Eventual loss of lens tolerance known as the 'corneal exhaustion syndrome'.

Although some of these problems were solved with the advent of hydrogel lenses, these also suffered from their own specific disadvantages (*see* Chapter 11).

- Poor or difficult correction of astigmatism.
- Tendency to deposit formation on the lens surfaces.
- Complex and expensive maintenance.
- Relatively short lens life.
- Corneal vascularization in some cases.
- Reactions to solutions and cleaners.
- Palpebral lid reactions, e.g. giant papillary conjunctivitis (GPC).
- Greater incidence (than for RGP lenses) of infective keratitis.

For these reasons, over the past 15 years the development has taken place of gas transmissible hard lenses. These are commonly referred to as 'gas permeable hard' (GP or GPH) lenses, or 'rigid gas permeable' (RGP) lenses. Although the

material is not rigid (*see below*), this latter term is sometimes used to avoid patient confusion with 'hard' PMMA lenses that may have given problems in the past.

Using a material which is transmissible to oxygen and carbon dioxide may be expected to provide the following specific advantages over other types of lens.

Advantages over hard (PMMA) lenses

- Fewer physiological problems such as central corneal clouding (oedema).
- Quicker adaptation.
- Few overwear syndromes.
- Less spectacle blur/post-wear refractive changes.
- Lenses may be fitted larger because anoxia due to corneal coverage by the lens is no longer of great significance. This will generally provide greater comfort because the lens edge can be fitted to locate under the upper lid and, secondly, a larger back optic zone will normally reduce night-time flare problems due to dilated pupils.
- Extended wear becomes possible as transmissibility increases.
- Alternation of daily and extended wear becomes feasible.
- Less likelihood of lens loss because RGP lenses can be fitted with minimal edge clearance (*see below*).

Advantages over soft (hydrogel) lenses

- Good visual stability and better correction of astigmatism.
- Less deposit problems and easier lens maintenance.
- Less solution allergy or toxicity problems.
- Excellent tear exchange and lack of debris build-up behind the lens.
- Ability to be modified or repolished in most cases.
- Interchange between daily and extended wear without the fragility problems associated with extended wear soft lenses.
- Less likelihood of GPC.

RGP lens materials

There is now a multitude of RGP materials for the practitioner to choose from (*Tables 10.3 and 3.3 and see* p. 351. *Also* Appendix B). While there has been a general trend towards meeting all the desirable criteria listed at the beginning of this chapter, often the gain of one material property, e.g. oxygen permeability, means a trade-off against another, e.g. increased flexibility. The majority of currently available materials can be grouped into the general headings below. By understanding the advantages and disadvantages of each group, practitioners can make a more logical selection of the material most appropriate for each individual patient.

Cellulose acetate butyrate (CAB)

This was one of the first gas permeable materials available in the early 1970s (Stahl *et al.*, 1974). Made from natural substances, it was originally developed by Eastman Kodak in 1938 for photographic purposes. The three major constituents are cellulose, derived from wood and cotton, acetic acid from vinegar, and butyric acid from natural gas. The initial prime attraction of the material as a plastic was that it was not flammable. As well as being slightly permeable to oxygen the material dissipates heat and wets much better than PMMA. This latter property should improve retro-lens tear flow and may help patients with marginally dry eyes. Several CAB materials are suitable for contact lens fabrication, all with slightly varying properties.

Advantages

- First RGP material available (Dk up to 8–10*).
- Good wettability.
- Not prone to protein deposition.
- Greater heat conductivity than PMMA reduces corneal oxygen demand by not increasing corneal metabolism.

Disadvantages

- Low modulus of elasticity, or poor shape retention. The material does not retain its shape when flexed or stressed. Clinically this leads to warpage of the lens from handling during cleaning procedures. The material tends to be distorted by the lathing bit and, unless great care is exerted during manufacture, the softness and heat sensitivity of the material will result in inaccurate or warped peripheral curves. Because of the small area used by a radiuscope, a blurred reading will sometimes be obtained. A more accurate reading of the BOZR will be obtained if a keratometer is used because of the larger lens surface area used.

  In order to minimize manufacturing problems some laboratories manufacture CAB lenses by moulding techniques. Such lenses appear to be less liable to distortion or warpage.
- Because of warpage, lenses are normally made thicker than equivalent PMMA and silicone–acrylate (*see below*) lenses. This may produce greater lens awareness and decreases oxygen transmissibility (*Dk/t*) (*see* Chapter 3).
- Ammonia-based polishing compounds, such as Silvo, will hydrolyse the lens material and turn it yellow. Alcohol and petroleum products also cause opacification of the material. Lens cleaners, such as Miraflow (Ciba) which contain alcohol, will not cause lens damage if used correctly for their purpose, i.e. lens cleaning, but may cause surface damage if inadvertently used as an overnight storage solution.

*Oxygen permeability units or Dk units are expressed as units of 10^{-11} (cm ml O_2)/(cm^2 s mmHg).

Table 10.3 Some of the gas permeable materials currently available, with PMMA for comparison (*see also* Appendix B)

*Brand name**	*Material*	*Water content (%)*	*Specific gravity*	*Oxygen permeability (Dk) at 35°C* $10^{-11} \times (cm\,ml\ O_2)/(cm^2\ smmHg)$	*Suggested engraving code*
PMMA	Polymethylmethacrylate	0.2–2.0	1.19	0.001	PMMA
Alberta II (XL 30) (GP IV) (Sil-O_2-Flex)	Silicone–acrylate	1.9	1.13	17	ALB2
Aquasil	Siloxanyl methacrylate			55	AQU
Boston Equalens	Flourosilicone–acrylate	1.0	1.18	49	EQ1
Boston Equalens II	Fluorosilicone–acrylate			127	EQ2
Boston ES	Fluorosilicone–acrylate	<1.0	1.22	31	BES
Boston II	Silicone–acrylate	0.9	1.14	14–15	B2
Boston IV	Silicone–acrylate			15	B4
Boston 7†	Fluorosilicone–actylate		1.22	73	B7
Boston RXD†	Fluorosilicone-acrylate			45	RXD
CAB (Persecon) (Paracab) (GPII)	CAB	1.8	1.20	4.5–10	CAB
Calgary (XL 20) (GP III)	50% PMMA + 40% CAB + 10% silicone	3.2		5	CAL
Euro 18	Fluorosilicone–acrylate			16	E18
Euro 32	Fluorosilicone–acrylate			30	E32
EuroPerm 30†	Fluorocarbon–silicone–acrylate			30	EP30
EuroPerm 60†	Fluorocarbon–silicone–acrylate			60	EP60
EuroPerm 90†	Fluorocarbon–silicone–acrylate			90	EP90
Excel O_2	Silicone–acrylate			16.5	EXL
Fluorex 400	Fluorosilicone–acrylate	<1.00	1.106	50	F400
Fluorex 600	Fluorosilicone–acrylate	<1.00	1.097	68	F600
Fluorex 700	Fluorosilicone–acrylate			70	FL7
Fluoropolymer	Perfluorether NVP/MMA			90–94	FLU
Fluoroperm	Fluorosilicone–acrylate		1.11	57	FPERM
Fluoroperm 30	Fluorosilicone–acrylate		1.14	30	F30
Fluoroperm 60	Fluorosilicone–acrylate		1.15	60	F60
Fluoroperm 92 (Fluorocon 92)	Fluorosilicone–acrylate		1.10	92	F92
Fluoroperm 151	Fluorosilicone–acrylate		1.10	151	F151
GP 26 (Boston IV) (Boston EW)	MMA/dimethyl itaconte/siloxane	1.75		26–27	GP26
Hyperm	MMA/siloxanylamyl methacrylate	1.0	1.12	18.5	HYP
LDF 10	Fluorocarbon–silicone–acrylate			6.5	LDF10
LDF 30	Fluorocarbon–silicone–acrylate			15	LDF30
LDF 40	Fluorocarbon–silicone–acrylate			26.5	LDF40
LDF 50	Fluorocarbon–silicone–acrylate			56	LDF50
LDF 70†	Fluorocarbon–silicone–acrylate			72	LDF70
LDF 90	Fluorocarbon–silicone–acrylate			85	LDF90
ML 92	Fluorosilicone–acrylate			92	ML92
Minicon O_2	Silicone–acrylate + MMA	1.4	1.11	10.5	N/A
Menicon SP	Fluoromethacrylate/siloxanyl methacrylate/methyl methacrylate		1.187	20	N/A
Menicon EX	Fluoromethacrylate/siloxanyl methacrylate/methyl methacrylate			40	N/A
Menicon Super EX	Fluorosilicone–acrylate + MA			162	N/A
Novalens	Stryl-silicone	Nil	1.05	55	NOV
Optacryl 60	Silicone–acrylate	1.61	1.12	10–12	OPT60
Optacryl K	Silicone–acrylate		1.11	20	OPTK
Optacryl EXT				39	OPTE
Optacryl Z				55	OPTZ
Oxyflow	Silicone–acrylate	5.4	1.08	28	OXY

Table 10.3 (*Continued*)

*Brand name**	*Material*	*Water content (%)*	*Specific gravity*	*Oxygen permeability (Dk) at 35°C 10^{-11} × (cm ml O_2)/ (cm^2 smmHg)*	*Suggested engraving code*
Paraperm O_2	Silicone–acrylate	1.1	1.12	12	PARA
Paraperm O_2 Plus	Silicone–acrylate	1.0	1.09	38–39	PARA02
Paraperm EW	Siloxymethacrylate copolymer	1.10	1.07	36	PAREW
Polycon II	Polysiloxanyl Alkyl acrylic/ester copolymer 30% silicone	0.7	1.13	11	POL2
Polycon HDK	Siloxymethacrylate copolymer	1.0	1.08	25	PHDK
Quantum	Fluorosilicone–acrylate			92	QU
Quantum II	Fluorosilicone–acrylate			145	QU2
SGP	Silicone–acrylate		1.27	19	SGP
SGP II	Silicone–acrylate		1.12	43.5	SGP2
Toray A	Fluorosilicone–acrylate			131	TORA
Transaire	FSA + acrylamide	<1.60	1.077	45	TRANS
Vistacryl 18	Silicone–acrylate			18	VS18
Vistacryl 32	Silicone–acrylate			32	VS32
Vistaflex 25	Fluorosilicone–acrylate			25	VS25
Vistaflex 50	Fluorosilicone–acrylate			52	VS50
Vistaflex 75	Fluorosilicone–acrylate			71	VS75
Vistaflex 100	Fluorosilicone–acrylate			102	VS100

*Alternative names are shown in brackets.
†UV absorber optional.
N/A = Not applicable/not possible.

4. The softness of the material leaves it vulnerable to scratches and chips.
5. Large hydration–dehydration changes. These may be similar to or greater than those for PMMA lenses (Pearson, 1978; Stone, 1978; Smith, 1979). Slow longer-term changes have also been reported and the BOZR should be rechecked on lenses where unexpected fitting changes have occurred. Where checking is carried out, the lenses should be blotted dry and quickly measured before curvature changes begin to take place.
6. The material appears prone to lipid deposition (*see Figure 18.16*).

CAB has now largely been superseded by other more gas permeable materials.

Silicone–acrylate (or siloxanyl–acrylate)

Although highly permeable to oxygen, pure silicone polymers are soft and hydrophobic. They are therefore normally combined with PMMA to enhance the hardness and stability of the material. To ensure adequate wettability, hydrophilic monomers such as methacrylic acid are also incorporated into the polymer. Surface treatment or special solutions are not therefore usually necessary to maintain adequate wettability and this allows subsequent laboratory and practitioner modification or repolishing of the lens. Different additives such as dimethacrylate may be used to enhance tensile strength and resistance to deformation.

The ratio of PMMA to silicone is generally 65% PMMA to 35% silicone. The greater the proportion of silicone the higher the oxygen permeability, but the poorer the wettability, stability and strength. Similarly, the greater the proportion of wetting agent, the greater the surface wettability but the poorer dimensional stability and the greater the affinity for surface deposition because of increased surface reactivity. Thus the range of Dk values between the materials commonly available is fairly limited (generally 9–30 units*), although some laboratories have achieved higher values by incorporation of proprietary compounds without too much sacrifice of other desirable properties.

As with all RGP materials, great care should be exerted during lens fabrication although there is less susceptibility to distortion than with CAB materials. Warpage often indicates excessive over-heating during the button blocking or lathing procedures (*see* Chapter 21). Ammoniated polishes are best avoided and alcohols, esters, ketones and aromatic hydrocarbons will damage the material.

Advantages

- PMMA acts as a thermal insulator. Not only does the lack of oxygen permeability create corneal hypoxia but, by insulating the cornea, it raises the basal metabolic rate and increases the oxygen demand of the corneal epithelium. However, silicones, either in the pure form or polymerized with PMMA, are thermal conductors which remove the heat of metabolism away from the corneal

*Oxygen permeability units or Dk units are expressed as units of 10^{-11} (cm ml O_2)/(cm^2 s mmHg).

surface thereby decreasing oxygen requirements. The silicone–acrylates are approximately twice as good thermal conductors as PMMA and CAB and this becomes extremely useful for patients living or working in warm or hot environments.
- The oxygen permeability of the silicone–acrylate group ranges from fifty to several hundred per cent greater than CAB.
- The material is less susceptible to warpage and hydration–dehydration changes than CAB.

Disadvantages

- The silicone–acrylate group of materials are still softer and more flexible than PMMA. Thus, lenses will still scratch more easily than PMMA lenses and flex on astigmatic corneas (*see below*). Most RGP lenses are also more easily broken than PMMA lenses.
- The hydrophobic nature of silicone and relatively high surface charge provides a propensity to attract protein deposits and often to bind these tenaciously.
- As a rough guide there is a manufacturing trade-off with increasing oxygen permeability. Thus increased permeability is often traded for poor optical quality, poor wettability etc. Manufacturers have attempted to incorporate proprietary ingredients to counteract these problems. Certain high Dk value silicone–acrylate materials also appear prone to surface cracking (*see* p. 347).

Fluorosilicone–acrylate (or fluoropolymers)

As stated earlier, attempts to increase the oxygen permeability of silicone–acrylate polymers, particularly for extended wear, resulted in compromises in dimensional stability, flexure resistance and/or lens surface interaction with tear components.

Fluorocarbon gases have been widely used since the early 1900s as a form of refrigerant (e.g. Freon), and gaseous propellant for aerosol sprays. Fluoroplastics include high temperature cable insulation, heat resistant plastics for piping and gaskets, low friction and anti-stick applications for non-lubricated bearings and coating of cooking utensils (e.g. Teflon). Recently, more elaborate uses of fluorine-based compounds have been investigated. Researchers have discovered that liquid fluorochemicals are highly efficient carriers of oxygen and carbon dioxide. These properties have led to the use of fluorochemicals in physiological salt solution as a form of artificial blood. The newly created 'blood' supplies oxygen to the body tissues while carrying away waste products such as carbon dioxide.

Early reference to fluoroplastics for contact lenses appeared in patents by the Dupont Corporation in 1970 and Gaylord in 1974. These early contact lens materials never reached the commercial stage of development partly due to the poor wetting characteristics, softness, high specific gravity (1.60) and low index of refraction (1.388) (Caroline and Ellis, 1986).

Polymer Technology were the first to attempt to avoid these problems in the 'Boston Equalens' by using a polymer incorporating a fluorinated monomer and combining it with a silicone–acrylate moiety. The fluorinated component enhances the material's capability of resisting mucus adhesion and deposit formation while promoting its affinity for tear mucin and soluble proteins for superior lens wettability *in vivo*. The high oxygen permeability (*see Table 10.3*) is provided by the siloxanyl groups while the itaconate backbone* of the molecule aids in maintaining the integrity of the optical surface of the lens for correcting corneal astigmatism.

An ultraviolet absorber has been integrated within the Equalens polymer matrix in response to growing concern over the potential cataractogenic and retinal toxic effects of ultraviolet light.

Many other fluorosilicone–acrylates are now available (*see Tables 10.3 and 3.3*) and together with the silicone acrylates make up the majority of RGP lenses currently being fitted.

Advantages

- High oxygen permeability
- Resistance to mucus and deposit formation.
- Dimensional stability equal to silicone–acrylate materials.
- Clinically acceptable flexure, scratch and fracture characteristics.
- Effective ultraviolet light filtration (in some lenses – *see* Chapter 23).
- Suitability for daily or extended wear, or intermittent extended wear.

Disadvantages

- Lenses are less resistant to breakage than silicone – acrylate lenses.
- The lens material is more vulnerable to flexure and is slower to recover from flexure. Hardness is also poorer so that lenses are vulnerable to abrasion.
- Although lenses are capable of being modified in both fitting and power, the response of the material is quicker than that of silicone–acrylate materials and should therefore only be done by skilled technicians. Polishing compounds that contain ammonia, alcohol or organic solvents should not be used.
- The incorporation of an ultraviolet absorber in some materials means that conventional hand ultraviolet lamps cannot be used for assessing fluorescein patterns. A white light with blue filter or the blue light of a slit lamp must be used (*see above*).

  Care must be taken in ascertaining if a new patient being seen for after-care is wearing a lens of this material

*The itaconate backbone is a patented monomer used in the Polymer Technology range of gas permeable hard materials to add rigidity to the polymer, i.e. to increase flexure resistance.

or a misjudgement of lens fitting may be made and inadequate edge clearance may be incorrectly assumed.
- The lenses are more prone to lipoidal deposits.

Other materials

Some materials, such as silicone rubber, cannot be defined as strictly RGP or soft. These lenses together with new materials developed over the last ten years have essentially created the need for a new category.

One such new material is used to create the Ultracon (Ultra Vision Inc.) and EpiCon (Specialty Contact Lens Ltd) lenses, which may best be described as flexible gas permeable (FGP) lenses.

The Ultracon lens polymer derives its basis from materials used to reoxygenate blood during heart/lung surgery. The material is claimed to be more durable than a conventional hydrogel lens and uniquely can be manufactured in varying degrees of flexibility from rigid to soft. Manufacture is via moulding and the lens is available in six BOZR, a total diameter of 13.50, and BVP range of –8.00 to +6.00 D in 0.25 D steps. The Dk value is between 100–150 but can be altered via polymer manipulation. The lens has a nominal centre thickness in minus lenses of 0.16 mm which gives an acceptable *Dk/t* (Hammack, 1993; Sturm, 1994).

Although the lens resembles a hydrogel lens, no water is necessary to achieve its flexibility and in this respect the lens is more typical of a conventional RGP lens. A high refractive index (approximately 1.50) and low specific gravity (approximately 1.01, increasing as the flexibility decreases) with excellent surface wettability are claimed.

The relative rigidity (compared with a hydrogel lens) means that there is a potential to correct a wide range of corneal astigmatic errors, especially difficult post-graft cases, dry eyes, irregular astigmatism, etc. Lens handling is similar to soft lenses except that a suction holder may be necessary.

The EpiCon lens utilizes the same material as the Ultracon lens but is made in a slightly more rigid form with a more complex design. The total diameter is 13.50 mm and the Dk 50–100. The lens is fitted using a trial set which encompasses a range of differing BOZR combined with unique aspheric edge lifts. At the time of writing there are three edge lifts designated *C* (least edge lift) to *E* (greatest edge lift). As a rough guide, changing the edge lift by one step is equivalent to changing the BOZR by 0.2 mm. Thus a 7.20*D* will give an equivalent edge clearance to a 7.40*C* (BOZR/edge lift design) on the same cornea.

A typical lens is described as follows:

BOZR and Edge Lift/BOZD/TD/BVP
e.g. 6.80*E*/7.00/13.50/–8.00

Fitting is carried out using fluorescein pattern evaluation similar to that of a conventional lens (*Figure 10.10*) or a silicone rubber lens (*see* Chapter 11).

Eight BOZR are available so that the sagittal depths can be varied and used, in conjunction with the specified edge lift, to control the lens fit. The lens can be fenestrated (0.2 mm–0.5 mm) to reduce the potential of bubbles forming and to improve the post lens tear pump action. This option is typically used only when very steep cones are being fitted.

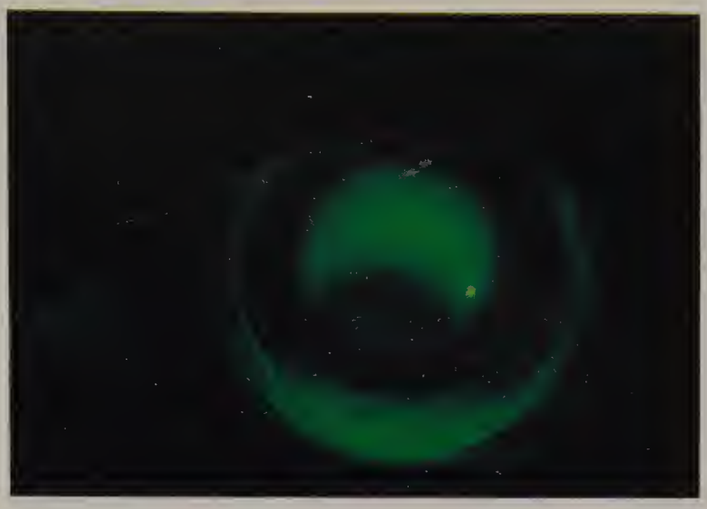


Figure 10.10 An EpiCon lens in a keratoconic patient with an inferiorly displaced cone. All conventional RGP lenses had decentred low exposing the top edge and were bound. The lens prescription was 6.80*D*/7.00/13.50–4.00. (Courtesy of J. Mountford)

The EpiCon lens finds particular use in pathological eye situations such as decentred cones or hypersensitive keratonus, high corneal cylinders, some proud or tilted grafts, pellucid marginal degeneration etc.

Advantages

- Excellent oxygen permeability.
- More comfortable than conventional RGP lenses in the adaptive phase.
- Less easily lost than the conventional RGP designs.
- Masks corneal cylinders better than standard hydrogel lenses (up to 2.00 D claimed, and significantly more with the Epicon design).
- Good wetting properties and deposit resistant.
- Not susceptible to dehydration on the eye as are normal hydrogel lenses.
- Wide range of pathological eye applications (as the EpiCon lens).
- Conventional fluorescein can be used for checking the lens fit.

Disadvantages

- The material is very new at the time of writing and possible long-term problems are unknown.
- There is a limited range of parameters at the time of writing.
- Astigmatism other than corneal cannot be corrected.
- The lens design does not yet encompass sophisticated designs, e.g. bifocal.

- Patients with narrow vertical interpalpebral apertures will still find small conventional RGP designs easier to handle. A suction holder is normally needed.

Modified surface materials

Some lenses have had their surfaces modified in order to optimize the surface wettability. Amongst these there are materials that have been introduced which claim to have characteristics of both RGP and hydrophilic materials, for example, Novalens and Aquasil which both have a hydrophilic 'skin'.

The Novalens (Ocu-Tec Ltd) is composed of rosilfocon A, a hydrophilic stryl-silicone material. The lens consists of a rigid core and a surface polymer that has hydrophilic properties. The surface polymer is claimed to give the lens the hydrogel-like characteristics of increased surface wettability and initial comfort while the rigid core provides the durability, flexure resistance and oxygen transmission (Dk 55) that RGP lenses provide.

Aquasil (Aquaperm) is a silicone acrylate co-polymer, which, immersed in a weak acidic solution, produces a thin layer of HEMA on the surface 15–20 μm thick. The hydroxyl groups of HEMA that are permanently bonded to the polymer are claimed to be non-reactive. Solutions uptake is less than 2%, making solution sensitivity unlikely provided that the correct cleaning regimen is used. Claims are again made of good initial comfort, good wetting, improved deposit resistance and good oxygen transmission (Dk 50). The hydrophilized surface can be re-treated if worn off or removed by repolishing or modification. Chlorhexidine-containing solutions should not be used with this material.

A different technique is utilized by Menicon in the Menicon Super-EX which is a very high Dk (162) surface modified fluorosilicone acrylate material. In this instance the very high Dk value has been gained at the expense of surface wettability, hence the surface treatment. Lens modifications are not possible in this design and the lens is contraindicated for patients with a dry-eye problem. The lens is mainly intended for those patients with a high physiological demand or for extended wear. Opinions vary as to the value of these surface modified materials; Hatfield *et al.* (1993) found no difference in initial comfort or wettability between the Novalens and two other RGP materials. Of twenty patients fitted by the author with an Aquasil material in one eye and a conventional FSA material in the other, only one could detect any improvement in comfort and wetting. Watt (1993) on the other hand reported improvements using the Aquasil material in patients over 35 years of age, in patients showing GPC, dry-eye cases and PMMA refit cases. Osterland (1992) reported similar good results using the Novalens and Brown (1991) with the Aquasil.

Advantages

- Possible improved surface wettability and initial comfort.
- Possible deposit resistance.
- Good oxygen permeability and extremely high permeability in the case of the Menicon Super-EX.

Disadvantages

- Many of the claimed advantages are disputed.
- The advantages may only apply to certain wearers.
- Specific cleaners or disinfecting regimens may be necessary (generally soft lens products).
- Abrasive cleaners should not be used.
- In some types, e.g. Super EX, re-application of the hydrophilic coating is not possible should this either wear off or be removed by modification or repolishing.
- Practitioners other than the prescribing practitioner may not appreciate that a surface-modified material has been used and may inadvertently repolish the lens.
- Some lenses appear vulnerable to parameter changes.
- The lenses are often more expensive than conventional RGP lenses.

Material and design classification

The British Association of Contact Lens Manufacturers has produced a method of classification for both rigid and soft lenses which differs from the American Food and Drug Administration (FDA) 'Approved Names' system (USAN) (*see* Chapter 21). The objective is more accurately to identify to the practitioner what each material is made of (BS 7208 pt II 1991; Burnett-Hodd, 1992). The system is broadly based upon the major chemicals contained in the material, 'Filcon' referring to soft lenses and 'Focon' for RGP lenses.

Lenses are described as Focon $n(x)$ where n is an integer and x is the material oxygen permeability. Examples include:

Focon 1a (0)	PMMA
Focon 1b (0)	modified PMMA
Focon 2a (8)	pure CAB, e.g. CIBA Vision Persecon E
Focon 2b (4)	modified CAB, e.g. Wöhlk Conflex Air
Focon 3 (26)	copolymer of alkyl and siloxanyl methacrylates, e.g. Boston IV
Focon 4 (66)	is formed from polysiloxanes, e.g. Alberta S (UV)
Focon 5 (92)	Focon 3 with at least 5% fluoroalkyl methacrylate or other fluorine containing monomers, e.g. Fluoroperm 92

Lens fitting designs

Lens designs may be described by their total diameter:

Extrapalpebral	i.e. the lens TD is larger than the vertical interpalpebral aperture
Interpalpebral	i.e. the lens TD is smaller than the vertical interpalpebral aperture

or by the geometry of the lens back surface:

Spherical as a single, monocurve, bi-curve, tri-curve etc.

Aspheric as a non-spherical design.

The design philosophy of the back surface typically, but not always, governs the lens TD and this section is therefore largely devoted to the design of the lens back surface.

Former PMMA designs

Many practitioners still possess and many laboratories still produce fitting sets originally designed for PMMA lenses but which still provide adequate results in RGP materials. Because of the wide variety of corneal shapes, lid position and tightness, en- or exophthalmos etc., no single technique or fitting set will fit all patients and sometimes a former PMMA design is found to work well.

Modified contour technique

As stated earlier, these designs utilized a fixed mathematical change between each curve on the back surface. These designs may be made in extrapalpebral or interpalpebral designs but are typically made in much larger diameters than their former PMMA equivalents. A typical fitting set is illustrated in *Table 10.4*.

The disadvantages of this simple approach to matching corneal topography will be discussed below but the fact remains that millions of wearers around the world have worn lenses of this general design for several decades.

Lens–lid attachment (parallel-surfaced or negative-carrier peripheral zone lenses)

Because almost all precorneal film movement is the result of upper lid action, and because the precorneal film may in effect be considered as attached to the upper lid, Korb and Korb (1974) argued that the ideal contact lens should therefore be effectively attached to the upper lid. This concept of lens performance, in which the lens remains immobile without upper lid action, or eye version movements, but moves during blinking as if the corneal lens were attached to the upper lid, facilitates the movement of tears during the acts of blinking and eye movement, and permits the successful training of blinking. The technique is particularly useful in patients with poor centring lenses, peripheral desiccation, or low lower lids.

Table 10.4 Four representative lenses from the 10.50 mm total diameter lens fitting set designed by J. Mountford

7.50:9.00/8.20:9.50/8.50:10.00/11.50:10.50	–3.00
7.80:9.00/8.50:9.50/8.80:10.00/11.50:10.50	–3.00
8.10:9.00/8.80:9.50/9.10:10.00/11.50:10.50	–3.00
8.40:9.00/9.10:9.50/9.40:10.00/11.50:10.50	–3.00

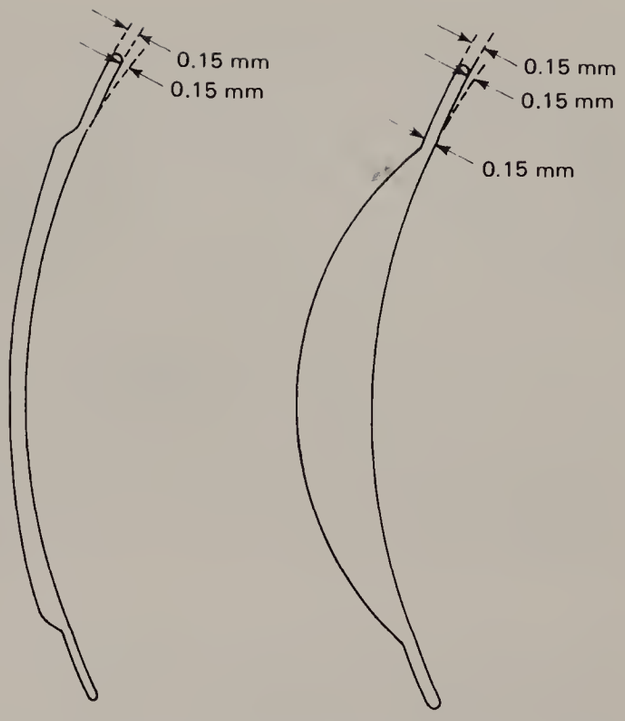


Figure 10.11 Cross-sections of parallel-surfaced peripheral zone lenses: negative (*left*) and positive (*right*). The carrier zone is held by the upper lid

The main technique of 'lid attachment' is achieved by arranging that 0.75–1.00 mm of the most peripheral portion of the lens has parallel front and back surfaces or is even slightly negative in cross-section (i.e. slightly thicker at the very edge) (*Figure 10.11*). This may be done by simply requesting it from the laboratory, by tables (Korb and Korb, 1974), or by calculation. The latter method is dealt with in Chapter 5, p. 192.

Unlike all other techniques, Korb and Korb recommend that the lens is fitted flatter than the central cornea to give an approximate alignment fit when riding superiorly on the cornea and actually moving some 3 mm on to the inferior sclera during blinking. The lens edge is made more blunt and rounded than normal to increase the tear meniscus. This is acceptable because the upper lid does not have to pass over the lens edge. Lens mass is kept to an absolute minimum.

During primary gaze, upward gaze and between blinks, the upper edge of the lens should be retained under the upper lid. The bottom edge of the lens should be above the lower lid but below the inferior pupillary margin in order to prevent flare. During primary gaze, the lens should not intrude upon the temporal or nasal limbus. The lens should move with the upper lid during blinking. To achieve this a lens BOZR approximately 0.1–0.3 flatter than the flatter *K* reading is usually necessary, together with a larger BOZD than used with the original PMMA design.

Another technique for assisting the upper eyelid to hold up a corneal lens was described by Hersh (1974). This involves making a groove, some 0.05 mm deep and

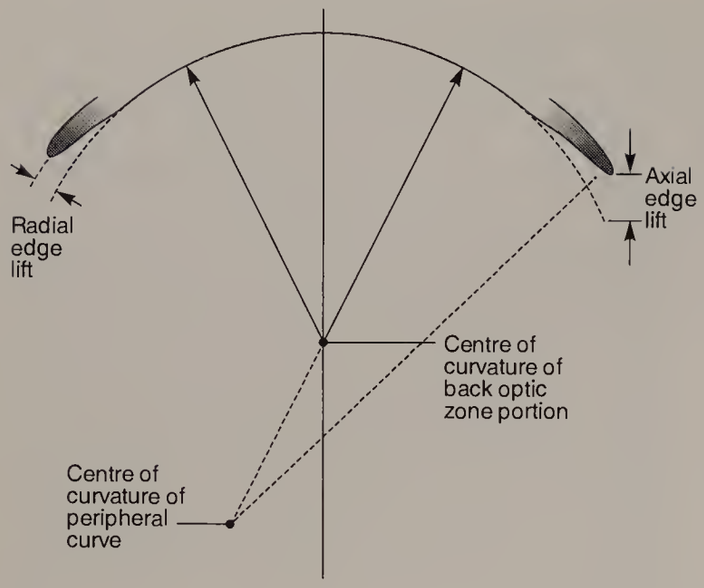


Figure 10.12 Contralateral offset or continuous bi-curve lens

0.08 mm in width, in the front peripheral portion of the lens, about 0.4–0.8 mm in from the edge depending on lens total diameter. The inner margin of the upper eyelid aligns and penetrates the groove at the upper part of the lens thereby holding it up. It is essential that the groove is well polished, otherwise the patient suffers considerable lid sensation.

Sphere/asphere designs (offset peripheral curve lenses)

This design represented one of the first attempts to eliminate the junction between the back optic zone and the peripheral curves. In this, the back peripheral curve is cut on a conventional lathe but the centre of curvature is offset so that its radius passes through the centre of curvature of the back optic zone at the transition between the two curves (*Figure 10.12*). This eliminates a sharp transition between the two curves which, at that point, both have a common tangent. As the centre of the peripheral curve is offset to the opposite side of the centre of curvature of the central portion, it is known as a 'contralateral offset continuous curve' lens. Bennett (1968) termed this type of lens construction a 'continuous bi-curve' lens.

The amount of flattening is usually specified by the distance, at the lens edge, between the back optic zone curve (extrapolated to this point) and the peripheral curve(s). The distance, in millimetres, is normally measured along a line parallel to the axis of symmetry (*Figure 10.12*) and is known as the axial edge lift (AEL) (Bennett, 1968). Some writers prefer to measure the radial edge lift (REL) along the radius of curvature of the back peripheral zone at the lens edge (Hodd, 1966; Ruben, 1966). When comparing peripheral lens flattening, it is important to check if axial or radial edge lifts are being referred to.

The centre of curvature of the peripheral curve may also be displaced to some homolateral point, although this does not give a 'continuous curve' lens when a flatter peripheral curve is used.

The disadvantage of single offset peripheral curves is that there may be inadequate peripheral clearance so that a small spherical tertiary curve is often necessary. Modern lathes allow the addition of second offset curves and it is surprising that these designs have not been more widely used. To some extent the development of offset designs has been overtaken by aspheric lenses (*see below*), although the offset lenses remain easier to check and retain the centration advantages of a spherical lens (*see below*). They are still often used in the fitting of keratoconus patients (*see* Chapter 20).

Constant axial edge lift

As stated earlier, it was obvious to clinicians even as early as the 1950s (Bier, 1957) that while the simple fitting set concept of providing a secondary curve of, say, 0.5 mm flatter than the BOZR worked well for average keratometer readings, at the extremes of corneal curvature the edge clearance became too great at the steep end of the range and too little at the flat end.

Work by Stone (1975) and others considerably improved fitting by the design of fitting sets of lenses having constant axial edge lift. Lenses were computed to provide the same axial edge lift at each of the peripheral curves over the whole range (*see Figure 10.12*). Many fitting sets of these designs are still in current use and provide a more uniform approach to the fitting of all corneas, from steep to flat, than the earlier sets mentioned above.

Typical fitting sets are shown in *Table 10.5*.

RGP lens designs

As knowledge of corneal topography has improved and the oxygen permeability of lens materials increased, it has been possible to adopt much more sophisticated approaches to lens design.

Tear lens thickness and axial edge clearance techniques

Careful observation of lenses fitted using the constant axial edge lift approach still frequently showed lenses on steep corneas that were often too steep at the centre and too flat at the periphery, and *vice versa* for flat corneas. To further improve the match of lens to corneal curvature, the concepts of tear lens thickness (TLT) and edge clearance (EC) were developed by Bibby (1979), Guillon *et al.* (1983, 1986), Atkinson (1984, 1985) and others (*Figure 10.13*). The underlying principles and assumptions should first be stated.

Table 10.5 Constant axial edge lift fitting sets designed by J. Stone

BOZR:BOZD	*BPR_1:BPD_1*	*BPR_2:BPD_2*	*BPR_3:TD*
(a) 9.80 mm total diameter set with 0.12 mm AEL			
7.00:8.00	7.30:8.80	7.75:9.40	8.90:9.80
7.10:8.00	7.45:8.80	7.90:9.40	9.15:9.80
7.20:8.00	7.55:8.80	8.05:9.40	9.40:9.80
7.30:8.00	7.70:8.80	8.25:9.40	9.65:9.80
7.40:8.00	7.80:8.80	8.40:9.40	9.95:9.80
7.50:8.00	7.90:8.80	8.55:9.40	10.20:9.80
7.60:8.00	8.05:8.80	8.70:9.40	10.50:9.80
7.70:8.00	8.15:8.80	8.85:9.40	10.80:9.80
7.80:8.00	8.25:8.80	9.00:9.40	11.10:9.80
7.90:8.00	8.40:8.80	9.15:9.40	11.40:9.80
8.00:8.00	8.50:8.80	9.35:9.40	11.70:9.80
8.10:8.00	8.65:8.80	9.50:9.40	12.00:9.80
8.20:8.00	8.75:8.80	9.65:9.40	12.35:9.80
8.30:8.00	8.90:8.80	9.85:9.40	12.70:9.80
8.40:8.00	9.00:8.80	10.00:9.40	13.05:9.80
8.50:8.00	9.15:8.80	10.15:9.40	13.40:9.80
8.60:8.00	9.25:8.80	10.35:9.40	13.75:9.80
8.70:8.00	9.35:8.80	10.50:9.40	14.10:9.80
8.80:8.00	9.50:8.80	10.70:9.40	14.50:9.80
(b) 9.50 mm total diameter set with 0.12 mm AEL			
7.00:7.50	7.45:8.20	7.90:9.00	8.15:9.50
7.10:7.50	7.60:8.20	8.05:9.00	8.35:9.50
7.20:7.50	7.70:8.20	8.20:9.00	8.50:9.50
7.30:7.50	7.85:8.20	8.35:9.00	8.70:9.50
7.40:7.50	7.95:8.20	8.50:9.00	8.90:9.50
7.50:7.50	8.10:8.20	8.65:9.00	9.10:9.50
7.60:7.50	8.20:8.20	8.80:9.00	9.30:9.50
7.70:7.50	8.35:8.20	9.00:9.00	9.45:9.50
7.80:7.50	8.45:8.20	9.15:9.00	9.65:9.50
7.85:7.50	8.55:8.20	9.20:9.00	9.75:9.50
7.90:7.50	8.60:8.20	9.30:9.00	9.85:9.50
8.00:7.50	8.75:8.20	9.45:9.00	10.10:9.50
8.10:7.50	8.85:8.20	9.65:9.00	10.30:9.50
8.20:7.50	9.00:8.20	9.80:9.00	10.50:9.50
8.30:7.50	9.10:8.20	9.95:9.00	10.70:9.50
8.40:7.50	9.25:8.20	10.15:9.00	10.90:9.50
8.50:7.50	9.40:8.20	10.30:9.00	11.15:9.50
8.60:7.50	9.50:8.20	10.50:9.00	11.35:9.50
8.70:7.50	9.65:8.20	10.65:9.00	11.60:9.50
8.80:7.50	9.80:8.20	10.80:9.00	11.90:9.50

- Because the cornea is aspherical in shape, a small amount of tear liquid must exist between the cornea and spherical back optic zone of the lens. This volume will increase or tend to increase when the lens is decentred and thereby serves to re-centre the lens after lens movement by the negative pressure thus induced. In the case of an aspheric lens, negative pressure can only be induced if the lens creates a positive tear layer between the lens centre and point of contact with the cornea.
- Although in practical terms the back surface of the lens will approximate the corneal shape, for calculation purposes there can be assumed to be a tear layer of finite thickness known as the tear lens (or layer) thickness (TLT) as shown in *Figure 10.13* trapped between the back of the lens and the cornea.

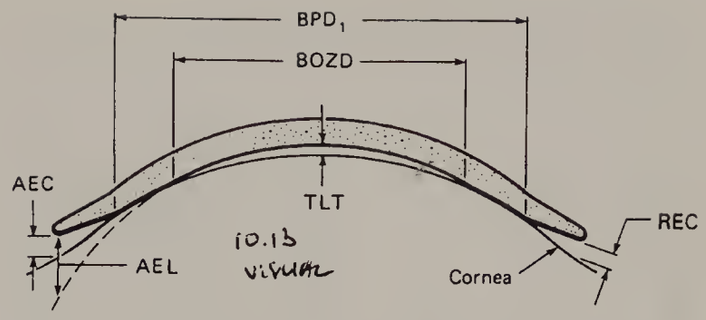


Figure 10.13 Diagrammatic representation of the tear layer trapped between the back optic zone of the lens and cornea. The central clearance (which may not exist in practice) between lens and cornea is known as the *tear layer thickness*. Also shown is the axial and radial edge clearance from the cornea and axial edge lift between the lens edge and extended BOZR (dotted). TLT = tear layer thickness; AEC = axial edge clearance; AEL = axial edge lift; REC = radial edge clearance; BOZD = back optic zone diameter; BPD_1 = first back peripheral curve diameter

Thus the TLT = sag of the BOZR – sag of the cornea at the BOZD where the sag of the contact lens = $r - \sqrt{r^2 - y^2}$ (r = BOZR and y = BOZD/2) and the sag (x) of the cornea (assumed elliptical) can be determined from

$$y^2 = 2r_o x - px^2 \text{ (see Figure 10.14.)}$$

where y = BOZD/2, r_o = apical corneal radius and p = asphericity ('shape' factor). Also $r_o = b^2/a$ and $p = b^2/a^2$ where a and b are the semi-major and semi-minor axes of the corneal ellipse (Baker, 1943; Bennett, 1988).

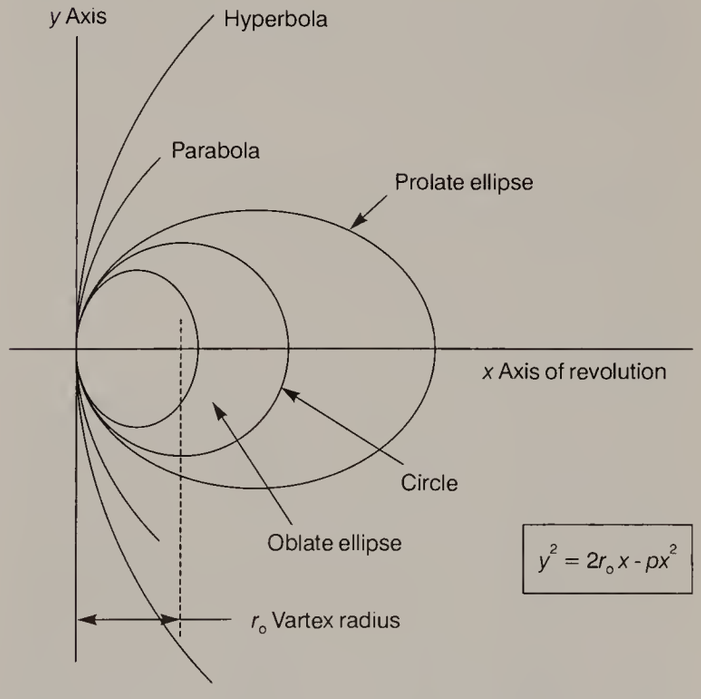


Figure 10.14 The conicoids in Cartesian co-ordinates with a circle shown as reference. The cornea and most aspheric lens designs are prolate ellipses (*see also Figure 10.5*)

Table 10.6 BOZD values giving fixed TLT of 0.02 mm for various asphericities (all BOZRs fitted 0.05 mm steeper than *K*)

Asphericity p	*BOZR (mm)*		
	7.20	*7.80*	*8.40*
0.70	6.70	7.20	7.60
0.75	7.00	7.40	7.90
0.79	7.20	7.70	8.20
0.83	7.50	7.90	8.40
0.88	7.90	8.40	8.90

r_o can be determined by assuming the *K* reading to represent a spherical reading of a 3 mm chord and from this sag it is possible to work back to r_0 for any given corneal asphericity (*p*).

- The axial edge clearance (AEC) represents the axial distance of the lens edge from the cornea and is therefore a more relevant term in the clinical context than axial edge lift (AEL) which relates to the lens and not the eye (*Figure 10.13*). The axial edge clearance can be calculated from:

  AEC = AEL – (sag of BOZR at lens TD – TLT – sag of cornea at lens TD)

  If intermediate values are to be calculated, i.e. from the point of touch of the BOZR at the BOZD outwards, it is only necessary to obtain the axial lift at that point and the sags of the BOZR and cornea at the same required diameter. From this information it is possible to draw up a profile of the tear layer thickness across the whole lens.
- At the beginning of this chapter the variations in corneal shape were stressed. *Table 10.6* sets out the BOZD values for steep (7.25 mm), average (7.85 mm), and flat (8.45 mm) keratometer readings, asphericities (*p*) of 0.70–0.88 and lenses fitted 0.05 mm steeper than *K* to give a TLT of 0.02 mm.* This value is considered optimal by Atkinson (1985) from clinical experience. Eliminating the more extreme values the majority of corneal shapes can therefore be covered by typical BOZDs of 7.20, 7.70 and 8.30 mm.
- The choice of peripheral curve diameters and total lens diameter is deduced as follows. The functions of the peripheral and edge curves are four-fold:
  (*a*) to allow proper circulation of tears beneath the lens during lens movement in order to maintain the correct metabolism of the cornea;
  (*b*) to prevent the edge digging into the corneal surface on lens movement;
  (*c*) to support a tear meniscus at the edge of the lens to provide forces that cause the lens to centre (following eyelid movement and lag of the lens when looking laterally);
  (*d*) to allow the lens to be removed.

*For thinner lenses greater lens flexure will occur and lenses should be fitted flatter as discussed below.

Functions (*a*) and (*b*) are partially contradictory to (*c*). The first two require increasingly flatter radii whereas (*c*) improves with a steeper radius and close edge alignment. With gas permeable lenses the edge clearance can be reduced from that required for PMMA lenses because tear flow under the lens is not so vital for normal metabolism due to the material's gas permeability. This in turn reduces edge sensation. An intermediate curve allows more accurate following of the corneal contour and reduces the sudden change in curvature from BOZR to edge curve.

Bibby (1979) has shown that the ideal width of peripheral curves is approximately 0.50–0.60 mm. For smaller widths of peripheral curve, a large change in radius is necessary to change the edge clearance significantly but a small error in the diameter during manufacture would change the edge clearance significantly. Similarly, at large peripheral curve widths, a small error in radius would be significant but a large error in diameter less significant.

From clinical experience total diameters of 8.70, 9.20 and 9.80 mm would cover the majority of cases normally encountered. For the BOZDs previously selected and the discussions above, the edge curve selected is 0.5 mm wide with the intermediate band width therefore 0.25 mm.

- Choice of intermediate peripheral radii: If the profile of a lens is assessed when the BOZR is 7.85 mm and the BOZD is 7.70 mm, with a first peripheral curve 0.25 mm wide and 0.50 mm flatter than the BOZR, we obtain a corneal clearance of 0.005 mm at the edge of the band. A curve 0.80 mm flatter than the BOZR will give 0.011 mm clearance, and 1.10 mm flatter will give 0.017 mm. From clinical experience, a clearance of 0.005 mm leaves too little clearance and 0.017 mm too much.

  It is recommended therefore that in clinical terms we should go 0.80 flatter for a BOZR of 7.85. For steeper and flatter radii in a fitting set the intermediate peripheral radii should be calculated to give the same 0.011 mm clearance. This will mean that the BOZR to BPR_1 will be less than 0.80 mm for steeper radii and greater than 0.80 mm for flatter radii. If this is done, however, the intermediate peripheral curve tends to be too tight on steeper eyes and too flat on flatter eyes. To overcome this it is recommended the first peripheral curve be 0.80 flatter than the BOZR throughout the trial set. The radii of the edge curve should then be chosen to give the final edge clearance.
- The peripheral curve, and edge clearance: Bibby (1979) suggested an average radial edge clearance for PMMA lenses of 0.08 mm. In axial terms this is approximately 0.093 mm. As mentioned above, this figure is now considered unnecessarily great for RGP lenses and Atkinson and Kerr (1987) consider a figure of 0.08 mm as being adequate even with the introduction of flatter BOZRs and the tendency to fit on alignment. Below this figure there is a risk of indentation into the cornea as the lens rides up.

Thus for a lens on a spherical cornea of 7.90 mm radius and fitted 0.05 mm steep, the final specification would be:

7.85:7.70/8.65:8.20/9.75:9.20

TLT 0.020 mm
AEL 0.101 mm
AEC 0.080 mm

For steeper corneas also fitted 0.05 mm steeper than *K* of, say, a 7.30 mm cornea, the lens will have the following specification:

7.25:7.70/8.05:8.20/8.75:9.20

The TLT now, however, will be slightly too great at 0.025 mm and the lens will effectively fit more tightly. Fitting the next lens flatter, i.e. specification:

7.30:7.70/8.10:8.20/8.85:9.20

would reduce the TLT to 0.017 mm which is significant, but the edge clearance would change only from 0.080 mm to 0.086 mm which is not so significant. For flatter corneas the opposite effect would occur.

A further option would be to reduce the BOZD of the lens for the steeper radii and vice versa. By keeping the same TLT, edge clearance and peripheral curve width, this gives smaller lenses at the steep end and larger lenses at the flat end of the range. This is a logical approach as steep corneas are usually smaller than flat ones. A fitting set on these lines has been designed by Atkinson (1985) and is partly shown in *Table 10.7*.

However, because of the variety of asphericities found for the human cornea as discussed at the beginning of this chapter, at least three different BOZDs and TDs are ideally required and fitting sets based on all the foregoing are now shown in *Table 10.8*.

As we acquire greater understanding of the corneal topography, tear volume under the lens, tear mixing and tear film formation over and under the lens, more sophisticated lens designs will undoubtedly continue to emerge.

McDowell (1995, Warragul, Victoria, Australia, personal communication) has taken Atkinson's design work one step further. He points out that Atkinson's design shows a relatively greater TLT at the steep end of the corneal range in order to achieve a desired AEC. McDowell's design is based on a shape factor (p) of 0.79 and utilizes three TDs to achieve TLTs typically between 10–15 μm and AEC of 78–79 μm. His design is shown in *Table 10.9*.

Over the next few years the use of computers to custom design lenses to practitioners' own preference for each particular patient will increasingly become available. Such a program has been developed by Tony Hough and the CD-ROM is available with this book for practitioner use. As corneal topographical measuring devices also become more popular practitioners will have access to corneal apical radius (r_o) and eccentricity (e) values which will make lens design more accurate and more specific for each patient and that patient's particular needs.

Table 10.7 A partly illustrated fitting set giving a tear layer thickness of 0.02 mm and axial edge clearance of 0.08 mm on corneas of average asphericities

7.25:7.10/7.75:7.60/ 9.15:8.60
7.45:7.30/8.05:7.80/ 9.35:8.80
7.65:7.50/8.35:8.00/ 9.55:9.00
7.85:7.70/8.65:8.20/ 9.75:9.20
8.05:7.90/8.95:8.40/10.00:9.40
8.25:8.10/9.25:8.60/10.25:9.60
8.45:8.30/9.55:8.80/10.50:9.80

All lenses fitted 0.05 mm steeper than *K* on a cornea with *p* 0.79. After Atkinson, 1985.

Table 10.8 Partly illustrated three fitting set approach incorporating the tear layer thickness and edge clearance technique

Set		*TLT*	*AEC*	*AEL*
1	7.25:7.20/7.75:7.70/ 9.15:8.70	0.020	0.081	0.105
	7.85:7.20/8.35:7.70/10.25:8.70	0.015	0.080	0.098
	8.45:7.20/8.95:7.70/11.50:8.70	0.012	0.081	0.095
2	7.25:7.70/8.05:8.20/ 8.75:9.20	0.025	0.079	0.111
	7.85:7.70/8.65:8.20/ 9.75:9.20	0.020	0.080	0.101
	8.45:7.70/9.25:8.20/10.95:9.20	0.016	0.080	0.098
3	7.25:8.30/8.05:8.80/ 8.60:9.80	0.033	0.080	0.123
	7.85:8.30/8.65:8.80/ 9.60:9.80	0.025	0.080	0.111
	8.45:8.30/9.25:8.80/10.60:9.80	0.020	0.079	0.102

After Atkinson, 1985.

Aspheric designs

In its simplest form aspheric merely means 'not spherical'. The cornea may generally be described as a prolate ellipse which flattens away from the apex (Bibby, 1976; Guillon *et*

Table 10.9 A 14-lens fitting set designed by Ross McDowell with lenses fitted 0.05 mm flatter than mean *K* to give a constant axial clearance of 78–79 μm

	TLT (mm)	*AEC (mm)*	*AEL (mm)*
7.00:7.80/7.60:8.40/ 8.15:9.40	0.015	0.079	0.110
7.10:7.80/7.70:8.40/ 8.30:9.40	0.014	0.079	0.108
7.20:7.80/7.80:8.40/ 8.45:9.40	0.013	0.078	0.106
7.30:8.00/7.90:8.60/ 9.00:9.40	0.014	0.078	0.101
7.40:8.00/8.00:8.60/ 9.10:9.40	0.013	0.078	0.100
7.50:8.00/8.10:8.60/ 9.30:9.40	0.013	0.079	0.099
7.60:8.20/8.20:8.80/ 9.40:9.60	0.014	0.079	0.100
7.70:8.20/8.30:8.80/ 9.60:9.60	0.013	0.079	0.100
7.80:8.20/8.45:8.80/ 9.70:9.60	0.012	0.078	0.097
7.90:8.20/8.60:8.80/ 9.90:9.60	0.012	0.079	0.098
8.00:8.20/8.70:8.80/ 9.55:9.80	0.011	0.078	0.099
8.10:8.20/8.80:8.80/ 9.75:9.80	0.010	0.079	0.099
8.20:8.20/8.90:8.80/ 9.90:9.80	0.010	0.079	0.097
8.30:8.20/9.00:8.80/10.05:9.80	0.009	0.078	0.096

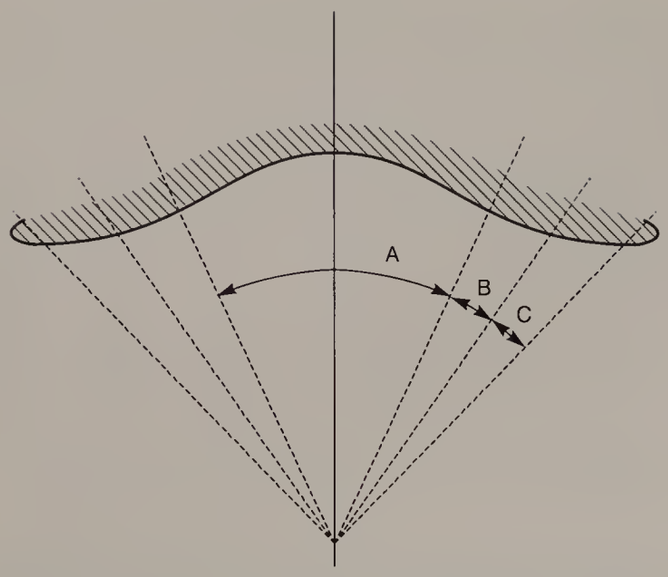


Figure 10.15 An example of a triple zone polynomial back surface lens shown diagrammatically. The asphericity changes across each of the three zones (A, B and C) according to the polynomial formula

al., 1986). It seems logical therefore to design lenses to match the true corneal shape for the following reasons:

- Better capillary attraction between lens and eye
- Less flare as the BOZD should, in theory, be the whole lens back surface
- No pressure from transition indentation
- Reduced thickness and better vision with aspheric front surfaces
- Easier to fit
- Less spectacle blur/corneal moulding
- The small edge clearance (20–60 μm) in some designs is helpful in decreasing lens edge sensation. Three and 9 o'clock staining may also be reduced for the same reason by allowing better lid contact with the cornea as long as lens movement is not compromised.

Aspheric surfaces can be defined by mathematical equations and describe a surface of revolution having continuously variable curvature from vertex to edge, these equations being used to derive the principal radii of curvature and axial edge lift at any given point on the lens (Bennett, 1988) (*see Figures 10.5 and 10.13*). Aspheric surfaces essentially consist of two 'families' of curves, the conicoids (*Figure 10.14*) and the polynomials (*Figure 10.15*).

The x and y co-ordinates of conicoids are linked by the equation

$$y^2 = 2r_o x - px^2$$

where p is a number (termed the p value) which describes each conic and its related conicoid and r_o is the central radius.

Polynomial theory is based on the formulae

$$x = Ay^2 + By^4 + Cy^6 + Dy^8 + Ey^{10} \text{ etc.}$$

and from the cartesian convention

$$x = y^2/r_0 + r_0 + py^2$$

In the first formula y^3 and y^5 etc. are not used because these do not give positive numbers on both sides of the axis. *Figure 10.14* shows a triple zone back surface polynomial lens design.

Another term used by some manufacturers to describe conic sections is the value e or 'eccentricity'. Fortunately this term can be equated to the p value, as stated earlier, by the formula: $p = 1 - e^2$.

The various p and e values for the conicoids are as follows:

Curve	***e***	***p***
Circle	0	1
Prolate ellipse	<1	<1
Parabola	1	0
Hyperbola	1	>0
Oblate ellipse	–	>1

Aspheric lenses are typically made with an eccentricity in the order of 0.40 ($p = 0.84$) to 0.50 ($p = 0.75$). An aspheric lens which exactly follows the corneal shape to the lens periphery would both dig in on lens movement and be almost impossible to remove. For this reason a variety of modifications to a true asphere have been produced:

- Full aspheric back surfaces, e.g. Boston Envision (central ellipse and peripheral hyperbola joined tangentially)
- Spherical BOZDs with an aspheric periphery, e.g. Bausch & Lomb Quantum
- Aspherical BOZDs with narrow spherical peripheral curves, e.g. CIBA Aspheric
- Bi-aspherics where both back and front surfaces are aspheric

Generally speaking the conicoid aspherics will give inadequate edge clearance without the addition of narrow spherical peripheral curves to give an edge clearance of 60–80 μm. In some lenses a bi-elliptical design, which has a periphery with a differing e number from the central area, is used to generate a greater flattening in the periphery. One design (B & L's Quantum) is of polynomial design but only after a 3.5–4.0 mm central spherical optical zone.

The fitting of aspheric lenses is described below.

The **disadvantages** of aspheric designs are as follows:

- Without a computerized topographical device, corneal asphericity is not easily measured nor considered totally accurate. Arbitrary values have therefore to be chosen and fitting done by the use of trial sets and observation.
- Spherical lenses rely on the negative pressure of the tear layer trapped between the lens and the cornea to centre the lens. This facility is absent in aspheric designs unless fitted slightly steep centrally. The advantage of matching

corneal shape is therefore partly lost and the back surface design compromised.

- For the above reason lenses may need to be fitted larger than normal or by lid attachment to assist centration. The variation in corneal shape over the normal population has been referred to earlier.
- Optical properties can be a problem in designs with aspheric central zones where lenses show poor centration. Lens profiles tend to flatten quite quickly away from the lens apex. This peripheral flattening creates an increase in plus power in both the sagittal and tangential meridians at each elliptical point from the apex onwards. In general, the radius change in the tangential meridian is about three times the corresponding change in the sagittal meridian and therefore the mean extra positive power change is accompanied by an astigmatic power of approximately the same magnitude. In practical terms this causes extra negative and/or unexplained residual astigmatism during over-refraction with lenses of this design that show poor centration (Meyler and Ruston, 1994).
- There is no freedom of manoeuvre in fitting. Practitioners must use the eccentricity value chosen by the laboratory.
- Aspheric lenses cannot be modified other than by adding spherical peripheral curves to loosen the fit.
- Lenses are difficult to check. A radiuscope can be used to check the posterior apical radius (PAR) but the degree of flattening is almost impossible to measure in general practice. A keratometer cannot be used to measure the nominal PAR.
- Many aspheric designs are not available in astigmatic form.
- The practitioner is forced to use the laboratory that produces the fitting set.
- Aspheric lenses are not easily identified by other practitioners seeing the patient.
- Aspheric lenses may be more difficult to manufacture. For example, overpolishing will change the degree of asphericity.

Front surface aspheric lenses have been used to reduce lens thickness, especially in aphakic designs, to provide presbyopic corrections (*see* Chapter 16), to reduce spherical aberration (Kerns, 1974; Oxenberg and Carney, 1989), and to improve acuity with residual astigmatism (Evans and Morrison, 1984).

Contact lens fitting with the EyeSys Corneal Analysis Contact Lens Fitting Program (Windows 2000 version)

Computerized corneal topographical devices have already been discussed in Chapter 6. By understanding the corneal topography of each individual eye it is possible not only to design lenses to fit the particular eye in question but also to use the computer facility to produce simulated fluorescein patterns of each design.

Major improvements in computer software now enable practitioners to use specific algorithms that design a lens based upon the patient's unique topography and clinician-specified tear layer thickness, or choose from a variety of manufacturers' stock lenses or proprietary designs (Soper, 1995).

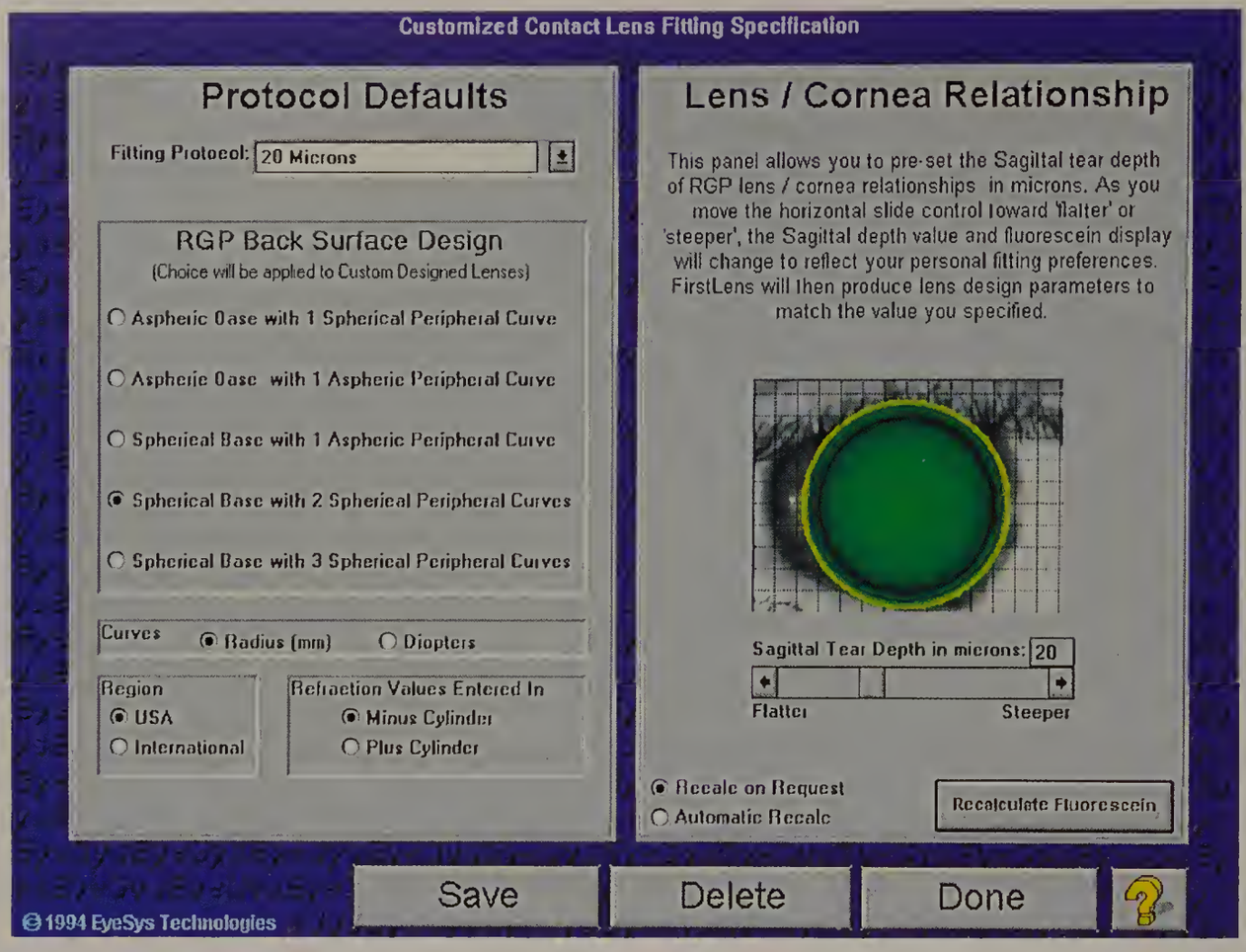
Practitioners first enter their individual fitting preferences and lens screening criteria in the Fitting Protocol Screen (*Figure 10.16a*). Customized fitting preferences for the number of peripheral curves and desired sagittal tear layer thickness can be assigned to defined protocols that are initially specified by the clinician upon installation of the software. This is especially useful when working in a multi-practitioner facility where the software can be modified to accommodate each practitioner's personal fitting philosophy.

The fitting process begins with the Patient Evaluation screen (*Figure 10.16b*). A fitting protocol is selected and the patient's spectacle refraction is entered. Keratometric readings and corneal eccentricity derived from the EyeSys topography exam are also displayed. The software calculates the Predicted Residual Astigmatism (PRA) for each lens type and the clinician selects their own lens fitting preference in order to begin the fitting process.

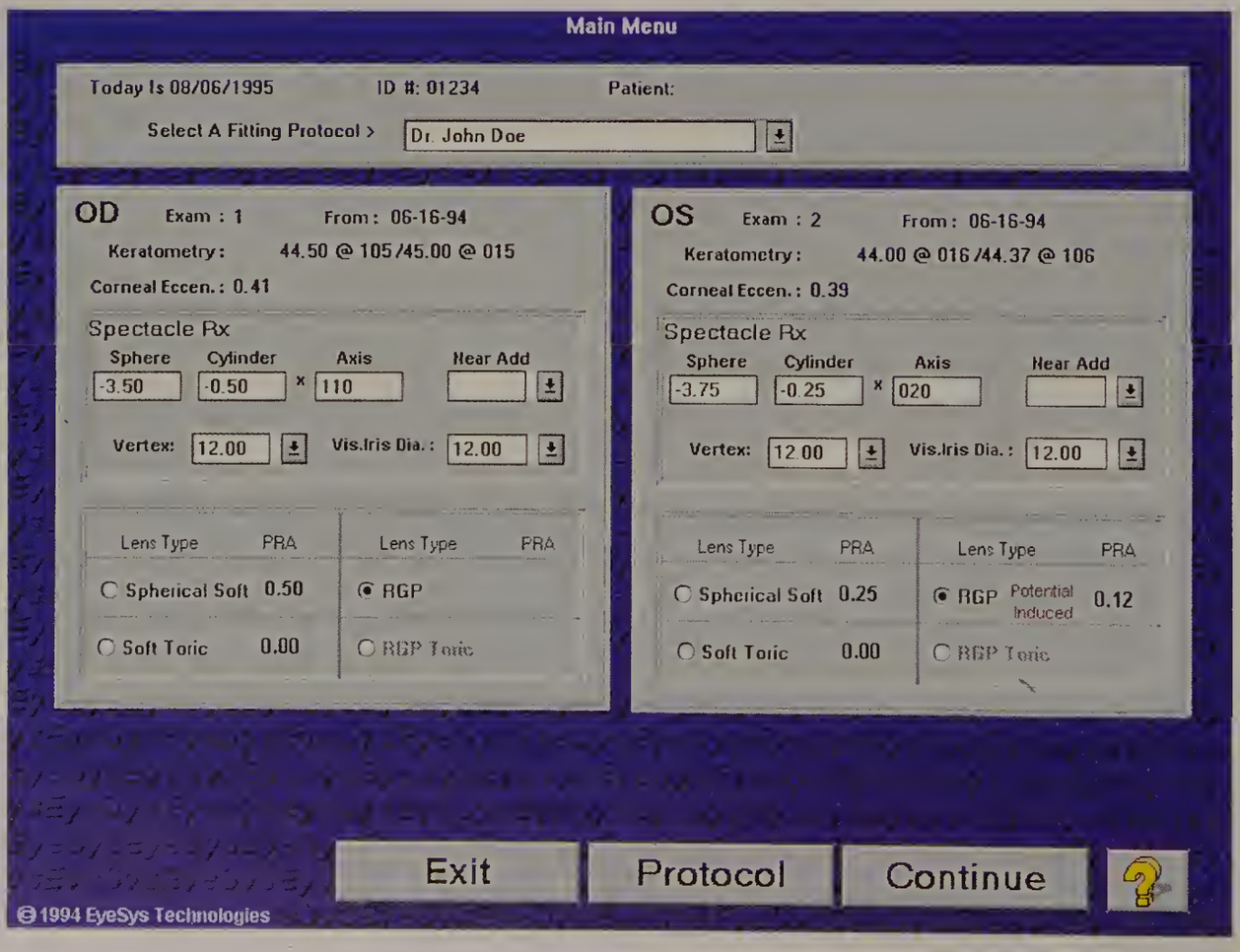
Figure 10.16c shows an example where the practitioner has specified a 10 μm sagittal tear depth in the fitting protocol and chosen a 9.50 mm total diameter from the RGP fitting preference screen. The system has designed a lens using the patient's topography information and incorporated the clinician's specifications for the desired tear layer thickness and total diameter. Using the arrows next to each of the parameters of the suggested contact lens, the design can be quickly and easily modified while viewing the changes induced in the simulated fluorescein display. Trial lens fitting can be accomplished from this screen and the patient's colour topography map can also be displayed.

Once the desired fitting relationship is achieved, a specialized order form for the lenses is generated by the system. The clinician formats their own laboratory and manufacturer database from which to order the lenses. Each laboratory's product details only need to be entered once to become part of a permanent list for future purposes. Other user-specified lists such as who orders the lenses and how the lenses are to be delivered to the patient, may be entered by the clinician. Additional lens information is also selected on the order form such as the type of peripheral curve blend, lens thickness, material and tint. Special lens or edge designs can be specified using a minus or plus carrier, or even the addition of a prism ballast (*Figure 10.16d*). Special ordering comments can be typed in at the bottom of the screen and will appear on the final printout. This printout can be inserted into the patient's permanent record or used to fax to the manufacturing facility.

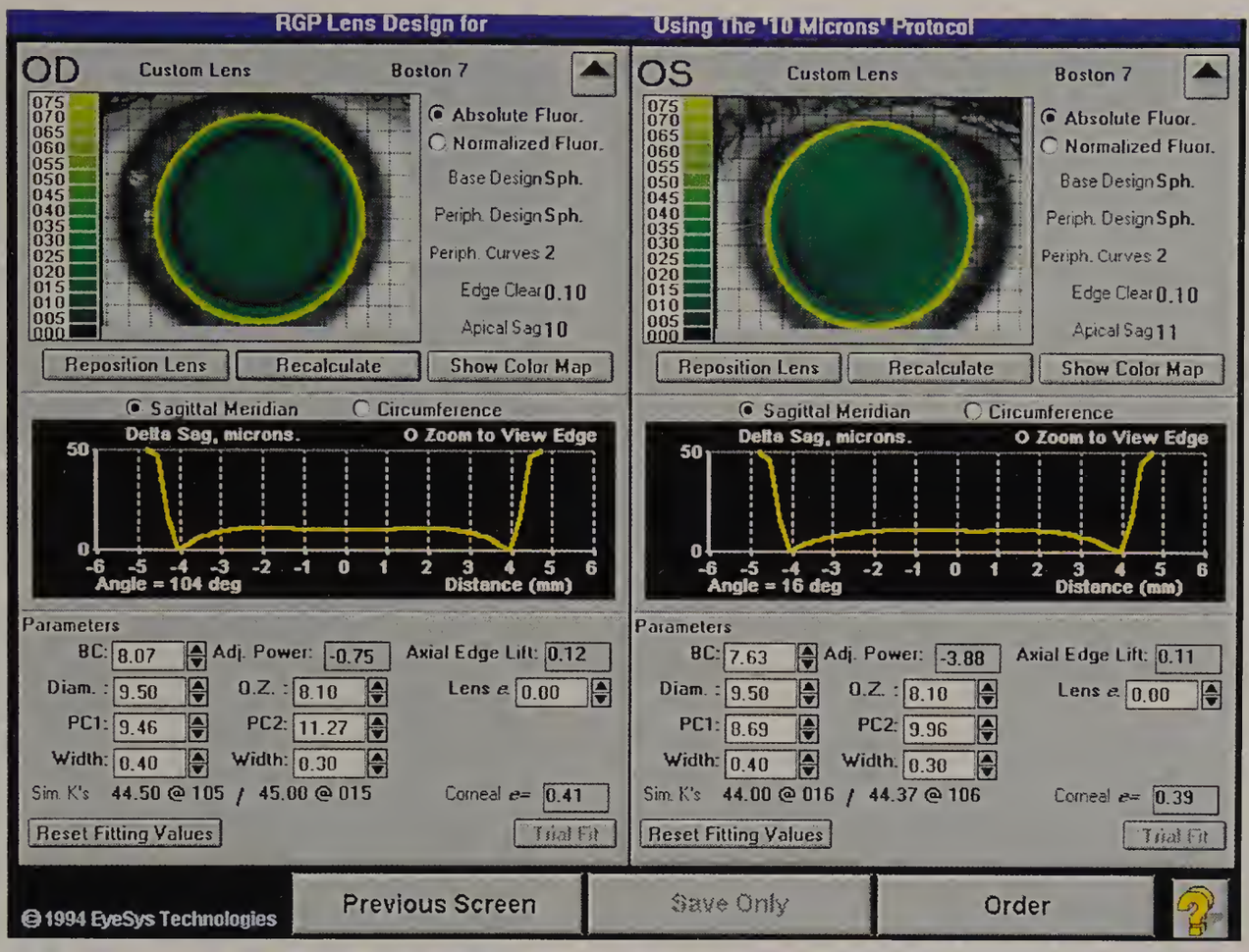
The system database holds records of all major manufacturers on a regional basis showing all RGP and soft lenses available with details of materials, tints and parameters of all proprietary designs.


Customized Contact Lens Fitting Specification
Protocol Defaults
Fitting Protocol: 20 Microns
RGP Back Surface Design
(Choice will be applied to Custom Designed Lenses)
Aspheric Oase with 1 Spherical Peripheral Curve
Aspheric Oase with 1 Aspheric Peripheral Curve
Spherical Base with 1 Aspheric Peripheral Curve
Spherical Base with 2 Spherical Peripheral Curves
Spherical Base with 3 Spherical Peripheral Curves
Curves
Radius (mm)
Diopters
Region
USA
International
Refraction Values Entered In
Minus Cylinder
Plus Cylinder
Lens / Cornea Relationship
This panel allows you to pre-set the Sagittal tear depth of RGP lens / cornea relationships in microns. As you move the horizontal slide control toward 'flatter' or 'steeper', the Sagittal depth value and fluorescein display will change to reflect your personal fitting preferences. FirstLens will then produce lens design parameters to match the value you specified.
Sagittal Tear Depth in microns: 20
Flatter
Steeper
Recalc on Request
Automatic Recalc
Recalculate Fluorescein
Save
Delete
Done
1994 EyeSys Technologies

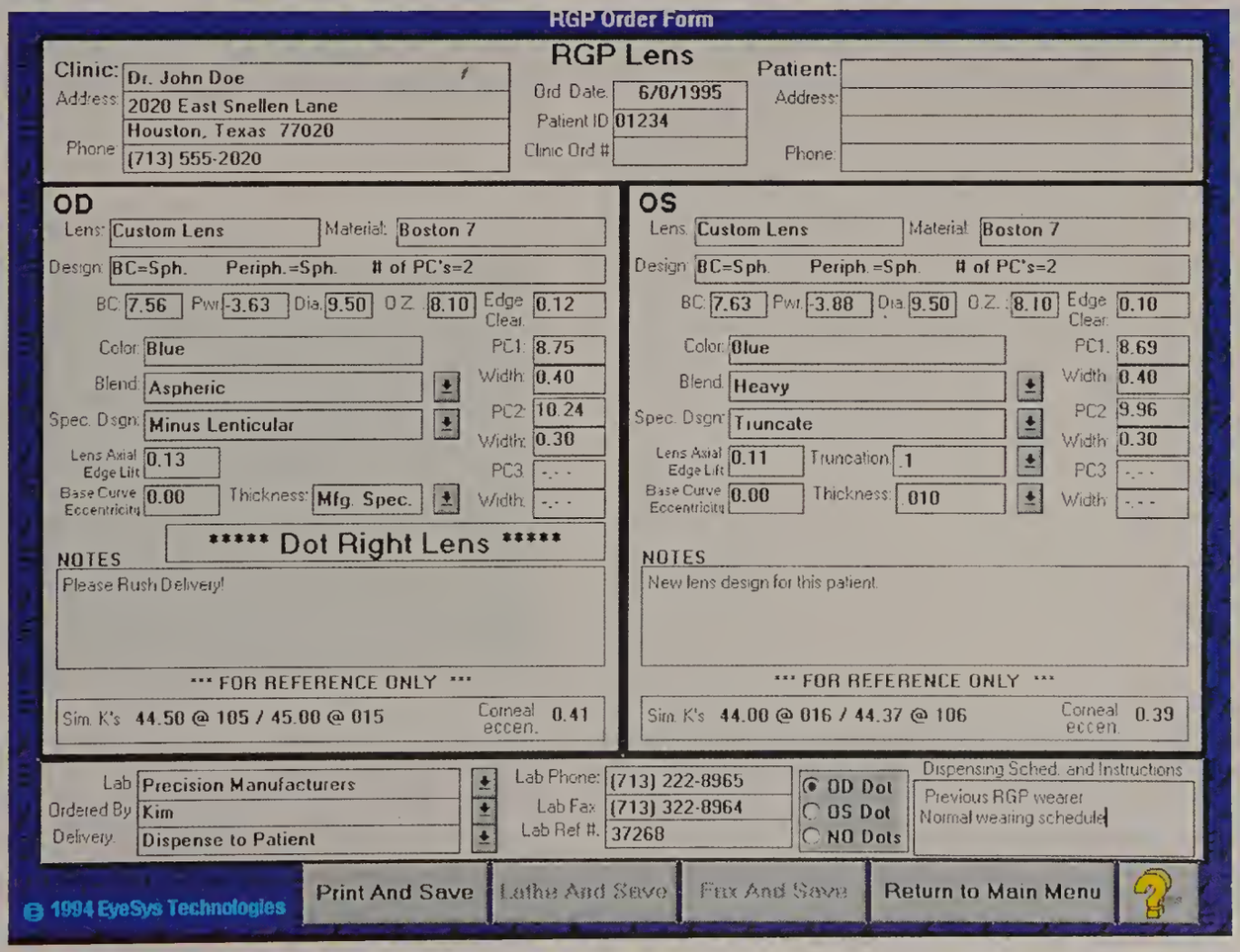
(a)


Main Menu
Today Is 08/06/1995
ID #: 01234
Patient:
Select A Fitting Protocol >
Dr. John Doe
OD
Exam : 1
From : 06-16-94
Keratometry : 44.50 @ 105/45.00 @ 015
Corneal Eccen. : 0.41
Spectacle Rx
Sphere -3.50
Cylinder -0.50
Axis 110
Near Add
Vertex: 12.00
Vis.Iris Dia. : 12.00
Lens Type PRA
Spherical Soft 0.50
Soft Toric 0.00
Lens Type PRA
RGP
RGP Toric
OS
Exam : 2
From : 06-16-94
Keratometry : 44.00 @ 016/44.37 @ 106
Corneal Eccen. : 0.39
Spectacle Rx
Sphere -3.75
Cylinder -0.25
Axis 020
Near Add
Vertex: 12.00
Vis.Iris Dia. : 12.00
Lens Type PRA
Spherical Soft 0.25
Soft Toric 0.00
Lens Type PRA
RGP Potential Induced 0.12
RGP Toric
Exit
Protocol
Continue
1994 EyeSys Technologies

(b)



(c)



(d)

Figure 10.16 (a-d) Contact lens fitting with the EyeSys Corneal Analysis contact lens fitting program (Windows 2000 version)

Contact lens fitting with the Tomey TMS-1 Topographical Modelling System

The Tomey TMS-1 (*Figure 10.17a*) utilizes a similar method to the EyeSys. A patented laser alignment focuses on the apex of the cornea and low luminosity, interchangeable light cones which project either 25 or 31 rings on to the surface of the cornea. As a result, the TMS-1 possesses excellent corneal coverage from 0.2 to 11 mm which provides the clinician with corneal curvature for both the central and peripheral cornea. In addition, the clinician is also given the corneal eccentricity, e (**C shape**), the apical zone (average curvature over the central 3 mm (**AP Zone**), the apical radius r_o (**AP1 RAD**) (manufacturer's terms) as well as conventional keratometry values.

The contact lens fitting program for the TMS-1 is designed to use the corneal eccentricity along with the dimensions and properties of several manufacturers (e.g. Boston, Paragon, Menicon etc). A simulated fluorescein pattern is then generated to provide the clinician with an assessment of the fit. In addition to the fluorescein pattern a graph of the clearance of the lens (TLT) in μm is also provided.

A lens design program is also available which allows the practitioner to design a custom-made lens for a particular patient. The practitioner specifies the total diameter (LD), back optic zone radius (CPC), back optic zone diameter (OZD) and the axial edge lift (EL) (abbreviations used by manufacturer). A typical generated fluorescein pattern is shown in *Figure 10.17(b)* and may be compared to the actual fluorescein fit of the same lens on the actual eye in *Figure 10.17(c)*. New parameters can be input and a new fluorescein pattern generated.

The program is designed to deal with spherical, aspheric and combinations of both spherical and aspherical designs.

Szczotka *et al* (1994) compared results of fitting 27 subjects using either a TMS-1 or diagnostic fitting sets. Comparison of BOZR chosen by the two methods showed no statistical difference. Differences occurred when lens decentration and flexure were present since these could not be anticipated by the computer. Approximately one-third of those lenses fitted by the computer needed changes to the lens BVP and this was felt to be due largely to high riding lid attachment fits producing apical tear pooling. Nevertheless the technique was felt to be more accurate than a previous study where fitting was done empirically, largely based on keratometer readings (Bennett *et al.*, 1989).

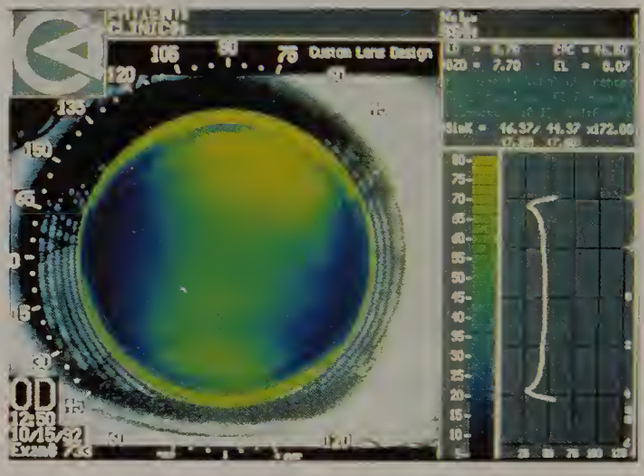
Other topographical devices are now available which include contact lens fitting programs.

The usefulness of the topographical techniques is:

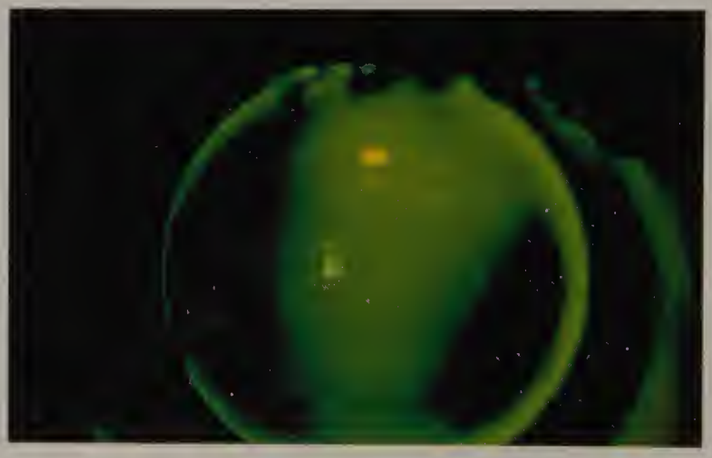
- The ability to customize lens designs, particularly for unusual shaped corneas, and assess the fitting without taking up prolonged chair time. Indeed the simulated fitting can be tried even in the patient's absence.
- Less patient discomfort is involved as fewer trial lenses are necessary.



(a)



(b)



(c)

Figure 10.17 The TMS system in computerized topographical RGP fitting. (*a*) The Tomey TMS-1; (*b*) the computer-generated fluorescein pattern on the eye being derived from the measured corneal shape; (*c*) the actual fluorescein pattern on the eye being measured with the lens parameters as selected by the computer

- The 'guestimation' for the ordering of trial lenses for unusual shaped corneas is put on a more scientific basis.
- Post-fitting analysis of the effect of a patient's contact lens can be accomplished from videokeratographs taken pre-fitting and compared to subsequent videokeratographs taken at follow-up visits.
- As modifications are made to the fit, alterations in the data can be assessed in order to consider further changes to the fitting.
- As an aid to teaching, e.g. to demonstrate the effect of various parameter changes.

The disadvantages of the techniques are:

- Factors such as lid tension and tear dynamics are not taken into account.
- The effect of lens design such as lens mass and centre of gravity cannot be assessed.
- For the above reasons a trial lens fitting is still essential.
- The subtle nature of some aspects of the post-lens fluorescein pattern cannot always be detected on the VDU screen.
- The accuracy of the lens design and fluorescein pattern can never be greater than the accuracy with which the original topographical plot has been made.

Fitting routine for RGP lenses

Most RGP fitting is still carried out in the conventional manner without the aid of topographical devices. Even where such equipment is available, the following are required before fitting commences:

- General discussion with the patient on advantages and disadvantages of contact lenses, patient suitability etc., as discussed in Chapters 8 and 9.
- Corneal, as well as lid and limbal, integrity should be established with a slit lamp (*see* Chapters 6 and 8). Tear film assessment should also be made.
- Accurate keratometer readings. These govern the choice of the BOZR of the first trial lens (*see* Chapters 5 and 6).
- Horizontal and vertical visible iris diameters (which approximately equal the corneal diameters). These partly govern the choice of total diameter.
- Interpalpebral aperture size. Again, this partly governs the choice of total diameter.
- Pupil size in average and low illuminations. This largely governs the choice of BOZD.
- Accurate spectacle refraction and calculation of ocular refraction. This enables a subsequent check on the liquid lens power to be made, which should be zero in a true alignment fit.
- Decision of lens type to be used – corneal, hydrophilic, scleral, or hybrid (e.g. Softperm).

Table 10.10

Astigmatism (by keratometer)	*Approximate BOZR*
Under 0.75 D (< 0.15 mm)	Flattest keratometer reading to 0.05 mm steeper
0.50–1.00 D (0.1–0.2 mm)	0.05–0.10 mm steeper than the flattest keratometer reading
1.00–2.00 D (0.2–0.4 mm)	Steeper than the flattest keratometer reading by approximately one-third of the difference between the principal meridians (consider a toroidal back optic zone)
Over 2.00 D (> 0.4 mm)	As above, but an aspheric or toroidal back optic zone should be considered (*see* Chapter 14)

Selection of the first trial lens (spherical designs)

BOZR

It is best to approach alignment from the steep side rather than the flat side as a central fluorescein pool is easier to see than fluorescein just inside the transition (*see* Assessment of fit *below*). For this reason, lenses as much as 0.20 mm flatter than correct alignment may *appear* to give an alignment picture. The student new to contact lens practice is well advised to select a BOZR approximately 0.15 mm steeper than the flatter keratometer reading for the first trial lens so that a definite central fluorescein pool is obtained. The BOZR may then be flattened in steps of 0.05 mm until central alignment is obtained.

The majority of contact lens patients have some degree of corneal astigmatism. Keratometry indicates the corneal radii and amount of corneal astigmatism. *Table 10.10* indicates the optimum value of BOZR found from clinical experience in the majority of cases.

An 'on-*K*' fitting, i.e. where the BOZR of the lens is the same as the horizontal corneal radius of curvature, can result in an alignment central fitting, a steep central fitting (apical clearance), or a flat central fitting (apical bearing) depending upon the BOZD, corneal shape (*e* or *p* factors), peripheral lens design and TD.

The practitioner's choice of the central tear layer thickness (TLT) profile will be dictated by the desired lens centration and movement. Fitting the lens with central alignment (TLT = 1–5 μm) to minimal apical clearance (TLT = 10–20 μm) will optimize the centration and movement characteristics. Conversely too great a TLT (> 25 μm) may result in transitional bearing and a 'tight' fit and possibly lens flexure (*see below*).

A flat central fitting (TLT = 0) with distinct apical bearing can result in greater discomfort due to excessive lens lag, unstable centration, rotation around the corneal apex, and possible lid margin irritation.

BOZD

This should be at least 1.00 mm larger than the pupil diameter in average room illumination, and larger still if the lenses are to be used in the dark (for example, for night-driving).

It has been found from clinical experience that if a given BOZR over a certain BOZD gives a satisfactory central alignment, then 0.05 mm should be added to the BOZR for each 0.50 mm increase in BOZD in order to maintain a satisfactory fit (*see* p. 350)

BPR

A lens that exerts excessive pressure on the mid-peripheral cornea can induce corneal distortion. Such a fitting (*see Figure 10.8(a)* will also decrease the tear exchange and flushing of debris from behind the lens. Ideally a lens that is fitted with central alignment or slight apical clearance should exert only mild peripheral pressure on the cornea.

The final peripheral curve(s) on the lens have the function of:

- Assisting lens centration by providing a tear meniscus.
- Encouraging retro-lens tear flow.
- Preventing edge indentation on lens movement to the flatter periphery.
- Aiding lens removal.

The axial edge clearance (AEC) will be dictated by the radius/i of the peripheral curve/s and its/their width. There are a number of fitting philosophies regarding the AEC required for optimum daily wear, ranging from 60 to 90 μm.

In patients with 3 and 9 o'clock staining a small (40–60 μm) AEC may be preferred (Bennett, 1985; Businger *et al.*, 1989). In such cases, by keeping the lens edge closer to the corneal surface there is better contact between the superior palpebral conjunctival surface and the cornea and limbal conjunctiva, reducing desiccation, providing the lens remains mobile and does not bind to the cornea. A small AEC has also been suggested as a way of promoting greater comfort with RGP lenses, as a lens edge that is closer to the cornea causes less irritation of the upper lid margin during blinking.

A lens with too small an AEC may, however, cause discomfort when it moves to a flatter part of the cornea as the lens edge will exert greater pressure on the corneal surface. It is necessary to weigh the advantages and disadvantages of fitting with reduced AEC for each patient.

Excessive AEC can result in a thinning of the corneal tear layer adjacent to the lens edge, resulting in punctate staining. A large AEC will also de-stabilize the lens fitting resulting in excessive movement. This is partly due to a reduction in the surface tension force caused by a change in the tear meniscus around the edge of the lens and partly to the effect of the lid action on blinking. Another consequence is formation of bubbles under or adjacent to the lens edge.

The ease and extent of lens movement is largely controlled by the peripheral zone width and the AEC. A small change in the width of the peripheral zone will generally not have as great an effect on the fitting characteristics as an increase or decrease in the AEC. However, a narrow peripheral zone combined with an average AEC may cause a problem when the lens moves towards the flatter corneal periphery. The peripheral zone fluorescein pattern will quickly disappear (*see Figure 10.8b*) resulting in the edge indenting the cornea and causing discomfort for the patient. An excessively wide edge will accumulate large amounts of debris in the tear reservoir which can be a source of foreign body irritation.

It is necessary, when fitting a patient, to assess the performance of trial lenses with a known peripheral curve radius and then to modify the design of the lens to ensure that the peripheral zone is neither inadequate nor excessive.

TD

Modern RGP materials have eliminated the need for minimal corneal coverage in most cases. The use of larger TD lenses has allowed for the lens to be fitted in such a way that the superior edge is positioned under the upper lid. Such a fitting can provide better comfort for the patient as the interaction between the lens edge and the lid margin will be reduced. Nevertheless, each case should be judged on its own merits.

Too large a TD may allow limbal bumping on ocular excursion and, in the case of moderately astigmatic corneas, may precipitate the need for an astigmatic fitting lens due to excess edge clearance along the steeper corneal meridian.

In cases where the upper lid margin lies above the lens, factors dictating comfort will be the design and shape of the edge of the lens.

Selection of the first trial lens (aspheric designs)

Due to the fact that the aspheric surface flattens away from the lens apex the sagittal depth of an aspheric lens is considerably less than a spherical lens with the same central radius. An aspheric lens must therefore be fitted steeper than a spherical lens to obtain the same corneal clearance. However, the degree of steepening will depend upon the design of the trial lens in use and also its *e* value. For example, a lens with a spherical BOZR and elliptical periphery may be treated much the same as any other spherical lens. Conversely a full aspheric lens with a high *e* value of, say, 0.6 will require a nominal central radius possibly 0.2–0.3 mm steeper than *K*.

Depending upon the specific design selected there are only two parameters that the practitioner can vary to modify central fit, lens positioning and edge clearance. These are the PAR and TD. Thus if a lens shows excess AEC the

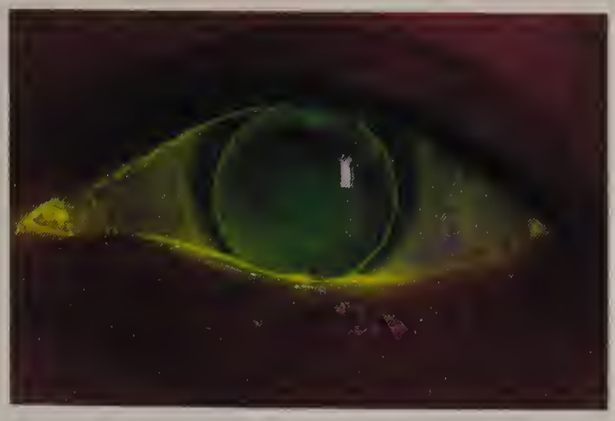


Figure 10.18 The tri-curve lens C3/7.80:7.00/8.30:8.80/12.25:9.20 on an eye with keratometer readings of 7.91 mm along 180, 7.81 mm along 90. The fluorescein pattern shows slight apical corneal clearance and very little peripheral clearance. This shows an ideal fit with the minimum peripheral clearance avoiding flare and lid sensation. (Courtesy of M. Wilson)

practitioner should steepen the PAR or reduce the TD; or choose a lens design with a lower *e* value.

In the event of too little AEC the practitioner must flatten the PAR, increase the TD, or, if necessary, add a small flat, spherical edge curve or choose a lens with a higher *e* value.

In lens designs with spherical back optic zones the same allowances as for normal spherical designs should be made to the BOZR if the BOZD is changed. However, this is commonly not allowable as the lens parameters are fixed. In an aspheric central design the flattening of the BOZR if the TD is increased, for example, is built into the asphericity itself and the PAR should not therefore be amended.

In conclusion practitioners must:

- understand the design and eccentricity of the trial lens in use;
- be guided by the manufacturer's literature in the choice of the first lens. Thus for the Ciba Aspheric range (PE, P92E and Aquila designs) the first lens is recommended to be fitted on flattest *K* or even slightly flatter. Conversely for the Wöhlk aspheric range (Conflex Air and A90 designs) the first lens recommended should be slightly flatter than the mid-*K* value.

Assessment of the fit

At least 5 minutes should be allowed after insertion of the first lens for lacrimation to subside. This is not normally necessary with subsequent lenses. Patients usually comment that the lens is more comfortable than expected and the practitioner should maintain conversation to reassure patients and to take their minds off any irritation produced by the lens. While adapting to the lens, the patient should be instructed to look downwards (where the lids are at their most relaxed) and blink normally.



Figure 10.19 The penta-curve corneal lens C5/8.10:7.00/8.60:7.60/9.60:8.20/10.80:8.80/12.25:9.20 on the same eye as in Figure 10.18. The fluorescein pattern shows the central flat fit with bearing on the apex of the cornea and a slight epithelial abrasion as a result. The lens is riding lower temporally. The lens periphery also appears to have excessive clearance, partially due to the central flat fit. (Courtesy of M. Wilson)

White light assessment

- Lids in the normal position: as the eye moves, the lens should remain within the limbal area, and the superior lens edge should be positioned under the upper lid.
- Lids separated: the lens should drop slowly when pushed to the top of the cornea. A flat fitting lens falls more quickly and often drops in a curved path as it pivots around the apex of the cornea (*see Figure 10.19*). A steep fitting lens falls more slowly and often remains at the corneal apex.
- The lens should promptly return to the same position after each blink. Ideally the post-blink movement should be 1.5–2.0 mm, smooth, medium to fast and vertical.

Ultraviolet light assessment

One drop of 2% fluorescein is applied from a wetted impregnated paper strip, or Minim (Smith & Nephew), on to the conjunctiva above the cornea with the patient looking down and the lids retracted. The series of fluorescein patterns depicted in *Figure 10.8* should be studied here.

Lens centred

Table 10.11 supplements the fluorescein patterns represented pictorially in *Figure 10.8* and *Figures 10.18 to 10.25*. The fluorescein picture of aspheric lenses is generally the same; there are no obvious transitions.

Lens displaced upwards

Fluorescein will disappear from under the upper periphery of the lens, except at the extreme edge, and will collect under the lower periphery and lower part of the back optic zone. Care should be taken to ensure that the extreme edge of the lens does not indent the peripheral cornea.

Movement

With fluorescein present, the movement of the lens is observed with the lids in the normal position, during

Table 10.11

Fit		*Fluorescein picture*
Central	*Peripheral*	
Ideal alignment	–	Even dark blue over BOZD with a 0.5–1.0 mm wide green band at edge of lens. A central trace of fluorescein is acceptable
–	Flat	Bright green under the entire peripheral zone possibly with bubbles at or under the edge
Flat	–	Dark blue centrally with green encroaching under periphery of back optic zone
–	Steep	Narrow blue touch band at extreme edge, green within this. Possible blue transition touch with wide peripheral curves
Steep	–	Blue transition with green under back optic zone and bubble if very steep

blinking and normal eye rotations (*Table 10.12*). The BOZD or the TD in the case of aspheric lenses, is checked relative to the pupil size as the lens moves. The lens should centre itself after each blink and eye movement. Whenever a lens consistently takes up an incorrect position, areas where the transition or edge may be bearing on the cornea should be looked for and blended.

Table 10.12

Lens position	*Possible cause**
Continually high, not dropping after blinks	Flat peripheral zone; too large a lens; too wide a peripheral zone; lens too thin; thick edges; lens slightly steep, occasionally; lens too light in weight due to small total diameter, or too thin, or both; negative lens
Continually low, with rapid dropping after blinks	Too small a lens; too thick a lens; lens fit slightly flat; (prism) ballasted lens; too heavy a lens due to large total diameter or thickness, or both; positive lens
Continually to one side	Apex of cornea displaced; lens too small or too flat; spherical lens on an 'against-the-rule' cornea
Hardly any movement from the centre	Lens too steep; inadequate edge clearance
Lens moving about too much and beyond limbus	Profuse lacrimation due to foreign body or poor lens edge; lens too flat, allowing excessive movement; lens too flat or too steep, causing irritation and lacrimation; spherical lens on a toroidal cornea

*Reference should also be made to *Figure 10.7* for the effects of centre of gravity on lens position.

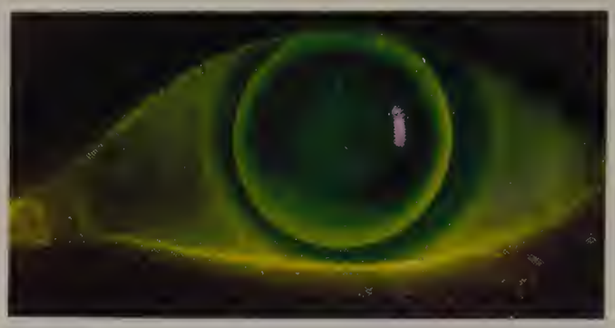


Figure 10.20 A penta-curve 'tapered' corneal lens C5/7.85:7.00/8.35:7.60/9.10:8.20/10.10:8.80/12.25:9.20 on the same eye as in Figure 10.18. The lens is fitted with the back optic zone in alignment with the cornea and with gradually increasing peripheral clearance which would be unnecessarily great for an RGP lens. A foreign body track is also prescnt as shown up by the fluoresccin staining of thc damaged epithelium. (Courtesy of M. Wilson)

Fitting astigmatic corneas

When fitting a spherical lens to an astigmatic cornea, a compromise fit is called for as dealt with under BOZR on p. 339. If a 'with-the-rule' astigmatic cornea (i.e. flatter meridian horizontal) is fitted with a lens showing central alignment of the flattest meridian and a peripheral zone also showing near alignment in this meridian, then the fluorescein picture should show:

1. *Centrally* – an elongated H or dumb-bell-shaped blue touch area as wide as the BOZD (*see Figures 10.21* and *10.22*).
2. *Peripherally* – blue touch in the horizontal meridian and green stand-off in the vertical. The peripheral alignment should not occupy more than one-third of the lens circumference. Vertical stand-off is liable to cause discomfort when blinking. This can be minimized by making the lens as small as possible and the peripheral zone narrow (*see Figure 10.21*).

Due to the reduced sagittal depth of aspheric lenses higher degrees of astigmatism can be fitted with these lenses but back toric lens fittings may still be necessary for corneas showing more than 1.5 D astigmatism in order to maintain good lens centration and comfort (see Chapter 14).



Figure 10.21 An interpalpebral spherical corneal lens with the back optic zone in alignment with the horizontal meridian of a toroidal cornea having 'with-the-rule' astigmatism. (Courtesy of M. Wilson)



Figure 10.22 A spherical lens fitted with a slight apical clearance to a 'with-the-rule' toroidal cornea, the steeper corneal meridian being 70°. The peripheral zone has been fitted slightly steep to prevent too much edge clearance at the top and bottom, in order to minimize discomfort when blinking. There are two crescentic bands of corneal touch on either side of the 160° meridian, and fluorescein shows on the front surface of the top of the lens. Slight central clearance can just be seen along the 70° meridian. (Courtesy of M. Wilson)

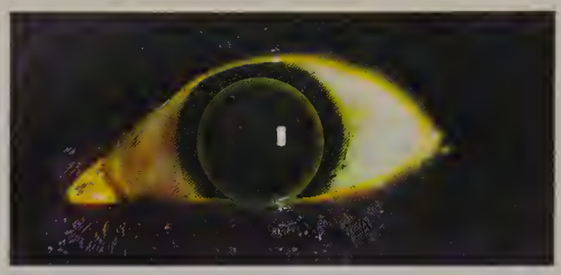


Figure 10.24 A spherical tetra-curve lens on a cornea with spherical keratometer reading. The optic zone and the first peripheral curves give an almost matching fit, and the second and third peripheral curves give gradually increasing clearance. (Courtesy of M. Wilson)

Refraction

This should be performed with the patient wearing the lens whose BOZR is the nearest to the correct fitting. The contact lens over-refraction is a means of checking the fit, as with exact alignment the liquid lens power should be zero and the over-refraction (plus any power of the trial contact lens) equal to the ocular refraction after allowing for the back vertex distance. If the contact lens refraction shows less negative or more positive power than the ocular refraction, then a slightly flat fitting should be suspected. A steep fitting (positive liquid lens) gives a more negative or less positive contact lens refraction.

Lens–cornea relationship and lens flexibility

Five factors should be taken into account.

1. Because the keratometer measures corneal curvature approximately 1.5 mm each side of the visual axis, it will not give the average curvature required for lens alignment with the large BOZDs commonly employed with RGP lenses. Thus a *K* reading of 7.90 may require a 7.90 mm BOZR lens to give correct alignment over a 7.00 mm BOZD. For an 8.50 mm BOZD this figure would typically increase to an 8.00 mm BOZR (see page. 350). Ideally trial lenses should always be used to verify the fitting.
2. When the eyelid moves over the cornea during blinking it presses the eye back about 1.25 mm (Holden, 1984). Clearly the front surface of the contact lens is subjected to considerable force. With PMMA, this results in distortion of the shape of the cornea over years of wear. In the case of the flexible RGP materials, the eyelid succeeds in distorting the shape of the lens itself. The lens does not then return to its original shape but stays flexed because the surface tension in the tear meniscus around the contact lens edge is sufficient to hold it in place. For PMMA, the critical centre thickness at which flexure on the eye can be observed is about 0.12 mm. For many RGP lenses flexure is still obvious at 0.15 mm (greater for CAB materials).

   One would expect to find that, if an RGP lens is placed on a with-the-rule astigmatic cornea, then with-the-rule



Figure 10.23 A 'continuous curve' lens with a single 0.25 mm diameter fenestration hole fitted with very slight central clearance. There is gradually increasing clearance at the periphery, more noticeable at the bottom of the lens which is situated over the central cornea following a blink. In RGP material the fenestration would not be necessary. (Courtesy of M. Wilson)

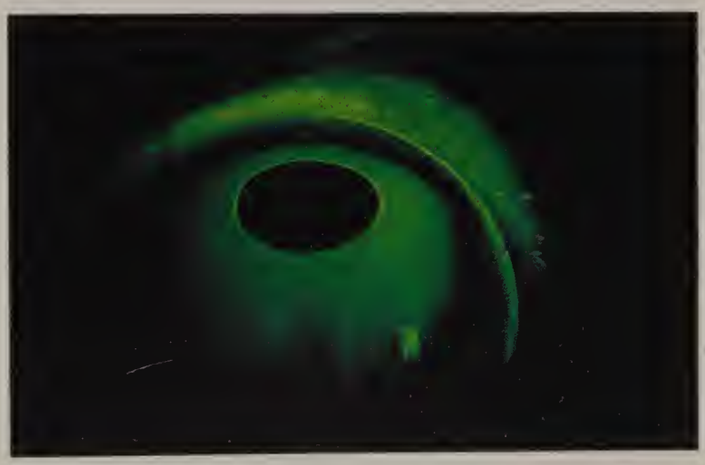


Figure 10.25 Although lens movement, centration and possible edge indentation should be assessed dynamically, the fluorescein pattern should be also assessed with the lens centred on the cornea. The lens above shows good alignment when centred but appears to be fitting steeply with a bubble, i.e. with central corneal clearance, when viewed located on the flatter, inferior cornea. (Courtesy of N. Brennan)

flexure of the lens on the eye would occur. In practice, not only will the degree of flexure depend upon the rigidity and thickness of the lens being used, but it will also depend upon the lens–cornea relationship. Stone and Collins (1984), Herman (1984) and others have shown that in the case of with-the-rule astigmatic corneas, as the BOZR becomes flatter than the flattest keratometer reading (K_F), the lens flexes in an *against-the-rule* fashion. Conversely, as the lens BOZR becomes steeper than K_F, the lens flexes in a with-the-rule direction.

The explanation for this is as follows (Herman, 1984): as the lens is fitted flatter, corneal adhesion is minimized while the influence of the upper lid is maximized. The pressure exerted by the upper lid will then be largely against the flat front periphery of the horizontal meridian of the lens (since the lens will have rocked to align the upper half of the corneal vertical meridian). This will cause the horizontal meridian of the lens to steepen which will then be accompanied by a corresponding flattening of the vertical meridian, i.e. the lens will flex against-the-rule. Correspondingly, as a lens is fitted steeper, corneal adhesion is maximized and the influence of the upper lid minimized. Tear film adhesion will obviously cause the lens to flex in the same direction as the corneal toricity, i.e. with-the-rule on a with-the-rule cornea. Herman found mathematically that at approximately 0.14 mm flatter than *K*, zero flexure (±0.25 D) was observed, i.e. lid compression and tear film adhesion cancel or negate each other allowing lens rigidity to dominate.

Thus, if a lens is actually required to flex with-the-rule (and sometimes this may be desirable to neutralize internal ocular astigmatism), it might be preferable to fit the lens slightly steep. This should allow the lens to centre so that it is not totally affected by the upper lid and is therefore allowed to flex somewhat with-the-rule. If, after the relationship of the *K* reading and refractive spectacle correction has been examined, it seems more desirable to minimize or create an against-the-rule effect, then the lens should be fitted flatter, allowing it to ride high, behind the upper lid, maximizing lid compression to minimize with-the-rule flexure.

The numerical BOZR/*K* reading relationship, however, must only be used as a guideline. Fluorescein patterns must be observed for individual cases. Such factors as peripheral corneal flattening and corneal diameter can make a significant difference. Thus the fluorescein pattern must be coordinated with the measured flexure (by keratometry over the lens) and overrefraction to produce both an optimal fit and visual result. It should be emphasized that, although the lens BOZR may be nominally flatter than K, large BOZDs are now relatively commonly used and the fluorescein picture may still be that of corneal alignment.

The foregoing explanation applies only to with-the-rule corneas. In the case of against-the-rule corneas both the tear film adhesion factor and the upper lid forces are additive, both acting in an against-the-rule direction, causing significant flexure in the against-the-rule direction of almost any BOZR placed on the eye. In such cases toric fitting lenses are preferable. The only possible exception is the higher values of hyperopic astigmatism where lens thickness may prevent flexure on the eye with the more rigid materials.

3. The increased flexibility of some RGP lenses reduces their capability of resisting the compression forces created during reflex blinking. If the lens is fitted even slightly on the steep side of alignment, blink-induced compression may create a temporary seal between the periphery of the lens and the underlying cornea. As the lens decompresses during the opening phase of each blink cycle, the resulting hydrodynamic forces can create a transient negative pressure at the corneal surface that will cause increasing lens awareness as well as unstable vision. The final fitting of lenses should therefore be slightly on the flatter side of alignment (*see also* Lens adhesion phenomenon *below*).
4. The amount of lens flexure may be influenced not only by peripheral corneal flattening, lid pressure and capillary attraction of the tears, but also by the back surface geometry of the lens and its cross-sectional thickness distribution which themselves have an influence on lid pressure and the tear meniscus. For example, an elliptical back surface lens may flex slightly differently from one with a multi-spherical curve back surface, and a lenticular construction may differ from a non-lenticular construction.
5. With early RGP materials, flexure was found to be greater as the material Dk increased. More recent research (Cornish *et al.*, 1991; Blehl *et al.*, 1991; Sorbara *et al.*, 1992) has shown that modern materials are now largely independent of their Dk value with regard to their tendency to flexure with the exception of new materials such as the Ultracon.

Astigmatism

It can now be appreciated that a different approach to dealing with astigmatism is needed with RGP lenses than for PMMA lenses. Ideally a short tolerance trial should be carried out with lenses of the same material, thickness and diameter as the final lens and practitioners are well advised to stockpile old or non-prescribed lenses for this purpose. As the centre thickness decreases, the fitting of the BOZR should approach the flatter *K* reading to slightly flatter than K_F in cases of with-the-rule astigmatism. In the case of against-the-rule astigmatism, the practitioner will fairly quickly require a toroidal back surface lens, if available (*see* Chapter 14).

Sevigny and Bennett (1984) advised increasing the centre thickness by 0.02 mm/D of corneal astigmatism or decreasing the BOZD by 0.2–0.4 mm to minimize flexure in cases of with-the-rule astigmatism. It should be remembered, however, that increasing the lens centre thickness will reduce its oxygen transmissibility.

Table 10.13 Choice of the initial BOZR as recommended by the Boston Equalens fitting manual

Corneal astigmatism (D)	*BOZR (mm) compared to K_F for lens total diameters of*		
	8.70 mm	*9.20 mm*	*9.70 mm*
0.0–0.50	0.10 flatter	0.10 flatter	0.15 flatter
0.75–1.25	On flat *K*	0.05 flatter	0.10 flatter
1.50–2.00	0.10 steeper	On flat *K*	0.05 flatter
2.25–2.75	0.15 steeper	0.05 steeper	On flat *K*
3.00–3.50	0.20 steeper	0.10 steeper	0.05 steeper

The approach becomes different again as the higher Dk value materials are used and flexibility may possibly increase. The Boston Equalens Manual gives the guide to the choice of initial BOZR shown in *Table 10.13*.

Lens adhesion phenomenon

The intermittent adhesion of the flexible high Dk value lenses to the cornea during sleep is a phenomenon almost unique to the overnight wearing of these lenses although it can occur with daily wear. Such lenses are found fixed to the underlying cornea, partially overlapping the limbus and with the patient usually asymptomatic. In most instances, the lens adhesion disappears spontaneously shortly after awakening leaving a compression ring that resolves after a few hours. This ring is identified by the instillation of fluorescein which collects in the circular groove (*Figure 10.26*). Too steep a fit or poor blending of the peripheral curves should be suspected if the base of the compression groove stains with fluorescein and causes discomfort. Some patients are more susceptible to this phenomenon than others (Swarbrick and Holden, 1989) and should be advised to check that the lenses move freely on waking. Patients experiencing occasional adhesion should be instructed to free the lens by compressing the lid margin just above or below the lens to release the suction. Additionally the centre thickness of the lens may be increased by at least 0.03 mm to reduce lens flexure, the BOZR flattened by 0.05–0.15 mm, or the edge clearance increased slightly if the problem persists (Kenyon *et al.*, 1989). However, some patients seem prone to lens binding and overnight wear should be discouraged if this problem resists all corrective measures (*see* Chapter 15).

Swarbrick (1988) has shown that fenestrating RGP lenses has little effect on lens binding indicating that lens flexure or tight fitting is not necessarily the causative factor. Sodium fluorescein also penetrates only very slowly under a bound lens, spreading in a fern-like pattern. From these observations, Swarbrick postulates that the lens preferentially expresses the aqueous layer of the tear film overnight leaving the mucus layer to act as an adhesive between lens and cornea.



Figure 10.26 Lens binding occurs with extended wear RGP lenses after overnight wear. The lens fails to move with normal blinking for 1–5 hours in 10–50% of wearers. On lens removal the epithelium typically displays some central punctate staining and often a prominent indentation or compression ring corresponding to the lens edge shown above. The compression ring may itself stain with fluorescein although more typically there is pooling rather than true staining. (From Swarbrick and Holden (1987), *Am J. Optom. Physiol. Optics*, **64**, 815, with kind permission. © The American Academy of Optometry, 1987)

Three and 9 o'clock staining

Although 3 and 9 o'clock staining of the exposed peripheral cornea was often seen in PMMA lens wearers (*see* Chapter 18 and *Figure 18.29*), it is more commonly observed in RGP lens wearers for the following reasons:

- The reduced edge clearance techniques used minimize lens movement.
- The larger TDs increase edge thickness for negative-powered lenses.
- Many gas permeable materials themselves, because of their tendency to attract deposits, cause reduced surface wettability and hence disruption of the tear film.

The effect of these is to create an inadequate tear film in the exposed 3 and 9 o'clock areas which leads to corneal desiccation. While minor 3 and 9 o'clock staining may be acceptable, persistent or marked conditions may lead to dellen (thinning of the epithelium), erosions and possible eventual local neovascularization or ulceration. Where necessary, the following action should be taken:

- Thin the edges if considered thick.
- Check the lens has not been fitted too steeply.
- Give blink exercises and lateral eye movement exercises.
- Flatten the peripheral curves to create more lens movement.
- Increase lens TD if considered small or decrease TD if considered too large.
- Steepen the peripheral curves if considered excessively flat, i.e. reduce the AEC.
- Flatten the fitting to utilize the lid attachment technique, i.e. create more lens movement.
- Try a better wetting material.
- Use in-eye lubricant drops.

- Consider a trial of temporary, collagen, punctal occlusion in recalcitrant cases.
- Refit with a soft lens

Algorithms for the treatment of recalcitrant 3 and 9 o'clock staining cases have been produced by Jones *et al.* (1989) and Businger *et al.* (1989).

Changes in BOZR

Lenses made from PMMA absorb 1–2% by weight water. It has been known for some years that as they hydrate or dehydrate PMMA lenses undergo cyclic changes in BOZR depending upon their centre thickness and BVP (Gordon, 1965; Phillips, 1969). The classic work of Gordon is shown in *Figure 10.27*. All PMMA lenses flatten with hydration.

The plethora of new RGP materials has discouraged the accumulation of similar data which would be of clinical value to the contact lens practitioner.

CAB materials are known to be at least, if not more, sensitive to hydration–dehydration changes as PMMA. Pearson (1977, 1978) and Smith (1979) found flattening of 0.05–0.10 mm in BOZR with hydration, with the degree of flattening increasing as the lens centre thickness decreased and high minus lenses being quite unstable.

The incorporation of wetting agents, such as methacrylic acid, into a silicone-acrylate polymer can be responsible for the BOZR flattening observed when this group of lens materials is hydrated. Kerr and Dilly (1988) reported increasing flattening of −10.00 D lenses made from this material from 0.08 mm after 24 hours to 0.11 mm after 3 months. For −15.00 D lenses the flattening increased from 0.09 mm after 24 hours to 0.15 mm after 3 months. With a fluoropolymer material the flattening effect found was slightly greater, a −10.00 D lens typically flattening 0.08 mm after 24 hours to 0.19 mm after 3 months and a −15.00 D lens, 0.12 mm after 24 hours to 0.34 mm after 3 months.

If these changes are modest, consistent and limited to the higher minus powers, they may be acceptable. Because of the lower water uptake than either PMMA and CAB, the silicone-acrylate and fluorosilicone groups generally undergo smaller hydration changes than these other two groups of materials. Significant and unpredictable fluctuation in BOZR measurements that occur after hydration are undesirable and may reflect a weakness in the design or polymerization of the material. Because of its potential to alter the anticipated fit and visual correction of the lens, the dimensional stability of all new products should ideally be evaluated by measuring the BOZR of a series of negative-powered lenses before and after 24 hours of hydration.

Occasionally flattening of lens BOZR will be observed that cannot be explained by normal hydration changes, e.g. 0.05–0.20 mm flattening on low-powered lenses. The common cause would appear to be stress put on the lens during the lathe-cutting process in the form of heat transfer (Schwartz, 1986). If the laboratory technician runs the cutting lathe too fast, makes the cuts too fast or too deep, polishes the lens too long or does not use enough coolant,

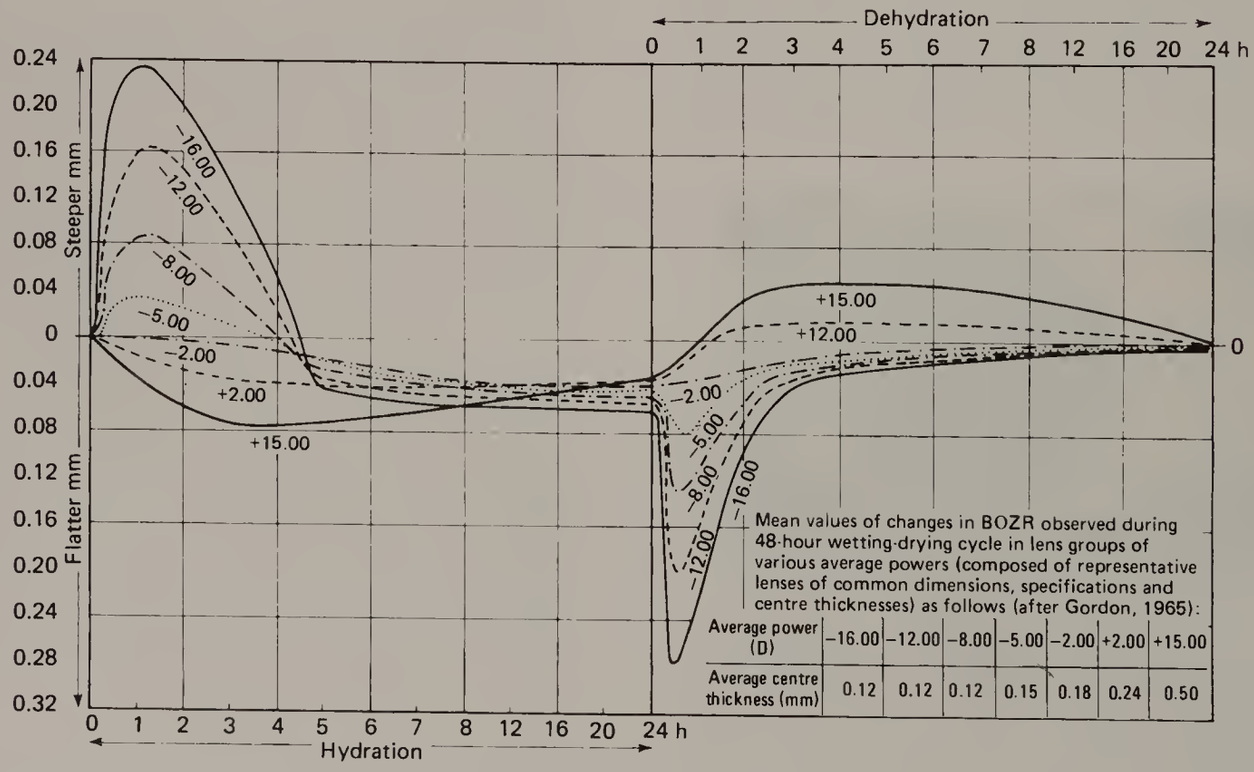


Figure 10.27 The wetting–drying cycle of polymethyl methacrylate corneal lenses

then stress is induced into the lens which will cause the subsequent lens flattening. This stress may be cumulative and is also more likely if the practitioner orders a lens too thin for a particular material. Finally, stress-induced flattening is more likely in larger diameter and higher minus-powered lenses due to the difference in thickness between lens edge and centre. To minimize this effect, front surface lenticulation may be ordered from BVPs of –3.00 D and +1.00 D upwards as opposed to the +/–5.00 D upwards of PMMA lenses.

Walker (1988) reported BOZR flattening with hydration of the order of 0.10 mm for –7.50 D and 0.25 mm for –15.00 D lenses made from Paraperm EW and 0.17 mm for –15.00 D lenses made from Boston IV and Equalens. Unlike PMMA, high positive-powered lenses (+15.00 D) are steepened by 0.05 mm for Paraperm EW and Equalens and 0.03 mm for Boston IV material. Interestingly, by using photokeratograms, Walker showed that these curvature changes were largely restricted to the central 3–4 mm so that the effect on fitting (but not vision) may not be as great as may be expected. Nevertheless, as the lens centre flattens the mid-periphery will steepen producing an unexpected fluorescein pattern. This may also be a factor in producing lens binding (see p. 345) in overnight wear with higher powered negative lenses.

Some materials may show no clinically significant changes with hydration. Pearson (1989) found BOZR changes of less than 0.05 mm over six weeks with a range of BVPs up to –14.00 D using Quantum material. Changes with hydration cannot, therefore, be assumed always to take place. Ideally all RGP materials, especially CAB, should be hydrated before being dispensed, and the BOZR periodically monitored.

Surface crazing and cracking phenomenon

Over a period of time, many patients show deposit build-up on lens surfaces. In some patients this appears as plaques or areas of deposit, while in others it may appear as surface lines or patterns. In this situation of surface crazing, the answer lies in improving the patient's cleaning regimen and including the addition of extra or more frequent use of proteolytic enzymes. Surface crazing is also sometimes amenable to repolishing by the laboratory.

More serious is the appearance of surface cracking. These are deep fissures within the lens surface (*Figures 10.28* and *18.32*) and, at the time of writing, appear largely in the higher Dk silicone–acrylate group of materials. Research by the author does not appear to show causative factors such as either ultraviolet or preservative exposure. It may possibly originate from either surface stress introduced during lens manufacture and ultimately show as cracking from repeated flexure during blinking on the eye, or from constant hydration–dehydration changes or from poor material design. Seidner (1987) postulated the cause to be the incorporation of too high a percentage of methacrylic acid in relation to the overall material formulation.

Surface cracking is often not visible to the patient, but symptoms of slight loss of comfort and visual deterioration are sometimes presented, especially if the cracking is central. Only rarely does it show on the lens back surface (Grohe *et al.*, 1987). Cracking is visible to the practitioner either by slit lamp examination or hand-held magnifier. It cannot be removed by repolishing and, in view of the subjective symptoms and potential for a bacterial nidus or base for foreign bodies or deposits, lens replacement is the only answer.

McLaughlin *et al.* (1988) and Moody *et al.* (1989) reported pseudomonal and staphylococcal infections respectively associated with the wearing of surface-cracked RGP lenses.

Lens care and maintenance

The solutions used with RGP lenses have been discussed in Chapter 4. Patients who have been previous PMMA wearers must be warned of the greater fragility of RGP materials, their greater vulnerability to scratching and distortion, and the greater emphasis on cleaning. Specifically, patients should be advised to:

- Exercise care when retrieving lenses from the storage case, especially if the lens has been inadvertently placed in its compartment convex side up.
- Minimize lens compression during cleaning and handling.
- Clean the lenses in the palm of the hand as with a soft lens rather than between the thumb and fingers.
- Avoid handling the lenses by the opposing edges.
- Avoid dropping the lenses on hard surfaces and exercise care when retrieving a dropped lens.
- Be sure that the lens is centred in the storage compartment before it is closed to avoid edge breakage during closing.
- Use only solutions advised by the practitioner as being suitable for the lens material prescribed.
- Regularly check the lens for deposit build-up after drying and observing against a good light. Most patients will benefit from the intermittent use (typically monthly) of an enzymatic cleaner.
- Not be over-zealous with the use of abrasive ('friction enhanced') cleaners. Boltz (1989), Bennett and Henry (1990) and Carrell *et al.* (1992) found that the over-zealous use of these cleaners can lead to an increase in lens thinning, lens warpage and the addition of minus power.
- Piccolo *et al.* (1990) found no significant change in RGP parameters of both silicone–acrylate and fluorosilicone–acrylate lenses stored in 3% hydrogen peroxide although a small amount of warpage was found in some cases (mean 0.04 mm). This is important as hydrogen peroxide is recommended as disinfecting lenses against the HIV virus (*see* Chapter 4).

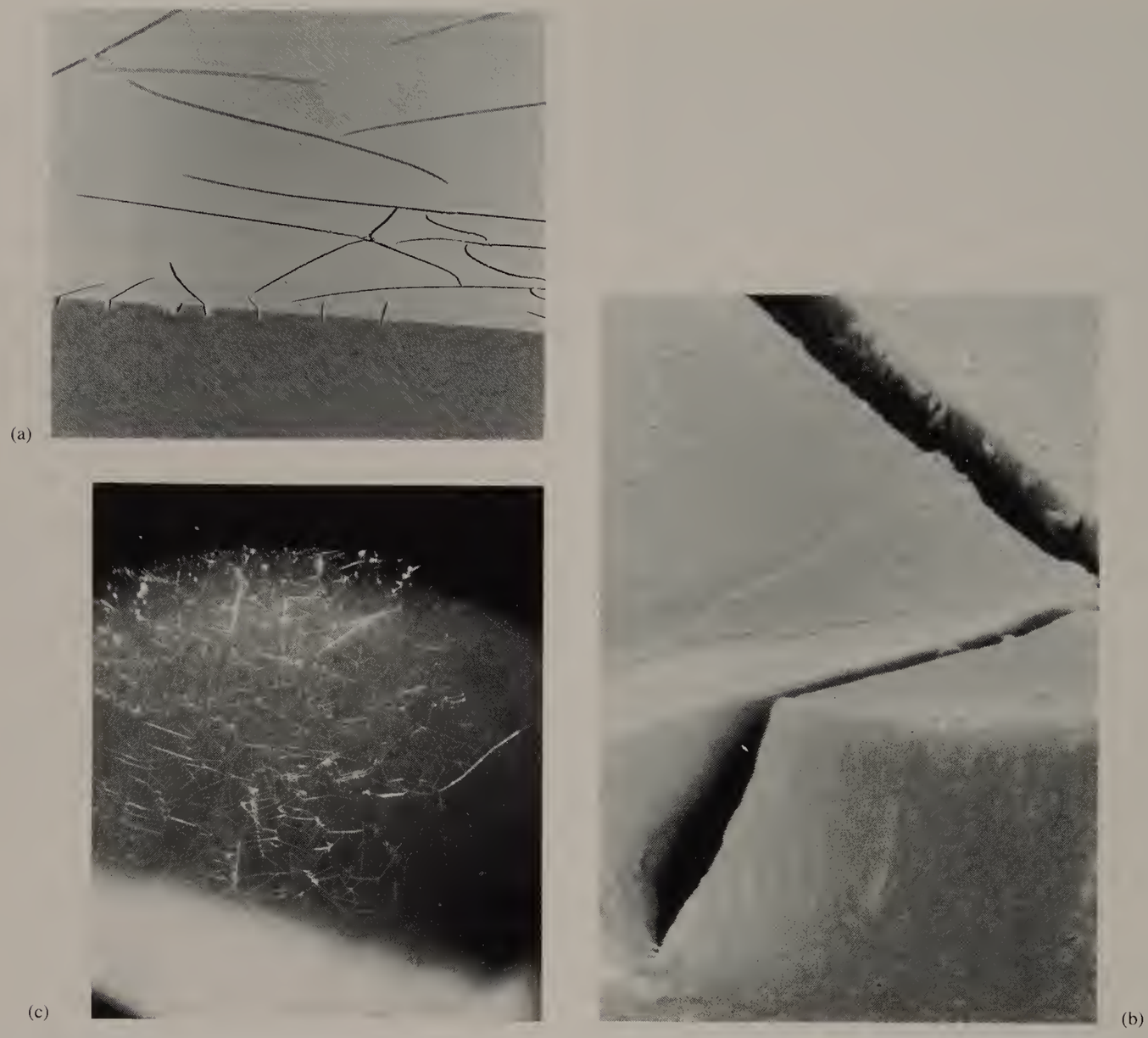


Figure 10.28 Surface cracking of an RGP lens. (*a*) Low magnification in cross-section showing both the surface pattern and depth of crack. (*b*) High magnification showing debris accumulating in the crack. Surface protein deposits are also visible. (*c*) Slit lamp appearance of surface cracking on the eye (*see also Figure 18.32*)

Refitting the former PMMA wearer

Although RGP lenses have become the material of first choice for all patients requiring a rigid lens, small numbers of former PMMA wearers require refitting with RGP lenses. The change of material is advisable for patients with marked spectacle blur, persistent corneal staining, decreased wearing time or endothelial changes. Methods of refitting long-term PMMA wearers include reducing wearing time, or immediate refitting. The advantages of immediate refitting with RGP lenses are that patients are not inconvenienced, because they can continue full-time wear with rigid lenses and, in most cases, experience no significant drop in visual acuity or inhibition of corneal recovery with the new lenses. However, the decision as to the optimum method of refitting depends upon the state of the patient's corneas.

To make an adequate assessment of corneal physiology (staining, oedema etc.) and post-wear spectacle refraction and acuity, a preliminary evaluation of the patient's eyes should be scheduled after a minimum of 4 hours of their PMMA lens wear. If the induced changes are minimal, the patient can be refitted at that time. If excessive corneal staining, oedema, significant spectacle refractive or acuity changes, or keratometric mire distortion is present, a more feasible option would be to gradually decrease the patient's lens wear, possibly one eye at a time if that is helpful, to the minimum number of hours possible or refit one eye at a

time. Spectacles, if available, usually fail to provide adequate visual acuity so that a decrease to 8–12 hours of lens wear is the minimum schedule most patients will adhere to.

The patient should then maintain a limited wearing schedule until the dispensing visit of the refitted RGP lenses. Although the patient's progress should be closely monitored, immediate full-day wear or rapid re-adaptation can be instructed. Spectacles can also be prescribed once the patient's refraction has stabilized although this may be 3–12 weeks after dispensing the RGP lenses, depending on the severity of the corneal changes. In the case of greatly distorted corneas, patients should be warned that further re-fitting is sometimes necessary as corneal regularity and curvature stabilize following the first refitting (*Figure 10.29*). A return to the original pre-PMMA-fitting keratometer readings often indicates when stability has been reached. If these are not available a request to the patient's original practitioner will often provide the necessary information.

Patients refitted with RGP lenses may initially complain of lens awareness even though the lens fitting may be excellent and corneal physiology improved. This 'initial transfer irritability' occurs because corneal sensation usually improves when a gas permeable lens is worn. Thus a PMMA lens-wearing patient who tolerates corneal oedema, erosions or epithelial infiltrates because of corneal hypo-aesthesia may be quite irritable with new lenses that are gas permeable even though the corneal state is much improved. The symptoms of increased sensation usually last 2–4 weeks and the patient *must* be warned in advance to accept this.

Fitting sets

Fitting sets are commonly still made from PMMA material as this is less expensive and more resistant to distortion with handling. The variation in flexure with the final lens should be borne in mind as discussed above. Most practitioners will

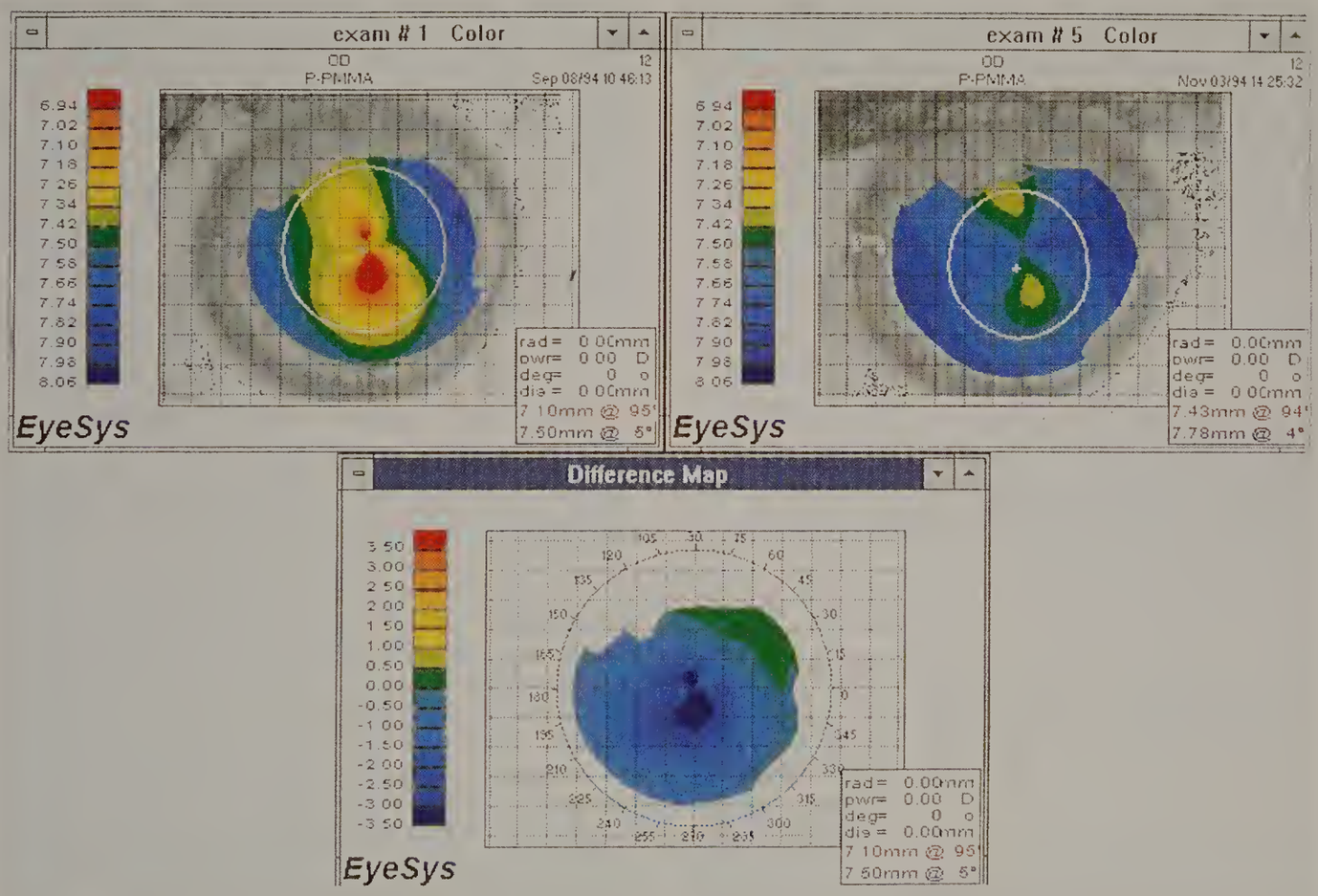


Figure 10.29 The corneal topographical plot (*top left*) was taken immediately post wear of a PMMA lens. PMMA lenses had been worn for approximately 15 years. The steepness of the central corneal apex can be seen in the top left-hand plot giving a picture of apparent early keratoconus. Eight weeks after wearing fluorosilicone acrylate RGP lenses the cornea (*top right*) resembles a normal with-the-rule astigmatic picture and the *K* readings have flattened by approximately 0.3 mm. The bottom 'difference map' shows a central change in corneal power of some –3.50 D! Lens refitting was necessary at the new corneal shape

accumulate lenses of different materials rejected for one reason or another and short wearing trials with lenses approximating to the patient's prescription and selected lens material usually prove very helpful.

It is essential to utilize trial lenses of the same or very similar design to the fitting philosophy selected by the practitioner. In the case of aspheric designs the fitting set must originate from the laboratory who will make the final lens. It is vital that all parameters are known and regularly checked for accuracy and freedom from distortion. All curvatures should be noted to the nearest 0.01 mm and ideally engraved with some identification marking.

Trial lenses may be ordered with slightly greater central thickness than prescription lenses to aid maintenance of lens curvature with handling. However, the effect of this on lens movement and centration should not be forgotten.

Because most contact lens patients are myopic, many trial sets are made with low to moderate negative power.

Further fitting sets may be acquired as practitioners develop their own techniques. Sets of high positive and negative lenses are useful for fitting aphakes and high myopes. The thickness variations cause such lenses to behave differently on the eye from low-powered lenses of otherwise similar specifications, although when made in lenticular form, as is usual, high positive lenses with parallel-surfaced or negative carrier zones, should behave like low-powered negative lenses. However, even when high-powered negative lenses are made lenticular, it is difficult to stop them from riding high on the cornea, due to upper lid traction.

Ordering

During the fitting routine a single lens may not be available which is correct in all its specifications. It may be necessary to combine specifications from more than one lens or to extrapolate a dimension from the nearest trial lens. The following notes indicate those allowances necessary.

BOZR

Effect of variations in the BOZD

As mentioned earlier, since the cornea flattens towards its periphery, as the BOZD is increased, the BOZR must be flattened to maintain the nearest to an alignment fit. The opposite applies on reducing the BOZD. It has been found from clinical experience that for *every 0.50 mm increase in BOZD the BOZR must be flattened by approximately 0.05 mm, and vice versa*. Atkinson (1990) pointed out that in terms of tear layer optics *a 0.70 mm increase in the BOZD for a 0.05 mm flattening of the radius, and vice versa,* is technically more correct and leaves the central tear layer thickness the same.

Effect of hydration

RGP lenses would appear to flatten less with hydration than PMMA lenses. Nevertheless, higher powered negative lenses are still sometimes vulnerable to this effect. Practitioners may prefer either to order lenses a few hundredths of a millimetre steeper initially to allow for this depending upon lens thickness and BVP (see p. 346) but detailed information on the specific material being ordered should be sought from the manufacturer or current literature. Lenses should be rechecked after hydration prior to being issued to the patient and at periodic intervals thereafter. At after-care examinations any apparent indication that negative lenses, which were of correct power, are now too strong would suggest that the BOZR has flattened.

BPR

The same allowances apply as for the BOZR, both for alterations in the total diameter and hydration flattening (usually taken to the nearest 0.05 mm owing to the difficulty of accurately manufacturing and checking peripheral curves).

BOZD and TD

See notes under BOZR and BPR.

BVP

Comparison of spectacle and contact lens correction

The initial spectacle refraction is best written in negative cylinder form because the tear lens acts as a negative cylinder in a lens aligning the flattest corneal meridian and corrects most of the corneal astigmatism (*see* Chapter 5). Thus, the power of these two negative cylinders can be compared and, where the spectacle astigmatism and keratometer astigmatism are approximately the same, the astigmatism should be corrected by the tear lens and then the cylinder in the spectacle correction may be ignored. The spherical component of the spectacle refraction referred to the corneal plane should then equal the liquid lens power along the flattest corneal meridian plus the BVP of the contact lens. If there is more than 0.50–0.75 D difference between spectacle and keratometer astigmatism, depending on the visual acuity and visual tolerance of each patient, it may be necessary to incorporate a front surface cylindrical correction. Because of possible lens flexure, residual astigmatism should be checked more than once before proceeding to incorporate a front surface cylinder or supplying any form of toric lens. To maintain lens orientation in these cases, a prism-ballasted lens or double truncation may be used where the cornea is close to spherical; alternatively a toroidal back surface lens may be fitted where possible (*see* Chapter 14).

Vertex distance

A refraction is carried out with the trial contact lens in place, and provided adequate visual acuity is achieved the 'best sphere' power is used.

The BVP of the trial contact lens is then added to the power of the spectacle addition, having made due allowance for the vertex distance, to give the BVP of the lens to be ordered.

A table of vertex distance allowances is given in Appendix A and on the CD-ROM or may be determined by calculation. It can be seen that for spectacle corrections of less than 4.00 D the effects of vertex distance may generally be ignored, provided that the latter lies within normal limits.

Effect of variations in the BOZR

It may be necessary to carry out the refraction with a trial contact lens whose BOZR is not the same as that to be ordered on the final lens. As any alteration of the BOZR alters the power of the tear liquid lens, an allowance must be made to the BVP of the lens to be ordered. It can be calculated that, for small amounts and for corneas of average curvature, *an alteration of 0.05 mm in the BOZR requires an alteration in BVP of 0.25 D.*

Thus, if the trial lens used is of BOZR 8.00 mm and BVP –3.00 D, and the lens ordered has a BOZR of 8.05 mm, then the liquid lens becomes more negative powered and the BVP of the lens must be ordered as –2.75 D to compensate for this.

No alteration to the BVP should be made where the BOZR is altered to compensate for flattening with hydration. This allowance normally disappears when the lens becomes fully hydrated.

Centre thickness

Although the centre thickness of a lens is normally specified, the edge thickness is just as important clinically. An edge which is either too thick or too thin gives rise to lid irritation. An edge thickness of around 0.14–0.18 mm appears to be the ideal.

A lens which is too thin centrally flattens excessively with hydration and often becomes distorted or damaged if handled incorrectly. Conversely, a lens which is too thick is relatively heavy and constantly positions low on the cornea. A list of suggested centre thicknesses for variations in BVP and TD is given in *Table 10.14*.

It is suggested that the higher powers are made in lenticular form because this provides a great reduction in lens weight, thereby aiding lens centration and giving easier control of edge thickness and reduces the effects of hydration. When a lens is ordered in lenticular form, it is necessary to specify a front optic zone diameter (FOZD), and the desired final edge thickness. The FOZD is generally around 0.50 mm larger than the BOZD. Junction thickness may also be specified (*see* pp. 217–219, Chapter 5).

Transitions

These may be left sharp or blended lightly, moderately or heavily. Although a heavily blended transition lessens any risk of corneal abrasion caused by this area, there are two possible disadvantages. First, it is difficult to check if the BOZD has been made correctly; if incorrect, it effectively alters the fit of the back optic zone. Secondly, the transition, if polished well into the BOZD, reduces its effective diameter, often causing flare under conditions of low illumination. Ideally, the transition should be ordered lightly blended and the blending increased later by the practitioner as necessary.

If blending is carried out, a tool should be chosen whose radius lies one-third to mid-way between the BPR and BOZR so that most of the lens substance is removed from the peripheral curve (*see* Chapter 22).

Lens engraving and distinguishing marks for right and left lenses

Right and left lenses should be distinguished by the letters R and L or by small dots – one for the right lens and two for the left (British Standard, BS 5562:1989). If dots are used for identification marks, often only the right lens is so marked because the drilling of two small marks in the lens surface may weaken the lens. A hole filled with black pigment shows less against the iris background in most cases. A small painted dot on the lens front surface is also possible and does not involve drilling into the lens surface. A dot is more easily visible to presbyopes even without their near correction. All marks are positioned near the lens edge so that there is no risk of visual interference and, ideally, both lenses should be engraved. A disadvantage of lens engraving marks is that they are sometimes inadvertently removed when power alterations are carried out. Also, like scratches, they may encourage deposits.

With the plethora of materials currently available, it is strongly recommended that all RGP lenses are engraved with a simple code to identify the material prescribed. A suitable recommendation for each material is shown in *Table 10.3*. This is extremely useful, not only when seeing patients fitted elsewhere but in the identification of old lenses, confirming that lenses are suitable for extended wear etc.

Toroidal lenses should have a dot marked at each end of the flattest meridian. This not only identifies the lens as toroidal but allows the practitioner to check if the lens has orientated correctly or rotated.

Material selection

PMMA is now considered the material of *last* choice, its only use now being for recalcitrant GPC sufferers where a high surface polish, good deposit resistance and thin edges are necessary, and for some 3 and 9 o'clock sufferers where a small lens with a thin edge is the only design that helps.

Table 10.14 Corneal lens thickness chart

Negative powered lenses

BVP (D)	*Total diameter (mm)*					
	8.50 to 8.80	*8.90 to 9.20*	*9.30 to 9.60*	*9.70 to 10.00*	*10.10 to 10.30*	*10.40 and over*
Afocal to −0.50	0.215	0.210	0.210	0.210	0.200	0.180
−0.75 to −1.00	0.215	0.210	0.200	0.190	0.190	0.170
−1.25 to −1.50	0.210	0.200	0.190	0.190	0.175	0.160
−1.75 to −2.00	0.200	0.200	0.190	0.180	0.165	0.155
−2.25 to −2.75	0.190	0.190	0.175	0.170	0.155	0.150
−3.00 to −3.25	0.180	0.180	0.160	0.155	0.150	0.145
−3.50 to −4.25	0.170	0.160	0.150	0.145	0.140	0.130
−4.50 to −5.00	0.160	0.155	0.140	0.135	0.125	0.115
−5.25 to −5.50	0.150	0.145	0.130	0.120	0.110	0.105
−5.75 to −6.00	0.140	0.135	0.120	0.105	0.100	0.100
−6.25 to −7.00	0.130	0.120	0.110	0.105	0.100	0.100
−7.00 and over	0.100	0.100	Make in lenticular form			

Positive powered lenses

BVP (D)	*Total diameter (mm)*					
	8.40 to 8.70	*8.80 to 9.20*	*9.30 to 9.70*	*9.80 to 10.00*	*10.50 (approx.)*	*11.00 (approx.)*
Afocal to +1.00	0.210	0.220	0.230	0.235	0.240	0.245
+1.25 to +2.00	0.230	0.240	0.250	0.255	0.265	0.270
+2.25 to +3.00	0.260	0.270	0.280	0.290	0.310	0.330
+3.25 to +4.00	0.280	0.295	0.310	0.325	0.350	0.370
+4.25 to +5.00	0.305	0.315	0.330	0.360	0.395	0.450
+5.25 to +6.00	0.330	0.345	0.365	0.385	0.420	0.470
+6.25 to +7.00	0.350	0.370	0.395	0.440	0.470	0.520
+7.00 and over			Make in lenticular form			

The figures given above for centre thickness (mm) are the average for the power and total diameter groups and generally give an edge thickness of about 0.14–0.18 mm for an average tri-curve lens (P. Bryant, 1975, personal communication). Lens thicknesses should be ordered to two decimal places only.

Note: Lenses with a BVP of about ±5.00 D should be made in lenticular form (*see also* p. 347). In general centre thicknesses of greater than 0.40 mm should be avoided where possible by the use of lenticulation. Some practitioners advocate lenticular construction for all positive lenses to minimize centre thickness but give adequate edge thickness and similarly for very low minus lenses, down to −2.00 D.

The advantages and disadvantages of the various RGP materials have been discussed earlier. New materials are constantly being introduced. As a general guideline only the following factors should be taken into account when prescribing a lens material for a specific patient.

Oxygen permeability

Is it adequate for the patient's needs? What lens thickness is being prescribed and, hence, what is the *Dk/t*? For higher prescriptions a higher Dk material should be used. Does the patient need extended-wear or flexi-wear capability? Have problems occurred in the past with lower Dk materials?

Wettability

Different materials show different wetting characteristics. Whilst various laboratory techniques exist for measuring surface wettability these do not represent the true *in vivo* situation since ocular lipids and proteins affect this property once the lens is in the eye. Nevertheless patients with surface deposition problems or a mild dry eye will be best fitted with a material with good surface wetting properties. A different material in each eye may offer a useful comparison of the *in vivo* situation. Surface wetting will also be affected by the blink rate, lens design, mode of fit and the nature of the visual task.

Flexure

If the degree of corneal astigmatism is greater than the ocular astigmatism it is actually beneficial to permit some lens flexure in order to minimize, or eliminate, a residual astigmatic error. Whilst the lens centre thickness is the major factor governing lens flexure this will also vary between different materials (*see* pp. 343–345).

Dimensional stability and durability

This may be affected by hydration, stresses induced during lens manufacture (e.g. radical flattening) and the lens polymer structure (e.g. surface cracking). A former PMMA wearer, used to fairly rough handling of lenses should be prescribed a material known for its good dimensional stability. In this regard it is also important that the laboratory being used is happy with the material prescribed and has not experienced problems during lens manufacture.

Deposit resistance

All RGP materials appear more prone to surface deposition than PMMA lenses. However, some materials are more prone to lipid deposits, e.g. CAB; others to protein deposits, e.g. silicone–acrylates; whilst some newer materials are claimed to be relatively protein resistant. Note should be taken of previous deposit problems, tear make-up, the working environment, any history of GPC etc., in determining the appropriate material choice.

In summary, many factors are involved, some conflicting. Most practitioners have 'first choice' materials that both they and their laboratory feel comfortable with. New materials should be tried as they are introduced. As with lens design one lens material may be optimal for a specific patient, for others several may prove acceptable.

Lens tint

The use of tinted plastic material enables the contact lens practitioner to prescribe a tinted lens for the patient either for photophobia or to alter or enhance the iris colour within certain small limits.

The arguments used by Giles (1960) to deprecate the over-prescribing of tinted spectacle lenses also apply to tinted contact lenses. However, the use of very light neutral tints in contact lenses is often beneficial in practice for two reasons. First, location of a clear lens on the sclera or in a bowl of water is extremely difficult, whereas even a lightly tinted lens can be easily observed. Secondly, the contact lens wearer is often more light sensitive than he was when wearing spectacles, and the use of a lightly tinted lens may help to relieve this. Three reasons for this photophobia have been suggested (Phillips, 1968), as follows:

1. The increased light transmission of the contact lens, since there is only one air–lens surface, which causes the greatest light loss by reflection. However, the wearing of plano spectacle lenses over the contact lenses does not relieve the photophobia (Bergevin and Millodot, 1967).
2. The small amount of corneal oedema usually present in new wearers while adapting to their lenses, which causes increased scattering of light.
3. The foreign body sensation of the lens edges, again present in new wearers, which probably causes reflex iris blood vessel dilatation, iris congestion and pain on sphincter constriction.

Because both (2) and (3) are normally temporary in nature, the temptation to prescribe a deeper tint should be avoided. However, in the case of a badly fitting lens causing increased corneal oedema, or a poor lens edge exaggerating the foreign body reflex, the photophobia may well be excessive and prolonged. In these instances, the answer lies in improving the lens design or construction and not in prescribing a deeper tint.

Many modern materials are, unfortunately, made in only one tint (or no tint!). Others are available in several colours. Only a very few are currently available in the deeper tints necessary to help the severe photophobic or to significantly change the iris appearance. In these cases a second, duplicate clear or lightly tinted pair should be prescribed for night-time use.

Fenestration

With the excellent gas transmissibility of modern RGP materials, fenestrating lenses is now rarely necessary. The value of lens fenestration with modern materials is either to rescue a mildly tight fitting lens, e.g. in a teenager whose cornea has flattened rapidly, or in case of irregular corneas, e.g. trauma, keratoconus etc., where fenestrations may be used to prevent tear stagnation.

Fenestrations should only be used in those areas which are definitely clear of the cornea, otherwise an additional tear meniscus is formed between lens and cornea which tends to reduce lens movement. In addition, there is a greater risk of epithelial trauma from the edge of the fenestration.

Central fenestrations are typically 0.10 mm in diameter but it is more usual to position a 0.25 mm fenestration near the edge of the back optic zone. Occasionally a 0.50 mm diameter fenestration is used.

Atkinson and Phillips (1971) listed the proposed advantages of fenestrations in PMMA corneal lenses. Hill and Uniacke (1968) showed that there is little oxygen movement (via the tears) through the fenestration itself but that any physiological improvement is more likely to be due to the prevention of negative pressure under the lens.

Methods of lens fenestration by the practitioner are described in Chapters 21 and 22. Lenses fenestrated by a laser beam permit multiple well-finished fenestration holes of 0.10 mm diameter. These were reported by Brucker

(1975) to be very successful, but further studies have been disappointing.

The edge shape

The lens edge shape is extremely important both for patient comfort and, to a lesser extent, in lens movement and centration. La Hood (1988) has shown that a well-rounded edge, particularly on the front surface, is essential for patient comfort. Too thick or square an edge may be uncomfortable whilst too thin an edge may be sharp or chip easily. Lens edge shapes may be checked as explained in Chapter 12 or modified as explained in Chapter 22. Some manufacturers designate several choices of edge design which the practitioner may select from.

The written prescription

The form of the written prescription has been recommended by British Standard BS 3521:1989.

The radius of each zone is given in turn from the centre outwards, immediately followed by its external diameter. Dimensions are invariably to be given in the following order:

(i) The letter C followed by the figure 1 for single curve, 2 for a double curve, 3 for a triple curve lens etc.
(ii) Radius of the back optic zone surface followed by its diameter or the total diameter, whichever applies.
(iii) Radius of each surrounding back surface followed by its external diameter or the total diameter, whichever applies.
(iv) Displacement of the optic (where applicable).

Examples

(1) Please supply one corneal lens
R C3/7.70:6.50/8.15:8.00/10.00:8.80/D1
(i) (ii) (iii) (iii) (iv)
BVP –6.00 D
Material: RXD
t_c 0.12 mm t_e 0.16–0.18
Transitions left sharp
Mark one dot (black) and RXD
Light blue tint

(2) Please supply one pair corneal lenses
R C2/8.00:7.00/8.50:9.30
BVP –3.25 D
t_c 0.16 mm
L C2/8.05:7.00/8.55:9.30
BVP –1.00 D t_c 0.19 mm t_e 0.16 +/–0.02 mm
Material: Equalens II
Transitions lightly blended
Engrave R & L and EQ2
Light blue tint

(3) Please supply one corneal lens
R C3/8.15:7.00/8.70:8.20/9.50:9.40
BVP –7.00 D
Material: Fluoroperm 60
Front surface lenticular, FOZD 7.50 mm to give te = 0.18 mm +/– 0.02 mm
Transitions moderately well blended
Engrave R and F60
Light grey tint

The final lens

Whatever the lens material, the final lens is first checked as described in Chapter 12. The lenses are fully hydrated before being checked on the eye – carried out in the same manner as in the fitting routine. A gradual transition across the lens from touch to clearance is the ideal for most fitting philosophies. If any hard blue arcuate bearing areas (possibly indicative of a relatively sharp transition or too steep a peripheral curve) are apparent, either with the lens centred or as it moves on the cornea, the lens transitions or peripheral curves should be modified.

The patient is instructed in the wear and handling of the lenses, as described in Chapter 9, and the period of after-care then begins.

Identification of RGP materials

From time to time, every practitioner is confronted by a patient wearing corneal lenses who has a complication, such as oedema, corneal staining or spectacle blur, of an unacceptable degree. If the lenses were fitted elsewhere, the practitioner must first establish the material from which the lenses are made. If the nature of the material can be discovered, correct management of the problem is facilitated. In some cases, this will constitute re-fitting with an RGP material or an alternative RGP material of high oxygen permeability.

There are several ways of identifying the material:

- **Ask the patient** – often the patient is aware of the fact that he or she is wearing RGP lenses if not the specific material. Specific solutions or cleaning techniques may give useful clues. Some patients are issued with lens prescriptions or identification cards. The patient's former practitioner, if available, will usually be able to supply relevant clinical information. In some countries the issuing of a contact lens prescription, including lens material, is now mandatory.
- **Check the lens** – some practitioners engrave a code to identify the lens material, as mentioned earlier.
- **Spectroscopy** – in theory, lens materials may be identified by spectroscopy, principally in the infrared region (Pearson, 1986). While materials may be identified in terms of their general groups, e.g. silicone–

acrylate, batch variations of materials and even variation along rods of materials, make specific identification difficult. Dain and Pye (1993) have also shown that combined ultraviolet and visible transmission curves can also be used to identify RGP materials.

- **Specific gravity** – Refojo and Leong (1984) used a series of 21 solutions of calcium chloride with concentrations ranging from 18% to 38%. Specific gravity was established by noting the solution in which the lens neither floated nor sank upon immersion. Materials of higher oxygen permeability were associated with lower values of specific gravity.

  A simplified specific gravity test was devised for use by the contact lens practitioner or manufacturer (Whitford, 1984; Hoffman and Allen, 1985). The lens, or button, is placed in a solution the specific gravity of which is probably about 1.17. Lenses or buttons which float are deemed to be gas permeable while samples which sink are either PMMA or CAB. Practitioner kits available for material identification include the Opti-Mis (Optacryl) and Clik Kit (Paragon). Specific gravities of various materials are shown in *Table 10.3*
- **Refractometry** – Hodur *et al.* (1992) suggest the use of the Atago N3000 refractometer to identify RGP material refractive index. This instrument is normally used to measure the water content of hydrogel lenses (*see* Chapter 13) but since the refractive index of RGP materials is commonly available, the instrument can be used for identification of the RGP material or its grouping. The method is as follows.

The clean, dry PMMA lens is placed convex side face-down on the face of the refractometer and a drop of non-preserved saline placed on the concave side of the lens. The saline thereby neutralizes the air space between the lens and prism cover. Care should be taken not to crack the contact lens by closing the prism cover too firmly. Nevertheless, the cover plate should be held sufficiently firmly to produce full optical contact and alignment of the lens with the prism. By looking against a suitable light or light coloured wall the boundary line can be seen to denote the refractive index. The reading of refractive index is taken from the internal scale and calibrated to 1.49 (for PMMA) using the screw ring. The unknown lens can now be measured in the same manner.

Typical refractive indices for some commonly used materials are shown in *Table 10.15*.

Table 10.15 Refractive index of some commonly used RGP materials as measured on the Atago N3000 refractometer

Material	*Refractive index (in ascending value)*
RXD	1.432
Equalens	1.433
Fluoroperm 92	1.447
Fluorex 700	1.451
Fluoroperm 30	1.457
Paraperm EW	1.460
SG II	1.464
Boston IV	1.467
SGP I	1.468
Boston II	1.469
Optacryl 60	1.471
Ocusil	1.475

Generally, a refractive index of less than 1.460 indicates a fluorosilicone–acrylate and an index of 1.460 or greater indicates a silicone–acrylate.
Source: After Hodur *et al.* (1992).

Summary

Although RGP lenses still suffer from certain disadvantages such as foreign bodies under the lens, 3 and 9 o'clock staining, greater initial sensation than soft lenses etc. (*see* Chapter 11), their usage in contact lens practice is essential. Many of the disadvantages of early RGP materials have been solved.

Competition between material manufacturers is such that materials of higher oxygen permeability, better wettability, reduced deposit tendency, greater rigidity etc., are increasingly likely to become available. Gas permeable lenses have found increasing favour with practitioners and are the lenses of first choice in most cases.

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Chapter 11

Soft (hydrogel) lens fitting

Andrew Gasson and Martin Lloyd

Introduction p. 358
Advantages of soft contact lenses p. 362
Disadvantages of soft contact lenses p. 364
Patient selection for soft lenses p. 365
Visual considerations p. 366
Water content and polymers p. 369
Classification p. 369
Lens thickness and 'thin' lenses p. 372
Additional techniques in soft lens fitting p. 373
Consulting room procedures and equipment p. 374
Clinical routine p. 377
Fitting characteristics p. 379
Fitting philosophies and soft lens selection p. 381
Examples of lens types p. 384
Disposable lenses and frequent replacement p. 394
Toric soft lenses p. 395
Soft lenses for presbyopia p. 396
Special features of soft lenses p. 397
Instructions to patients p. 400
Disinfection of soft lenses p. 400
After-care p. 401
Lens ageing p. 402
General comments on soft lens practice p. 403

Introduction

The introduction of hydrophilic lenses in the early 1970s signalled the start of a boom in investment and technology in the contact lens industry which has resulted in soft lenses being the most prescribed lenses throughout the world. Improvements and changes in polymers and materials, manufacturing techniques, cleaning and disinfection procedures and methods of fitting have given an array of options, including conventional daily wear, extended wear, weekly or monthly disposable, and more recently daily disposable wear. During the past 20 years the status of soft lenses has changed from occasional experimental use in difficult cases to a routine and indispensable part of contact lens practice.

Terminology

Since their introduction, in addition to brand names, the new lenses became known by a variety of descriptions such as soft, hydrophilic, hydrogel, gel, flexible and pliable, in order to distinguish them from corneal lenses, rigid gas permeable and PMMA. 'Soft' (defined as yielding to pressure), with the advantage of simplicity, has become the most acceptable and widely used term. Hydrophilic (water-loving), although applicable to most lenses mentioned in this chapter, is not strictly an accurate description, since it is more properly used to define the surface characteristics of a material in relation to the angle of contact, or wetting angle (*see* Chapter 3). It is a term which can also be applied to PMMA and rigid gas permeable lenses, so that a hydrophobic hard lens may be coated to become hydrophilic. Similarly, a flexible silicone lens is extremely hydrophobic unless the surface is treated to become hydrophilic. The term 'hydrogel' signifies a material made from a hydrogel polymer, which absorbs and binds water into its molecular structure. It usefully describes those lenses mentioned as having a percentage water content, although not all hydrogels need necessarily be soft.

Before hydration these hydrogels are referred to as xerogels. Within the category of hydrogels there are a great many individual polymers, some of which, such as hydroxyethyl methacrylate (HEMA) have themselves become generic. *Figure 11.1* shows a high water content soft lens (*a*), and a smaller corneal diameter lens (*b*) which cosmetically is almost invisible on the eye.

Figure 11.2 shows the considerable elasticity of a typical soft lens.

Historical background

The first soft lenses were produced in Czechoslovakia by Wichterle and Lim, two polymer chemists from the Prague Institute of MacroMolecular Physics. Having worked in association with Dreifus, they reported that certain hydrogels developed for biological application could successfully be used for the manufacture of contact lenses (Wichterle and Lim, 1960).

The early lenses, known as Geltact or Spofa, were made by spin-casting HEMA. They were successful in a country which had no hard lens industry but, when compared by foreign researchers with their own corneal lenses, were found to be difficult to fit and to give unsatisfactory vision. The material was of variable quality and the life span short. They nevertheless represent an important milestone in the history of contact lenses, for they provided the impetus to the rest of the world for the vast programmes of research and development undertaken since that time into new materials and lens forms. This has resulted in soft lenses being routinely fitted in practice as an acceptable form of



(a)



(b)

Figure 11.1 (*a*) Large diameter, high water content semi-scleral lens. (b) Corneal diameter soft lens

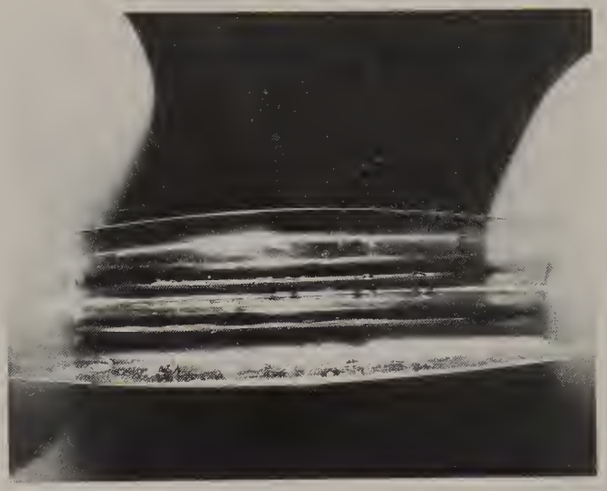


Figure 11.2 The elastic property of a low water content hydrophilic lens being stretched

visual correction and, indeed, due to their ease of fitting and good comfort characteristics, they are now the lenses of first choice for a high proportion of practitioners and patients.

The rights to the Czechoslovakian lens were acquired in 1965 by the American company National Patent Development Corporation who, in turn, during 1966, licensed Bausch & Lomb in the USA to continue its manufacture by the spin-casting process. At the same time, production of lenses was started in various other countries around the world by the more usual method of lathing or 'lathe-cutting' under the name of Hydron, as well as using the same HEMA material for many other applications such as biological implants. Bausch & Lomb spent 5 years on improving and developing all aspects of the spun-cast lenses, and eventually gained approval from the US Food and Drugs Administration (FDA) in March 1971.

In the mid-1960s a great many non-HEMA materials were investigated, together with the then new method of semi-scleral fitting. In the UK, Sauflon material was investigated from 1968, and fitted to patients in 1970, at about the same time as early Permalenses were first fitted (de Carle, 1972). Bionite was first prescribed in 1971; Hydron early in 1972; and the Bausch & Lomb Soflens in July of the same year. Since then there has been a huge proliferation of new materials and lenses, mostly HEMA based and for daily use. The majority of early high water content soft lenses, despite the recognition of their physiological advantages for problem-solving, did not gain widespread acceptance because of repeated difficulty with fragility, reproducibility and discoloration.

By the mid-1970s, when it was realized that the HEMA lenses then used could cause problems such as oedema, vascularization, arcuate staining and giant papillary conjunctivitis (GPC) – sometimes referred to as contact lens-induced papillary conjunctivitis (CLIPC) – soft lenses evolved into smaller and thinner designs of the same low water content material because by then high water content lenses had proved to have predictable problems. Indeed, 'thin' HEMA maintained its almost universal position and continued to work very well for daily use despite the introduction of medium to high water content lenses, such as Hydrocurve II and Duragel, with such descriptions as 'extended wear capability'. Since the mid 1980s a whole new generation of high water content materials has appeared from many of the major laboratories. These include, among others, B&L 70, Excelens, Lunelle, Omniflex and Permaflex. Most of the new lenses have significant advantages and can also claim suitability for extended wear to a greater or lesser degree. Nevertheless, they are not without problems (see p. 364) and this has created the need for frequent replacement and disposable lenses. With the advantages of large scale moulded production the first truly disposable lens (Danalens) was introduced in Denmark in the early 1980s. The rights were sold to Johnson & Johnson

Table 11.1 Properties of currently available soft lenses*

Lens	*Laboratory*	*Polymer*	*Water content (%)*	*Dk*	*T °C*	t *(–3.00)*	*Fit*	*Manufacture*	*Mode of wear*
U3/U4	Bausch & Lomb	HEMA (Polymacon)	38.6	8.5	21	0.07	One fit/2 TD	Spun-cast	D
O3/O4		HEMA (Polymacon)	38.6	8.5	21	0.035	One fit/2 TD	Spun-cast	D
Optima 38 and SP		HEMA	38.6	8.5	21	0.06	2 BOZR/SD	Spun-cast & lathed	D
B&L 70		Lidofilcon A	70	31.6	35	0.14	3 BOZR/SD	Lathed	D
Medalist 66		Alphafilcon A	66	27	35	0.11	One fit	Cast-moulded	D monthly disposable
Proclear	Biocompatibles		60	40		0.07	MBOZR/MD	Lathed	D+
Hydrofit 38	Cantor & Silver	HEMA	38	8.5	21		MBOZR/MD	Lathed	D
Hydrofit HP55		Filcon 4a	55	17	21	0.09	MBOZR/MD	Lathed	D+
Hydrofit 74		Filcon 4a	74	33	21	0.12	MBOZR/MD	Lathed	D/EW
Focus 60		Filcon 4a	58	21	21		2 BOZR/SD	Lathed	D+
Weicon 38E	CIBA Vision	Tefilcon 1a	37.5	8.5	21	0.09	2 BOZR/3 TD	Lathed	D
Weicon CE		Filcon 2a	60	28	35	0.09	2 BOZR/3 TD		Flexi-wear
Cibasoft		Tefilcon 1a	38	8.5	21	0.07	3 BOZR/SD	Lathed & moulded	D
Excelens visitint		Atalfilcon A	64	27	35	0.12	3 BOZR/SD	Cast-moulded	D/EW
Focus visitint		Filcon 4a	55	20		0.10	2 BOZR/SD	Cast-moulded	D monthly disposable
Scanlens 75		Filcon 4a	71	36	35	0.12	MBOZR/2 TD	Lathed	D/EW
ST09	David Thomas	Filcon 1a	38	9.5	21	0.09	MBOZR/SD	Lathed	D
Ultima		Filcon 1a	38	9.5	21	0.08	One fit	Moulded	D
Lunelle ES 70	Essilor	Filcon 4a	70	35	25	0.20	2 TD 3/5 BOZR	Lathed	D/EW
Hoya Soft T40	Hoya	HEMA	38	10.5	35	0.10	MBOZR/2 TD		D
Hydron Z6	Hydron	Filcon 1a	38	11	35	0.06	3 BOZR/SD	Lathed	D
Hydron Mini		Filcon 1a	38	11	35	0.12	MBOZR/small TD	Lathed	D
Sofblue Z4		Filcon 1a	38	11	35	0.04	One fit	Cast-moulded	D+
Omniflex		Lidofilcon 4a	70	32	35	0.12	2 BOZR/SD	Lathed	D/EW monthly disposable
Igel CD	Igel	Filcon 1a	38	13	35	0.07	MBOZR/SD	Lathed	D
Igel 77		Filcon 4a	77	53	35	0.15	MBOZR/MD	Lathed	D/EW
EV38	Nissel	Filcon 1a	38	11	35	0.10	BOZR/SD	Lathed	D
Incanto		Filcon 3a	78	64	35	0.12	MBOZR/SD	Moulded	D/EW
Acuvue	Vistakon	Filcon 1b	58	28	35	0.07	3 BOZR/SD	Wet moulding	D/EW daily/1/2 weekly disposable
Surevue		Filcon 1b	58	28	35	0.10	2 BOZR/SD	Wet-moulded	D monthly disposable
Classic	Wesley-Jessen	Tetrafilcon A	42.5	13	35	0.06	3 BOZR/SD	Moulded & lathed	D+
CSI		Crofilcon A	38.5	12	35	0.06	MBOZR/SD	Lathed	D
Permaflex 74		Surfilcon A	74	43	35	0.14	One fit	Cast-moulded	D/EW
Hydrocurve II		Bufilcon A	55	22	35	0.05	2 BOZR/2 TD	Lathed	D/EW
Permalens		Perfilcon A	71	43	35	0.22	MBOZR/2	Lathed	EW
Precision UV		Vaserfilcon 1a	74	43	35	0.14	One fit	Cast-moulded with UV block	D/EW monthly disposable
Hydroflex SD	Zeiss (Wöhlk)	Filcon 1a	38	8.1	20	0.08	MBOZR/MD	Lathed	D
Geaflex		Filcon 4a	70	43	35	0.24	MBOZR/SD	Lathed	D/EW
Hydroflex Mini		Filcon 1a	38	8.1	20	0.10	MBOZR/MD	Lathed	D
Silflex		Filcon 5	0	200		0.15	MBOZR/MD		D/EW
Weflex 55		Filcon 4a	55	23	21	0.16	MBOZR/2 TD	Lathed	D
W50D		Filcon 4a	50	23	20	0.16	2 BOZR/SD	Lathed	D

*This table represents a selection of lenses currently available. Inclusion in this list is not intended as endorsement nor exclusion as criticism of any particular contact lens product.
For material classification, *see* Chapters 3 and 21.
Dk = oxygen permeability: $\times 10^{-11}$ (cm ml O_2)/(cm^2s mmHg).
SD, Single total diameter; MD, multiple total diameter; BOZR, Back optic zone radius; BOZD, back optic zone diameter; MBOZR, multiple BOZR; D, daily wear; EW, extended wear; D+, daily plus.

who refined the process before introducing the Acuvue lens in 1988.

The new lenses and materials have been accompanied by the development of such allied technologies as lens disinfection, storage and cleaning, while many of the earlier lens forms have already disappeared because of their unsatisfactory clinical performance.

Table 11.1 provides brief details for many lenses available. This list is by no means exhaustive but it illustrates the range of polymers, water contents, oxygen

permeability (Dk) values and fitting methods currently in use (*see also* Efron *et al.*, 1994). These are continually being supplemented by the arrival of new lens forms (*see also Table 3.2*).

Permeability, transmissibility and equivalent oxygen performance

Oxygen permeability is an inherent property of a material and is independent of thickness. It is frequently expressed as the Dk value where D represents the diffusion coefficient and k the solubility of oxygen (Fatt, 1977). The oxygen tension at the lens–cornea interface is less than that at the front surface of the lens, the drop in oxygen tension being a function of the oxygen permeability for that material. There is a further relationship between oxygen flow and lens thickness (Larke and Sabell, 1971; Fatt, 1977), so that the transmissibility for a particular lens is thickness-related and given by the expression Dk/t, where t refers to the thickness. Strictly speaking the oxygen permeability of a soft lens is solely dependent on the water content but it is easier to use the term Dk as lenses can then be compared. Lenses are, however, being developed that will have an inherent Dk prior to hydration.

The normal values for oxygen tension at the corneal surface are 155 mmHg (20.9%) and 55 mmHg (7.7%), respectively, for open- and closed-eye conditions (Fatt and Bieber, 1968; Benjamin, 1982) and it is to this latter figure that many considerations for long-term corneal health are related.

Equivalent oxygen performance (EOP) means that the cornea responds as if it were in an atmosphere containing a particular percentage of oxygen (Hill, 1977). *Figure 11.3a* shows the relationship between equivalent oxygen performance and lens thickness for a variety of contact lens materials (*see also* Chapter 15). *Figure 11.3b* shows the relationship deduced by Loshaek and Hill (1977) between EOP and oxygen permeability over a range of lens thicknesses†. The correlation between EOP and Dk was further explored by Fatt and Chaston (1982).

Holden and Mertz (1984) showed that the mean oxygen requirement necessary to avoid oedema on a daily wear basis is an EOP of 10%, but with individual variations from only 4% to atmospheric 21%. This would suggest that only lenses which have a Dk/t of 24×10^{-9} (cm ml O_2)/(sec ml mmHg) are suitable for long-term corneal health in daily wear for the majority of wearers. This criterion is met by a number of currently available lenses (*see Table 15.1*), specifically standard thickness high water content lenses (e.g. Permaflex), ultrathin mid-water lenses (e.g. Acuvue), hyperthin HEMA (e.g. B&L O4) and Proclear.

Under closed eye conditions the Dk/t requirement is three times this value at approximately 75×10^{-9} (cm ml O_2)/(sec ml mmHg). Since existing hydrogel lenses do not meet this criterion for extended wear, a level of oxygen supply which allows the cornea to retain normal daytime thickness following overnight wear of 34×10^{-9} (cm ml O_2)/(sec ml mmHg) has been suggested (Holden *et al.*, 1984). Most commercially available hydrogel lenses are unable to meet this requirement hence long-term hypoxic

† The CD-ROM available with this book allows calculations of Dk/t and EOP to be carried out for specific materials.

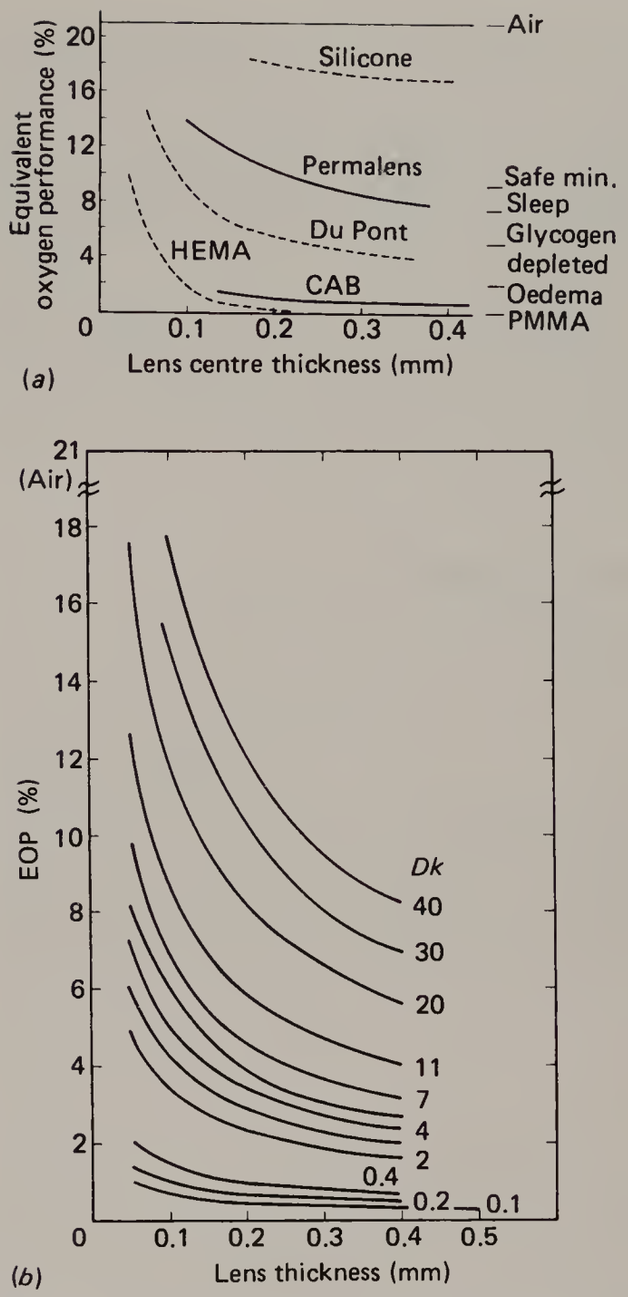


Figure 11.3 (*a*) A comparison of the equivalent oxygen performances of several general classes of rigid and soft contact lens material. Performances vary within a given class depending on differences in the particular material and lens fabrication techniques used by each manufacturing laboratory. No account has been taken of any mechanical 'pump' effect under the lens. (By 'equivalent oxygen performance' is meant that the cornea responds as if it were in an atmosphere containing that particular percentage of oxygen; after Hill, R. M., 1977.) (*b*) The calculated curves of equivalent oxygen performance (EOP) responses anticipated for materials with various permeability constants (Dk) measured at 23 °C in units $\times 10^{-11}$ (cm ml O_2)/(cm^2 s mmHg), over the range of lens thicknesses shown. (After Loshaek and Hill, 1977)

changes are induced with hydrogel extended wear (Bruce and Brennan, 1990) (*see also* Chapter 15). Oedema, of course, is not only caused by anoxia, but may also be regarded as the cornea's response to a variety of disturbances. One of the most significant of these is osmotic imbalance which can cause epithelial oedema by the flow of water across the tears/cell membrane barrier (Hill and Uniacke, 1969). In addition, Hill and Terry (1978) have described the diurnal variations in the tears and concluded that some patients are naturally so near their oedema threshold that they cannot be successfully managed as contact lens patients. Mandell (1975a and b) pointed out that there are many substances in the tears necessary for corneal health, and Hamano *et al.* (1980) advocated that, over a long period, the exchange of tears is as important as oxygen supply.

Methods of soft lens manufacture

Lenses may be manufactured by moulding, spin-casting or lathing.

Moulding and spin-casting are ideal for mass production of lenses. The Bausch & Lomb Soflens, following the principle of the original Czechoslovakian production method, is manufactured by the spin-casting process. Now that the original patents have expired, other laboratories are also employing this method. Certain lenses, such as the Bausch & Lomb Optima, are hybrid in character, being lathe-cut after initial spin-casting. Other lenses, such as the Wesley-Jessen Permaflex, are produced by the cast-moulding method. The Vistakon Acuvue lens is a modification of this technique and is wet-moulded. Silicone rubber lenses, on the other hand, are compression moulded in the same way as some rigid lenses. The majority of laboratories, however, still manufacture by lathing. This technique is ideally suited to the production of individual lenses and specialized designs but, with modern automatic lathes, it is also successfully used for mass production. Clinically, the different flexibility and surface characteristics of a spun-cast or moulded lens mean that it may centre less well than the equivalent lathe-cut lens, even if manufactured to the identical specification (Burgess *et al.*, 1985, *see Figure 11.19*).

Advantages of soft contact lenses

There are numerous advantages which soft lenses of all types possess in common.

Greater comfort

Hydrophilic lenses are, in nearly all cases, significantly more comfortable than RGP lenses; patients frequently stating that they can scarcely feel the presence of the lens even from the first moment of insertion. With all types of contact lens, there are two different adaptation processes involved. The first is that of the lids to the sensation caused by the presence of a foreign body on the eye; the second is that of the cornea to changes in its normal metabolism. It is the reduction, or even complete absence, of lid sensation which allows a hydrophilic lens to be almost immediately comfortable. The softness of the lens material contributes to this initial comfort, but just as important is the hydrophilic nature of the lens surface. The lid is in contact with a smooth, moist surface which gives a very similar sensation to that of the cornea itself. Soft lenses of smaller than corneal size tend to be unstable in fitting and in order to reduce edge awareness and excessive movement, lenses are now more commonly fitted slightly larger than the cornea diameter (13.50–14.50 mm).

The earlier differentiation between corneal size and larger 'semi-scleral' lenses is now less often made because the smaller diameter lenses are used so rarely and also because of the greater overlap between the various fitting methods (*see* pp. 381–384).

Stability, currently achieved through larger total diameters, is also an important requirement for comfort. On initial insertion there is no differential sensation of the lid making and breaking contact with the edge of the lens. Manufacturing considerations are also important, and the lens edge must be thin and well formed.

Ease of adaptation

Soft lens wearers are normally able to adapt to their lenses within a very few days. This is due to the physical and chemical properties of the hydrogel material, and absence of lid sensation, so there is no disincentive to proper blinking. As most soft lenses now drape as opposed to bridging the peripheral cornea, a tear pump mechanism is less significant than in older, thicker soft lens designs.

However, some tears exchange and tears mixing must occur. The cornea thus receives an adequate supply of oxygen with a minimum of disturbance to its normal metabolism.

Normal head posture and facial expression

Abnormal head posture and unnatural facial expressions are commonly seen with rigid lens wearers in the early stages of adaptation. Because of the initial comfort, soft lens wearers generally look perfectly natural from the beginning of their wearing schedule.

Longer wearing time

Hydrophilic lenses can frequently be worn for longer periods of time than corneal lenses. This is especially true of those patients who have achieved only limited success due to discomfort of rigid lenses.

Lower incidence of corneal oedema

Although corneal oedema is not usually a problem with RGP wearers, it is even less frequent with soft lenses and, if

present, it is usually only of a mild degree, detectable by the presence of vertical lines (striae) in the posterior stroma.

Rare occurrence of the 'over-wear syndrome'

Acute epithelia necrosis (often referred to as 'over-wear syndrome') is rarely seen in RGP lens wearers but is very uncommon in patients who wear modern soft lenses for excessively long periods. Moderate stinging and burning with conjunctival injection may be encountered, but this usually disappears rapidly when the lenses are removed (*see* Disadvantages *below*). Over-wear is normally self-limiting with soft lenses, because discomfort usually occurs before they have caused any severe epithelial damage (*see* Disadvantages *below*)

Absence of spectacle blur

It is uncommon for spectacle blur to occur with either hydrophilic or modern RGP lenses because, under normal circumstances, they do not produce significant changes in central corneal curvature. In soft lens wear, if oedema is present the increase in corneal thickness is uniform and extends from limbus to limbus.

There is little or no localized change in radius or physical distortion of corneal curvature such as can occur with low Dk or poorly fitted RGP lenses. Even when small changes of corneal curvature do occur, these are of a transient nature (Hill, 1975, 1976a).

The absence of noticeable spectacle blur means that patients can change from soft lenses to spectacles whenever they wish, and the long-term management of their spectacle refraction is straightforward. This can be undertaken at any convenient time, without requiring lenses to be removed for any length of time (*see* Chapter 18).

Maintenance of corneal sensitivity

The reduced oxygen availability leading to loss of corneal sensitivity caused by PMMA lens wear is almost a thing of the past. With soft lenses there is only minimal loss of sensitivity; wearing of hard lenses can cause a temporary but significant loss of corneal sensitivity, although the current range of high Dk rigid lenses now also retain corneal sensitivity (Millodot, 1971, 1974, 1976; Douthwaite and Connolly, 1986 (*see also* Chapter 2).

Lower incidence of corneal staining

Because hydrophilic lenses are soft, large and stable, corneal insult of the sort inherent in the use of rigid lenses is not commonly encountered. However, soft lenses can give rise to corneal staining (*see* p. 371).

Occasional wear

The ease of adaptation and the absence of spectacle blur mean that soft lenses are ideal for patients who wish to wear contact lenses irregularly for sporting or social occasions. Daily disposable lenses are especially suitable for this.

Absence of photophobia and lacrimation

The typically adaptive photophobia and lacrimation found with rigid lenses is almost invariably absent with hydrophilic lenses.

Lower incidence of flare

Because of their large optic zone diameter, patients rarely complain of flare or peripheral reflections when wearing soft lenses.

Less difficulty with dust and foreign bodies

Because the lenses cover the cornea, they effectively protect the eye against dust and wind. Except on insertion (for it is quite easy to inadvertently place a lens on the eye with a speck of dust underneath) patients wearing soft lenses are rarely troubled by foreign bodies.

Lower risk of loss

Well-fitting soft lenses do not generally fall out except in cases of extreme dehydration. They are not easily ejected from the eye by rubbing or lid tension and are not normally dislodged on to the sclera. The excellent stability and initial comfort of soft lenses has made them a first choice lens for many sporting activities.

Therapeutic uses

Hydrophilic lenses have proved effective in treating or relieving several pathological conditions, their main role being to protect the anterior segment (Astin, 1991). These include bullous keratopathy, corneal burns and sterile indolent ulcers. Apart from their use as a corneal bandage, they can also be employed as a drug release mechanism (Hillman, 1976; *see also* Chapter 20.7).

The successful re-fitting of rigid lens failures

A major advantage of soft lenses is that it is now possible to re-fit many patients who have previously failed with rigid lenses. The instant comfort of soft lenses by comparison with the earlier discomfort of rigid lenses proves a reassuring factor in the decision of many patients to recommence contact lens wear.

Disadvantages of soft contact lenses

Despite their many advantages, soft lenses have several drawbacks. Although the use of diposable lenses has overcome some of these, any potential drawbacks should be carefully evaluated for each patient.

Distance vision

Visual acuity is often not as good as that obtained with rigid lenses. Even if Snellen acuity is found to be the same, a difference in subjective quality of vision may be encountered which can only be measured at low contrast sensitivity. Poor vision generally relates to uncorrected astigmatism, but may also result from limitations imposed by lens geometry or the inherently more variable nature of soft lens acuity.

Conventional soft lenses have been described as producing images of a different quality (Ho and Bilton, 1986) when compared with spectacles or hard lenses. The materials are softer than the cornea and so are more readily deformed by eyelid pressure.

Near vision

It is quite common for patients to complain of poor near vision, while distance acuity is satisfactory (see p. 369).

Variable vision

Visual acuity can vary with hydrophilic lenses as a result of fluctuations with blinking and in the tear film. Also environmental factors may affect the level of hydration and fitting characteristics (*see* p. 365).

Breakage and tearing

Soft lenses can suffer from tearing, breakage and edge nicks. In conventional lens fitting, the frequency of replacement depends on the tensile strength and water content of the lens, as well as the handling ability of the patient.

Lens ageing and surface degradation

Hydrophilic lenses deteriorate with age. They discolour and the surfaces become deposited with mucoprotein, calcium and lipids. Lenses eventually become uncomfortable, their fitting characteristics alter, and visual acuity may be reduced, particularly at low contrast sensitivity.

Lenses showing surface deposits and scratches are shown in *Figure 11.4*.

Difficulty of cleaning

The various cleaning processes which have been introduced must be applied by the patient with painstaking regularity if they are to be effective. They are frequently expensive and time-consuming.

The need for lens disinfection

Hydrophilic lenses must be cleaned and disinfected daily to avoid the risk of contamination by microorganisms. Hydrogen peroxide, chlorine disinfection and the newer preservative systems have become most popular, whilst traditional heat and earlier chemical systems are declining in use. However, all systems have been criticized for patient non-compliance which continues to be a major source of problems in soft lens wear (*see* Chapter 4).

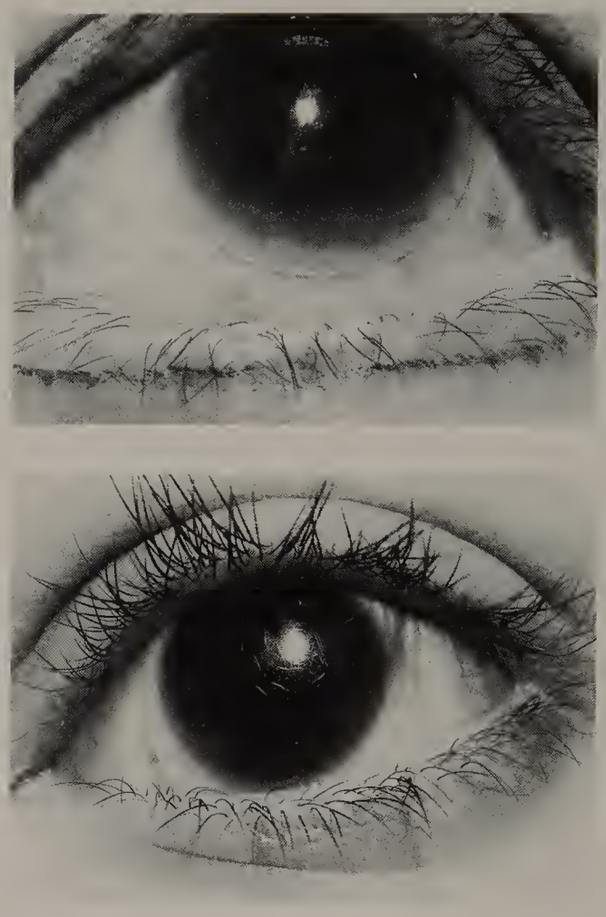


Figure 11.4 (*a*) An old worn lens exhibiting surface deposits and discoloration. (*b*) Surface scratching of an old, loosely fitting, low water content soft lens

Unknown but limited life span

It is not possible to predict with certainty the life span of any given soft lens, but it is almost invariably less than that of a rigid lens. High water content lenses, in particular, last only a few months (Haig-Brown, 1985; Jones, 1994). The modern approach of planned replacement and disposable lenses has done much to overcome these problems.

The inability to modify soft lenses

It is not feasible to modify either the power or the fitting parameters of soft lenses. If the patient's refractive error should alter, it is necessary to supply a new lens. The limited modifications possible are discussed in Chapter 22.

Difficulty of lens checking and verification

Methods for checking and verifying soft lenses are not as straightforward for speedy use in the consulting room as those for rigid lenses. In addition, such factors as temperature and storage solution must be taken into account. Chapter 13 covers these aspects in detail.

Vascularization and other complications

Long-term wear of hydrophilic lenses has produced a number of hypoxic, mechanical and/or allergic complications. Corneal vascularization (*see Figure 11.36*) has been observed averaging up to 0.47 mm penetration into the cornea in a group of daily wear soft lens wearers (Efron, 1987), but only 0.22 mm in a comparable group of rigid lens wearers. Allergic and mechanical complications include enlarged papillae of the upper palpebral conjunctiva, contact lens-induced papillary conjunctivitis (CLIPC), possibly even reaching the severest grade (GPC) (*see* Chapter 18). Other conditions can also develop, such as general conjunctival injection, stromal and endothelial disturbances of the cornea with rare cases of apparent endothelial detachment and nummular keratitis (Allansmith *et al.*, 1977; Mackie, 1977).

Chemical contamination

It is possible for hydrophilic lenses to absorb chemicals into their naturally porous structure, for example if worn in a polluted environment or used for swimming in chlorinated water. Chemicals may be retained and become a future source of ocular irritation. It is also advisable to avoid eye drops not specifically formulated for use while wearing soft lenses. Even with those so formulated, care must be taken that there is no allergic reaction to the preservatives used.

Cost factors

Apart from the initial fitting fees, there is an increased ongoing cost of solutions if soft lenses are to be correctly cleaned and disinfected throughout their life span.

Patient selection for soft lenses

With so many advantages and disadvantages, careful discussion is required with patients at the first consultation to determine their full history and discover their reasons for wanting to wear contact lenses. These aspects are fully covered in Chapters 8 and 9.

Generally, if patients have not already tried contact lenses and are willing to persevere with the normal range of adaptive symptoms, rigid gas permeable lenses may well be the first choice. If patients have already failed with a rigid lens, or their tolerance looks unpromising at the initial consultation, then soft lenses should be tried. There are many instances where a soft lens is the obvious choice with which to commence fitting. The various factors in evaluating this decision of rigid or soft may be considered briefly under the headings of ocular factors and other factors, but it should always be remembered that any influence which tends to cause or exacerbate dry eyes is more likely to contraindicate specifically the use of soft lenses.

Ocular factors

Considerations here are the type and degree of astigmatism, the standard of vision likely to be obtained with a soft lens and the standard of vision actually required by the patient. There is little point in insisting that patients should obtain 6/5 acuity with a rigid lens, when 6/9+ with an immediately comfortable soft lens is adequate for their needs. Corneal and lid sensitivity, accounting for the majority of rigid lens failures, are equally important factors. A soft lens may prove the answer where a rigid corneal lens gives flare, and where increasing the total diameter causes oedema which cannot be resolved by improvements to the fit or even by the use of a higher Dk material.

Hydrophilic lenses should be considered for patients who may be unhappy with rigid lenses because of the relative thickness and weight, which in turn gives rise to excessive lens mobility on blinking. Pupil size is not as important because the flare from rigid lenses is nearly always avoided with the larger optic zone diameter of a soft lens. Patients with awkward anatomical features for corneal lenses, such as proptosed eyes, a low lower lid position or a decentred corneal apex, may prove more successful with a hydrophilic lens.

The presence of any abnormal ocular condition may well be a contraindication.

Other factors

It is essential to determine from patients the reasons for wanting contact lenses, and the regularity of the wearing schedule which they intend to adopt. The irregular or intermittent wearer is better suited to soft lenses, particularly if sporting requirements demand a stable fitting. Economic factors must be taken into account, not only the fees for initial fitting, but also the long-term costs of future lens replacements, accessory solutions and cleaning agents.

Solution availability must be considered as well as geographical location and working environment; whether they are hot or cold, humid or dry, dusty or clean, and whether they are likely to contain noxious fumes or chemicals.

The prolonged use of computer screens in centrally-heated or air-conditioned offices particularly causes dryness and poor blinking which may contraindicate the use of soft lenses (Gasson, 1983).

Airline crews have noted difficulty in the low humidity and pressurized atmosphere of aircraft cabins. Typically, cabin pressures are stabilized at 8,000/10,000 ft which, together with low humidity, will affect both hydration and

EOP performance. Arias (1968, 1973) reviewed problems encountered at high altitude. It is not surprising that difficulties occur, since Hill (1976b) showed that, in Mexico City, the percentage of oxygen in the atmosphere is only 16% compared to 21% at sea level. On the summit of Mount Everest it is only 7%. Clarke (1976) reported the successful use of Permalenses at up to 24,000 feet, some 5,000 feet below the summit. Efron *et al.* (1986), in a study with high water content lenses, found a reduction in EOP levels, through the lens, of as much as 30% in low humidity. Surprisingly, in hot and dry climates soft lenses still tend to be more popular. Sweeney *et al.* (1991) found that in Australia 83% of contact lenses fitted were hydrophilic.

Psychological factors should be considered for those patients who need the sense of security of a stable fitting lens which is almost impossible to dislodge from the eye by accident, or for those who are temperamentally unsuited to undergo the slower or more difficult adaptation process required by rigid gas permeable lenses. Many patients having experienced successful wear of both rigid and soft lenses will still prefer the advantages offered by soft lenses (Johnson and Schnider, 1991).

Visual considerations

The refractive result obtained with soft lenses, as opposed to rigid lenses or spectacles, is neither fixed nor absolute. It may be of extreme variability, changing from moment to moment, or from day to day, depending on external environment and lens fitting and performance.

The visual standard is a subjective interpretation by the patient, and does not necessarily correlate with the Snellen acuity on the letter chart. As long ago as 1975, Applegate and Massof found marked changes in contrast sensitivity although the visual acuity remained the same, stressing that acuity is only one aspect of visual performance. Similar conclusions were reached by Rosenblum and Leach (1975) with Bausch & Lomb Soflens patients.

Guillon *et al.* (1983) confirmed that, with larger groups of patients, contrast sensitivity is able to pinpoint the exact nature of any reduction in visual performance and whether this occurs for distance or near, or for high or low spatial frequencies. They found specifically that soft lenses showed a poorer performance for high frequencies at near, and that both soft and RGP lenses showed a decrease in contrast sensitivity for mid-frequencies under high illumination.

The defining of visual acuity therefore represents a problem, because the quality of vision is just as important as the precise number of lines read on the test chart. In some circumstances, a good 6/9 may be more acceptable than a poor 6/6, so that Snellen acuity is not always a reliable guide to a patient's potential visual success with soft lenses. Practitioners are obliged to place more than usual reliance on patients' subjective impression of whether vision is good enough for their needs, although by evaluating low contrast acuity in addition to standard contrast acuity (e.g. on a Baillie–Lovie chart) more accurate information can be obtained. This is especially true of near vision, and this factor must always be considered in relation to the patient's work and visual requirements. Variations of vision with hydrophilic lenses can be due to several different causes, as follows.

Environmental factors

The power of a lens depends upon its basic lens dimensions of back and front optic zone radii, thickness, refractive index and total diameter, which can all vary with environmental factors. These include such ocular effects as temperature and the pH, tonicity and volume of the tears. Some of these are, in turn, influenced by external factors such as ambient temperature, humidity, atmospheric pressure or the state of the lens when placed on the eye.

Generally, lenses manufactured from HEMA-based polymers undergo smaller variations than those made from high water content materials as, for example, with the effect of temperature and humidity. In normal humidity (typically 45–90%) and temperature (14–24°C) ranges, the water content in all soft lenses is stable (Brennan *et al.*, 1988). However, in drier atmospheres, such as that experienced in an air conditioned office, a noticeable degree of dehydration occurs with mid and high water content lenses (Andrasko and Shoessler, 1980).

Tonicity was investigated by Poster and Skolnik (1974), who demonstrated a 1.6% decrease in size when a Bausch & Lomb Soflens was taken from distilled water and placed in isotonic saline solution. A further decrease of 2.8% occurred when the lens was transferred to hypertonic, 1.8% saline solution.

Harris and Mock (1974) were able to demonstrate changes in both power and light transmission according to the tonicity of lens storage solutions. Ford (1974) showed how the degree of lens hydration, and all of these other influences, can summate to give a significant error of power when a lens has fully settled on the cornea.

Another cause of power change is the effect of lens flexure. This has been argued for all types of lenses, whatever the size, and occurs when a flexible lens, fitted either flatter or steeper than *K*, bends to conform to the corneal curvature. Wichterle (1967) gave a mathematical analysis of this effect and, in 1967, Vincent (Blackstone, 1968) reported that in practice the original Czechoslovakian lenses increased their effective negative power when allowed to steepen. Sarver *et al.* (1974) described how a thin corneal-sized soft lens with back and front surface radii of 8.00 mm and 8.50 mm, respectively, increased its power from –3.25 D to –4.00 D when allowed to steepen by 1.00 mm, and proposed the term 'supplemental power effect'. This represents the total change in power, due first to lens flexure and secondly to a liquid lens if the posterior surface of the contact lens fails to conform to the front surface of the cornea. In practice, any supplemental power effect is likely to be created by a combination of these two causes, with the greater proportion resulting from flexure. In the case of a modern, 'thin', soft lens which completely

drapes over the cornea, it can be assumed that there is virtually no liquid lens power.

Strachan (1973) suggested that both positive and negative lenses increase their power on steepening in direct proportion to the degree of flexure and to the power of the original lens. A different mathematical analysis by Bennett (1976), assuming only that the volume of the lens remains constant, showed that refractive changes due to flexure are independent of power and invariably add negative power. This closely agrees with the earlier analysis of Wichterle, as well as with Sarver's clinical findings.

Refractive index

Another variable factor which can affect the power of a hydrophilic lens is refractive index (*see* Tables 5.6 and 5.7, Chapter 5 and Appendix B). Strachan (1973) evaluated a hypothetical case of a 60% water content lens, with a refractive index (n) of 1.52 in the dry state. When fully hydrated this lens becomes a mixture of 40% polymer (n = 1.52) and 60% water (n = 1.333) with a resultant refractive index of 1.40. If the lens is in a state of partial dehydration on the eye, the refractive index increases, with a consequent change of power. In Strachan's example, a –3.00 D lens becomes –3.12 D and –3.37 D, when the refractive index changes from 1.40 to 1.42 and 1.46 respectively, and conversely a +3.00 D lens alters its power to +3.18 D and +3.55 D respectively. Ford (1976) demonstrated a typical water loss of 8.79% when a 70% water content soft lens reached a state of equilibration on the eye, with the refractive index changing from 1.4300 to 1.4397.

When a soft lens is placed on a toroidal cornea, the final refractive result depends on the way in which the lens moulds itself to the corneal topography. If a thick soft lens partially dehydrates within the palpebral aperture, there can be an astigmatic power change due both to alteration in the refractive index and to the lens becoming less flexible meridionally. The resulting flexure also causes differential power changes. These effects tend to become very complicated, but they can sometimes partially neutralize corneal astigmatism, reducing it to a level suitable for spherical soft lens fitting.

Ageing effects

Changes in visual acuity also occur with time and use. Discoloured lenses, and those affected by mucoprotein or calcium deposits from the tears, are commonly seen (*Figure 11.5 and see Figure 18.19*). Such deposits and discoloration may sometimes cause a serious reduction in visual acuity, particularly at low contrast (Doane *et al.*, 1990). At the same time, older lenses have a greater tendency to dehydrate on the eye so that noticeable alterations in fitting characteristics are frequently observed. Apparent refractive changes of –0.50 D are quite common and marked differences have been shown in the light transmission curves between new and old lenses (Gasson, 1975).

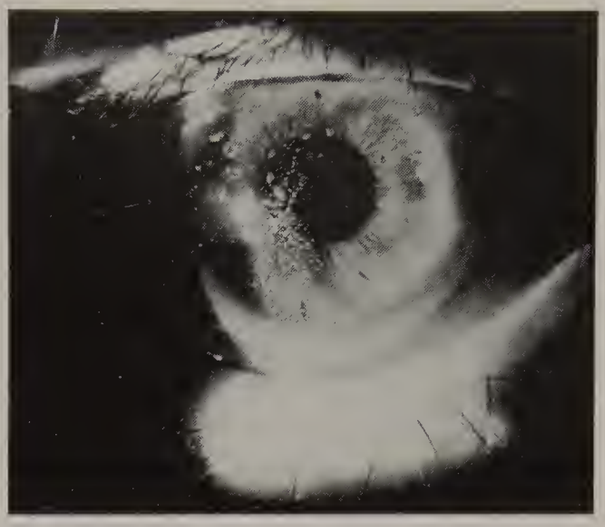


Figure 11.5 White spots (calcium) on a high water content soft lens (Courtesy of CLM)

Over-refractions

The various factors already mentioned (environment, flexure, degree of hydration, ageing and dimensional changes) all combine to give a refractive result at a particular time for a particular set of conditions. It cannot be assumed that this refraction will remain constant, and it does frequently change by small amounts. If, for example, a patient should move from indoors to outdoors, temperature and humidity will alter, and the lenses must reach a new state of equilibration on the eye. Usually no problems occur, although there may be complaints of visual fluctuation, especially in the early days of wear when the tear flow has still not returned to normal.

If the over-refractions are carefully monitored, these changes can be easily demonstrated. Also, cylinder power and axis can both vary widely and apparently at random and there appears to be no correlation with the K readings (Larke and Sabell, 1971). Gasson (1975) showed the same type of variation with a series of different lens types on the same eye, as well as with the same lens on the same eye examined on different occasions. More recent work (Guillon and Schock, 1991) showed that different manufacturing techniques can affect overall visual quality, with cast-moulded lenses outperforming spun-cast lenses.

Generally, lenses with a thickness of approximately 0.10–0.14 mm are likely to give the best visual result but thicker lenses should be avoided for physiological and cosmetic reasons, and ultrathin lenses of 0.07 mm or less often do not give as good a quality of vision on toroidal corneas. When a soft lens is placed on the eye, the spherical anterior surface may become an aspherical or irregular curve with different optical qualities. Such effects are not predictable, so that the prescription and quality of vision must be determined empirically by placing lenses on the cornea. Even if the same over-refraction and Snellen acuity can be demonstrated with quite different designs of lens, it may be only one type of fitting which gives an acceptable

visual result to the patient. Stability of vision is important, and a larger stable lens is often preferred by patients with corneal astigmatism. It can be demonstrated that the addition of a small cylinder, perhaps only 0.50 D, can give a significant improvement in acuity, eliminating ghosting and distortion. The typically small degree of residual astigmatism, which can be easily ignored by both patient and practitioner when prescribing rigid lenses, cannot always be so readily discounted with soft lenses. It is also found that the binocular visual acuity is frequently better and out of all proportion to the monocular results, so that R and L 6/9+, may well give 6/6+ binocularly. For this reason, essentially monocular patients may find their visual acuity less acceptable with soft lenses, particularly with toric or bifocal lenses where variations in vision are more common.

Corneal and residual astigmatism

Two basic assumptions should be made when assessing the potential success of astigmatic patients being fitted with spherical soft lenses.

1. Total ocular astigmatism = corneal astigmatism + lenticular astigmatism.
2. All corneal astigmatism is transferred through the lens to its anterior surface.

Patients may therefore be divided into the following four groups at their initial examination by reference to spectacle correction and keratometry (*K*) readings.

1. Spherical cornea with spherical refraction
Rx: –3.00 DS
K : 7.85 mm along 180° (43.00 D)
7.85 mm along 90° (43.00 D)

This is the ideal optical situation for contact lens fitting. Vision should be equally good with either rigid or soft lenses.

2. Spherical cornea with astigmatic refraction
Rx: –2.00/–1.75 × 90
K : 7.85 mm along 180° (43.00 D)
7.90 mm along 90° (42.75 D)

The astigmatism is almost entirely lenticular so that the visual result is the same with either a rigid or soft lens. In both cases, a front surface toric lens is required to correct the 1.50 D of residual astigmatism.

3. Astigmatic cornea with astigmatic refraction
Rx: –2.00/–1.75 × 180
K : 7.80 mm along 180° (43.25 D)
7.50 mm along 90° (45.00 D)

All of the astigmatism is corneal, so that a spherical rigid gas permeable lens, or a toric soft lens should be fitted.

4. Astigmatic cornea with spherical refraction
Rx: –3.00 DS
K : 7.80 mm along 180° (43.25 D)
7.50 mm along 90° (45.00 D)

In this last example, there is 1.75 D of with-the-rule corneal astigmatism together with an equivalent degree of against-the-rule lenticular astigmatism, to give a resultant spherical refraction. A spherical rigid lens form would leave a residual cylinder of –1.75 D × 90. A soft lens, *because* it transfers all of the corneal astigmatism through to its front surface without optically neutralizing it, is the lens of choice.

These theoretical considerations should be confirmed by clinical observation with a soft lens placed on the eye. The arbitrary figure of 1.00D ocular astigmatism is frequently given as the upper limit for which good visual acuity can be obtained with a spherical hydrophilic lens. In practice, this limit can be as low as 0.50D for patients who are critical observers, accustomed to good vision and required by their occupation to undertake exacting visual tasks. This intolerance to small, uncorrected astigmatism is also more likely where the minus cylinder is vertical or especially with an oblique axis. Conversely, satisfactory acuity has occasionally been obtained with spherical lenses, with cylinders as high as 4.00 D for less critical and strongly motivated patients. In these cases, the distance visual acuity is usually more acceptable than that for near. With such a high degree of astigmatism, however, success is unlikely and patients should not be unduly encouraged. Nevertheless, it may be worth trying a spherical soft lens, especially for patients who have failed with rigid lenses and where time and costs rule out toric fitting. Such a procedure, in any case, demonstrates to the patient the visual limitations of a spherical soft lens. In order to make a proper assessment, trial lenses should be as close as possible to the expected prescription. The most satisfactory vision is usually obtained for myopic patients with the least myopic focal line on the retina, rather than with the predicted best vision sphere. For example, with a spectacle Rx –3.50/–1.00× 180, the likely back vertex power (BVP) of soft lens is –3.50 DS. In borderline cases, plano-cylindrical spectacles can be worn for critical vision and driving, and cylinders may be incorporated into a normal presbyopic correction. However, the improvement in toric lens manufacture makes the fitting of astigmatic eyes relatively straightforward nowadays (*see* Chapter 14).

Near vision problems

When prescribing soft lenses, near vision should be carefully assessed as a separate function from distance acuity. As previously mentioned, patients who can wear soft lenses comfortably and see well for distance find their near vision completely unsatisfactory.

Clinical results show that the deciding factor for soft lens success or failure can be the quality of near vision, especially if it interferes with work or study. There are many

causes of near vision difficulty. Stone (1967), in an assessment of this problem with hard lenses, suggested four main reasons, as follows:

- Alteration in the accommodation–convergence relationship.
- Reduced size of palpebral aperture.
- Increased evaporation of tears.
- Alteration in corneal curvature during convergence.

From their very nature, the last two of these effects are likely to be of greater significance with hydrophilic lenses, but there are several other possible causes, any or all of which could produce problems.

- Borderline acuity for distance.
- Lid pressure, causing irregular buckling or flexure of the lens when the eyes are in the near vision position.
- Irregular astigmatism at near.
- Reduced blink rate, causing drying of the lens surface.
- Changes in scleral topography during convergence.
- A decentred lens.
- A poor fitting.

Visual advantages of soft lenses

Despite all the visual problems which can arise, the majority of patients do achieve a good and worthwhile standard of vision with soft lenses. Indeed, many claim that their quality of vision and field of view are better with soft lenses than with either rigid lenses or spectacles. The size and stability of fitting ensure that hydrophilic lenses have certain natural advantages over corneal lenses. There is a significant reduction in the incidence of flare and peripheral reflections, especially at night or in dim illumination when the pupils are enlarged. Patients adapting to soft lenses, which have relatively large optic zone diameters, rarely complain of the flare commonly observed with rigid lenses. For those with naturally large pupils and where corneal lenses cannot be made to give satisfactory centration, a hydrophilic lens may be the only means of eliminating intolerable visual disturbance. Many patients wearing RGP lenses of relatively small total diameter find the constantly altering vision, which is unstable after blinking, quite unacceptable. A soft lens with its limited vertical movement nearly always provides a satisfactory solution.

Water content and polymers (*see also* Chapter 3)

In this context the following definitions are used:

Percentage water content =

$$\frac{\text{Weight of fully hydrated lens} - \text{Weight of fully dehydrated lens}}{\text{Weight of fully hydrated lens}} \times 100\%$$

British Standards recommends that this should apply to lenses under equilibrium conditions with physiological (normal) saline solution at a temperature of 20 ± 0.5 °C.

Percentage water uptake =

$$\frac{\text{Weight of fully hydrated lens} - \text{Weight of fully dehydrated lens}}{\text{Weight of fully dehydrated lens}} \times 100\%$$

Thus, lenses with a water content of 38% have a water uptake of approximately 62%. Care must be exercised when interpreting brand names which include a numerical suffix, because these do not always accurately reflect the water content.

Classification

Ionic and non-ionic materials

Classification of soft lenses is based on both their water content and the ionic nature of the polymer. The majority of low water content soft lenses are fabricated from HEMA (38% water content), but high water content lenses are more commonly referred to as either ionic (Group IV) or non-ionic (Group II) (*see* below) depending on whether negatively charged components such as methacrylic acid have been used to increase the water content of the material. The addition of methacrylic acid in ionic high water content lenses (e.g. Acuvue) renders the lenses more surface active and these lenses are more prone to protein spoilation than their non-ionic counterparts (e.g. Omniflex, Lunelle ES70). This has led to recommendations of more frequent lens replacement of ionic high water content lenses (Bleshoy *et al.*, 1994) although Jones *et al.* (1997) have shown that Groups I and II non-ionic lenses attract more lipid deposits.

In the context of soft lens materials, the term 'filcon' is the generic term used for polymer names. In the USA the FDA classification of the various materials is based on the water content and ionic nature of the polymer (*see* Chapter 21 and *Tables 21.2* and *21.3*). The following is a summary of this grouping, which also applies in other parts of the world.

Group I: Low water content, non-ionic polymers, e.g. Crofilcon (C.S.I., 38.5%)

Group II: High water content, non-ionic polymers, e.g. Lidofilcon A (B&L 70, Omniflex)

Group III: Low water content, ionic polymers, e.g Bufilcon A (Durasoft 2)

Group IV: High water content, ionic polymers, e.g. Etafilcon A (Acuvue)

Lenses have been produced with water contents from 3 to 85%, with the wide range of polymers indicated in *Table 11.1*. Many of the lenses currently being used are still HEMA-based with water contents in the 35–45% region but the increase in use of mid-and high water content lenses (>50%) continues.

Low water content lenses have been predominantly fitted in the past because of their greater tensile strength and longer life span. They have the further advantage that they can be made thinner because of their smaller swell factor during hydration.

High water content soft lenses

High water content lenses have significant advantages as well as some disadvantages.

High Dk values

As previously mentioned, current soft materials do not truly have a Dk value – they allow transmission of oxygen to the cornea as a result of their water content. However, to simplify soft lens data this dissolved oxygen transmission is referred to as the Dk. New materials are being developed which have an intrinsic Dk value prior to hydration.

Most high water materials have Dk values between three and six times that of HEMA, although their greater thickness reduces the *Dk/t* to lower levels than this. The better oxygen permeability of these lenses means that they are suitable in this respect for almost all new patients. In addition, the lenses have two other obvious applications.

- For cases of early vascularization – although a rigid gas permeable or silicone rubber lens is more effective in allowing vessels to empty or recede.
- Cases of oedema with low water content materials, especially with hypermetropic patients (La Hood, 1991), where lens thickness is considerably greater.

Better comfort

Because these materials are much softer, often matching the water content of the cornea, there is frequently less lid sensation.

Longer wearing time

As a result of the first two advantages, patients often achieve a longer wearing time.

Faster adaptation

The majority of patients can build up their wearing time more rapidly with higher water content lenses.

Extended wear/prolonged wear

The ultimate example of this rapid adaptation is given by the true extended wear lenses where both all day and all night wear can be achieved from the beginning.

Easier to handle

Most high water content lenses are thicker than their low water content 'thin' counterparts, making particularly the lower negative powers easier to handle. The additional thickness of plus and very high minus lenses, however, can be a disadvantage in removal because of their reduced flexibility in these power ranges.

Better vision

For the same reason of increased thickness, some patients with moderate astigmatism (0.75 D to 1.25 D) may achieve a better visual result than with thinner, low water content lenses (Guillon *et al.*, 1993).

Better for intermittent wear

Longer periods of intermittent wear for social and sporting use are easier with high water content lenses.

Ease of fitting

Because some of these lenses have only one predominant fitting, lens selection is rapid and simple.

Tear film stability

Improved tear film stability has been shown on standard thickness high water content lenses when compared to thin low water content lenses (Guillon *et al.*, 1989). However, symptoms of dryness have been shown to be similar with both types of lens (Pritchard and Fonn, 1993).

Disadvantages of high water content lenses

Despite the foregoing, it is also necessary to consider a number of disadvantages.

Environmental sensitivity

High water content lenses are more sensitive to environmental factors. Chief among these are temperature and humidity, which may have a significant effect on dimensional stability, lens hydration and Dk value (Rocher, 1977).

Greater fragility

Although modern high water content lenses are far superior to many of the earlier examples of this type, breakage can still present a major problem.

White spots (calculi/jelly bumps)

White spots have previously been associated more with extended wear than with daily wear lenses. Some high water content materials seem particularly prone to this problem even when worn purely on a daily basis. Patients are less concerned whether the origin is lipid or calcium than with the fact that a new lens – often within a few weeks of fitting – has developed irreversible deposits and needs replacement.

The main factor appears to be dryness. The origin may be **ocular**, because of minimal tear flow, wide palpebral aperture or poor blinking; **environmental**, because of factors such as air conditioning or central heating; or **occupational**, for example with the use of visual display unit (VDU) screens (*see* p. 365).

In addition, within the same make of lens there often seem to be variations in material, because one lens may exhibit severe white spots (*see Figure 11.5*) within a very short time, while its successor may prove to be altogether free of this particular problem (*see* Chapters 3 and 4).

Discoloration

Many high water content lenses suffer from brown discoloration (*see Figure 18.19*). Indeed, many new lenses appear marginally discoloured on removal from their laboratory sealed vials. In addition, they seem more prone to pink or blue discoloration which possibly emanates either from disinfection solutions, melanin-induced by nicotine, metallic ions in the tear film or the use of systemic medicines (*see* Chapter 4).

Disinfection

Because discoloration is greatly exacerbated by heat disinfection, this is rarely the method of first choice with high water content lenses (except in children's lenses). In addition, because these highly absorptive materials are more likely to retain the chemical preservatives used in earlier disinfecting solutions, within their structure, there is an increased possibility of either stinging or a serious solutions reaction. The preferred methods, which may also conveniently bleach away some of the discoloration, are therefore peroxide, chlorine or high molecular weight preservative systems (*see below*, Disinfection of soft lenses, Chapter 4).

Poor reproducibility

Once again, modern lenses show a significant improvement over their historical counterparts. Nevertheless, problems with reproducibility are still encountered in practice, even with some of the moulded lenses.

Longer fitting time

It takes longer for high water content lenses to reach proper equilibration on the eye before the fitting can be reliably judged, and significant power changes can occur while settling. The fitting characteristics of these lenses, particularly where smaller diameters of 13.50 mm or less are used, mean that it is not always possible to achieve ideal centration and movement.

Dryness problems

The main problem with high water content lenses has been an increase in dryness-related symptoms. Patients with apparently normal tear flow may complain of discomfort and reduced wearing times, despite having previously worn standard thickness HEMA lenses without difficulty.

In some of these cases of failure, slit-lamp examination reveals no corneal insult, but the patients complain of varying degrees of dryness and discomfort. In many instances, however, there is very evident arcuate staining. This proves more common towards the upper limbus, but also occurs in various other midperipheral areas of the cornea (*see* Chapter 18). Some eyes produce the same type of stain in different regions of the cornea with a succession of different makes of lens, whereas others may only be affected by specific types.

It is particularly interesting that this sort of stain is very similar in appearance to that seen with old-fashioned, thick, 'semi-scleral' lenses made from HEMA, and rarely observed since the use of 'thin' HEMA lenses. Its reappearance with modern high water content lenses, which are frequently fitted in a 'semi-scleral' fashion, suggests a strong correlation with their relatively greater thickness and fitting technique. The staining now, as then, seems to be due to a combination of indirect mechanical pressure from the upper lid (Young and Mirejovski, 1993) through the portion of the lens near its lenticular junction, and increased dehydration of the material on the eye (*see also* Chapter 15).

Dehydration of soft lenses

One of the major reasons for the clinical success or failure of a particular lens on the eye relates to its dehydration characteristics. The literature on this complex subject is sometimes contradictory and is not always consistent with actual clinical experience.

Dehydration of a lens on the eye causes a reduction in the effective Dk value, changes in lens parameters and, hence, fitting characteristics, increased deposition and generally reduced comfort. In addition, with all soft lenses the pre-lens tear film non-invasive break-up time (PLTF NIBUT) is reduced during contact lens wear.

Frankland (1980) considered the water content contained within the polymer matrix to consist of 'bound' water, which is directly attached to the hydrophilic sites by van der Waals forces, and 'free' water, which is readily lost from the lens by evaporation. Notionally, the higher the 'bound' water, the less any particular material will dehydrate on the eye and cause clinical problems.

The lower limitation on lens thickness with high water content lenses is dictated in part by the higher tendency for these materials to lose water. Orsborn and Zantos (1988) showed that a critical thickness exists for each high water content material, below which dehydration of the lens can cause corneal desiccation. High water content lenses (> 60%) all tend to be designed in standard thickness to limit corneal drying.

Andrasko and Schoessler (1980) described how the amount and speed of evaporation depend upon ocular

factors, such as volume and quality of tears, blink habits, osmolarity and palpebral aperture, and environmental factors which include temperature, relative humidity and wind velocity. Young and Mandell (1983) stressed that the success of a contact lens for extended wear depends upon the transport of water molecules through the material and that water loss is proportional to water content. This relationship was quantified for certain conditions by Kohler and Flanagan (1985) who proposed that dehydration can increase by approximately 1% for each 4% increase in water content. They also concluded that temperature is a highly significant factor in lens dehydration.

On a practical level, except when a lens is in its vial, it is rarely at its full, stated hydration level. Indeed, Wechsler *et al.* (1983) suggested that the main water loss occurs within the first 5 minutes on the eye. Andrasko (1983) found that high and low water content lenses lose, respectively, 14.8% and 10.4% after 30 minutes. Other investigators have quantified water loss for different materials and found that, under adverse environmental conditions of very low relative humidity, a lens might lose nearly 20% of its water content (Hill, 1982).

More specifically, Bilton and Guillon (1984) found that Permalenses took 30 minutes to equilibrate on the eye and lost 15% water to achieve a final water content of 56%. Standard and 'thin' HEMA lenses lost, respectively, 4% and 8%. They also proposed a water gradient across the thickness of the lens. Fatt and DiMartino (1985), however, concluded that both the front and the back surface of a lens on the eye maintain the same water content, and that the tear film beneath a soft lens contains only non-aqueous mucin and lipid components.

Bilton and Guillon (1984) also recognized the importance of the tear film and refer to J. P. Guillon's work in relation to different lens materials and thicknesses with normal eyes. Thick HEMA lenses give the most stable tear film. The prelens tear film for Permalens proves thin but stable, whereas those for Duragel and Sauflon are thin and unstable. Very thin HEMA lenses, such as the Bausch & Lomb 'O' series, have a thin aqueous tear film with no lipid content.

These last results are very much in accord with clinical experience, where drying problems are frequently encountered with very 'thin' HEMA, and such lenses are almost unwearable in hot, dry climates (Rocher 1977). They also explain why patients who are perfectly comfortable with HEMA lenses are sometimes unable to wear high water content lenses.

The rehydration characteristics of the lens should also be considered. Hill (1983) suggested that it can take nearly one hour for a lens to stabilize at a higher hydration level, when changing from an adverse to a favourable environment. Young and Mandell (1983) suggested that the ratio of water loss to gain is different for each lens and that, in some cases, the hydrated level on the eye is governed by evaporation but in others by rehydration.

Dry eyes

Soft lenses may be contraindicated for patients working in an unsuitably dry atmosphere or where there is a serious deficiency in tear flow. In the case of the marginally dry eye, it is necessary to evaluate whether it is likely to benefit from the greater volume of fluid contained within a lens of higher water content and which will remain greater than a lower water content material even after partial dehydration, or whether a lower water content lens will prove better because relatively reduced dehydration will cause less disturbance to an already minimal tear film.

In most cases, it seems preferable to avoid higher water content and thinner lenses in favour of lower water content and thicker lenses, although this could then compromise corneal physiology. The only lenses which do not require a good tear film are those made from flexible silicone rubber which have virtually no water content and can be successfully fitted for the clinically dry-eyed (Woodward, 1984; Astin, 1991).

Success with high water content lenses depends upon many factors. The lens must have a high enough water content to offer a worthwhile advantage over HEMA, but not so high that it will dehydrate too rapidly or too much on the eye. It must be fitted thick enough to maintain a stable tear film and take advantage of good vision, but not so thick that it can cause arcuate staining. It must be thin enough to be comfortable and give proper fitting characteristics, but not so thin that it will upset tear film stability or cause visual problems.

These factors explain why different makes of high water content lens give completely different clinical results and why sometimes they may all perform significantly worse than HEMA. There is no certain way of predicting how well a particular lens will perform on a particular eye even with a normal tear film, until it has been worn by the patient in his or her normal environment.

Lens thickness and 'thin' lenses

Originally, the centre thickness for corneal diameter HEMA lenses of power –3.00 D was in the region of 0.10–0.15 mm. Before the advent of daily wear, high water content lenses, the only method of increasing oxygenation to the cornea was to decrease the centre thickness below 0.10 mm. Lenses of less than 0.10 mm centre thickness became known as 'ultrathin' and represent a very satisfactory way of increasing oxygen transmissibility (Dk/t) and improving physiological performance. Since then standard thickness designs have been mainly restricted to the higher water content.

On the basis of centre thickness, a reduction from 0.11 mm to 0.07 mm is likely to give an improvement in transmissibility of nearly 40% and an increase of about 60% in the estimated oxygen tension at the anterior surface of the cornea for a HEMA lens. Wilson *et al.* (1978) found a fourfold increase in the oxygen diffusion rate for a thin compared with standard thickness Hydrocurve lens.

It is important to remember that the oxygen performance for a lens cannot be judged solely in relation to its specified centre thickness but must be considered for the entire lens. Edwards (1986) analysed the zonal oxygen transmission (EOP) profiles for hyperthin HEMA lenses (i.e. centre thickness less than 0.05 mm) of various powers across the whole lens. These showed that over about –4.00 D the increased peripheral thickness would be unlikely to meet Holden's 10% criterion for oedema-free daily wear. Sammons (1980, 1981) showed the mathematical complexities of analysing the harmonic or mean lens thickness, and that taking an inappropriate average thickness could result in a 30% error in the predicted oxygen flux. Plus and aphakic lenses cannot truly be considered as 'thin' because of their necessarily greater centre thickness. Nevertheless, positive lenses such as the Hydron Z Plus and Hydroflex SD are significantly thinner than their standard counterparts and often resolve cases of oedema. However, to avoid long-term affects of hypoxia it has been suggested that low water content plus lenses should be avoided (La Hood, 1991).

A centre thickness of 0.05 mm or less is theoretically necessary to sustain extended wear in closed eye conditions with a 38% HEMA lens (Fatt, 1977). However, many patients have been known to sleep wearing lenses of even standard thickness for varying periods of time. In these cases ultra- and hyperthin lenses much more closely approach the theoretically required figure and possess an inherent safety factor. Theoretical considerations are well confirmed by good clinical results in practice (Haig-Brown, 1978; Solomon, 1978). Fanti and Vollmer (1979) found a much reduced increase in corneal thickness after 9 hours of wear of ultrathin lenses compared to that measured with standard thickness wear. The fitting characteristics of thin and standard lenses differ, even if otherwise they have the same specification. Generally, ultrathin lenses completely drape the cornea and may become immobile. The thickness of the lens may therefore be regarded as an additional fitting variable.

Advantages of thin soft lenses

- Lower incidence of corneal oedema because of the improved transmissibility.
- Reduced lid sensation because of the much thinner lens edge. This is especially beneficial for sensitive patients at their initial fitting.
- Reduced limbal irritation for the same reason and because lenses are fitted slightly larger.
- The different fitting characteristics often permit better centration compared with standard thickness lenses.
- They are easier to fit because their increased flexibility means that fewer fitting radii are necessary.
- They are safer should patients doze while wearing them.

These important factors mean that thin lenses are usually preferred to standard thickness lenses, but there are certain disadvantages, which should also be taken into account.

Disadvantages of thin soft lenses

- Handling is more difficult, particularly in the low minus power below –2.00 D.
- The breakage rate is somewhat greater than with standard thickness lenses, although not as much of a problem as that experienced with high water content soft lenses.
- The life span of thin lenses is shorter, particularly when heat disinfection is used. With current thinking towards more frequent replacements, this is not regarded as so much of a problem.
- For patients with toroidal corneas, visual acuity may be less satisfactory than with standard thickness lenses (*see* p. 368).
- Thin lenses have a greater tendency to dehydrate on the eye and may disturb the precorneal tear film (*see* p. 371).

Additional techniques in soft lens fitting

Certain techniques additional to those routinely used with rigid lenses may be helpful in soft lens fitting.

Slit lamp techniques

Pachometry (*see* Chapter 6)

If increased corneal thickness is to be used as a potential indicator of oedema, a pachometer attachment to the slit lamp is required (Stone, 1974), although accurate observation of corneal striae may give a direct indication of percentage increase in corneal thickness (Holden, 1990).

Photography (*see* Chapter 7)

The use of clinical photography permits a permanent record to be maintained of the eye, particularly its vascular state prior to fitting (*see Figure 7.1*).

Graticules

A calibrated graticule in the slit lamp eyepiece can be used to assess both the corneal diameter and the total diameter of a soft lens in wear. It can also be used to estimate the rotation of a marked toric lens (*see Figure 11.16*).

Placido disc and Klein keratoscope

These simple devices permit a qualitative assessment to be made of the regularity of the anterior surface of a soft lens while it is being worn. Any noticeable distortion of image quality suggests a poor fitting, and is likely to be accompanied by poor subjective acuity (*Figure 11.6*).

Aesthesiometry

If it is desired to monitor corneal sensitivity, aesthesiometry should be carried out prior to fitting (*see* Chapters 2 and 8).

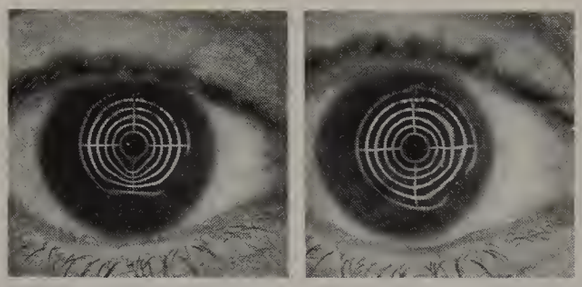


Figure 11.6 Photokeratoscopy showing distortion from the front surfaces of steeply fitted soft lenses during wear. (*a*) A high water content lens of corneal size; (*b*) a low water content semi-scleral lens

Corneal mapping/videokeratography

These devices give both a qualitative and quantitative assessment of corneal shape and regularity. Measurement over a settled lens allows assessment of the quality of the lens surface (or, more accurately, the tear film) and may explain instances of poor vision (*see* Chapter 6).

Lens verification and inspection

The instruments for this purpose are fully described in Chapter 13 but essentially the practitioner needs an easy method to verify the radius, diameter and power. The spherometer principle or projection magnifier such as the Optimec (*see Figure 13.15*) can assess the lens radius and diameter, whilst the power can be checked by a focimeter method. The projection magnifier is also an easy method of assessing lens condition and also for demonstrating to the patient any flaws which might have developed in the surface or edge. Also useful are a dark-field analyser for demonstrating surface deposits, and a refractometer for providing an assessment of water content.

Consulting room procedures and equipment

A constant supply of physiological saline is required in the consulting room for rinsing and cleaning lenses prior to insertion and for their subsequent disinfection after use. Ideal for this purpose is one of the proprietary aerosol salines, either buffered or unbuffered. These contain no preservatives and employ sterile air or nitrogen as the propellant, but they are frothy. Where frothing is a problem, modern preserved (bacteriostatic) salines can be substituted, (e.g. Allergan Lens Fresh Purite).

Lenses are most easily extracted from their vials by means of soft-ended plastic tweezers or a glass rod. For the more fragile high water content lenses, the complete contents of the vial should be tipped into the hand or a small sterile dish. This has the advantage of making sure that the storage solution is changed on each occasion that the lens is used, and is therefore a good procedure to adopt with any type of lens.

Sterile 5 ml or 10 ml lens vials are useful for storing patients' lenses when they are removed during an after-care examination, or if lenses are retained for cleaning and rejuvenation.

Trial lens disinfection

Several methods are available for the disinfection of trial lenses (Gasson and Morris, 1992).

- Heat: autoclaving or boiling in 0.9% saline is the safest method, but the high temperatures can reduce the life span of high water content lenses.
- Preserved soaking solutions are most convenient but a 4–6hr soaking time is required before use and some patients may be sensitive to the preservatives.
- Most hydrogen peroxide systems require less time, but this procedure can be complicated for routine trial lens storage. However this method is recommended for use against the HIV virus (*see* Chapter 4).
- Chlorine tablets represent greater convenience, but some patients experience stinging on insertion with high water content lenses stored in vials too small to allow for the correct dilution.
- Ciba's Instacare allows rapid disinfection of trial lenses which can then be stored in Instacare Finishing Solution (*see* Chapter 4).

The smaller pharmaceutical vials will require a crimping device for resealing their metal caps either during or after disinfection. Because many soft lenses are not marked and are therefore unidentifiable without time-consuming measurement, small self-adhesive labels are useful for the identification of lenses temporarily stored in otherwise plain bottles. A selection of lens vials is shown in *Figure 11.7*.

Hygienic procedures are extremely important in practice to avoid cross-infection within the consulting room (Sheridan, 1987).

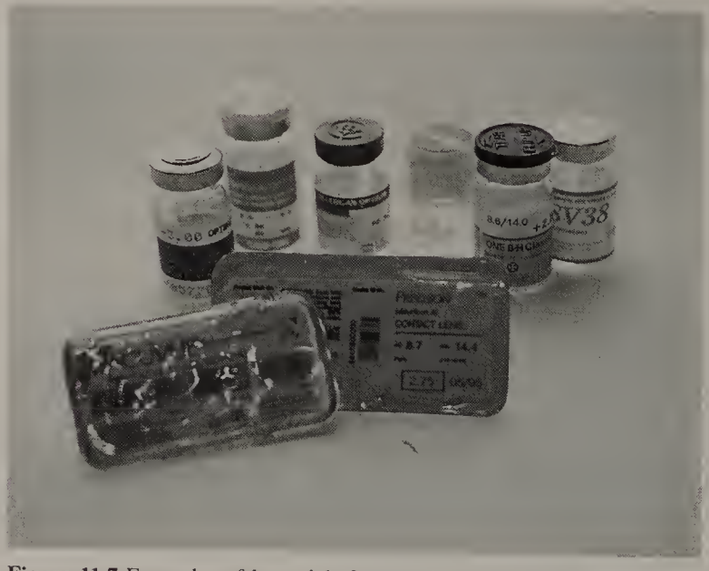


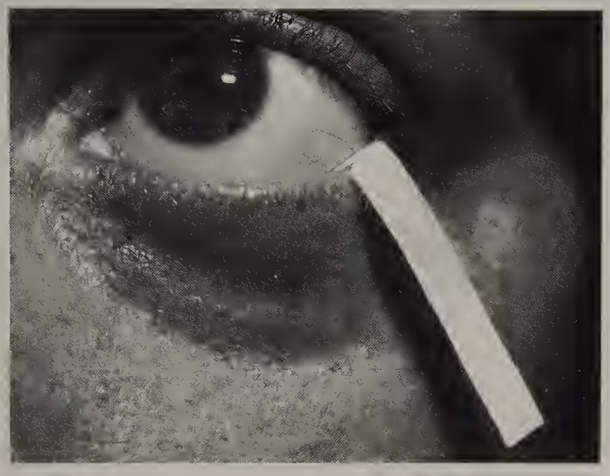
Figure 11.7 Examples of lens vials from various soft lens manufacturers

Assessment of tear flow

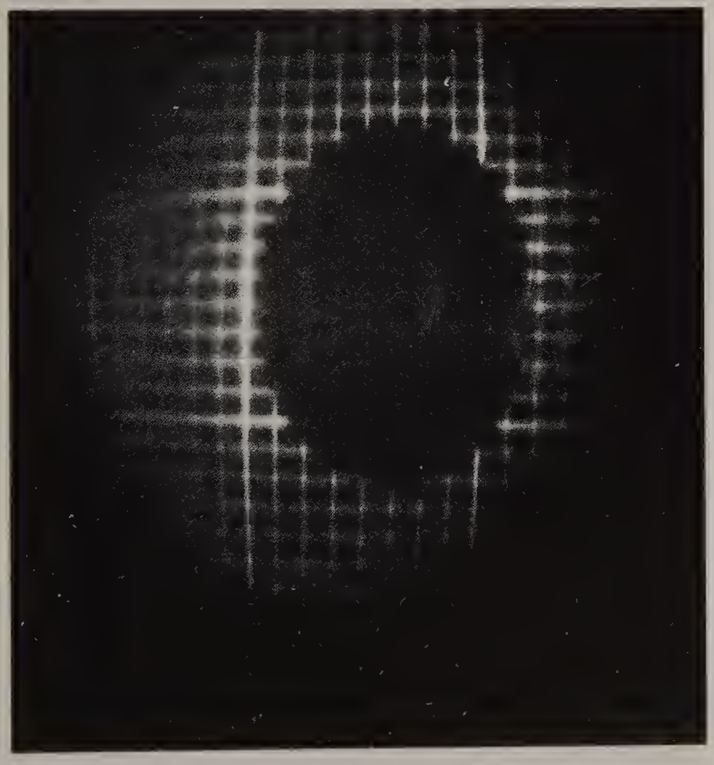
Invasive assessment

It is important to be able to recognize a patient who is likely to develop a tears-related problem with contact lenses. The major factors which contribute to dry-eye symptoms can be considered in three groups: lid anomalies, tear anomalies and contact lens surface anomalies (Guillon and Guillon, 1990; Forst, 1992). A number of tear diagnostic techniques have developed over the years, two of the earliest being the Schirmer test (*Figure 11.8a*) and fluorescein break-up time (BUT). These assess deficiencies respectively in quantity and quality. Neither, however, is a particularly reliable method and the use of a series of tear tests together with positive slit lamp findings (staining) has been shown to be more predictive (Orsborn and Zantos, 1988). A less irritating version of the Schirmer test is the Phenol Red Thread test developed by Kurihashi (1978) which uses a raw cotton thread dyed yellow with 0.05% phenol red solution. The thread turns yellow in the tear pH range so that the length of discoloration indicates the amount of tears produced (*see* Chapter 8). Tear film height (tear prism) on the lower lid is a similar quantitative test and easy to use in routine practice (Port and Asaria, 1990).

With the invasive technique of fluorescein break-up time (*see* Chapter 8, p. 271), 10–60 seconds has been considered normal. If break-up occurs in less than 10 seconds, a deficiency in the quality of the tears is indicated or may suggest the presence of meibomian gland dysfunction (Larke, 1985). Norn (1974) described a more elaborate quantitative procedure whereby fluorescein is mixed with 1% Rose Bengal, the colour of the composite stain indicating the tear volume.



(a)



(b)

Figure 11.8 (*a*) Schirmer's test showing how the tear fluid wets the paper strips. (*b*) Non-invasive HIRCAL grid reflected off the precorneal tear film as seen through an adapted Bausch & Lomb keratometer – see text for normal range. (Courtesy of Sudhir Patel)

Non-invasive break-up time

The mean fluorescein break-up time is approximately 10 seconds. However, the actual non-invasive break-up time (NIBUT) for a tear film which is undisturbed by fluorescein is typically 36 seconds (Loveridge, 1992, *Table 11.2*). This more accurate and repeatable assessment of tear film stability (quality) can be observed by projecting a grid on to the pre-ocular tear film (*Figure 11.8b*). Several forms of this technique have been developed (Mengher device, HIR/CAL grid, Loveridge grid and Guillon Tearscope). A NIBUT of greater than 20 seconds is considered normal and under 15 seconds as a clear indicator of dry eye.

Tears pH

Norn (1974) discussed the use of bromothymol blue as a pH indicator for the tears in the range 6.8–7.6,. The colour is assessed after exactly 5 seconds, before carbon dioxide from the tears renders the lacrimal rivus more alkaline.

Table 11.2 Comparison of tear break-up times

Technique	*Mean break-up times (sec)*	*Intra-subject variation (%)**
Fluorescein	9.7	38.1
Keratoscope	24.5	42.9
Mengher	26.5	19.5

*Standard error of the mean expressed as a percentage.
Source: Reproduced by kind permission of R. Loveridge

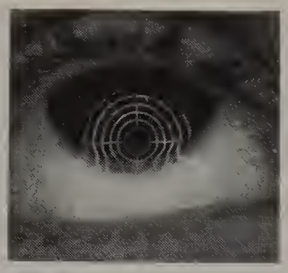


Figure 11.9 Limbal photography as shown by reflection from an A.I.M. photokeratoscope. The patient is looking up at the fourth ring from the centre

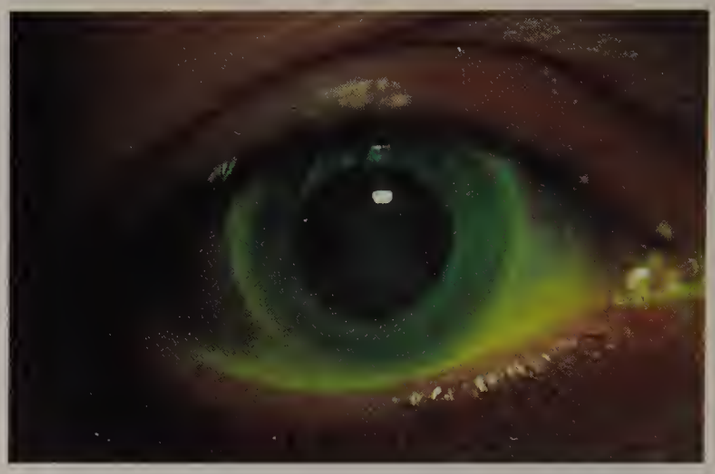


Figure 11.10 Softperm lens with high molecular fluorescein instilled showing steep fitting central rigid zone

Assessment of limbal topography

Chapters 10 and 17 on corneal and scleral lens fitting stress the respective importance of corneal and scleral topography. In the fitting of soft lenses these factors are no less important, but practitioners are also concerned with those aspects of global topography which it is least easy to quantify and measure. These are the diameter of the cornea, the rate of flattening of the corneal periphery and the configuration of the corneoscleral junction, all of which can only be assessed by observation rather than by direct measurement. They can often account for the unusual behaviour of a soft lens, and explain why two eyes with the same refractive error and keratometer readings may require soft lenses with completely different specifications in order to establish a satisfactory fit.

Corneal diameter is usually measured as 1 mm more than the horizontal visible iris diameter (HVID). The mean corneal diameter is 12.90 mm ± 0.60 mm (Martin and Holden, 1982). Direct measurement with, for example, a graticule in the slit lamp eyepiece (*see Figure 11.16*), only gives an assessment of the dimensions concerned, because it is not truly possible to ascertain exactly where the cornea finishes and the sclera begins. The horizontal axis is normally longer than the vertical by between 0.50 mm and 1.00 mm. The effective corneal diameter is perhaps best evaluated by placing a corneal soft lens of known total diameter on the eye and examining it *in situ*.

Peripheral flattening of the cornea can be studied with the new range of corneal mapping devices. These instruments measure a much larger area of the cornea than traditional keratometry e.g. the Corneal Modelling System TMS (11 mm – 14 mm) and the EyeSys ES-100 (9.60 mm) but they can be time-consuming and expensive to incorporate into routine practice. Alternatively, peripheral K readings can be taken and an auto-keratometer can achieve this with simple routine measurement (*see* Chapter 6).

Limbal topography can also be assessed by observing the continuity of a slit beam as it crosses the corneoscleral junction and is most easily seen with a vertical slit at the lower limbus with the patient looking upwards. The reflection of a Placido disc at the limbus is also helpful in assessing its contour, as shown in *Figure 11.9* in which the patient's gaze is directed slightly upwards. A corneal diameter lens on an eye with a shallow corneoscleral junction typically decentres and lags more easily than on an eye with a well-defined junction.

The use of fluorescein in fitting

Ordinary fluorescein cannot be used with hydrophilic lenses because it will be absorbed into the porous structure of the material. Except for high water content polymers, from which the colour may gradually fade, the lenses can be almost permanently stained (however it is sometimes possible to bleach out the stain with a chlorine tablet (e.g. Softab/Aerotab) or hydrogen peroxide). Because soft lens fitting criteria rely on movement and centration the routine need to observe tear flow under the lens is less important. There are, however, various forms of high-molecular-weight fluorescein, such as Fluoflex and Sauflon's Fluoresoft where the molecular size is sufficiently great to prevent immediate penetration into the soft lens materials (*see* Chapter 4). They have been suggested as a routine requirement in the fitting of hybrid lenses such as the Wesley-Jessen Softperm (*Figure 11.10*, *see also* pp. 398–400).

Poster (1977) found much better clinical results with these dyes by using a Kodak Wratten filter (No. 15). One or two drops are instilled into the lower fornix and the eye observed after a few blinks. If fluorescein can then be seen beneath the lens, it confirms that an interchange of tears occurs on blinking. If no fluorescein is observed, it suggests that the fitting is too tight, and the lens periphery is creating a seal where the edge of the lens presses against the bulbar conjunctiva.

Clinical routine

The complete clinical routine consists of the following steps:

- The taking of general and optometric history.
- A complete routine optometric examination, including all the usual procedures such as ophthalmoscopy, tonometry, fields and tests of binocular function.
- Keratometry or computer assisted keratoscopy.
- Preliminary external eye examination, including slit lamp examination, lid eversion, tear film assessment and other techniques as outlined on p. 373 onwards.
- Discussion with the patient about lens types, motivation, leisure activities and the decision to fit soft rather than other types of contact lens.
- The decision as to which variety of soft lens should be fitted or tried initially.
- Insertion of lenses.
- Initial assessment of fitting, vision and over-refraction.
- Tolerance trial with sufficient time for lens settling and equilibration.
- Re-assessment of vision, over-refraction, fitting and lens type.
- Re-examination with slit lamp, and other instruments as required.
- Ordering of lenses, where necessary.
- Dispensing of lenses, patient instruction and informed consent.
- After-care examinations.

Preliminary examination

The first steps are refraction, recording of monocular and binocular acuities and keratometry. These are all especially important with soft lens fitting, because an early assessment of visual suitability has to be made with respect to corneal and refractive astigmatism. A detailed slit lamp examination should then be made, paying particular attention to the limbus and the perilimbal blood vessels. If it is intended to insert soft lenses shortly afterwards, fluorescein and Rose Bengal should not be used at this stage. However, they should be employed where the possibility of some prevailing corneal or conjunctival condition is suggested, warranting a more definite diagnosis before fitting can be safely commenced. Alternatively it may be a good idea to have a separate appointment for lens fitting after a routine eye examination and full slit lamp examination have been carried out. In cases where these dyes are used on the same day as fitting, the conjunctival sac should be irrigated with saline solution afterwards.

External eye examination should always include eversion of the upper lid to confirm the normality of the palpebral conjunctiva (Allansmith *et al.*, 1977) and an assessment of the patient's tear film. An estimate of the horizontal corneal diameter is made and, if available, clinical photography and pachometry are carried out prior to fitting (*see* p. 373).

Lenses may be inserted by the practitioner in a variety of ways. Those of corneal size may be handled in much the same way as a hard lens, and placed directly onto the cornea. Thin lenses, however, are particularly unstable at the moment of insertion if an air bubble should be trapped behind and they may be expelled by an involuntary blink. The risk of this occurring is reduced if patients are requested to look down with gentle eye closure after insertion. Allowing the lens to dry for several seconds on the practitioner's finger prior to insertion encourages its transfer to the eye as the patient's tear film attracts it onto the eye from the finger, and prevents a thin lens from folding back on itself.

A second method is for the patient to look upwards or downwards at some suitable fixation target, and then to place the lens onto the inferior or superior sclera respectively, from which it will position itself correctly on the cornea when the eye returns to the primary position. A further method is to have the patient look down and nasally, while the lens is placed on the temporal sclera. It may then be slid across quite easily into the correct position. A right-handed practitioner may well find it simpler with a tight-lid patient to approach the left eye first. In some cases, where the palpebral aperture is small, it may be necessary partially to fold a standard thickness lens between finger and thumb effectively to reduce its total diameter during insertion. This method can also be effective in holding the lens more securely, which may be useful if the patient has tight lids or a marked blepharospasm. Alternatively, it is sometimes helpful to balance the lens between the first and second fingers, particularly if it is a high positive lens, and unstable on only one finger because of its weight and the steep curvature of the lenticular portion of the front surface.

Certain of the proprietary solutions for storing hydrophilic lenses may cause some degree of stinging with sensitive eyes so that lenses should be cleaned and rinsed with sterile, non-preserved saline prior to insertion. This also removes any particles which may be present on the lens surface. Care should be taken to avoid touching the back surface of the lens after it has been rinsed. Once the lens has assumed its correctly centred position on the cornea, the patient should be no more than slightly aware of its presence. Any significant level of discomfort is likely to be due to a foreign body trapped behind the lens. This may have been a speck of dust or make-up carried in from the eyelashes, or it may have been already present in the tear film and subsequently trapped by the lens. If discomfort is only mild, and patients sometimes describe this foreign body sensation as stinging, the lens should be slid onto the temporal sclera and allowed to recentre. This wiping action is usually sufficient to eliminate the cause of the discomfort but if it persists the lens should be removed from the eye, cleaned and re-inserted.

Removal can sometimes be effected by the rigid lens method of applying lid pressure, but a much simpler technique is to slide the lens onto either the temporal or inferior sclera from where it is gently pinched directly out of the eye. Although not ideal, suction holders can sometimes be used, as described in Chapter 9.

Initial assessment of fitting and vision

When a hydrophilic lens is removed from its vial, it is fully hydrated with the maximum water uptake permitted by its particular storage medium. The lens, in settling on the eye, loses water by evaporation from its anterior surface and by the squeezing action of the eyelids. Part, but not all, of this water loss is replenished by normal tear flow, until a state of equilibrium has been achieved for the environmental conditions prevailing in the consulting room. At the same time, the lens is adjusting to the temperature of the cornea, and to the pH and tonicity of the tears. The movement of the lens and therefore its fitting characteristics, unless grossly loose or tight, cannot be reliably judged for several minutes, until this state of equilibrium on the cornea has been reached. The vision, on the other hand, if it is going to prove satisfactory, usually settles within the first 5 minutes, although the refractive result is not necessarily accurate after so short a time. If the visual acuity is initially poor it is unlikely to improve and the lens should be changed.

In some instances, particularly with ultrathin lenses, false fitting results can occur. A lens sometimes settles within its storage vial so as to adhere to the base, neck or lid. It therefore has a temporarily distorted shape, unrelated to its true fitting parameters, and its behaviour on the eye may be very different from that of the same lens in an unstressed state. Similarly, if a lens has been disinfected by heating and not allowed sufficient time to cool and revert to its proper dimensions, it may well appear to fit too tightly.

The same effect can be produced by a lens stored in hypotonic saline solution, which may sometimes even give a temporary osmotic adhesion to the cornea. Eventually, the patient's natural tear flow restores the osmotic balance and allows the lens to move but the process is assisted by the liberal application of physiological saline. In practical terms, this means that if a lens is completely immobile just after insertion it may be a tonicity rather than a fitting problem.

Methods of observing the fit

Lens movement and position are most easily observed by using the slit lamp with low magnification and white light. The action of the lens edge on blinking can be judged in relation to the position of the limbal vessels. In some eyes with rather loose conjunctival tissue, however, the appearance can be misleading.

Movement of possibly even a tight fitting may be attributed to the lens when it is, in fact, motion of the bulbar conjunctiva. A further indication of fit may be obtained by using $\times 35$ or $\times 40$ magnification and observing the passage of blood through the limbal vessels beneath the lens edge, to ensure that there is no obstruction. Without a slit lamp, lens movement is best seen by directing the beam from a hand-held pen torch, not necessarily from in front, but from the side or below so that the edge of the lens can be viewed.



Figure 11.11 Push-up test. The lens is digitally moved with the lid. The degree of resistance to movement and speed of recentration indicates the acceptability of fit (*see Table 11.3*). (Courtesy of Graeme Young)

A further simple test and one that has been shown to be the most consistent in determining a successful fitting with modern lenses is the push-up test (Young, 1992) (*Figure 11.11*). The patient is asked to look up and the lid is used manually to push the lens up by about one-third of the corneal diameter. A correctly fitting lens has a quick recovery movement, whereas that of a flat fitting is considerably more sluggish. A tight lens, although recentring sharply, will be difficult to slide off the cornea.

Because most fitting criteria relate to lens movement and quality of vision, the slit lamp and retinoscope have become important fitting instruments.

Tolerance trials

Once the initial fitting characteristics have been confirmed as satisfactory, ideally the next stage of the clinical routine is a longer tolerance of about 2–4 hours, using, where possible, lenses of the correct power and fitting. Patients can then wear lenses in their normal daily environment, carrying out their usual visual tasks. In this way a fairly reliable assessment is possible of their potential success, and latent problems such as dry eyes or near vision difficulty may be discovered. When a lengthy trial is not practicable, it still remains essential to leave lenses for enough time to settle fully – a minimum of 20–30 minutes is recommended. A tolerance trial of several days, may be useful for previous lens failures so that the practitioner can be more certain of a satisfactory result, and the patient may be reassured in the light of the earlier failure.

After the tolerance trial, fitting and refraction are carefully reassessed. Any marked deterioration in visual acuity other than that due to uncorrected astigmatism suggests the fitting is steep. This occurs when tear flow has returned to normal, lens mobility decreases and an initially acceptable fit has become tight. Examination of the eye

itself should confirm the absence of corneal oedema and striae, punctate epithelial staining with fluorescein, limbal or conjunctival irritation, and scleral indentation. If any elevations of the upper palpebral conjunctiva had been previously noted, the lids should be everted to make sure that there is no irritation or staining of these areas with fluorescein.

At this stage, the clinical decision can usually be made as to whether the patient is suitable for hydrophilic lenses. In cases of doubt, either visual or physiological, the tolerance trial should be repeated on another occasion. If possible, patients are loaned lenses of optimum fitting and power for several days, in order to extend the trial period. This procedure is straightforward if lenses are fitted from stock.

Patients frequently confuse right and left lenses and it can be particularly difficult to identify two unmarked lenses of only 0.25 D power difference. When feasible, it is easier to avoid this problem by ordering the final powers to be the same for both eyes. The alternative is to make the two lenses as different as possible so that the patient is more likely to realize if they have been inadvertently switched. It is also possible to have a dot marked on one lens (*see* Chapter 22) or even order one lens in a design available with a handling tint.

Fitting characteristics

The general fitting characteristics for soft lenses are summarized in *Table 11.3*, although these are not as obvious with ultra thin lenses as with standard thickness lenses.

Characteristics of a good fitting

A lens which is fitting well is comfortable in all directions of gaze, gives complete corneal coverage and appears properly centred. Normal blinking results in up to 0.50 mm of vertical movement when the eye is in the primary position. The lens lags by no more than 1.00 mm on upwards gaze or lateral movements of the eye. Vision is good, remaining stable on blinking.

Refraction gives a precise end-point, correlating with the BVP of the spectacles. The retinoscopy reflex is crisp and sharp both before and after a blink. The slit lamp shows no irritation of the limbal vessels or compression of the conjunctiva. If carried out, keratometry of the front surface of the lens on the eye shows the mires to be stable and undistorted.

Characteristics of a steep fitting

A lens fitting too steeply gives little or no movement either on blinking or as the eye changes fixation. Initially, a tight fitting is quite comfortable, sometimes more so than a correct fit, because a completely immobile lens produces the minimum of lid sensation. Centration is usually good, although a corneal-sized or spun-cast lens may sometimes assume a decentred position.

This is easily differentiated from a decentred flat fitting because of the lack of movement. The slit lamp may show irritation of the conjunctival or limbal vessels and, with very tight lenses, an annular ring of conjunctival compression may be seen. This is often visible even after the lens has been removed (*Figure 11.12*).

Table 11.3 Fitting characteristics of soft lenses

Observation	*Good fit*	*Steep fit*	*Flat fit*
Comfort	Good	Good initially	Poor
Centration	Good – complete corneal coverage	Usually good – may be decentred	Poor
Push-up test	Easily moved – good recentration	Sluggish – poor recentration	Easily moved – poor recentration
Movement on blinking	Up to 0.50 mm	Minimal	More than 1.00 mm and unstable
Movement on upward gaze	Less than 1.00 mm	Minimal	More than 1.00 mm, may move off cornea
Movement on lateral gaze	Less than 1.00 mm	Minimal	More than 1.00 mm, may move off cornea
Vision	Good	Poor and variable – may improve on blinking	Variable, may improve on staring
Over-refraction	Precise end-point/power correlates with spectacle Rx	Poorly defined end-point	Variable end-point
Retinoscopy reflex	Clear before and after blinking	Poor and distorted, central shadow, momentary improvement on blinking	Variable, may be clear centrally with peripheral distortion
Slit lamp after settling	No limbal injection or scleral indentation	Conjunctival or scleral injection and/or indentation	Localized limbal injection – possible edge stand-off
Keratometer mires	Sharp and stable before and after blinking	Irregular – momentary improvement on blinking	Variable and eccentric – changing on blinking
Placido disc	Regular image	Irregular – momentary improvement on blinking	Irregular image – worst at periphery

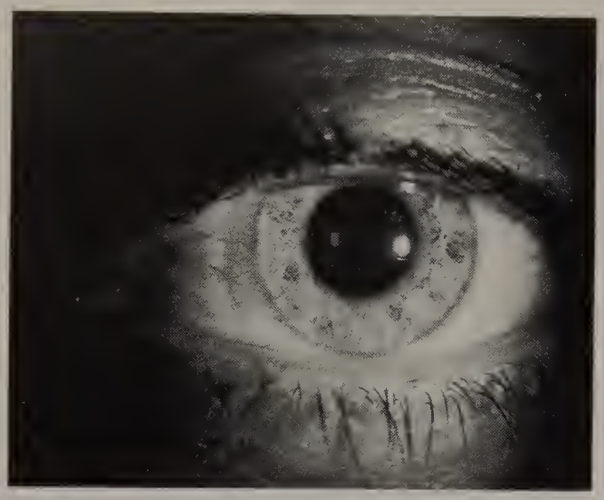


Figure 11.12 Nasal scleral indentation following the wearing of a tight lens

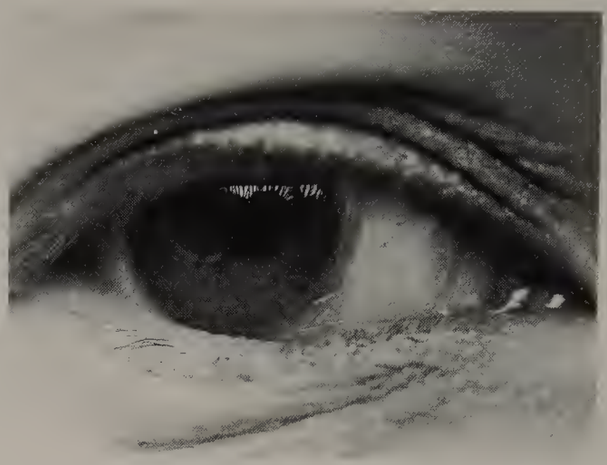


Figure 11.14 Very loose fitting showing buckling of lens edge

A steep fitting, standard thickness soft lens may vault the corneal apex, but is momentarily pressed on to the eye on blinking. Vision is, therefore, unstable and of poor quality, although showing some transient improvement after a blink. Subjective refraction is difficult, with no clearly defined end-point, and more negative power than predicted may be required because of a positive liquid lens and flexure. Retinoscopy reflex and keratometer mires both show irregular distortions, such as those indicated by photokeratoscopy in *Figure 11.6*. They may also improve momentarily on blinking.

Characteristics of a flat fitting

A flat fitting is more easily diagnosed because of the absence of proper centration, greater lens mobility on blinking and excessive lag on lateral eye movements, as shown in *Figure 11.13*. Such a fit may be very uncomfortable, especially on looking upwards, when the lens may slide off the cornea and catch against the upper lid on blinking. In the primary position, lower lid sensation is experienced if the lens drops, and discomfort is accentuated if the lens is so flat that the periphery buckles to give edge stand-off (*Figure 11.14*). Vision and overrefraction are variable, but nevertheless may still give a satisfactory result. The retinoscopy reflex may be clear centrally but with peripheral distortion. Keratometry mires change according to lens movement, showing an eccentric shape on blinking. *Figure 11.15* shows the photokeratoscope image from a flat lens and *Figure 11.13* a flat-fitting spun-cast lens of corneal size showing excessive lag on temporal excursion of the eye. The edge of the lens is clearly visible and peripheral distortion is most marked. Occasionally a flat fitting lens may appear to fit well but in a decentred position.



Figure 11.13 A flat-fitting spun-cast lens of corneal size showing excessive lag on temporal excursion of the eye. The edge of the lens is clearly visible

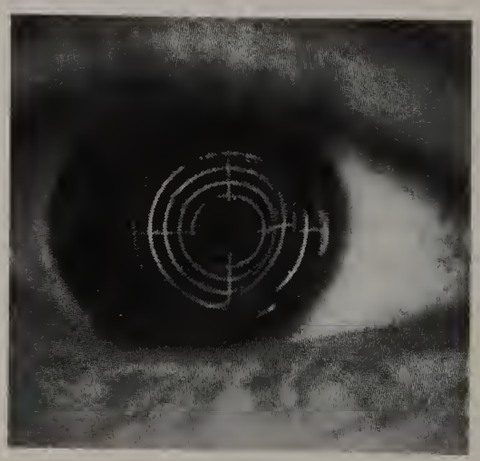


Figure 11.15 An eye wearing a flat-fitting low water content lens of corneal size. The photokeratoscope shows up the peripheral distortion

Fitting philosophies and soft lens selection

Current soft lens fitting is based on the following criteria:

- Complete corneal coverage;
- Correct lens movement;
- Good vision;
- Good comfort;
- Adequate oxygen supply – using either ultrathin low water content lenses or higher water content lenses.

As previously mentioned the mean horizontal corneal diameter is approximately 12.90 mm ± 0.60 mm (Martin and Holden, 1982). To allow full corneal coverage, therefore, most soft lens diameters available are between 13.50 and 14.50 mm. Many lenses have a choice of size (e.g. Bausch & Lomb, U3/U4; Zeiss, Hydroflex) whilst others have a fixed total diameter (e.g. Wesley-Jessen Classic, Acuvue).

With development towards more flexible, thin soft lens designs, the historical relationship between mean keratometry and BOZR is now less important. This has allowed the introduction of 'one-fit' lenses which can accommodate a wide range of corneal curvatures. In one study (Mertz *et al.*, 1992) a single lens design was found to fit successfully a range of keratometer readings from 7.20 mm to 8.60 mm.

Less flexible lenses are generally thicker and lathe-cut (*see Figure 11.21*). These often require more than one fit to cover the same range of corneal curvature, but allow adjustments of fit that are not possible with one-fit options. Lowther and Tomlinson (1981) using standard thickness HEMA showed that a change of greater than 0.40 to 0.50 mm in BOZR was required in these lenses to give only minimal change of fit. This tends to confirm the common choice of three base curve options to cover the normal range of corneal curvature in ultrathin lathe-cut lenses (e.g. Hydron Z6: 8.40; 8.70; 9.00 mm and Wesley-Jessen Classic: 8.30; 8.60; 8.90 mm).

Lens movement

Whilst older lens designs tend to move significantly on the eye (> 1.00 mm on blinking), the thinner, more flexible materials can now be successful with a much smaller degree of movement. This should not be confused with a tight fitting lens as, although not moving more than 0.20 to 0.30 mm (Young, 1992), the lens may still be freely mobile. It should also be remembered that the perception of movement can be deceptive through the slit lamp eyepiece. In the past this has led to some measurements such as degree of lens movement being overestimated (Lloyd, 1992). *Figure 11.16* shows a graticule superimposed on the cornea.

Historically the two main fitting philosophies into which soft lenses have been divided are semi-scleral and corneal. Both have their merits, but with the current range of lenses, many of which are only available in a single diameter, a degree of overlap has developed between the two.

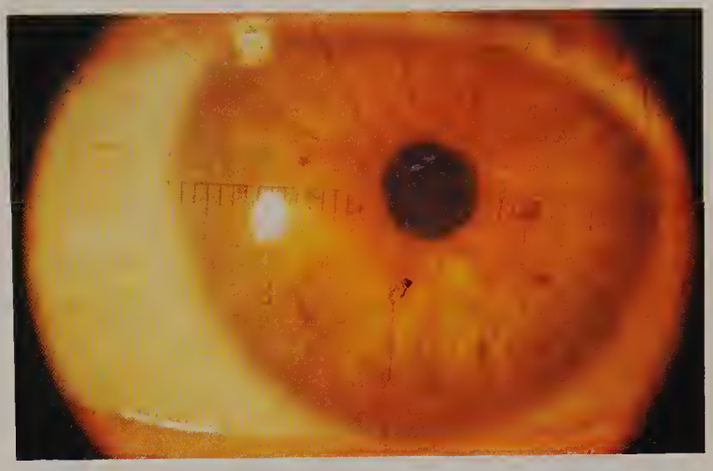


Figure 11.16 Slit lamp graticule superimposed on the cornea. Each increment on the graticule is 0.3 mm – an amount equivalent to the average movement exhibited by a well-fitting soft lens

'Semi-scleral' lenses

Semi-scleral lens fitting, where the soft lens overlaps the cornea, has become the main fitting technique for modern soft lens designs. They are larger than the visible iris diameter and give deliberate apical touch with further support beyond the limbus where they overlap onto the sclera. Alternatively, the more flexible designs will drape over the cornea gently resting on the conjunctiva. They vary in size from 13.50 mm to 16.00 mm with the majority in the range 14.00–15.00 mm. Lathed semi-scleral lenses usually have a greater thickness than corneal lenses so that, although it is possible to manufacture them from the entire range of materials, for physiological reasons nearly all such lenses are now of medium to high water content. These larger lenses frequently give greater stability of vision and fitting than corneal lenses and prove more successful for patients with sensitive lids or limbus.

The high water content varieties give good initial comfort and their high Dk values mean that they can be recommended for patients prone to corneal oedema. For this reason they are often the preferred choice for hypermetropes, where they also achieve better centration. Being slightly thicker than normal, they can also be fitted to moderately astigmatic eyes.

Cosmetically, the thicker designs (> 0.10 mm) are more noticeable on the eye.

Fitting technique

Most of the early forms of hydrophilic lens, made the same size as, or smaller than the cornea, proved to be very unstable because of their relative thickness. They gave poor vision and were very uncomfortable because of lid sensation. It is for these reasons that the larger 'semi-scleral'

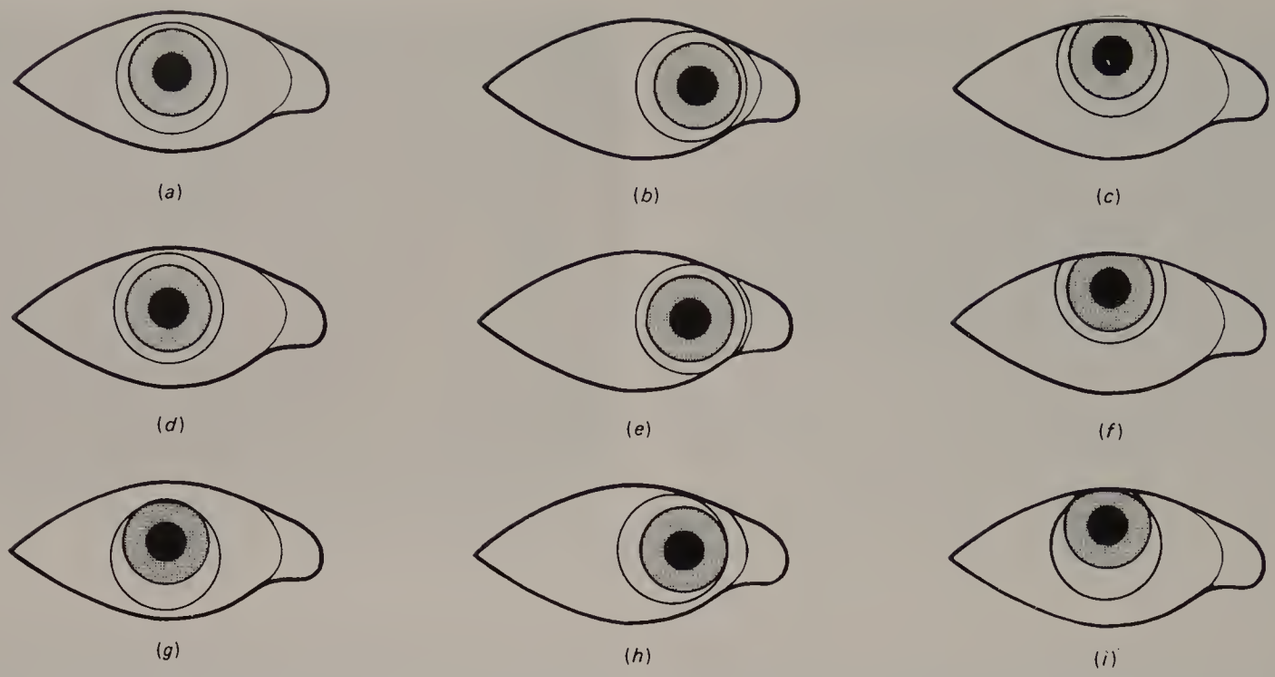


Figure 11.17 Semi-scleral lenses shown with the eye in the primary position, on the left-hand side, looking laterally in the centre column and looking upwards on the right-hand side. The upper three diagrams, (*a*), (*b*) and (*c*), show a correctly fitting lens: the centre three diagrams, (*d*), (*e*) and (*f*), show a tightly fitting lens: the lower three diagrams, (*g*), (*h*) and (*i*), show a loose fitting lens

method of fitting evolved in order to give stability of fitting and vision.

The intention of the fitting philosophy, as mentioned, is to give definite apical touch, with further support for the lens edge being provided beyond the limbus by a much flatter peripheral curve resting on the sclera. It is essential that the total diameter of the lens is large enough not to interfere with the blood vessels in the limbal region.

Initial lens selection is determined by two factors: the keratometer readings, and the horizontal visible iris diameter (HVID).

Thicker HEMA lenses are not often used now but were usually fitted between 0.7 mm and 1.3 mm flatter than the flattest '*K*'.

High water content materials may be fitted more steeply than this. Where a choice is available, the total diameter is selected to be 2 mm larger than the HVID.

The fitting characteristics of correct, steep and flat lenses are as described on p. 379 and summarized in *Table 11.3*. *Figure 11.17* shows diagrammatically the limits of acceptable lens movement and position for modern soft lenses with the eye in the primary position and in lateral and upward gaze respectively. *Figure 11.17*(*d–f*) shows the lack of movement with a tight lens; *Figure 11.17*(*g–i*) shows the excessive mobility of a loose fitting lens, as also shown in *Figure 11.18*.

Primary sagitta

The choice of actions required to correct an unsatisfactory semi-scleral fitting was related by Brailsford (1972), Rocher and Schwegler (1974) and Hodd (1976) to the primary sag or sagittal height of the lens in the same way as described for FLOM lenses (fenestrated lenses for optic measurements) in Chapter 17. In this way, a steep lens is corrected by decreasing the sag (flatter radius or smaller total diameter), and a flat lens by increasing the sag (steeper radius or larger total diameter) (*Figure 11.19*).

The principle of clinical equivalents therefore also applies, as it does to FLOM lenses, so that two lenses of different but related specification may behave in the same way on the same eye. For many semi-scleral lenses a change of radius of 0.30 mm is approximately equivalent to altering the total diameter by 0.50 mm.

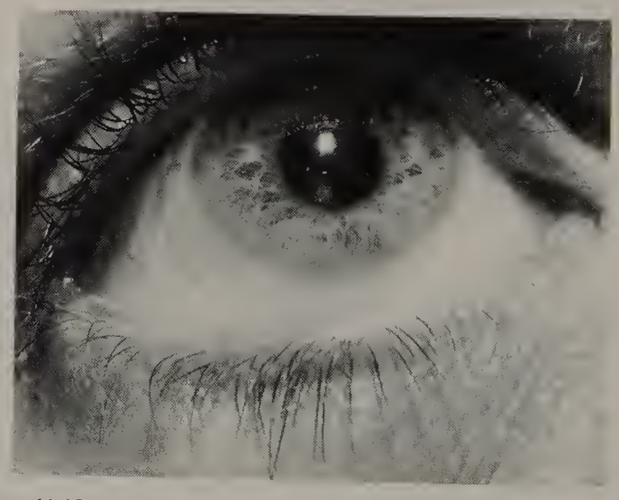
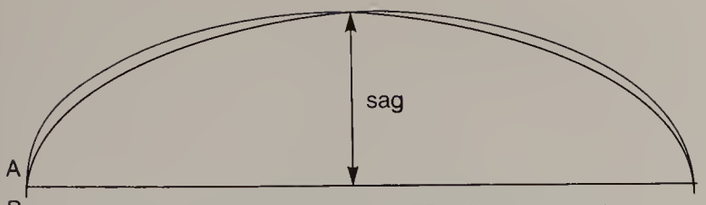
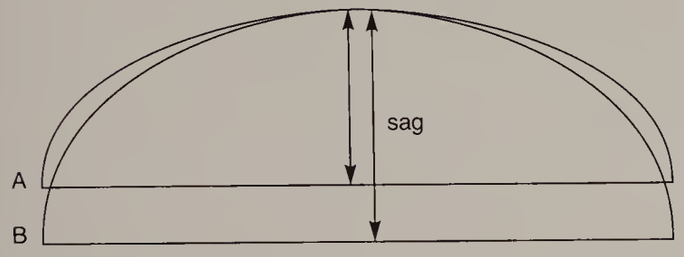


Figure 11.18 A slightly loose semi-scleral lens



Two spun-cast lenses with same TD, different posterior geometries but constant sagittal depth, e.g. B&L U4

(*a*)



Two lathe-cut lenses with same TD, different posterior geometries (BOZR) and correspondingly different sagittal depth, e.g. Hydron Z6

(*b*)

Figure 11.19 Sagittal depth comparison for spun-cast and lathe-cut soft lenses

Clinical equivalents do not, in fact, have the same primary sag because of their different diameters, and Cooke, (G. E., 1976, personal communication) suggested that the ratio between primary sag and total diameter is more meaningful. Thus, 8.40:14.0, 8.70:14.5 and 9.00:15.0, which may be considered clinically equivalent in terms of their fitting characteristics, have almost the same sag to total diameter ratios.

A steep fitting may, therefore, be corrected in two ways: either by selecting a lens with a flatter radius, or by employing a smaller total diameter. If the initial lens has proved very tight, it may be necessary to combine both of these fitting changes. For example, if a lens of specification 8.7:14.5 is too steep, it may be progressively loosened by the following lenses: 8.7:14.0 or 9.0:14.5, and then 9.0:14.0.

Conversely, a flat fitting may be corrected by choosing a steeper radius, or a larger total diameter, or possibly both. Thus, 8.70:14.0 may be progressively tightened by the lenses: 8.70:14.5 or 8.40:14.0 and then 8.40:14.5.

Corneal diameter soft lenses

Some corneal diameter soft lenses are still manufactured from low to medium water content materials to give reproducible lenses of good durability (e.g. Hydron mini). The thinner varieties, in particular, give a minimum of interference with normal corneal metabolism and they have an excellent cosmetic appearance. They can be used in straightforward cases, patients with poor handling ability, particularly those with small palpebral apertures, and cases prone to oedema with low Dk rigid gas permeable lenses. They may be contraindicated for some patients with tight lids and shallow corneoscleral junctions as these may cause lens decentration and consequent visual problems, or peripheral arcuate staining. Patients with sensitive lids may find adaptation difficult because of the sensation experienced each time the lid margin crosses the edge of the lens on blinking.

Fitting technique

A correctly fitting corneal diameter soft lens gives complete corneal coverage with proper centration. It should be the same size as or slightly larger than the HVID extending beyond the limbus by up to 0.50–0.75 mm. The majority of lenses vary between 12.50–13.50 mm in diameter. The thin varieties, as well as high water content, and high positive and negative lenses, are fitted approximately 0.5 mm larger than those of standard thickness in order to ensure stability on the cornea.

The radius for standard HEMA lenses is usually between 0.3 mm and 0.6 mm flatter than flattest *K*. High water content lenses are fitted closer to alignment whereas the more rigid lower water content materials may require radii 0.7 mm or more flatter than flattest *K*. Generally, most manufacturers will give guidance as to the particular fitting philosophy for their specific design of lens.

Most corneal diameter soft lenses have a mono-curve back surface and the two principal parameters of radius and diameter frequently have fitting steps of 0.2 mm and 0.5 mm, respectively.

Fitting characteristics are mainly as outlined in *Table 11.3*. Corneal diameter lenses require careful observation of centration and movement since they can be significantly influenced by such factors as corneal and limbal topography, lid pressure and size and position of the palpebral aperture.

Figure 11.20 shows the four common ways in which a lens may position on the cornea with the eye in the primary position. In *Figure 11.20(a)* an optimum fitting is shown. The lens is perfectly centred and there should be up to 0.5 mm of vertical movement on blinking. In *Figure 11.20(b)* the lens is riding slightly high, influenced, for example, by a tight upper lid. This may prove acceptable provided the decentration is no more than about 0.5 mm, but an attempt should be made to improve the fitting by selecting a larger diameter. In *Figure 11.20(c)* the lens is shown riding in a low position. It generally represents an unsatisfactory fitting which is too small or too flat and the patient is likely to complain of unacceptable lid sensation. It can also result from the downwards pressure of a relatively heavy upper lid on a fitting which is too tight, although initially quite comfortable. There is the possibility of arcuate staining at the superior limbus after several hours of wear together with oedema because of insufficient tear exchange. In *Figure 11.20(d)* the lens is eccentrically located. This may also be due to a fitting which is too small or too flat, or because of lid pressure combined with a shallow corneoscleral junction. It represents a rather unsatisfactory fitting although it may sometimes prove

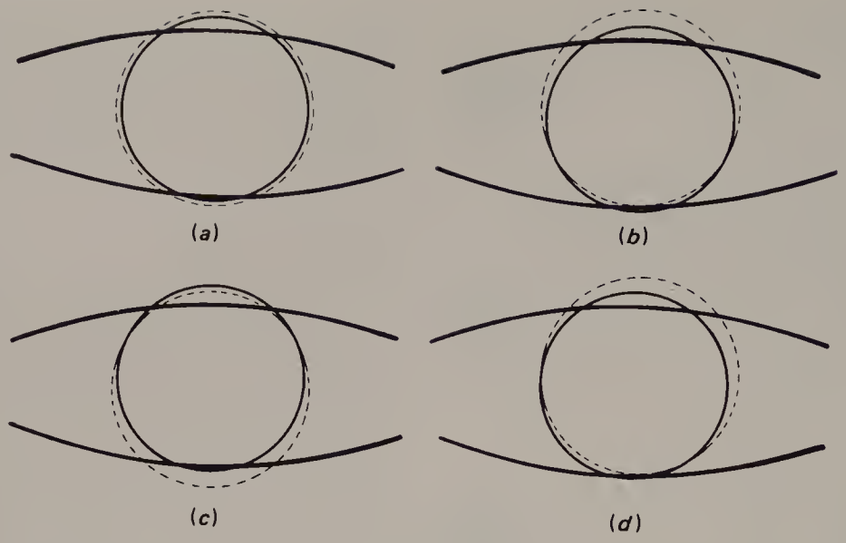


Figure 11.20 The four common positions taken up by soft lenses of corneal size (shown with dashed outline), on an eye in the primary position. (*a*) Correctly centred; (*b*) slightly high; (*c*) slightly low; (*d*) laterally decentred

acceptable if the decentration is limited to 0.50 mm. A larger total diameter should be tried.

Lenses must give complete corneal coverage to avoid the risk of epithelial dehydration and arcuate staining of any exposed area. An attempt should always be made to improve the fitting characteristics of a decentred lens by selecting a larger diameter.

The principle of clinical equivalents generally applies so that a change in diameter of 0.50 mm is equivalent to a change of radius of 0.20 mm. Thus, 7.90:12.50 is approximately clinically equivalent to 8.10:13.00, and 8.30:13.00 is approximately clinically equivalent to 8.50:13.50.

A loose fitting may be improved by choosing either a larger total diameter or a steeper radius, but it is usually preferable to achieve a more stable fitting by increasing the total diameter. By maintaining a flatter radius better visual acuity may be achieved as the lens is in better alignment with the cornea.

A tight fitting may be improved by selecting a flatter radius or a smaller total diameter. It may, however, not be possible to reduce the total diameter without producing limbal touch. It is important to avoid fitting too tightly because of the risk of oedema. This can occur even with thin or high water content lenses with high Dk values. It is also essential to ensure adequate lens mobility to allow proper tear flow for removal of debris from beneath the lens.

General fitting points

With all soft lens fitting, if there is a possible choice between two radii when selecting a lens, it is better to commence with the flatter unless the manufacturer's instructions recommend otherwise. There are three main reasons for this:

- It is easier to see the excessive movement of a loose lens than the relative lack of movement of a steep fitting.
- A sharper end-point can be obtained with over-refraction.
- Soft lenses become tighter as they settle.

The BOZR of a lens needed to successfully fit a steep cornea is much flatter, relative to flattest keratometry readings, than that of a flat cornea. This applies to both corneal and semi-scleral lenses. Thus, a radius of 8.10 mm may be necessary for a 13.00 mm lens on a 7.40 mm cornea, whereas an 8.40 mm cornea might well require a radius of 8.70 mm or even 8.50 mm.

Lens flexibility

A further important influence on the fitting characteristics is the flexibility of the material. This accounts for two lenses of the same specification, but different materials behaving very differently on the cornea. *Figure 11.21* illustrates the difference in flexibility of several soft lens materials (Burgess *et al.*, 1985). Permalens, which is very flexible, is fitted less flat than other more rigid materials. Similarly, thin spun-cast and moulded lenses with inherently greater flexibility than their lathed counterparts, lend themselves better to a one-fit fitting philosophy which relies on draping the cornea.

Examples of lens types

It is not possible in a chapter of this nature to include a detailed description of the fitting procedures for each and every soft lens currently available. Existing lens designs are constantly being improved upon while new varieties are continually being introduced. The lenses described here, although relating to an individual laboratory, have been

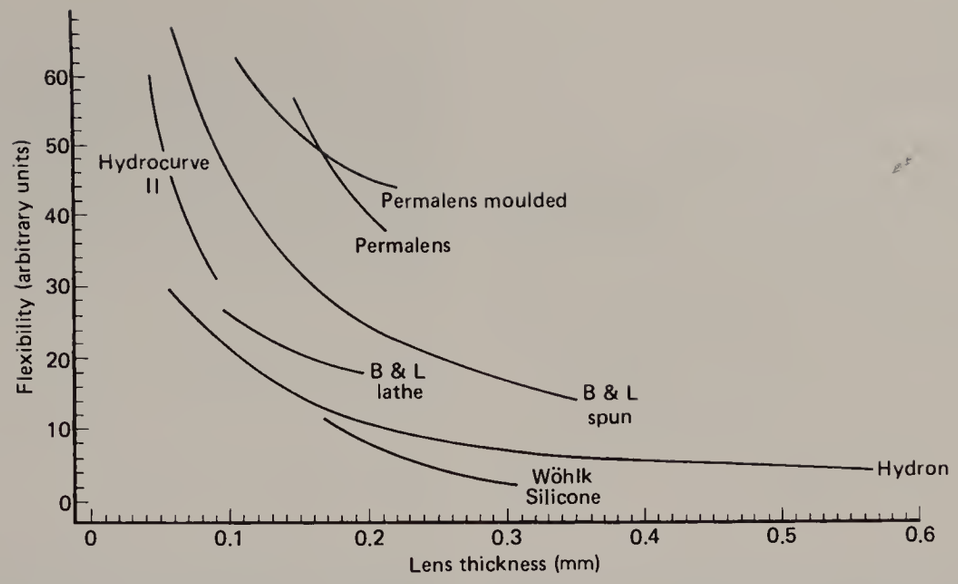


Figure 11.21 Flexibility of soft contact lenses of various materials and thicknesses (Courtesy of Bausch and Lomb, UK, Ltd)

chosen as typical examples of the same general type. It should therefore be possible to deduce the fitting method for any soft lens not specifically mentioned by reference to the general fitting principles described.*

A selected list of commonly available lenses is given in *Table 11.1*, which is intended to give an idea of the range of polymers, water contents and oxygen permeabilities currently in use.

Low water content lathe-cut lenses

(e.g. Hydron Zero 6 and Z Plus)

Thin HEMA lenses.
Manufactured by Hydron Ltd.

Material properties

Chemical nature:	Filcon 1a, HEMA
Water content:	38.6%
Oxygen permeability:†	11×10^{-11} at 35 °C
Refractive index:	1.43 (wet)
Swell factor (not linear):	1.19
Optical transmission:	95%
Density:	1.17 g/ml
Tensile strength:	8 kg/cm^2

Manufacturing method

Lenses are lathe-cut to the tolerances shown in *Table 11.4*.

*Inclusion of certain manufacturers is not an endorsement of their products nor is omission intended as a criticism of their work.
†In this section all oxygen permeabilities (Dk) values are in units of ($\times 10^{-11}$) (cm ml O_2)/(cm^2 s mmHg).

Table 11.4 Tolerances of Hydron soft lenses

Parameter	*Dry*	*Hydrated*
Back optic zone radius (mm)	±0.04	±0.05
Thickness (mm)	±0.02	±0.024
Total diameter (mm)	±0.05	±0.06
Power (D)	±0.12	±0.14

Table 11.5 FOZD and centre thickness for Hydron Zero 6 and Z plus lenses

BVP (D)	*FOZD (mm)*	*Centre thickness (mm)*
–20.00	6.7	0.06
–10.00	6.7	0.06
–5.00	9.0	0.06
–3.00	11.0	0.06
–1.25	13.4	0.08
Plano	10.8	0.12
+2.00	9.6	0.16*
+6.00	9.0	0.25*
+10.00	8.3	0.31*

*Average overall thickness = 0.10 mm.

Table 11.6 Parameters available for Hydron Zero 6 and Z Plus lenses in the UK

BOZR (mm)	8.10, 8.40, 8.70, 9.00, 9.30
TD (mm)	14.00
BVP (D)	+20.00 to –20.00

NB: A wider range of parameters is available in other countries.

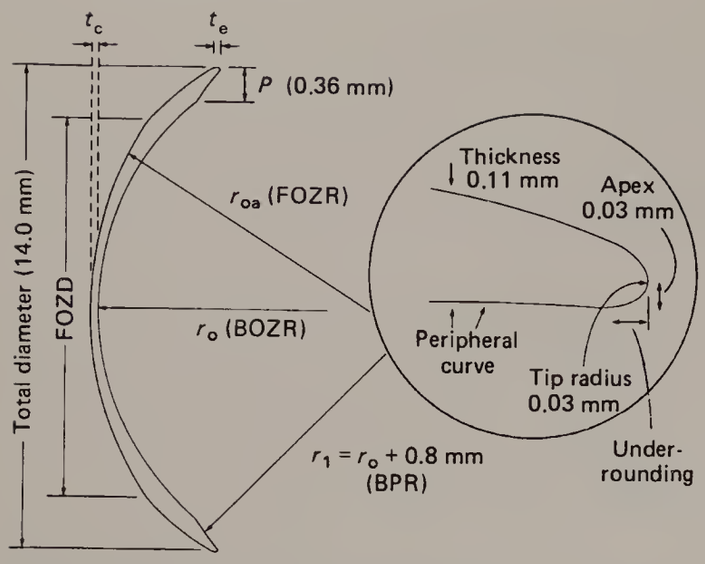


Figure 11.22 Geometry and edge design for Hydron Zero 6 (Courtesy of Hydron, UK)

Lens geometry

The Zero 6 geometry and edge design are shown in *Figure 11.22*. Negative lenses with powers of –3.00 D and greater, all have a centre thickness of 0.06 mm. Lenses are designed to give a deliberately thickened mid-periphery to assist with handling. This is particularly useful for low negative powers. *Table 11.5* shows the centre thickness and FOZD for the remainder of the power range. The BOZD and peripheral curve width are constant at, respectively, 13.28 mm and 0.36 mm for all powers.

Parameters available

The parameters available in the UK are shown in *Table 11.6*.

Fitting set

The fitting set is shown in *Table 11.7*.

Table 11.7 Recommended fitting set for Hydron Zero 6 and Z Plus lenses

BOZR (mm)	*TD (mm)*	
	Zero 6	*Z Plus*
8.40	14.00	
8.70	14.00	14.00
9.00	14.00	14.00
9.30		14.00
Back vertex power (D)	–3.00	+3.00

Fitting technique

There is no firm relationship between flattest K and BOZR because of the greater lens flexibility. Approximately 70% of negative and positive prescriptions are successfully fitted with respective BOZRs of 8.70 mm and 9.00 mm. Fitting criteria are as noted in *Table 11.3* and *Figure 11.17*. Because in some countries only one diameter is available, Zero 6 and Z Plus lenses may prove unsuitable where the cornea is either very small or very large.

Typical specification

A typical specification is: 8.70:14.00 –3.00 D.

Additional comments

The Zero 6 and Z Plus designs are the basis for fitting other, related lenses: a range of tinted lenses and the Zero 6 front toroidal surface design.

Medium water content, spherical lathe-cut lenses (e.g Hydrocurve II 55)

A medium water content lens for daily or extended wear. Manufactured by Wesley-Jessen.

Material properties

Chemical nature:	Filcon 3b a copolymer of HEMA, N– (1, 1-dimethyl-3-oxobutylacryl-amide) and methacrylic acid
Water content:	55%
Oxygen permeability:	14.2×10^{-11} at 21 °C
Refractive index:	1.41
Light transmission:	90%
Specific gravity:	1.15

Manufacturing method

Lathe-cutting, although spherical lenses have a moulded back surface radius.

Lens geometry

The posterior surface is of mono-curve construction. Centre thickness is 0.05 mm for a lens of power –3.00 D.

Parameters available

The parameters available are 8.50:14.00 and 8.80:14.50 (mm) in powers from +20.00 D to –12.00 D.

Fitting set

Lenses are provided in a range of powers for the two available fittings. The preferred method of fitting is from a lens stock.

Fitting technique

The flatter fitting, 8.80:14.50, is used in the majority of cases. It is, therefore, the initial choice of lens unless the cornea is obviously small. The total diameter should be 1.50–2.00 mm larger than the horizontal visible iris diameter. A lens which is too flat tends to buckle at the edge and gives unacceptable lid sensation (*see Figure 11.14*).

Typical specification

A typical specification is: 8.80:14.50 –3.00 D.

Additional comments

Hydrocurve II lenses are available in a variety of other forms:

- With a lower water content of 45%. Fitting parameters are: 8.30:13.50, 8.60:13.50 and 8.90:14.50, all in the same power range of +20.00 D to –12.00 D.*
- A toroidal back surface design.
- A concentric bifocal consisting of a central distance portion surrounded by a variable focus near portion (*see* Chapter 16).
- A range of four tints (with the name 'Softmate 1').
- The 'Elite', with deposit-resistant properties.

Medium water content, spherical front surface, elliptical back surface, lathe-cut lenses

(e.g. Weicon CE)

Medium water, elliptical geometry, spherical soft lens; indicated for 'flexible' or 'convenience wear'.
Manufactured by Ciba Vision

Material properties

Chemical nature:	Filcon 4a; copolymer of methyl methacrylic acid and vinyl pyrrolidone
Water content:	60%
Oxygen permeability:	28×10^{-11} at 35 °C
Refractive index:	1.404
Specific gravity:	1.10 (wet); 1.19 (dry)
Linear swell factor:	1.38
Elongation at break:	332%
Centre thickness:	0.09 mm at –3.00 D
Edge thickness:	0.12 mm
Manufacture:	Lathe-cut
Posterior design:	Elliptical
Engravings:	e.g. CIBA C FL C indicates the Weicon CE FL indicates the flat fitting ST indicates the steep fitting

*The high plus (aphakic) powers are not available in all countries.

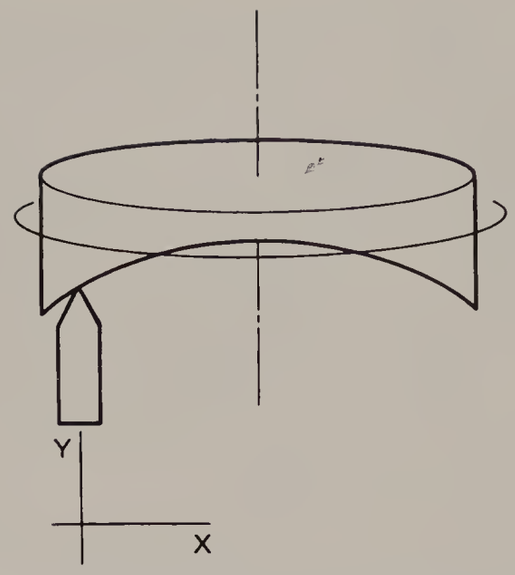


Figure 11.23 Schematic representation of computer numeric controlled (CNC) lathe, where X and Y coordinates are controlled by a microprocessor (Courtesy of Ciba Vision, UK, Ltd)

Care system compatibility:	Recommended for use with hydrogen peroxide care systems; *not* recommended for use with thermal or sorbic acid systems.

Manufacturing method

All lenses are manufactured on computer numeric controlled (CNC) lathes. This is represented schematically in *Figure 11.23* where the X and Y coordinates of the diamond tool are controlled by a microprocessor (*see* Chapter 21).

Lens geometry

All lenses have an elliptical back surface and are engraved with the parameters (*Figure 11.24*). Lenses do not have a true back surface radius, but have a choice of two 'fitting values' which are designated either 'flat' (FL) or 'steep' (ST). Both vertex radius and eccentricity are varied to give a consistent performance throughout the power range. Lenses also feature the 'tangential bevel' shown in *Figure 11.25*, which gives a continuous transition from the back surface to the lens edge where it permits a 'ski' effect

Parameters available

These are indicated in *Table 11.8*.

Fitting technique

Initial trial lens fitting: start with flat 13.80 mm lens. Because of the aspherical back surface, changing the total diameter does not necessarily alter the fitting character-

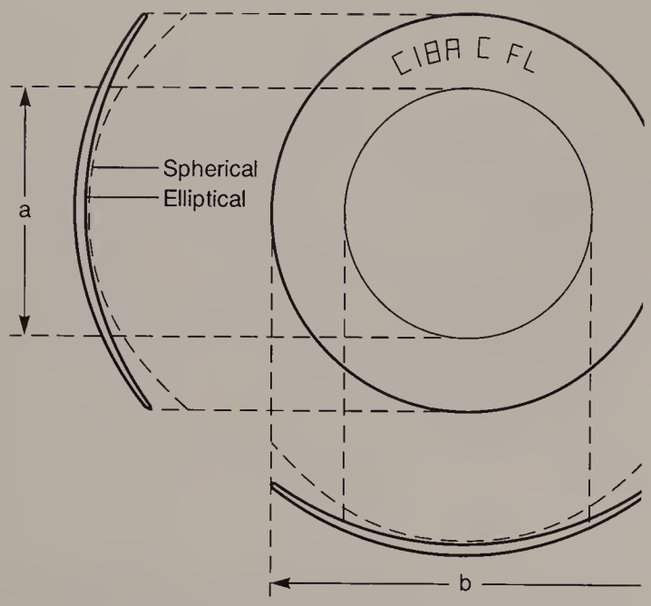


Figure 11.24 Diagram of a typical Weicon 38E lens showing (*a*) how the elliptical back surface geometry differs from that of a spherical lens, and (*b*) a Ciba Vision-style engraving for lens identification (Courtesy of Ciba Vision, UK, Ltd)

istics. The steeper fitting value is tried only if the lens is obviously mobile after complete settling.

A correctly fitting lens will behave as indicated in *Table 11.3*, but lens mobility up to 0.50 mm may be acceptable. Although the elliptical design is suitable for a wide range of patients, there are nevertheless some corneal geometries for which a satisfactory fitting cannot be achieved. These require a more traditional lens design with a spherical back surface.

Typical specification

A typical specification is C FL 13.80 –3.00 D

Additional comments

The lens is also available in HEMA material as the Weicon E. Alternative spherical designs are available (e.g. Cibasoft). Weicon CE is also available in a toric design.

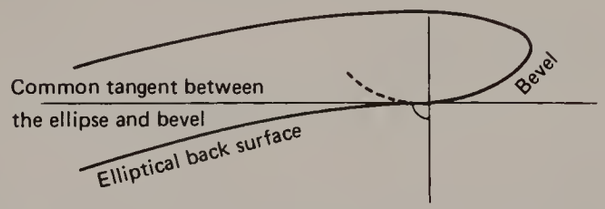


Figure 11.25 'Tangential bevel' of the Weicon 38E which allows a continuous transition from the elliptical back surface to the lens edge (Courtesy of Ciba Vision, UK, Ltd)

Table 11.8 Parameters available for Weicon CE

BOZR (mm)	*TD (mm)*	*Power (D)*	*BOZD (mm)*
Flat/steep	13.00	(+20.00	7.50 to 9.00
Flat/steep	13.80	to	(varies with)
Flat/steep	14.60	–20.00)	power)

High water content aspherical cast-moulded lenses

(e.g. Excelens)

Manufacured by Ciba Vision

Material properties

Chemical nature:	Atalfilcon A. High water content spherical soft lens. (Manufacturer claims new generation deposit-resistant material)
Water content:	64%
Oxygen permeability:	27×10^{-11}
Refractive index:	1.386
Specific gravity:	1.09 (wet); 1.21 (dry)
Elongation at break:	330%
Centre thickness:	minus: 0.12 mm up to –3.00; 0.11 mm to –6.00 D plus: varies with power; e.g. 0.167 mm at + 3.00 D
Manufacturing method:	Cast-moulded
Lens geometry:	Anterior design: tri-curve Posterior design: bi-curve
Engravings:	eg. CIBA X4 Letter X indicates 14.00 mm diameter '4' indicates 8.40 BOZR; '6', 8.60 mm and '8', 8.80 mm respectively
Tint:	Blue visibility handling tint

Parameters available

The parameters available are shown in *Table 11.9*

Table 11.9 Parameters available for Excelens

BOZR (mm)	*TD (mm)*	*BVP (D)*	*BOZD (mm)*
8.40	14.00	(+6.00	8.00 for – powers
8.60	14.00	to	7.00 for + powers
8.80	14.00	–10.00)	

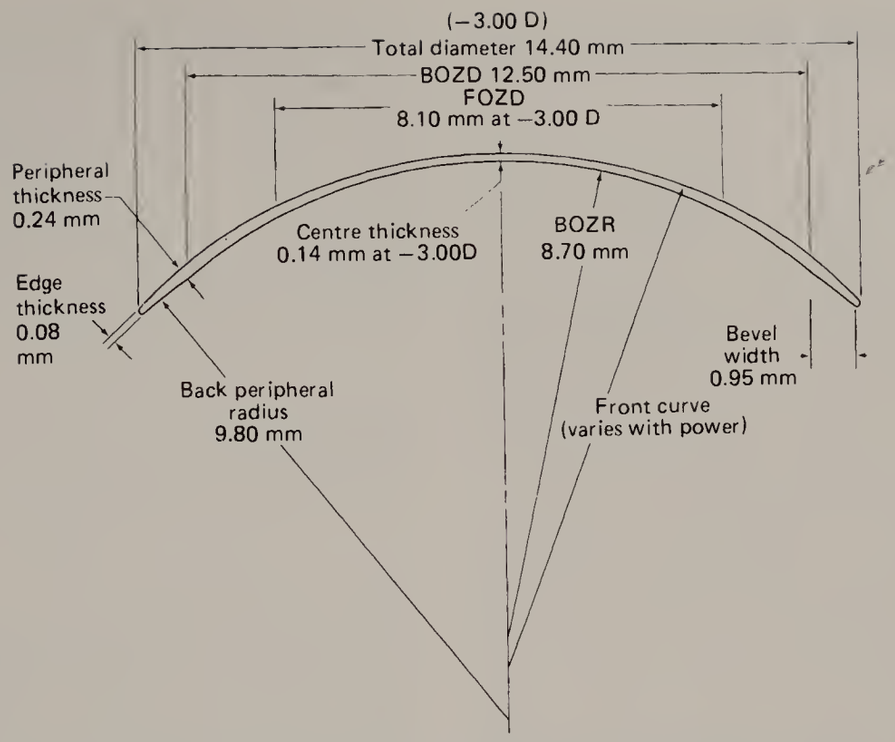


Figure 11.26 Geometry of a Permaflex soft lens with the specification: 8.70:14.40 – 3.00 (Courtesy of Wesley-Jessen)

Fitting technique

Start with middle BOZR: 8.60/14.00

Care system compatibility

Suitable for use with all care systems – thermal, chemical, peroxide, chlorine.

High water content spherical moulded lenses

(e.g. Permaflex 74)

A high water content lens for daily or extended wear. Manufactured by Wesley-Jessen.

Material properties

Chemical nature:	Filcon 4a. A hydrophilic cross-linked copolymer of methyl methacrylate, vinyl pyrrolidone and other methacrylates
Water content:	73.5%
Oxygen permeability:	34×10^{-11} at 25 °C 43×10^{-11} at 35 °C
Refractive index:	1.385
Linear swell factor:	1.60 at 21 °C
Tensile strength:	7.6 kg/cm
Elongation at break:	315%

Manufacturing method

Lenses are cast-moulded.

Lens geometry

A typical lens of power –3.00 D is shown in *Figure 11.26*. Centre thickness varies from 0.08 mm to 0.22 mm for negative powers with a minimum FOZD of 7.50 mm.

Parameters available

These are shown in *Table 11.10*.

Fitting set

Lenses are provided in a range of powers for the two radii. The preferred method of fitting is from a lens stock.

Fitting technique

The spherical 8.70 mm BOZR fits a high percentage of patients. Because of the high water content, sufficient time

Table 11.10 Parameters available for Permaflex lenses

BOZR (mm)	8.70
TD (mm)	14.40
BVP (D)	−10.00 to + 8.00

must be allowed for lens settling or an apparently correct fitting may subsequently become tight.

Typical specification

A typical specification is: 8.70:14.40 –3.00 D.

Additional comments

Permaflex lenses also form the basis of the Precision UV monthly disposable lenses.

High water content spherical, lathe-cut lenses *(e.g. Lunelle ES 70)*

A high water content lens available for corneal and semi-scleral fitting.
Manufactured by Essilor.

Material properties

Chemical nature:	Filcon 4a. Copolymer of PMMA and polyvinyl pyrrolidone
Water content:	70%
Oxygen permeability:	35×10^{-11} at 25 °C
Refractive index:	1.38
Linear swell factor:	1.50
Optical transmission:	98.6%
Modulus of elasticity:	15.00 kgf/cm^2
Tensile strength:	18 ± 2 kgf/cm^2

Manufacturing method

Lathe-cutting

Lens geometry

Lenses have a spherical back surface with an average thickness of 0.15 mm. The relative stiffness of the material gives a claimed advantage in correcting low to medium degrees of astigmatism (0.75 to 1.25 D).

Parameters available

These are given in *Table 11.11*.

Table 11.11 Parameters available for Lunelle ES 70 lenses

BOZR (mm)	*TD (mm)*	*BVP (D)*
7.70 to 8.30 (0.30 steps)	13.00	Plano to –12.00
8.00 to 9.20 (0.30 steps)	14.00	±20.00

Table 11.12 Recommended fitting set for Lunelle ES 70 lenses

BOZR (mm)	*TD (mm)*	
7.70	13.00	
8.00	13.00	
8.30		14.00
8.60		14.00
8.90		14.00
Back vertex power (D)	–3.00	±3.00

Aphakic trial lenses also available

Fitting set

This is given in *Table 11.12*.

Fitting technique

A total diameter of 13.00 mm is the initial selection for 11.25 mm corneal diameter or less; for larger corneas 14.00 mm lenses are used. The manufacturers recommend fitting 0.30 mm and 0.60 mm flatter than flattest K for 13.00 mm and 14.00 mm lenses respectively. Both Atkinson (1986) and Fanti (1986), however, achieved better clinical results with flatter back surface radii. Lens movement should be about 0.50 mm on blinking. The most common fittings are, therefore, 8.60 and 8.90 mm back surface radii with the 14.00 mm total diameter.

Typical specification

A typical specification is 8.60:14.00 –3.00 D.

Additional comments

A low rate of lens dehydration is claimed, which is useful to avoid or assist dry eye problems. Fanti (1986), however, deduced from refractive results that there was some degree of reduced water content on the eye, requiring over-correction in the higher power ranges.

The Lunelle ES 70 provides the basis for fitting other Lunelle lenses:

- Two toroidal front surface designs.
- The Solaire, which includes a sun-filter and an ultraviolet inhibitor.
- The aphakic UV, which contains an ultraviolet inhibitor.

Medium water content spherical lathe-cut lenses *(e.g. Weflex 55)*

A multiple fitting mid-water content standard thickness lens. Manufactured by Wöhlk Contact Linsen, a subsidiary of Zeiss.

Table 11.13 Parameters available for Weflex 55

TD (mm)	*BOZR (mm)*	*BVP (D)*
13.70	8.10 to 9.30 (0.30 steps)	–20.00 to +20.00 (0.25 steps)
14.30	8.40 to 9.60 (0.30 steps)	–20.00 to +10.00 (0.25 steps)

Material properties

Chemical nature:	Filcon 4a. Poly-alkylmethacrylate-NVP
Water content:	55%
Oxygen permeability:	23×10^{-11} at 21 °C
Refractive index:	1.409
Tensile strength:	13.9 ± 7.1 kgf/cm^2

Manufacturing method

All lenses are lathe-cut

Lens geometry

Lenses have spherical back surface with a geometric centre thickness at –3.00 D of 0.16 mm.

Parameters

Parameter availability is shown in *Table 11.13*.

Fitting technique

The fitting guides to the Weflex 55 suggest the more traditional fitting method of selecting the mean *K* reading and adding a specified value to select the initial fitting lens BOZR. These values are 0.70 mm and 1.00 mm for the 13.70 mm and 14.30 mm diameters, respectively. The final fit should be as flat as possible whilst still maintaining good lens stability and vision.

Typical lens specification

8.70:13.70–3.00 D.

Spun-cast lenses

Bausch & Lomb Soflens

The Bausch & Lomb Soflens is manufactured by the spin-casting process, which is the same in principle as the centrifugal technique employed for the original gel lenses from Czechoslovakia. Bausch & Lomb extensively refined the basic spinning process from 1966 onwards. The lens geometry was redesigned and elaborate techniques introduced to ensure quality control and reproducibility.

Bausch & Lomb was the first contact lens manufacturer to receive FDA approval, in 1971, not specifically for the lens, but for the entire system. It therefore included such items as the carrying case, heat disinfection unit and storage case.

Material properties

Chemical nature:	Filcon 1a. HEMA cross-linked polymer
Equilibrated in 0.9% saline:	38.6%
Oxygen permeability:	8.0×10^{-11} at 20 °C
Refractive index:	1.43 (wet)
Linear swell factor:	1.18
Softening point:	120 °C
Visible light transmission:	>97%

Manufacturing method

The manufacturing process has been described by Watts (1971) and Wycoff (1972). The monomer mixture and the solvent, glycerol, are introduced into ground and highly polished female moulds, which are mounted on a central spindle to permit rotation at speed. Polymerization takes place while the mould is spinning about its central axis. Water is then pumped in to replace the glycerol and to hydrate the lens, which is afterwards removed manually from the mould for edging. The lenses are extracted for 22 hours in circulating distilled water at 87 °C to remove any remaining unreacted monomers, catalyst or water-soluble polymer. After checking, the lenses are finally sealed in 5 ml pharmaceutical vials for autoclaving. The process is different from the cast-moulding or pressing techniques employed by other manufacturers for two reasons. First, the mould is open and, secondly, it is spinning during polymerization.

Lens geometry

The spherical curvature of the mould itself determines the anterior surface of the lens which is designated the 'base curve' or Series. The posterior lens surface, which governs the power, is aspherical, due to centrifugal force distributing liquid polymer away from the apex of the mould according to its speed of rotation. A faster speed gives a higher minus lens, and *vice versa*. The exact shape of the back surface depends on a number of other factors, including the volume of polymer used, surface tension, rate of polymerization and the duration of the polymerization process. The following formula, associated with *Figure 11.27*, has been applied (Wichterle and Wichterle, 1970; Coombs, 1981).

$$Z = \frac{W^2 X^2}{2g} + K$$

where Z = distance on vertical axis
X = distance on horizontal axis
W = speed of rotation
g = gravity constant
K = a function of surface tension

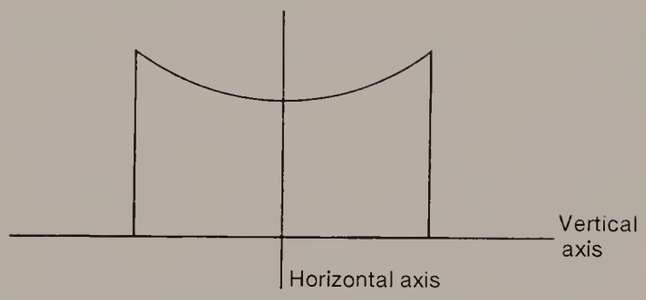


Figure 11.27 Female mould used for spin-casting

The aspherical posterior surface of the lens was related by Poster (1975) to the mathematical form of an ellipse. Within a particular series, the surface shape gradually changes from oblate to prolate as the power is increased, as indicated in *Figure 11.28*.

The back surface cannot therefore be defined as having a BOZR since only the central 2–3 mm is in fact spherical. Thus, the term 'posterior apical radius' (PAR) is used. To aid understanding of fitting the term 'equivalent base curve' was introduced.

Figure 11.29 shows how progressively higher powers are obtained by using steeper posterior apical radii in conjunction with a constant sag and fixed radius for the front surface. It illustrates the way in which a spun-cast lens differs fundamentally from any other type of lens, either hard or soft. First, the 'base curve' or Series relates to the anterior surface of the lens; this is the opposite of lathe-cut lenses where the BOZR, sometimes referred to as the 'base curve', is always the posterior surface. Secondly, the power for any given series is determined by the back surface, also the opposite of all other lenses.

The spin-casting process has certain advantages. It is possible to design and manufacture lenses with better surface quality and edge shape. It is a mass production process so that reproducibility and consistency of manufacture are more easily maintained (Hanks, 1976). However, the method imposes limitations on the variety of back surface forms which may be conveniently obtained and the entire range of powers is not produced for every anterior surface radius.

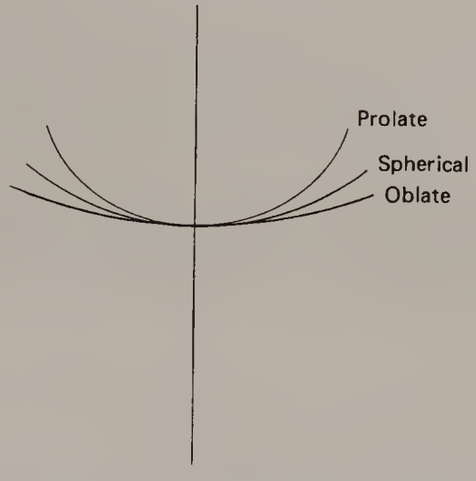


Figure 11.28 Aspherical back surfaces of spun-cast lenses: the steepest curve, associated with the highest negative power, is in the form of the prolate portion of an ellipse, while the flattest curve is that of the oblate portion of an ellipse, the intermediate curve being spherical

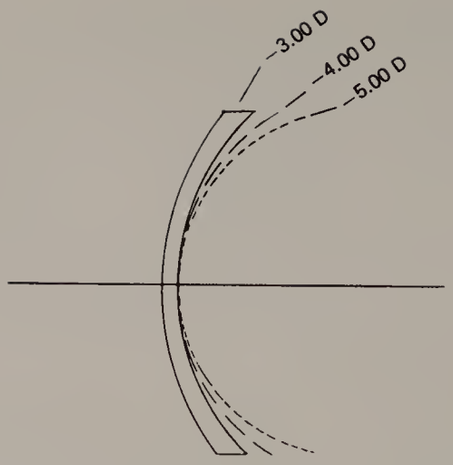


Figure 11.29 Bausch & Lomb Soflenses. The front surface radius is constant. Variation in power is achieved by altering the posterior apical radius (PAR); the steeper it is, the higher the negative power

Parameters available

The parameters available are shown in *Table 11.14*.

Fitting set

The preferred method of fitting is from a comprehensive lens stock but six lens trial sets are available for most series.

Fitting technique

The range of Bausch & Lomb HEMA lenses currently available is shown in *Table 11.14*. All are spun-cast with the exceptions of the Optima 38 and SP which are hybrid in character, the Soflens 66 which is dry cast moulded, and the Optima Toric which is fully lathe-cut. The Optima 38 and SP have a spun-cast front and lathed posterior surface. Most of the lenses for myopia have a constant centre thickness and, since the lenses for a given series are produced from identical moulds, the sag of all lenses in that series is constant.

Spun-cast lenses possess greater flexibility than their lathed counterparts (Burgess *et al.*, 1985). Lenses therefore drape more effectively over the cornea. This factor and the constant sag means that for any given series, a 'one-fit' approach is more feasible, despite variations in the PARs. (A change in power of 0.25 D is approximately equivalent

Table 11.14 Parameters available for Bausch & Lomb soft lenses

Lens series	*BVP (D)*	*TD (mm)*	*Centre thickness (mm)*	*Sag (mm)*
Sofspin	–0.25 to –12.00	14.00	0.05 to 0.09	
U3	–9.00 to +6.00	13.50	0.07 to 0.18	3.09
U4	–9.00 to +6.00	14.50	0.07 to 0.18	4.05
B3	–20.00 to +6.00	13.50	0.12 to 0.30	3.10 (3.20)*
B4	–9.00 to + 6.00	14.50	0.12 to 0.30	3.59
O3	–1.00 to –9.00	13.50	0.035	3.18 (3.20)†
O4	–1.00 to –9.00	14.50	0.035	4.10 (3.68)‡
HO3	–8.00 to –20.00	13.50	0.035	3.61
HO4	–8.00 to –20.00	14.50	0.035	3.67
M3	+3.00 to +14.00	13.50	0.23 to 0.44	3.41 to 3.61
M4	+3.00 to +14.00	14.50	0.23 to 0.44	3.66 to 3.86
H3	+10.00 to +20.00	13.50	0.48 to 0.61	3.40 to 3.47
H4	+10.00 to +20.00	14.50	0.48 to 0.61	3.69 to 3.80
Optima 38 and SP	–12.00 to +5.00	14.00	0.06 at –3.00	(8.40; 8.70; 9.00)§
Seequence (Disp)	–9.00 to +4.00	14.00	0.035 at –3.00	
Medalist (Disp)	–9.00 to +4.00	14.00	0.035 at –3.00	(8.40; 8.70; 9.00)§
Medalist 66 (Disp)	–9.00 to +6.00	14.20	0.08 to 0.12	

Sag values are those shown but the values in parentheses apply to the following denoted BVP ranges (D):
*–12.50 to –20.00; †–1.00 to –1.25; ‡–1.00 to –1.75.
§Equivalent base curve.
(Disp) = disposable

to a change in PAR of 0.05 mm.) Fitting therefore depends mainly upon lens thickness and total diameter, and the specification is expressed as a letter and a number. The letter for a series not only defines the front surface curvature, but also the centre thickness.

The number refers to the total diameter. Thus the suffix '4' denotes a 14.50 mm diameter; the suffix '3' a 13.50 mm diameter; and where there is no numerical suffix, as for the original F Series, a 12.50 mm diameter.

The recommended fitting method is to select lenses on the following basis:

- Power according to spectacle Rx and vertex distance.
- Diameter on the basis of horizontal corneal diameter: 13.50 mm lenses are used where the HVID is less than 11.75 mm, and 14.50 mm lenses where this is greater.
- Series and thickness according to physiological and handling considerations.

The U3 and U4 Series lenses with a centre thickness of 0.07 mm are the most commonly used and generally provide good comfort. They have continued to be the first choice option within the Bausch & Lomb range, but the recently introduced Medalist lens is growing in popularity in common with other diposable lenses.

Fitting characteristics for Bausch & Lomb lenses are mainly as described in Table 11.3, except that movement on blinking may be less than 0.3 mm, and slight lens decentration is common. It is particularly important to achieve adequate centration with complete corneal coverage. A decentred lens, because of its aspheric optic, can give poor visual acuity. It can also result in arcuate staining at the limbus where the lens edge produces a combination of corneal drying and abrasion. This would occur on the nasal cornea of the eye in *Figure 11.30*, which shows a lens decentred slightly temporally. Lens decentration might occur with either a loose or a tight fitting, but in the latter case there is no recovery movement on blinking.

If adequate centration cannot be obtained with the initial total diameter, the next larger lens in the same 'letter' series, should be tried. For example if a U3 lens is too small, a U4 should be tried.

Plus lenses are selected according to similar principles, although centre thickness varies with power. It should also be noted that the power range is divided into three overlapping groups, each with a different sag.

A typical specification is: –3.00 U4.



Figure 11.30 A soft lens decentred temporally. This can give rise to nasal corneolimbal drying and abrasion

Additional comments

The U3, U4 and Optima are produced in a range of three tints (blue, aqua and green). Bausch & Lomb also have available a toric lens – Optima Toric – and lenses potentially capable of extended wear – the B&L 70 and the high plus CW79.

Since the expiry of the Bausch & Lomb patent, other companies such as Hydron have begun to produce spun-cast lenses of different design, including the Ultra-T toric lens. The fitting principles, however, are similar.

Extended wear lenses

Extended wear is covered in detail in Chapter 15, but it may be noted here that soft lenses have been routinely fitted for this purpose since the early 1970s with the introduction of Permalens by de Carle (1972) and Sauflon PW by the C.L.M. Group Ltd. Since then, improvements have occurred not only in lens designs and materials, but also in the understanding of the physiological requirements of the cornea to achieve extended wear more safely.

An essential requirement is for lenses to provide an adequate supply of oxygen to the cornea even under closed eye conditions. As mentioned previously soft lenses attempt to achieve this in one of two ways:

1. By means of a high water content, e.g. Permaflex (74%) and Lunelle (70%). Lenses have high Dk values, but the potential problems with this approach are lens fragility, deposits and discoloration, and a greater likelihood of solution reaction with a preserved system.
2. By making lower water content lenses extremely thin, e.g. Bausch & Lomb O series (t_c = 0.035 mm) and CSI-T (t_c = 0.035 mm). These have good *Dk/t* values, but there can be problems with handling and less efficient tear exchange on blinking to remove debris from beneath the lens.

With both types of approach, problems may arise with lens dehydration and corneal desiccation, oedematous responses such as striae or microcysts, giant papillary conjunctivitis, long-term vascularization and the ever-present risk of infection. Extreme care is, therefore, required by both patient and practitioner in fitting extended wear lenses. The patient must be made aware of the potential hazards and given careful instructions, preferably in writing, regarding:

- How and when to remove lenses.
- The need for regular lens replacements.
- Proper lens cleaning and disinfection. The preferred system comprises:
  (a) The compulsory use of a surfactant cleaner.
  (b) Hydrogen peroxide disinfection for re-useable EW types or
  (c) Chemical disinfection, e.g. Optifree or Complete, suitable for disposable lenses.
  (d) Regular replacement of lens cases.

When used for purely cosmetic reasons, the clinical need must be carefully balanced against the possible risks. However, there are many patients for whom extended wear lenses are the most suitable if not the only possible form of visual correction:

- Aphakes, where handling difficulties preclude daily wear.
- Other poor lens handlers.
- Therapeutic cases where the lens is used as a corneal bandage for conditions such as bullous keratopathy, recurrent erosions and burns (*see* Chapter 20.7).
- Young children, where daytime sleep may occur and or if daily handling is not feasible (*see* Chapter 20.6).
- For certain occupations or vocational uses where good acuity is required immediately on wakening, e.g. medical personnel in hospitals, firemen, etc.
- Where soft lens patients may intermittently have no facility for lens disinfection, e.g. bush walking and other outdoor pursuits.
- As one component of a low vision aid system, where poor acuity precludes regular lens handling.

In addition, there are obvious advantages in wearing, on a mainly daily basis, lenses which are suitable for extended wear because of their excellent physiological properties. Although lenses are removed nearly every evening, most patients may be permitted the flexibility of using them on an occasional overnight basis with little or no chance of adverse ocular response. This form of occasional overnight wear is referred to as flexible wear or daily wear plus.

Disposable lenses and frequent replacement

Clinical experience confirms that the performance of a soft contact lens is best when it is new. Specific problems with lens deposits, ageing and inadequate cleaning and disinfection can lead to gradual reduction in both vision and comfort with subsequent increased risk of infection. The need to enable lens performance to be more consistent led to the introduction of more frequently replaced and disposable lenses throughout the 1980s.

Although the term 'disposable' was originally applied to single use lenses worn continuously for one week and then discarded, it has now been expanded to include lenses used for up to one month of conventional daily wear. Frequent replacement is used to describe lenses replaced on a regular basis, such as 3 months, 6 months or 12 months. In reality contact lens companies offering lenses on a frequent replacement system generally base this frequency on either 3 or 6 months.

The development of the first disposable lens (Danalens) took place in Denmark in the early 1980s, and was restricted to weekly extended wear. Subsequent development and introduction worldwide of the Acuvue lens has been instrumental in making disposable lenses the first choice for extended wear for many patients.

The use of disposables for conventional wear has developed more recently, during the late 1980s and early 1990s. The constant difficulty of rejuvenating old lenses and their related problems has led to the widescale use of frequent replacement or disposable lenses as the preferred system for much soft lens wear. Many practitioners now prescribe them as first choice. Consequently many contact lens companies offer disposable lenses, whether these were specifically developed for the purpose (e.g. Vistakon Acuvue and Surevue) or are modifications of existing lenses (Wesley-Jessen Precision UV; Bausch & Lomb Medalist).

Daily disposable lenses are also becoming more readily available. The Vistakon Acuvue lens, for example, is made in two BOZRs of 8.50 and 9.00 mm and a TD of 14.20 mm with powers from –9.00D to +6.00D; this range of parameters makes the lenses a viability for a large number of ametropes. However, whilst the contact lens revolution that has been brought about by the introduction of such lenses has solved most of the problems of deposit formation, as well as those of compliance, it must be remembered that good fitting criteria are still important. It is especially important to recognize when a fitting is unsatisfactory and to refit the patient accordingly. Also, any disposable lenses that are worn more than once, must still be rigorously cleaned and disinfected in order to avoid unnecessary risk of infection (Radford *et al.*, 1993).

Toric soft lenses

Full details of toric lenses are given in Chapter 14 but the following practical considerations should be taken into account during fitting.

- Unlike most rigid lenses for astigmatism, toric soft lenses are prescribed, not to improve the physical fitting, but to provide good visual acuity where spherical lenses are unable to achieve this.
- Several different designs have evolved so that toric soft lenses may be of corneal or semi-scleral diameter, with the toroidal curve on either the back or front surface, and of low, mid or high water content. They are also available as disposable lenses (e.g. Ciba Focus; Hydron Acti toric lenses).
- The main influences acting on a soft lens have been described as gravity, hydrostatic forces, lens elasticity and lid pressure (Grant, 1986).
- In cases of with-the-rule astigmatism, the thickest portions of the visually correcting toric lens lie at the top and bottom. The normal action of the lids is to rotate the lens 90% off-axis to bring the thickest part of the lens into the horizontal meridian. To prevent rotation, and to maintain correct orientation of the lens with respect to the cylinder axis, soft lenses must be stabilized on the eye. Various methods have been used for this purpose, either on their own or in combination: prism ballast, truncation, 'dynamic stabilization', back surface toricity, and shapes other than circular.

Toroidal back surface soft lenses

Toroidal back surfaces have evolved logically from the fact that the astigmatism encountered in practice is predominantly corneal. It is measurable with the keratometer and a comparison with the spectacle refraction gives an immediate prediction of the likelihood of visual success. Because the back surface of the lens is essentially designed to neutralize the toroidal cornea, by replacing it with the spherical front refracting surface of the lens, lenticular astigmatism is not theoretically correctable with such a lens. Clinically, however, reasonable results can sometimes be obtained. Despite the complexity of the actual lens design, fitting procedures are straightforward and the toric calculations relatively simple. Cylinders of 6.00 D and more can be corrected.

The toric difference between the radii of the principal meridians, representing the cylinder to be corrected in minus form, may be determined from a radius to surface power conversion chart. Additional considerations relating to induced astigmatism are discussed in Chapters 5 and 14.

Because least distortion occurs when it is correctly aligned, the elasticity of the lens ensures that the back surface has a natural stabilizing effect when placed in apposition to an equivalently toroidal cornea (Grant, 1986). However, stabilization is markedly assisted either by prism ballast (e.g. Hydroflex/m-T, Hydron Ultra-T, Hydrocurve 3) or by truncation (e.g. Hydroflex TS).

Toroidal front surface soft lenses

Toroidal front surfaces are capable of correcting both corneal and lenticular astigmatism, although constraints of lens thickness and geometry generally put an upper limit of about 4.50D on the cylinder to be corrected. Several designs of lens are possible, the methods of stabilization being prism ballast (e.g. Bausch & Lomb), truncation, or dynamic stabilization (e.g. Weicon, Lunelle). The back surface may be either spherical (e.g. Igel) or aspherical (e.g. Hydron).

Truncation has been much less popular since the introduction of slab-off and thin-zone designs but is feasible in either single or double form. Sometimes it is sufficient to achieve stabilization using truncation on its own, but single truncated lenses are usually more effective when incorporating base-down prism of 1 or $1\frac{1}{2}\ \Delta$. Dynamic stabilization was a term first used by Fanti (1975) with the introduction of the Weicon-T design. The method consists of chamfering the top and bottom portions of the front of the lens in order to reduce the thickness where the stabilization zones fit beneath the eyelids. The BOZD is typically 8.00 mm and, therefore generally lies within the palpebral aperture.

For either toroidal back or front surfaces, a further refinement of lens design is to incorporate the stabilizing prism only in the peripheral areas of the lens (e.g. Hydron Zero 6 Toric). A prism-free optic allows lenses to be made thinner. It has the additional advantage that, where only one eye requires toric correction, there is no likelihood of introducing vertical imbalance. Toric lenses should ideally

be made from high Dk materials to compensate for their greater thickness. However, physiological requirements must be balanced against greater difficulty in manufacture and shorter life span. With all types of toric soft lens, there is a much greater tendency for deposition at the thicker base of the lens or along the edge of the truncation. Patients must therefore be advised to pay particular attention to surface cleaning in this area of the lens.

Toric lenses may be either individually prescribed and calculated or selected from a simplified range predetermined by the laboratory.

The former method permits the fitting of most prescriptions which it is technically feasible to manufacture, with a comprehensive range of lens parameters, water contents, spherical and cylinder powers, and axis positions. The main disadvantages are the length of time required to obtain lenses and additional costs.

The latter, simplified method enables rapid fitting from either the practitioner's or laboratory's stock of lenses. However, for this to be feasible, fitting parameters are usually very restricted. Cylinder powers may be limited to 0.50 D or 0.75 D steps with an upper limit of about 2.50 D, because this will be sufficient for about 90% of patients (Holden, 1975).

Oblique cylinders, which are generally more difficult to fit, are frequently omitted, axes being limited to about 20° either side of horizontal and vertical.

Fitting routine

- Decide on whether a toroidal back or front surface is required with respect to corneal or lenticular astigmatism and cylinder power.
- Decide on the method of stabilization. A prism ballast lens placed on one eye and a thin-zone design on the other usually determines both a preference in comfort by the patient and whether prism or thin-zone is likely to give better stabilization.
- Determine the best fitting trial lens.
- Determine the lens orientation on the eye from the angle at which the truncation settles or from the lens markings present on most non-truncated trial lenses. These are usually a dot or radial engravings; either at the base of the lens or in the 3 and 9 o'clock position. Trial lenses establish at the fitting stage whether compensation is required for the cylinder axis. The most common result is a 5° nasal rotation of the lens base. Success is unlikely if the rotation is more than 20°, even if consistent, and it is usually better to try a different fitting or lens type.
- Over-refract with a fully settled spherical trial lens of power as near as possible to the spectacle Rx. Apart from any vertex distance considerations, this is always worthwhile to ensure that the results correlate, particularly in respect of cylinder power and axis. If there is any discrepancy, the procedure should be repeated with a different trial lens.
- If axis compensation has been incorporated because of lens rotation at the initial fitting, the prescription lens should also settle with exactly the same degree of rotation.
- The nature of the over-refraction may be used as a guide with the prescription lens. If cylinder is present at the original axis or at 90° to this, under- or over-correction is suggested. If it takes the form of a plus sphere with a minus cylinder of twice the power (e.g. +0.50 D/–1.00 DC) at an oblique axis, it is likely to be caused by mislocation of the cylinder axis.

Particular care should be taken with fitting essentially uniocular patients. They are much more disturbed by any instability of vision caused by lens rotation on blinking.

Soft lenses for presbyopia

Presbyopic contact lens correction is an ever-increasing challenge for both patient and practitioner (Lloyd, 1984; Hine and Holden, 1992). Despite the number of potential patients however, the use of bifocal contact lenses accounts for only a small proportion of contact lenses prescribed (Back *et al.*, 1989). As a result a number of different fitting philosophies and contact lens designs continue to be developed for the presbyopic patient.

The three main options open to the practitioner are:

- Reading spectacles
- Monovision
- Bifocal soft lenses

Whilst the first option is the simplest, it is not always the most acceptable to the patient. Consequently monovision, bifocal lenses or a combination of the two are preferred by the strongly motivated contact lens-wearing presbyope.

The easiest contact lens system, monovision, still remains the more successful alternative to reading spectacles (Back *et al.*, 1992). It is usual to correct the non-dominant eye for near and the dominant eye for distance, especially where driving is of prime concern. However, other considerations may be of more importance, such as the position of reading material at work. In all cases good patient counselling is important and an extended tolerance trial, preferably for a few days, can confirm whether this relatively simple approach is successful.

If the visual demands are not met with monovision there are a number of soft bifocal designs. Bifocal soft lenses, like torics, may be either individually prescribed by the practitioner or selected from predetermined laboratory designs.

Various designs are now available (*see* Chapter 16), although most of the more successful current types are concentric and based on the principle of simultaneous vision. The majority of these have a central distance portion surrounded by an annulus containing the reading addition (e.g. Hydrocurve, Bausch & Lomb PA1, Weicon 38E). The reverse approach is also possible (centre-near, e.g. No. 7 (UK) Simulvue). This can also be combined with a blended varifocal design (e.g. Nissel PV200), with the reading area

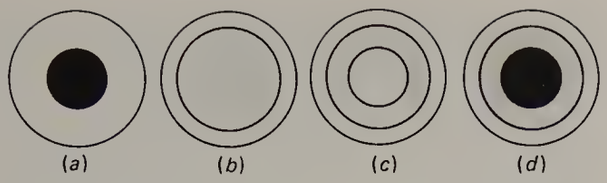


Figure 11.31 Variations possible with soft lens tints. (*a*) A black (opaque) pupil on a clear lens; (*b*) a tinted iris with clear peripheral annulus; (*c*) a tinted iris with clear peripheral annulus and clear pupil; (*d*) a tinted iris with clear peripheral annulus and black (opaque) pupil (Courtesy of Igel International Ltd)

at the geometric centre of the lens surrounded by the distance portion. There are also segment bifocals and those based on the principles of diffraction (Hydron Echelon) which are independent of pupil size.

Special features of soft lenses

Lens identification

Several makes of soft lens have some form of identification at the periphery. This may represent:

- A code, serial or lot number.
- Details of partial or complete lens specification.
- Location of cylinder axis or prism base.
- Position of segment to assist bifocal fitting.

The earlier problems with mechanical engravings, which could either develop fractures or attract deposits, have largely been eliminated by modern laser techniques. An alternative method imprints the information on to the lens by photographic means; and this same method can be used by the practitioner to mark prescription lenses with 'R', 'L' or dots (*see* Chapter 22). In general, lens markings prove useful because they assist both patient and practitioner with lens identification.

Tinted and cosmetic soft lenses (*see* Chapter 20.6)

Many soft lenses are only available as clear lenses, although the introduction of a pale blue handling tint is becoming more popular. Several laboratories offer a range of tinted lenses, mainly for cosmetic reasons. Tints may be translucent, to enhance the colour of the patient's own iris pattern, or opaque and semi-opaque to provide a more radical change of appearance. Solid tints may be either printed or produced photographically. Lenses usually have an iris diameter of about 11.50 mm, surrounded by a clear annulus to give a natural appearance on the eye. It is also possible to provide clear or black pupils (*Figure 11.31a–d*).

Figure 11.32 shows the transmission curves for brown and blue lenses of 37% water content.

Brown tints are generally more effective at reducing light transmission than blues or greens both in the visible and ultraviolet parts of the spectrum. Soft lenses have also been produced with inhibitors, specifically to eliminate the ultraviolet part of the spectrum.

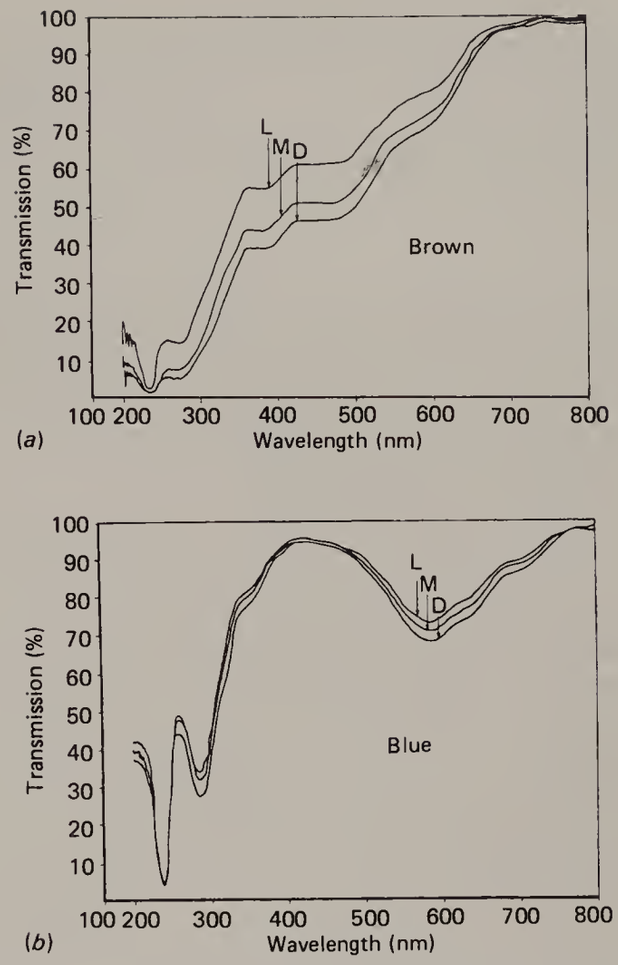


Figure 11.32 (*a*) Light transmission curves for brown-tinted soft lenses (light, medium and dark) with 37% water content. (*b*) Light transmission curves for blue-tinted soft lenses (light, medium and dark) with 37% water content (Courtesy of Igel International Ltd)

A further application of tinting is with the dark red X-Chrom lens. The monocular use of this colour is intended to enhance colour discrimination in patients having a red–green deficiency (*see* Chapter 23).

Silicone rubber lenses

Silicone rubber has been investigated as a material for contact lens use since 1962. It is chemically and physiologically inert (Breger, 1971; Elze, 1976), and its very high permeability to oxygen and carbon dioxide, together with its negligible effects on corneal physiology, were demonstrated respectively by Fatt (1969), Hill (1966, 1977), Hill and Schoessler (1967), Fatt and St Helen (1971) and by Burns *et al.* (1971). Roth *et al.* (1980), however, reported on a variety of clinical complications found with these lenses.

Silicone lenses differ from RGP lenses in several ways. They can be flexed, stretched and turned inside out; they have excellent elastic properties, partly conform to the shape of the cornea in wear, and have an oxygen permeability several times greater than either HEMA or most RGP lenses. They are also unlike hydrophilic lenses because they are extremely

Table 11.15 Parameter range of Silflex lenses

BOZR (mm)	7.30 to 9.0 in 0.10 steps*
TD (mm)	11.2, 11.7, 12.2, 12.7, 13.2
BVP (D)	±20.00*

*Wider range of parameters available on request.

tough, and their natural state is dry. Since they do not absorb water to any significant extent, fluorescein can be used in their fitting, and they do not need disinfecting in the same way as soft lenses. Silicone should therefore be regarded as a completely different category of flexible lens which lies somewhere between 'hard' and 'soft'.

Because of the amorphous nature of the silicone rubber raw materials, lenses are produced by a moulding and vulcanization technique, which also assists in maintaining good reproducibility. The main difficulty with silicone is that its natural surface is extremely hydrophobic, and it has been necessary to devise a method of rendering the surface permanently hydrophilic without interfering with any of its optical or physical properties. The final stage of manufacture is therefore surface treatment by ion bombardment.

The first silicone lenses were fitted with a total diameter of 10.50 mm, but, because of their relatively large centre thickness of 0.30 mm, they tended to be low riding (Black, 1972; Long, 1972). Subsequent lenses have been made either thinner or larger in order to achieve better centration e.g. Zeiss (Wöhlk Silflex).

The parameter range of Zeiss (Wöhlk) Silflex lenses is shown in *Table 11.15* (*see also Table 20.5.2*).

Advantages of silicone lenses

- Very high oxygen permeability.
- Better and more stable visual acuity than many soft lenses.
- Less variation in comfort or fitting with environmental factors.
- Little likelihood of loss or damage.

Disadvantages of silicone lenses

- They are difficult to fit, requiring as much or greater precision than rigid lenses and a longer time to settle.
- A negative pressure effect, particularly if not fitted correctly, so that some lenses have a tendency to stick to the cornea (Fatt, 1979).
- Short lifespan because of breakdown in surface coating and build-up of deposits (*see Figure 20.5.6*). With modern trends of planned replacement of lenses though, this need not be too much of a problem.
- Difficulties with surface wetting, if the coating becomes scratched or wears off.
- They are relatively expensive.

Because of the disadvantages, silicone has remained very much a minority lens with the following types of limited application:

- Dry eyes and other therapeutic cases (Woodward, 1984; Astin, 1991).
- Fitting corneas where vascularization has occurred with other lens forms.
- Fitting very young children who rub out or break soft lenses (*see* Chapter 20.5).
- Where a very high oxygen permeability is required for high-powered and therefore thick lenses.
- Occasionally where soft lenses have caused problems and RGP lenses are uncomfortable.

Fitting silicone rubber lenses

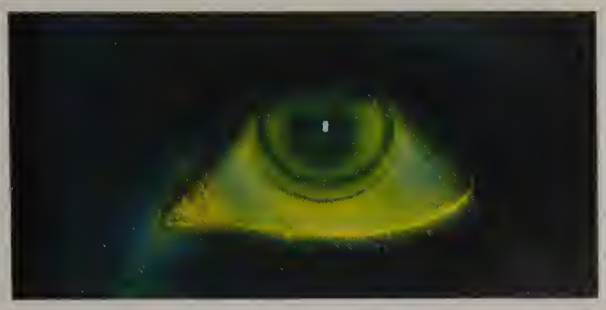
The first trial lens is chosen 0.30 mm flatter than mean *K*. The diameter should be 0.50–0.70 mm larger than HVID although fitting slightly smaller than HVID may be successful.

The fit needs to be checked as soon as any tearing has subsided, 10 minutes later and, assuming the fit is acceptable at that time, allowed to settle for a further 40 minutes. The lens should be comfortable, move 0.50–1.00 mm on blinking and version movements at this stage and continue to show adequate fluorescein, as in *Figure 11.33a* or with slightly less central touch. *Figure 11.33b* shows a flat fitting lens with areas of stand-off. The main thing to avoid is a lens that is fitting too tightly (*Figure 11.33c*) as it may be necessary to remove the lens using a suction holder.

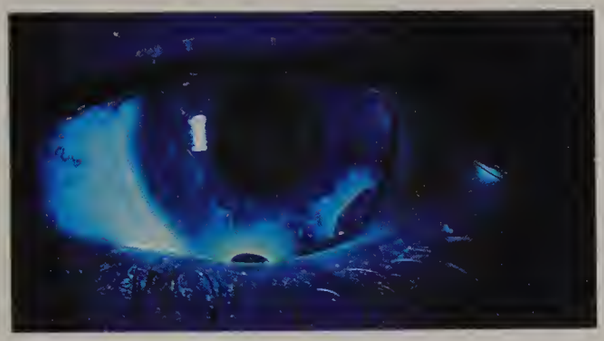
Rigid–soft combination lenses

The idea of combining the comfort advantages of soft lenses with the visual advantages of rigid lenses has been considered for some time. The use of a rigid–soft combination lens for keratoconus was first described by Little in 1971. The soft lens achieves comfort with an otherwise sensitive cornea and the rigid lens, fitted to match the anterior surface of the soft lens, provides a good visual result (*Figures 14.25 and 14.26*). Combination lenses have also been used in fitting pathological cases (Westerhout, 1973; *see also* Chapter 20.7), and astigmatic patients (Mavani, 1976*a*,*b*; Harwood, 1977). McKay Taylor (1976) suggested that the hydrophilic-base lens could be fenestrated, channelled or toric-edged in order to promote tear flow. De Carle (1985) described how a rigid corneal lens could be inset into the front surface of a carrier lens and sandwiched by a further soft lens.

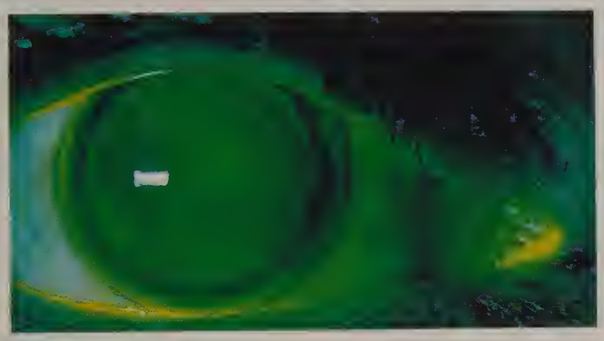
The first manufactured lens with a rigid centre and soft periphery was the Saturn II lens. However, it achieved only limited success due to weaknesses between the rigid and soft lens junction and difficulty in lens removal. More recently Pilkington Barnes–Hind have reintroduced it as the redesigned Softperm lens (Wesley-Jessen) (*Figure 11.34*) with the following features:



(a)



(b)



(c)

Figure 11.33 Silflex silicone rubber lens fitting: (*a*) good fit; (*b*) flat fit; (*c*) steep fit. (*a*, Courtesy of D. C. Campbell-Burns; *b*, *c*, courtesy of D. Westerhout)

Table 11.16 Parameter range for Softperm

BOZR (mm)	7.10* to 8.10 in 0.1 steps
TD (mm)	14.30
BVP (D)	–13.00 to + 6.00

*Lenses are available up to 6.40 in some countries.

Material classification:

Synergicon A

RGP (centre):	Pentasilcon P	
	Dk	14
	Specific gravity	1.05
	Refractive Index	1.13
	tc at –4.00	0.08 mm
Hydrophilic (skirt):	HEMA (modified)	
	water content	25%
	Dk	5.5
	Electrostatic status	non-ionic
	Thickness (constant)	0.08 mm

Although fabricated from low Dk rigid and soft lens materials, it sometimes provides a useful clinical option for fitting irregular corneal contours, keratoconus and grafts, as well as some other contact lens failures (Morgan, 1992). It has not, however, proved very successful for purely toric corneas. *Table 11.16* shows the parameter range for Softperm.

Fitting

- Select BOZR of diagnostic lenses as function of corneal toricity:
  - 1.37 D or less corneal toricity – flattest *K* to 0.10 mm steeper than flattest *K*
  - 1.50 – 2.75 D corneal toricity – 0.10 to 0.20 mm steeper than flattest *K*
  - over 2.75 D corneal toricity – 0.20 to 0.30 mm steeper than flattest *K*

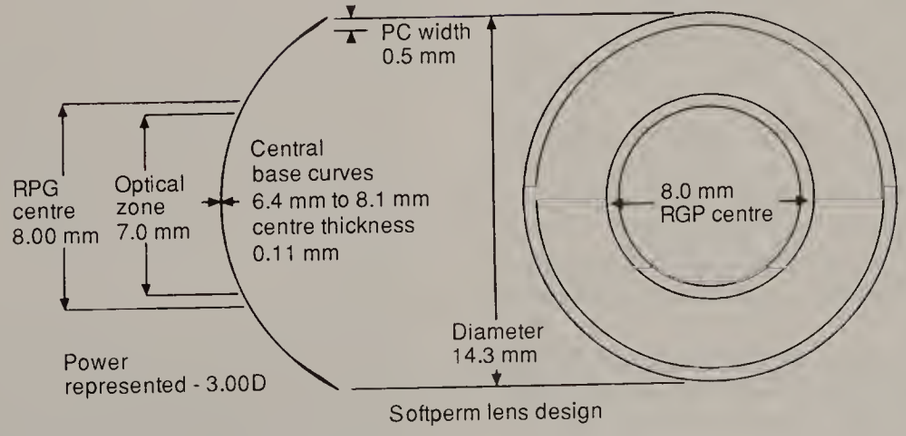


Figure 11.34 Softperm lens design (Courtesy of Wesley-Jessen Ltd)

- Allow minimum of 15 minutes for settling.
- An ideal fit provides good comfort and centration without limbal impingement and at least 0.25 mm of movement on upgaze. Good tear exchange is indicated by rapid outflow of fluorescein (high molecular weight must be used) and an absence of trapped tears (*see Figure 11.10*).
- Order the lens based on BOZR of central rigid lens.
- Only cold soft lens care systems that do not contain chlorhexidine may be used.
- The lens is inserted in a similar manner to a conventional soft lens. For removal, the edge of the soft skirt is gently pinched off using dry fingers.

Instructions to patients

Patients should be given clear instructions, both verbally and in writing. This need has been highlighted with the publication of a suggested 'informed patient consent' form by the Department of Health in the UK. Lens handling is fully described in Chapter 9, but the most important points to be discussed with the patient may be listed as follows:

- Any identification marks on the lenses.
- The wearing schedule. This should be uncomplicated with a typical example of 3–4 hours on the first day for low water content lenses, increasing by 2 hours extra each day. Positive lenses may well require a slower rate of adaptation. If the patient is wearing disposable lenses, they need to be told how often to start a new pair and how many pairs they will receive at one time.
- Lens comfort, which should be no worse than that already experienced on a tolerance trial, and the eyes should not become unduly red or sore.
- The method of lens disinfection.
- The importance of cleaning lenses daily, and the distinction between cleaning and disinfection. Also the need for weekly or fortnightly enzymatic cleaning for non-diposable lenses.
- The need to change the solution in the lens case every day, and to clean the case regularly (at least once a week). Also the importance of regular case replacement.
- Rigid lens solutions should never be used.
- Spectacle blur should not be experienced.
- Soft lenses should not be worn if eye drops or ointment are being used for any reason, without first discussing it with the practitioner.
- Environments containing fumes, chemicals or sprays should be avoided.
- The importance of always removing any trace of noxious chemicals or hand creams from the hands.
- Extreme environments in terms of temperature or humidity may temporarily affect both comfort and vision.
- If a patient falls asleep or enters certain extreme environments, lenses may give a temporary adhesion to the cornea. This can be released by the application of saline solution.
- The lens case should be carried at all times, containing the appropriate storage solution.
- Lenses are not necessarily spoiled if they dry out, since they recover their normal shape after rehydration, but they are very fragile when dry.
- Patients should bring with them for their first after-care examination both their lens case and their spectacles. They should arrive having worn the lenses for as long as possible on that particular day.

Disinfection of soft lenses

A continuing concern with soft lenses is the risk of contamination by harmful micro-organisms. It can be argued, however, that other problems have been created by the disinfection procedures themselves. Many recent studies have cited poor compliance with the cleaning and disinfection systems as a major contributory cause of complications such as microbial keratitis (Radford *et al.*, 1993). It is, therefore, essential that all patients are properly advised with respect to the appropriate disinfection and cleaning procedures for their particular type of lens. It is also important that they understand the distinction between cleaning and disinfection, because a sterile but 'dirty' lens produces as many problems as a clean, contaminated one. Full details of the methods currently employed for lens disinfection are described in Chapter 4.

In the past, heat and chemical disinfection systems were widely used but these have largely been superseded by oxidative systems incorporating hydrogen peroxide (e.g. AO sept, Oxysept) and chlorine (e.g. Softab) together with a modern generation of chemical systems using less irritating disinfectants (e.g. Renu, Optifree, Complete).

Heat

Heat disinfection is best carried out by using a thermostatic or time-controlled heating unit designed for this purpose. Alternatively, a suitable storage case containing the lenses in unpreserved physiological saline may be placed in boiling water for approximately 15 minutes or in a vacuum flask containing water which has just been boiled. These procedures are not truly sterilization, because they fall short of the absolute efficacy of autoclaving, and are better described as disinfection – sometimes referred to as pasteurization or ascepticizing (*see* Chapter 4). Care must be taken that lenses being sterilized in this way will not be damaged by the high temperature.

Chemical

Rigid lens solutions, which contain such preservatives as benzalkonium chloride or chlorbutanol, should under no circumstances be used with soft lenses because of their propensity to concentrate on and within the hydrophilic material.

Chemical disinfection was originally carried out with a variety of proprietary soft lens solutions commonly based on chlorhexidine and thiomersalate (thiomersal or thimerosal), which are effective against bacteria and fungi, respectively. Unfortunately, chlorhexidine also tends to concentrate within hydrogel materials to a certain extent and bind to deposits on the lens surface.

Allergic responses, sometimes extremely severe, are also quite common with thiomersal. Nevertheless the chlorhexidine–thiomersal combination is an effective antimicrobial system and is still used successfully by many contact lens wearers. Newer all-in-one solutions which contain the less potentially irritating disinfecting agents dymed and polyquad are becoming increasingly popular. Their high molecular weight prevents the molecules entering the soft lens matrix thereby preventing both its concentration within the lens and subsequent ocular irritation.

Oxidizing systems

Oxidizing systems, such as those based on 3% hydrogen peroxide or chlorine, have emerged as the preferred method of lens disinfection for many patients because, when properly used, allergy problems are rare. Peroxide, in particular, apart from being a very efficient disinfecting agent, has cleaning properties which enhance the life span of the lenses.

After-care

After-care for patients fitted with soft lenses is very much an extension of the fitting procedure. Frequently patients may have lenses fitted and dispensed on the first visit and at a subsequent visit may require the lenses to be changed to a different fitting or power. A comprehensive treatment of all aspects of after-care is to be found in Chapter 18, but the clinical routine should contain the following steps:

- Discussion with the patient.
- Over-refraction.
- Examination of the lenses, with and without magnification.
- Slit lamp examination and staining, with lenses removed.
- Consideration of lens fitting or lens type.
- (If necessary) possible reappraisal of wearing schedule.

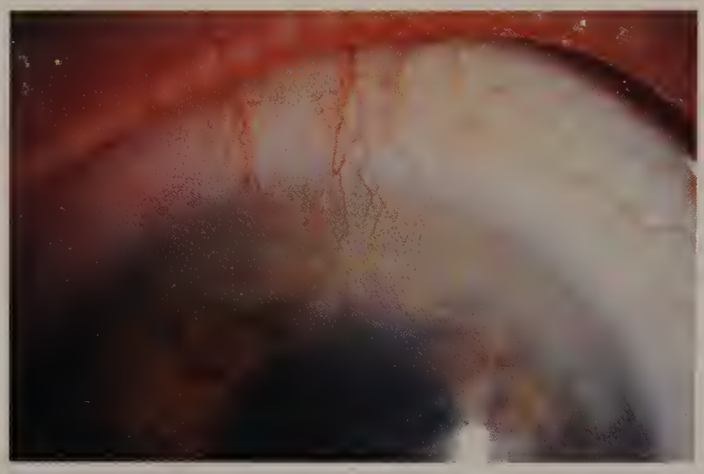
The initial discussion with the patient establishes the wearing time that has been achieved, together with the wearer's subjective appraisal of comfort, distance vision and near vision. The monocular and binocular visual acuities are then recorded, and over-refraction carried out to determine any residual error. The usual importance is given to the quality of the retinoscopy reflex. Lenses may then be examined *in situ*, with the slit lamp. This is especially useful because not only can the fitting best be judged with low-to-medium magnification, but so also can the general condition of the lens surface. Embedded foreign particles can easily be seen, as can possible deposits from the tears, or contamination from make-up. The integrity of the lens edge is also studied in this manner, as well as its possible effect on the limbal or conjunctival blood vessels. Lenses engraved with identification marks are easily confirmed as being worn both the right way round, and in the correct eye. Further assessment of the fit can be made using a keratometer, or Placido disc, or videokeratography.

Lenses are then removed, cleaned and placed in the patient's carrying case. It is sometimes necessary at this stage to consider a change of fitting, power, or even lens type. By the time of the first after-care examination, lenses will have been worn for 1 or 2 weeks, tear flow will be back to normal and the fitting may have significantly altered. Usually lenses become tighter rather than looser, so that a reduction in visual acuity or scleral indentation may have occurred. For physiological reasons, it may be necessary to change the type of lens. If there is some doubt about the comfort given by a particular lens, it is often instructive deliberately to switch right and left lenses into the opposite eyes. If the discomfort follows the lens into the alternate eye, then the lens must be suspected as being faulty and replaced. Assuming that no other lenses are to be tried on this occasion, ordinary fluorescein is used and the slit lamp examination continued to confirm the absence of corneal insult.

It may be necessary to alter the wearing schedule at this stage. Finally, patients are instructed that the lenses may be worn again after a gap of 2 hours or after irrigating the eye with saline, by which time, virtually all traces of fluorescein should have disappeared from the eye.

Severe problems do not arise frequently with hydrophilic lenses, but it should not be assumed that, because they are so soft and flexible, ocular changes will not occur. Practitioners must expect at least some of their patients to present with a suddenly contracted red eye. Most of the ocular changes that take place, however, are not as severe. They include the following.

- **Punctate staining** of an adaptive nature observed centrally or peripherally – crescentic areas of stain in the mid periphery, and arcuate stains at the limbus with some types of corneal-sized lens. This is due to a combination of corneal drying by the lens edge, and physical abrasion.
- **Corneal desiccation**, seen with some ultrathin or high water content lenses (*see Figure 18.33*). Patients who are hypersensitive to disinfection or cleaning solutions show diffuse punctate erosions in the superficial epithelium and small stromal opacities (*see Figures 15.14* and *18.15*). They usually exhibit discomfort and/or photophobia and lacrimation.
- **Striae** (*see Figure 15.6* and Appendix D) seen as folds in the posterior stroma (Wechsler, 1974; Katz, 1976). These are the first visible sign of corneal oedema and occur if corneal swelling exceeds 4% (Polse *et al.*, 1975).



(a)



(b)

Figure 11.35 (*a*) Corneal vascularization due to soft lens wear. (*b*) Angiogram of corneal vascularization, showing slight vessel leakage (Courtesy of E.G. Woodward)

- **Limbal injection** (*see Figure 18.10*) may be observed either in association with these foregoing conditions, or on its own.
- Long-term soft lens wearers can produce **neovascularization** spreading from the limbal arcades (*Figure 11.35*); arcuate staining near the superior limbus can also occur accompanied by vascularization caused by the downward pressure of a tight upper lid (*see Figure 18.35*).
- Greyish **infiltrates** in the corneal stroma (*see* Chapter 18 p. 649).
- **Disciform (nummular) keratitis** and **superficial punctate keratitis** are occasionally seen.

Corneal oedema is sometimes present, but compared to that found with rigid lenses it is difficult to observe. It is usually an overall effect, extending from limbus to limbus with no clearly defined edge to be seen against the background of the pupil area. The resulting tissue stress manifests itself as striae and folds in Descemet's membrane but there is usually little or no change in either refraction or *K* readings, which accounts for the absence of spectacle blur. Carney (1975) found that epithelial anoxia gives both central and peripheral thickness changes, so that there is no actual change in the corneal topography. Holden (1989) suggested that the number of vertical corneal striae bore a direct relationship to corneal oedema, with the first stria equivalent to a 3.5% swelling and each additional stria increased this figure by 1%. Pachometry is probably a more accurate tool in diagnosing the low levels of oedema encountered with soft lenscs.

Lens ageing

Hydrophilic lenses stored in sealed vials continue to remain in good condition for several years, but once they are worn regularly lens deterioration occurs in a variety of ways. Unlike rigid lenses, ageing effects are a more common cause of lens replacement than either loss or damage. The degree to which any particular lens is affected depends on several factors.

- The polymer from which the lens is manufactured. HEMA lenses age differently from those of higher water content.
- The wearing schedule. Extended wear lenses are more badly affected than daily wear lenses and these are, in turn, more badly affected than those worn only occasionally.
- The nature of the tear chemistry (Larke, 1985). Some patients' lenses last only a few months, whereas others remain in good condition for several years.
- Method of disinfection. Lenses generally have a shorter life span when sterilized by heat as opposed to solutions. Hydrogen peroxide, in particular, is beneficial in maintaining optimum lens condition.
- The regularity and method of cleaning.
- The environment in which the lenses are worn. Dry atmospheres are especially problematic.

Types of ageing effect

Protein deposition

Most lenses suffer from mucoprotein deposits, although high water ionic materials are more badly affected (Jones, 1994). Cumming (1973) considered that there is a chemical bonding between the proteins of the tears and the hydroxyl groups of the polymer. Some degree of deposition is therefore inevitable, but heat disinfection compounds the problem by denaturing protein on the lens surface which has not been removed by proper cleaning. In the early stages a blue-grey film is seen when the lens is observed by oblique illumination against a dark background, or if the patient refrains from blinking and the lens is allowed to dry on the eye during slit lamp examination (*see Figure 18.41*). Eventually large areas of deposit are clearly visible, even without magnification. As long ago as 1974 Spring described the allergic response of some patients to the

protein deposits on their lenses, which has now become known as GPC or CLIPC (*see* Chapter 18).

Discoloration

High water content lenses very commonly suffer from brown discoloration, even when not disinfected by heat. HEMA lenses can also be affected. Gasson (1975) and Ganju and Cordrey (1976) demonstrated a reduction in light transmission of such discoloured lenses. The brown colour may be due to adrenaline compounds in the tears, or if the lenses fluoresce under ultraviolet light, it may be due to chlorhexidine bound to surface deposits (*see Figure 18.19*). High water content lenses have also been observed with pink and blue discoloration (*see* Chapters 4 and 13).

White spots

These are usually considered to be largely lipid in content, often containing some calcium. They rarely occur with low water content lenses, and spun-cast lenses rarely exhibit these deposits. High water content lenses are more often affected, particularly with dry-eyed patients who are poor blinkers. White spots always occur on the front surface of the lens. They may sometimes be observed as a cloud of fine punctate dots, but are more usually seen as quite noticeable discrete white spots scattered irregularly over the lens surface in the area of the exposed palpebral aperture. In severe cases, particularly with extended wear lenses, they can be extremely large and uncomfortable. These larger deposits are sometimes referred to as 'mulberries' (inorganic), 'jelly bumps' (organic), or calculi, as shown in *Figure 11.5*.

Rust spots

Rust spots affect all types of hydrophilic lens. They are mainly due to atmospheric pollution, but have occasionally been found as a manufacturing fault. Loran (1973) showed them to be a form of ferrous contamination, and they are more often observed in patients who live or work in industrial areas (*see also* Chapter 13)

Surface and edge deterioration

Lathe-cut HEMA lenses can develop fissures relating to manufacturing lathe marks (Barradell, 1973) and they gradually suffer from surface scratching. The integrity of the edge, with age, can break down to produce small chips and imperfections; and engraving marks can sometimes become encrusted with deposits (*see Figure 13.34*). Lenses affected by protein tend to dry more easily on the eye and, if this occurs unevenly at the periphery, the edge may become crenellated.

Fitting changes

Lenses with deposits, scratches or other surface irregularities, are more influenced by the mechanical pressure of the upper lid, so that significant changes in fitting characteristics can occur. Usually they appear to become looser, and corneal diameter lenses may become badly decentred because the lens surface tends to adhere to the upper lid. High-riding lenses are frequently associated with CLIPC, because the papillae 'grip' the lens and displace it superiorly. As a secondary effect, apical or peripheral corneal staining is sometimes observed.

Refractive changes

Old lenses frequently give a reduced standard of vision, not only because of surface deposits, but also as a result of spurious changes in the over-refraction of as much as 1.00 D. If the patient is subsequently checked with a new lens, the refractive change is often found to be either smaller or unnecessary. This may be due to refractive index and flexure changes commonly caused by protein and other deposits both on the lens surface and within the lens matrix (*see* Chapter 5).

The majority of the foregoing difficulties are partially resolved by thorough lens cleaning or frequent regular replacement. It is not possible to predict with any degree of certainty the life span for a soft lens. Although the various cleaning and rejuvenation procedures available could make 2–3 years feasible, there are considerable clinical benefits from regular lens replacement. For the lifetime of the lenses, however, using the appropriate solutions will help reduce deposit formation. Ideally patients should use a surfactant cleaner effective against non-denatured mucoprotein, combined with a periodic enzymatic cleaning process.

General comments on soft lens practice

There are now a great many types of hydrophilic lens available to the practitioner. They differ in water content, chemical composition, size, geometric construction, method of manufacture and technique of fitting so that they may have little in common, except for the fact that they are described by the adjective 'soft'. They are best regarded as complementary rather than competitive systems; an individual lens type may best suit a particular patient, or perhaps even a particular eye. If it is intended to fit as many patients as possible, it is essential to have available more than one variety of lens, of different sizes, water contents and fitting techniques. It is not possible to prescribe lenses of one type based on the fitting set of another. A comprehensive range of lenses for one preferred fitting philosophy should therefore be supplemented by at least a minimum set of an alternative type.

The majority of soft lenses, even when produced by smaller laboratories, emanate from the larger lens material manufacturers who are required to carry out the necessary preclinical studies to ensure the safety of their material. It is advantageous to use a lens which is part of a complete system, backed by an easily workable warranty, exchange and replacement scheme. This enables the practitioner to

maintain an efficient fitting service, and the patient to have at least some idea of what the future costs might be as a soft lens wearer.

The material from which conventional lenses are made must avoid rapid deterioration, and it must withstand patient handling in order that a reasonable life span may be expected. Good reproducibility is essential and lenses should be capable of being autoclaved, so that any method of disinfection may be used.

The preferred way of prescribing soft lenses, of any variety, is from a substantial lens stock. This facilitates lengthy tolerance trials when necessary and the clinical evaluation of lenses close to the patient's fitting and power. If, however, a start is made with a limited trial set, it should be possible to extend this by the subsequent addition of further fitting units.

Because positive and negative lenses can behave very differently on the eye, both should be included in even a basic fitting set. Lenses with standardized parameters and recommended fitting procedures are preferred in most cases, but any soft lens system should ideally be sufficiently versatile to provide non-standard lenses when clinically necessary.

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Chapter 12

Rigid lens verification procedures

Rita Watts

Parameters to be checked p. 407
Verification procedures p. 407

Addenda p. 423:
I Dimensional tolerances for hard contact lenses (BS 7208: Part 1: 1992; ISO 8321–1: 1991(E))
II Optical tolerances of corneal lenses and scleral lenses (BS 7208: Part 1: 1992; ISO 8321–1: 1991 (E))

Contact lenses should be checked for quality and physical characteristics whether they are for prescription use, contact lens fitting sets or research purposes. Many laboratories publish details of the accuracy to which their lenses are made, and the British Standards Institution has issued dimensional tolerances and requirements of finish for contact lenses, together with methods of test (BS 7208) for use by practitioner and manufacturer (*see* Addenda I and II, p. 424). Instrumentation should be checked for working efficiency and periodically against test standards for precision (Wehking, 1981).

BS 7208: Part 3: 1992 describes a number of methods of test for contact lenses and calibration procedures. The standard also describes conditioning of contact lenses prior to testing.

Various instruments, although designed for a specific purpose, can also be adapted to check certain contact lens parameters, and these adaptations are described in this chapter, although some of the adapting devices are not readily available. Practitioners could contact a local precision engineering company for help in the fabrication of similar devices.

Parameters to be checked

Table 12.1 shows the various parameters which may need checking in each group for corneal and scleral lenses. *Table 12.2* gives the various test methods available that will be discussed in this chapter.

A pair of lenses should match for tint, transition and edge forms. Diameters and zone widths should not differ by more than a certain tolerance. The maximum difference in thickness for a pair of lenses of relatively equal power should not exceed a specified tolerance unless this is specifically requested to facilitate lens checking.

Verification procedures

Radii

Various methods are available for verifying contact lens radii.

Optical microspherometers (radiuscopes)

The optical microspherometer is commonly known as a radiuscope (the trade name of an American Optical Company instrument) and the latter term will be used in this chapter. There are several such instruments available (*Figure 12.1* and *see Figure 12.3*) which differ in construction, but all use Drysdale's method for the measurement of small radii (Drysdale, 1900). This method is based on the principle that for a curved mirror an image is formed in the same plane as the object when the object is at the centre of curvature of the surface. This is because the reflected light returns along its incident path. An image may also be formed on the surface, and thus the distance between the two images – which is equal to the radius of the surface – may be measured (*Figure 12.2*).

A radiuscope consists essentially of a microscope with a linear scale (calibrated to 0.01 mm) to read the position of the microscope body or microscope stage. Light from an illuminated target (consisting of a ring of dots or radial lines) attached to the microscope is imaged by the microscope objective after being reflected through a right-angle by a semi-transparent mirror.

Some radiuscopes (*Figure 12.3*) have dispensed with the external dial gauge shown in *Figure 12.1*, and the radius reading is shown on a scale at one side of the field of view in the microscope. The knurled knob on the left-hand side of the instrument in *Figure 12.3*, just above its nameplate, is used to set a pointer to zero on this scale when the surface image of a concave surface is in focus. To focus the centre

Table 12.1 Contact lens parameters which may need verifying

Group	*Corneal lenses*	*Scleral lenses*
Radii (spherical and/or toroidal)	Back optic zone radius Back central optic zone radius Back peripheral optic zone radius/radii* Back peripheral zone radius/radii* Front optic zone radius Front central optic zone radius Front peripheral optic zone radius/radii* Front peripheral zone radius/radii*	As for corneal lenses
	Effective or equivalent back optic zone radius	Back scleral zone radius/radii* Back transition zone radius/radii*
Diameters and linear parameters (maximum and minimum dimensions if not circular)	Back optic zone diameter Back central optic zone diameter Back peripheral optic zone diameter(s)* Back peripheral zone diameter(s)* Front optic zone diameter Front central optic zone diameter Front peripheral optic zone diameter(s)* Front peripheral zone diameter(s)* Total diameter Displacement of optic Bifocal segment size and position	As for corneal lenses
	Back diffractive zone diameter	Primary optic diameter Back scleral size
	Axial and/or radial edge lift	Transition width(s)
Thickness	Central (optic and/or geometric) Edge Lenticular junction At any other specified point	Central optic Average scleral Edge Transition At any other specified point
Optic – lens prescription	Back vertex power Front vertex power Near addition Prism and base direction Cylinder power and axis Aberration	As for corneal lenses
Quality etc.	Finish and quality Polish Edge form Transitions Tint Material	As for corneal lenses

*Where there is more than one such zone.

of curvature image, the coarse and fine focusing wheels at the lower back of the instrument are used to raise the microscope objective and, at the same time, this movement is recorded by the pointer on the scale – so giving the radius reading directly. The use of instruments with dial gauges is outlined below.

Procedure for using a radiuscope – concave surfaces

- A suitable lens holder is filled with water.
- The clean lens is placed centrally on the holder, convex surface in complete contact with the water. The water minimizes reflections from the front surface of the lens because its refractive index is very similar to that of the lens material. (Without the water present, the images formed by reflection at the front surface are as bright as the images formed by the back surface, and it then becomes difficult to tell quickly which image is required.) Only a small quantity of water should be used, otherwise the lens floats and may move during measurements.
- The holder is placed on the microscope stage and centred.

Table 12.2 Possible methods of test for rigid contact lenses

Back central optic zone radius	(1) Optical Radiuscope microspherometer (2) Keratometer (calibrated for concave surfaces) (3) Interferometry techniques
Back (central) optic zone diameter	× 10 measuring magnifier
Back scleral zone radius (of preformed lenses)	(1) Radiuscope (2) Keratometer (calibrated for concave surfaces)
Basic or primary optic diameter	Sagitta method
Back peripheral (optic) radius	(1) Radiuscope (2) Topographical keratometer (3) Interferometry techniques
Back peripheral (optic) diameter	× 10 measuring magnifier
Axial edge lift, radial edge lift	(1) Radiuscope (2) Sagitta method
Total diameter	(1) V-channel gauge (2) × 10 measuring magnifier (3) Projection magnifier with scale
Front (central) and/or peripheral optic zone diameter	× 10 measuring magnifier
Bifocal segment height	× 10 measuring magnifier
Centre thickness	(1) Measuring dial gauge (2) Radiuscope (3) Projection magnifier with scale
Edge thickness	Measuring dial gauge
Scleral vertex clearance (from cast)	Measuring dial gauge
Back vertex power, prism, optical centration	Focimeter with contact lens support
Surface quality, edge form	(1) Binocular microscope (2) Projection magnifier (3) Measuring magnifier

- The microscope eyepiece is correctly adjusted and then, by observation through the microscope, the target is imaged on the surface of the lens by moving either the microscope and target or the microscope stage, depending on the type of instrument used.
- The dial gauge reading is recorded (or the dial gauge is set to zero).
- A second focus, at the centre of curvature of the surface, is obtained by racking the microscope up or the stage down.
- The second reading is recorded.
- The difference between the two dial gauge readings gives the radius of curvature of the surface.
- This procedure should be repeated twice and the average of the three readings taken. To minimize user errors, the fine focusing drum should be racked in the same direction when making each setting. The radius should also be measured at different points on the lens as it may vary (Tannehill and Sampson, 1966).

The focused target must be central. Usually, it is possible to move the microscope stage horizontally to centralize the image. A diaphragm and/or rheostat is incorporated in most instruments to reduce brightness.

The target image will appear distorted if the surface is irregular. If any water is left on the surface being measured, it can result in distorted surface images. On toroidal surfaces, two measurements for the principal radii must be made. When a radial line target is being used, the lens must be rotated so that its principal meridians coincide with one pair of perpendicular radial lines.

On some instruments it is necessary to use a special holder (*Figure 12.4*) when measuring the back scleral radius. By using the holder, the travel of the microscope is increased to cope with the larger radii encountered.

Measurement of back peripheral radii

A similar procedure is followed but the lens holder is tilted and the microscope stage moved across so that the target is focused in the peripheral band of the lens. Care is needed to centre the surface image in this band. Provided that the band is 1 mm wide and light incidence is still normal to the surface being measured, it is possible to measure its radius. It is therefore possible to measure any intermediate radii on the lens which occur over a wide enough band. Where each peripheral curve is too narrow, the centre of curvature image is similar to that of a toroidal surface. A line image (formed by the surface along the band) can be focused and is parallel to the direction of the tilt. This is closest to the correct radius. The image formed by the surface across the width of the band is longer than the correct radius because it is influenced by the areas of surface to either side of the band being measured.

Attempts were made (Brungardt, 1962) to measure back peripheral radii using a focimeter. Because of the change in back surface radius between the centre and the periphery, it may be possible to obtain two power readings on the focimeter. Provided that the front surface is one single curve, the difference between the two power readings is due to the radius difference on the back surface. If the back optic zone radius is known, its corresponding negative surface power may be obtained from the radius/power formula $(n-1)/r$ and the back peripheral surface power found by adding the difference in focimeter readings (the periphery has the less negative value). By further using radius/power formula the back peripheral radius may be determined. This method is inaccurate with multi-curve lenses. The thickness difference between centre and periphery contributes to the inaccuracy for all lenses.



Figure 12.1 American Optical Company Monocular Radiuscope with corneal lens in place for measurement of back optic zone radius. Inset: close-up of lens in place, holder tilted to measure back peripheral radius.

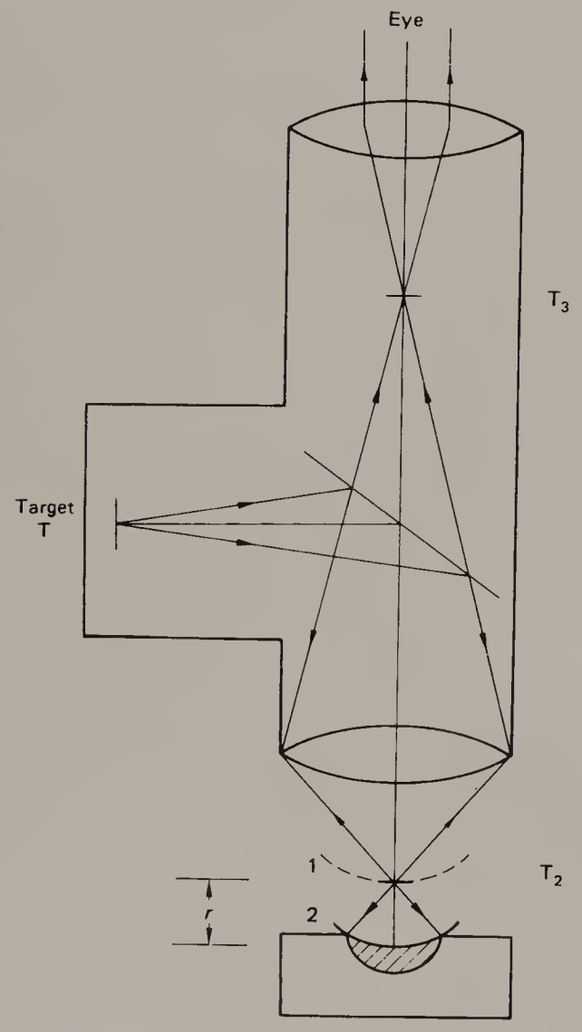


Figure 12.2 Diagram to show Drysdale's principle. (1) First position of lens, image focused on lens surface; (2) second position of lens, image is now at centre of curvature of surface. r = lens radius

Measurement of convex surfaces

The concave surface is mounted on water, if possible, or blacked out with a soft grease pencil or felt-tip pen. The convex surface is placed uppermost on a special holder (*Figure 12.5*) on a radiuscope. A similar procedure to that outlined above for concave surfaces is followed, but the surface and centre of curvature images are reversed.

Keratometers

The keratometer is used with a special contact lens holder (*Figure 12.6*) which utilizes a front surface silvered mirror and a lens support. The lens rests on water in a small depression on a horizontal support. The mirror is set at 45° to the optical axis of the instrument and reflects light from the instrument on to the surface to be measured.

Another type of holder (*Figure 12.7*) requires that the lens be attached to a depression, which lies in a vertical plane, by some adhesive substance such as Plasticine or double-sided sticky tape. There is a possibility that the lens may be distorted using this procedure.

The keratometer can be used to measure optic zone radii of corneal lenses and optic radii of scleral lenses. Because an area of approximately 3 mm in diameter is needed to check a particular radius using conventional keratometers (Lehmann, 1967), it is not possible to measure intermediate and peripheral radii on corneal lenses by this method. Using a single mire of the topographical keratometer (*see* Chapter 6), which utilizes a very small area of reflecting surface, such readings may be possible, however.

Because the keratometer mires are reflected from regions of the surface outside the paraxial zone, an allowance is made during calibration for the aberrations thus introduced. As keratometers are calibrated for convex surfaces and,



Figure 12.3 American Optical Company Binocular Radiuscope with internal scale. (Courtesy of British American Optical Company)

when used to measure back optic radii of contact lenses, concave surfaces are involved, an error is introduced. This is because the aberrations produced by a concave surface are different from those produced by a convex surface. Bausch & Lomb and other keratometer manufacturers have produced conversion tables for converting convex to concave radii and these show the error to range from 0.02 mm for steep radii (of the order of 6.50 mm) up to 0.04 mm for flat radii (of about 9.50 mm). In all cases, the radii for concave surfaces are greater than for convex

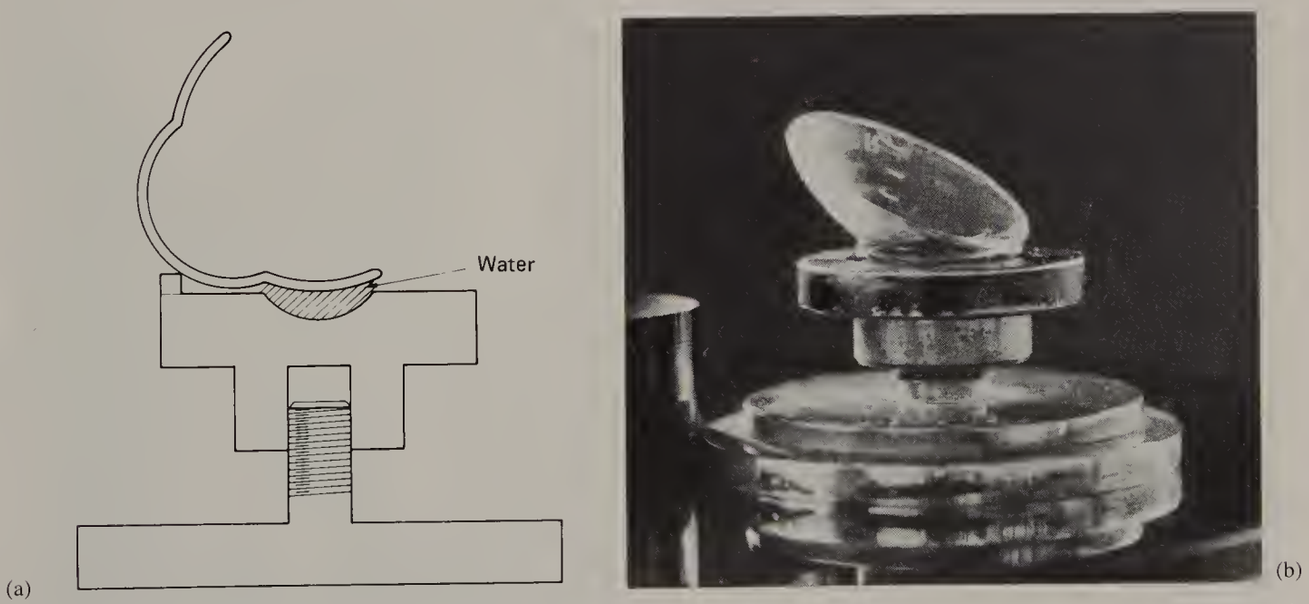


Figure 12.4 Scleral lens holder for use with Drysdale's method. (*a*) Diagram of section through holder with lens in place. Note screw section by means of which a greater distance may be obtained between the lens surface and microscope objective. (*b*) Holder in use, back scleral radius being measured



Figure 12.5 Holder for measuring convex surfaces on the radiuscope. The lens has been displaced slightly in order to make it visible.

surfaces. Thus, for most of the back optic zone radii encountered in contact lens work, it is sufficient to add 0.03 mm to the radius reading given by the keratometer.

To measure back scleral radii the range of the keratometer needs extending. This may be done by recalibrating the keratometer using a –1.00 D or –2.00 D trial case lens taped in front of the objective as mentioned on p. 236. Three steel balls are used for recalibration having accurately known radii of, say, 9.00 mm, 12.00 mm and 15.00 mm. A graph is then drawn of measured radius (ordinate) against actual radius (abscissa). Provided the same trial case lens is always employed, the same graph may then be used for determining longer radii than the keratometer was designed to measure. Steep radii may be determined similarly, by taping a positive trial case lens, of about +1.50 D, in front of the keratometer objective and recalibrating with steep steel balls and drawing another graph. (This is useful for measuring the radii of keratoconic corneas, if sufficiently undistorted readings can be obtained.) Computer assisted video keratography equipment, such as the EyeSys, can also be used to measure concave surfaces although not to the same degree of accuracy.

The radius checking device

This was a plastic device developed by Sarver and Kerr (1964), and used in conjunction with a focimeter. Although not now in common use, the device can be fabricated by most contact lens laboratories. Details may be found in the original reference of the 3rd edition of this book. It was used to measure the back optic zone radius of a corneal lens.

Templates

Plastic rings of various radii, with chamfered edges, have been used to measure back scleral radii (Stone, 1964).



(a)



(b)

Figure 12.6 Mirror-type contact lens holder for use with a keratometer. (*a*) On the keratometer; (*b*) close-up. The lens, which is resting on the concave depression of the support, can be seen reflected in the mirror

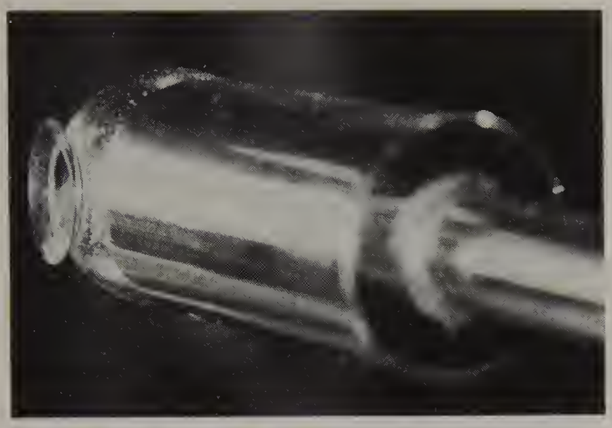


Figure 12.7 Contact lens holder for use with keratometer. The holder is screwed to the head-rest arm, and the lens is held in the depression by an adhesive substance

Other methods

There are various other methods for measuring contact lens radii which are, in the main, only historical techniques. It is possible that other instrumentation may be developed using these techniques.

Interference patterns

Interference patterns, which may be parallel fringes or rings, can be produced in a number of ways. Interference fringes are the basis of many lens testing techniques. Moiré fringes were utilized in the Toposcope, now no longer available, to measure radii and diameters of corneal lenses. The target, which consisted of a series of straight lines, was viewed through a screen with similar lines. The shape and orientation of the fringes formed were a function of the relationship between the two sets of lines. Straight parallel fringes indicated a spherical surface, curved fringes indicated an elliptical surface (*Figure 12.8*). Any warpage or dimples in the surface was indicated by irregularly shaped fringes.

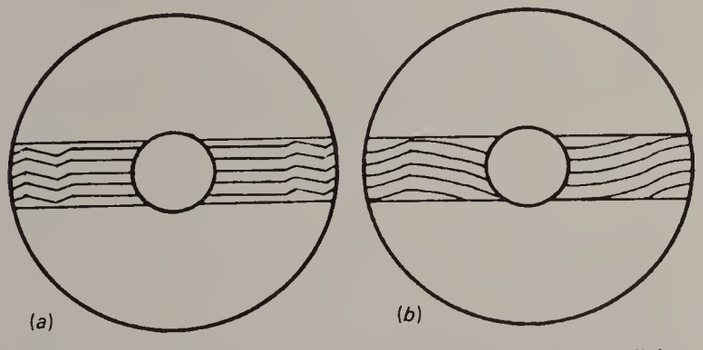


Figure 12.8 Fringes as seen with the Toposcope. (*a*) Straight parallel fringes indicate spherical curves: central fringes correspond to the back optic zone radius; peripheral fringes, the back peripheral radius. A transition zone and edge bevel are apparent. (*b*) Curved fringes indicating an elliptical surface

Methods of measuring radii using fringes may be developed for aspheric and continuous curve lenses, because it is not possible to measure these surfaces accurately with the other methods discussed. Moiré fringes have been utilized in the measurement of lens power and quality assessment in the Rotlex Con Test.* Although used primarily for soft lenses, the machine works equally well with rigid lenses (*see also* Chapter 13).

Garner (1970) undertook an investigation concerning the measurement of contact lens radii using Newton's rings. Although his apparatus was too complicated to form the basis for an instrument for use by practitioners, it made use of test plates and was accurate to 0.003 mm in radius determination. With it he showed that hydration of hard lenses maintains the spherical nature of their surfaces (if spherical to start with), and that surface polishing with wax tools can lead to flattening of the periphery of a spherical surface with effective steepening at the centre due to distortion.

Pneumatic gauging

This method used an air jet as part of a direct reading spherometer (Smith, 1966), the pressure from a small air jet being proportional to the sagitta of surfaces to which it is applied.

Focimeter and trial lenses

Linnell Fearn (1970) suggested taking a focimeter reading with the front surface of a trial lens resting on the back surface of a test lens of unknown dimensions. A second reading is taken with water between the contact surfaces. The difference between the readings gives the liquid lens power. Knowing the front surface radius of the trial lens, and assuming a negligible liquid lens thickness and refractive index of 1.336, the back optic zone radius (BOZR) of the test lens can be determined. The fluid lens power must be kept to a minimum. This requires the use of about three trial lenses with different known front surface radii depending on the BOZR of the lens to be tested.

Accuracy of methods

Of the methods described for determining contact lens radii, the radiuscope appears to be the most accurate and versatile (Dickins and Fletcher, 1964). The keratometer is limited because a large area is usually needed on which to take measurements. Most keratometers are not calibrated with a sufficiently small scale to measure to 0.01 mm accurately. Because a keratometer utilizes reflections from outside the paraxial zone, it is calibrated to allow for the aberrations introduced by convex surfaces. When used for measuring concave surfaces the radius is slightly underestimated by approximately 0.02–0.04 mm (Bennett, 1966) (*see* p 412).

*Rotlex, Temed Industrial Park, Arava, Israel.



(a)



(b)

Figure 12.9 (*a*) Lens being positioned against scale of measuring magnifier. (*b*) Appearance of zones of corneal lens as seen through a measuring magnifier

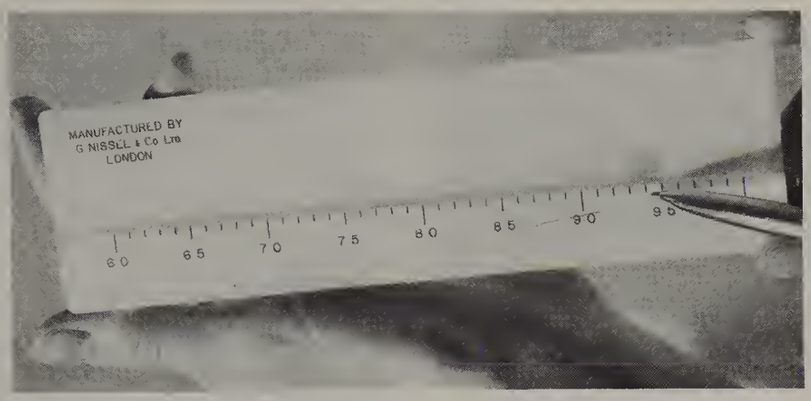


Figure 12.10 V gauge in use. Pen indicates position to read lens total diameter of 9.40 mm to nearest 0.10 mm

Measurements can be made to an accuracy of 0.02 mm (Dickens, 1966a,b) provided that the constants of the device are accurately known.

Templates provide only an approximate value for the back scleral radius. Sources of error are the pliability of the lens and the difficulty of rotating the template about the axis of symmetry of the lens.

In an investigation into the accuracy of the Toposcope, Storey (1969) found it to be poor, particularly for peripheral radii, and most errors were negative. However, a study by Janoff (1977) showed that, with an experienced observer, the Toposcope proved quicker to use and gave less variable readings than the radiuscope. Also the Toposcope utilized fringes formed over the whole back optic zone and was capable of detecting and measuring aspherical surfaces to a limited degree of accuracy.

For most instruments, the precision (repeatability) of measurements is high, but the accuracy may not be high. The quality of the image obtained may vary according to the material used for the contact lens.

It should be remembered when checking contact lens radii that finished corneal lenses alter in curvature with hydration and with release of any stresses in the lens material (Phillips, 1969).

Diameters and linear parameters

Several devices are available for measuring the different linear parameters. With some methods, the problem of parallax occurs as the measuring scale is not in the same plane as the parameter being measured.

Measuring magnifier

The measuring magnifier (*Figure 12.9* and *see Figure 21.15*) has an adjustable eyepiece through which an engraved scale is viewed. The lens is held with the concave surface towards the scale. The total diameter of the lens may be checked with this device. The back optic zone diameter and any intermediate optic diameters may also be checked in this way provided that the transitions are reasonably sharp. The lens should be rotated and several readings taken to check overall and optic zone roundness. Any displacement of the optic may be checked with this instrument. Because the scale is usually only 20 mm long, the device is only used with corneal lenses.

V gauge

V gauges (*Figure 12.10*) are made of metal or plastics and have a V-shaped channel cut into the material. The channel may vary in width from 6.00 to 12.50 mm. The corneal lens to be measured is placed at the widest end of the channel, concave side downwards, and then allowed to slide down under gravity until it is stopped by the sides of the gauge. The total diameter is then read from a scale beside the channel. The lens must be clean and dry or it will not slide freely. The lens must not be forced along the channel as this can result in compression and even breakage.

Other methods

Various contact lens viewers are available for determination of linear parameters as shown, for example, in *Figure 13.17*. These usually incorporate a screen and use projection magnification. The principle on which they are based is that of the microfiche viewer.

Alternatively, a reticule within the eyepiece of any viewing instrument can be used for linear measurements.

Cast, dividers, transparent rule

Most scleral lens parameters are measured on a cast of the lens (*Figure 12.11*). The cast is made from dental stone mixed with a small amount of water to a smooth paste as described in Chapter 17. It has all the lens features clearly marked on it. The transition width, back optic zone diameter and optic displacement can be measured from the cast by placing the dividers at the appropriate points and measuring the distance apart of the dividers with a rule. The primary optic diameter of a preformed scleral lens may be deduced by adding the transition width to the back optic zone diameter, measured on a cast at the point where the transition curve intersects the optic curve. Displacement of

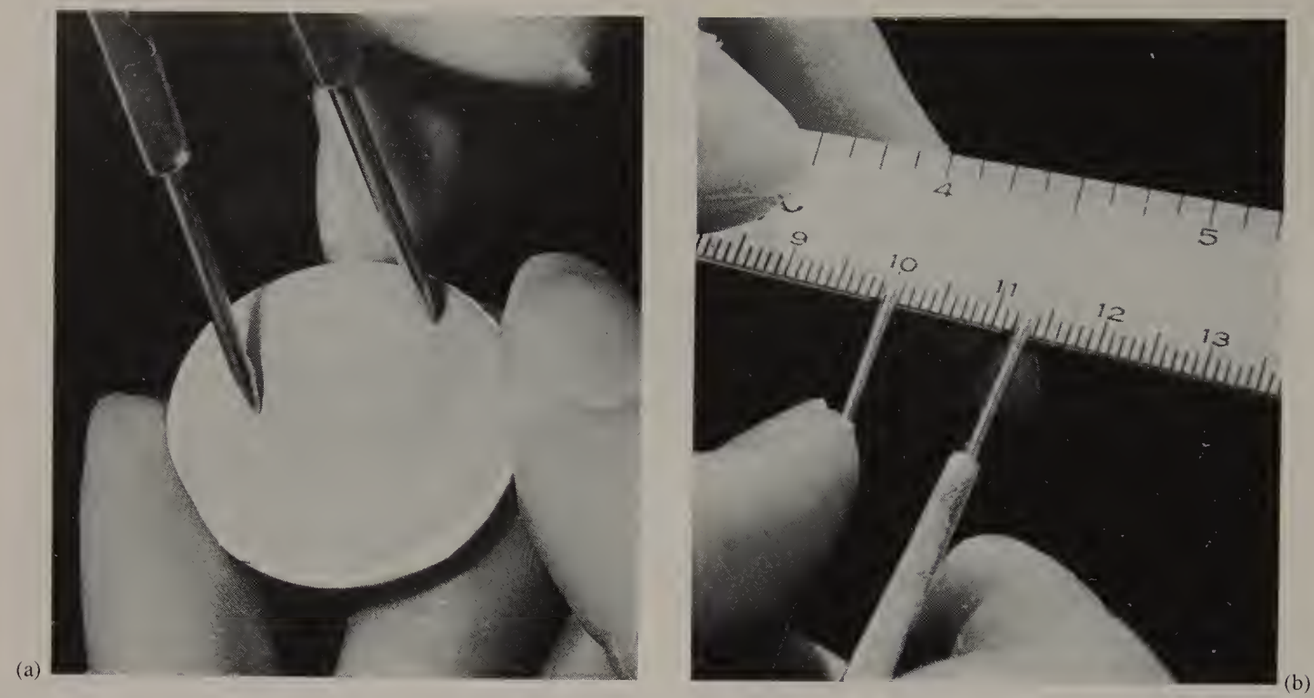


Figure 12.11 (*a*) Cast of scleral lens with dividers placed to measure back optic zone diameter. (*b*) Dividers placed against scale giving measurement of 13.0 mm

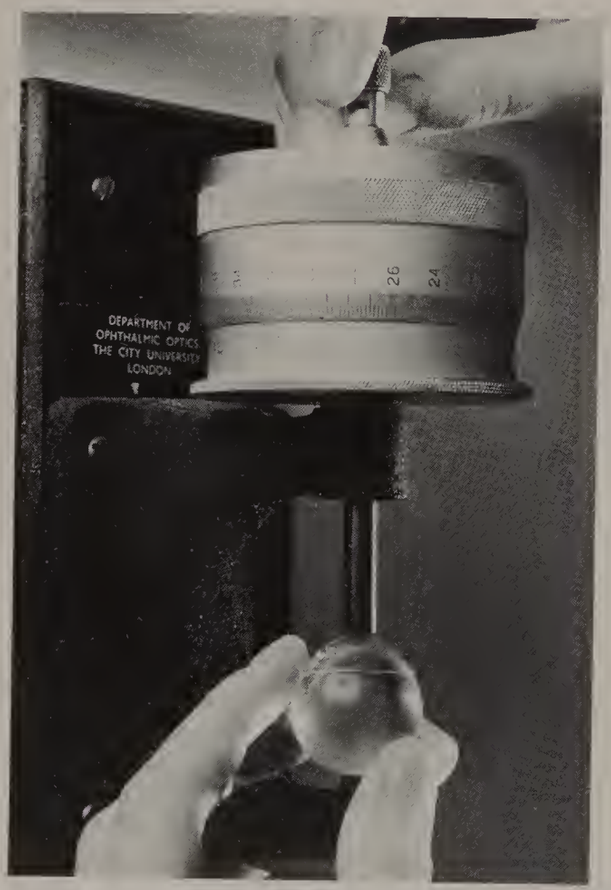


Figure 12.12 Micrometer method of measuring primary optic diameter. The lens is placed on a sphere. When the vertical plunger is in contact with the front surface of the lens the scale reading gives the distance *x* (*see Figure 12.13*)

the optic is found by measuring on the cast, the major and minor scleral chords (usually on the temporal and nasal sides, respectively) and taking half the difference between the two. A scleral chord is measured from the outer edge of the transition to the edge of the cast.

The total diameter and back scleral size of a scleral lens are determined by direct measurement with a transparent rule.

Vertex clearance for impression lenses is the distance from the front surface of the cast to the back surface of the shell, measured at the geometric centre of the back optic zone. This, and the apical projection of RGP scleral lenses (*see* Chapter 17), can be measured using a dial gauge or micrometer. The height from the front vertex of the lens to the base of the cast on which it is mounted, is measured using calipers. From this is subtracted the geometric centre thickness of the lens and the height of the cast from base to vertex.

Micrometer and spheres

A special problem arises in checking the primary optic diameter of a scleral lens because the sharp demarcation between back optic zone and scleral surfaces is usually removed by the transition. It is possible to measure this diameter by finding the difference between optic and scleral zone sags (Stone, 1964).

A sphere with radius equal to the back scleral radius of the lens to be measured is placed on the base plate of a vertical micrometer (*Figure 12.12*) with the lens on top. The maximum measurement *x* (*Figure 12.13*) is determined.

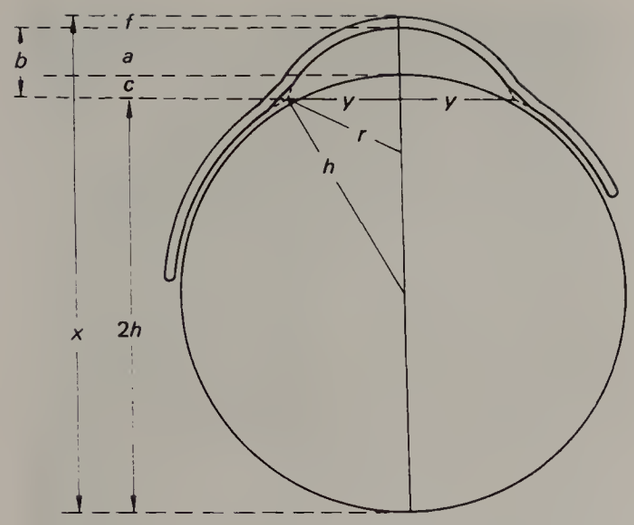


Figure 12.13 Principle of micrometer method of measuring primary optic diameter. h = back scleral radius; r = back optic zone radius; $2y$ = primary optic diameter; b and c are determined from the exact sag formula

From this is subtracted the thickness of the optic, t, and $2h$, the diameter of the sphere, to find the difference between the sags, a.

The value a is found in the appropriate table* indicated by the back scleral radius and back optic zone radius, and the primary optic diameter can then be read off. Values of a have been computed for back optic zone radii from 7.00 to 10.50 mm in 0.125 mm steps, back scleral radii from 11.50 to 15.50 mm in 0.25 mm steps, and primary optic diameters from 12.00 to 15.50 mm in 0.125 mm steps.

Axial edge lift measurement

Stone (1975) has described two methods, as follows.

Method 1

The lens is placed on the radiuscope holder in the usual manner, and a microscope cover slide placed on top (*Figure 12.14*). Central readings are taken successively on the underside of the cover slide and then the back surface of the lens. The difference between these readings gives the lens primary sag. From the sag formula $s = r - \sqrt{r^2 - y^2}$, where r = radius of curvature, s = sagitta at a semi-aperture y. The sag b, corresponding to the back optic zone radius of the lens under test at a diameter corresponding to the total diameter of the lens, is found. The axial edge lift $e = b - s$ (*Figure 12.15*). This does not allow for edge rounding. In a similar method used by Pearson (1990) a device was constructed for use with the radiuscope which used a plastic

*Tables used when measuring primary optic diameter with a micrometer (Stone, 1964).

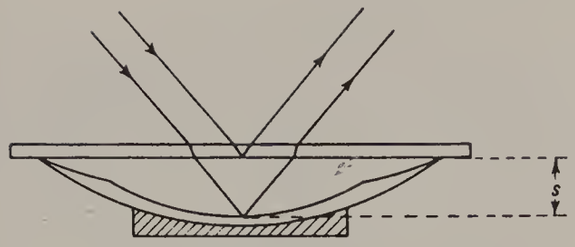


Figure 12.14 Axial edge lift measurement. A cover slide on the lens (which is placed in the radiuscope holder) permits s to be measured

support for a glass slide. The contact lens was placed on the lower surface of the glass slide, its edge being moistened so that it adhered to the glass. This method of support avoids possible error due to tilting of the lens.

Method 2

The radiuscope is first focused on the flat uppermost surface of a holder or stem of known diameter such as that shown in *Figure 12.15*. The test lens is then placed on this, convex surface upwards, and the radiuscope is re-focused at the apex of the convex surface. The difference between these readings gives the sag s plus the lens thickness. From the sag formula the sag b, corresponding to the back optic zone radius of the lens under test at a diameter equal to that of the stem, is found. The axial 'edge' lift e is then given by $e = b - s$. This gives the true axial edge lift at the known diameter of the stem.

Radial edge lift

As described by Newlove (1974) and Stone (1975), and shown in *Figure 12.16*, the radial edge lift also may be found by placing the lens concave surface down on a holder of known diameter. It can be seen from the right-angled triangle in *Figure 12.16*, that by Pythagoras' theorem:

$$(\text{Radial edge lift} + \text{BOZR})^2 = \left(\frac{\text{Stem diameter}}{2}\right)^2 + (\text{BOZR} - \text{sag})^2$$

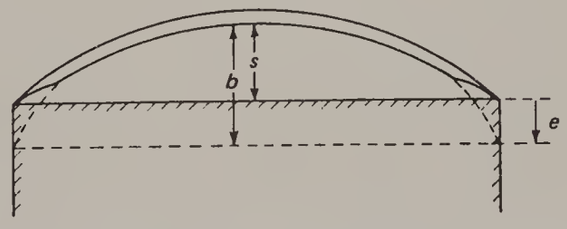


Figure 12.15 Axial edge lift $e = b - s$. Here the lens is placed on a holder having a stem diameter equal to its total diameter. Other stem diameters may be used

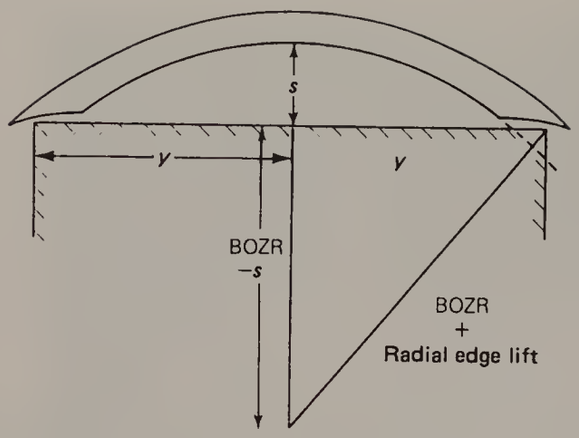


Figure 12.16 Determination of radial edge lift. (After Newlove, 1974)

If stem diameter = $2y$ and sag = s, then

Radial edge lift = $\sqrt{y^2 + (\text{BOZR} - s)^2} - \text{BOZR}$

s is found as described above, by focusing the radiuscope first on the upper flat surface of the stem and then at the apex of the front surface of the lens, and subtracting the centre thickness of the lens from the measurement obtained.

Note. If the stem diameter is the same as the total diameter of the lens, the sag value, s, obtained is that of the primary sag of the lens.

Thickness

The thickness of the centre and edge, or any other part of a corneal lens, as well as the optic and scleral zones of a scleral lens, may be determined with a suitable thickness gauge which usually incorporates a dial gauge calibrated to 0.01 mm (*Figures 12.17* and *12.18*). **Radial thickness** is measured perpendicular to the front surface of a lens (although in practice, when the two surfaces are not parallel, the actual measurement may be made along an axis which is the nearest compromise to being perpendicular to both surfaces – *see Figure 12.18b*). **Axial thickness** is measured parallel to the primary axis of the lens. For most lenses the centre thickness is measured at a common geometric and optical centre, and at that point radial and axial thickness are the same. For points away from the optical centre, while radial thickness is easy to measure, axial thickness is not; but from the manufacturer's point of view it is axial thickness which is the easier value to calculate from the sagitta values of the lens surfaces – *see* Chapter 5. This may mean that practitioner and manufacturer have a different understanding of 'edge thickness' for example. Pearson (1986) has discussed in detail the calculation and measurement of both radial and axial thickness as well as the relationship between them, and he has derived approximate conversion formulae. He also gave equations for deriving

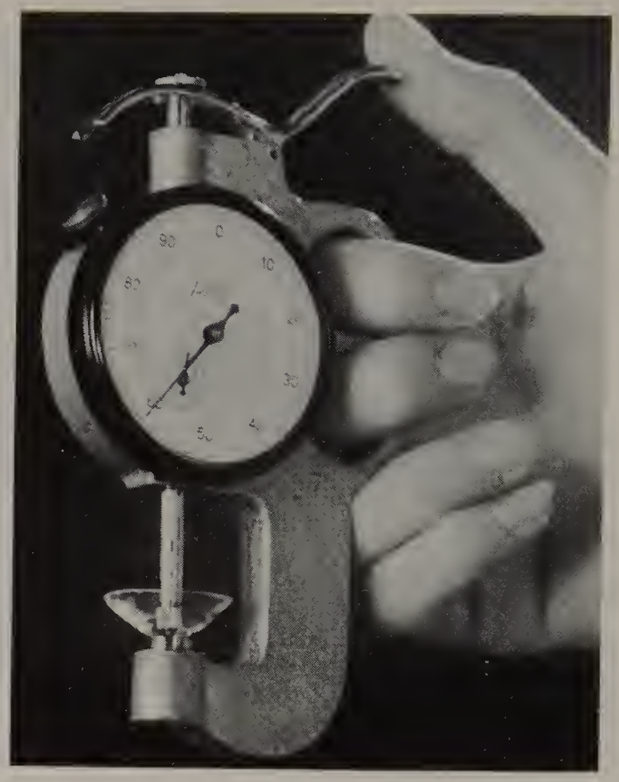


Figure 12.17 Measurement of the optic thickness of a scleral lens. Scale reading 0.60 mm

average thickness which is of significance when considering the oxygen transmission of a lens.

Guillon *et al.* (1986) described the use of a modified digital pachometer for the measurement of axial edge thickness of rigid lenses, giving an accuracy for single measurements of ±20 μm.

A modified thickness gauge (*Figure 12.18*) permitting radial edge thickness measurement at a precisely determined distance in from the very edge of the lens, was evaluated by Port (1987). The instrument permits accurately positioned centre thickness measurement and determination of the base–apex line of prismatic lenses. Supplied with a pre-programmed computer, it can be used to compare theoretical values of axial and radial thickness of rigid lenses of known geometry with the actual thickness at any realistic distance from the lens edge.

A spectacle lens measure may be used for thickness measurement if the lens is placed convex side down on a flat surface. The two outer legs of the lens measure should contact the flat surface outside the lens, and the centre leg be located on the concave surface of the lens where the thickness measurement is needed. The sag value obtained is then equal to the thickness of the lens. (Note: this method should not be attempted if the legs of the lens measure have sharp points; it is only safe if the legs have rounded tips.)

Another method is to use the radiuscope. Water is not used in the lens holder when the thickness of a lens is being determined. The target is focused on each lens surface in turn. The distance between the two foci multiplied by the

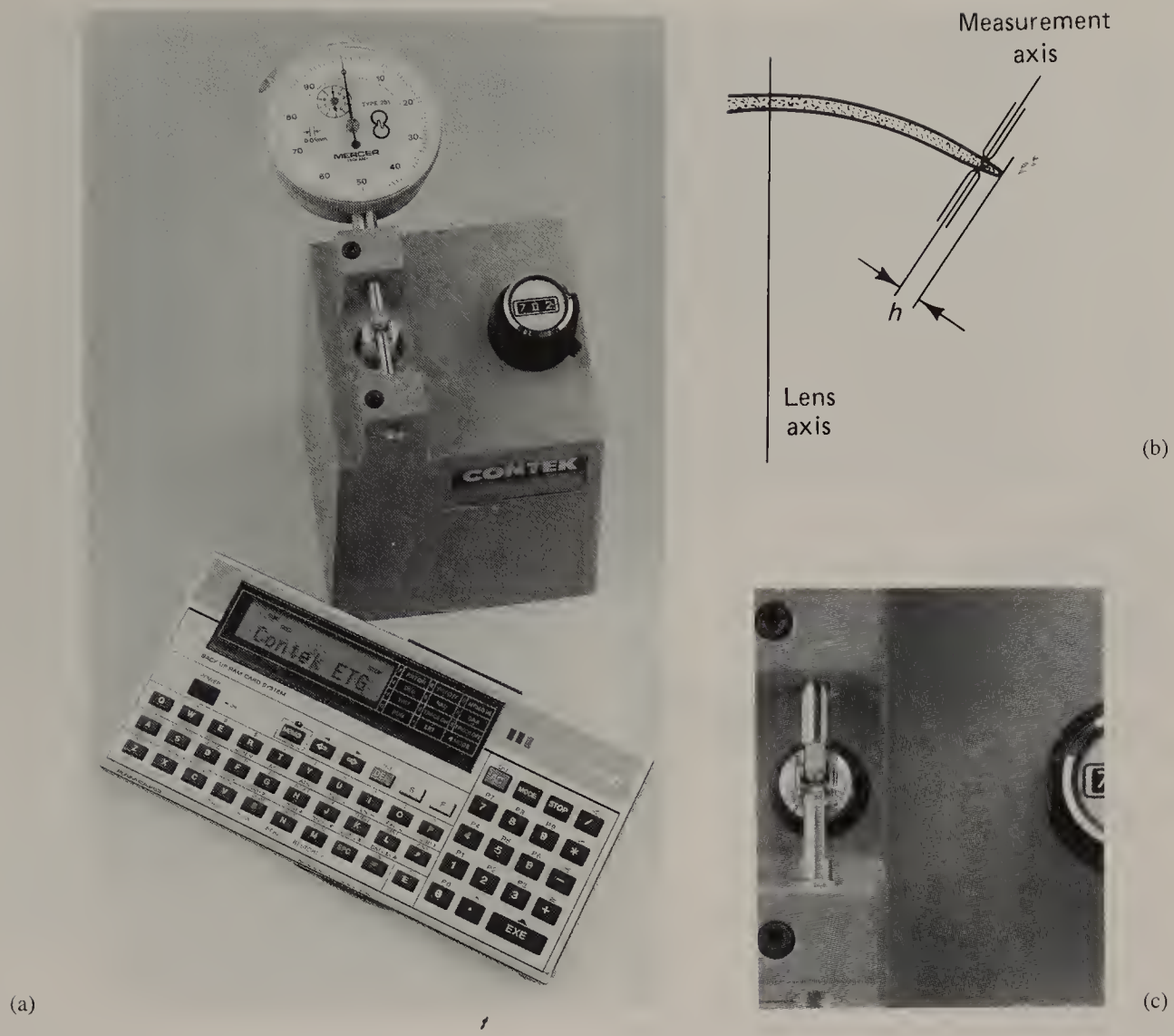


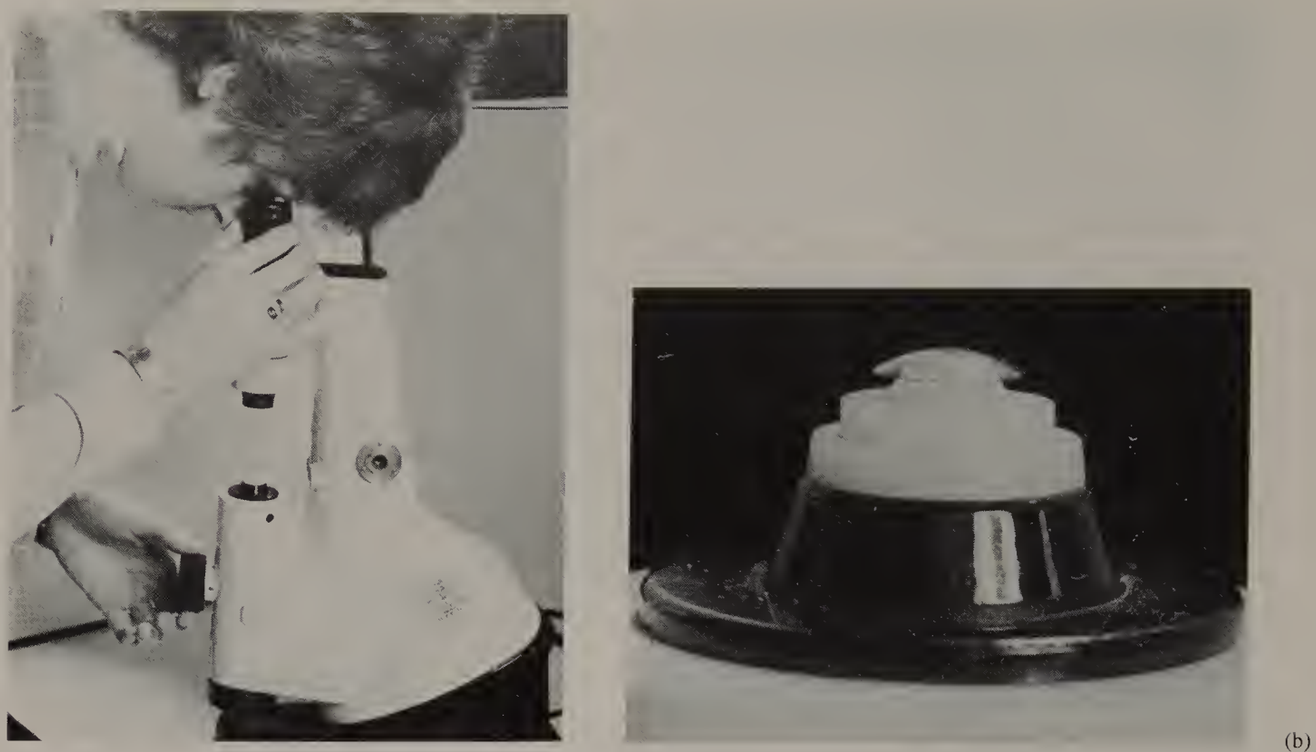
Figure 12.18 (*a*) The Contek edge thickness gauge and computer; (*b*) the radial thickness measurement it makes at a precise distance, *h*, in from the edge; (*c*) close-up of lens in place during edge thickness measurement. (Reproduced by kind permission of Microturn Ltd)

refractive index of the material gives the lens thickness. Or a flat plate may be put on the radiuscope holder, on which surface the radiuscope is first focused and set at zero. The lens is then placed, convex side down, on the plate and the radiuscope focused at the centre of its back surface. This gives a direct reading of the lens centre thickness.

Optic–lens prescription

The back vertex power of a contact lens may be measured using a focimeter. If the focimeter is mounted vertically, the lens can rest freely on the stop. A corneal lens, if held against the stop, may be distorted by the pressure of the fingers. Unless its construction permits angling to a vertical position, it is possible to arrange for a focimeter to be mounted vertically by means of a special stage (*Figure 12.19*). The focimeter is used in the normal way to determine the prescription. Care is needed in centring the lens to determine any prism.

One problem in determining the back vertex power of a contact lens is that the back surface of the lens may not be in the plane of the focimeter stop. This is because contact lenses have highly curved surfaces. With scleral lenses, the scleral zone may prevent the back surface of the lens from lying in the correct plane. The back vertex power may therefore be recorded as being a greater positive or smaller negative value than it actually is. This is because the back vertex focal length of a lens is measured from the plane of the stop to the target position (*Figure 12.20*). Because the back surface of the lens is not in the plane of the stop, the true back vertex focal length is acutally greater. This error can be minimized either by using a smaller stop or removing the stop collar, if possible, so that the back surface of the lens is in approximately the correct position. Special contact lens holders are available for many focimeters. (Rodenstock make a special attachment to their focimeter, for measuring corneal lenses. The stop may be screwed up or down depending on the BOZR of the lens which is indicated on a scale.)



(a) (b)

Figure 12.19 (*a*) Measurement of back vertex power on a focimeter; (*b*) close-up of lens in place against stop. It can be seen that the back vertex of the lens is not in the plane of the stop

Alternatively, instead of back vertex power, front vertex power may be measured by resting the front surface of the contact lens on an optical flat placed in the focimeter's stop. The back vertex power F'_v may then be determined by calculation if the central optic thickness and back optic zone radius are known, by using the formula:.

Back vertex power

$$F'_v = \frac{F_1 + F_2 - t/_n (F_1 F_2)}{I - t/_n (F_1)}$$

where F_1 = front surface power
F_2 = back surface power
t = centre thickness of lens
n = refractive index of lens

Surface quality and polish, edge form, material tint

A binocular microscope (*Figure 12.21a*), radiuscope, contact lens viewer or measuring magnifier may be used to

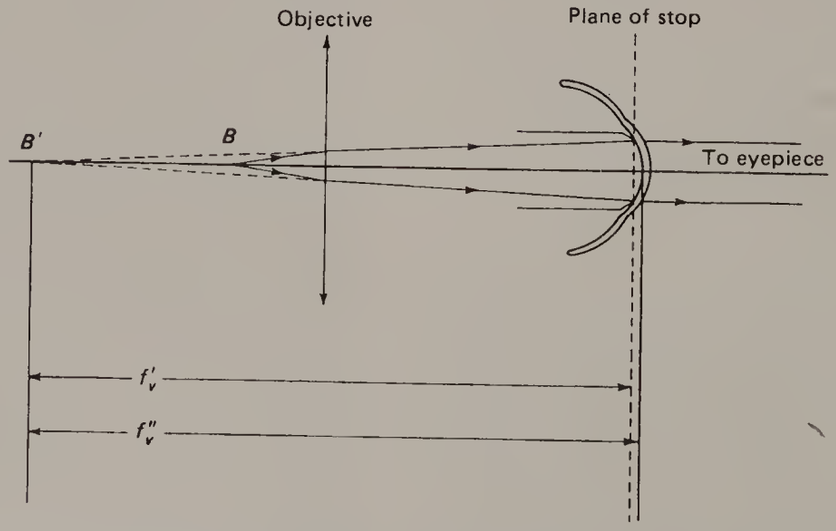


Figure 12.20 Error in measuring back vertex power, f_v' = back vertex focal length of lens under test as measured on the instrument; f_v'' = true back vertex focal length: B = target: B' = image of target formed by objective

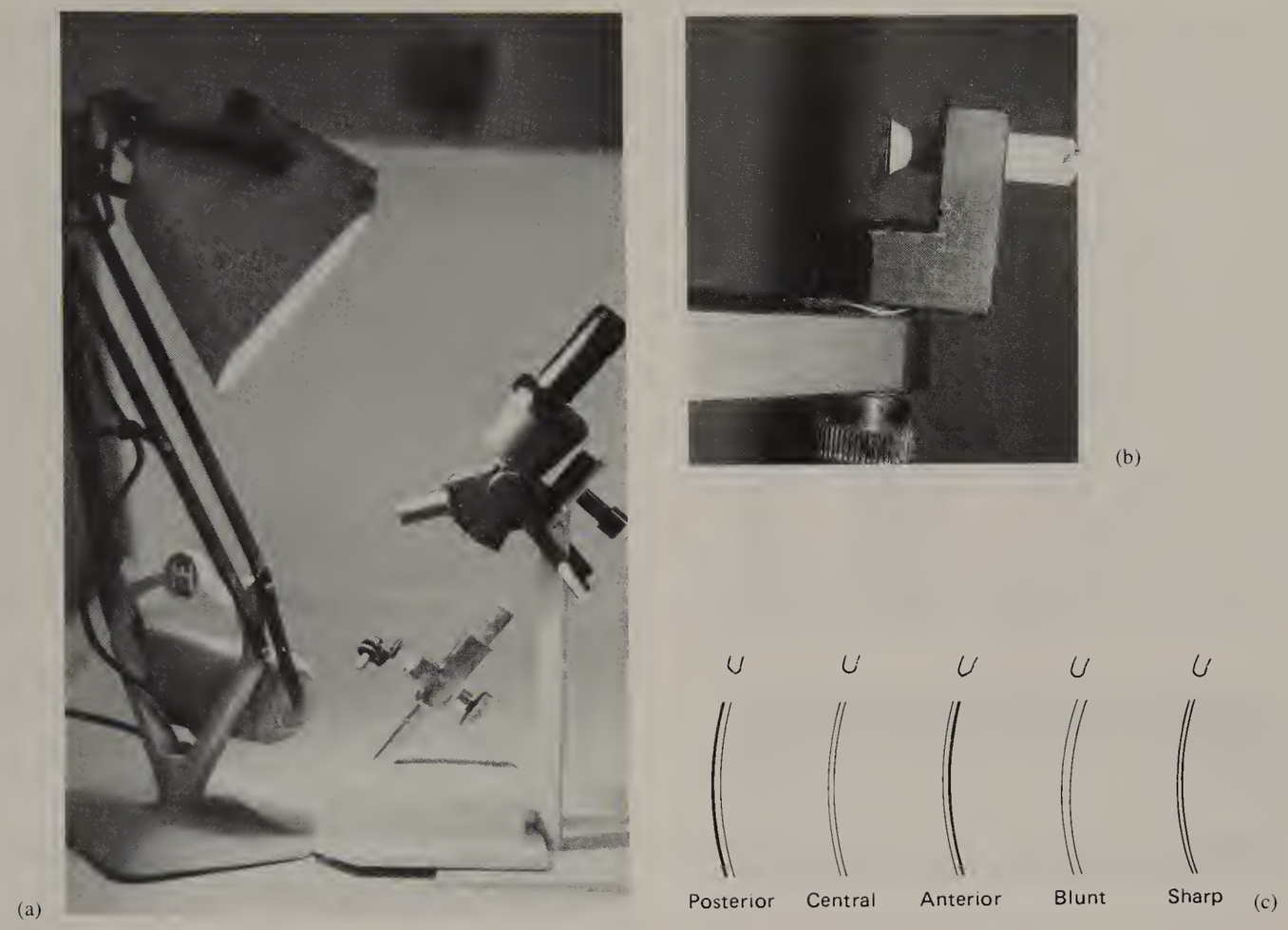
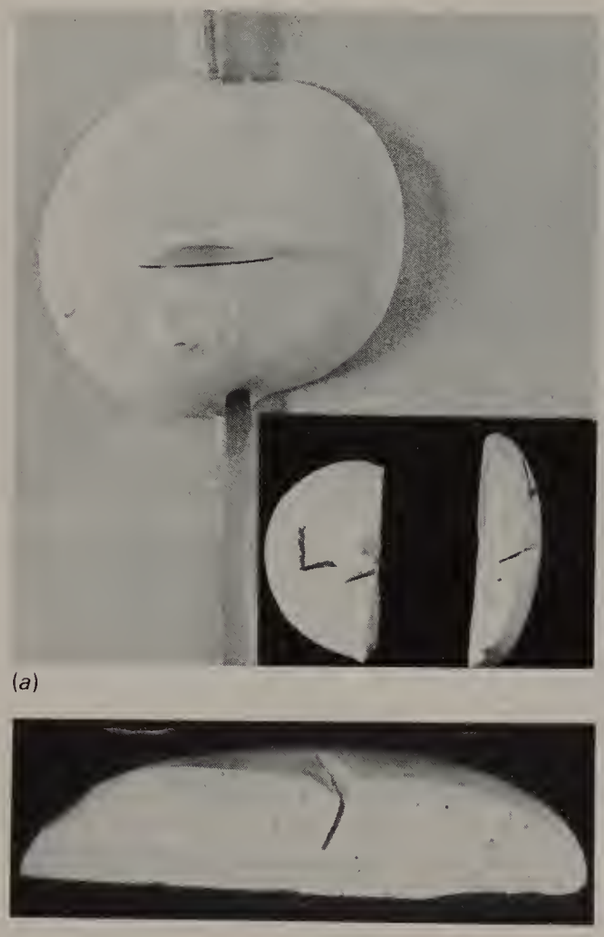


Figure 12.21 (*a*) Binocular microscope used to inspect lens surfaces and edges. An external light source is used. The lens is held on the suction holder which can be rotated about its own axis and about the plane of the lens, the rotating holder being movable along its angled support to permit accurate focusing. The rotating holder and support were built by Ronald B. Rabbetts (Rabbetts, 1978) for The London Refraction Hospital (LRH, now the Institute of Optometry). (*b*) Lens edge. When seen through the microscope the width of the central bright reflection, at the very edge nearest the observer, can be used to judge the edge shape as in (*c*). (*c*) The position and width of the bright edge reflection – shown as the gap between the lines – from several corneal lens edges whose profiles are shown above, and with the position of the peak of the edge given below. (*a* and *c* reproduced by kind permission of R. B. Rabbetts)

examine the surface of a contact lens. Alternatively, the lens is observed against a uniformly illuminated background with or without magnification. The blending of the transition may be observed at the same time. For the back transitional curve, the horizontal image produced from an elongated light source such as a fluorescent tube can be observed with a ×10 loupe or hand magnifier (*see Figures 12.9a* and *21.15* and Bailey, 1959; McMonnies, 1986). Lenses should be free from material defects and surface imperfections.

Any distortion of the optic zone or unwanted cylinder may be found using a cross-line chart and the lateral and rotational tests, or by using a focimeter or radiuscope.

The shape of the edge of a contact lens may be examined by observation with a binocular microscope with the lens mounted on a suitable rotating holder as shown in *Figure 12.21*, or by projecting a shadow of the edge onto a screen. Casting the edge in dental stone or impression materials, or pressing the lens edge into Plasticine may be utilized and in each case the impression left on the material is examined under magnification with a binocular microscope, for example, on a slit lamp. The edge is cast by inserting the edge of the lens into a small pool of dental stone on top of a rubber band on a square of plastics material (*Figure 12.22*). The lens is placed at right-angles to the rubber band. When the dental stone is just set, the lens is gently removed and the dental stone is pulled off the rubber band. The dental stone is scored on the back by the rubber band so that it is easy to break in half and the edge cast can be examined in cross-section. With more fragile rigid gas permeable lenses, it is better to use impression material which sets quickly and can be cut with a razor blade to reveal the contour of the lens edge in cross-section. However, because impression material dehydrates and shrinks, the cast is only accurate for a short time, compared to the permanent record provided by a dental stone cast.



(a)

(b)

Figure 12.22 (*a*) Lens edge being cast in dental stone. Inset: cast broken in half. (*b*) Magnified view of section through cast. A square-shaped edge is seen. Provided that it is not distorted, impression material is quicker and safer to use

Plasticine provides a quick and easy means to examine the edge, but the cast tends to lose shape. If the lens is left in the Plasticine, the edge shape can be seen in profile against the Plasticine when examined with the binocular or slit lamp microscope.

McMonnies (1986) advocated the use of a × 20 hand magnifier to inspect the outer edge profile, the lens being held in a horizontal plane, concave surface down, between index finger and thumb, with the magnifier being held in the other hand in the same way. The thumbs can be kept in contact with each other to minimize movement. The illumination from a single fluorescent tube reflected in a bench-mounted mirror obviates the need to raise the hands above the head (*see Figures 18.50* and *18.51*).

The edge should be examined at a number of different points by one of the above methods.

The entire circumference of the lens edge should also be rotated before a binocular microscope to check for any localized distortions.

The colour of a contact lens may be observed against a white background.

A specific gravity test may be used to establish the basic type of material (*see* Chapter 10, p. 355). Some rigid gas permeable lenses are engraved with a material identification mark by the manufacturer.

Dain and Pye (1993) propose that the use of spectral transmittance characteristics in the UV and visible regions can characterize a lens material sufficiently to identify it.

Rigid gas permeable lens materials can also be identified using a hand held refractometer (Hodur *et al.*, 1992). The instrument was calibrated using a PMMA contact lens (refractive index 1.49). Refractive index measurements of 1.46 or greater indicate silicone acrylate materials whilst readings of less than 1.46 are fluorosilicone acrylate lenses (*see also* Chapter 10).

Stress

Stress may be checked by placing the lens between crossed polarized filters. If stress is present a strain pattern is seen, otherwise the appearance is devoid of any pattern.

Surface and undersurface stresses can lead to subsequent flaking of the surface layers, in final lens working, polishing or in later use (Cordrey, 1973).

Stress and electrical charges such as static and piezo-electric effects are thought to be responsible for the spontaneous fracture and surface crazing of many rigid gas permeable (RGP) lenses. A surface-crazed lens is shown in *Figure 18.32*). The whole subject of stress in polymers is a very complex one. Silk (1987) discussed the matter in some detail indicating all the factors to be taken into consideration to avoid problems for wearers of PMMA and RGP lenses (*see also* Chapter 8).

Toric lenses

When a radiuscope is used to check toroidal surfaces, the target image formed on the lens surface appears uniformly focused as seen through the microscope, but, as a toroidal surface has two centres of curvature corresponding to the two principal meridians, there is not a uniformly focused target image formed at the two centre of curvature positions. Instead, only one of the target lines will appear sharply focused and the lens must be rotated so that each principal meridian coincides with one of the target lines. Then the centre of curvature of each principal meridian is located by focusing the two perpendicular target lines in turn. If the target consists of a ring of dots there is no need to rotate the lens to locate the principal meridians.

If a keratometer is used, the procedure is the same as for carrying out keratometry on a toroidal cornea, the usual allowances being made for the measurement of a concave surface instead of a convex one.

The back optic zone diameter of a corneal lens may be oval, depending on the method of manufacture, so maximum and minimum values should be found.

For checking the power of toric lenses the axes are aligned on the focimeter and the powers read directly.

Aspheric lenses

DeFazio and Lowther (1979) investigated two methods of clinically inspecting and verifying aspherical back surfaces of hard contact lenses. In the first method a radiuscope was modified with a tilting table. By measuring radii at off-axis points, the eccentricity was calculated for each aspherical surface tested. The conformity of the surface to a true conicoid could then be evaluated.

Garner (1981) described a method of assessing the back surface of hard contact lenses using a modified low-power stereomicroscope to view the interference fringes formed between the contact lens and a test plate. He outlined how the instrument could be used to measure the radius of curvature of the optical zone and the periphery of aspheric contact lenses, and to assess the quality of the back surface of the lens.

The ability to reproduce aspherical back surface designs to nominal specifications is important. Garner (1981) and DeFazio and Lowther (1979) produced results that suggested some variation between the nominal specifications of the lens surfaces and the measured values.

Bifocal lenses

The near addition may be checked using a focimeter. For solid PMMA bifocals, where the addition is on the back surface, its value in air is 3.18 times that on the eye (*see* Chapter 16 p. 541). The diameter and position of the near vision zone may be checked using a measuring magnifier.

Diffractive bifocal lenses

At the time of writing, there are no rigid lenses of this type being manufactured. The Pilkington Diffrax was one such lens and since it may be necessary to check these lenses from time to time, the following explanation is included (*see* Chapter 16).

The various diameters and thicknesses are measured in the conventional way. The effective BOZR is a non-existent curve. A radiuscope measurement of the diffractive surface is easily obtained, but its value is not that of the effective BOZR. The radius measured depends on both the dioptric value of the addition and the effective BOZR (*Table 12.3*). For example, a lens having a near addition of +2.00 D and an effective BOZR of 7.5 mm would give a radiuscope reading of 7.925 mm. Thus, the near addition of the lens must be known and checked in order to ascertain the effective BOZR.

Verification of the near addition is simply related to the number of diffractive zones appearing as rings on the back optic zone of the lens. *Table 12.4* shows the number of diffractive zones for each of the available near addition powers.

Table 12.3 Determination of the effective BOZR of Pilkington Diffrax bifocal lenses from the measured radius (using a radiuscope) and near addition

Near addition (D)	*+1.00*	*+1.50*	*+2.00*	*+2.50*	*+3.00*
Effective BOZR (mm)	*Measured radii* (mm)				
7.10	7.283	7.380	7.480	7.582	7.687
7.20	7.389	7.488	7.591	7.696	7.804
7.30	7.494	7.597	7.702	7.810	7.922
7.40	7.600	7.705	7.813	7.925	8.040
7.50	7.705	7.814	7.925	8.040	8.158
7.60	7.811	7.922	8.037	8.155	8.277
7.70	7.917	8.031	8.149	8.271	8.396
7.80	8.023	8.140	8.261	8.386	8.515
7.90	8.128	8.249	8.374	8.502	8.634
8.00	8.234	8.358	8.486	8.618	8.754
8.10	8.340	8.467	8.598	8.734	8.874
8.20	8.447	8.577	8.712	8.851	8.993
8.30	8.553	8.686	8.825	8.967	9.114
8.40	8.659	8.796	8.937	9.084	9.235
8.50	8.765	8.906	9.051	9.201	9.356
8.60	8.872	9.016	9.165	9.318	9.477

Table 12.4 Near addition power corresponding to number of diffractive zones or visible rings of the Pilkington Diffrax bifocal RGP lens

Near addition (D)	*No. of diffractive zones*
+1.00	6
+1.50	8
+2.00	11
+2.50	14
+3.00	17

The distance back vertex power (BVP) of the lens cannot be determined directly from the focimeter reading in air, as this produces several images, some of them coloured. The maximum positive green reading is used and from this value, twice the near addition is deducted to obtain the distance BVP. For example, a Diffrax lens with a maximum positive power reading of +2.00 D and eight diffractive zones (+1.50 D near addition) has a true distance BVP of +2.00 D – (+1.50 × 2) = –1.00 D.

Addenda

BS 7208: Part 3: 1992 describes a number of methods of test for contact lenses and calibration procedures. The standard also describes conditioning of contact lenses prior to testing.

Extracts from BS 7208: Part 1: 1992 are reproduced here with the permission of BSI.

Addendum I Dimensional tolerances for hard contact lenses (BS 7208: Part I: 1992; ISO 8321–1: 1991 (E))

Dimension	*Corneal*		*Scleral (mm)*
	Polymethyl methacrylate (PMMA) (mm)	*Gas permeable (mm)*	
Back optic zone radius	±0.025	±0.05	±0.010
Back optic zone radii of toroidal surfaces			
where $0 < \Delta r \leq 0.2$	±0.025	±0.05	±0.12
where $0.2 < \Delta r \leq 0.4$	±0.035	±0.06	±0.13
where $0.4 < \Delta r \leq 0.6$	±0.055	±0.07	±0.15
where $\Delta r > 0.6$	±0.075	±0.09	±0.17
(*see* notes 1 and 2)			
Back optic zone diameter (*see* note 3)	±0.20	±0.20	±0.20
Back scleral radius (of preformed lens)	–	–	±0.10
Basic or primary optic diameter	–	–	± 0.20
Back or front peripheral radius (where measurable)	±0.10	±0.10	±0.10
Back peripheral diameter (*see* note 3)	±0.20	±0.20	±0.20 (for preformed lenses)
Total diameter (*see* note 2)	±0.10	±0.10	±0.25
Front optic zone diameter (*see* note 3)	±0.20	±0.20	±0.20
Bifocal segment height	–0.10 to +0.20	–0.10 to +0.20	–0.10 to +0.20
Centre thickness	±0.02	±0.02	±0.10
Vertex clearance from cast (for impression scleral lenses)	–	–	±0.02

Notes
1 Δr is the difference between the radii of the two principal meridians.
2 The tolerance applies to each meridian.
3 These tolerances apply only to lenses with spherical surfaces and distinct curves; they are for a finished lens and any blending may make measurement difficult.

Addendum II Optical tolerances of corneal lenses and scleral lenses (BS 7208: Part 1: 1992; ISO 8321–1: 1991 (E))

Dimension	*Corneal or scleral (including gas permeable)*
Back vertex power in the weaker meridian	±0.12 D
0 to ± 5.00 D	
over ±5.00 D to ±10.00 D	±0.18 D
over ±10.00 D to ±15.00 D	±0.25 D
over ±15.00 D to ± 20.00 D	±0.37 D
over ±20.00 D	±0.50 D
Prismatic error (measured at geometrical centre of the optic zone)	
Back vertex power 0 to 6 D	± 0.25 Δ
Back vertex power over 6 D	± 0.50 Δ
Prescribed prism	± 0.25 Δ
Optical centration for scleral lenses only (maximum error)	0.50 mm
Cylinder power	
up to 2.00 D	±0.25 D
over 2.00 D to 4.00 D	±0.37 D
over 4.00 D	±0.50 D
Cylinder axis	±5°

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Chapter 13

The verification of hydrogel contact lenses

D. F. C. Loran

Manufacture of hydrogel contact lenses p. 427
Lens specification p. 430
Definitions p. 430
Standards p. 432
Quality assurance p. 433
Verification procedures p. 436
Radiuscope (optical microspherometer) p. 446
Classification of deposits p. 460
Conclusion p. 460

Hydrogel contact lenses are flexible and if exposed to the atmosphere they dehydrate and alter their contour; thus, conventional methods of measuring rigid lens parameters are not applicable to this type of contact lens. As a consequence, practitioners may feel unable to check the specification of these lenses conveniently and this may, in turn, result in frustration and disappointment if a lens received from the laboratory does not provide the expected performance *in situ*. Such a situation is obviously most unsatisfactory and practitioners are urged to verify the parameters of soft contact lenses within the limitations of present instrumentation.

Undoubtedly, it is most convenient to check soft lens parameters directly in air using conventional instruments, although such methods may present inaccuracies due to surface deformation, shrinkage of the hydrogel on dehydration and also accumulation of surface moisture. In order to overcome these artefacts liquid cells as shown in *Figures 13.1* and *13.2* have been utilized to measure the parameters of soft lenses.

The Draft International Standard ISO/DIS 8321/-2 recommends that, following equilibrium, soft contact lenses should be measured in freshly prepared, normal, isotonic, buffered saline at a pH of 7.4 ± 0.1 with an osmology of 310 ± 5 milliosmol/kg. It is anticipated that this standard will be the basis for future European Committee for Standardization (CEN) and International Standards (ISO 10344). British Standard BS 7208 Part 1 recommends that the solution should be at a temperature of 20 ± 1.0 °C. However, as the lens equilibrates it will continuously change shape which is a potentially error-prone part of the measuring process.

If hydrogel lenses are mounted in a transparent cell containing a compatible medium such as sterile physiological saline solution (without a preservative) then the lens should assume its natural, undistorted form. Masnick and Holden (1972) ascertained that changes in pH and tonicity of the lens environment produced clinically significant alterations in the water content with associated parametric variations. Measurements of the total diameter and also primary sagitta of soft lenses by Poster and Skolnik (1974) indicated that these changes varied with tonicity, but not pH, while Masnick and Holden (1972) observed a decrease in total diameter in alkaline solutions. Kemp (1979) and Port (1982b) noted that, as the pH of the ambient saline is increased, the back optic zone radii flatten significantly and consequently physiological, buffered saline is recommended as the test medium. Phillips (A. J., 1987, personal communication) suggested this flattening was caused by an increase in water content which is more likely to occur in polymers containing methacrylic acid and which are more pH sensitive.

Furthermore the refractive index increases and the water content reduces with increased temperature (Fatt and Chaston, 1980). As water is lost the lens becomes thinner and less positive but this is more than offset by the increase in positive power of plus lenses as the refractive index increases. Thus, the accumulative effect is towards more positive power. In general these parametric changes are greater for high water content lenses and these findings emphasize that environmental factors need to be specified, standardized and carefully controlled when measuring soft lens parameters.

In a comprehensive survey Harris *et al.* (1973) checked soft lenses in air and concluded that, with the notable exception of radii, these parameters could be checked in air with a reasonable degree of accuracy. Mandell (1974a) recommend the following procedure for air measurement of soft lens power:

- The lens should be removed from its liquid environment using a sterile spatula or soft plastics-protected forceps.
- The lens is then placed on a lint-free tissue and the tissue folded over the uppermost convex surface of the lens.
- The lens is transferred onto a dry area of tissue and the above step repeated to make sure that both surfaces are blotted dry.
- The lens is dried in air with forceps.
- The lens surfaces are examined macroscopically and, if smudges are present, the process is repeated.

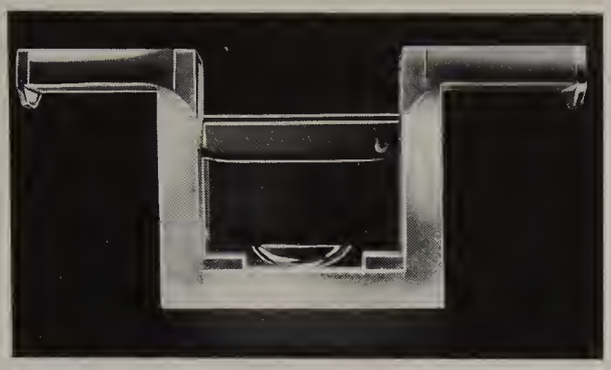


Figure 13.1 Hydrogel lens immersed in physiological saline solution in a liquid cell. (Photograph by courtesy of Söhnges Optik)

- Although it is probably preferable to check the lens within an overall period of one minute of air exposure (Titmus Eurocon, 1974), the lens essentially maintains its contour within clinical limits for up to four minutes during which time the measurements should be completed.

Before considering the verification of soft contact lenses, however, it is expedient to consider the lens specification which, in turn, is predetermined by the method of manufacture which may be spin-casting, lathe-cutting or moulding.

Manufacture of hydrogel contact lenses

(*see also* Chapter 21)

Spin-casting (spin-moulding)

The Bausch & Lomb Soflens (Polymacon) is produced by a computer-controlled method of axial spin-casting originally introduced by Wichterle and Lim (1960) and Driefus (1968) for the Czechoslovakian Geltakt lens.



Figure 13.2 Liquid cell, showing an immersed lens, used to determine power of lens in saline solution, to measure diameters with a band magnifier, or for surface inspection

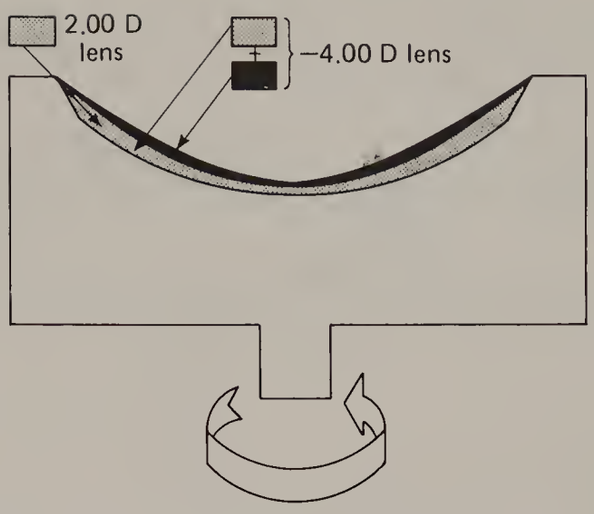


Figure 13.3 Axial spin-casting method of producing the Bausch & Lomb Soflens and the Hydron Ultra-T by injecting liquid monomers into a rotating mould where polymerization occurs. The lens is indicated by the grey shaded area within the concave mould. The darker area above indicates the lens shape and the additional minus power produced either by a higher speed of mould rotation or a greater injection pressure

Liquid monomers of 2-hydroxyethyl methacrylate and ethylene diglycol methacrylate are stored at a temperature of −5°C and injected through a polythene tube into a rotating female mould where polymerization occurs in a carbon dioxide atmosphere at a temperature of 65°C (Hartstein, 1973).

By controlling three variables – mould diameter, spin-speed and the volume of monomer injected – it is possible to produce a variety of shapes and curves. As illustrated in *Figure 13.3*, the lens is formed front surface downwards through the action of centripetal force and gravity (Bausch & Lomb Ltd, 1975, personal communication from R. Myers). The front curve is therefore determined by the shape of the female mould. The Bausch & Lomb Optima and Medalist (among others) have a spun-cast front surface with a lathed back surface. Chapter 11 includes greater details of these lenses (*see* for example, *Table 11.14* and *Figures 11.27–11.29*).

As the injection pressure or the speed of rotation is increased, more material is projected towards the periphery, thereby increasing the edge thickness. Consequently, as negative power is increased for a given series, the back surface steepens and the lens fits more tightly, the reverse occurring as negative power is reduced or positive power is increased.

The spin-casting process is fully automatic and produces smooth, reproducible surfaces free from tool marks, peripheral grooves and other imperfections which may occur in the polishing and finishing of lathe-cut lenses.

Table 13.1 Examples of some moulded hydrogel contact lenses

Manufacturer	*Spun-cast*	*Cast-moulded*	*Spun-cast/lathed*	*Moulded/lathed*	*Soft stabilized moulded*	*Wet-moulding*
Aspect		Formula 55 VHT				
Bausch & Lomb	B Series, O Series, SeeQuence Sofspin, U Series		Medalist 66 Optima FW Optima 38 SeeQuence II			
CIBA Vision		Spectrum Visitint Newvues Excelens		Visitint		
Eye Tech (CLM)		Eurosoft (38) Eurothin				
Hydron		Hydron Echelon				
Igel International		Igel Omega				
Lunelle		Variation				
Nissel		Incanto				
Vistakon					Acuvue Surevue	
Wesley–Jessen		Precision UV		Classic, Hydrocurve II SS Permaflex 74 Soft Mate B Soft Mate II		Freshlook

Source: Efron, 1994

Lathe-cut lenses

Traditionally hydrogel contact lenses are lathed in a similar manner to rigid lenses except that the lathing process is slower, and non-toxic, and aluminium oxide-based polishes* are used. This technique offers a broad spectrum of parameters as dictated by a patient's fitting and refractive considerations. However, with the advent of thinner and/or higher water content soft lenses, often based on a one-fit philosophy, there is now a trend towards alternative methods of manufacture. Automatic lathing, spin-casting, spin-casting one surface and lathing the other, cast-moulding or stabilized soft moulding may all yield more reproducible lenses and are methods which may be more readily adapted to computer-controlled mass production techniques. However, lens lathing technology has also been considerably improved and updated. In the lathing method of production the front and back optic radii are cut and polished from stress-free, dehydrated buttons, allowance being made for a predetermined linear swell on hydration. Consequently the radii are steeper and the thickness less by a known amount in the dry state, than in the hydrated state.

The linear swell may be defined (H. Gee, 1980, personal communication) as:

$$\text{Linear swell } (\%) = \frac{L_g}{L_p} \times 100 = \frac{V_g}{V_p} \times 100$$

where L_g = linear dimension of the hydrated polymer
L_p = linear dimension of the dehydrated polymer
V_g = volume of hydrated polymer
V_p = volume of the dehydrated polymer

It has been shown that, provided ambient variables such as temperature and humidity are carefully controlled during manufacture, then the hydrated parameters such as centre thickness can be predicted with reasonable accuracy from the linear swell value (Loran *et al.*, 1982).

Moulding

A moulded contact lens is produced by pressing, usually between dies, and is defined as one manufactured primarily in a mould (ISO/DIS 8320 and BSI 3521). Moulded scleral lenses have been produced for many years by heating a Perspex laminate to softening point and then pressing onto a hard cast.

Provided that plastic memory can be controlled, moulding is generally considered to be a satisfactory manufacturing process and should result in relatively thin, smooth and reproducible surfaces. Indeed, most polymers, if they are not cross-linked, are suitable for moulding (H. Gee, 1980, personal communication) and consequently this process has also been used to produce soft contact lenses.

Current fitting philosophy is now directed towards higher Dk lenses that are discarded after a short period of time. Disposable and frequent or planned replacement lenses need to be both reproducible and economical. Moulding is a suitable manufacturing process to produce relatively inexpensive lenses to fulfil these criteria.

*Examples of soft lens polishes are: Vistalox and Vistagel manufactured by Vista Optics Ltd; Lamda SL1 and SL2 manufactured by Lamda Engineering Ltd; and Sauflon SP1 and SP2 manufactured by Sauflon Pharmaceuticals Ltd.

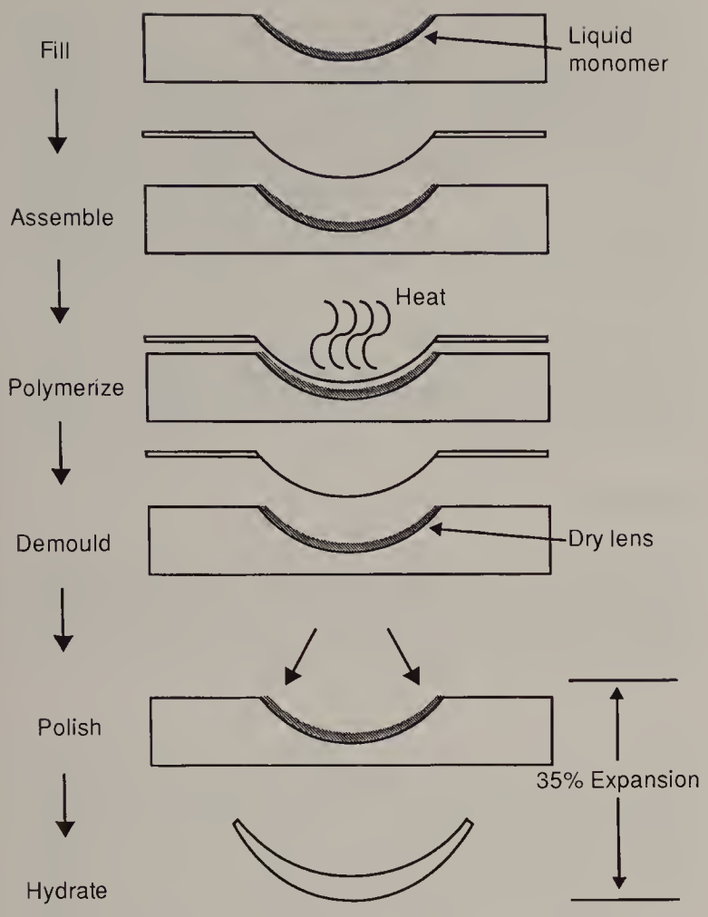


Figure 13.4 The cast moulding method of producing soft contact lenses. (Redrawn from Heyda, 1991 with permission)

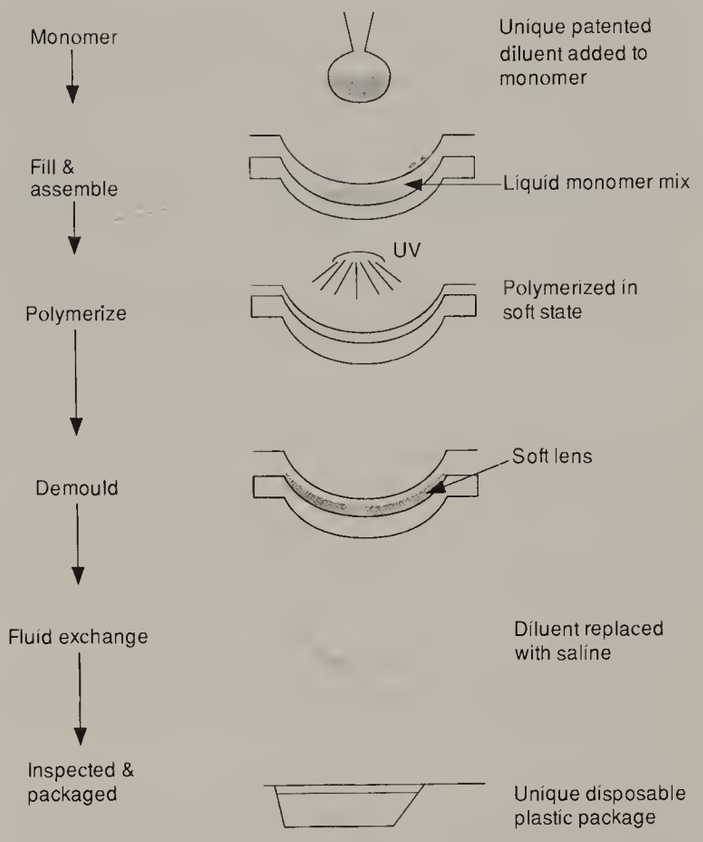


Figure 13.5 The soft stabilized moulding method of producing soft contact lenses in the wet state. (Courtesy of Vistakon UK, Johnson & Johnson)

Table 13.1 lists some soft contact lenses manufactured by moulding and also illustrates some hybrid lenses which are fabricated by lathing one surface and contouring the other, either by moulding or by spin casting.

Many frequent replacement and soft disposable contact lenses are produced by cast moulding (*Figure 13.4*). By this process, the liquid monomer is heated and polymerization occurs by the mechanical action of two moulds, one from above and the other from below. The lens is then taken from the mould and polished in the solid state. It is then rinsed, hydrated and sterilized and allowed to expand in a controlled manner similar to that of lathed lenses. In contrast, the Vistakon Acuvue and Surevue lenses are produced by a process of soft stabilized moulding and the Wesley–Jessen Freshlook lens by wet-moulding.

Soft stabilized moulding is illustrated in *Figure 13.5* and in this method a diluent whose molecules mimic those of water is added to the polymer. Whilst the lens is in its wet state, polymerization occurs between the moulds which are stimulated by ultraviolet radiation. After removing from the mould, the diluent is then replaced by saline. The final lens, in common with other disposable systems, is packed in single blister packs with multi-layer edges which, according to Heyda (1991), guarantees sterility for a four-year period.

Efron and Veys (1992) compared the quality of three soft disposable lenses. The results indicated that the prevalence of edge and non-edge (lens body) defects was as high as 75% when viewed at ×16 magnification. A typical edge profile of one of the disposable lenses in Efron and Vey's study is illustrated in *Figure 13.6*. In the case of stabilized soft moulding such defects are presumably a consequence of the production process which, in the wet state, would not

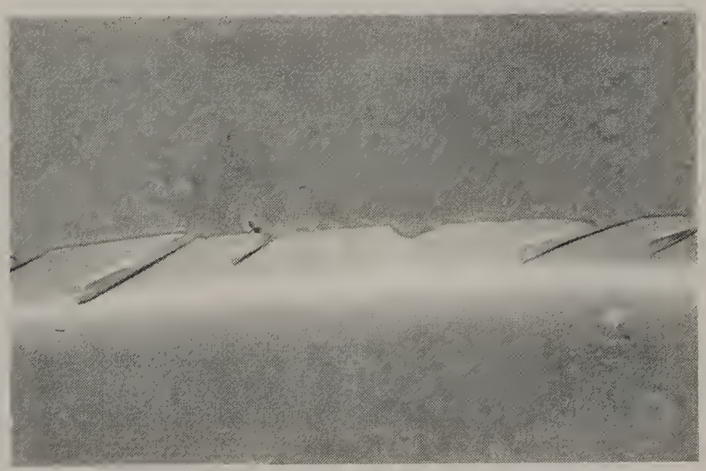


Figure 13.6 The profile of a soft contact lens produced by the soft stabilized moulding method illustrating edge defects (Courtesy of N. Efron)

permit the edges to be smoothed or polished. At the time of writing, the clinical significance, if any, of these lenses has not been established (Holden, 1992). Poggio and Abelson (1993a,b) found the ocular complications from disposable lenses produced by stabilized soft moulding were less than that of other soft lenses. Edge defects and optical zone eccentricity of stabilized soft-moulded lenses was reported by Wodis *et al.* (1990) who found a high reproducibility of sagittal heights, total diameters and back vertex powers but variations in the centre thickness and presumably transmissibility between lenses of the same powers.

Lens specification

Although manufacturers and practitioners may specify lenses in an abbreviated form, the British Standard 7208 Part 1 and ISO/DIS 8321–1 recommended a more detailed specification, examples of which are as follows:

(*a*) Single curve, soft hydrophilic corneal lens

L C1 Hyd/8.40:13.00/–3.50/t_c0.15/FOD12.00/HEMA 38%
(i) (ii) (iii) (iv) (v) (vi)

which denotes the following:

(i) Left single curve soft hydrophilic contact lens.
(ii) Back optic zone radius and total diameter.
(iii) Back vertex power.
(iv) Centre thickness.
(v) Front optic (zone) diameter.
(iv) PHEMA (polyhydroxyethyl methacrylate) with 38% water content.

(*b*) Bi-curve soft hydrophilic scleral lens

R S2 Hyd/8.50:11.00/9.70:14.50/+4.00/t_e 0.17/HEMA 60%
(i) (ii) (iii) (iv) (v) (vi)

which implies:

(i) Right bi-curve soft hydrophilic contact lens.
(ii) Back optic zone radius and back optic zone diameter.
(iii) Back peripheral radius and total diameter.
(iv) Back vertex power.
(v) Edge thickness.
(vi) PHEMA with 60% water content.

Definitions

Before considering the verification of soft contact lens parameters, it would perhaps be helpful to define some of the terms used. In practice, however, this is not entirely straightforward as confusion exists in the terminology, not only between the layman and the scientist, but also perhaps more significantly between one science and another. It is hoped that standardization and agreement will occur with the fullness of time.

Accuracy

Accuracy refers to the degree of agreement between a measured and a true value (C. N. French, 1986, personal communication) or how close a measured value is to the true value (M. Sheridan, 1986, personal communication). Guillon *et al.* (1986), however, using meteorological terminology, define accuracy (A) as the sum of the quadrature precision (R) and the systematic uncertainties (S) so that:

$$A = \sqrt{R^2 = S^2}$$

For a fuller discussion of errors in physical science reference should be made to Bevington (1969).

Calibration

Calibration is a process of supplementing a measuring instrument with a complementary statement regarding likely errors inherent in the system (Draft British Standard, 1986).

Error

Error (E) is the difference between a measured and a 'true' value and may either be greater than the true value, in which case it is positive, or negative if less.

$$E = x - x'$$

whereby x = true value; x' = measured value.

Gauge mechanisms

These should eliminate backlash so that this source of error need not be considered if readings are taken in one direction only.

Independent readings

This means that the lens on test (and the wet cell where appropriate) is removed from the instrument and remounted between readings.

Number of readings

The number of readings should be stated. The International Standards Organization (ISO 5725, 1986) recommends tolerance should be based on a 95% confidence level.

If MT = the measurement tolerance
S_R = the unbiased standard deviation of the reproducibility data
and n = the number of readings at 95% confidence level

$$\text{then } n = \frac{(1.96\ S_R)^2}{MT}$$

(D. A. Hough, personal communication, 1994).

Precision

Precision, repeatability or reliability refers to the stability or consistency of a reading when it is repeated and may be expressed in terms of the standard deviations of these repeated readings, and more properly referred to as the standard error of measurement.

Random error (Re)

A random error has an equal probability of being positive or negative and may be reduced by learning, operator skill or taking a series of measurements. Examples of random error include the judging of alignment or just contact between two surfaces.

Repeatability

Repeatability refers to the closeness of agreement between mutually independent test results obtained under repeatability conditions (International Standard ISO 5725, 1986).

Repeatability conditions

Repeatability conditions are conditions where mutually independent test results are obtained with the same method on identical test material in the same laboratory by the same operator using the same equipment within short intervals of time (International Standard ISO 5725, 1986).

Repeatability value (r)

The value below which the absolute difference between two single test results obtained under repeatability conditions may be expected to be within a probability of 95% (International Standard ISO 5725, 1986).

Reproducibility

The closeness of agreement between mutually independent test results obtained under reproducibility conditions (International Standard ISO 5725, 1986).

Reproducibility conditions

Conditions where mutually independent test results are obtained with the same method on identical test material in different laboratories with different operators using different equipment (International Standard ISO 5725, 1986).

Reproducibility value (R)

The value below which the absolute difference between two single test results obtained under reproducibility conditions may be expected to be within a probability of 95% (ISO 5725–1986).

Standard deviation

Standard deviation (σ)

$$= \sqrt{\Sigma (x - x')^2/(n - 1)}$$

in which x = any measurement, x' = the mean of the measurement, n = the number of measurements.

Repeatability standard deviation (S_r)

An unbiased estimate of the repeatability.

Reproducibility standard deviation (S_R)

An unbiased estimate of the reproducibility.

If S_R = unbiased standard deviation of the reproducibility data,
MT = measurement tolerance
and n = number of readings

then $$MT = \frac{1.96\ S_R}{\sqrt{n}}$$

(D. A. Hough, personal communication, 1994).

Systematic error (Se)

A systematic error is one due to bias and which tends to be constant or in one direction only. It will persist over a series of measurements and is equally likely to be either positive or negative, and may be minimized by good experimental design such as correct calibration. An operator reading a scale from an oblique angle or prejudiced observations are examples of systematic errors.

Tolerance

Tolerance is the maximum permissible difference by which a parameter is allowed to deviate from the stated or ordered value. The tolerance should be twice the accuracy of the measuring instrument and the test method should be stated (British Standard, 1986).

Tolerance limit

Tolerance limit refers to the upper and lower bounds of permissible deviation from a prescribed value (British Standard, 1986).

Validity

Validity refers to the extent by which a supplied value deviates from the ordered value. Measuring instruments should be calibrated against a range of known standards and a compensation factor applied where necessary.

In physical science accuracy is a function of both validity and reliability. Reliability, repeatability or precision are all the same thing, although precision and accuracy are often confused and incorrectly used synonymously. In attempting

Table 13.2 Soft contact lens tolerances (American National Standard Z80.8–1986)

Parameter	*Water content*		
	11–49%	*50–69%*	*70% and above*
Base curve (CPC) (mm)	±0.15	±0.20	±0.25
Diameter, total (chord or curved) (mm)	±0.20	±0.25	±0.25
Central thickness (mm)			
up to 0.15	±0.02	±0.02	±0.03
from 0.16 to 0.25	±0.03	±0.03	±0.04
0.26 and above	±0.04	±0.04	±0.05
Vertex power in air (D)*†			
0–10.0	±0.25	±0.25	±0.25
10.25–20.0	±0.50	±0.50	±0.50
above 20.0	±0.75	±0.75	±0.75
Prismatic power (Δ)			
0–10.0	±0.25	±0.25	±0.25
above 10.0	±0.50	±0.50	±0.50
Cylinder power (D)‡			
0–5.0	±0.25	±0.25	±0.25
above 5.0	±0.50	±0.50	±0.50
Cylinder axis (°)*			
Reference point is cylinder axis (°)			
0.50–1.50 D	±8	±8	±8
above 1.50 D	±5	±5	±5
Truncation (°)¶			
Reference point is prism axis (°)	±5	±5	±5

*Tolerances are greater than those accepted for spectacle ophthalmic lenses but represent the current state of the art of measuring soft lenses in the hydrated state.
†Conventionally, most soft lenses are specified with back vertex power, although the difference between respective vertex powers may be negligible. In those cases in which the difference may be meaningful, the manufacturer shall provide proper notification to the practitioner.
‡For measurement purposes, spherocylinder powers will be transformed to meridional powers and that tolerance applied to each individual power.
¶For truncations that appear to be arcs rather than chords, the truncation line will be assumed to be the chord connecting the ends of the arc.

to verify soft contact lens parameters, this licence is perhaps understandable as validation is at present difficult if not impossible to establish. The accuracy of a measuring instrument may be determined against a test object such as a thickness gauge or a master sphere which has previously been measured with a high precision instrument and certified by a recognized, authoritative body such as the National Physical Laboratory in the UK. A series of measurements on test objects may then be made to calibrate the measuring instrument over a range of anticipated parameters and a compensation factor then applied as appropriate.

American standards for soft contact lens tolerances are available (American National Standard Z80.8, 1986) and are illustrated in *Table 13.2*. These were based on a survey involving manufacturers and practitioners and conclude that, as the lens becomes thinner or as the water content increases, a more generous tolerance of back optic zone radius is permissible. This is not an unreasonable suggestion, because as a soft lens becomes thinner or as the water content increases, it becomes more flexible (Layland *et al.*, 1980).

Having considered the manufacture and specification of soft hydrophilic lenses it is now in order to consider the quality control of these parameters, namely radii, diameters and linear parameters, thickness, back vertex power and surfaces.

Standards

Technical verification is necessary in order that specifications are repeatable as well as reproducible and practical. This ensures a meaningful assessment of material and products and is assigned to Standard Organizations which may be national, such as the British Standards Institution (BSI); regional, for example the European Committee for Standardization (CEN), or international, which is the International Organization for Standardization (ISO) – a worldwide union of national standard organizations which operates technical committees. Member bodies have a statutory right to be represented on these committees which, like regional and national bodies, will after due deliberation and, where appropriate, validation, agree to circulate Draft International Standards (DIS) for voting. Publication of an International Standard (ISO) necessitates the approval of three-quarters of those member bodies casting a vote.

British Standards were available for the Specification and Tolerance Limits on Dimensional and Optical Properties of Soft Contact Lenses (BS 5562, 1978). These were withdrawn, however, in 1985 as, in the light of rapidly changing contact lens technology, the standard was considered obsolete. In 1989, a Draft British Standard for Contact Lenses: Part 3, Specification for Soft Contact Lenses (Hydrogel Lens) was considered by the British Standards Sub-Committee HCC/781 for Contact Lenses. This docu-

Table 13.3 Soft contact lens standards at the time of writing

British Standard 4778 Part 3 (1991) Quality vocabulary – Availability, reliability and maintainability terms. Guide to concepts and related definitions
British Standard 7208 Part 2 (1991) Contact lenses – Method of classifying contact lens materials
British Standard 7208 Part 3 (1992b) Contact lenses – Method of test for contact lenses
British Standard. Draft British Standard for Contact Lenses (1989) Part 3. Specification for soft contact lenses
International Standard ISO 2859–1 (1989) (Same as BS 6001 Part 1: 1991) Sampling procedures for inspection of attributes – Sampling procedures plans indexed by acceptable quality level (AQL) for lot-by-lot inspection
International Standard ISO 3591 (1979) (Same as BS 6002, 1979) Specification for sampling procedures and charts for inspection by variables for percentage defects
International Standard ISO 5725 (1986) (Same as BS 5497) Precision of test methods – Part 1: Guide for the determination of repeatability and reliability for a standard test method by interlaboratory tests
International Standard. Draft International Standard ISO/DIS 8321–1 (Revision of BS 7208: Part 1) Specification of hard corneal and scleral contact lenses
International Standard. Draft International Standard ISO/DIS 8321–2. Specification for hydrogel contact lenses
International Standard. Draft International Standard ISO/DIS 9314. Optics and optical instrumentation – Determination of the refractive index for contact lens material
International Standard. Draft International Standard ISO/DIS 9337 (rev.) Optics and optical instrumentation – Contact lenses – Determination of back vertex powers
International Standard. Draft International Standard ISO/DIS 9338. Optics and optical instrumentation – Contact lenses – Determination of diameters
International Standard. Draft International Standard ISO/DIS 9339-2 (or EN ISO 9339-2). Optics and optical instrumentation – Determination of thickness of soft contact lenses
International Standard. Draft International Standard ISO/DIS 9340. Optics and optical instrumentation – Determination of strains of contact lenses
International Standard. Draft International Standard ISO/DIS 9913. Optics and optical instrumentation – Contact lenses – Determination of permeability and transmissibility
International Standard. Draft International Standard ISO/DIS (Same as BS 7208 – Contact lenses – New part) Optics and optical instrumentation – determination of the curvature of contact lenses
International Standard. Draft International Standard ISO/DIS 10338 (Same as BS 7208 – Contact lenses – New part) Method of determination of curvature
International Standard. Draft International Standard ISO/DIS 10339. Optics and optical instrumentation – Determination of water content of contact lenses
International Standard. Draft International Standard ISO/DIS 10344 (1992) Optics and optical instrumentation – Saline solution for contact lenses

ment was forwarded to CEN and ISO for private circulation to form the basis of Draft Standards.

At the time of writing the Soft Contact Lens Standards as listed in *Tables 13.3, 13.4* and *13.5* are available in published, draft or committee form.

Quality assurance

Traditionally, contact lenses tended to be fitted and prescribed individually for each wearer. The lenses were then fully specified, ordered, manufactured and finally inspected and verified both by the manufacturer and the practitioner.

With the advent of computer-controlled, automated production and one-fit designs, contact lenses were mass produced in batches of common material, design and parameters. If such lenses were then sealed in sterile blister packs, 100% routine verification became uneconomical, impractical or impossible. As a precaution, new lenses continued to be checked in the wearer's eye both at the collection and after-care visits. However, with the introduction of disposable lenses, patients are now wearing unverified lenses.

Nowadays, contact lenses are generally only inspected and verified on the production line by sampling. This is an important shift in procedure as it means that the quality control of many contact lenses is not controlled by the contact lens practitioner but rather by the manufacturer's acceptable quality level (AQL), the latter being the maximum percentage defect that can be tolerated in batches submitted for manufacturer's inspection.

In determining a practical AQL policy, manufacturers need to be mindful of the accepted standards. A European standard is mandatory for EU member countries whereas the acceptance of International Standards (ISO) is voluntary. It is the policy of the British Standards Institution (BSI) to accept International Standards. The completed International Standard is implemented in the UK by the publication of a dual numbered standard identical to the

Table 13.4 Dimensional and optical tolerances

Property	*Water content*	
	< 70%	*≥ 70%*
Back optic zone radius* (see Note 1)	± 0.20 mm	± 0.25 mm
Sagitta at specified diameter* (see Note 1)	± 0.05 mm	± 0.05 mm
Total diameter*	± 0.20 mm	± 0.25 mm
Central optic zone diameter	± 0.20 mm	± 0.20 mm
Centre thickness		
≤ 0.10 mm	± 0.010 mm + 10%	± 0.010 mm + 10%
> 0.10 mm	± 0.015 mm + 5%	± 0.015 mm + 5%
Back vertex power		
$\lvert F'_v \rvert \leq 10$ D	± 0.25 D	± 0.25 D
10D < $\lvert F'_v \rvert \leq 20$ D	± 0.50 D	± 0.50 D
$\lvert F'_v \rvert > 20$ D	± 1.00 D	± 1.00 D
Prism error (see Note 2)		
$\lvert F'_v \rvert \leq 6$ D	0.25 Δ	0.25 Δ
$\lvert F'_v \rvert > 6$ D	0.50 Δ	0.50 Δ
Cylinder power		
$\lvert F'_c \rvert \leq 2$ D	± 0.25 D	± 0.25 D
2D < $\lvert F'_c \rvert \leq 4$ D	± 0.37 D	± 0.37 D
$\lvert F'_c \rvert > 4$ D	± 0.50 D	± 0.50 D
Direction of cylinder axis*		
$\lvert F'_c \rvert < 2$ D	± 5°	± 5°
$\lvert F'_c \rvert \geq 2$ D	± 5°	± 5°
Bifocal*		
Addition power	± 0.25 D	± 0.25 D
Segment height	− 0.1 to + 0.2 mm	− 0.1 to + 0.2 mm

Note 1. Tolerance is applicable when this property is the one specified by the manufacturer as the expression of the back surface curve.
Note 2. Prismatic error is measured at the geometrical centre of the optic zone
*A ring test is considered indispensable before finalizing the tolerance listed in this table. These tolerances should be modified in the light of the ring test results.
Source: ISO/DIS 8321–2. After Heyda (1991).

ISO, e.g. ISO 8320–1986; Contact Lens Vocabulary and Symbols became BS 3521, Part 3 (1988). For a standard to be acceptable, it is necessary to consider its effect on performance, cost, accuracy of measurement and minimum prescribing increments (Sheridan, 1994).

Quality of conformity (QOC) refers to the extent by which a product is free from defects. Quality Assurance (QA) in turn is a measure of conformity together with its application to the user and the product. Quality Assurance Standards (QAS) are a compromise between cost and quality and are determined by acceptable standards, competition, corporate image, consumerism, product liability laws and statutory requirements such as the United States Food and Drug Administration (FDA) (Gibson, 1994).

Sampling procedures (British Standard BS 4778, 1991)

Sampling clearly involves risk both for the manufacturer and the consumer but the use of sampling techniques ensures that such risks are clearly recognized prior to quantification of the AQL. Consequently, sampling on the basis of accepted probability is the accepted method of choice, in order to avoid the unjustifiably high risk of random sampling or the excesses of checking all lenses. With improvements in manufacturing technology, the reproducibility of contact lenses is extremely high. If this assumption can be accepted, then if a batch parameter is fabricated to a certain standard, which may or may not be as ordered, then it follows that all other lenses in the same batch will be the same or similar (Wodis *et al.*, 1990). Most manufacturers undertake 100% visual inspection of lenses and verify parameters by batch acceptance sampling (Bausch & Lomb, 1994, personal communication; CIBA Vision, 1994, personal communication; Vistakon, 1994, personal communication), based on probability theory developed for defence and military standards during the Second World War (Caplen, 1988: Juran and Gryna, 1988; International Standards ISO 2859–1, 1989 and ISO 3951, 1979). Lenses are removed from the vials, the specifications measured in batches, and the unsterile lenses subsequently destroyed. If these sampled lenses are within acceptable standards, it is assumed that all other lenses in the same batch are also correct. Failed lenses will in turn undergo further acceptance sampling but if a defective batch cannot

Table 13.5 Material and/or lens physical properties

Refractive index/ Luminous transmittance			
UV transmittance (Note 1)	UV reduction class 1	UV-B 280 nm to <315 nm	UV-A 315 nm to <315 nm 350 nm to <380 nm
	UV reduction class 2	UV-B 280 nm to <315 nm	UV-A 315 nm to <350 nm 350 nm to <380 nm
Water content (Note 1)		±2%	
Oxygen permeability		±20%	
Oxygen transmissibility		±20%	

Note 1. This standard shall be applied to contact lenses for which UV absorption is claimed.
Source: ISO/DIS 8321–2. After Heyda (1991).

be rectified, the complete batch will have to be quarantined and destroyed (Gibson, 1994).

Instrument calibration

When a measurement is made, the resultant reading may, or may not, represent the true value. The error (E) in a system is represented as the difference between the true and the measured value. In taking measurements a learning curve is involved for both the operator and the instrument (the Man – Machine system). With experience, repetitive learning or practice, the spread or standard deviation of multiple measurements is normally reduced and the reliability of the system improved. Ideally, measurements should be calibrated, independent, multiplc, masked and randomized.

The calibration procedure requires validation in the form of test plates. These should be of confirmed and known accuracy which have been certified by an independent, acceptable and traceable source. *Table 13.6* illustrates some of the calibration procedures recommended by ISO.

Providing calibration is carefully undertaken, the accuracy of the system is assured and precision now becomes the more significant variable.

Determination of the precision of measurement

Products are determined by standards which need to consider safety, fitness of purpose, economics and also measurement capability. Standards in turn should be verified by measurement and it is meaningless to specify tolerances which cannot be measured. Tolerances need to exceed the measurement error by at least a factor of two (Sheridan, 1994) or alternatively 10% of the product specification.

Two important aspects of precision are repeatability (R) and reproducibility (r). The former occurs under stable conditions such as a single operator using a single specific instrument. If, however, the test conditions vary, for example different operators, instruments, and/or laboratories, then reproducibility conditions are involved. Ring testing (*see below*) is the recommended technique to determine the reproducibility and repeatability of a standard test method (International Standards ISO 5725, 1986, ISO/DIS 8321).

Ring testing

Typically, coded soft contact lenses stored in saline corresponding to International Standard ISO/DIS 10344 would be distributed to a predetermined number of operators by the central organizer or ring test monitor (RTM). A spare lens also coded would be included in case of damage. Such test lenses might also be supplied to more than one laboratory. Experienced operators would then independently measure the specific parameter (s) being investigated before forwarding the same lens to be independently remeasured by further operators in the same or another laboratory. Alternatively the operator could use the same, similar or different instruments (*Table 13.7*).

Precision of measurement is also improved by taking more than one measurement. In assessing and evaluating the precision of measurements, it is necessary to consider both repeatability and reproducibility. The latter should be determined under the widest possible conditions, for example by employing a range of laboratories, operators and instruments.

Table 13.6 Some recommended calibration methods

Parameter	*Reference*	*Recommended test plates and procedures*
Curvatures	BS 7208 ISO/DIS 10338	Crown Glass, concave test plates, radii of curvature (*a*) 6.30 mm to 6.70 mm (*b*) 7.80 mm to 8.20 mm (*c*) 9.30 mm to 9.70 mm
Back vertex powers	ISO/DIS 9337 (rev.)	Using a focimeter which conforms to ISO/DIS 8598, calibrate four test lenses which in turn conform to ISO/DIS 9342 with nominal back vertex powers of –20.00 D, –10.00 D, +10.00 D and +20.00 D
Diameters	ISO/DIS 9338	Three discs accuracy machined (± 0.01 mm) to (*a*) 11.00 mm diameter (*b*) 9.50 mm diameter (*c*) 7.50 mm diameter NB: A repeatability of ± 0.02 mm is deemed acceptable.
Thickness	ISO/DIS 9339–2	High precision shims, the thickness of each being known to ± 0.0005 mm and traceable to a calibrated standard unit of recommended test plates and procedures. Measurement with a range of: (i) just less than the thickness to be measured (ii) just greater than the thickness to be measured (iii) = $\frac{\text{(i)} + \text{(ii)}}{2}$

NB: Draft International Standards are liable to be changed and are not final recommendations.

Table 13.7 Some recommended precision measurements of spherical hydrogel contact lens parameters

Parameter, symbol and reference	*Precision (SR)*	*Reproducibility value (R)*	*Repeatability standard deviation (s_r)*	*Repeatability value (r)*
Radii of curvature (r_0) (*a*) sagittal height method (BS 7208, new part, 1994 and ISO/DIS 10388)		±0.05 mm in saline solution for 38% water content (WC) lenses with a centre thickness (t_c) >0.10 mm ±0.100 mm in saline for 55% WC lenses with t_c >0.10 mm ±0.200 mm in saline for 70% WC lenses with t_c >0.10 mm ±0.05 mm in saline for 38% WC lenses with t_c >0.10 mm		
(*b*) keratometry* Zeiss keratometer, model D-7082 (Quesnel and Simonet, 1994)				±0.117 to ±0.14 mm in saline for 38% WC lenses and ±0.14 to ±0.198 mm in saline for 55% WC lenses
Centre thickness (tc) (ISO/DIS 9399–2) using a low force gauge	±0.006 mm	±0.017 mm		
Back vertex power, (F'_v) in air using a focimeter (ISO/DIS 9337 rev.)	±0.143 mm ≤10.00 D	±0.400 mm ≤10.00 D	±0.128 mm ≤10.00 D	±0.3584 mm ≤10.00 D

*BS 7208, new part, 1994 and ISO/DIS 10338.

Verification procedures

Radii

The use of reflected light to determine soft contact lens radii

The optic zone radii are probably the most clinically significant variables in fitting standard thickness soft contact lenses, but paradoxically they are the most difficult to check. An undistorted lens is a necessity for the measurement of soft contact lens radii and because of the inherent flexibility of the material it is preferable, if not essential, to support the lens in a liquid-filled, parallel, flat-surfaced cell in order to determine radii, which may be measured by reflected light, microspherometry or optical gauging.

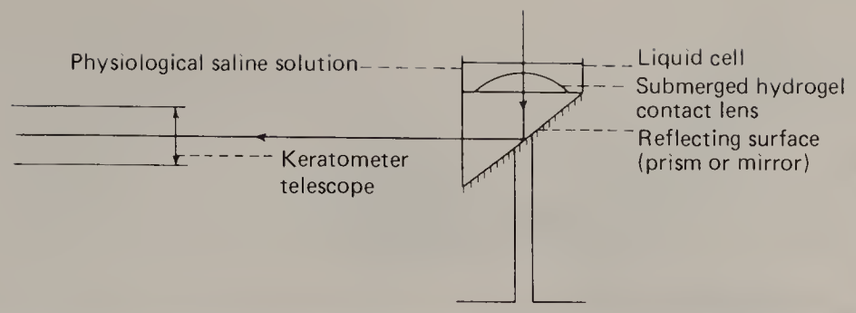
Keratometers

A keratometer is part of the armamentarium of the contact lens practitioner, and its use has therefore been considered in determining the radii of hydrogel lenses (Chaston, 1973) and an accuracy of ±0.10 mm is claimed (Forst, 1974). As illustrated in *Table 13.6*, keratometers should be calibrated against test plates. British Standard BS 7208 Part 3 (1992) and International Standard ISO/DIS 10338 recommend the use of three glass, concave test plates of known accuracy to ±0.0075 mm with radii ranging from 6.30 mm to 9.70 mm. A precision reproducibility (R) of ±0.05 mm is also recommended for 38% water content (WC) contact lenses with a centre thickness greater than 0.10 mm.

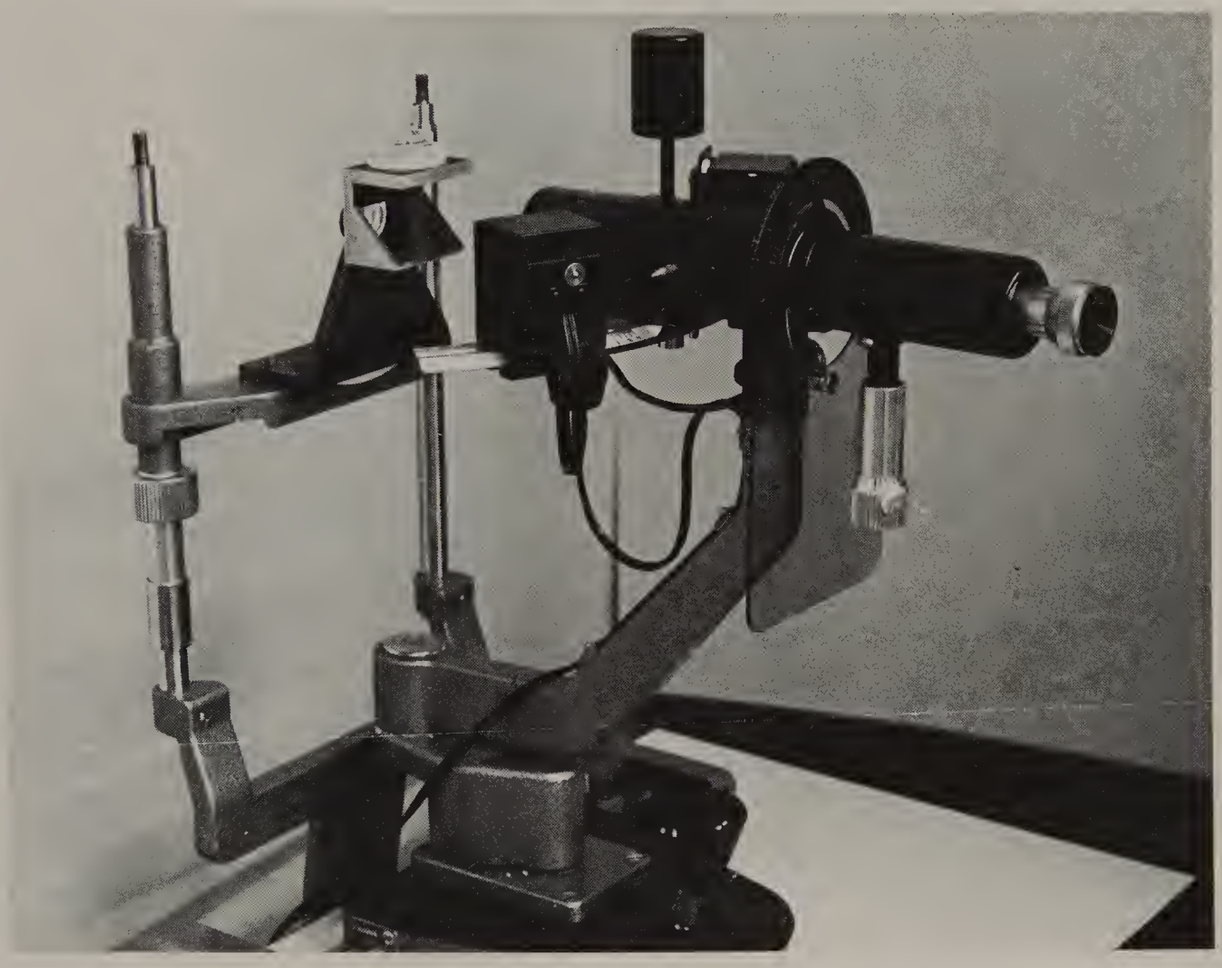
The precision repeatability of keratometry in measuring the BOZR of soft contact lenses was investigated by Quesnel and Simonet (1994). Thirty-two lenses with back vertex powers from +5.00 D to −5.00 D and WCs of 38% and 55% respectively were measured. At 95% limits of confidence, repeatability coefficients (r) ranging from ±0.058 to ±0.107 mm for the 38% WC, and ±0.140 to ±0.198 mm for the 55% WC lenses were found. These results suggest that keratometry is a valid technique to measure the BOZR of low and medium WC soft contact lenses under 5.00 D with a centre thickness over 0.10 mm. As shown in *Tables 13.2* and *13.4*, the American National Standards (ANSI Z80.8–1986) and also British and International Standards (BS 7208 and ISO/DIS 8321–2) recommend tolerances for lower and higher WC lenses of ±0.15 and ±0.20 mm and ±0.20 and ±0.25 mm respectively.

It is essential that the lens is mounted in a liquid cell and the mire images are then reflected into the telescope either by a prism as illustrated in *Figure 13.7a* or, alternatively, by an inclined mirror, as shown in *Figure 13.7b*.

The lens is completely immersed in physiological saline solution of refractive index 1.336 but separated from the



(a)



(b)

Figure 13.7 (*a*) Measurement of the back optic zone radius of a soft contact lens by keratometry. (*b*) Soft contact lens immersed in saline solution and mounted on a Javal–Schiötz keratometer. (Photograph by courtesy of Smith & Nephew Research Ltd)

telescope by air. The contact lens/liquid lens/air system thus acts as an equivalent mirror (Chaston, 1973) so that the vertex of the mirror and the centre of curvature of the equivalent mirror are displaced towards each other as illustrated in *Figure 13.8*. Consequently, the measured radius of curvature is shorter than the true radius of curvature by an amount dependent on the refractive index of the saline solution. Furthermore, a keratometer calibrated for convex surfaces will slightly underestimate the radii of concave surfaces by approximately 0.03 mm (Emsley, 1963; Bennett, 1966).

Therefore: $r = nr' + Y$

where r is the radius of curvature in air
r' is the radius of curvature in liquid
n is the refractive index of saline solution = 1.336 $\simeq \frac{4}{3}$

and Y is the concave compensation factor so that

$$r = \frac{4r'}{3} + (\simeq)\ 0.03$$

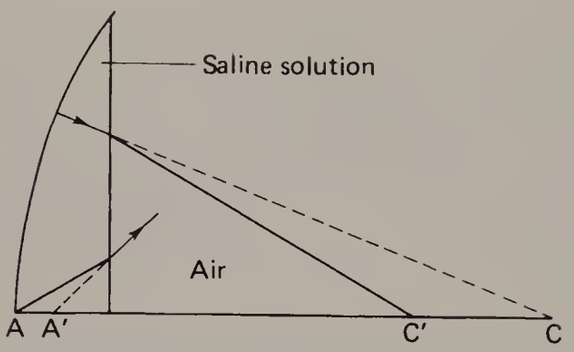


Figure 13.8 The equivalent mirror effect which results in a reduced back optic zone radius when a liquid-immersed lens is measured by keratometry. (From Chaston, 1973)

Thus:

$\frac{4}{3} \times r'$	*Corrected values (Bausch & Lomb) for concave surfaces*
7.00 mm	7.02 mm
7.50 mm	7.525 mm
8.00 mm	8.030 mm
8.50 mm	8.535 mm

The radius of curvature of the lens in air, however, may be more easily determined from a graph as shown in *Figure 13.9*. Some keratometers, such as the Rodenstock CES, have a replaceable objective lens which gives a direct reading of the convex surface being measured.

It is suggested that an instrument for checking soft lens radii should have a range from 7.40 to 9.50 mm which by liquid immersion is transferred to the range 5.40 to 7.10 mm. *Table 13.8* illustrates the range of radii of some keratometers and from this it is noted that the radii are too flat to measure soft lenses in 50% of the instruments. However, as pointed out by Hartstein (1973), it is possible to place a +1.25 D spherical auxiliary lens over the telescope objective, in order to extend the range of steeper radii by approximately 1.30 mm. This topic is also covered in Chapters 6 and 12.

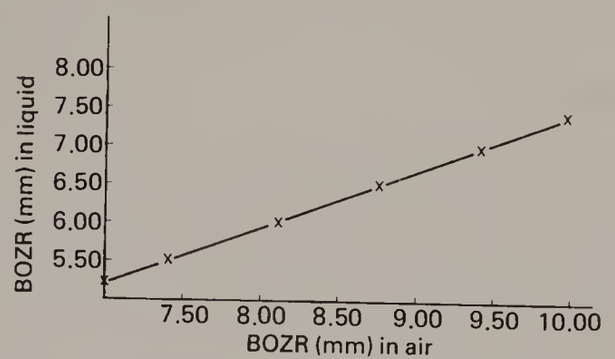


Figure 13.9 Conversion from the back optic zone radius measured in saline solution by the keratometer, to the back optic zone radius in air

Table 13.8 The steepest soft contact lens radii which can be measured by keratometry due to the limitations of the steep end of the scale

Instrument	*Steepest scale reading in air (= soft lens radius measured in saline (mm))*	*Corresponding soft lens radius in air (= radius in saline (mm) × 1.336)*
Bausch & Lomb	6.40	8.55
Carl Zeiss ZL 490	5.50	7.35
CZ	5.00	6.70
Gambs	5.50	7.35
Magnon OM 250	6.50	8.70
Magnon OM 450	6.50	8.70
Rodenstock C MES	5.50	7.35
Rodenstock KER 200	5.60	7.50
Takadi MT	6.00	8.05
Topcon OMT	5.60	7.50
Topcon OM 4	5.50	6.10

NB: Keratometer range can be extended, see Chapter 6.

Further complications, as listed below, arise in the use of keratometers with liquid immersion.

- In a liquid environment less light is reflected from each lens surface than when the lens is in air. Fresnel's law for light of normal incidence is:

$$R = \left[\frac{n' - n}{n' + n}\right]^2 \times 100\%$$

where R is the percentage of reflected light, n is the refractive index of the surrounding medium (= 1.336 for saline solution and 1.00 for air), n' is the refractive index of the second medium ($\approx$ 1.430 for hydrogel material). In air, therefore, R = 3.13%, and in saline solution R = 0.115%.

  The luminosity of the mires has therefore to be significantly increased to compensate for the reduction in intensity of the reflected light when a lens is measured in a saline solution cell.
- In order to increase the luminosity it is feasible that excessive heat could be generated, and Loran (1974) showed that increasing the ambient temperature of the liquid would steepen the radii. Ideally, soft lens parameters should be checked at the environmental temperature of the conjunctival sac. The temperature of the cornea exceeds that of the atmosphere, but is slightly below body temperature (Mandell, 1994) although when a soft lens is inserted into the eye a temperature gradient is manifested which may vary from 37°C on the back surface to 20–25°C on the front (Ruben, 1973, 1974). Furthermore, the temperature of the conjunctival sac may vary with factors such as lid closure, blepharospasm and palpebral aperture size (Hill and Leighton, 1964).
- If an attempt is made to utilize reflected light to measure the radii of a submerged lens then a double image is formed by reflections at the front and back surfaces of



Figure 13.10 The Autostigmatic Microscope based on the Drysdale principle incorporating a clear Perspex wet cell with a light trap. The height of the microscope stage is shown on the digital probe. (From Steele and Freund, 1985, by permission)

the lens, respectively, so that the operator must first identify, and secondly, ignore the unwanted image. The image formed by the surface proximal to the mires will be brighter, and if the back vertex power of the lens is negative the back surface will produce the smaller image; the reverse occurring with positive lenses (Forst, 1974).

Although the above-mentioned limitations are not confined to keratometry it is obvious that this technique is not entirely straightforward and practice is necessary to achieve the claimed reliability.

Many modern keratometers are illuminated with brightness controlled halogen bulbs and provide scale intervals of 0.01 mm which read to radii of 5.0 mm or less. Some instruments such as the Carl Zeiss (Jena) Ophthalmometer CZ110 provide a wet cell as a standard accessory whilst the Rodenstock C.E.S. keratometer incorporates an additional objective lens mounted on a turret on the telescope to measure directly the radii of soft lenses in saline.

Radiuscopes (optical microspherometers)

In employing a radiuscope to determine the back optic zone radii of a rigid lens, the front of the lens is immersed in a liquid-filled concave holder which avoids distortion of the lens and also eliminates unwanted reflections from the front surface. A similar technique for hydrogel soft lenses was suggested by Stone (J., 1975, personal communication) who recommended blotting the back surface dry and carefully floating the convex surface in a concave holder filled with saline solution. Capillary attraction, however, between the lens and the holder tends to tilt and distort the lens and accumulation of surface moisture often precludes a clear image. Tajiri (1974) designed a conical corral-type holder which permitted a clear radiuscope reading parallel to the saline surface and to act as a pump to suspend the lens at the liquid–air surface.

Garner (1981) described a modification of the radiuscope to measure the sag of a soft lens in air mounted convex side upward on a lens support. The total sag is defined as the distance between the microscope focused on the edge of the lens support and the front vertex of the lens while the sag to be measured is the total sag less the centre thickness which is measured in the conventional way with the microscope. Although this method is time consuming and requires operator skill, it nevertheless shows good repeatability.

Autostigmatic Microscope

The Autostigmatic Microscope (Steele and Freund, 1985) is illustrated in *Figure 13.10*. This is another example of a conventional Drysdale microscope modified to measure soft lens parameters. The beam splitter is relocated in front of the objective and is dipped into the saline of the wet cell into which the lens is mounted, concave surface upwards. To enhance light intensity, one of the prisms is anti-reflection coated and the wet cell, which is made of clear plastic, incorporates a black plastic light trap below. Location of the target graticule is assisted by surrounding it with a clear wire ring which can be closed down by an iris diaphragm when the image has been found, thus further reducing stray light. The radii are measured as with a conventional radiuscope giving a population standard deviation of ±0.07 mm on repeated measurements of the back optic zone radius (Carney *et al.*, 1985).

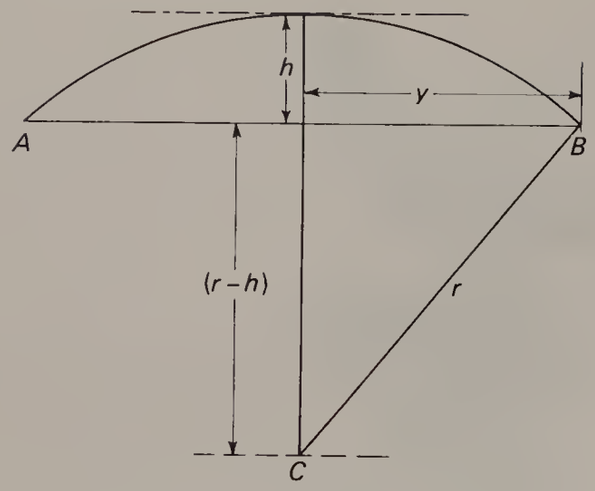


Figure 13.11 Principle of microspherometry

Microspherometry

Contact lens radii are steep and the curvatures represent a small part of a complete sphere. In such circumstances the radii may be determined indirectly by microspherometry.

In *Figure 13.11, AB* represents a small portion of a spherical curve where C is the centre of curvature, r is the radius of curvature, and h is the primary sagitta (or sag) given the chord $2y$, so that:

$r^2 = y^2 + (r - h)^2$ therefore $r = y^2/2h + h/2$

Thus, if the chord diameter and the primary sag can be measured for a given segment it is possible to deduce the radius of curvature. Alternatively, a lens surface of known diameter may be specified in terms of its sag (e.g. Bausch & Lomb Optima lenses, *see* Chapter 11). The lens is usually placed on an anvil, the diameter of which is critical to the measurement of the sagitta. When a lens is mounted this way it may flatten due to gravitational sag, a phenomenon referred to as 'the slumping problem' (Loran and Hough, 1987). Small changes in the measured sagittal height will cause larger (implied) changes in the parameter of interest which is the back optic zone radius. For example, consider a soft contact lens which, when placed on an anvil of 6.25 mm diameter, slumps downwards by 0.02 mm; although the actual back optic zone radius may be 8.60 mm, the implied radius will be 8.90 mm, but this obviously depends on the anvil diameter $2y$.

If $h = r - \sqrt{r^2 - y^2}$

$$\text{Then } \frac{dh}{dr} = 1 - \frac{r}{\sqrt{r^2 - y^2}}$$

This suggests that for an anvil diameter of 10 mm, an error in sag height yields four times the error in the back optic zone radius (Loran and Hough, 1987, citing Campbell, 1987). A tolerance of ± 0.05 mm on sagittal height measurement is suggested.

Aspherical surfaces

An aspherical surface is one without transitions which continuously alters its radius of curvature and offers several advantages if introduced in the design and fitting of contact lenses (*see* Chapters 10 and 11).

The flattening of the cornea has been likened to a conoid (Bennett, 1968/69; Lam and Douthwaite, 1994) in which:

$$y^2 = 2r_0x - px^2$$
or $$y^2 = 2r_0 - (1 - e^2)\,x^2$$

where r_0 = the vertex radius at the apex or origin of the coordinates
p = the conic flattening
x and y = the coordinates
e = the eccentricity value of the conic section

Depending on the value of p, different curves pertain (*see also* Chapter 10):

$p < 0$ = hyperbola
$p = 0$ = parabola
$0 < p < 1$ = prolate ellipse (flattening peripherally)
$p = 1$ = circle
$p > 1$ = oblate ellipse (steepening peripherally)

The above equations, whilst mathematically correct, nevertheless do not afford a convenient clinical method to describe or verify contact lens flattening. The flattening of an aspherical surface may, however, be more conveniently expressed and verified by the concept of a spherical equivalent radius (SER) at a specific diameter. This, in effect, is the 'radius of the spherical surface, which, at the specific diameter, would have the same sagitta as a particular aspherical surface' (British Standard BS 7208, Part 1 (1989), in which:

$$\text{SER} = \frac{h}{2} + \frac{d^2}{8h}$$

where h = sag
d = known chord diameter

It would be helpful if the concept of SER were more widely utilized, and such data provided for aspherical lenses, by the manufacturers (Port, 1994).

The principle of microspherometry was used in the Wet Cell Radius Gauge (C.L.M. Group Ltd, 1975). This instrument, illustrated in *Figure 13.12*, was a magnified vertex depth gauge which permitted approximate determination of the back optic zone radius of a spherical hydrogel contact lens in the hydrated state.

The lens rests on a support ring which determines the chord diameter and is centred in physiological saline solution by four obliquely directed posts covered with soft plastic sleeves. A sagittal section of the lens is viewed through an inclined, externally illuminated monocular microscope. A micrometer probe is then viewed, and



Figure 13.12 The Wet Cell Gauge produced by C.L.M. Group Ltd, which utilizes microspherometry to determine the approximate radius of curvature of a liquid-immersed contact lens. Inset: soft lens in place in saline cell. The supporting ring, oblique centring posts and central probe can be seen. (Courtesy of C. L. M. Group Ltd)

adjusted vertically upwards through the support ring until contact is made with the back surface of the lens. The upward probe movement is continued until one or both sides of the lens are just perceptibly raised from the support ring. The probe movement necessary to lift the lens represents the sag for a known chord diameter, and the back optic zone radius is directly read off the micrometer adjustment screw. Although this instrument is now obsolete, it was one of the earliest instruments designed to measure the back optic zone radius of soft lenses. It showed a remarkable reliability for such a simple and inexpensive instrument.

Electronic microspherometers

Electric circuit microspherometry utilizes the hydrogel property of conducting electricity in order to facilitate the critical point of contact between the palpating pin and the back surface of the lens (Forst, 1979; Chaston and Fatt, 1980).

The upward movement of the probe is monitored and displayed continuously on a digital read-out and, at the point of contact, an electrical pathway is established between the support ring and the probe where a difference in potential is maintained. A signal is then relayed back to the measuring device, which it blocks, and the corresponding sag value appears on the read-out display. Electronic microspherometers include the B.C. Tronic (Médicornéa), the Rehder Gauge ET1 and ET2 (The Rehder Development Co.) and the S.M. 100 Softometer (Neitz Optical Co.).

Ultrasonography

The sagittal height of a lens may be measured in saline employing ultrasound (Port, 1975, 1976). The lens is mounted on a support and ultrasonic pulses, emitted from a transducer to the back surface of the lens, are reflected back and electronically analysed. The time for the signal to travel from the back vertex of the lens to a reference plane is a function of the speed of sound in saline and the distance travelled, the latter being the sag for that specific chord. The following soft lens radius meters, though no longer generally available, utilize ultrasound: the Panometrics Ultrasound System (Patella *et al.*, 1982) showing an average standard deviation of ±0.02 mm; the A.M.S. Optison (±0.03 mm at an ambient temperature of 24.0°C (Port, 1982a) and the Neitz (Softometer) S.M.100 giving a reliability of ±0.10 mm (Port, 1981b).

Interferometry

Interferometry has been suggested as an accurate and reproducible method to measure the radii of both rigid and soft contact lenses (El-Nasher and Larke, 1980). A lens is suspended in physiological saline and the interference patterns formed by incident monochromatic light are measured with a microdensitometer and converted mathematically into radii. This system produced a maximum coefficient of variability between 0.6% for back optic zone radii and 2.0% for the front optic zone radii compared to the manufacturers' published results.

Optical gauging

Master spheres

One of the simplest methods of obtaining an approximate value for the radius of a soft contact lens is to utilize master spheres and apply a system known as optical gauging. The lens, in the hydrated state, is placed with its convex face upwards onto one of a series of accurately made acrylic spheres of known radii. If the two surfaces are not aligned, a bubble forms and its location determines the relative curvature of the hydrogel lens with respect to the master sphere. If the back optic zone radius is steeper than the master sphere a bubble forms centrally, whereas a peripheral bubble indicates that the back surface of the lens is flatter than the test plate. The Lensmaster is an example of this type of system and is shown in *Figure 13.13*. This

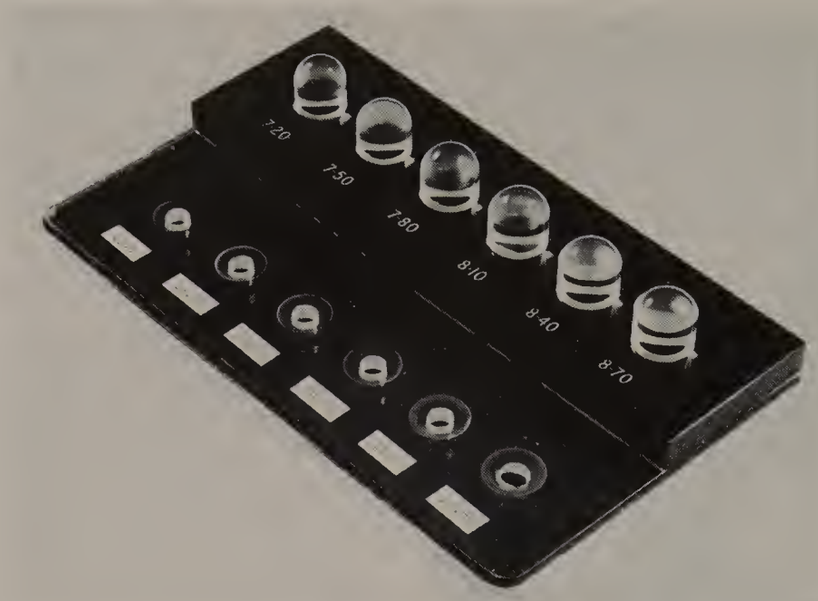


Figure 13.13 The Lensmaster, formerly produced by Contactalens Ltd, which uses optical gauging to determine the approximate back optic zone radius in air, using the hemispheres at the back and determining total diameter, using the circles engraved at the front. Known as a comparator

system is relatively inexpensive, is rapid and simple and has the advantage of allowing the checking to be done in air, but according to Harris *et al.* (1973, 1981) only produces a reliability of ±0.30 mm. Hampson (1973) attributed inaccuracies to capillary attraction and also to stretching between the master spheres and the hydrogel material. For these reasons, assessment of the relative curvature should be made within a few seconds of placing the lens on the master sphere. Only thicker lenses can be checked in this way.

Projection methods

Contact lenses may be mounted on a suitable anvil support and the profile projected on to a screen for inspection and measurement. The contact lens support should be orientated horizontally, and adjusted vertically. Additionally the image scale should be at least 20:1, with a minimum accuracy of ±0.05 mm and the test device should incorporate a telecentric ray path (International Standard ISO/DIS 9338).

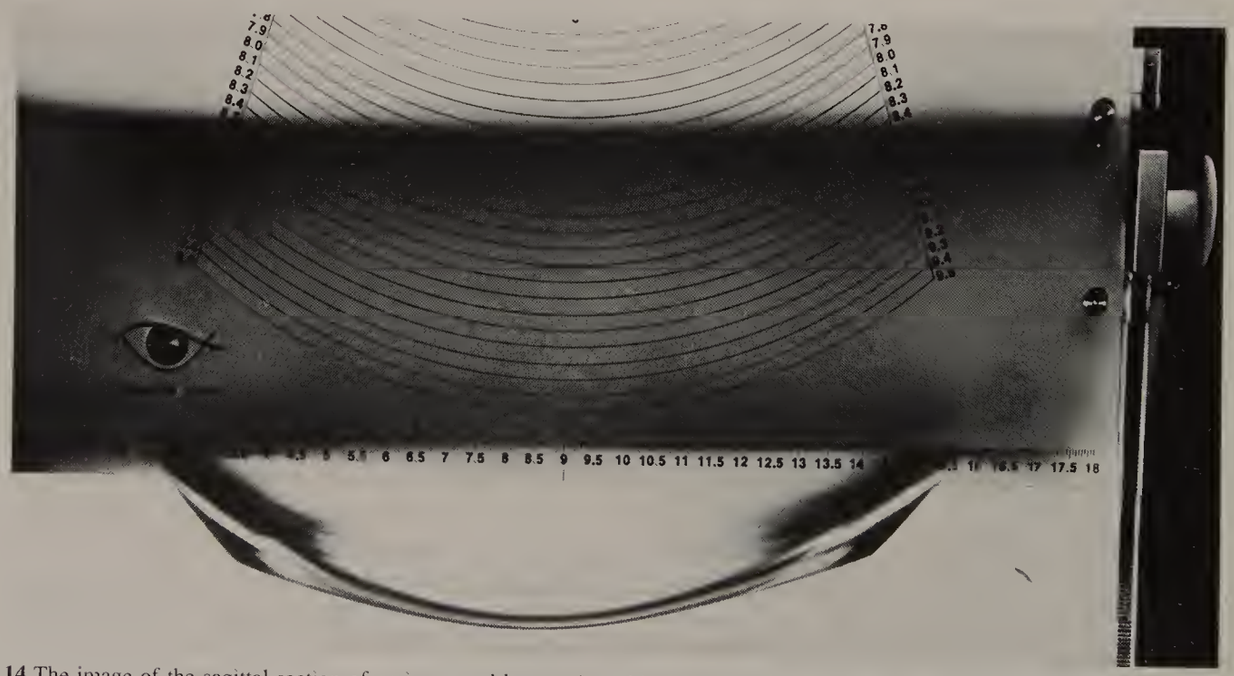


Figure 13.14 The image of the sagittal section of an immersed lens projected in the Söhnges System on to a screen containing annuli which may be adjusted vertically until alignment is achieved (Courtesy of Söhnges Optik; reproduced by kind permission of the National Eye Research Foundation)

Variations in results may occur if operators use different end-points, such as the probe just touching the lens vertex or the edge, just clearing or just returning to the support. Clearly standardization is needed on such criteria and, in common with other meteorological techniques, operator training is necessary to ensure repeatability.

The Söhnges control and projection system

Söhnges Optik (1974) projects the profile of a fluid-immersed lens on to a screen by means of a projector incorporating a high luminosity 24 volt/250 watt halogen bulb and a cooling system. The screen is engraved with horizontal and vertical linear millimetre scales and a series of annuli, graded from 7.20 to 9.50 mm in 0.10 mm steps, which may be adjusted vertically. The projection distance is approximately 1 m and is determined by calibrating the instrument against a known test plate. The profile of the lens is projected on to the graticules which are adjusted vertically until alignment is achieved (*Figure 13.14*).

Inaccuracies may occur with the Söhnges system due to an increase in the ambient temperature of the saline solution and also from eccentricity of projection. Loran (1974) and Loran and French (1978) claimed an error of measurement of −0.107 mm in measuring production lenses and a reliability of ±0.10 mm for this instrument.



Figure 13.15 The Chiltern Optimec Soft Lens Analyser, Front Projection Model with temperature control and saline filtration. (Courtesy of Optimec Ltd)

The Optimec Soft Lens Analyser

This is also a projection system which is essentially available in two forms, both providing temperature control of the wet cell and also saline filtration (Port, 1981a) as available extras. The original model employed back projection while the Chiltern model illustrated in *Figure 13.15* is a front projection system. In both models, the lens is mounted convex surface upwards in saline on an 8.50 mm diameter cylinder and centred. The lens profile is then viewed on a built-in screen at ×15 magnification and a probe manually advanced until contact is confirmed by the observer detecting a just perceptible edge lift. The probe is then lowered by the same amount and the back optic zone radius read directly in millimetres. Port (1981a) stated that the centration system was both easy to use and efficient. For lenses of 40% water content, the reported precision for the model without temperature control is ±0.03 mm and ±0.05 mm for the Chiltern with temperature control (Port, 1982b). Although one would expect a smaller standard deviation when temperature is controlled, these findings do not confirm this assumption. According to Port (M. J. A., 1987, personal communication), there was only a small variation of temperature in either experiment, back projection is more reliable than front projection and day-to-day variation in repeatability may have occurred. Certainly, careful control of the ambient variables is very important, especially with higher water content lenses. Grant (1987) calibrated an Optimec Chiltern with temperature control against three PMMA buttons previously verified with a radiuscope and then measured three Weicon 38E (Ciba Vision) lenses 10 times each at a temperature of 21°C. The reported precision of the instrument was ±0.07 mm and the accuracy of the readings ±0.02 mm

Measurement of parameters in air

Lathe-cut hydrogel lenses are made in the dry state and are then smaller and steeper than in their final form. The parameters of the xerogel lens may be checked in air using conventional instruments to achieve a similar tolerance to rigid lenses. After xerogel verification, the lenses are rigorously sterilized, the assumption being that a known and predetermined expansion factor may be applied to determine the hydrated parameters. Unfortunately, the hydrogel material does not possess plastic memory and, if allowed to dry spontaneously in air, does not normally contract in a regular manner because of differential hydration across the lens surface due to differences in lens thickness. If, however, the ambient humidity is monitored and slowly reduced in a controlled environment, then the lens may dehydrate without significant distortion and, indeed, limited modifications may be possible (Bier and Lowther, 1977) (*see also* Chapter 21).

Consequently, although xerogel lenses may be verified with a high degree of accuracy, there is normally no way this tolerance may be checked once the lens is received by

the practitioner in the hydrated state. It might therefore be argued that the accuracy claimed by the manufacturers is to some extent academic.

Diameters

Diameters are an important parameter in the specification, fitting and duplicating of contact lenses and a tolerance of ±0.20 mm for the BOZD and ±0.05 mm for the total diameter of rigid lenses (British Standard BS 7208 Part 1 (1992) and International Standard ISO/DIS 8321–1), and ±0.20 mm for soft lenses is recommended (International Standard ISO/DIS 8321–2).

Soft contact lenses are often mono-curve on one surface and bi-curve on the other, and while verifying diameters, it is important to examine the transition between adjacent radii which, in the author's experience, are sometimes sharp. If sharp transitions are present in large lenses, they may present a potential source of limbal indentation, corneal anoxia and abrasion.

The back optic zone diameter is a significant parameter in determining the primary sag and hence the physical and physiological fit of the lens. A complete lens specification should include total and intermediate diameters. In practice, however, it is more convenient to specify the total diameter, which for a given edge form and thickness varies directly with the back optic zone diameter.

Ruben (1974) and Bailey (1975) suggested that diameters should be measured in a liquid, while Stone (J., 1975, personal communication) and Mandell (1974a) believe checking in air to be clinically adequate and certainly more convenient. It should be pointed out, however, that diameters measured in air may differ from those measured in liquid and account for apparent discrepancies between the laboratory and the practitioner if different measuring techniques are used. If diameters are measured in air it is normal to dry the lens and mount it on a plane surface such as a microscope slide. Initially, the lens size increases due to surface tension and adhesion between the lens and the glass mount (Bailey, 1975) followed by contraction on dehydration.

Band magnifier

It is without doubt more convenient to check diameters and, indeed, all soft lens parameters in air using conventional instrumentation, and for measuring the total diameter and intermediate diameters the band magnifier is recommended (Bailey, 1975; J. Stone, 1975, personal communication).

The air-dried lens is mounted horizontally and, orientating the axis of the instrument vertically, the lens is measured against an external light source; with this technique one may expect a reliability of approximately ±0.10 mm, which is similar to that achieved for the diameters of rigid lenses.

Bailey (1975) measured the transverse section of a liquid-immersed soft lens with a band magnifier placed in contact with the liquid cell wall. This should be as thin as possible to reduce parallax errors. A microscope slide offers reasonable optical quality and is recommended for this purpose.

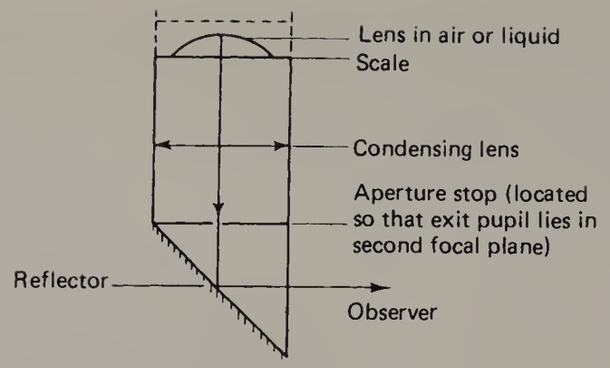


Figure 13.16 Modification of a band magnifier to determine the diameters of a hydrogel lens in a liquid or in air

If a band magnifier is modified, as illustrated in *Figure 13.16*, it is possible to examine the transverse lens section either in air or liquid. The scale and the lens plane almost coincide, and the telecentric principle may be incorporated by placing an aperture stop in the second focal plane of the lens thereby overcoming most of the objections previously mentioned.

Measurement of diameters in a liquid

As with other parameters, variations of temperature can affect the diameters of soft, hydrogel contact lenses and therefore close temperature control is essential. Such changes are more apparent in high water content (HWC) lenses and it is recommended that the lens should be fully hydrated and stabilized in saline corresponding to International Standard ISO/DIS 10344 prior to measurement. The ambient temperature should be stated, in the range of 18–35 °C, be maintained to ±1.0 °C for lenses above 50% WC, and ±2.0 °C below 50% WC. The arithmetic mean of five measurements should be determined to an accuracy of ±0.05 mm (Draft International Standard ISO/DIS 9338).

Projection

Both the Söhnges and Optimec provide an efficient and reasonably accurate method of determining the back and front surface optic zone diameters and also the total diameter of a liquid-submerged lens. Either a sagittal or transverse section may be projected as illustrated in *Figures 13.14* and *13.17* respectively and the pertinent diameters read off a millimetre scale previously calibrated against a test plate to determine the correct projection distance. Microfilm projectors may also be used, preferably adapted to take a parallel optically flat-surfaced cell containing the lens in saline solution. A millimetre scale, engraved on one surface of the cell against which the edges of the lens rest, is magnified along with the lens and thus the appropriate

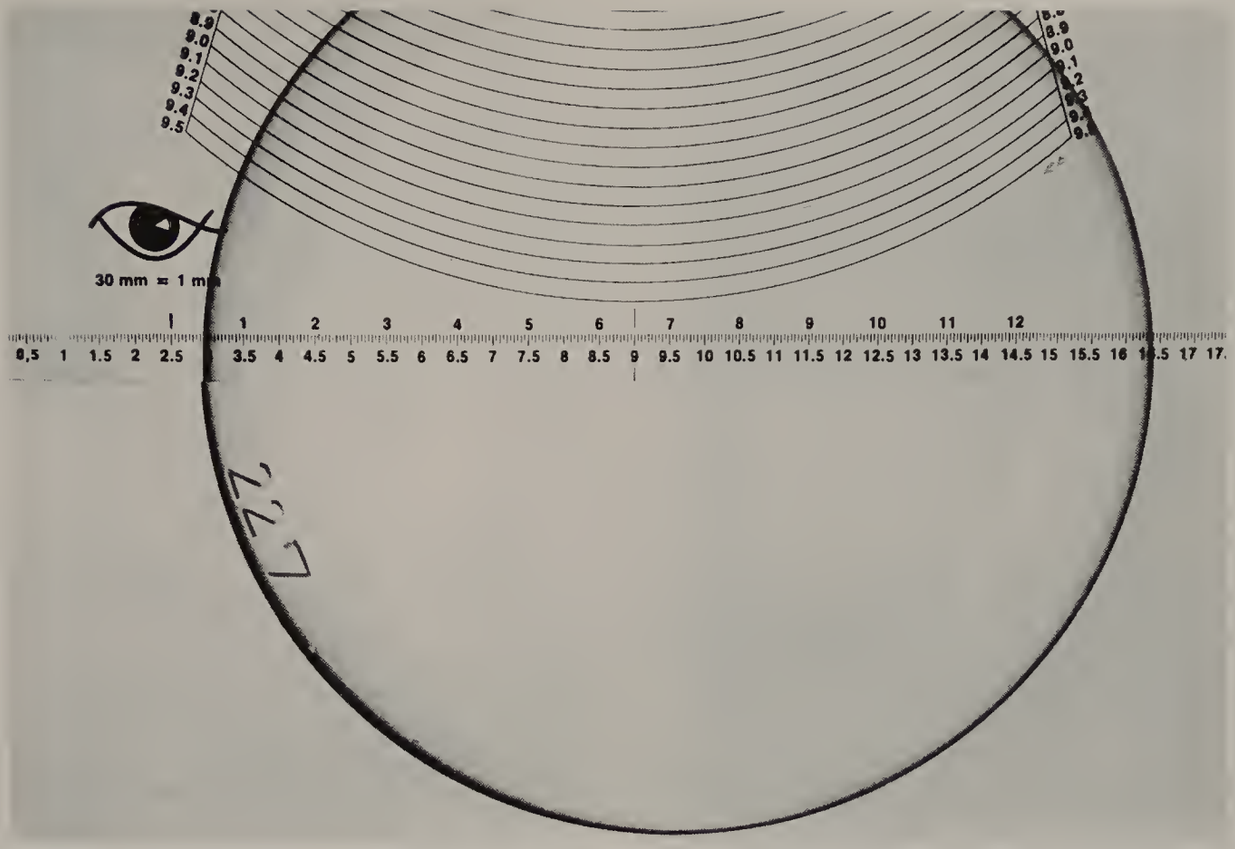


Figure 13.17 Projection of a transverse section of an immersed lens onto a linear scale to determine diameters. (Courtesy of Söhnges Optik; reproduced by kind permission of the National Eye Research Foundation)

diameters may be read off the receiving screen. This is an excellent system used by some lens manufacturers. An example of such a projection magnifier is shown in *Figure 13.18*, but here the scale is printed on the screen.

Travelling microscope

Ruben (1974) recommended the use of a travelling microscope to measure the total diameter of a liquid-immersed soft lens, although the reliability of this method is not stated.

V gauge

The V gauge illustrated in *Figure 13.2* has been designed to hold the lens while the back vertex power in a liquid is determined, but could presumably be modified by incorporating a millimetre scale adjacent to the channel, from which the total diameter could be quickly and conveniently read off.

Comparators

An example of a comparator is illustrated in *Figure 13.13* and comprises a series of translucent annuli inscribed in a translucent Perspex base. The air-dried lens is simply superimposed onto the test circle to which the total diameter is compared. This method is quick and simple but accuracy is no better than ±0.25 mm as the graduations are in 0.50 mm steps.

Thickness

Centre thickness

The thickness of a hydrogel contact lens affect the oxygen transmissibility, optical stability and durability of a lens. As thickness is reduced, a hydrogel lens becomes fragile and more difficult to handle. Conversely, thinner lenses offer the advantages of greater oxygen transmissibility, improved comfort and better centration. At the time of writing ultrathin hydrogel lenses are widely fitted and some of those currently available are listed in *Table 13.9*.

The practitioner should be able to examine the lenticulation and also measure the thickness within reasonable limits, from the centre to the periphery. Due to the fragility and distensible nature of the hydrogel matrix, however, normal thickness measuring devices such as micrometers, verniers or thickness gauges cannot be utilized, but instead indirect measurements which employ reflected light, optical doubling or projection are used.



Figure 13.18 Zeiss Dokumator showing projection of a soft lens. (Reproduced by kind permission of Zeiss (Wöhlk) Contact Lenses Ltd)

Radiuscope (optical microspherometer)

The conventional radiuscope, which employs Drysdale's method to determine the radii of reflecting surfaces, may be used to measure lens thickness by focusing the vertically travelling microscope first on the centre of one surface of the lens, and then on the centre of the other surface. Hartstein (1973) recommended the following procedure:

1. The lens is mounted, back surface down, on a master sphere with a steeper curvature than the lens being measured so that centre contact occurs.
2. The target is first focused on the sphere and the dial gauge zeroed. This may be done with or without the lens in place.
3. The radiuscope is now refocused on the front surface of the lens and the travel noted on the dial.
4. Although not mentioned by Hartstein, if step (2) is carried out with the lens in place, the apparent thickness should now be multiplied by the refractive index of the hydrogel material to obtain the real thickness. If step (2) is carried out without the lens in place, step (3) will give the real thickness directly.

Table 13.9 Some ultrathin hydrogel contact lenses

Lens	*Manufacturer*	*Geometrical centre thickness*
Optima FW	Bausch & Lomb	0.026 mm to 0.039 mm
O Series	Bausch & Lomb	0.035 mm
SeeQuence	Bausch & Lomb	0.038 mm
Hyperthin	Nissel & Co.	0.05 mm
CSI–T	Wesley–Jessen	0.036 mm
Hydrocurve II 45	Wesley–Jessen	0.05 mm
Hydrocurve II 55	Wesley–Jessen	0.05 mm
Soft Mate II	Wesley–Jessen	0.05 mm
Durasoft 3	Wesley–Jessen	0.05 mm

The accuracy of this technique depends on the location and precise focusing of the two images of the radiuscope target and this process was improved by employing a special holder known as a bi-surfaced hydrogel lens platform (BHLP). This was essentially an aluminium cylinder, one half of which was highly polished and the other half dull. The lens was dried and mounted in air, concave side upwards, on the platform which fitted over the lens holder part of the microscope. The radiuscope was first focused on the polished half of the cylinder and then on the back surface of the lens by observing the target against the dull side of the holder (Paramore and Wechsler, 1978; Wechsler and Paramore, 1978). This produced a repeatability range of ±0.01 mm.

The 1986 American National Standards (Z80.8–1986) (*see Table 13.2*) suggest a range of acceptable tolerances for centre thickness. A Draft International Standard (ISO/DIS 9339-2; or EN/ISO 9339-2) on precision measurements of hydrogel lens centre thickness is shown in *Table 13.7*.

A survey by Loran and Hough (1987) covering 30 laboratories, practitioners and academics suggested a tolerance range of ±0.012 mm for lenses of under 50% water content and less than 0.05 mm centre thickness, to ±0.028 mm for those of above 70% water content with a centre thickness of 0.20 mm and above (*Table 13.10*).

Pachometry

This is the method recommended by Ruben (1974) to give an approximate thickness of a hydrogel lens mounted on a scleral contact lens in saline solution. The apparent thickness of the lens is measured with the pachometer attachment of a Haag–Streit slit lamp, and while this technique is subject to errors, a reliability of ±0.02 mm is claimed. Although the thickness of a soft contact lens in both air and liquid is of theoretical interest, it could be argued that it is the lens dimensions *in situ* which are significant, and these may alter with environmental vari-

Table 13.10 Soft contact lens tolerances: survey of 30 practitioners, laboratories and academics to recommend acceptable realistic soft contact lens tolerances

Back optic zone radius			
Centre thickness (mm)	Tolerances (mm) for lenses of water content		
	<50%	*50–69%*	*>70%*
<0.05	±0.18	±0.23	±0.27
0.06–0.10	±0.16	±0.21	±0.25
0.11–0.15	±0.14	±0.17	±0.21
0.16–0.20	±0.12	±0.18	±0.21
>0.20	±0.10	±0.16	±0.19
	Mean ±0.14	Mean±0.19	Mean±0.23
Centre thickness			
Ordered (mm)	Tolerances (mm) for lenses of water content		
	<50%	*50–69%*	*>70%*
<0.05	±0.012	±0.012	±0.012
0.06–0.109	±0.012	±0.017	±0.02
0.11–0.15	±0.014	±0.020	±0.028
>0.20	±0.018	±0.022	±0.028
Back vertex power			
BVP in air (D)	Tolerances (mm) for lenses of water content		
	<50%	*50–69%*	*>70%*
>10.00	±0.21	±0.23	±0.32
10.25–20.00	±0.337	±0.40	±0.52
<20.00	±0.57	±0.57	±0.70

Source: Loran and Hough, 1987

ables such as osmolarity, pH, tear evaporation and temperature. Presumably the thickness of the lens could also be measured on the eye using pachometry.

Projection

In addition to the annuli and the horizontal millimetre scale, the screen of the Söhnges and Optimec systems also incorporate a vertical millimetre scale which is adjusted to determine the edge and the centre thickness of the lens profile.

Electric circuit micrometry

Water-bearing hydrogels conduct electricity and this property was utilized in a modified micrometer which claimed to measure the thickness of a hydrogel contact lens to an accuracy of ±0.003 mm (Fatt, 1977).

The probes, made of plastic, incorporate an electric wire cast into the centre line so that when the probes just make contact an electric circuit is completed. An ohm-meter was incorporated into the circuit so that when the probes either just contact each other, or the front and back surfaces of a hydrogel lens, a deflection was recorded on the needle. The probes were first brought into contact, the deflection noted and the instrument zeroed. The probes were then separated and a hydrogel lens was mounted convex side up on the lower support; the upper probe was then lowered until the ohm-meter needle was again deflected and the thickness read from the micrometer.

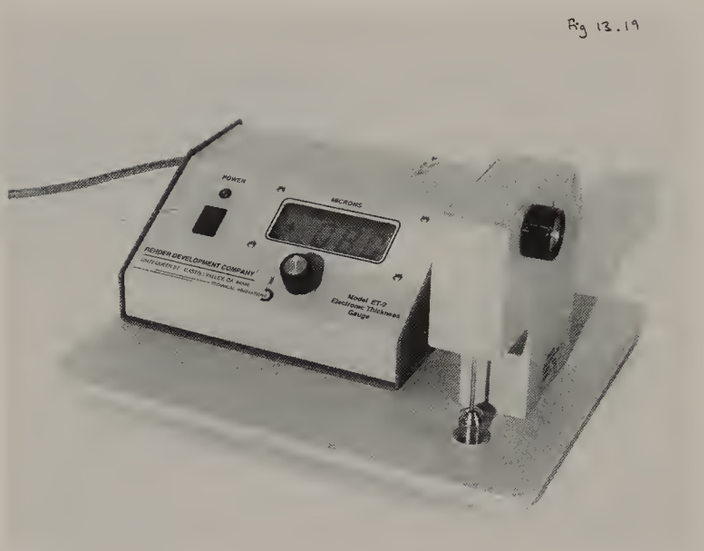


Figure 13.19 Model ET-2 Rehder Electronic Thickness Gauge which measures the thickness of soft contact lenses in air. (Courtesy of the Rehder Development Company)

The Rehder Electronic Thickness Gauge

The ET-2 Rehder Electronic Thickness Gauge (Rehder Development Co.), is one of the more widely used instruments to measure the thickness of soft contact lenses. As shown in *Figure 13.19*, the essential instrument components are the anvil, a measuring sensor and a transducer.

The anvil is designed to support the lens with the convex surface upwards. The sensor is counterbalanced and is moved vertically by a hand-operated lift which is designed so that a maximum force of only 0.50 g is applied to the lens surface. This precaution reduces measurement errors due to indentation and also possible damage to the lens surface. The transducer, in turn, is a precision electronic system designed to detect accurately the location of the measuring sensor, which is shown on a liquid crystal, digital display. The method of operation is as follows.

The instrument is switched on, the sensor lowered to contact the anvil and the read-out zeroed. The sensor is then raised and the blotted lens mounted on to the anvil after which the sensor is again lowered to gently contact the front lens surface and the thickness is measured in microns (μm) (0.001 mm).

A precision gauge is available for calibrating thickness whilst a dynometer is also available to verify the force of the sensor. The manufacturers claim an accuracy of ±2 μm, a resolution of 1 μm and that the measuring repeatability is virtually zero.

A software pack is also available to provide data acquisition and recording facilities. Additionally a statistics window provides analytical summaries whilst the output file is compatible with most software of database programs.

Average thickness

The specification of central thickness is convenient and reasonably representative in low-powered lenses but, when the back vertex power exceeds ±1.50 D, it does not reflect the true thickness across the lens diameter. The concept of specifying both centre and edge thicknesses certainly provides a better overall view, but as one approaches the periphery, thickness measurement, while still possible, is more difficult. Specifying the average thickness (t_a), however, is clearly more meaningful and may be approximated by:

t_a = ⅓ Centre thickness + ⅔ Edge thickness (across a specific chord) (Fatt, 1979)

The edge thickness may be specified either axially or radially whereby axial edge thickness is measured parallel to the axis of symmetry and radial edge thickness normal to the front lens surface, both parameters specified at a point near to the edge (Pearson, 1986). The radial edge concept is generally considered to be the more meaningful measurement as heat, water and gases flow normally to the lens surface.

The arithmetical mean thickness (t_{am}) is given by Fatt (1979) as:

$$t_{am} = \frac{1}{a \int t dA}$$

in which A is the area under consideration and t is the minimum lens thickness within that area.

An alternative concept of harmonic mean thickness (t_{hm}) was suggested by Sammons (1981) in which the lens is considered as a series of annuli and:

$$t_{hm} = \frac{N}{\frac{1}{t_1} + \frac{1}{t_2} + \frac{1}{t_3} \ldots\ldots\ldots + \frac{1}{t_N}}$$

Further and more complex calculations have also been published (Fatt, 1979; Sammons, 1981; Brennan, 1984a) which consider a number of continuous variables over the area at which the average thickness is to be calculated. It would clearly be more convenient if this information could be simplified, but graphs unfortunately do not traditionally lend themselves to presenting more than two variables.

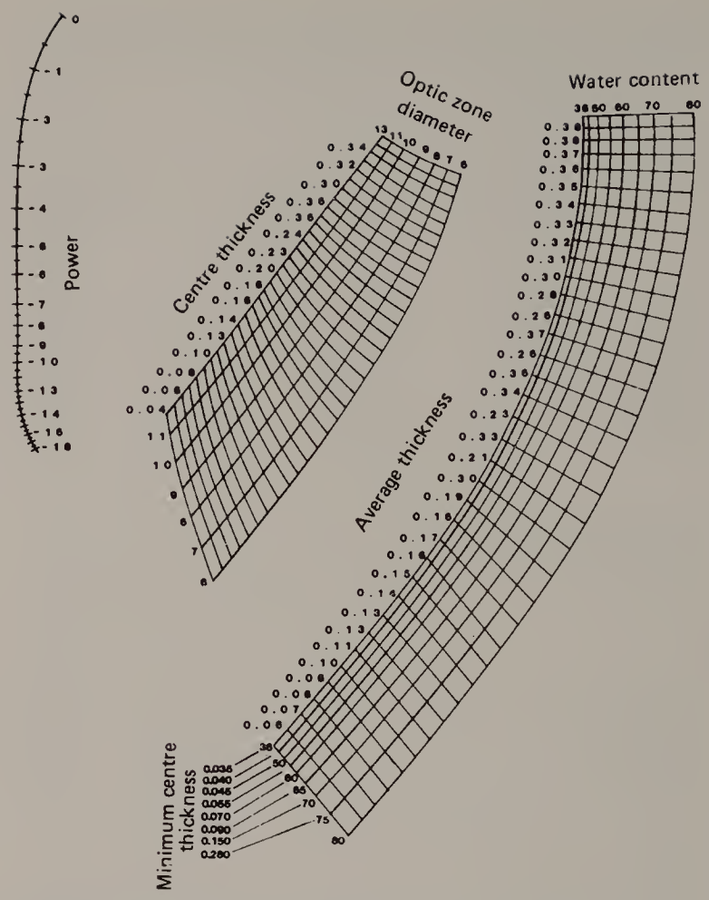


Figure 13.20 Nomogram for determining the average thickness of a minus hydrogel contact lens. If a line is projected from the left side for a specific back vertex power, through the point in the middle graph where the known centre thickness and optic zone diameter values intersect, to the right hand side, the average thickness can then be read off. (From Brennan, 1984b, by permission)

Brennan (1984b) overcame this dilemma by structuring the necessary information in the form of nomograms in which these continuous variables, including back vertex power, centre and average thickness, the optic zone diameter, water content and minimum centre thickness for a specific water content, are included. Using the nomogram illustrated in *Figure 13.20* for negative lenses and a similar but separate one for positive lenses, the average thickness can be estimated to less than 5% for negative lenses, and generally less than 5% for positive lenses compared to the calculated value (Efron and Brennan, 1985).

Point-to-point thickness

A method to determine the point-to-point thickness of a contact lens was described by Fatt and Ruben (1993) using a formula by Campbell which they quoted under private correspondence:

$$t_r = \frac{t_c - (pr^2 \times 10^{-3})}{(1.048 - 4.10 \times 10^{-3} - 3WC)}$$

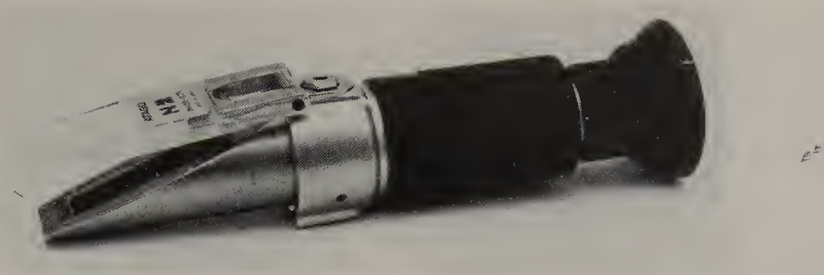


Figure 13.21 The Atago CL-1 Soft Lens Refractometer showing the clear Perspex daylight plate which applanates the hydrogel lens onto the opposing prism face. The rim adjacent to the rubber eye cup may be adjusted to focus the eyepiece. (From Efron and Brennan, 1985, by permission)

in which

t_r = thickness at a distance r from the optical centre
t_c = centre thickness
p = back vertex power
r = distance from the optical centre
WC = percentage water content

Using the Campbell formula with a spreadsheet computer program, and if the Dk is known, the point-to-point transmissibility of any contact lens can be determined.

Laboratory measurement

The average thickness of a soft contact lens may be determined *in vitro* by measuring the total diameter and accurately weighing the lens which has been suitably blotted dry. If the specific gravity is either known or measured (Refojo and Leong, 1984) and if we equate the hydrogel spherical cap to a disc then the average thickness:

$$t_a = \frac{m}{(\phi/2)^2 \pi \rho}$$

where ϕ is the total diameter of the lens; ρ is the specific gravity, and m is the mass of the lens (W. N. Charman, 1987, personal communication).

Water content (WC)

The water content of a hydrogel contact lens affects lens flexibility, comfort, dehydration characteristics and permeability and, consequently, it would be most helpful if the water content could be verified. The water in a lens is expressed as a percentage of the total mass of the lens in its hydrated state under equilibrium conditions with physiological saline solution corresponding to International Standard ISO 10344.

The WC of hydrogel contact lenses may be accurately measured using a sensitive microbalance. The instrument, which should be capable of measuring to 0.10 mg, measures the mass of a dehydrated lens, which has been completely dried either in a vacuum or microwave oven. To reduce blotting errors it is recommended that the mass of the lens should be between 100 and 300 mg (Draft International Standard ISO/DIS 10339).

$$\% \text{ Water content} = \frac{\text{Mass of water}}{\text{Mass of hydrated lens}} \times 100$$

Limitations of this technique (which is clearly unsuitable for the practice, office or smaller manufacturing laboratories), include the use of expensive equipment, the fact that it is time consuming and lens destructive, and that there is difficulty in accurate and reproducible surface blotting of the hydrogel lens surface.

An alternative and simpler technique has been suggested to estimate the water content indirectly by measuring the refractive index (Brennan, 1983; Efron and Brennan, 1985). As the water content of a hydrogel increases, the refractive index reduces and there is a close correlation between these variables especially in the range between 30 and 70% water content (Fatt and Chaston, 1980; Teuerle, 1984). It is postulated, therefore, that the measurement of refractive index could provide a rapid and non-destructive method of estimating the water content. The refractive index under specific environmental conditions and for a given wavelength is the sine of the angle of incidence divided by the sine of the angle of reflection and the angle at which internal reflection occurs can be easily measured using a hand-held Abbé Refractometer (Brennan, 1983; Efron and Brennan, 1985). The hydrated lens is blotted dry and, using a glass daylight plate, is applanated on to the fixed prism of the refractometer as illustrated in *Figure 13.21*. The instrument is then directed towards an external light source and the border between the dark and light fields is viewed in the eyepiece; the water content is then read directly from the scale as shown in *Figure 13.22*. This system assumes that the hydrogel acts as a simple solvent and, providing the instrument is periodically calibrated against a medium of known refractive index (e.g. saturated sodium chloride) and the ambient temperature is controlled and specified, then the estimated refractive index correlates well with both measured and manufactured stated values (Brennan, 1983). The reported reliability of this instrument is ±1.0% (Efron, 1987).

If the refractive indices (RI) of the the saline and the hydrated and dehydrated materials are also known, the WC may be recalculated thus (Draft International Standard ISO/DIS 10339):

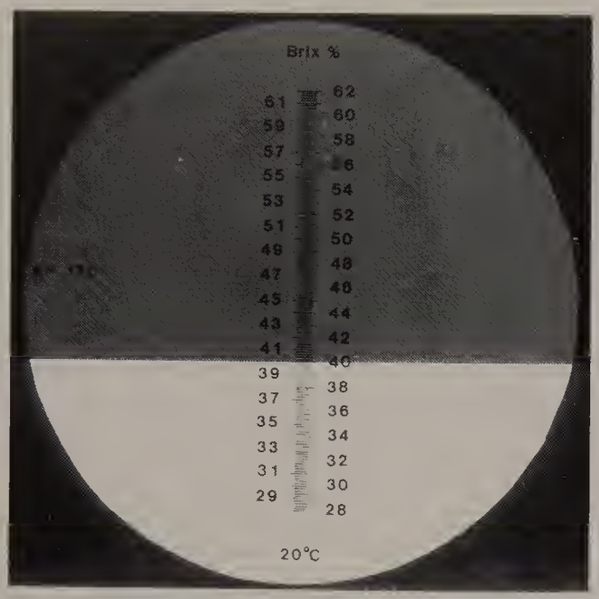


Figure 13.22 Scale of the Atago CL-1 Soft Contact Lens Refractometer as seen by the operator in which the upper field appears dark and the lower field clear. The boundary between the upper and lower portions of the field indicates the water content of the lens which is read directly from the scale. (From N. Efron, 1987, by permission)

$$\% \text{ WC} = \frac{\text{RI of dehydrated material } (N_1) - \text{RI of hydrated material } (N_2)}{\text{RI of dehydrated material } (N_1 - \text{RI of saline } (N_3)} \times 100$$

Oxygen transmissibility

Although there is considerable debate about the oxygen requirements of the human cornea, which shows significant individual variation, it is nevertheless agreed that the critical oxygen performance ranges from 8% to avoid loss of corneal sensitivity (Millodot and O'Leary, 1980), 10% equivalent oxygen performance to avoid oedema (Holden, *et al.* 1984), 13% to maintain epithelial mitosis and avoid lactate accumulating in the anterior chambers (Hamano *et al.*, 1983), to 15% to avoid the formation of microcysts and polymegethism in extended lens wear (Holden, 1986). The passage of oxygen to the cornea through the water phase of hydrogels is therefore of critical significance and may be quantified in terms of transmissibility in which:

$$\text{Transmissibility} = \frac{\text{Dk}}{\text{t}}$$

where *t* refers to the lens thickness and Dk the rate of flow of a gas, usually oxygen, at a specified temperature through a unit area of unit thickness of the lens and subject to a specified unit pressure difference.

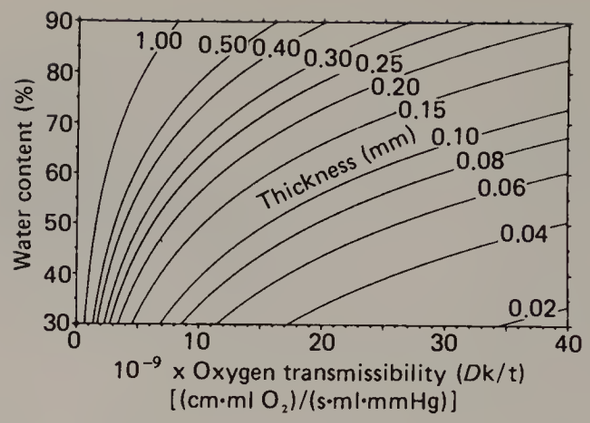


Figure 13.23 Graph illustrating the relationship between percentage water content and oxygen transmissibility (*Dk/t*) for a lens of specific average or centre thickness. (From Efron and Brennan, 1985, by permission)

So

$$\text{Dk} = \frac{\text{Amount of gas (ml } O_2) \times \text{Thickness (cm)}}{\text{Area (cm}^2) \times \text{Time (s)} \times \text{Pressure difference (mmHg)}}$$

It is clearly advantageous for the practitioner to know and, if possible, measure or estimate the transmissibility of a lens of known material. This important information facilitates the design, identification and verification of the chosen lens and affects the dehydration, monitoring and after-care of the patient. By measuring the centre thickness or preferably determining the average thickness with the Brennan nomogram (*see Figure 13.20*) and knowing the water content, the centre or average transmissibility may be conveniently read off the graph in *Figure 13.23*. Although *Dk/t* (previously referred to as *Dk/L*) is the generally accepted parameter for oxygen transmissibility, Flynn *et al.* (1983) suggested the hydration/thickness (*H/t*) index as an alternative which gives a correlation coefficient of +0.90 with oxygen performance and is easily calculated. The *H/t* index is defined as the quotient of water content and centre thickness. However, thick and thin lenses should not be inter-compared by the *H/t* index. Also the *H/t* index does not indicate the effect of flexibility or oxygen transmission in the midperiphery or the periphery of the lens (A. J. Phillips, 1987, personal communication). If the centre thickness were to be replaced by average thickness then both the average transmissibility (Dk/t_{av}) and the average hydration index (H/t_{av}) would be more meaningful values, albeit more difficult to measure and calculate.

New high Dk hydrogel co-polymers are currently being developed which incorporate silicone, fluorine and other materials. These permit oxygen permeability in excess of the water content (H. Gee, personal communication, 1995).

Back vertex power

A possible limitation of hydrogel contact lenses is that the visual acuity with the contact lens may be less than the

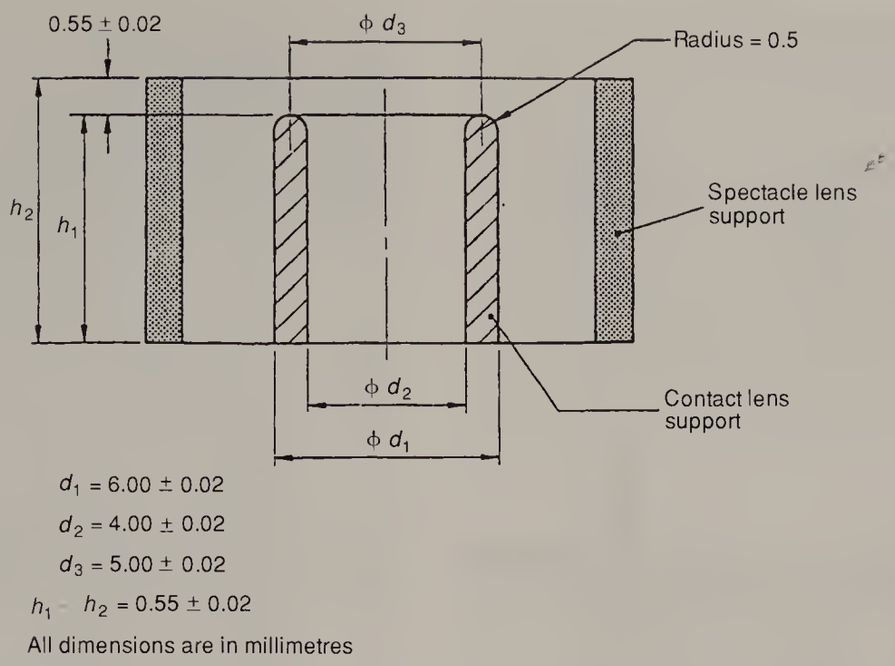


Figure 13.24 Contact lens support ring designed to replace the conventional spectacle lens support of a focimeter. (After BS 7208, Part I, 1992, by permission)

equivalent acuity obtained with spectacles or rigid contact lenses. It is therefore important that the refraction is accurate, the lens is fully settled on the eye (to allow for ambient environmental factors), before an over-refraction is attempted and, finally, that the back vertex power of the lens has been accurately worked and verified.

Focimetry

Liquid cells

In measuring the back vertex power of a soft contact lens, it is preferable that a projection focimeter is utilized to enhance the accuracy of the reading, and Nakijima *et al.* (1974) recommended mounting the lens in a liquid cell or cuvette and reading off the power of the resultant thick polymer–liquid lens on a projection focimeter.

The back vertex power (BVP) of a soft contact lens may be measured, either in air or liquid, using a focimeter corresponding to International Standard ISO 8598 which also incorporates a contact lens support ring, as illustrated in *Figure 13.24* and ISO 9337 Rev.).

The clarity of the focimeter image relates closely to the optical quality of the lens whose power is being measured and may be used as a pass/fail criterion. However, artefacts can and do occur, for example from incomplete surface blotting or drying and dehydration. If the initial image quality is suspect the lens should then be reconditioned and the process repeated. If the image quality is still poor, then the optical quality of the lens is in question possibly due to a heterogeneous polymer, surface deposits or imperfect polishing.

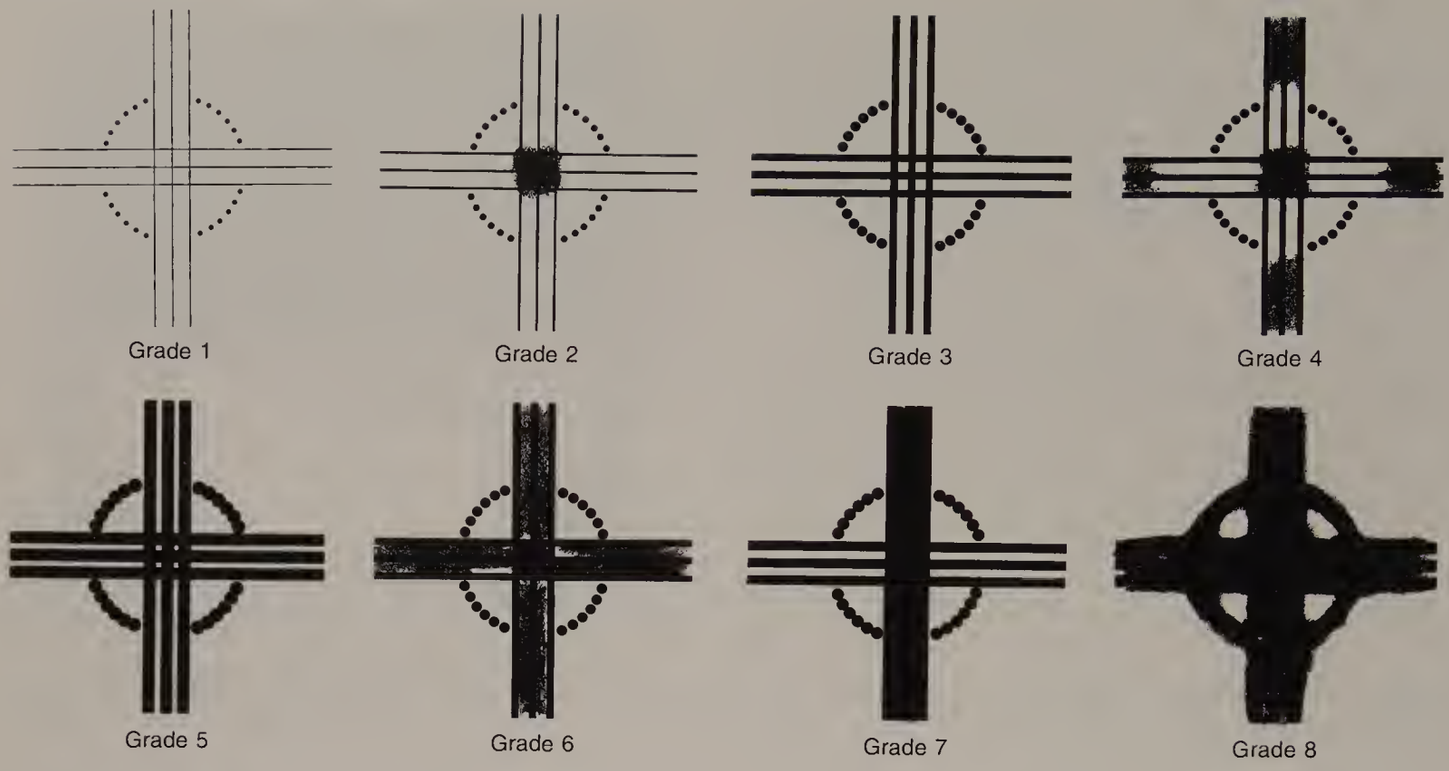
In order to monitor, quantify and establish pass/fail criteria a grading system as outlined in *Figure 13.25* is recommended. By this protocol, the focimeter image quality in air of the dried lens is compared to a series of illustrated and pre-determined graded images. Background haze may persist due to surface moisture and should be ignored. In the examples outlined, grades 1 to 4 would be passed, 5 to 6 marginal pass and 7 and 8 rejected. It is hoped that a Standards Organization will publish an agreed format for public comment in due course.

Whilst a soft contact lens may be mounted convex side upwards on a suitable support and measured either in air or liquid, a more satisfactory technique is to use a focimeter attachment, which centres the lens with a minimum amount of distortion. An example is the Soft Lens Power Check (Optical Science Ind. Inc., Spices, MN, USA), which is a wet cell.

Figure 13.26a shows how a projection focimeter may be modified to measure the back vertex power of a soft contact lens in saline. *Figure 13.26b* shows the Soft Lens Power Check and *Figure 13.26c* shows the device mounted on a focimeter.

The Tori-Check (Specialist Optical Service) is a simple and effective lens holder which is widely used to measure the spherical, toric or prismatic powers of soft contact lenses and is illustrated in *Figure 13.27* (*see also Figures 14.27–14.30*).

After careful blotting, the lens is adhered to a rotatable disc which fits into the handle of the instrument. The Tori-Check is then centred in the focimeter stop so that the back



Grade	*Image quality*	*Background haze*	*Pass/Fail criteria*
1	Excellent	Absent	Pass
2	Excellent	Perceptible	Pass
3	Good	Absent	Pass
4	Good	Present	Pass
5	Marginal	Absent	Just Pass
6	Marginal	Just Acceptable	Just Pass
7	Marginal but unwanted cylinder	Absent	Fail
8	Unacceptable	Unacceptable	Routine Fail

Figure 13.25 Determination of the optical quality of hydrogel contact lenses in air using graded focimeter images

vertex power can be measured without distortion. Spherical powers may be read off directly. In the case of cylinders or prisms, the device incorporates a projection scale. The lens markings are then aligned and the cylinder power and axis of the prism read off directly. Suggested tolerances for these parameters are outlined in *Tables 13.2* and *13.4*.

The Rotlex ConTest* uses Moiré Deflectometry to measure the back vertex power of a soft lens immersed in saline. All lenses can be checked; spherical, toric and multifocal, and the instrument can also be used for checking rigid lenses in air. The Moiré fringes are imaged on a computer screen and the optical quality assessed at the same time. An accuracy of 0.06 D is claimed for 38% water content lenses.

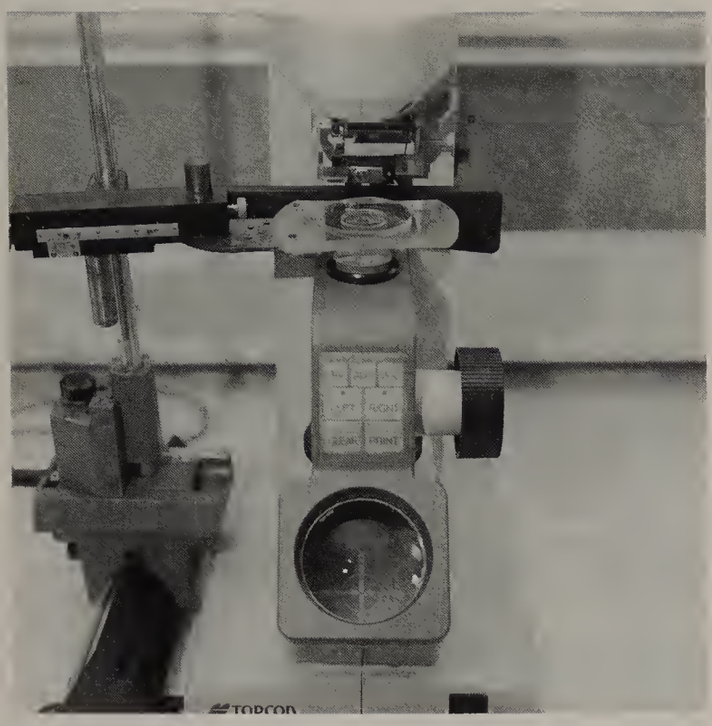
In order to determine the back vertex power in air of a lens measured in liquid a compensation factor, K, must be applied (Poster, 1971).

*Rotlex, Temed Industrial Park, Arava, Israel.

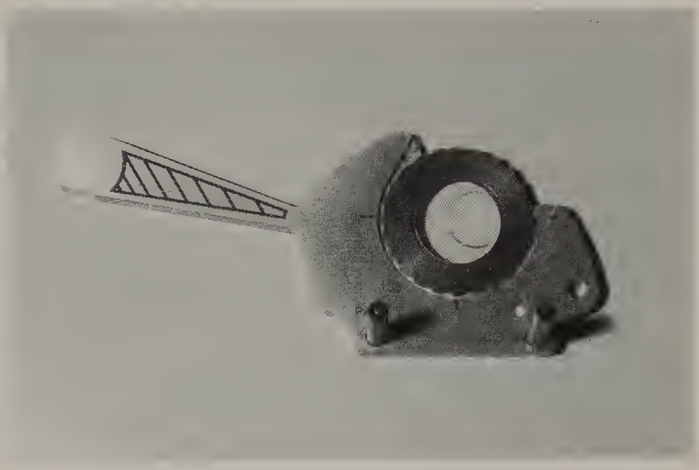
If n is the refractive index of air = 1.00
n' is the refractive index of the saline solution = 1.336
n'' is the refractive index of the hydrogel material $\simeq$ 1.430
F_1 is the back vertex power in air
F_2 is the back vertex power in the liquid
Then $F_1 = F_2K$
Where, approximately,

$$K = \frac{(n'' - n)}{(n'' - n')} = \frac{1.43 - 1.00}{1.43 - 1.336} = 4.57$$

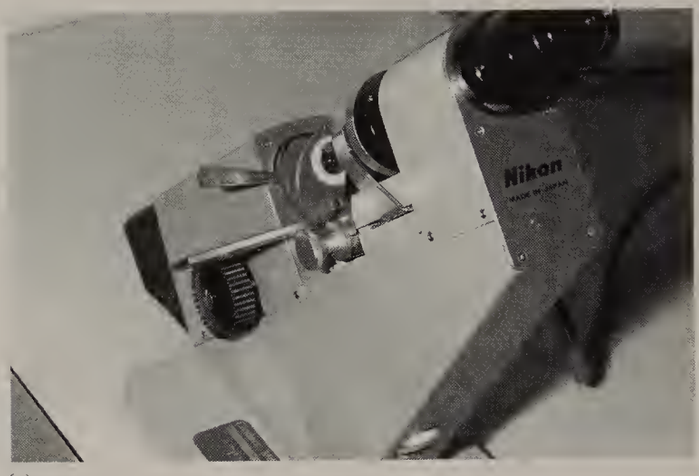
The Poster conversion factor, which converts the lens power in saline to the power in air, only applies to thin lenses (Pearson, 1980, citing Wray, personal communication). Although complex equations may be applied to thick lenses (Wichterle, 1965), these presume an accurate knowledge of the front optic zone radius, back optic zone radius and centre thickness.



(a)



(b)



(c)

Figure 13.26 (*a*) Measurement of the back vertex power of a soft contact lens in saline using a projection focimeter and a wet cell. NB: A glass plate covers the wet cell to reduce artefacts from vibrations producing currents in the saline (Courtesy of W. N. Charman). (*b*), (*c*) the Soft Lens Power Check: the lens is removed from the saline and immediately placed on the mount and covered with a flexible membrane to keep it wet. The device is mounted on a focimeter and the back vertex power read directly. (Courtesy of A. J. Phillips)

Thus, the back vertex power measured through the liquid cell must be multiplied by the compensation factor. This may be more conveniently read off from tables or from a graph as illustrated in *Figure 13.28*. This means that the accuracy of focimetry must be improved by 457% and the required sensitivity necessitates readings of 0.05 D. Thus, an error of 0.12 D in the focimeter reading would lead to an error of over 0.50 D in the actual lens power in air. Hampson (1973) also pointed out that surface distortions of the hydrogel lens may be masked by the ambient saline solution; furthermore pseudocylinders, prisms and other distortions may be introduced by the cell walls. In view of these limitations it is doubtful if liquid immersion offers substantial advantages for checking the power of soft contact lenses.

By using the Autostigmatic Microscope (*see Figure 13.10*), the BVP of the saline-immersed lens mounted with the back surface upwards may be calculated. In *Figure 13.29* a focused target image is seen on the front lens surface A, at its apparent centre of curvature D, also at the back lens surface B and at its centre of curvature C (Steele and Freund, 1985, and personal communication, 1989). The back vertex power may be calculated thus:

$$\text{BVP} = (n - 1)\left(\frac{1}{b} - \frac{1}{r} - \frac{S}{(nb^2 + bS)}\right)$$

in which

S = AB
r = BC
t = BD
n = the refractive index of the lens
n' = the refractive index of saline
b = distance from D to actual centre of curvature of front surface

$$\text{and } \frac{1}{b} = \frac{n'}{nt} + \frac{(n - n')}{nr}$$

The average standard deviation of the BVP of lenses ranging from 38% to 70% water content, from +4.25 D to –4.00 D and any thickness is ±0.37 D.

Air checking

This was recommended by Isen (1972), Gasset (1972), Hampson (1973), Ruben (1974), Mandell (1974a) and Stone

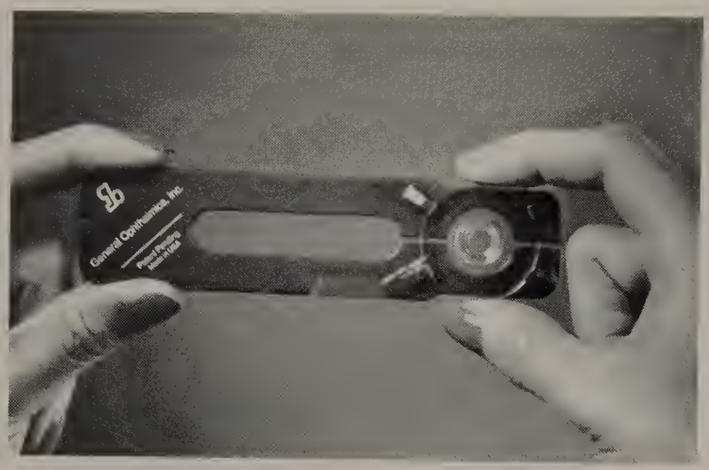


Figure 13.27 The Tori-Check, which is a holder designed to measure the spherical, toric and prismatic powers of soft contact lenses in air, is also an axis marker checking device (Courtesy of Specialist Optical Source Limited) (*see also Figures 14.27–14.30*)

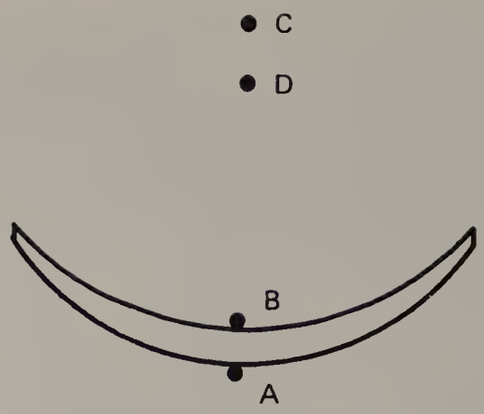


Figure 13.29 Measurement of back vertex power of a soft contact lens in saline using the Autostigmatic Microscope (*see Figure 13.10*). The target is focused in turn on A and B which represent the front (lower) and back (upper) surfaces of the lens; C is the centre of curvature of the upper surface while D is the image of the centre of curvature of the lower surface as viewed through the upper surface. (From Steele and Freund, 1985, by permission)

(J., 1975, personal communication) and a projection focimeter is recommended. There is a critical period after removing the lens from the saline solution. For 30 seconds this image is hazy (Isen, 1972), after which the reading should be taken. The focimeter scale is initially set to the expected reading (J. Stone, 1975, personal communication), the lens carefully dried and placed convex side upward either on a reduced aperture focimeter or a conical contact lens holder, and the reading taken in air. With practice a reasonably clear image can be obtained with this method and a reliability of ±0.25 D is claimed (Harris *et al.*, 1973). Pearson (1980) found a standard error of measurement of BVP of ±0.09 D in air and ±0.05 D in saline and while recommending wet cell checking acknowledged the problems of converting wet to air power.

Surface inspection

Hydrogel contact lenses are inherently fragile and are also liable to exogenous and endogenous contamination, examples of which are given in *Figures 13.30–13.32* and *Tables 13.11–13.13*. It is generally accepted that continuous irrigation is an efficient method of removing debris and micro-organisms, and this important function is performed in the conjunctival sac by the tears. If the irrigation interface (and this includes the cornea or the contact lens) presents an irregular surface resulting, for example, from scratches, crevices and other lesions (*see* Figure 18.23), the surface may harbour micro-organisms which collect and multiply away from the natural protective mechanisms (Tripathi and Ruben, 1972/73). It therefore follows that the importance of inspection of the surfaces and edges of hydrogel contact lenses both on and off the eye cannot be over-emphasized.

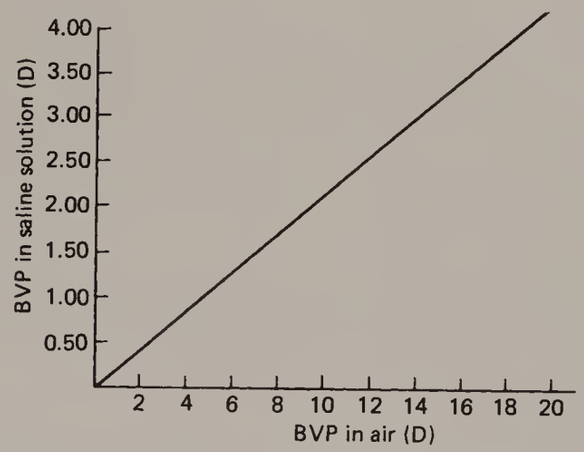


Figure 13.28 Conversion from back vertex power in liquid to back vertex power in air



Figure 13.30 Hydrogel surface contaminated with hair rinse

Table 13.11 Potential lesions of hydrogel surfaces

Lesion	*Possible cause*	*Possible effect*	*Possible remedy*
Tears, cracks and splits*	Mishandling or manufacturing defect	Accumulation of debris. Discomfort, abrasions and infection	Replacement lens
Linear indentations*	Polishing marks in manufacture	Accumulation of debris. Discomfort, abrasions and infection	Replacement lens
Lens engraving	Inscribed in xerogel state	Accumulation of debris. Discomfort, abrasions and infection	Replacement lens although debris may be removed by surfactant cleaning followed by boiling, enzyme or oxidative cleaning
Foreign bodies	Airborne debris	Discomfort, lacrimation, abrasions and infection	Massage and irrigation with 0.9% saline solution
Aerosol sprays	Make-up incorrectly applied	Discomfort and reduced wetting	Surfactant cleaning followed by boiling or oxidative cleaning. Replacement lens often necessary
Fungi	Poor hygiene	Enzymatic degradation of material	Asepticization. Replacement lens often necessary
Microbes	Exogenous or endogenous aetiology	Infection	Surfactant cleaning followed by heat or chemical disinfection
Chemical binding	Incorrect or incompatible solution (for example, rigid lens solution, eyedrops and medications)	Eye irritation, chemosis, infection	Discontinue soft lens wear and seek medical treatment. If binding is due to protein deposits on lenses, clean lenses to remove deposits. May need replacement
Surface crazing and cracks	Hydrogel dehydration followed by stress. Incomplete polymerization or degradation of the material	Accumulation of debris and microbes. Discomfort, abrasion and infection	Replacement lens

*Most lenses carry a manufacturer's warranty against mechanical defects.
See also Chapters 3 and 4.

Table 13.12 Potential surface films on hydrogel lenses

Lesion	*Possible cause*	*Possible effect*	*Possible remedy*
Tenacious milky film which may appear green on phase contrast microscopy (*see Figure 13.38*)	Proteins deposited on the lens surface which may become denatured, especially if heat disinfected. May contain albumin, γ-globulin, α_1-lipoprotein, mucopolysaccharides, lipids and phospholipids. Predisposition to the build-up of other inorganic materials (for example, chlorhexidine binding) and inactivation of anti-microbial additives. Bacteria	Impaired wettability, reduced vision. Red eye reaction, tarsal papillae (giant papillary conjunctivitis), mucus discharge, itching and increased lens movement. Infection	Non-denatured protein build-up may be prevented by surfactant cleaning or treatment by electrical pull copolymers. Denatured proteins may be treated by broad-spectrum proteolytic enzyme cleaners, bleaching (for example, chlorine) or hydrogen peroxide. Lipoprotein treated by lipase cleaners and phospholipids by phospholipase cleaners. Sanitizing (cleaning and autoclaving) or lens replacement
Greasing	Biofilm of meibomian secretions, sebaceous secretions or tear cholesterol	Intermittent blurring, reduced acuity and adhesion of pathogens	Surfactant cleaning. Lipase and phospholipase cleaners

Table 13.13 Potential discoloration of hydrogel lens material

Lesion	*Possible cause*	*Possible effect*	*Possible remedy*
White spots	Tear calcium. Crystalline deposits from solutions prepared from non-purified water	Lens intolerance	Possible treatment with calcareous chelating agent such as EDTA or oxidization cleaners. May need replacement
Red spots	Ferrous particles endogenously or exogenously induced. The ambient saline solution and also heat sterilization make them highly susceptible to corrosion	No known adverse effects to date, although the possibility of ocular siderosis must be considered	Probably replacement lens though possibly inhibited by ferrous chelating agents such as EDTA or oxidization cleaners. May need replacement
Green film	Accidental contamination with fluorescein	Discoloration of lens, and possibly exogenous infection by pathogenic microbes such as *Pseudomonas aeruginosa*	Heat or boil in physiological saline solution. If heavily stained then soak in Milton* for 15–30 minutes. Place in a vial containing sterile, physiological saline solution and boil for 30 minutes. Transfer to a clean vial and fresh saline solution and repeat the boiling process (up to four times) until the pH returns to normal. Finally, rehydrate in appropriate solution
Red film	Accidental contamination with rose bengal	Discoloration of lens. Possible exogenous infection	Not normally removed by boiling
Yellow/brown discoloration	Tobacco smoke. Aromatic compounds in tears. Chlorhexidine reaction especially with chlorinated cleaners	Reduced acuity, discomfort and possible infection	Boiling in saline solution followed by the use of strong oxidization cleaners

*Milton (Richardson-Merrell).
See also Chapters 3 and 4.

Figures 18.23 and *18.40–18.46* should be studied with this in mind.

Light microscopy

The surface area of a soft contact lens varies from approximately 140 to 200 mm^2 and clinically it is necessary to scan the hydrogel surface not only with reasonable speed but also to employ high magnification to critically evaluate suspect areas such as those illustrated in *Figures 13.33* and *13.34* which show how easily debris can accumulate in scratches and engravings. In practice a range from × 5 to × 40 is adequate and the slit lamp biomicroscope performs the function admirably, although, if preferred, a separate stereomicroscope can be used.

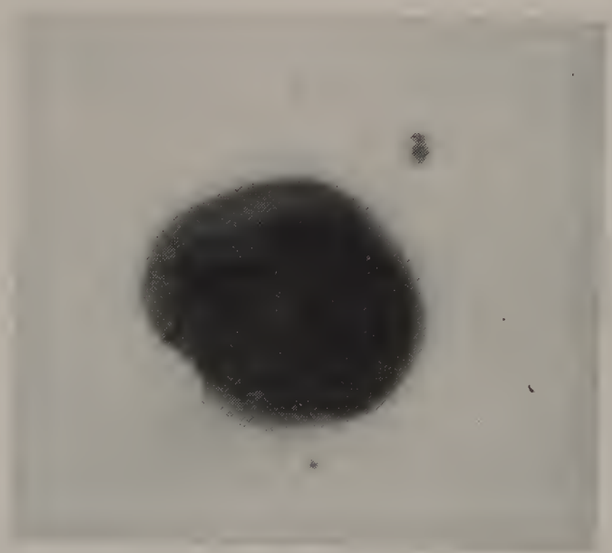


Figure 13.31 Contaminant embedded on the front surface of a semi-dehydrated hydrogel contact lens in contact with a saline solution droplet × 40

When the lenses are inspected in air they should be shaken or blotted dry and examined under magnification, preferably on glass, against a white background. For this purpose, the lens may be mounted on a microscope slide with a white adhesive background (*Figure 13.35* and *Figure 18.19*) or, alternatively, the test plate of the slit lamp may be modified as shown in *Figure 13.36*. It should be pointed out, however, that if the test plate is mounted on the body of the slit lamp in the normal manner, then the lens plane is displaced forward slightly from the focal plane of the microscope and the lens surface is permanently out of focus unless the microscope has an independent focusing control. It may therefore be necessary to hold the lens mount by hand which may be tilted and moved as necessary. By employing conventional variations in slit lamp illumination the lens surface may be examined and evaluated. Brandreth (1975) recommended that the examiner use moderate magnification with direct focal illumination, 'sclerotic scatter', to evaluate the edges, and parallelepiped illumination with moderate magnification for inspection of the lens surfaces.



Figure 13.32 Sagittal section of a red spot which shows a deeply embedded ferrous particle of unknown aetiology. The location of the contaminant, however, suggests an endogenous aetiology possibly introduced during spin-casting

Dark-field illumination is also useful, where the lens is illuminated by the slit beam against a dark background. Imperfections and deposits on the lens then show up light against the dark background much as corneal irregularities may show up against the dark background of the pupil. Some deposits or irregularities not seen against a light background may show up in this way (*see Figure 18.45* and *Figure 4.19e*).

If the practitioner wishes to employ even higher magnification, Brandreth (1975) suggested modifying the slit lamp in the following manner. The lens is mounted on a glass slide or held by hand in the region of the head-rest directly in the beam of light. The illuminating system is aligned with the axis of the microscope set opposite to each other at a zero reading, so that the contact lens is located between the light source and one of the microscope objectives. By moving the eyepiece, if necessary, a greatly magnified image may now be projected onto a convenient wall and examined for imperfections.

Degradation of the lens surfaces can and does occur in wear as *Figures 13.37* and *13.38* illustrate, and such lesions may not only interfere with vision or cause discomfort but may be extremely hazardous. It is therefore necessary for the practitioner to critically examine the lens surfaces each and every time the patient is seen for soft lens after-care. The practitioner would normally employ the slit lamp while the lenses are *in situ* to evaluate



Figure 13.33 Polishing marks seen on a lathe-cut lens at × 40 magnification. (Reduced to three-quarters in reproduction)



Figure 13.34 Appearance of lens engraving at × 40 magnification showing accumulation of dirt and debris which may harbour pathogenic microbes. (Reduced to three-quarters in reproduction)

centration, lag and conjunctival disturbances, at the same time the lens surfaces should be examined (*see Figures 18.41* and *18.42*). The lens should also be examined out of the eye as previously explained either using the slit lamp or a stereomicroscope.

International Standard ISO/DIS 8321–2 recommends that 'when examined at 10× magnification in standard saline (International Standard ISO/DIS 10344), the lens shall not exhibit any inclusions or surface imperfections which interfere with its intended functional use. When examined at 7× magnification the lens edge shall meet the quality characteristics mutually agreed to by the supplier and customer with respect to shape, smoothness and polish'.

Electron optics

Light microscopy is limited by the wavelength of light to a magnification of approximately ×1000 and a resolution from 100 to 200 nm which is considerably greater than is required clinicaily. In research, however, greater magnification may be necessary to make ultrastructural studies of the hydrogel polymer (Matas *et al.*, 1972; Tripathi and Ruben, 1972/73; Filippi *et al.*, 1973; Loran, 1973; Holden *et al.*, 1974; Stern *et al.*, 1985; Hart and Shi, 1987; Brussel-Lawin *et al.*, 1991; Tripathi *et al.*, 1994).

If it is necessary to employ higher magnification, electron optics must be used, which is that branch of physics concerned with the projection of an electron beam. Electron microscopy permits 1000 times greater resolution than light microscopy so that magnification of up to ×100 000 may be achieved. The beam is focused directly on to a suitably sectioned specimen, through electron lenses in transmission electron microscopy, or arranged to scan the specimen in scanning electron microscopy, the latter technique being recommended by Holden *et al.* (1974) for hydrogel contact lenses. The reflected electrons are then picked up by a

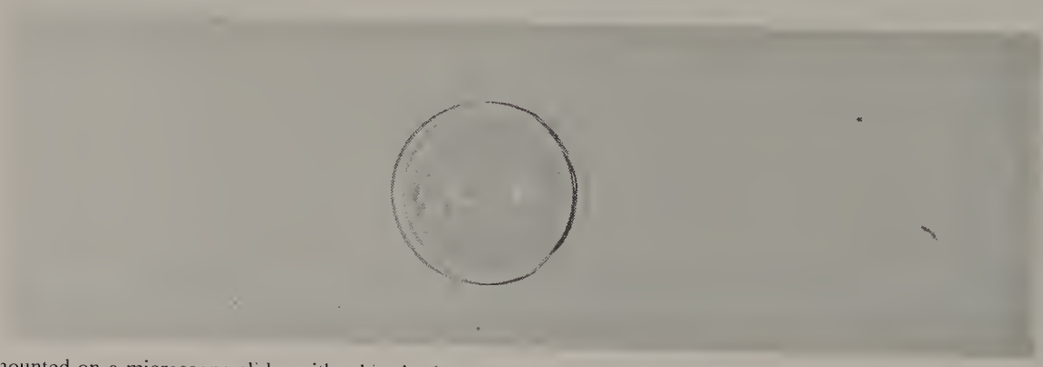


Figure 13.35 Lens mounted on a microscope slide, with white background, for air surface inspection



Figure 13.36 Lens mounted on a slit lamp test plate (with white background) for air surface inspection

suitable detector and finally the signal is amplified and is displayed on a cathode ray tube where the electron image may be photographed as a micrograph as shown in *Figures 13.39* and *13.40*.

It is also possible to identify some hydrogel contaminants by a technique known as electron microprobe analysis in which the electron probe scans a prepared specimen, which, subsequent to excitation, emits characteristic X-rays. The latter may then be analysed and identified by crystal spectrometry. An example of an X-ray scan superimposed on an electron image of ferrous contamination of a hydrogel lens is illustrated in *Figure 13.40*.

Microbial contamination

Microbes may proliferate in the tear film and adhere to the surfaces of soft contact lenses. Such deposition is especially likely if the lens is coated with a biofilm of glycoproteins or glycolipids or has a reduced pH which results in a decreased negative ionic charge in the polymer matrix (Ratner *et al.*, 1994). Bacteria tend to form a milky film, fungi appear as fine filaments whilst Acanthamoeba are visible either in the cystic or trophozoite forms by high magnification light and electron microscopy (*see Figure 4.2*).

Dart *et al.* (1991) found that, compared to daily wear RGP contact lenses, the risk of developing microbial keratitis with soft contact lenses was 21 times greater for extended and 4 times greater for daily wear. Extended wear of contact lenses enhanced the adhesion of *Pseudomonas aeruginosa* to the host corneal epithelium (Fleiszig *et al.*, 1992), and Brussel-Lawin *et al.* (1991) showed that significantly less bacteria adhered to new than worn soft contact lenses irrespective of type.

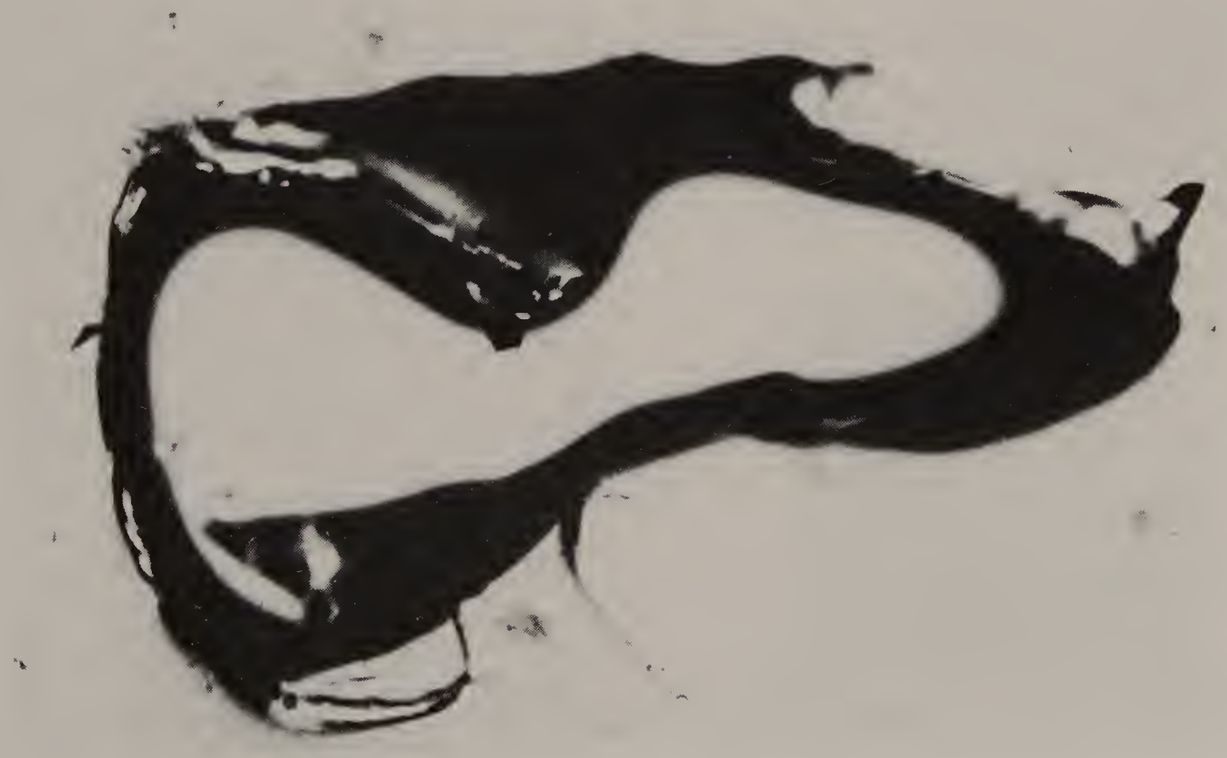


Figure 13.37 Appearance of a hole in the hydrogel matrix caused by a penetrating foreign body without ocular damage

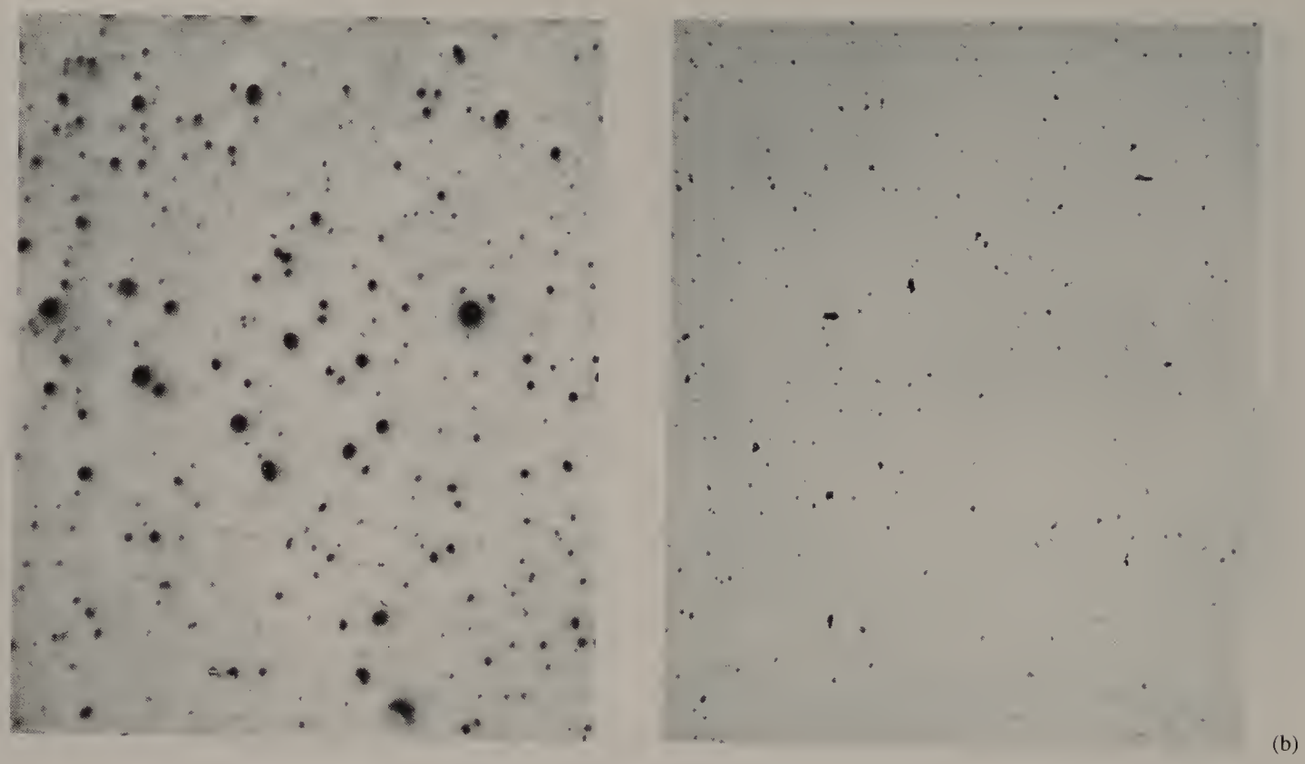


Figure 13.38 (*a*) Coagulated proteins on the surface of a hydrogel lens. (*b*) The same surface after treatment by a proteolytic enzyme cleaner

Classification of deposits

Lens deposits may conveniently be described, monitored and quantified by applying a modified Rudko system (Hathaway, 1976, Benjamin and Hill, 1980) as illustrated in *Table 13.14*.

Using this grading method, the heaviness, appearance and extent of surface lens deposits may conveniently be described by a clinical coding system. For example IIFc would indicate that a lens was deposited with a light film which covered between half and three-quarters of the lens surface.



Figure 13.39 Electron micrograph showing the relatively rough appearance of a lathe-cut lens at × 3000 magnification. (From Matas *et al.*, 1972 and reproduced by kind permission of the American Medical Association; reduced to three-quarters in reproduction)

Conclusion

Contact lenses may only be manufactured and prescribed as accurately as they may be checked, and in attempting to establish an acceptable system of tolerances for contact lens parameters, it is necessary first to establish fitting criteria which should then be correlated with the cost of manufacture and also the reliability and validity of available quality control instrumentation. Fitting criteria and cost considerations must take into account the opinions of those personnel engaged in the manufacture and prescribing of contact lenses. A cross-section of the views of manufacturers, practitioners and academics to recommend acceptable and realistic tolerances is illustrated in *Table 13.10* (Loran and Hough, 1987).

Contact lens technology is continuing to develop rapidly and published information is likely to become rapidly out of date. References to Draft Standards have been included to reflect contemporary opinions and debate. These are, however, intended for public comment and may be subject to alterations before final authorization. Furthermore, the need for validity and precision considerations also means that publication of approved standards is often delayed.

At the time of writing, Draft International Standards, based on confirmed precision and validity considerations are available for public comment (ISO/DIS 9314, ISO/DIS 9337, ISO/DIS 9338, ISO/DIS 9339–2, or EN/ISO 9339-2, ISO/DIS 9340, ISO/DIS 10338 and ISO/DIS 10339).

It is therefore suggested that tolerances published by the American Standards Institution, New York (Z80.8–1986)

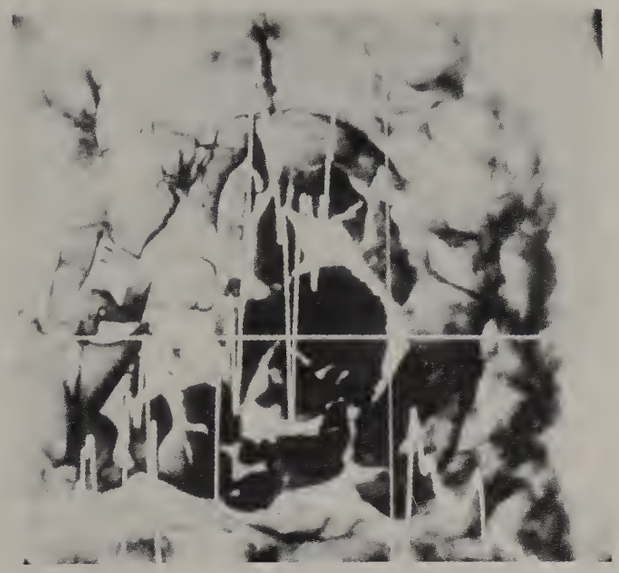


Figure 13.40 Electron microprobe analysis of the contaminant illustrated in *Figure 13.31* which was coated with a thin layer of carbon to enhance conductivity of the electrons. The subsequent X-ray scan was superimposed on a ×300 electron image and shows strong iron radiation in the alpha (mean) component of the K band of the spectrum. A less intense oxygen radiation was also present. (From Loran, 1973; reduced to three-quarters in reproduction)

(*Table 13.2*) should act as a guide for laboratories, teachers, researchers and practitioners.

Acknowledgements

Several soft contact lens verification instruments described in earlier editions are now obsolete. Some have therefore been omitted to make way for more recent developments, whilst those of historical interest have been retained.

I am most grateful to those authors and laboratories who supplied photographs of their instruments and to the publishers who kindly granted permission for the reproduction of these illustrations in the text. I should also like to acknowledge the assistance of those colleagues cited under personal communications and thank Bill Corbett, Michael Port and Michael Sheridan for their guidance on the deliberation of the British Standards Institute and the International Standards Organisation. Finally I should like to thank Freda Taylor and Sara Ball for typing the manuscript.

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Table 13.14 Classification using a modified Rudko system

Code	*Heaviness of deposit*	*Code*	*Type of Deposit*	*Extent*	*% of lens surface affected*
I	Clean	C	Crystalline	a	0–24
II	Visible in the wet state using oblique light and ×7 magnification	G	Granular	b	25–49
III	Visible in the dry state without magnification	F	Film	c	50–74
		P	Plaque		
IV	Visible in the dry or wet state without magnification	D	Debris	d	75–100
		Co	Coated		

Rearranged from Benjamin and Hill, 1980

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Chapter 14

Toric contact lens fitting

Richard G. Lindsay and David I. Westerhout

Fitting toric rigid gas permeable lenses p. 464
Indications for the use of toric contact lenses p. 464
Forms of toric lens p. 465
Optical considerations of toroidal back optic zones p. 468
Toroidal front surfaces combined with spherical back optic zones p. 477
RGP lens flexure p. 481
Checking toric RGP lenses p. 481
Fitting toric soft lenses p. 481
Criteria for use of toric soft lenses p. 482
Design of toric soft lenses p. 482
Principles of correction p. 485
Methods of fitting p. 488
Stock lenses versus custom-made lenses p. 489
Limitations of toric soft lenses p. 490
Checking toric soft lenses p. 491
Trends in toric soft lens design p. 492

Toric forms of contact lenses have been in use for many years and, now that laboratories are prepared to devote more time and resources to the manufacture of such lens forms, they are being used more widely.

In the early years of contact lens practice, many practitioners attempting to fit a patient for whom a toric lens might have been of value were reluctant actually to use one, partly due to their lack of experience of such lenses as well as the acknowledged difficulty in having them manufactured accurately, and the high cost involved. Since the early 1980s, however, there have been significant developments in toric lens design and manufacture. As a result, improvements have been noted in the performance and reproducibility of toric contact lenses, such that practitioners are now more likely to prescribe these lenses when their use is indicated.

Fitting toric rigid gas permeable lenses

The majority of toric rigid lenses currently fitted throughout the world incorporate some form of rigid gas permeable (RGP) material. The advantages of RGP lenses over hard (PMMA) lenses, such as higher oxygen transmissibility and less spectacle blur, have previously been discussed in Chapter 10 and apply equally to toric RGP and toric hard lenses.

Consequently, the focus here will be on toric RGP lenses such that mention of toric hard (PMMA) lenses will occur infrequently in this chapter. It should be noted that the design and optical principles of toric RGP lenses are similar to those for toric hard lenses. The major distinctions revolve around the differences in lens flexure effects and the different refractive index of RGP materials (generally between 1.43 and 1.48) compared to PMMA (1.49).

Indications for the use of toric contact lenses

The main uses of toric lenses are as follows:

- To improve the vision in cases where a lens employing spherical front and back optic zone radii is unable to provide adequate refractive correction.
- To improve the physical fit in cases where a lens with a spherical back optic zone radius (BOZR) and spherical back peripheral zone radii fails to provide an adequate physical fit. The terms 'spherical BOZR' and 'spherical back peripheral zone radii' include, in this context, any lens of any construction whether it be aspheric, conoidal or using any non-spherical curves, provided that the BOZR specifications are the same in any two meridians at right-angles to one another and the peripheral construction has the same specification in all meridians.

These two main uses of toroidal surfaces on contact lenses are not always distinct, such that occasionally a toric lens will be used for both physical and optical reasons. For example, when fitting an eye with both a high degree of residual astigmatism and a large amount of corneal toricity, a toric lens is required optically (to correct the

residual astigmatism) as well as physically (to optimize the fit of the lens).

Forms of toric lens

There are seven main varieties of toric corneal lens available to the practitioner, as follows:

1. with a toroidal back optic zone and peripheral zone;
2. with a toroidal back optic zone and spherical peripheral zone;
3. with a spherical back optic zone and toroidal peripheral zone.

4–7. Each of 1–3 can be produced with or without a toroidal front optic surface, as can a lens with a spherical back optic zone and spherical peripheral zone.

This classification may be subdivided as follows. A lens which has a toroidal back optic zone and a toroidal front surface has a **bitoric construction**. If the principal meridians of the toroidal front and back surfaces are not parallel, then the lens is of **oblique bitoric construction**.

With respect to toric contact lenses, British Standard 3521 (1987) states that a toroidal surface should be specified by the radii of curvature in its two principal meridians, the radius in the flatter meridian being written above a line and the radius in the steeper meridian below it. For example:

$$\text{C3 Toric } \frac{8.00}{7.50}:7.00/\ \frac{8.80}{8.30}:8.00/\ \frac{10.00}{9.50}:9.00$$

Where it is necessary to specify the orientation, the direction of the flatter meridian in standard axis notation should be written after the longer radius, prefixed by the letter 'm' to denote meridian. The abbreviation 'Tor' may be used with 'BS' to denote back surface, 'FS' to denote front surface, 'OZ' for optic zone and 'PZ' for peripheral zone so as to indicate which surface is toroidal.

Lenses with toroidal back optic and peripheral zones

This type of lens is generally used in attempting to obtain a good physical fit on a cornea that is too toroidal to allow a good fit with a lens having a spherical BOZR and spherical peripheral radii.

Although corneal lenses in general may be successfully fitted with either apical clearance or apical contact, it is generally more satisfactory to fit lenses with toroidal back optic zones in or near alignment. Fitting in alignment is usually held to mean fitting with a BOZR of the same radius as the corneal radius in its flattest meridian, as found by keratometer (or *K*) reading. This may be a reasonably accurate interpretation when the cornea to be fitted is almost spherical, but 'fitting on flattest *K*' is unlikely to represent alignment in medium or high degrees of corneal astigmatism. Alignment, to some practitioners, may mean a situation in which the lens fitted shows no apical clearance with fluorescein, but if the BOZR is decreased or the BOZD is increased by clinically significant amounts, then the fluorescein picture would change to one of apical clearance (Westerhout, 1969).

Since the lens form under discussion is made with a toroidal back optic zone to fit the contour of an astigmatic cornea, it may be seen that there is sound reasoning in trying to match the BOZR to the corneal radii. (Note: BOZR indicates back optic zone radius for a spherical surface and back optic zone radii for a toroidal surface.) This generally means fitting on or near the *K* reading in each meridian. Such a lens usually gives a good physical fit in close alignment, especially if the peripheral toroidal curves are fitted with similar consideration to the difference in peripheral radii of the corneal principal meridians. The physical fit, as denoted by the fluorescein pattern, will be similar to that seen with a well-fitted spherical lens in alignment to a cornea devoid of clinically significant astigmatism.

A lens with both spherical BOZR and peripheral radii fitted to an eye with a clinically significant degree of corneal astigmatism does have an inbuilt advantage in that the slight looseness in the meridian of steepest corneal curvature helps the lens to rock slightly on the flattest corneal curve, thus aiding the interchange of tears across the cornea behind the lens. Indeed, this rocking motion tends to act as a pump, and it is interesting to watch the flow of tears behind such a lens with a slit lamp biomicroscope – especially as the lens moves with and between blinks.

A lens in close alignment, however, is sometimes likely to create physiological problems. It may happen that a spherical lens closely fitted to a spherical cornea, or an astigmatic cornea fitted with a lens utilizing toroidal back optic and peripheral curves, gives poor tear interchange, and it may be necessary to aid the maintenance of normal corneal metabolism by using a slightly modified lens form.

To prevent a toric lens from aligning too closely to the cornea, it is advisable to use a toroidal back optic zone with the steeper radius fitted slightly flatter (longer radius) than the corresponding corneal radius to assist the interchange of tears. The flatter radius will generally be fitted 'on *K*' or else a little steeper than its corresponding corneal radius.

Despite the improved physiological performance with RGP lenses, practitioners need to be careful not to forget the importance of the tear film circulation between lens and cornea. Many of today's RGP lens designs have inadequate tear circulation and this is often seen at its worst when closely aligning toroidal back surfaces are used. Sufficient peripheral clearance should always be maintained with all forms of rigid lenses, especially when a fully toroidal back surface is used. The trend towards poor design is largely due to the fact that, in many countries, practitioners no longer design a lens themselves, complete with suitable edge clearance. Instead, they prefer to use a standard laboratory-designed lens in the hope that it will fit acceptably, rather than optimally.

Lenses with both toroidal back optic and peripheral curves are much easier to fit if *K* readings are available, and still easier if the practitioner has a fitting set of such lenses. Most practitioners, however, will usually have access only to spherical trial lenses and the use of these for toric lens fitting means that a certain amount of empirical judgement is required.

Consider the type of physical fitting which might be derived from *K* readings:

Keratometry reading:

7.90 mm (42.72 D) along 180
7.35 mm (45.91 D) along 90

Prescribed lens:

$$\text{C3 Toric/}\ \frac{7.85}{7.40}:7.50/\ \frac{8.45}{8.00}:8.50/\ \frac{9.25}{8.80}:9.50$$

Note that the toroidal peripheral curves differ by the same amount (0.45 mm) as the corresponding BOZR.

A correctly made lens with a toroidal back optic zone and toroidal peripheral curves, which differ by the same amount from the corresponding BOZR, has a similar appearance to a lens with a spherical BOZR and spherical peripheral radii. In both cases, the transition between the back optic zone and the peripheral zone is circular, or almost so. If the peripheral radii do not lie along the same meridians as the corresponding BOZR (i.e., the flatter peripheral radius does not lie along the same meridian as the flatter BOZR), the result is a lens which appears to have a markedly elliptical or oval back optic zone.

When to fit a toric lens

Since corneal lenses with both spherical BOZR and peripheral radii are often used successfully on corneas with medium to high degrees of astigmatism, it is important to decide what degree of astigmatism should indicate the use of toroidal back optic zones. In general, these should only be used when a lens with a spherical BOZR cannot be made to fit successfully. It is rare to find that toroidal back optic zones are necessary unless the corneal astigmatism exceeds 2.50 D (i.e., the difference in the corneal radii, as measured with a keratometer, exceeds 0.5 mm).

Note that the back optic zone radii should always be chosen such that the contact lens toricity is about 1.50 D or greater. The contact lens toricity is the toricity of the contact lens with respect to the eye and is obtained by the calculation $336/BOZR_1 - 336/BOZR_2$. (This is derived from the surface power formula, $[F = n - 1/r]$ where n = the refractive index of the tears = 1.336.) Based on the approximation (*see* Chapter 5) that a 0.05 mm meridional difference in radii is equivalent to 0.25 D, a contact lens toricity of 1.50 D equates approximately to a meridional difference of 0.3 mm and so the difference in the back optic zone radii should be at least this amount. Otherwise, the toroidal BOZR may not position properly on the toroidal cornea leading to lens rotation and possible visual disturbance depending on the type of toric lens design.

In cases of uncertainty (for example, where the corneal astigmatism is between 2.00 and 3.00 D), a toroidal back optic zone would be used in preference to a spherical back surface curve when:

- A spherical lens exhibits poor centration or excessive movement.
- Excessive lens flexure is noted with a spherical lens (*see* Chapters 5 and 10).
- Fluorescein patterns with a spherical lens reveal excessive bearing along the flatter corneal meridian, regardless of what BOZR is fitted.
- Significant 3 and 9 o'clock staining occurs with a spherical lens.
- There is marked corneal distortion and spectacle blur upon removal of the spherical lens from the eye. This occurs as a result of poor alignment between the spherical lens and the toric cornea, with the spherical lens subsequently having a moulding effect on the toric cornea.
- There is significant residual astigmatism. In this case, a spherical back surface may provide an adequate fit, however a toric back surface is utilized to stabilize the lens and prevent rotation, due to the presence of the correction for the residual astigmatism on the front surface of the lens.

A great deal depends on factors other than corneal astigmatism. Lid positions and tension are important. In a case of high corneal astigmatism, with-the-rule, and a low, loose lower lid, a toroidal back optic zone may be needed to obtain a good physical fit and centration. But a similar eye with a firm, high lower lid may well be successfully fitted using a lens with spherical back surface curves.

The majority of cases of corneal astigmatism are found with the steeper corneal curve in the vertical meridian (with-the-rule). If an attempt is made to fit such an eye with a spherical BOZR, the lens often drops low on the cornea, causing physical discomfort and/or poor vision. Such an example is illustrated in *Figure 14.1*. If the same eye is fitted using a lens with toroidal back optic and peripheral curves, then the physical fit and centration are usually much improved (*Figure 14.2*).

Sometimes, with such astigmatism, it is found that a lens with a spherical BOZR is lifted high on the cornea by the top lid. This may give a reasonable standard of steady vision but can cause physiological problems through its immobility and tendency to cause a stagnant pool of tears just below the upper limbus.

It is understood that the majority of practitioners will use spherical trial lenses when fitting toric RGP lenses. A fitting set of lenses with both toroidal back optic and peripheral curves is extremely valuable, however, as already mentioned. Even a limited set can be of great value. A suggestion for a minimum set is one covering the range

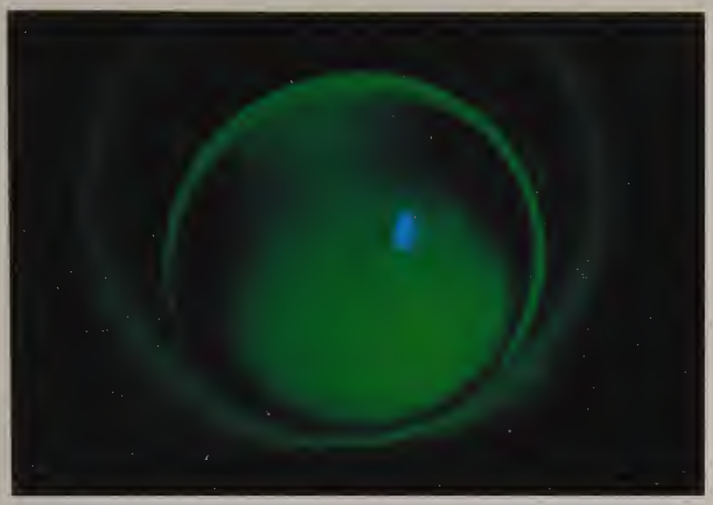


Figure 14.1 Left eye with high corneal astigmatism. Keratometer reading 8.17 mm along 10, 7.67 mm along 100. Optimum fit with spherical (8.25 mm) BOZR reveals heavy bearing along the horizontal (flatter) meridian and poor centration. Note the engraving on this trial lens which provides easy identification of the lens BOZR and TD

7.50 × 7.00 mm to 8.50 × 8.00 mm BOZR in 0.1 mm increments in both meridians.

The peripheral radii are usually chosen to reflect the type of peripheral fit preferred by the practitioner concerned. Each meridian is considered separately, and the peripheral fittings in the two principal meridians are selected to provide the same difference between back optic and peripheral radii most commonly used by the practitioner in fitting spherical corneas. In addition, the peripheral curves will usually have the same degree of toricity as the BOZR (in other words, the difference in the toroidal peripheral curve radii will be the same as the difference in the toroidal BOZR). For example, if a practitioner usually specifies the back peripheral radius 0.9 mm flatter than the BOZR for a spherical lens, then for a lens with toroidal BOZR of 7.90/7.40, the back peripheral radius ordered would be 8.80/8.30.

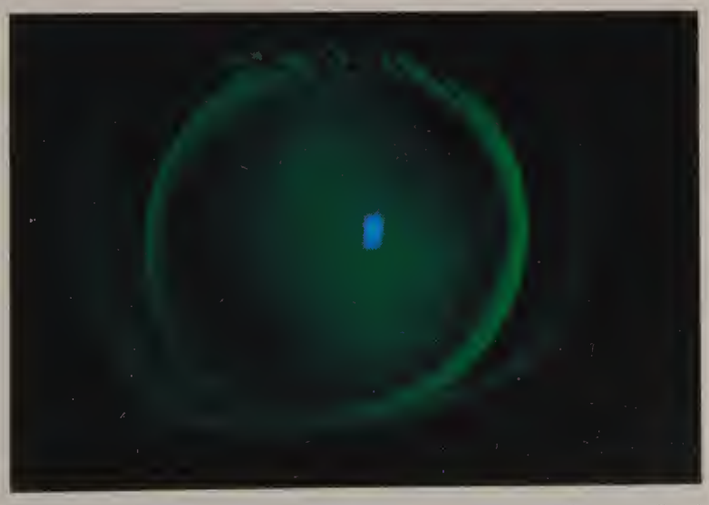


Figure 14.2 Same left eye as in *Figure 14.1* wearing an alignment fitted corneal lens using a toroidal back optic zone of BOZR 8.20 × 7.80 mm

Since the cutting and polishing of each pair of peripheral radii on a toroidal surface is such a complicated and costly process, it is best to choose the simplest possible form of peripheral fit preferred. If a tri-curve periphery, i.e. a tetra-curve lens, is normally used when fitting only spherical back surface zones, a less sophisticated lens with just two pairs of toroidal peripheral curves, i.e. a tri-curve lens in each principal meridian, may be advantageous.

Lenses with toroidal back optic zones and spherical peripheral zones

As previously mentioned, it can be useful to use spherical peripheral radii with the intention of improving the circulation of tears beneath these lenses. However, when this is done, it is possible that the lens may become less stable with regard to resisting rotation. A fully toroidal peripheral zone may assist in preventing lens rotation, and this can be helpful if it is necessary to hold the lens in a non-rotating position to correct residual astigmatism or to position a bifocal segment correctly.

One difficulty that may arise with the use of a toroidal back optic zone and a spherical front surface, is that there is a variation of edge thickness, which may give rise to discomfort. The use of spherical peripheral radii makes it easier for the laboratory to produce a more uniform edge thickness, and this may be of some slight physical advantage in certain cases.

It is often said that toric lenses cannot be adjusted, but this is not correct. If, for example, a lens with toroidal back optic and peripheral curves provides too little tear flow behind the lens, it is possible to recut or polish the peripheral radii to spherical form using a radius or radii identical to, or flatter than, those used for the original flatter meridian. One limitation on spherical peripheral radii is that they have to be greater than, or equal to, the flatter radius for the preceding toroidal curve.

In theory, if a lens with an all toroidal back surface rotates, then the steeper peripheral radii may come to rest along the flatter corneal meridian. In this position, it is far too tight and may cause corneal abrasions or disturbance. This is seldom seen as a problem in practice, but if encountered, it may provide an indication for the use of spherical peripheral radii.

The back surface specification of a fitting set having the first back peripheral curve toroidal, as well as the back optic zone, but with the two most peripheral curves being spherical, is given in *Table 14.1*.

Lenses with spherical back optic zones and toroidal peripheral zones

These lenses are frequently used as a means of attempting to improve the physical fit of a lens on an astigmatic cornea without the optical complications inherent in the use of lenses with toroidal back optic zones.

Since the BOZR of such a lens has to align as well as possible with a toroidal cornea, these lenses are usually

Table 14.1 Fitting set of toroidal back surface corneal lenses, but with two final spherical peripheral curves

Toroidal BOZR (mm)	*:BOZD (mm)*	*Toroidal BPR_1 (mm)*	*:BPD_1 (mm)*	*Spherical BPR_2 (mm)*	*:BPD_2 (mm)*	*Spherical BPR_3*	*:TD (mm)*
7.00 × 7.60	:7.00/	7.55 × 8.30	:7.80/	8.70	:8.60/	9.30	:9.00
7.10 × 7.70		7.70 × 8.45		8.90		9.60	
7.20 × 7.80		7.80 × 8.55		9.00		9.90	
7.30 × 7.90		7.95 × 8.70		9.20		10.10	
7.40 × 8.00		8.10 × 8.80		9.40		10.30	
7.50 × 8.10		8.20 × 8.95		9.60		10.50	
7.60 × 8.20		8.30 × 9.05		9.80		10.70	
7.70 × 8.30		8.45 × 9.25		10.00		11.00	
7.80 × 8.40		8.55 × 9.30		10.20		11.30	
7.90 × 8.50		8.70 × 9.50		10.30		11.50	
8.00 × 8.60		8.80 × 9.60		10.50		11.80	
7.00 × 8.00		7.55 × 8.80		9.10		9.90	
7.10 × 8.10		7.70 × 8.95		9.30		10.10	
7.20 × 8.20		7.80 × 9.05		9.50		10.30	
7.30 × 8.30		7.95 × 9.25		9.60		10.50	
7.40 × 8.40		8.10 × 9.30		9.80		10.80	
7.50 × 8.50		8.20 × 9.50		10.00		11.00	
7.60 × 8.60		8.30 × 9.60		10.30		11.30	
7.70 × 8.70		8.45 × 9.80		10.50		11.60	

BVP of all lenses: −3.00 D on flattest meridian

fitted fairly small to minimize meridional sag differences and slightly steeper centrally than the flatter corneal meridian to achieve a compromise fit. Many practitioners favour fitting steeper than the flatter keratometer reading by about one-third of the difference between the keratometer readings. Back optic zone diameters are usually around 6.5 mm, with a commonly encountered range of between 6.0 and 7.0 mm. The peripheral curve region should be as large as possible to increase the likelihood of alignment with the toric cornea.

The toroidal peripheral zones are chosen in much the same way as when fitting lenses with all toroidal back surface curves. The practitioner, however, is using a spherical BOZR trial set and is able to observe the fitting set lenses on the cornea with fluorescein. Observing the peripheral fit along the flatter corneal meridian assists the choice of an appropriate radius or radii for the steeper peripheral meridian by consideration of the keratometer reading and/or fluorescein pattern.

A typical case might be as follows:

Keratometry reading:

7.90 mm (42.72 D) along 180
7.30 mm (46.23 D) along 90
BOZR chosen: 7.70 mm
BOZD chosen: 6.50 mm
TD chosen: 9.50 mm

Prescribed lens:

$$\text{C4/7.70:6.50/}\frac{8.50}{7.90}\text{:7.50/}\frac{9.20}{8.60}\text{:8.50/}\frac{10.00}{9.40}\text{:9.50}$$

Note that this lens will have a vertical oval back optic zone.

While this type of lens can be very useful in certain cases where a fully spherical lens is not adequate, the toroidal peripheral zones are, at best, only an attempt at compromise. Such lenses frequently rotate too much to stabilize a front surface correction for residual astigmatism or to keep a bifocal addition in the correct position. They usually rotate more than lenses with all-toroidal back surface curves, and the steeper peripheral radii occasionally end up in close proximity to the flatter corneal meridian, thus causing slight corneal abuse.

It is comparatively easy to see if the lens is rotating by observing the peripheral fit with fluorescein, but the inexperienced practitioner may find it helpful to have the steeper peripheral meridian marked with two dots, one at each edge of the lens. Two dots are much more useful than one for this purpose.

Lenses with spherical back optic zones and toroidal peripheral zones can also be used, to enhance lens centration and eradicate inferior lens stand-off, when fitting contact lenses to keratoconic eyes (*see* Chapter 20).

Optical considerations of toroidal back optic zones

The calculations involved in determining the necessary radii and power of these lenses are quite straightforward and the complexity of this topic is often exaggerated. It is important, however, that the fundamentals of the optics of contact lenses are understood if some of the complications of

toroidal optic surfaces on corneal lenses are to be apprcciated.

To help understand and perform some of the calculations needed in toric lens work, the reader is referred to Chapter 5, particularly pp. 171, 172 (*see also* The CD-ROM accompanying this book) and also to *Optics of Contact Lenses*, 5th edition by A. G. Bennett (1985), and to *Contact Lens Optics and Lens Design* by W. A. Douthwaite (1995).

Corneal astigmatism and the effect of the tear lens

As previously discussed in Chapter 5, the front surface astigmatism of the cornea is only partly neutralized by the back surface astigmatism of the resultant tear lens when an RGP contact lens with spherical back surface is placed on the eye. The refractive index of tears is 1.336, while the refractive index of the cornea is 1.376. The amount neutralized is thus 336/376, which is almost 90%. It is assumed that the back surface of the cornea itself neutralizes the remaining 10% of its front surface astigmatism. In other words, the tears neutralize all but one-tenth of the front surface corneal astigmatism, and this is likely to be corrected by the back surface corneal astigmatism, which is assumed to be equal to approximately one-tenth of the front surface astigmatism and opposite in effect.

The index of calibration of most keratometers (1.3375) is chosen to take this effect of the corneal back surface into account, in order to give the user a guide to the total refractive effect of the cornea. Hence, keratometers measure front surface corneal radii but give *total* corneal power on the assumption that the back surface has –10% of the power of the front surface.

In contact lens practice, this refractive index of 1.3375 is very helpful because it is so close to that of the tears (1.336). Thus, the corneal astigmatism measured with the keratometer should be completely corrected by the tear lens between the cornea and contact lens, provided the back of the contact lens is spherical.

Expected residual astigmatism

If the amount of corneal astigmatism measured is different from the cylindrical element in the most accurate spectacle prescription, then a certain amount of residual astigmatism may be expected when a spherical rigid contact lens is fitted. The degree of this residual astigmatism should, in theory, be equal to the difference between the corneal astigmatism and spectacle astigmatism (or ocular astigmatism if an allowance is made for the vertex distance). In practice, however, this is rarely the case.

Many examples of the lack of correlation between calculated and measured residual astigmatism can be quoted, and it has been estimated that in no more than 38% of eyes do the two closely approximate (Fairmaid, 1967). This is due, in part, to the fact that the estimated residual error is based on measurement of corneal astigmatism over a small area of the corneal surface, whereas the refractive effect of the cornea is also influenced by areas of the surface other than that used by the keratometer.

The amount of residual astigmatism is also based on two measurements of astigmatism – one taken from the spectacle refraction of the eye and the other taken from a refraction over a contact lens. These measurements are almost invariably fully or partly subjective, and are hence subject to some degree of error.

Unfortunately, the term 'residual astigmatism' is often used loosely and is frequently confused with induced astigmatism or corneal astigmatism. Residual astigmatism has been variously defined (Goldberg, 1964), including the simplistic definition which states that residual astigmatism is the component of the spectacle (ocular) astigmatism which is not due to the cornea. In the context of RGP lens fitting, a better definition would be that *residual astigmatism is the astigmatic component of a lens required to fully correct an eye wearing a spherical powered RGP contact lens with a spherical back optic zone radius.*

To complicate matters, the degree and axis of residual astigmatism varies with different lenses. If the parameters of the lens *in situ* for refraction are changed, then the measured residual astigmatism is also likely to alter. In particular, changing the back optic zone diameter, total diameter, amount of prism, back optic zone radius, thickness and position on the cornea, are likely to have a noticeable effect on the measured residual astigmatism. When stating the degree of residual error, therefore, it is as well to state the specification of the lens through which the astigmatism has been measured.

Residual astigmatism is probably most commonly anatomical, the site of which may be in the cornea, crystalline lens or retina. The effect may also be due to irregularities in the refractive index of the transparent media of the cornea and/or crystalline lens, or due to obliquity of one or more of the surfaces to the direction of the incident light.

Residual astigmatism measured over a lens having a spherical BOZR may also be induced by the following:

- An irregular tear film caused by a tilted or poorly centred lens.
- The obliquity of a tilted lens to the incident light.
- Irregular refractive index of the tear lens caused by stagnation or partial evaporation of the tear lens.
- Warping of a lens due to bad handling, or even under the influence of heavy lid pressure. The effects of the latter are discussed below and also in Chapter 5.

There are other factors which individually or collectively may have an influence on residual astigmatism (Goldberg, 1964), but the most important aspect of this subject is its clinical significance and correction, which is dealt with in the following section.

Refraction with toroidal back optic zones

Calculating the back vertex powers for an RGP lens with toroidal back optic zone is undoubtedly a more complex task than determining the back vertex power for a spherical

lens and yet the two processes involve the same basic principles. For spherical lenses, the power of the contact lens in air plus the power of the tear lens in air should add up to the ocular refraction. With toric lenses, the same rule applies, but here the two separate meridians must be considered.

Unfortunately, many practitioners have difficulty with power calculations for toric RGP lenses, due to such factors as induced astigmatism, residual astigmatism and differences between the principal corneal radii and the axes of the spectacle refraction. While these effects are important and are discussed at length later in this chapter, their presence leads to the false perception that calculation of toric RGP lens powers is too complex a task for the average contact lens practitioner.

Thankfully, nothing could be further from the truth and this point will be demonstrated by consideration of the following examples.

Example 1: Calculating the back vertex power for an RGP lens with a toroidal back optic zone

Spectacle refraction (vertex distance ignored):

$$+2.50/-3.00 \times 180$$

(Note that the effect of the vertex distance must be taken into account if this distance is great or if the refractive power in either meridian exceeds 4.00 D.)

Keratometry reading:

8.04 mm (42.00 D) along 180
7.50 mm (45.00 D) along 90

A spherical RGP trial lens with BOZR 7.95 mm and BVP +1.00 D is placed on the cornea. Refraction with this lens *in situ* gives +1.00 DS (no residual astigmatism) and 6/6 acuity. Note that the over-refraction is usually best performed over a spherical trial contact lens aligned along the flattest meridian of the cornea and only *one* over-refraction is required to calculate both back vertex powers.

Based on the keratometry readings, BOZR of 8.00 mm and 7.55 mm are chosen to fit the horizontal and vertical meridians respectively.

The power determination is now performed in the same way as with a spherical RGP lens, except that we are working with two meridians instead of one. The back vertex power we need to order (BVP_{CL}) is calculated by taking into account the back vertex power of the trial lens (BVP_{trial}) and the over-refraction (BVP_{OR}) and then using the formula, $BVP_{CL} = BVP_{trial} + BVP_{OR}$.

For a spherical lens, if the BOZR of the trial lens is different from the BOZR we actually wish to order, then, when determining the BVP_{CL}, we also need to take into account the change in tear lens power which will occur as a result of changing the BOZR.

Based on a tear lens refractive index of 1.336, this change in tear lens power is given by the formula:

$$\left(\frac{336}{BOZR_{final}} - \frac{336}{BOZR_{trial}}\right)$$

where $BOZR_{final}$ is the back optic zone radius we have chosen for the lens we are going to order and $BOZR_{trial}$ is the back optic zone radius of the trial lens.

The approximate rule (2) on p. 173 (Chapter 5) is based on this formula. This rule requires that, when fitting RGP lenses, we add –0.25 D to the BVP of the contact lens for every 0.05 mm decrease in BOZR. Likewise, +0.25 D must be added to the BVP of the contact lens for every 0.05 mm increase in BOZR. Note that this approximation only holds for relatively small differences in BOZR and, if in doubt, it is safer to use the above formula.

Given we are changing the BOZR from that used for the fitting, the back vertex power we need to order (BVP_{CL}) is given by:

$$BVP_{CL} = BVP_{trial} + BVP_{OR} - \left(\frac{336}{BOZR_{final}} - \frac{336}{BOZR_{trial}}\right)$$

When calculating the back vertex powers for a toric RGP lens based on fitting with a spherical trial lens, there will be a change to the trial lens BOZR in at least one meridian. In this example, the back optic zone radii to be ordered are both different from the trial lens BOZR and so we will need to allow for the change in tear lens power in both meridians.

Along 180, BVP_{CL}

$$= +1.00 + 1.00 - \left(\frac{336}{8.00} - \frac{336}{7.95}\right) = +2.25 \text{ D}$$

Along 90, BVP_{CL}

$$= +1.00 + 1.00 - \left(\frac{336}{7.55} - \frac{336}{7.95}\right) = -0.25$$

(When calculating BVP, values are rounded off to the nearest 0.25 D)

Final Rx of lens:

BOZR 8.00 mm m 180 +2.25 D
BOZR 7.55 mm m 90 –0.25 D

Example 2: Calculating the back vertex power for an RGP lens with a toroidal back optic zone when there is residual astigmatism present

Spectacle refraction (vertex distance ignored):

$$+2.50/-2.00 \times 180$$

Keratometry reading:

8.04 mm (42.00 D) along 180
7.50 mm (45.00 D) along 90

A spherical RGP trial lens with BOZR 7.95 mm and BVP +1.00 D is placed on the cornea. Refraction with this lens *in situ* gives +2.00/–1.00 × 90 and 6/6 acuity.

Based on the keratometry readings, BOZR of 8.00 mm and 7.55 mm are chosen to fit the horizontal and vertical meridians respectively.

In this case, we have residual astigmatism equal to –1.00 DC × 90. Obviously, if we are to give the patient the best possible vision, we will need to incorporate the correction for this residual cylinder into the BVP to be ordered.

The method for determining the back vertex powers is the same as used in the previous example.

Along 180,

$$BVP_{CL} = +1.00\ \mathbf{+1.00} - \left(\frac{336}{8.00} - \frac{336}{7.95}\right) = +\ 2.25\ D$$

Along 90,

$$BVP_{CL} = +1.00\ \mathbf{+2.00} - \left(\frac{336}{7.55} - \frac{336}{7.95}\right) = +\ 0.75$$

The values for the over-refraction are in bold type to emphasize the fact that there is residual astigmatism present in this case. In other words, the over-refraction along 180 is not equal to the over-refraction along 90.

Final Rx of lens is therefore:

BOZR 8.00 mm m 180 +2.25 D
BOZR 7.55 mm m 90 +0.75 D

In these two examples, the powers specified are the back vertex powers of the toric lens in the appropriate meridians. These are the powers read by the laboratory when checking the lens on a focimeter (vertometer).

It is frequently useful, in considering bitoric lenses, to draw a representation of meridional powers to ensure that simple errors in confusing axes and meridians are not made. Such a power cross is shown in *Figure 14.3*.

The incorporation of the correction for residual astigmatism into the toric lens prescription often creates needless anxiety for the contact lens practitioner. If residual astigmatism is measured in negative cylinder form and has its axis parallel to the negative cylinder axis in the spectacle prescription, then the spectacle astigmatism is greater than the corneal astigmatism by an amount equal to the residual astigmatism. Alternatively, if the residual negative cylinder axis is perpendicular to the negative cylinder axis in the spectacle prescription, then the corneal astigmatism is greater than the spectacle astigmatism by an amount equal to the residual astigmatism.

Sometimes, the calculations involved are not as simple as those shown in Example 2. It is rare, for example, for the axis of the residual astigmatism to correspond exactly with one of the principal meridians of curvature of the cornea. In addition, as noted earlier, it is unusual for residual astigmatism, measured by refraction through a spherical corneal lens, to equal exactly that expected from consideration of the spectacle correction and keratometer readings.

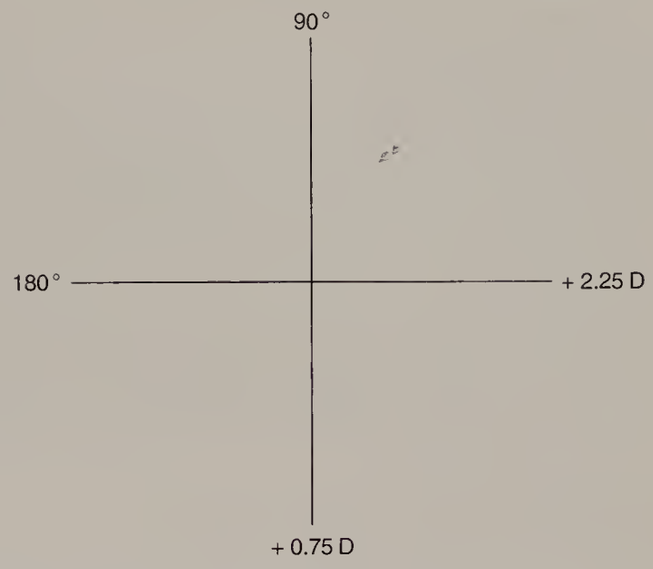


Figure 14.3 Meridional powers required in Example 2. This shows the powers and directions as they will be measured by the contact lens laboratory

A slightly more complicated example is now shown, in which the axes of the spectacle refraction do not correspond with the principal meridians of corneal curvature.

Example 3

Spectacle refraction (vertex distance ignored):

–0.50/–3.25 × 180

Keratometry reading:

8.20 mm (41.16 D) along 20
7.70 mm (43.83 D) along 110

BOZR chosen for the toroidal back surface of the lens:

8.15 mm on 20
7.75 mm on 110

$$\text{Tear lens power } BVP_{tears} = \frac{336}{BOZR} - \frac{336}{K}$$

where K is the keratometry reading along the particular meridian.

$$\text{Along 20, } BVP_{tears} = \frac{336}{8.15} - \frac{336}{8.20} = +0.25\ D$$

$$\text{Along 110, } BVP_{tears} = \frac{336}{7.75} - \frac{336}{7.70} = -0.28\ D$$

Hence, BVP_{tears} = +0.25/–0.53 × 20

The back vertex power required on the toric lens to correct the ametropia = ocular refraction – power of tear lens.

Back vertex power with:

BOZR 8.15 mm on 20
7.70 mm on 110

$= (-0.50/-3.25 \times 180) - (+0.25/-0.53 \times 20)$

$= (-3.75/+3.25 \times 90) - (+0.25/-0.53 \times 20)$

$= -4.00/+3.25 \times 90$ with $+0.53 \times 20$

These oblique cylinders must be resolved. A discussion of the methods for dealing with oblique cylinders is beyond the scope of this book. For this, the reader is referred to *The Principles of Ophthalmic Lenses*, 4th edition by M. Jalie (1984), particularly pp. 294–301. (*See also* the CD-ROM accompanying this book).

Sphere/cylinder effect of resolved cylinders = $+3.32/-2.86 \times 176.6$

Total back vertex power of toric lens = $-0.68/-2.86 \times 176.6$

This type of lens specification is difficult for the laboratory to interpret and convert to lens fabrication specifications. In addition, implicit in these calculations is a value for the residual astigmatism based on the spectacle refraction and keratometry reading and yet, as was noted earlier, the degree and axis of residual astigmatism will vary with different lenses.

What if, for this example, we had performed a refraction with trial lens *in situ?* We would be most likely to end up with the situation where the axes of the spectacle refraction over the lens do not correspond with the principal meridians of corneal curvature. Again this would lead to the same inherent complexity in calculating the back vertex powers.

One solution is to use a fitting set of lenses, all of which have a toroidal back optic zone and a spherical front surface. A refraction is performed over the appropriate trial lens and then the oblique cylinder obtained from this refraction is incorporated onto the front surface of the lens. While this method obviates the need for resolving obliquely crossed cylinders, the addition of the oblique cylinder to the front surface of the lens can often present a challenge to the contact lens laboratory. Furthermore, there is the limitation that not all practitioners would have access to a fitting set of lenses with toroidal back optic zones.

Another solution, and one that works well in practice, is to make an approximation when the axes of the spectacle refraction over the lens do not correspond with the principal meridians of corneal curvature. In this case, we simply assume that the axes of the spectacle refraction over the lens *do* correspond with the principal meridians of corneal curvature. By doing this we obviate the need for any complex oblique cylinder calculations and the resulting error in the power calculations is usually not significant, especially if the difference between the axes of the spectacle refraction and the principal meridians of the cornea is marginal.

Consider the following example, where we are calculating the back vertex power for an RGP lens with a toroidal back optic zone when there is residual astigmatism present, and the axes of the spectacle refraction over the lens do not correspond with the principal meridians of the cornea.

Example 4

Spectacle refraction (vertex distance ignored):

$-1.00/-2.00 \times 165$

Keratometry reading:

8.04 mm (42.00 D) along 180
7.50 mm (45.00 D) along 90

A spherical RGP trial lens with BOZR 7.95 mm and BVP −1.00 D is placed on the cornea. Refraction with this lens *in situ* gives $+0.25/-1.00 \times 80$ and 6/6 acuity.

Based on the keratometry readings, BOZR of 8.00 mm and 7.55 mm are chosen to fit the horizontal and vertical meridians respectively.

In this case, there is residual astigmatism equal to −1.00 DC × 80 and the axes of the spectacle refraction over the lens (80 and 170) do not correspond with the principal meridians of the cornea (90 and 180). We now simply assume the axis of the residual cylinder to be at 90 rather than at 80, therefore simplifying calculations.

The method for determining the back vertex powers is the same as used in Examples 1 and 2:

Along 180, BVP_{CL}

$$= -1.00 - 0.75 - \left(\frac{336}{8.00} - \frac{336}{7.95}\right) = -1.50\,\text{D}$$

Along 90, BVP_{CL}

$$= -1.00 + 0.25 - \left(\frac{336}{7.55} - \frac{336}{7.95}\right) = -3.00\,\text{D}$$

Final Rx of lens:

BOZR 8.00 mm m 180 −1.50 D
BOZR 7.55 mm m 90 −3.00 D

The information provided so far in this section on refraction with toroidal back optic zones is actually sufficient to be able to calculate the back vertex powers of toric RGP lenses and yet no mention has been made of terms such as induced astigmatism and bitoric lenses.

While it is important that the practitioner understands these terms and their relevance to toric lens fitting, discussion and elaboration of these areas has been saved until now to emphasize the point that power calculations for toric RGP lenses are relatively straightforward. Furthermore, factors such as induced astigmatism arise from the specified back optic zone radii and calculated back vertex powers, such that they are incidental to the determination of the toric lens prescription.

Induced astigmatism

Induced astigmatism is the astigmatic effect created in the contact lens/tear lens system by the toroidal back optic zone bounding two surfaces of different refractive index, namely the lens (refractive index 1.43 to 1.49 depending on the material) and the tears (refractive index 1.336).

Induced astigmatism is introduced into the system every time toroidal back optic zone surfaces are used and it is due only to the lens/tear boundary, remembering that a contact lens back surface power will change depending on the refractive index of the media with which it is in contact.

Example 5

Spectacle refraction (vertex distance ignored):

$$-1.00/-2.75 \times 180$$

Keratometry reading:

8.20 mm (41.16 D) along 180
7.70 mm (43.83 D) along 90

An afocal corneal lens of BOZR 8.20 mm might be inserted and a refraction of –1.00 DS found with this lens *in situ* (note the absence of any residual astigmatism). As previously discussed, the back surface of the tear lens neutralizes all the corneal astigmatism. Hence, for a spherical BOZR of 8.20 mm, the BVP required is –1.00 DS.

If, however, the lens is changed to one having a toroidal back optic zone to align with the cornea (i.e. BOZR 8.20 mm and 7.70 mm), the power of the surface combining the lens BOZR and tear lens is as follows (assuming a refractive index of 1.45 for the RGP lens material):

In the vertical meridian

Lens back surface power in air:

$$\frac{1000(1-1.45)}{+7.70} = -58.44\,\text{D}$$

Tear front surface power in air:

$$\frac{1000(1.336-1)}{+7.70} = +43.64\,\text{D}$$

Total power in vertical meridian = –14.80 D

In the horizontal meridian

Lens back surface power in air:

$$\frac{1000(1-1.45)}{+8.20} = -54.88\,\text{D}$$

Tear front surface power in air:

$$\frac{1000(1.336-1)}{+8.20} = +40.98\,\text{D}$$

Total power in horizontal meridian = –13.90 D

Total effect of lens/tear surface =
–13.90 DS with –0.90 DC × 180

The back surface of the tears remains unchanged in its effect.

Thus, if the front surface of the contact lens remains spherical, a spectacle lens of +0.90 DC × 180 is needed in front of the contact lens to fully correct the eye. Alternatively, the normal solution is for this cylinder to be added to the front surface of the contact lens (*Figure 14.4*).

Consider the required back vertex powers of this toric lens:

Along 180, BVP_{CL}

$$= \text{plano} - 1.00 - \left(\frac{336}{8.20} - \frac{336}{8.20}\right) = -1.00\,\text{D}$$

Along 90, BVP_{CL}

$$= \text{plano} - 1.00 - \left(\frac{336}{7.70} - \frac{336}{8.20}\right) = -3.75\,\text{D}$$

(this actually equals –3.66 D but rounded off to the nearest 0.25 D)

For a lens with spherical front surface, giving –1.00 D on 8.20 mm BOZR:

Back surface lens astigmatism

$$= \frac{1000(1-1.45)}{8.20} - \frac{1000(1-1.45)}{7.70}$$

$$= -3.56\,\text{DC} \times 180$$

Hence total power = –4.56 D on 7.70 mm BOZR.

Thus for a lens with spherical front surface but toroidal BOZR of 8.20 mm and 7.70 mm, the powers would be –1.00 D on 8.20 mm BOZR and –4.56 D on 7.70 mm BOZR. This is different from the required BVP, due to the absence of the correction for the induced astigmatism. This is shown diagrammatically in *Figure 14.4a*.

Lens after adding +0.90 DC × 180 to front surface (*Figure 14.4b*):

Powers are –1.00 D on 8.20 mm BOZR
and –3.66 D on 7.70 mm BOZR (which is rounded off to –3.75 D)

These are the required back vertex powers (as calculated previously).

It should be noted that this front surface cylinder correction for the induced astigmatism is automatically incorporated into the lens when the practitioner calculates the back vertex powers for the toric RGP lens. Hence, once the practitioner has calculated the required BVP, it is *not* necessary to perform these additional calculations to determine what cylinder is needed on the front surface of the lens to correct for the induced astigmatism. The induced astigmatism arises from the specified back optic zone radii and calculated back vertex powers. In other words, the ascer-

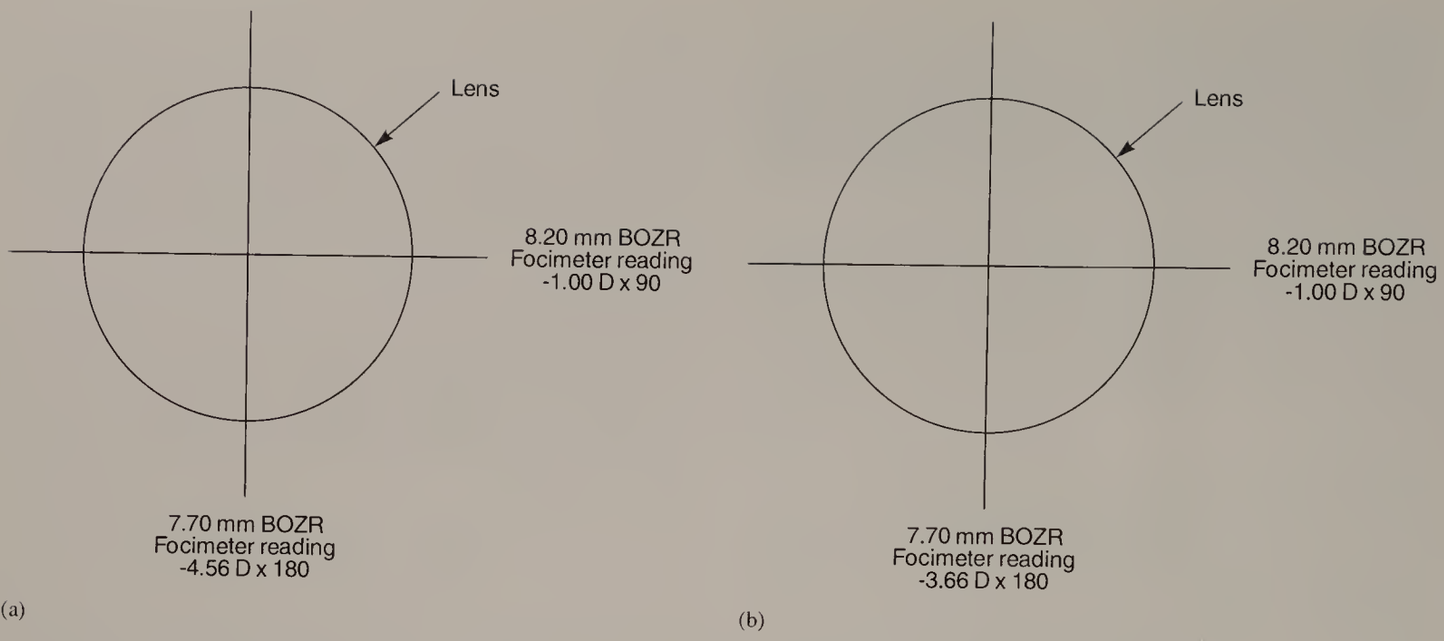


Figure 14.4 (*a*) Focimeter readings of a toric lens with BOZR 8.20 × 7.70 mm, BVP –1.00 D along the flatter meridian and no correction for induced astigmatism. Consequently, the resultant back vertex powers are incorrect. (*b*) Focimeter readings of the same lens shown in (*a*) with +0.90 DC × 180 added to the front surface. The back vertex powers are now as required. (Note: focimeter targets are invariably in focus along a *power axis, not a power meridian*)

tained toric lens specification determines the degree of induced astigmatism, not the other way around. This important point is demonstrated by the following example.

Example 6

Spectacle refraction (vertex distance ignored):

$$+3.00/-6.00 \times 180$$

Keratometry reading:

8.00 mm (42.19 D) along 180
7.00 mm (48.21 D) along 90

A spherical RGP trial lens with BOZR 8.00 mm and BVP +1.00 D is placed on the cornea. Refraction with this lens *in situ* gives +2.00 DS (no residual astigmatism) and 6/6 acuity.

Based on the keratometry readings, BOZR of 8.00 mm and 7.00 mm are chosen to fit the horizontal and vertical meridians respectively.

Along 180, BVP_{CL}

$$= +1.00 + 2.00 + \left(\frac{336}{8.00} - \frac{336}{8.00}\right) = +3.00\,\text{D}$$

Along 90, BVP_{CL}

$$= +1.00 + 2.00 + \left(\frac{336}{8.00} - \frac{336}{7.00}\right) = -3.00\,\text{D}$$

Specification of these BVPs (+3.00 D and –3.00 D) along with the respective BOZR (8.00 mm and 7.00 mm) will *automatically* bring about the incorporation of the front surface cylinder to correct for the induced astigmatism. This can be demonstrated by calculating the resultant front surface powers based on the BVPs and BOZR to be ordered.

Along 180:

Back surface power of the contact lens

$$= \frac{1000(1 - 1.47)}{+8.00} = -58.75\,\text{D}$$

Back vertex power = +3.00 D

Assume the refractive index for the RGP lens material is 1.47 and the lens centre thickness is 0.30 mm.

Using thick lens formula for the front surface power F_1:

$$F_1 = \frac{F_{v'} - F_2}{1 + (F_{v'} - F_2)^{t/n}}$$

Front surface power of the contact lens = +60.98 D

Along 90:

Back surface power of the contact lens

$$= \frac{1000(1 - 1.47)}{+7.00} = -67.14\,\text{D}$$

Back vertex power = –3.00 D

Again, using thick lens formula:

Front surface power of the contact lens = +63.31

Hence, the total power of the front surface is +60.98 DS with +2.33 DC × 180. This front surface cylinder represents the correction for the induced astigmatism.

The correction for the induced astigmatism is always a plus cylinder with *same axis as the flatter principal meridian of the cornea* (in other words, the same axis as the corneal cylinder). The magnitude of the induced astigmatism is directly proportional to the degree of contact lens toricity and the refractive index of the lens material.

A quick way to calculate the induced astigmatism is to use the appropriate radii considered with the change when travelling from the RGP lens to tears:

i.e. power of the RGP lens/tear boundary

$$= \frac{1000(1.336 - 1.47)}{r}$$

$$= \frac{-134}{r}$$

where r = radius in mm and the refractive index of the RGP material is assumed to be equal to 1.47.

By subtracting the values found of $-134/r$ for one principal meridian from the other, the value for the induced astigmatism may be obtained directly. With RGP materials of refractive index not equal to 1.47, the figure of $-134/r$ no longer applies: for example, a refractive index of 1.45 would yield a figure of $114/r$ for determining the surface power at the lens/tear boundary.

One of the advantages of RGP materials is that many of them have lower refractive indices than the 1.49 of PMMA. Thus the induced astigmatism created by a RGP toroidal back surface is usually less than that for PMMA material. If a toric RGP lens were made from a material with a refractive index of 1.336, then a perfectly fitting toroidal back surface and spherical front surface could be used to correct large degrees of corneal astigmatism with no induced astigmatism.

The above example deals with the most commonly encountered type of case – namely, corneal and spectacle astigmatism with-the-rule. The induced astigmatism is, however, against-the-rule (positive cylinder axis horizontal), which is of the same form that the majority of residual astigmatism takes.

It is often thought that the induced astigmatism created by using a toroidal back optic zone surface on an eye with corneal astigmatism and residual astigmatism will fortuitously cancel out the residual astigmatism. In practice, however, this will only occur in a small percentage of cases. Inded, the induced astigmatism usually exaggerates the effect of the residual astigmatism.

Spherical power equivalent bitoric lenses (compensated bitorics)

These are lenses which do not correct for any residual astigmatism. They are bitoric because the front surface contains a cylinder solely for the correction of the induced astigmatism. The lenses designed in Examples 1 and 6 would be classed as compensated bitoric lenses. One can think of a compensated bitoric as a lens designed to correct all of the refractive cylinder created due to the corneal toricity (Lowther, 1990). If the corneal toricity is equal to the spectacle astigmatism, when a compensated bitoric is placed on the cornea the cylinder will be fully corrected.

A compensated bitoric lens can rotate on the eye without visual disturbance since any power change due to the lens rotation is fully compensated by an equal power change in the tear lens. In regard to the front surface cylinder, remember that the correction for induced astigmatism is only necessary because the toroidal back optic zone creates the induced astigmatism along its principal meridians. Consequently, it does not matter if the lens does rotate as the lens carries its correction for induced astigmatism with it when it moves away from its intended position. In other words, once the correction for induced astigmatism is incorporated on to the front surface of the lens in the appropriate meridian, the correcting cylinder then rotates with the surface inducing the astigmatism.

Cylindrical power equivalent toric lenses

All other types of toric RGP lenses come under this classification and the one thing these lenses all have in common is that they incorporate a correction for residual astigmatism. This category can be further subdivided as follows.

Alignment bitorics

These have both a toroidal front and back surface. The front surface incorporates correction for residual astigmatism as well as for the induced astigmatism. In addition, the axes of the spectacle refraction over the lens correspond with the principal meridians of corneal curvature, so the correction for the residual astigmatism will be along one of the principal meridians of the lens (hence the name 'alignment bitoric'). As such, the use of the term alignment bitoric here should not be confused with alignment in regard to lens fitting. The lens specified in Example 2 is an alignment bitoric lens.

Back surface torics

These have a toroidal back surface but a spherical front surface. The design principle is similar to that for alignment bitorics. As with alignment bitorics, the front surface incorporates correction for residual astigmatism as well as for the induced astigmatism and the axes of the spectacle refraction over the lens correspond with the principal

meridians of corneal curvature, so the correction for the residual astigmatism is along one of the principal meridians of the lens.

In the case of a back surface toric lens, however, the correction for the residual astigmatism is equal and opposite to the correction for the induced astigmatism. Hence the two required cylindrical corrections cancel each other out, meaning that the front surface can be left spherical.

Very occasionally a case of induced and residual astigmatism cancelling out one another is encountered in practice, as in the following example.

Example 7

Spectacle refraction (vertex distance ignored):

$$+3.00/-4.00 \times 180$$

Keratometry reading:

8.04 mm (42.00 D) along 180
7.50 mm (45.00 D) along 90

A spherical RGP trial lens with BOZR 7.95 mm and BVP +1.00 D is placed on the cornea. Refraction with this lens *in situ* gives $+1.50/-1.00 \times 180$ and 6/6 acuity. Hence we have residual astigmatism equal to $-1.00\,DC \times 180$.

Based on the keratometry readings, BOZR of 8.00 mm and 7.55 mm are chosen to fit the horizontal and vertical meridians respectively.

The induced astigmatism can be determined using the method described previously of calculating the change in power of the RGP lens/tear boundary:

i.e. power of the RGP lens/tear boundary

$$= \frac{1000(1.336 - 1.47)}{r}$$

$$= \frac{-134}{r}$$

where r = boundary radius in mm and the refractive index of the RGP material is assumed to be equal to 1.47.

By subtracting the values found of $-134/r$ for one principal meridian from the other, the value for the induced astigmatism is obtained.

$$\text{Induced astigmatism} = \frac{-134}{8.00} - \frac{-134}{7.55} = +1.00\,D$$

The correction for the induced astigmatism is always a plus cylinder with same axis as the flatter principal meridian of the cornea (in other words, the same axis as the corneal cylinder). Hence, in this example, the induced astigmatism will be corrected by $+1.00\ DC \times 180$.

The correction for the residual astigmatism is $-1.00\,DC \times 180$, so the residual astigmatism and the induced astigmatism should cancel each other out. This can be confirmed by calculation of the back vertex powers and the front and back surface powers of the lens (assuming a lens centre thickness of 0.25 mm).

Along 180:

$$BVP_{CL} = +1.00 + 1.50 + \left(\frac{336}{7.95} - \frac{336}{8.00}\right) = +2.75\,D$$

Back surface power of the contact lens

$$= \frac{1000(1 - 1.47)}{+8.00} = -58.75\,D$$

Front surface power of the contact lens = +60.86 D

Along 90:

$$BVP_{CL} = +1.00 + 0.50 + \left(\frac{336}{7.95} - \frac{336}{7.55}\right) = -0.75\,D$$

Back surface power of the contact lens

$$= \frac{1000(1 - 1.47)}{+7.55} = -62.25\,D$$

Front surface power of the contact lens = +60.86 D

The front surface is spherical (same power along both principal meridians) so the residual and induced astigmatism have indeed cancelled each other out. (When calculating surface powers, for clinical purposes a difference in power of ≤0.12 D between the principal meridians constitutes a spherical surface.)

A back surface toric design is only possible if the correction for the residual astigmatism is *equal* and *opposite* to the correction for the induced astigmatism. The residual astigmatism will be *opposite* to the induced astigmatism when the axis of the residual astigmatism is the same as the flatter principal meridian of the cornea. In the above example, both the axis of the residual astigmatism and the flatter principal meridian of the cornea were along 180.

Many practitioners believe that most toric RGP lenses can be made to correct residual and induced astigmatism utilizing a back surface toric design only and yet the preceding discussion clearly demonstrates the absurdity of this position. The likelihood of the residual astigmatism being both equal and opposite to the induced astigmatism is low, so only in a small percentage of cases will a back surface toric design be appropriate. As was stated earlier, the induced astigmatism will generally exaggerate the effect of the residual astigmatism.

Front surface torics

These have a toroidal front surface and a spherical back surface. They are generally used when there is significant residual astigmatism but minimal corneal astigmatism, so a

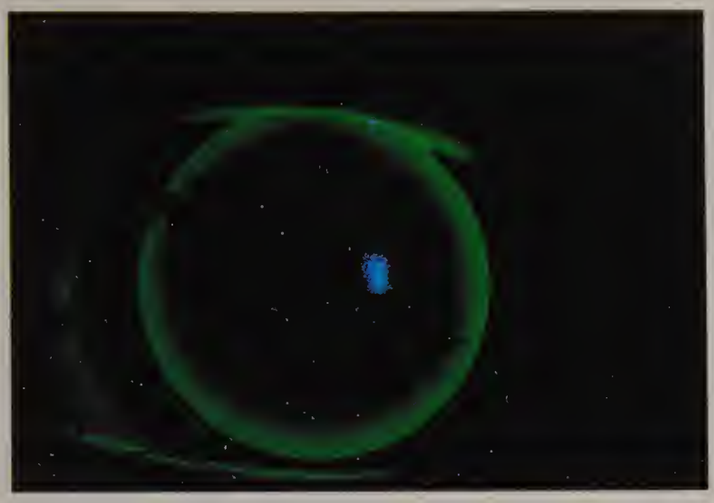


Figure 14.5 A right lens with a toroidal back optic zone fitted in alignment. Keratometer reading 8.13 mm along 160, 7.62 mm along 70. Lens BOZR 8.10 × 7.70 mm. The 8.10 meridian is marked with grease pencil and can be seen aligning well with the 160 meridian. There is no significant rotation, thus permitting accurate correction of *residual* astigmatism, as well as induced astigmatism, with a front surface cylinder

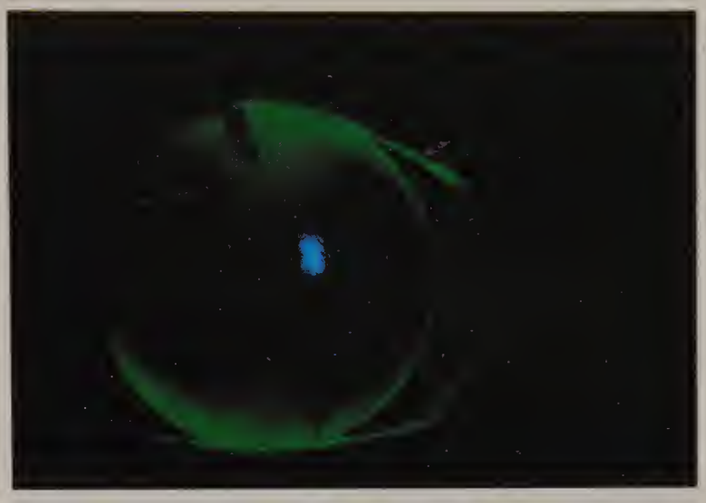


Figure 14.6 Same right eye as in *Figure 14.5*. Lens BOZR 8.05 × 7.75 with 8.05 meridian marked with grease pencil. This should be located along the 160 meridian, but, as shown, this lens rotates, thus permitting only the accurate correction of *induced* astigmatism with a front surface cylinder

toroidal BOZR is not an option due to reasons of rotation and stability. These will be covered in greater detail in the next section.

Oblique bitorics

As with alignment bitorics, these have both a toroidal front and back surface. With oblique bitorics, however, the principal meridians of the toroidal back and front surfaces are not parallel, due to a difference between the axes of the spectacle refraction and the principal meridians of corneal curvature. The lens designed in Example 3 was an oblique bitoric, and, as this example showed, the specification and manufacture of this type of lens is very difficult. These lenses are not often prescribed.

With all cylindrical power equivalent bitoric lenses, some visual disturbance will occur with rotation as the lenses incorporate a correction for residual astigmatism and the axis of correction for the residual astigmatism remains fixed in relation to the eye.

This limitation on rotation is important, for when residual astigmatism is of a low degree, from the clinical standpoint, it is not worthwhile incorporating its correction with that for the induced astigmatism. If, however, the residual astigmatism is clinically significant, then it is worth incorporating provided that lens rotation can be kept to a minimum (*Figure 14.5* and *14.6*). With lenses incorporating a toroidal back surface, rotation is generally not a problem due to the stabilizing effect of the toric back surface on the toric cornea (provided there is sufficient corneal toricity).

It is important to have marks on these lenses to denote the position of one of the principal meridians of the back surface. These marks should be permanent as they provide a check on the amount of rotation with the lens *in situ* and also provide an axis of orientation about which the accuracy of the powers and axes of the surfaces produced by the laboratory can be checked.

Toroidal front surfaces combined with spherical back optic zones

Residual astigmatism frequently needs to be corrected in cases where a lens utilizing a spherical back optic zone fits well physically. Such a lens therefore requires a toroidal front surface but must not be allowed to rotate sufficiently to cause the changing cylinder effect, otherwise visual disturbance will result.

When a toroidal front surface is required to correct residual astigmatism, a toroidal back optic zone can be used to minimize lens rotation if the corneal astigmatism is 2.00 D or more. (2.00 D of astigmatism equates approximately to a meridional difference of 0.4 mm.) This applies even if a spherical back optic zone provides a satisfactory fit. When the corneal astigmatism is less than 2.00 D, a toric back surface will not generally prevent lens rotation and so other forms of lens stabilization, such as prism ballast or truncation, are required.

Prism ballast

Prism ballast is the most commonly used method of lens stabilization for RGP lenses which have toroidal front surfaces combined with spherical back optic zones.

Prism ballast may also be used in combination with a toroidal back surface where a patient's corneal astigmatism is too small (<2.00 D) to maintain the proper position of a bitoric lens but large enough (>1.00 D) to cause a front toric lens to become unstable (Gonce and Kastl, 1994).

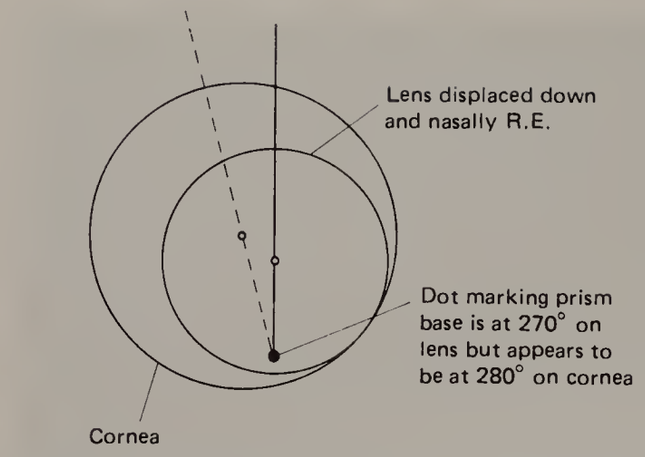


Figure 14.7 The importance of the position of the prism base–apex line is indicated relative to the lens when the latter is off-centre. The position of the prism base relative to the cornea is irrelevant

With prism ballasting, the lens is prescribed in the normal manner with the addition of between 1 and 3Δ. When ordering the lens, practitioners assume that the weight or prism ballast orientates the lens in a certain fixed position on the cornea and order the cylinder axis with respect to this position.

Alternatively, the lens can be made without the front cylinder but with the position of the prism base marked with a small permanent dot. The spherical power is calculated to give the necessary cylinder in *positive* form. A refraction is performed over the lens *in situ* and the average position of the dot in normal, common directions of gaze is estimated. The laboratory is then asked to add the residual refractive error – expressed in positive cylinder form – to the front of the lens, using the dot position as a point of reference for the cylinder axis. Note that it is impossible to add a negative front surface cylinder to the lens without transposing to positive cylinder form and altering the sphere power. Only positive cylinders, therefore, should be prescribed.

To avoid recording the prism base position as 'down along 90' or 'down along 100', its actual location is recorded as being at 270 or 280 respectively.

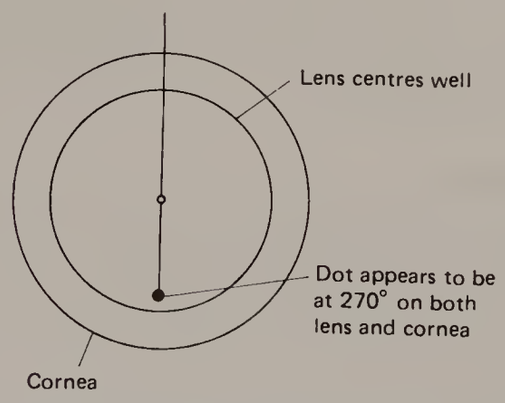


Figure 14.8 If the lens centres well, then the prism base–apex line is at the same angle with respect to either the lens or cornea



Figure 14.9 Right eye and prism ballasted corneal lens with base–apex along an average angle of 100°

It is important to realize that it is the angular position of the dot on the lens that is significant and not the position of the dot on the cornea. This is illustrated in *Figure 14.7* and *14.8*.

Once the lens is on the eye, the practitioner needs to assess the axis taken up by the prism base–apex line. The most commonly used method for doing this is to place a trial frame before the eye and hold a transparent ruler through the dot and through the middle of the lens. Alternatively, a transparent plastic disc or afocal trial case lens, with a diagonal line finely drawn upon it, can be placed in the frame and rotated until the line passes through the dot and contact lens centre. The angles are read from the trial frame protractor. Note that if the patient has an occupation involving unusual positions of gaze, the prism base position should also be observed with the eyes held in the appropriate direction.

It is difficult to predict the final position of the prism base and effect of the nasal rise of the lower lid. The latter has been estimated at 10–15° (Fairmaid, 1967) while the former has been quoted as being 20° displacement nasally (Goldberg, 1964) and 10° nasally (Westerhout, 1971). The differences in these figures may be accounted for by the fact that the authorities quoted used different lens designs, sizes, thicknesses and amounts of prism ballast.



Figure 14.10 Left eye and prism ballasted corneal lens with base–apex along an average angle of 80°

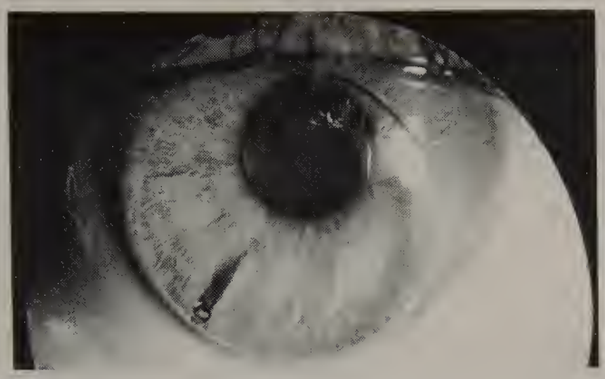


Figure 14.11 Right eye and prism ballasted lens with base–apex along 35° (prism base at 215°). This is some 45° off the expected position

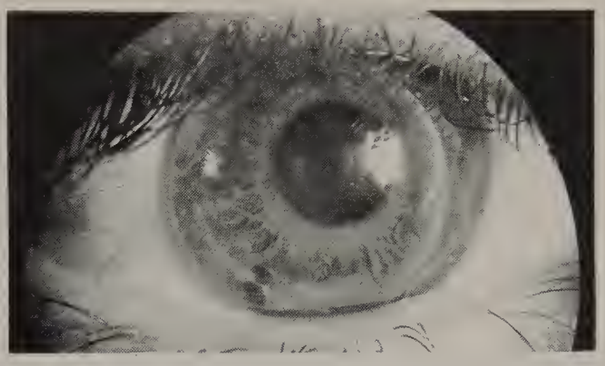


Figure 14.13 A prism ballasted lens with single truncation. This often proves very successful in preventing unwanted rotation

The average positions of the prism base and wide variations from the normal are shown in *Figures 14.9–14.12.*

If it is intended to use a prism ballasted lens with a toroidal front surface, it is important when refracting to use a trial lens with similar specifications to the lens to be prescribed. If possible, the trial lens should also contain the appropriate amount of prism. As was noted earlier, it is not uncommon to measure different degrees of residual astigmatism with lenses of different specifications.

One of the disadvantages of fitting a prism ballasted lens with a spherical front surface and subsequently adding a front cylinder is that the modified lighter lens may well take up an entirely different position on the cornea – especially if a positive cylinder is added with its axis horizontal, thus thinning the upper and lower edges. The influence of the lids may well be altered. Furthermore, the lens may become less comfortable after the addition of the toroidal surface if the altered edge finish has not been reworked and repolished sufficiently. Since the upper edge of a prism ballasted lens is very thin, it may be worth while ordering the original lens about 0.2 mm larger in total diameter to allow for re-edging after the cylinder is added.

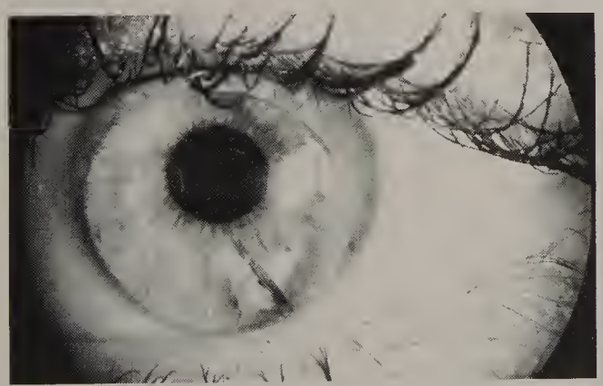


Figure 14.12 Left eye and prism ballasted lens with base–apex along an angle of 120°. This is some 40° off the expected position

Truncation and double truncation

Truncation of corneal lenses has long been used as a method of stabilizing bifocal and toroidal front surface lenses. It is generally found associated with prism ballast, and the combination of both methods is frequently very effective.

The usual method with truncated prism ballasted lenses is to prescribe the lens in the normal way with the addition of the front surface cylinder at the correct angle relative to the estimated or observed position of the prism base. The relationship of the lower lid to the edge of the lens is observed and a truncation is then cut to align with the lower lid (*Figures 14.13–14.15*).

In *Figures 14.14* and *14.15*, the lower lid chord makes an angle of 5° to the horizontal at its contact with the lens, and the truncation might well be cut at that angle. The lower edge is thick at the truncation, and thus the lens is unlikely to slip below the lower lid and tends to be influenced by it. If the nasal rise of the lower lid during blinking is excessive, then in the case illustrated the angled truncation may cause the lens to rise too much

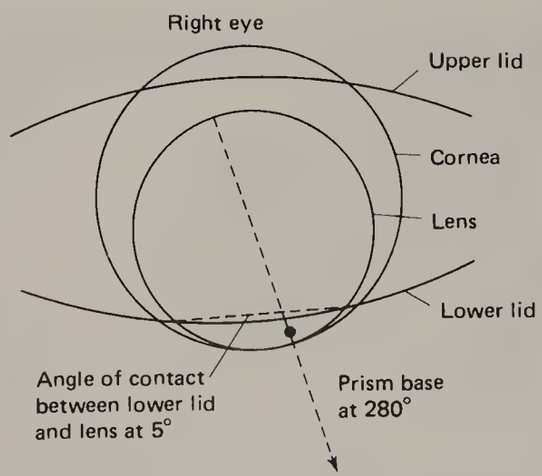


Figure 14.14 The position of contact between a prism ballasted corneal lens and the lower lid margin

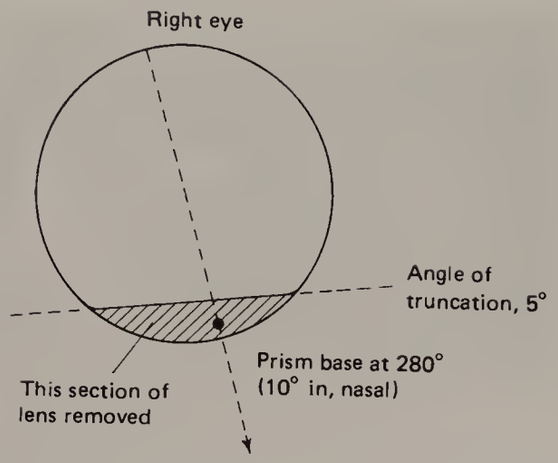


Figure 14.15 The lens shown in *Figure 14.14* has been truncated to enable the lower edge of the lens to align with the lower lid margin

nasally. A truncation at 10° may be more effective in these circumstances.

Much depends on the position of the lower lid. Clearly, if the lower lid is situated well below the lower limbus, or even below the average position of the lens, it cannot be depended on to give a great deal of stable support for the lens. Some degree of support from the lower lid can almost certainly be counted on with the patient looking down; but unfortunately, the resultant position of the lens may be entirely different from that taken up in distance vision. This is probably one of the reasons why some patients wearing a high correction for residual astigmatism, which is stabilized by prism and/or truncation, complain that either distance or near vision is poor in comparison with the other.

Prism ballasted lenses, with or without truncation, are not always as physically comfortable as non-prism lenses. Fortunately, it is possible to use truncation or double truncation to stabilize a lens without the use of a prism

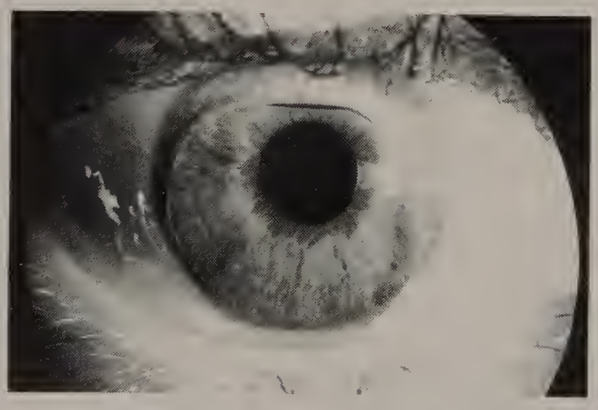


Figure 14.16 A double truncated lens without prism. This lens contains a front surface cylinder correction of 1.50 D which remains stable and gives a visual acuity of 6/4.5 and complete comfort. The patient had previously had seven other pairs of unsuccessful lenses from various sources

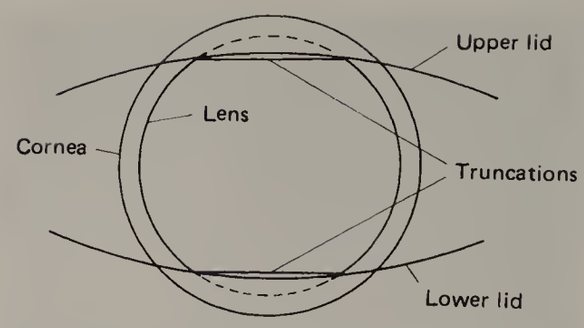


Figure 14.17 The correct positions for double truncations to permit upper and lower edges of the lens to align with the lid margins

(*Figure 14.16*). Such truncations often work well even if the lower lid position is well below the limbus. This type of lens relies on the effect of blinking on the truncations and is not required to rest on the lower lid. Blinking helps to prevent lens rotation as any movement of the truncations away from the horizontal will result in asymmetric lid contact and a subsequent return to the horizontal position.

The horizontal total diameter should be about 0.5 mm larger than would normally be used for a conventional lens. The vertical total diameter should be as small as possible consistent with good visual acuity, and considering possible use for night driving. Generally both truncations will be between 0.3 and 0.6 mm. The greater the discrepancy between horizontal and vertical total diameters the better, since this gives a greater truncated chord length on which the lids can act.

The longer axis of the double truncated lens almost invariably aligns with the flattest corneal meridian, which is usually nearly horizontal. If this is nasally slightly down (i.e. at 170 in the right eye), then the effect is generally counteracted by the tendency for the lower lid to rise nasally.

In most cases, it is not necessary to cut the truncations to correspond with the lid angles, and unless the nasal rise of the lower lid is excessive, it is best to cut the truncations horizontal – especially if the practitioner has little experience in judging the effect of lids upon truncations. Wide departures from normal lid orientation should be noted, however, especially if the front surface cylinder is high.

A lens which is overlapped by one or both of the eyelids in normal use can be converted to an interpalpebral design by double truncation (*Figure 14.17*).

One final comment should be made here with regard to the prism ballasting and truncation of toric RGP lenses. Prism ballasting can often cause RGP lenses to sit inferiorly, causing patients to experience symptoms of discomfort and flare. Truncations can also be uncomfortable for the patient and they are not always successful in preventing lens rotation. Consequently, these days most practitioners will generally choose toric soft contact lenses in preference to toric RGP contact lenses when fitting patients who have significant residual astigmatism but negligible corneal astigmatism.

RGP lens flexure

Lens flexure has previously been covered in Chapters 5 and 10. However, it needs to be considered briefly here, as it can often influence the decision regarding whether to prescribe a spherical or toroidal back surface for an RGP lens when fitting a cornea with a moderate to high degree of astigmatism.

Lens flexure and distortion can be a problem with RGP materials. It is well known that RGP materials flex much more than PMMA and that, in general, the higher the oxygen permeability the greater the flexibility of the material. Visual acuity with lenses demonstrating flexure is often variable and poor. Subjective refraction over these lenses can be unreliable and retinoscopy reflexes irregular.

There is no doubt that RGP lenses which are below a certain thickness flex with lid movement and pressure, and the warping effect induces an astigmatic component in the system. Harris *et al.* (1987) investigated flexure with RGP lenses on toroidal corneas. The results indicated that thinner lenses flexed more and the critical thickness to avoid flexure seemed to be 0.15 mm. While the same study found no relationship between corneal toricity and flexure with the RGP materials used, it is universally accepted that a spherical RGP lens will exhibit a greater degree of lens flexure than an equivalent PMMA lens when placed on a cornea with a moderate to high degree of toricity.

Consequently, RGP lenses are more likely to require toroidal back surfaces. For example, a cornea with 3.00 D of front surface toricity may have been adequately fitted in the past with a spherical PMMA lens. A spherical RGP lens on the same cornea, however, would be expected to show a higher degree of flexure (given the same lens thickness) leading to a drop in visual acuity and necessitating the use of a toroidal back surface.

As noted in Chapters 5 and 10, flexure-induced astigmatism can be beneficial to the patient. For example, if a cornea has with-the-rule astigmatism and a thin RGP lens is fitted to this eye, the induced astigmatism caused by the lens flexure will also be with-the-rule. Consider now if this eye has against-the-rule residual astigmatism. The flexure-induced with-the-rule astigmatism can be used to partially or completely neutralize the against-the-rule residual astigmatism.

Checking toric RGP lenses

Although covered in Chapter 12, a brief summary of verification techniques for toric RGP lenses is appropriate here, with elaboration of certain points.

Many of the parameters of toric lenses are checked as for spherical lenses. Total diameter and thickness are measured in the conventional way, not forgetting that truncated lenses need to have their total diameter dimensions measured along the major and minor axes, and the edge finish in the truncated area should be checked to ensure that it is satisfactory. Similarly, lenses with spherical back optic zones and toroidal peripheral zones, or *vice versa*, should have both diameters of the back optic zone measured. Lenses with toroidal back optic zones and toroidal peripheral zones may also appear to have slightly oval back optic zones, if the difference between the two BOZR is very large, or the difference between BOZR and peripheral radius in one meridian is different from that in the other meridian.

Toroidal back optic zone surfaces are usually measured on a radiuscope (optical microspherometer) and, as in focimetry, it is useful to remember that on most instruments the line in focus is at right-angles to the meridian whose radius is being measured when the target image is formed at the centre of curvature. (In order to locate the meridians accurately, the lens must be rotated until one of the target lines is sharply in focus.)

The radiuscope provides as excellent method of checking the actual cylinder power added to the front surface of a lens. The front surface radii are measured using the radiuscope and the radii are then converted to dioptric power using the refractive index of the RGP lens material (usually somewhere between 1.43 and 1.48) and simple surface power formula. A focimeter is normally used to measure the back vertex powers of the toric lens.

Meridian-identification dots or markers are required for toric RGP lenses to denote the position of one or both of the principal meridians of the back surface. These marks provide an axis of orientation about which the accuracy of the powers and axes of the surfaces produced by the laboratory can be checked. Where a prism ballast and/or truncation has been used for lens stabilization, the reference point will generally be the position of the prism base or the axis of the truncation.

Fitting toric soft lenses

Soft contact lenses have made an enormous impact on contact lens practice since their introduction by Wichterle and Lim (1960). The unique form of the soft lens material has enabled a large number of difficult cases to be fitted, many of whom had failed to wear well-made hard or RGP corneal lenses. Despite this, for many years it was held that a contraindication for soft lenses was the presence of significant astigmatism.

More recently, however, notable advances in toric soft lens technology have been made such that the correction of astigmatism with soft lenses is now a viable option for most contact lens patients with significant degrees of astigmatism. This is important, given the large number of soft contact lens wearers throughout the world today and the fact that more and more patients need a correction for the residual astigmatic errors present when soft lenses are being worn.

Much of the earlier development of toric soft lenses took place in Australia and New Zealand. Useful forms of toric soft lenses became available in the UK in 1975, but from that time onwards there has been development in many countries.

It is clear that a soft flexible material tends to follow the curvature of the underlying cornea and thus any corneal astigmatism tends to be transferred through the lens material. Hence, unlike hard and RGP lenses, soft lenses do not mask corneal astigmatism but rather conform to the shape of the cornea. In the early years of the development of soft lenses, it was postulated that the use of thick lenses would reduce the amount of corneal astigmatism transferred to the front surface of the lens. It is obvious, however, that attempts to use a thick soft lens result in a poorer physiological performance due to reduced oxygen transmissibility (Brennan *et al.*, 1991).

Numerous manufacturers of soft contact lenses have made extremely optimistic claims of their spherical lenses being able to correct, satisfactorily, astigmatism of between 1.00 and 2.00 D. Only rarely is this achieved. Bernstein *et al.* (1991) showed that there was no statistically significant masking of corneal cylinder with standard thickness soft spherical lenses. Indeed, the most helpful indication of the likely residual astigmatism found while wearing a spherical soft contact lens is the ocular astigmatism determined from an accurate subjective spectacle refraction.

Criteria for use of toric soft lenses

Due to the complexity, expense and time delay of manufacturing toric forms of soft lenses, most practitioners are inclined to prescribe them only when it is absolutely necessary. Obviously, orthodox RGP lenses are able to cope with a large variety of astigmatic problems but in many instances the patient may be unable to wear a lens with sufficient comfort. If a soft lens is preferred by a practitioner or patient for physical reasons and the resultant residual astigmatism is significant, then the use of a toric soft lens should be considered.

When deciding whether or not to prescribe a toric soft lens, practitioners should avoid using criteria such as 'all patients with cylinders greater than a certain amount should be fitted with toric soft lenses'. Instead, each patient should be assessed separately, taking into account the factors outlined below.

Degree of astigmatism

The question here is how much astigmatism should we be prepared to leave uncorrected? There is no simple answer to this question. As a generalization, 1.00 D or more of astigmatism should be corrected, although there will be significant variability between patients. Holden (1975), in discussing the criteria for the prescribing of toric lenses, showed that 45% of the population required a cylindrical correction of up to 0.75 D and 25% of the population required a correction of 1.00 D or more.

Ocular dominance

This is a very important factor. Uncorrected astigmatism is far more likely to be accepted by the patient if it is in the non-dominant eye. For example, patients may tolerate uncorrected cylinder of up to 2.00 D in their non-dominant eye, while at the same time requiring that a cylinder as small as 0.50 D be corrected in their dominant eye. Related to this is the situation where a patient has unequal visual acuities. In this case, higher degrees of uncorrected astigmatism will usually be tolerated in the eye with the poorer acuity.

Viability of other alternatives

The practitioner needs to consider whether toric soft lenses are the best option or if the patient would be better off with spectacles or RGP lenses. For example, a patient with high degrees (>5.00 D) of both corneal and spectacle astigmatism would most likely achieve better acuities with a toric RGP lens.

Assessment of patient's visual needs

Usually, the less critical the visual task, the greater the amount of astigmatism that can be left uncorrected (and *vice versa*). For example, a musician may require that a cylinder as small as 0.50 D be corrected to enable music to be read. On the other hand, a person with no specific critical visual tasks may be happy with a cylinder as high as 2.00 D left uncorrected so long as the spherical component of their refractive error is corrected.

Design of toric soft lenses

There are two aspects of toric soft lens design, namely **surface optics** and **lens stabilization**.

Surface optics

In this regard, the two principal categories of design are as follows:

- Toroidal back surface with a spherical front surface.
- Spherical back surface with toroidal front surface.

Note that with toric soft lenses, regardless of which type of lens design is prescribed, we will end up with a bitoric lens form on the astigmatic cornea due to the wrapping of the front and back surface on to the cornea.

The optical considerations for toric soft lenses are different from those encountered when using hard or RGP lenses. This is primarily because a toric soft lens will tend to wrap on to the cornea such that a negligible tear lens forms between the back surface of the lens and the front

surface of the cornea. Consequently, the optical principles of toric RGP lenses do not apply. There are no difficult tear lens calculations to perform and all the ocular astigmatism will usually be corrected by incorporation of cylinder into the back vertex power of the toric soft lens.

The choice of design (i.e. toric back surface, toric front surface) is generally based more on considerations relating to manufacture, lens stability and physiological performance. Presently, most toric soft lenses are made by either a process of crimping or generating, the latter being a specific form of lathe cutting devoted to the production of toric surfaces. As a general rule, generated toric lenses will be thinner and show better reproducibility than those made from crimping techniques.

Stabilization techniques

All forms of toric soft lenses need to be stabilized to prevent unnecessary rotation. The orientation of a toric soft lens on the eye must be predictable and consistent. With many years of experiencc of stabilizing hard corneal lenses, practitioners and laboratories initially turned to the tried and proven methods, such as prism ballast and truncation. In recent years, however, there has been the development of the technique of dynamic stabilization which has resulted in an overall improvement in the performance of toric soft lenses.

Toroidal back surface

While many practitioners and laboratories believe that a toric soft lens with a toric back surface will generally locate better than a front surface toric, a toroidal back surface on its own is not enough to achieve lens stabilization.

Prism ballast

The use of prism ballast is well known in stabilizing toric forms of lens but it does have certain disadvantages when applied to soft lens designs. Since many forms of soft lenses are relatively thick in comparison to RGP lenses, and are made larger than the corneal diameter, the additional thickness brought about by the use of a prism can be a problem with regard to oxygen transmissibility. The additional thickness can also cause physical discomfort in patients with sensitive lids, but a great deal depends on the position of the lids relative to the edge of the contact lens. Fortunately, the thicker edge in the region of the prism base can be thinned during the manufacturing stage, usually without negating the effect of the prism ballast. The problem here is finding an acceptable compromise between comfort and lens stability.

One of the difficulties which arises with the use of prism ballast is that if it is going to be prescribed monocularly it may well cause vertical prismatic effects which may make the patient uncomfortable. This then requires the use of a similar prism for the other eye, which can prove difficult if the other eye requires a spherical lens or is emmetropic.



Figure 14.18 This shows a prism ballast, single truncated, soft lens with a spherical back surface and toroidal front surface. The lower truncation has been cut at the angle of the middle third of the lower lid, but it can be seen how far below the lower limbus it is situated. In this photograph the patient had to look up in order to bring the truncation near the lower lid. The lid margin may thus only have a limited effect on the truncation

Fortunately, however, prism ballast does not often give rise to binocular problems (Gasson, 1977).

The underlying principle of prism ballast is to balance the forces acting on the lens in order to stabilize it. Originally it was thought that the major locating force was provided by displacing the centre of gravity away from the geometric centre of the lens – this was subsequently shown not to be the case (Hanks, 1983).

Peri-ballast

This method of lens stabilization features a lens with a minus carrier, with the carrier being thicker inferiorly. In other words, the prismatic thickness profile changes are confined to the thicker inferior lens carrier (prism base down). This design is fabricated simply by removing the high minus lenticular carrier from the superior portion of the lens. In effect, it is similar to prism ballast except that with peri-ballast all the prism is outside the region of the optic zone.

Truncation

Truncation has already been described in the section dealing with toric RGP lenses and is a well-tried and reasonably successful method of stabilizing lenses. Either a single or double truncation can be used (Strachan, 1975). With the former, the truncation can be anywhere between 0.5 and 1.5 mm and is usually inferior so that the truncated edge lies along the lower lid. The angle of the middle third of the lower lid is measured and then the lens is truncated at that angle.

It must be said that the use of truncation in soft lens fitting is totally different from that used in corneal lens

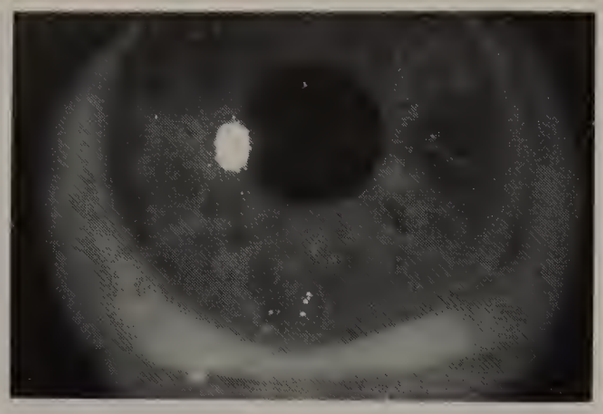


Figure 14.19 A successful toric soft lens with the lower truncation orientated at an entirely different angle from the lower lid. Despite this, the lens does not rotate. Note the deposits just above the truncation, a common site for such deposits

fitting. Indeed it can be observed that only in pronounced vertical movements of the eyes do the lid margins actually have any direct contact with the truncated edge or edges. This point is illustrated in *Figure 14.18*. For this reason observation of the angle of the middle third of the lower lid may be better noted with the eyes looking up and noting the lid angle at the point of expected contact with the truncation. For double truncations, the upper lid angle is then noted while looking down, using the same principle.

There are problems with the use of truncation in toric soft lens fitting. The truncated edge can make the soft lens uncomfortable to wear. The measurement of the lid angle can be difficult and imprecise. Often the truncation does not work, with the lid angle appearing to have no effect on the positioning or location of the truncated lens (*Figure 14.19*).

A common problem with lower truncations is that, although the lens may be well fitted and perform well in the earlier part of the day, later in the day the lens begins to dry out and the truncation stands away from the globe forming a small bubble and irritating the lower lid (*Figure 14.20*). Another difficulty with truncations (and prism ballasting) is the instability which can occur with oblique cylinders. The uneven thickness produced by oblique cylinders can make lens stabilization very difficult.

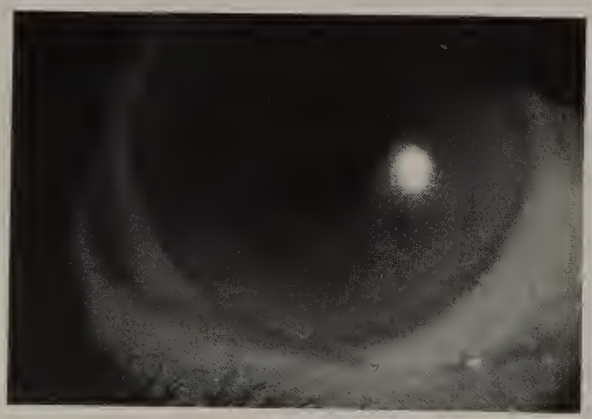


Figure 14.20 A truncated lens drying later in the day and standing off from the globe. Such a condition can be irritating for the lower lid

Dynamic stabilization

With the truncated and prism ballasted designs, it was originally thought that lens stabilization was due to a combination of lower lid interaction with the truncation and gravity acting to drag the thicker portion of the lens downwards. Many workers, however, including Hanks (1983), observed that patients wearing toric soft lenses with prism ballast stabilization who were turned upside down still had the prism base at the lower lid position, despite the fact that the heavier part of the lens was now higher than the lighter, prism apex. Hanks, using the 'watermelon seed' principle, where pressure on a wedge causes movement away from the wedge apex, went on to show that gravity has a far less significant effect and the thickness profile interaction with the upper lid is the dominant stabilizing component.

The technique of dynamic stabilization was initially developed by Fanti (1975) and these days is the most commonly used method of stabilization for toric soft lenses. With this technique, the dominant lens orientation effect is achieved by pressure from the upper lid (primarily) and the lower lid as per the 'watermelon seed' principle. In other words, lens stabilization is brought about by the kinetic forces associated with blinking.

With dynamic stabilization, the contact lens toricity is confined to the central portion of the lens and the superior and inferior ('dynamic stabilization') zones of the lens incorporate a thickness differential. The action of the lids on these superior and inferior lens chamfers stabilizes the lens. One of the first toric soft lenses to incorporate dynamic stabilization was made by Titmus Eurocon (now part of the Ciba Vision group) under the name Weicon-T (*Figure 14.21*). Many similar designs, referred to as 'double slab-off', 'thin-zone' or 'reverse prism' stabilized, are now manufactured by other laboratories.

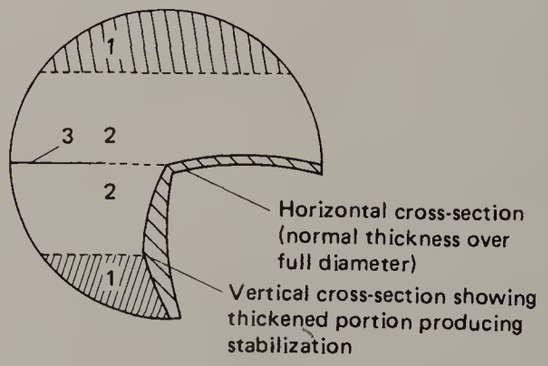


Figure 14.21 Weicon-T lens showing the form and position of the dynamic stabilization zones. This diagram shows a plano lens with a cylinder of –3.00 DC × 180, worked on as +3.00 DC × 90.
(1) Dynamic stabilization zones: (2) optic zone: (3) engraved line marking axis of stabilization

Dynamic stabilization avoids the complications of truncation and prism ballast. Although originally considered difficult to make, improvements in lathing technology and lens design over the past 10 years have made this form of toric soft lens readily available, as well as being easily reproducible and providing stable axis orientation. The excessive thickness of prism ballast lenses can be avoided and, by producing toroidal back surfaces, the average lens thickness can be made to be only slightly more than that of spherical designs.

The method in which a lens incorporating dynamic stabilization is inserted is generally not important since the action of the lids during blinking stabilizes the lens very quickly. Note that with some designs a longer, i.e. larger, thinned zone is provided superiorly to utilize the fact that most of the blink action is performed by the upper eyelid. With these designs it is more important that the lens is inserted the correct way up. To facilitate this, lenses will generally have some form of marking at the 6 or 12 o'clock position which also helps the practitioner with determination of lens rotation.

Principles of correction

It is clear that to produce a stable ocular correction for the astigmatic eye, the lens must align closely over the central cornea in front of the pupil. It must provide the correct power while it is *in situ* and must stabilize effectively to prevent the rotation of the meridional powers away from their correct meridians.

Fitting

The fitting principles for toric soft lenses are very similar to those previously outlined for spherical soft lenses in Chapter 11. A well fitting lens is comfortable in all directions of gaze, gives complete corneal coverage and appears properly centred. On blinking there should be about 0.25 to 0.5 mm of vertical movement when the eye is in the primary position. On upwards gaze or lateral movements of the eye, the lens should lag by about 0.5 mm.

The total diameter of the lens is very important because this parameter will influence both lens centration and lens stability. Generally, when specifying the lens diameter the practitioner should err on the large side, as a larger diameter means more area available for the stabilization zones in the periphery of the lens.

Some practitioners advocate fitting toric soft lenses very steep (tight) with minimal lens movement on the assumption that this will aid stability and reduce lens rotation. With the designs available today, however, this is not necessary and, if a lens is too tightly adherent to the eye, it will not be affected by the locating forces designed to stabilize lens orientation (Holden, 1975). Consequently, a steeply fitting lens may actually decrease stability and lead to undesirable factors such as limbal indentation and fluctuating vision, the latter being caused by the soft lens vaulting the corneal apex.

A well-fitting lens will reveal stable lens orientation with a quick return to axis if mislocated. A tight fitting lens will show stable lens orientation but a slow return to axis if mislocated. A loose fitting lens will demonstrate an unstable and inconsistent lens orientation (Hanks and Weisbarth, 1983).

Back vertex power determination

The determination of back vertex power for a toric soft lens is much easier than that for a toric RGP lens. Due to the absence of a tear lens, the back vertex power for a toric soft lens should be similar to the spectacle refraction (or ocular refraction if the vertex distance effect is significant).

A factor that has to be taken into account when prescribing toric soft lenses is the change in power which results from lens flexure when the lens is placed on the eye. For spherical soft lenses, this is not a problem if the power of the final lens is similar to the trial, spherical lens. For toric lenses, however, one meridian will usually be of greater power than the other and lens flexure will have differential power effects in the two meridians (Holden, 1975). This effect, however, is not usually significant with present toric soft lens designs and, on those rare occasions when it is, due allowance will generally be made by the contact lens manufacturer.

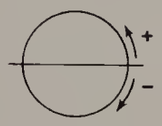
The back vertex power can be determined in one of three ways. It can be deduced empirically, whereby the back vertex power ordered for the toric soft lens is based on the spectacle (or ocular) refraction. The other two methods involve performing a spectacle refraction over spherical and toric soft trial lenses respectively. The former method, like the empirical method, has the drawback of not being able to fully predict meridional power changes due to lens flexing or lid action on the cylinder axes. Conversely, the latter method can give the practitioner a good idea of the power changes due to lens flexure, but may require the practitioner to perform oblique cylinder calculations if the principal meridians of the spectacle refraction over the lens do not coincide with the principal meridians of the toric trial lens (*see also* the CD-ROM accompanying this book).

When determining back vertex power the practitioner should take note that the astigmatism may vary with different directions of gaze. These changes are mainly due to the varying effects of the lids in different positions of gaze. In addition, Westerhout (1976) reported variations in the degree and axis of astigmatism in transferring the gaze from distance to near. These effects, however, are generally of minimal significance.

Effect of lens rotation

It is surprising how much induced cylindrical error is produced when a lens does not stabilize satisfactorily and rotates. Holden and Frauenfelder (1973) produced a table indicating the degree of error induced when a lens rotates

Table 14.2 Residual refractive error induced by mislocation of toric lenses of various cylindrical powers



Convention
(1) Axes in standard axis notation
(2) Anti-clockwise is +ve, clockwise –ve

Example: (a) –2.00 × 180 required refractive correction
(b) –2.00 × 170 obtained, i.e. –10° mislocation
(c) Residual cylinder axis is +40°
(d) Residual spherocylinder power is +0.35/–0.69
(e) Expected residual error +0.35/–0.69 × 40

Mislocation (degrees)	*–1.00 D*	*–2.00 D (×2)*
5	+0.08/–0.16 × 42.5	+0.17/–0.34 × 42.5
10	+0.17/–0.34 × 40	+0.35/–0.69 × 40
15	+0.26/–0.52 × 37.5	+0.52/–1.04 × 37.5
20	+0.34/–0.69 × 35	+0.68/–1.37 × 35
25	+0.43/–0.85 × 32.5	+0.85/–1.69 × 32.5
30	+0.50/–1.00 × 30	+1.00/–2.00 × 30
35	+0.57/–1.14 × 27.5	+1.14/–2.29 × 27.5
40	+0.64/–1.28 × 25	+1.29/–2.57 × 25
45	+0.71/–1.42 × 22.5	+1.41/–2.83 × 22.5
50	+0.76/–1.53 × 20	+1.53/–3.06 × 20
55	+0.82/–1.64 × 17.5	+1.64/–3.28 × 17.5
60	+0.87/–1.73 × 15	+1.73/–3.46 × 15
65	+0.90/–1.82 × 12.5	+1.81/–3.63 × 12.5
70	+0.94/–1.88 × 10	+1.88/–3.76 × 10
75	+0.96/–1.93 × 7.5	+1.93/–3.85 × 7.5
80	+0.98/–1.97 × 5	+1.97/–3.94 × 5
85	+0.99/–1.99 × 2.5	+1.99/–3.98 × 2.5
90	+1.00/–2.00 × 180	+2.00/–4.00 × 180

Reproduced by kind permission of Holden and Frauenfelder (1973).

(*Table 14.2*). For example, if the correction requires –2.00 DC × 180, the table reveals that a mislocation of the axis by 10° results in a cylindrical error of –0.69 DC × 40. A 20° movement gives a cylindrical error of –1.37 DC × 35 and a 25° rotation gives a cylindrical error of –1.65 DC × 32.5. Some practitioners advocate the use of this table in assessing the amount of rotation of the lens by carrying out an accurate refraction with the lens *in situ*. The cylindrical error thus determined can then be related to the induced error in the table to show the degree of lens rotation. Determining the degree of lens rotation using this method, however, is fraught with trouble as it relies on both the practitioner being able to perform an accurate refraction over the lens and the contact lens laboratory making the toric lens to exact specifications.

Predicting lens rotation

Hanks and Weisbarth (1983) showed that, on average, toric soft lenses will tend to rotate nasally by about 5 to 10°, where nasal rotation is classed as rotation towards the nose with respect to the inferior aspect of the lens. They also showed, however, that there was significant variability between toric soft lens wearers in the actual amount and direction of lens rotation. This is due to a range of factors.

Lid anatomy

Variation in lid tension (tightness), lid location, lid angle and lid symmetry can all have a significant effect on the location and stability of a toric lens on the eye. For example, clinical experience tells us that tight lids are more likely to affect lens movement and location than loose lids.

Lens–eye relationship

The optimal fitting relationship between the lens and the eye may vary from one patient to the next. The type of fit (steep, good or flat) will, in turn, have a significant bearing on lens position. For example, the degree of adherence between lens and eye is a very important factor (Holden, 1975). If a lens is too tightly adherent to the eye, it will not be affected by the locating forces designed to stabilize lens orientation.

Lens thickness profile

This may be important because it has been noted previously that, with dynamic stabilization, the thickness profile interaction with the upper lid is the dominant stabilizing component. While most toric soft lenses manufactured today have the contact lens toricity confined to the central portion of the lens, this thickness differential due to the astigmatic correction can still have a significant effect on lens location.

The lens thickness profile is determined by the power of the lens, in particular the axis and magnitude of the astigmatic correction. For toric soft lenses incorporating dynamic stabilization, Gundel (1989) showed that rotational influence is greatest for lenses with cylinders at oblique axes (either between 30 and 60 or 120 and 150), followed by lenses incorporating correction for with-the-rule astigmatism (150 to 30) and is least for lenses with against-the-rule axes (60 to 120).

It has been postulated (Gundel, 1989) that the principal factor affecting lens rotation is the initial point of contact between the upper lid and the thicker meridian of the lens. For toric lenses with oblique axes, the implication is that there will be notable rotational effects as contact from the upper lid will always affect one edge of the thicker meridian before the other. As the upper lid comes down, it will force the lens down at this first point of contact, causing it to rotate in a certain direction. A dislocating effect also occurs with lenses correcting for with-the-rule astigmatism as the lid contraction angle will usually be at a slight angle to the thickest axis of the lens (Holden, 1975). For toric lenses with against-the-rule astigmatism, upper lid contact with the thicker (horizontal) meridian will be fairly symmetrical and so the rotational effect is minimal.

For example, consider a toric soft lens with the prescription –1.00/–2.00 × 45 being worn in the right eye.

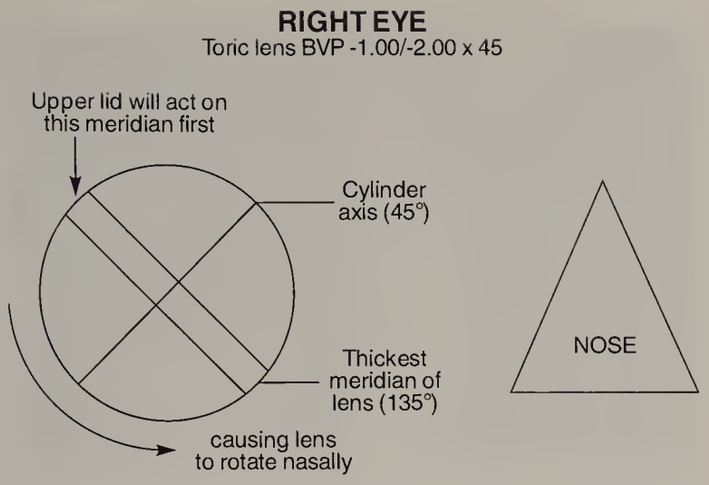


Figure 14.22 The effect of lid action on lens rotation for a toric soft lens with the prescription –1.00/–2.00 × 45 being worn in the right eye. As the upper lid comes down, it will first act on the lens (at the 135° meridian) at around the 10 o'clock position on the cornea. The downward motion on the lens at this point will cause it to rotate nasally

Remember that, for a spherocylindrical lens, the thickest meridian will be at 90° to the axis of the negative cylinder. Hence, for this lens the thickest meridian will be along 135. As the upper lid comes down, it will first act on the 135° meridian at around the 10 o'clock position on the cornea. The downward motion on the lens at this point will cause it to rotate nasally, as illustrated in *Figure 14.22*.

Using this model, Gundel (1989) predicts nasal rotation for oblique axes near 45° in the right eye and 135° in the left eye and temporal rotation for oblique axes near 45° in the left eye and 135° in the right eye. Note this is based on the lens thickness profile being the only factor effecting lens rotation.

Allowing for lens rotation

If it is expected that the toric soft lens to be ordered will rotate when placed on the patient's eye, then an allowance must be made for this rotation, otherwise the cylinder axis of the lens when on the eye will not coincide with the required cylinder axis for the contact lens correction.

Consider a toric soft lens being fitted to a *left* eye. Trial lens fitting and over-refraction gives a required back vertex power for the contact lens of –1.00/–2.00 × 150. No allowance is made for any lens rotation. When this lens is placed on the left eye, it is observed to rotate 10° nasally (i.e. clockwise). As a result, the cylinder axis of the lens will now, in effect, be along axis 140. Consequently, if we wish to make allowance for this 10° nasal rotation, the cylinder axis specified in the contact lens must be 160. The expected nasal rotation of 10° will then move the cylinder axis of the lens around to axis 150, which is the required cylinder axis for the contact lens correction.

Conversely, if the same toric soft lens (BVP of –1.00/–2.00 × 150) is fitted to a *right* eye, nasal (i.e. counter-clockwise) rotation will result in the cylinder axis of the lens now being along 160. In this case, if we wish to allow for this 10° nasal rotation, the cylinder axis specified in the contact lens must be 140.

Following on from this, when allowing for nasal rotation in the right eye, the amount of rotation should be subtracted from the required cylinder axis and *vice versa* for the left eye. When allowing for temporal rotation in the right eye, the amount of rotation should be added to the required cylinder axis and *vice versa* for the left eye.

Hence:

- If left eye and nasal rotation – add
- If left eye and temporal rotation – subtract
- If right eye and nasal rotation – subtract
- If right eye and temporal rotation – add

The acronym 'LARS' (left add, right subtract) for nasal rotation can be quite useful.

Many practitioners find it simpler to work on the principle that clockwise rotation necessitates adding the allowance for rotation to the required cylinder axis and counter-clockwise rotation requires subtracting the allowance for rotation to determine the final cylinder axis.

Hence

- If clockwise rotation – add
- If counter-clockwise rotation – subtract

If, at the dispensing or after-care visit, the lens rotation is not what was expected but the lens location is stable, simply reorder the lens with the revised allowance for lens rotation. Note that changing the cylinder axis to allow for the observed amount of lens rotation will alter the lens thickness profile, and hence may lead to a different degree of rotation from that observed previously. In view of this, it may be better to only allow for a certain amount of the observed rotation. For example, if no allowance has been made for lens rotation but the toric soft lens subsequently rotates nasally by 10°, the practitioner may then choose to allow for just 5° nasal rotation.

Generally speaking, rotational stability is a more important factor than the degree of rotation. Lenses which give suboptimal, but stable acuity are more likely to be acceptable than those which give moments of clear vision followed by moments of poor vision as the lens rotates.

Measurement of lens rotation

The laboratory making the toric lens will usually put some type of marking on the lens at a specific reference point so the degree of rotation can be assessed when the lens is on the eye. Note that this marking does not represent the cylinder axis but rather is a point of reference with regard to which the rotation of the lens can be assessed.

These markings may either be at the 6 o'clock position of the lens or in the horizontal lens meridian at the 3 and 9 o'clock positions. The latter situation is preferable as the markings can be then observed without altering the lid action. As the orientation of toric lenses depends largely on lid action, it is clearly unsatisfactory to have to retract the



Figure 14.23 Toric soft lens with ink dots as markers. The reference point is the 6 o'clock position. Note the use of two dots is merely to help with lens identification, with the patient's other lens just having the one ink dot. The lens is exhibiting about 10° nasal rotation. (Lens by Capricornia Contact Lens (Australia) Pty Ltd)

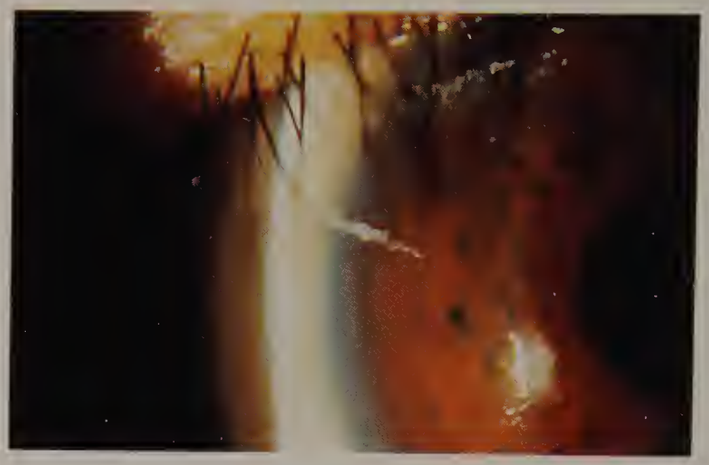


Figure 14.24 Scribe line on toric soft lens. This Torisoft lens from Ciba Vision has two scribe lines as markers with the reference points being 3 and 9 o'clock. Note the significant lens deposits on the scribe line, a common site for such deposits

lids and thereby lose the effect of lid and lens interaction, in order to observe the marks. In addition, having two markings (at 3 and 9) as opposed to one (at 6) makes it easier to quantify the angle of rotation.

The markings may be in the form of ink, laser trace, scribe lines or engraved dots. Ink markings are usually easy to see when the lens is dispensed, however they fade after a while, making assessment of lens rotation at future after-care visits quite difficult. Scribe lines are a commonly used marking, but have the disadvantage that their introduction can result in a potential mechanical weak point in the lens (Hanks and Weisbarth, 1983). Many laboratories provide three lines on their lenses, each separated by the same known angle, thus making it easier for the practitioner to quantify the degree of lens rotation. Engraved dots are made by the same principle as scribe lines. Laser trace gives a marking similar to scribe lines but supposedly without detriment to the mechanical properties of the lens. Examples of lens markings for toric soft lenses are shown in *Figures 14.23* and *14.24*.

There are a number of means by which the practitioner may assess the degree of lens rotation. A good method involves using a special slit lamp eyepiece containing a graticule ruled as a protractor, on which the axis of rotation can be read off directly (*see Figure 11.16*). Other methods include the use of the rotating slit on the slit lamp, measurement with a trial frame and cylindrical lens, and simple estimation.

Estimation is a straightforward and reasonable technique, made simpler if the practitioner remembers that there is 30° between each hour on a clock face. Clinical experience has shown that this is a satisfactory method of assessing lens rotation, with errors more likely to occur when evaluating higher amounts of lens rotation (Snyder and Daum, 1989).

A common misconception amongst practitioners is that the toric soft lens has to position at the reference point, otherwise that lens will not be a success. For example, a lens with a marking at the 6 o'clock position should always locate on the eye such that the marking is at 6 o'clock. As previously mentioned, a small degree of lens rotation is acceptable, provided it is consistent and the lens is stable at this point. The movement of the lens marking away from its reference point permits us to assess the amount and direction of the lens rotation, with appropriate allowance then being made in the final lens order.

Methods of fitting

The method chosen for fitting will depend on the trial lenses at the practitioner's disposal and whether the practitioner chooses to use mass-produced (stock) or custom-made lenses. Some form of trial lens fitting is required for most lenses, although one can never be exactly certain how the final (prescribed) lens will perform on the eye.

Empirical prescribing

In this case, a trial lens fitting is not performed, rather the order for the toric soft lens is based on empirical readings. The lens back optic zone radius specified is based on the keratometry readings and lens design, the lens diameter is chosen according to the corneal diameter (approximated by the horizontal visible iris diameter) and the back vertex power is derived from the spectacle refraction with possibly some allowance being made for lens rotation.

While this method obviates the need for trial lenses, it does require the practitioner or the laboratory to make some arbitrary judgements regarding the lens fit. It does not take into account factors previously discussed such as lid anatomy, lid–lens interaction and lens thickness profile, all of which can have an effect on lens location and fit. Empirical prescribing can be successful, especially given

the recent advances in toric soft lens manufacture and design. It is usually preferable, however, to perform a trial lens fitting when prescribing toric soft lenses.

Fitting using toric trial lenses

Fitting can be performed using toric trial lenses which incorporate all the lens stabilization features of the actual toric lenses to be ordered. This is the method generally used by practitioners who primarily prescribe mass-produced (stock) toric soft lenses. The trial lenses used should have a prescription as similar as possible to the expected final prescription. After the optimal fitting trial lens has been found, a spherocylindrical over-refraction is performed and the required back vertex power is calculated. This will usually require resolution of oblique cylinders and for a discussion on this area the reader is again referred to the CD-ROM accompanying this book and also to *The Principles of Ophthalmic Lenses*, 4th edition by M. Jalie, particularly pp. 294–301. The rotation of the toric trial lens is also noted and allowance made for this in the final lens order.

The advantage of this method is that it allows the practitioner to predict orientation and lens stability based on a lens very similar to the final prescription. Many practitioners claim that they are better able to predict lens orientation and stability using toric trial lenses.

Using toric trial lenses does, however, have its drawbacks. First, determination of back vertex power usually requires complex calculations with oblique cylinders. Secondly, if the practitioner wishes to cater for all patients, a large inventory of toric trial lenses covering a reasonable number of permutations of cylinder powers and axes is needed. Thirdly, if the cylinder power and axis in the final lens order are not quite the same as in the trial lens then the edge and centre thickness may vary in the final lens form leading to a difference in the expected lens location and stability.

Fitting using spherical trial lenses

Fitting can be performed using ordinary trial lenses with spherical back vertex powers which do not incorporate any lens stabilization features. This method of fitting is mainly used by practitioners who prescribe custom-made toric soft lenses. In this case, a spherocylindrical refraction is performed over the optimal fitting trial lens. As the trial lens has a spherical back vertex power, the resultant prescription is easy to calculate. An allowance can be made in the final order for some degree of lens rotation. This may be an arbitrary allowance (e.g. 10° nasal) or it may be partly based on the lens thickness profile (resulting from the required back vertex power) and the lens–eye relationship. In some cases, it will be assumed that the lens will be stable at the reference point and so no allowance will be made for lens rotation.

Note that some toric lens manufactures provide spherical trial lenses for fitting which have all the lens stabilization features associated with their toric lens design but a spherical back vertex power. With these lenses the practitioner can get a better idea as to the likely degree of lens rotation without, at the same time, having to perform difficult oblique cylinder calculations to determine the back vertex power.

Compared to toric trial lenses, using spherical trial lenses is easier (as it does not require any oblique cylinder calculations) and less expensive (as the practitioner does not need an extensive inventory of toric trial lenses). Using spherical lenses to predict toric lens rotation does have the disadvantage that the actual amount of rotation may be different when the ordered lens is placed on the eye, due to the change in lens thickness profile which results when the cylindrical correction is incorporated into the lens (Hanks and Weisbarth, 1983).

Stock lenses versus custom-made lenses

While most practitioners pride themselves on the accuracy of their refraction, they are often prepared to accept toric lenses available in only one or two cylindrical powers set at perhaps six or eight axes. This has arisen because the thousands of permutations of possible cylindrical powers and axes do not lend themselves to the mass production techniques and inventory supply of the larger international laboratories. Further, since many of these laboratories manufacture in one country and then export lenses to several other countries where subinventories are held, it would be impossible to produce lenses and have them available everywhere in all possible permutations, and equally impossible to provide a custom-made service.

The larger laboratories therefore typically produce a stock range of lenses encompassing two cylindrical powers such as –1.25 D and –1.75 D, set at eight axes, usually 20°, 10°, 180°, 170°, 160°, 80°, 90° and 100°. The choice of BOZR and TD for these lenses is also usually restricted. As most patients accept cylindrical corrections that are within ±0.25 D of the correct power, and since cylinders of under –1.00 D need correcting only infrequently, this effectively covers astigmatic errors up to 2.00 D in the most common axes and makes disposable toric lenses viable, e.g. Ciba Focus toric lens.

As all practitioners fitting appreciable numbers of contact lenses are bound to come across patients requiring cylindrical corrections not covered by the above range, it is essential to have access to a custom laboratory which can produce lenses to any required parameter. Many practitioners prefer to use custom-made toric lenses for all astigmatic patients. This enables them to alter parameters in any possible direction if the lens rotates or prescription changes. Note that the trial lens fitting for most custom-made toric lenses can generally be performed with spherical trial lenses or dynamically stabilized, spherically powered lenses.

While stock toric lenses have the disadvantage of limited parameters, they do enable rapid supply, easy exchange facility and high reproducibility. It is also possible for practitioners to hold a selection of lenses in their own

inventory, permitting a more accurate assessment of the effects of lens rotation by using a lens of almost correct power and axis on the eye. In contrast to custom-made toric lenses, much of the trial lens fitting for stock toric lenses is performed using toric trial lenses.

The majority of practitioners will fit both mass-produced (stock) and custom-made lenses. In general, a greater success rate in toric soft lens fitting will be achieved with the latter, due to the (almost) unlimited range of parameters and the greater flexibility in manufacture available to the practitioner. Stock lenses and their limited range of parameters constantly force the practitioner to compromise which reduces the possibility of a high success rate.

The practitioner with only limited experience of toric soft lens fitting is also well advised to use a laboratory offering exchange facilities. Remba (1986) found an average of 1.8 lenses per eye were used in successful cases, although one would expect this average to be considerably lower these days with all the improvements in toric lens design that have taken place since then.

Limitations of toric soft lenses

There will be a certain number of cases encountered in clinical practice where toric soft lenses are either less likely to be successful or do not represent the best option for the prospective contact lens patient. In these situations, the practitioner should take extra care when prescribing toric soft lenses.

Low spherical components

Example: +0.25/–2.50 × 180. These patients are very critical of axis alignment because the astigmatism is the most significant component of their refractive error. In addition, with some of the older toric soft lens designs, the thickness differentials (to aid lens location), which can usually be achieved, are reduced with small spherical components (Hanks and Weisbarth, 1983).

Oblique cylinders

Example: –2.00/–2.00 × 45. As previously discussed (Holden, 1975; Gundel, 1989), toric soft lenses incorporating oblique cylinders may show poorer stability due to complex lid–lens interactions.

Large cylindrical components

Example: +4.00/–6.00 × 180. Obviously, lens rotation becomes more significant as the degree of cylinder is increased. For example, a patient with a toric lens incorporating a 1.25 D cylinder may be able to tolerate a 5° rotation from the expected lens location, whereas a toric lens patient with a 3.50 D cylinder will notice a significant drop in vision for the same degree of rotation off axis.

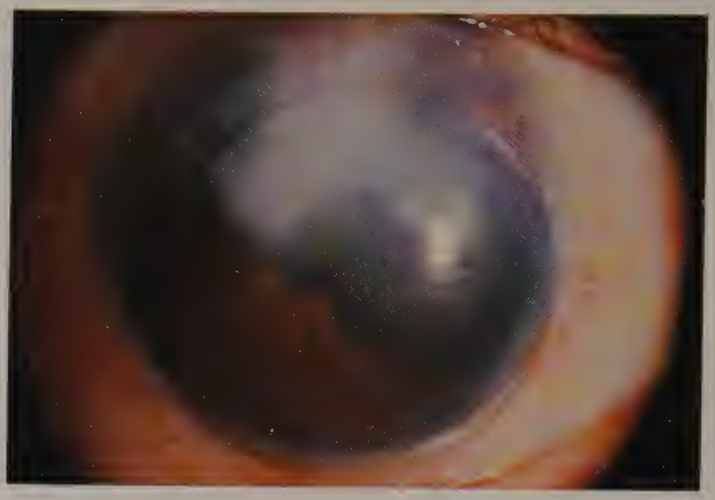


Figure 14.25 A combination of hard on soft lens on a severely damaged eye incapable of obtaining good vision with any other device.

Irregular astigmatism

No form of toric soft lens is able to correct irregular astigmatism. Conventionally, astigmatic errors of this nature are corrected with RGP lenses but in some severe types of irregular astigmatism, such as that encountered in moderate or advanced keratoconus, some patients are physically unable to wear such lenses satisfactorily. The use of toric soft lenses should generally be avoided in the management of keratoconus because, as noted in Chapter 20.1, they can cause physiological changes, such as corneal neovascularization, to the detriment of a possible future keratoplasty. In addition, such patients do not easily adapt to the RGP lenses which almost inevitably become necessary, as the condition worsens with time.

One solution to this problem is the use of a lens with a rigid centre which corrects the irregular astigmatism, and a soft periphery which is flexible and fits the irregular cornea and limbus with comfort while holding the rigid central portion in place. Such a lens is the SoftPerm lens, which is manufactured by Wesley-Jessen in the USA (*see* Chapter 11).

Another approach is to use a 'combination' or 'piggyback' system (Westerhout, 1973) in which the eye with irregular astigmatism is fitted conventionally with a soft lens so as to provide an artificial cornea over which an RGP lens can then be fitted, as shown in *Figures 14.25* and *14.26*. This 'piggyback' system is probably preferable to the SoftPerm lens due to its great flexibility and unlimited range of parameters; however, both these options are presently of limited use.

Physiological considerations

Because of the addition of cylinder and the creation of thickness differentials throughout the lens, the overall thickness of a toric soft lens will be significantly greater than that of a spherical soft lens. Consequently oxygen



Figure 14.26 Sunken piggyback lens. In cases of gross irregularity and high sensitivity, e.g. advanced keratoconus, an RGP lens may have to be fitted over a soft carrier lens. In order to prevent lens decentration the RGP lens has been inset into a recess cut into the soft lens (Lenses by Hydron (Australia) Ltd.) (Courtesy of A. J. Phillips)

transmissibility will be reduced and mechanical irritation increased, as compared to a spherical lens, with the result that compromises to ocular health are more likely to occur.

Conditions which are seen quite often with toric soft lens wear include corneal oedema (especially in patients with hypermetropic astigmatism), corneal neovascularization (usually inferior and superior and more likely in myopic patients), contact lens induced superior limbic keratoconjunctivitis and scleral or conjunctival indentation (especially with large, tight-fitting lenses).

If corneal hypoxia is a suspected cause of any ocular changes seen with toric soft lens wear, then a possible strategy is to increase the water content of the soft lens material so as to improve the oxygen transmissibility of the toric lens (Brennan *et al.*, 1991). Practitioners should note, however, that a high or medium water content toric soft lens may not show the same level of performance, with regard to lens stability, as a toric soft lens made from a low water content material. One explanation for this observation is that the higher water content materials generally have a higher surface flexibility which means they have less resistance to applied force. Consequently, the effectiveness of the lid–lens interactions in achieving stability may be reduced (Newman, S., 1994, personal communication). Another possible reason is that the manufacture of toric soft lenses in a high water content material to exact specifications can be difficult and any errors in the finished lens will influence its performance on the eye.

Checking toric soft lenses

Methods of checking soft lenses are covered in Chapter 13 but a few points are worthy of emphasis here. The special

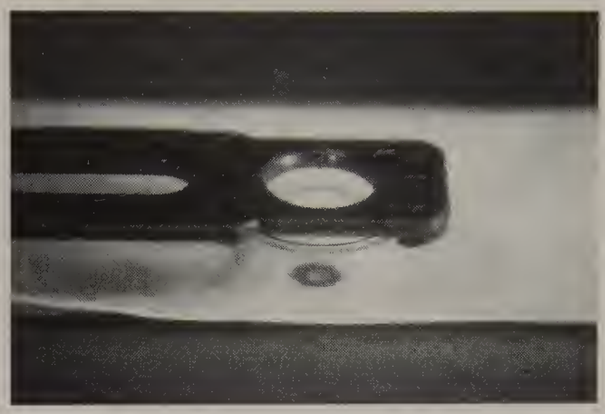


Figure 14.27 Use of the Tori-check instrument. The instrument is inverted and brought into contact with the blotted lens. The lens adheres to the clear rotatable disc seen under the grey handle

features of lenses with toroidal surfaces apply as much to soft lenses as RGP lenses and the approach to verification is similar (*see* p. 481). Because of the relative fragility of the soft lens material it is important to look for areas of damage to the lens where axis markings or other engravings have been made. These areas are also more likely to become contaminated during use (*see Figure 14.24*).

Measurement of back vertex power

Projection focimeters, with small aperture stops, are best for this purpose, although the problem of orientating the identification marks is not easy to solve without a satisfactory way of holding or supporting the lens.

The basic difficulty in checking the power of a soft lens is to attempt to dry the lens in such a way as to leave it lint or dust free. (The use of wet cells is best reserved for inspecting and measuring surface quality, diameter and radius on special instruments.) Lint-free filter paper is the most effective way of drying a lens before inspection. Unfortunately, however, the dried lens rapidly dehydrates causing its power to change. It is essential, therefore, to carry out the mounting of the lens on the instrument and the subsequent power measurement as quickly as possible. This is difficult with a toric soft lens. When a lens is placed on the small stop of a focimeter it tends to droop over the stop causing distortion. The lenses can wrinkle and fold up and, even if they can be placed on the stop without distortion, they cannot be placed with the orientation marks in a specific, accurate direction.

Consequently, the most common form of toric soft lens check is to place the lens on the eye and check visual acuity.

Instruments like the Tori-Check device can facilitate the support of a soft contact lens on a focimeter and permit the practitioner to position the orientation marks accurately, before the power and axis are read. With the Tori-Check, the lens is first blotted dry and mounted on the rotatable disc (*Figure 14.27*) which is turned so that the lens marks are in an appropriate position – usually vertical



Figure 14.28 The rotatable disc of the Tori-check is turned so that the orientation marks or truncations are in the desired position (usually in the horizontal or vertical).

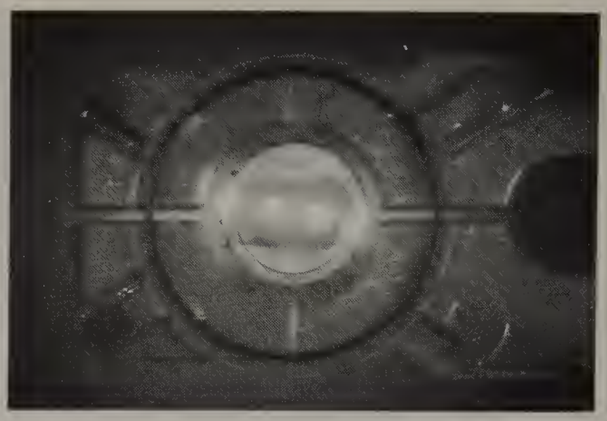


Figure 14.30 Incorrectly marked 'thin-zone' soft toric lens on a Tori-Check instrument. The 'thin-zone' lens has been rotated so that the shadows indicating the thin zones are parallel to the instrument axis. The orientation marks are incorrectly engraved and can be seen at approximately 10° off axis

or horizontal (*Figure 14.28*). The Tori-Check handle is then placed on the spectacle frame platform to orientate it horizontally (*Figure 14.29*) and the measurements are then taken on the instrument. If it is found that a lens is mismarked, with respect to stabilization zones, prisms or axes (*Figure 14.30*), the handle is placed on a compatible protractor and the marking error can then be measured, and reported to the laboratory or used as a basis for reordering.

Trends in toric soft lens design

Analysis of the lens designs currently available reveals that the majority of lenses are orientated by means of dynamic stabilization or zonal thinning.

The improvement in toric lens design has led to an overall reduction in the thickness of most toric soft lenses, which in turn has led to a decrease in the number of physiological problems encountered with toric soft lenses.

More and more toric soft lenses are being made from medium and, to a lesser extent, high water content materials. While the lower water content materials are still the easiest to manufacture, the improvements in the design and production process for toric lenses means that practitioners are now less reluctant to order their toric soft lens in a medium to high water content material. Low water content toric lenses work well from the physiological standpoint provided that they are thin. Unfortunately, the incorporation of the appropriate back vertex power into the lens often results in a thick lens form. In these cases a medium to high water material is required to ensure adequate oxygen delivery to the cornea and maintain normal ocular physiology.

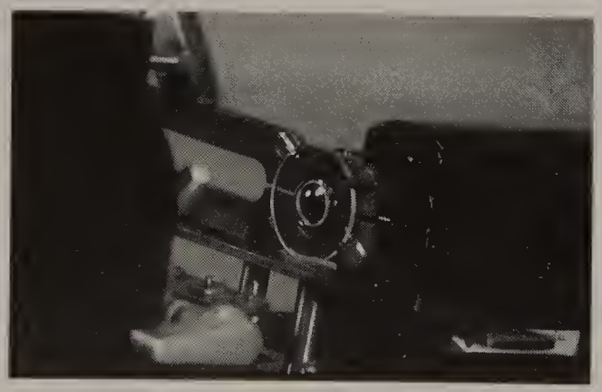


Figure 14.29 The handle on the Tori-check is placed on the spectacle frame platform, or held parallel to the platform, with the rotatable disc centred on the lens stop to check power

Acknowledgements

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Chapter 15

Extended wear lenses

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Introduction p. 494
The ocular environment p. 494
Hydrogel extended wear p. 498
RGP extended wear p. 522
The future of extended wear p. 531

Introduction

Extended wear of contact lenses can be defined as the wearing of lenses without removal during eye closure, for periods ranging from occasional overnight wear up to 30 days or more of continuous wear. Extended wear has long held considerable attraction for prospective contact lens wearers because of the possibility of being totally free of spectacles. Continuous contact lens wear holds the promise of normal vision without glasses, or as some patients put it: 'a chance for new eyes'. Certainly, wherever extended wear is publicized, patient demand is high because of the attraction of this modality of contact lens wear.

Over the years, there have been anecdotal reports of patients sleeping in lenses, including polymethyl methacrylate (PMMA) lenses. In spite of the extremely disadvantageous physiological conditions imposed by this activity, a few patients appear to be able to tolerate this stress, at least in the short term. However, contact lenses, in hydrogel materials, were first intentionally used on an extended wear basis as bandage lenses (Gasset and Kaufman, 1970) to minimize patient discomfort and promote wound healing of the cornea in cases of trauma or corneal perforation due to disease and following surgical procedures. The advantage of minimal handling with this mode of lens wear led to the use of extended wear lenses for elderly aphakes who had difficulty in inserting and removing lenses on a daily basis. More recently, extended wear lenses have become increasingly popular for cosmetic use by patients with a wide range of refractive errors.

Although hydrogel, silicone elastomer and rigid gas permeable lens materials may be prescribed for extended wear usage, in practice hydrogel lenses have been used most commonly for extended wear. Compared to daily wear lenses, extended wear lenses must transmit considerably more oxygen in order to minimize disruption to corneal physiology during closed-eye wear. This basic physiological requirement has led to the formulation of a wide range of hydrogel lens materials with high water content, and correspondingly greater oxygen permeability, and the development of techniques to manufacture very thin lenses in low water content materials. Silicone elastomer lenses, which have very high oxygen transmissibility, have also been in use since the mid-1970s for aphakic and cosmetic extended wear.

The aggressive marketing of '30-day lenses' in the early 1980s, particularly in the USA, led to considerable consumer pressure for extended wear lenses. Reports in the scientific literature and popular press of devastating corneal infections associated with extended wear lenses, however, have led to a re-evaluation of the safety of this wearing modality. In addition, increasing practitioner awareness of factors predisposing the patient to acute complications, and dissemination of information on the subtle long-term effects of hydrogel extended wear lenses on corneal structure and function, have emphasized the need for a more conservative attitude to extended wear (Holden, 1986). In particular, this has meant a re-orientation in attitude to the '30-day lens' concept, and it is now generally accepted that more frequent lens removal, at least once a week and preferably more often, is imperative in order to minimize the risks of both short- and long-term complications during hydrogel extended lens wear.

The development in the 1980s of rigid gas permeable (RGP) materials with high oxygen permeability has encouraged investigation of the feasibility of RGP lenses for extended wear. Although not in widespread usage, these lenses have been shown to have a number of advantages over hydrogel lenses for extended wear. For many practitioners RGP lenses are therefore the lenses of choice for extended wear, at least until soft lens materials with higher oxygen permeability become available.

The ocular environment

Oxygen needs and supply

When the eye is open, oxygen is supplied to the cornea directly from the atmosphere (Smelser and Ozanics, 1952; Hill and Fatt, 1964). At sea level, the concentration of oxygen in the atmosphere is approximately 21%, corresponding to a partial pressure (PO_2) of 155 mmHg

(21 kPa*). During eye closure, oxygen is provided to the cornea almost exclusively from the capillary plexus of the palpebral conjunctiva, but at much reduced levels (PO_2 = 60 mmHg or 8 kPa; Efron and Carney, 1979; Holden and Sweeney, 1985).

An adequate supply of oxygen is essential to maintain normal epithelial aerobic metabolism. When the level of oxygen at the anterior corneal surface is reduced, there is a decrease in the rate of aerobic metabolism, and a consequent increase in the rate of anaerobic metabolic activity in the epithelium. One major metabolic waste product of anaerobic glycolysis is lactate, which is usually oxidized in the presence of oxygen, but which accumulates in the epithelium and stroma under hypoxic conditions, as it gradually moves towards the aqueous where it is eliminated from the tissue. According to the theory of Klyce (1981), the increased concentration of lactate in the corneal tissue during hypoxia osmotically induces an influx of fluid into the stroma, leading to corneal swelling or oedema.

There was some early controversy as to the minimum level of oxygen required at the anterior corneal surface to maintain normal epithelial metabolism and thus to prevent oedema. Polse and Mandell (1970) found that an atmospheric level of only 1.5–2.5% oxygen (11–19 mmHg or 1.5–2.5 kPa) was required to avoid corneal oedema. This critical level was later increased to 3.5–5.5% oxygen following further work by Mandell and Farrell (1980). However, subsequent studies have demonstrated that, in fact, much higher levels of oxygen are necessary. Holden, Sweeney and Sanderson (1984) found that in the majority of patients at least 10% oxygen must be available to the cornea to prevent oedema (*Figure 15.1*). This confirmed parallel work by Mizutani *et al.* (1983), who reported a critical level of approximately 15% oxygen from similar studies. These results are supported by findings from other laboratories. For example, Hamano *et al.* (1983) found that the rate of epithelial mitosis was reduced, and lactate began to accumulate in the aqueous if less than 13% oxygen was supplied to the anterior corneal surface. Millodot and O'Leary (1980) reported that corneal sensitivity is decreased when the eyelids are closed and oxygen availability falls to 8% oxygen. In addition, Williams (1986) reported that an endothelial bleb response is generally induced if oxygen levels fall below 15%. There are also considerable individual variations in the minimum oxygen requirement; Holden, Sweeney and Sanderson (1984) reported that a range of between 7.5% and 21% oxygen was required to avoid oedema in their eight subjects.

During contact lens wear, the passage of oxygen to the anterior corneal surface is impeded by the lens. This is particularly significant during overnight wear of lenses, because less oxygen is available from the palpebral conjunctival vessels than from the atmosphere. Thus, most contact lenses induce a state of relative hypoxia, particularly during overnight wear.

*kPa = kiloPascals, where 1 Pascal = 10 millibars.

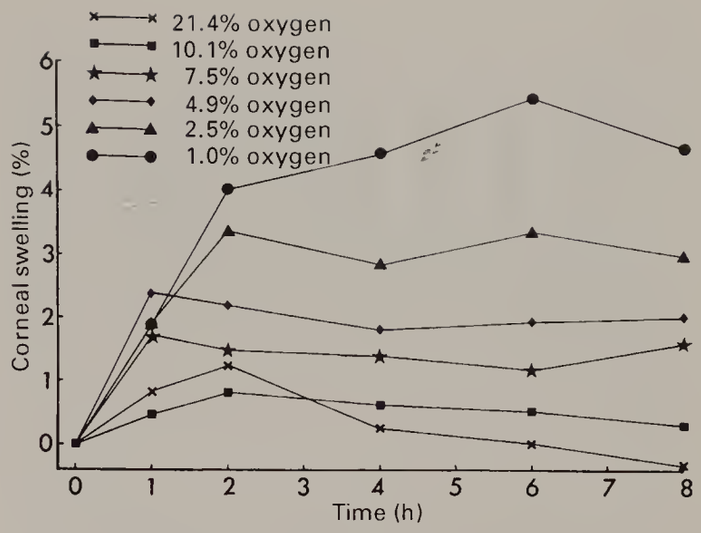


Figure 15.1 To determine the minimum oxygen requirements of the cornea to avoid oedema, average corneal swelling was measured for a range of precorneal oxygen concentrations. Gas-goggles were used to expose the cornea to gases of various oxygen tensions over an 8-hour period. Eight human subjects were used. On average, a precorneal oxygen concentration of 10.1% was required to avoid corneal oedema in this group of subjects. (×) 21.4% O_2; (■) 10.1% O_2; (★) 7.5% O_2; (♦) 4.9% O_2; (▲) 2.5% O_2; (●) 1.0% O_2. (From Holden *et al.*, 1984, by permission)

Oxygen can reach the cornea during contact lens wear via two mechanisms: by circulation of oxygen-rich tears behind the lens, driven by a lid-activated tear pump, or by diffusion of oxygen through the lens material.

The tear pump is active only during open-eye lens wear. Although it has been suggested that tear circulation due to eye movements during rapid eye movement (REM) sleep may provide some corneal oxygenation, Benjamin and Rasmussen (1985) showed that such a mechanism is unlikely to supplement oxygen availability to any significant extent.

During closed-eye wear, therefore, oxygen is supplied to the anterior corneal surface predominantly by diffusion through the lens material. The rate of diffusion of oxygen (j) is dependent upon the diffusivity (D) and solubility (k) of oxygen in the lens material, and the lens thickness (t), and can be expressed by the equation:

$$j = Dk/t\ (P_1 - P_2)$$

where P_1 and P_2 are the oxygen tensions at the anterior and posterior lens surfaces (Fatt and St Helen, 1971). The term Dk represents the oxygen permeability of the lens material, and Dk/t represents the oxygen transmissibility of the lens itself. Lenses with higher Dk/t values provide more oxygen to the cornea, and thus induce less corneal oedema. Corneal oedema can therefore be minimized by using a lens material with a high Dk value, or by reducing lens thickness to increase the Dk/t value of the lens itself.

Efron and Carney (1979) demonstrated that oxygen diffusion through hydrogel lenses under closed-eye condi-

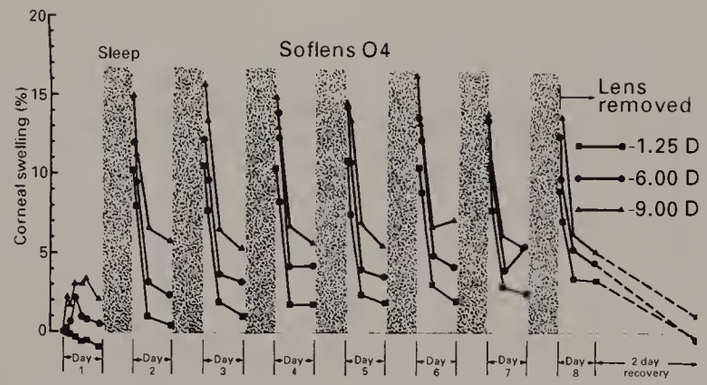


Figure 15.2 The typical 'oedema cycle' associated with hydrogel extended wear is shown in this graph of average corneal swelling versus time for 10 unadapted subjects wearing Bausch & Lomb Soflens O4 series contact lenses continuously for a period of one week. All subjects wore –1.25 D lenses on one eye, half wore –6.00 D lenses and half wore –9.00 D lenses on the other eye. (■) –1.25 D; (●) –6.00 D; (▲) –9.00 D. (From Holden *et al.*, 1983, by permission)

tions is insufficient to maintain normal epithelial functioning, and that some corneal oedema during sleep is therefore inevitable. This was confirmed by the work of Holden, Mertz and McNally (1983). The same is true of many RGP lenses that have been used for extended wear (La Hood *et al.*, 1988), although advances in the field of polymer chemistry have now provided new materials with Dk properties approaching those of silicone elastomer lenses, which apparently avoid overnight corneal oedema (Sweeney and Holden, 1987).

The major difference between hydrogel and RGP lenses in the mechanism of oxygen provision to the anterior corneal surface becomes apparent when the eyes are opened after overnight lens wear. Both lens types provide oxygen to the cornea during closed-eye wear by diffusion through the lens material. Thus hydrogel and RGP lenses of comparable *Dk/t* will induce similar levels of overnight oedema. However, the lid-activated tear pump mechanism with rigid lenses is considerably more efficient than with hydrogel lenses. An estimated 10–20% tear exchange occurs under a rigid lens with each blink (Cuklanz and Hill, 1969; Fatt and Hill, 1970). In comparison, Polse (1979) estimated a tear exchange per blink of only 1% under hydrogel lenses, due to their greater flexibility and larger diameter. Thus, when the eye is opened after overnight wear, oxygen is provided to the anterior cornea much more efficiently with RGP lenses compared to hydrogels, facilitating rapid corneal recovery from overnight hypoxic stress. Andrasko (1986) and Holden, Sweeney *et al.* (1988) clearly demonstrated that the cornea deswells more rapidly after overnight wear of RGP lenses than with hydrogel lenses as a result of the greater tear pumping efficiency of rigid lenses. Andrasko (1986) also suggested that the smaller area of the cornea covered by RGP lenses, and possible differences in anterior–posterior distribution of oedema through the cornea with RGP lenses, may also contribute to the more rapid deswelling.

The cornea appears to be able to eliminate approximately 8% corneal oedema during the open-eye phase following overnight wear of hydrogel lenses (Holden, Mertz and McNally, 1983). Thus hydrogel lenses worn for extended wear which cause more than 8% overnight oedema will induce a state of low-level daytime residual oedema. The cornea then undergoes an 'oedema cycle' of high overnight swelling, followed by partial recovery during the open-eye phase of extended wear (*Figure 15.2*).

The amount of oedema that the cornea is able to eliminate following RGP overnight wear has yet to be clearly defined, as it varies with the relative efficiency of the tear pump, which in turn is a function of the fit of the lenses and the blink frequency (Fatt, 1969). Data from a study reported by Holden, Sweeney *et al.* (1988) suggested that approximately 10% oedema can be eliminated with these lenses because of the supplementation of corneal oxygenation by the tear pump. However, an oedema cycle similar to that accompanying hydrogel extended wear can also occur with RGP extended wear.

Elimination of waste products

As well as impeding the supply of oxygen to the anterior corneal surface, contact lenses may also provide a barrier to the elimination of waste products from the anterior cornea, in particular carbon dioxide and cellular debris.

Carbon dioxide

For many years, it was widely accepted that hydrogel lenses do not restrict carbon dioxide efflux from the eornea, based on the assertion that the carbon dioxide permeability of hydrogel materials is in the order of 20 times that of oxygen (Fatt *et al.*, 1969); this has since been confirmed by Ang and Efron (1989). However, a study by Holden, Ross and Jenkins (1987) demonstrated that even very thin (0.035 mm) hydrogel lenses provide a significant barrier to carbon dioxide efflux. This implies that during extended contact lens wear, the cornea may experience chronically raised levels of carbon dioxide, or hypercapnia, with little opportunity for recovery to normal open-eye levels.

The effects of chronically raised carbon dioxide levels on corneal physiology are not known. Increased carbon dioxide concentration is likely to lead to an increase in the concentration of carbonic acid in the tissue and associated stromal acidosis. Such an effect has been demonstrated during eye closure and contact lens wear by Bonanno and Polse (1987a,b,c). Holden, Williams and Zantos (1985) suggested that such a pH change may be responsible for the endothelial bleb response. It is also possible that chronic stromal acidosis may contribute to changes in stromal thickness and endothelial cell morphology accompanying long-term hydrogel extended wear (Holden, Sweeney *et al.*, 1985).

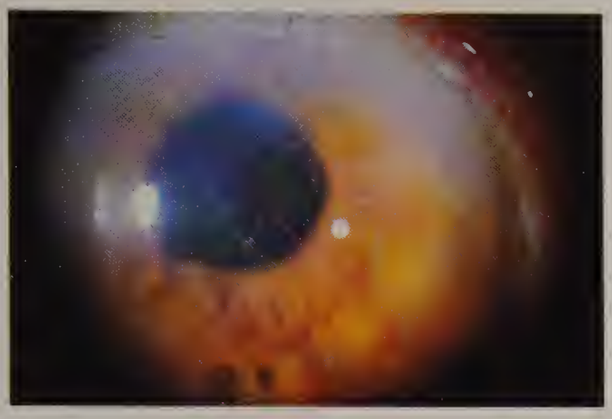


Figure 15.3 Contact lens-induced acute red eye (CLARE) reaction. Some superior corneal neovascularization can also be seen in this photograph. (Courtesy of A. J. Phillips)

Cellular debris

The corneal epithelium is continually replenishing cells by mitosis. Traditionally it has been accepted that these cells are produced at the basal layer and move towards the corneal surface until they are eventually sloughed off and washed away in the tears. The role of limbal stem cells as a primary or alternative source of epithelial cells (Davanger and Evensen, 1971; Lemp and Mathers, 1991), and the slow centripetal movement of epithelial cells from the limbus towards the centre of the cornea during their maturation (Thoft and Friend, 1983), has sparked considerable interest and is currently under intensive investigation (*see* Chapter 2).

During rigid lens wear, cellular debris and exfoliated cells are readily flushed out from behind the lens. However, debris is more likely to become trapped behind a hydrogel lens because of the larger diameter and lower rate of tear exchange (*Figure 15.3*). Enzymes released during breakdown of this cellular material have the potential to provoke a toxic reaction from the epithelium. This mechanism has been implicated in the acute red eye reaction seen in some extended wearers of hydrogel lenses (Zantos and Holden, 1978; Mertz and Holden, 1981). RGP extended wear lenses have less potential to provoke such a response because debris trapped behind the lens during overnight wear is more rapidly removed after eye opening due to the greater tear exchange with these lenses. However, RGP lenses may occasionally provoke an acute red eye reaction if the lens remains persistently 'bound' or adherent to the cornea following eye opening (Schnider, Zabkiewicz and Holden, 1988; *see* p. 525 *and also* Chapters 10 and 18).

Environmental changes under the closed lid

Overnight corneal oedema (no lens)

Following 8 hours of overnight eye closure without contact lenses, the cornea normally exhibits 3–4% corneal oedema (Mandell and Fatt, 1965; Mertz, 1980; La Hood *et al.*, 1988). Because the capillary plexus of the palpebral conjunctiva supplies oxygen to the cornea at a lower level (8%) than that required to avoid corneal oedema (10%; Holden, Sweeney and Sanderson, 1984), it is reasonable to assume that this relative hypoxia during eye closure contributes to the normal, no-lens overnight corneal oedema response. However, Holden, Sweeney and Sanderson (1984) found that a gas mixture containing 7.5% oxygen, approximately the level of oxygen available during eye closure, induced an average of less than 2% corneal oedema over 8 hours of exposure to the gas. This suggests that other factors, such as changes in temperature, tear pH and tonicity under the closed lid, may also contribute to the overnight swelling response.

Temperature

The temperature of the anterior corneal surface of the open eye is approximately 34.5°C (Fatt and Chaston, 1980; Martin and Fatt, 1986). When the eye is closed, however, and the cornea exposed to the palpebral conjunctiva at a temperature of 36.2°C (Holden and Sweeney, 1985), the corneal surface temperature increases by approximately 2°C (Fatt and Chaston, 1980; Martin and Fatt, 1986). It is possible that this increase in corneal temperature influences the rate of metabolic activity in the epithelium (Freeman and Fatt, 1973), inducing an increase in epithelial oxygen consumption. Thus, during closed-eye wear of contact lenses, the effects of reduced oxygen availability may be exacerbated by an increased epithelial demand for oxygen. In this way, temperature effects may contribute to the overnight corneal swelling accompanying both sleep and extended lens wear.

Tear pH

Carney and Hill (1976) established that tear pH usually exhibits a pattern of diurnal variation about a mean of 7.45 ± 0.16 in the open eye, with a general increase in alkalinity during the day. When the eye is closed, the tear pH shows an acid shift. Immediately on eye opening after sleep, tear pH is reduced on average to approximately 7.25, and recovers to average open-eye levels within 3–4 hours of eye opening.

Tear pH may also be reduced in neophyte contact lens wearers (Hamano, 1978), although attempts to determine long-term changes in tear pH with contact lens wear have been less conclusive. It is probable that reductions in tear pH with eye closure and contact lens wear are due in part to the restriction of carbon dioxide efflux from the cornea, and reflect parallel changes in stromal pH under these conditions (Bonanno and Polse, 1987a,c).

Changes in ambient pH have been shown to alter the ion transport properties of the epithelium (Fischer *et al.*, 1978), and may therefore affect corneal hydration. Thus the normal acid shift in tear pH during eye closure, possibly compounded by reduced pH accompanying contact lens wear, could contribute to the overnight swelling of the cornea. It

has been suggested, however, that an acidic environment may decrease corneal oxygen consumption (Carney and Efron, 1980). Furthermore, a number of authors (Carney, 1974; Holden, Williams and Zantos, 1985; Sweeney, 1991) have reported that exposure of the cornea to gas mixtures containing oxygen and carbon dioxide, which would be expected to lower tear film and corneal pH, does not induce corneal oedema.

Tear osmolarity

Terry and Hill (1978) found a shift in tear tonicity from 0.97 ± 0.02% NaCl in the open eye to 0.89 ± 0.01% NaCl following sleep periods of 6–8 hours. This overnight hypotonic shift may be explained by reduced tear evaporation during eye closure. O'Neal and Polse (1985) demonstrated that corneal thickness recovery from induced oedema in a 100% humidity environment is significantly impeded when compared to recovery in a normal (60% humidity) environment. This appears to confirm the role of tear film evaporation in the control of normal corneal thickness, as suggested originally by Mishima and Maurice (1961).

Rigid contact lens wear can induce a hypotonic shift in tear tonicity, particularly due to reflex tearing during adaptation (Harris and Mandell, 1969). In comparison, hydrogel lenses induce only transient and small changes in tear osmolarity (Martin and Holden, 1983), probably due to their greater 'on-eye' comfort. Because changes in the tonicity of the precorneal environment can osmotically induce changes in corneal thickness, it is therefore possible that osmotic swelling during overnight contact lens wear, due to a hypotonic tear shift, contributes to the overall closed-eye eye swelling response.

In a series of studies, Sweeney (1991) examined the separate effects of hypoxia, temperature, osmolality, humidity and carbon dioxide on the corneal oedema response. Extrapolating from her results, she demonstrated that hypoxia during eye closure accounts for approximately half of the normal overnight oedema response. Changes in temperature, osmolality and humidity approximating those found during overnight eye closure induced low and similar levels of oedema, accounting for the remainder of the overnight oedema response. Increases in ambient carbon dioxide partial pressure, which would be expected to influence tear and stromal pH, did not induce corneal swelling.

In summary, environmental changes under the closed lid may have a subtle influence on corneal physiology, and contribute to the normal slight swelling of the cornea during sleep. Hypoxia due to reduced oxygen availability, increased temperature and tonicity changes due to the elimination of tear evaporation during eye closure, are probably the most significant contributors to this normal overnight swelling.

Overnight contact lens wear, which further reduces oxygen availability, may also exert an influence on other aspects of the precorneal environment and thus exacerbate the overnight swelling response. However, the extent to which corneal homeostasis is affected by these subtle alterations in corneal environment is generally masked by the more prominent effects of restricted oxygen availability.

Hydrogel extended wear

Historical review

The development of a hydrophilic material suitable for contact lens applications was first reported by Wichterle and Lim in 1960. Hydrophilic lenses achieved widespread use as daily wear lenses, and were also found to be useful as bandage lenses for the treatment of ocular diseases such as bullous keratopathy, recurrent corneal erosions, corneal ulcers and perforation, and dry eye syndromes. As it became apparent that these bandage lenses could be worn for 24 hours a day, and with their increasing use for aphakic patients with postsurgical complications, it was recognized that aphakic extended wear was a viable alternative to aphakic spectacle correction, intraocular lens implantation or daily contact lens wear. Although in use in some countries since the mid-1970s, extended wear lenses for aphakic correction received FDA (Food and Drug Administration) approval in the USA in 1979.

The development of high water content hydrophilic lenses for extended wear was pioneered by John de Carle in England in the early 1970s (de Carle, 1972). The early promising performance of the Permalens, a 71% water content lens, stimulated further developments in this area, including the Sauflon lens (promoted by Philip Cordrey), and the Duragel material (developed by Highgate and Frankland), which was investigated by Klas Nilsson and marketed in Sweden under the trade name Scanlens. Because oxygen permeates through the water contained in the polymer, the high water content of these lenses increased the amount of oxygen reaching the anterior corneal surface compared to daily wear low water content materials. With the development of more sophisticated manufacturing techniques, it also became possible to produce very thin lenses in low water content materials which rivalled the high water content lenses in their ability to transmit oxygen to the cornea. Both lens types are currently used for extended wear; their relative advantages and disadvantages are discussed below.

In 1981 hydrogel lenses were approved by the FDA for cosmetic extended wear in the USA. During the following decade, cosmetic extended wear lenses grew enormously in popularity, due in part to aggressive consumer marketing of these lenses. By 1983, it was estimated that more than 500,000 people in the USA were wearing extended wear lenses, with 40,000 new fittings every month, resulting in approximately 4 million extended lens wearers by 1985. The rapid growth in the use of these lenses, however, was not without problems due in part to poor follow-up and patient advice by some practitioners. Early reports from England (Ruben, 1976) and Australia (Cooper and Con-

stable, 1977; Zantos and Holden, 1978) suggested that these lenses could induce severe corneal complications. These warnings went largely unheeded at first in the USA, until the issue was raised by Barry Weissman in 1983. Clinical reports of corneal infections associated with extended wear then began to appear with increasing frequency in the US scientific literature. Subsequent US media reports of gross corneal infections and associated litigation led to a re-evaluation of the safety of this modality, and a down-turn in patient pressure for extended wear.

A variety of patient management strategies have been used to reduce the risks associated with hydrogel extended wear. The concept of regular lens replacement originated in Sweden, and has been utilized in that country for many years. This approach to patient management was pioneered by Klas Nilsson (1983) with high water content lenses, and by Ake Gustafsson with low water content lenses. Nilsson's care system, developed over 10 years' experience with hydrogel extended wear, included 6-monthly replacement of lenses, avoidance of preserved solutions and the use of oxidizing disinfection systems. The low complication rates found using this system were encouraging although Holden, Sweeney *et al.* (1985) reported an incidence of acute red eye reactions of 7% per year.

In the early 1980s a similar approach, the 'Gold Card' regular replacement scheme, was introduced in the USA by Cooper Vision, but did not achieve significant use. The Fresh Lens ProCare System from Bausch & Lomb was launched in the USA in 1986, with similar initial low acceptance. Typically, lenses worn for extended wear were replaced on a regular three- or six-monthly basis, and clinical reports suggested that this approach contributed significantly to increased success rates and low complication rates (Holden, Sweeney *et al.*, 1985; Nilsson and Persson, 1986; Kotow, Grant and Holden 1987; Kotow, Holden and Grant, 1987; Ames and Cameron, 1989).

Perhaps the most significant clinical advance in the field of hydrogel extended wear over the last decade has been the introduction of disposable lenses for daily and extended wear. For many years the concept of disposable lenses, which could be worn for a short period (1–2 weeks) and then discarded, remained an unachievable goal because of the cost of such a system. Disposable lenses were first pioneered in Denmark as the Danalens. This scheme foundered, however, due mainly to problems with parameter reproducibility and variable packaging standards (Benjamin *et al.*, 1985). In the US, manufacturing innovations by Vistakon in the late 1980s enabled lenses (Acuvue) to be produced cheaply enough to allow true disposability on a weekly, fortnightly or monthly basis. Other companies soon followed, with the SeeQuence lens from Bausch & Lomb, and NewVues from Ciba Vision.

Disposable lenses were marketed initially as extended wear lenses, to be worn for up to two weeks and then replaced with a fresh lens. After the FDA issued a recommendation in 1989 for a maximum six-night extended wear regimen, the recommended extended wear period was reduced to one week before disposal. The attractions of the disposable lens modality for patients and practitioners included improved ocular health, freedom from complicated care and maintenance routines, and better patient compliance. Despite initial scepticism with regards to cost and the potential for patient non-compliance (to save money by wearing lenses longer than recommended), early clinical studies indicated good compliance to the disposable regimen, and few complications were initially reported (Donshik *et al.*, 1988; Grant and Holden, 1988; Maskell, 1989). However, subsequent reports of serious infections with extended wear of disposable lenses (for example, Dunn *et al.*, 1989; Kent *et al.*, 1989; Kershner, 1989; Killingsworth and Stern, 1989; Rabinowitz *et al.*, 1989; Ficker *et al.*, 1990), and improper care of these lenses with daily wear leading to severe complications (Efron *et al.*, 1991), have shown that improper use of this lens modality can have serious consequences.

Early research on hydrogel extended wear placed much emphasis on the oxygen-transmitting properties of these lenses, particularly during overnight wear. The relative simplicity of fitting hydrogel lenses, and the ready patient acceptance due to improved comfort and minimal handling, suggested that all that was required to guarantee success was the provision of adequate oxygen to the anterior corneal surface to maintain normal epithelial functioning. While this aspect of lens performance is certainly of major importance, it soon became apparent that other aspects of hydrogel lens performance play a subtle but important role in maintaining corneal health. Hydrogel lens material properties and design are now recognized as significant factors in the clearing of debris that collects behind the lens, in minimizing deposit formation, and in the provision of tear-carried metabolites essential for the maintenance of epithelial growth and repair during extended wear. More recently, research interests have focused on the pathogenesis of contact lens-related corneal infection, and the problem of acute and chronic inflammatory responses during lens wear.

With increasing knowledge of the subtle long-term effects of hydrogel extended wear, and of the factors which may predispose the cornea to acute complications, it has become clear that careful patient selection and instruction, rigorous follow-up, strict care and maintenance procedures, frequent overnight rest periods and regular replacement or disposal of lenses are vital factors in maintaining corneal health and maximizing extended wear success.

Advantages and disadvantages

The principal advantage of extended wear over daily wear of contact lenses is that of convenience. As the lenses do not have to be inserted and removed each day, extended wear is of considerable benefit for patients who have difficulty in handling the lenses, such as elderly patients and children. In these two groups, extended wear lenses are particularly useful for aphakic correction. Ellis (1983) and others also reported extended wear success with highly myopic and anisometropic children. Nevertheless, daily wear is still the preferred option for these groups, if handling permits.

Many ametropic patients are also attracted to the convenience of the extended wear modality, and direct consumer advertising, particularly in the USA, fostered a considerable demand for extended wear. The attractive prospect of being able to see well immediately on awakening, while not considered important by many emmetropes, is often mentioned by prospective extended wearers. In addition, many prospective patients, particularly current or past daily lens wearers, are keen to avoid the ritual of daily lens care and maintenance. Extended wear is also a particular advantage in some occupations, such as the military services (Nilsson and Rengstorff, 1979; Leibrecht *et al.*, 1989; Lattimore and Cornum, 1993), where time-consuming lens insertion may be more than just an inconvenience.

It is important, however, that extended wear patients are made aware that extended wear does not mean continuous wear and that, although lens handling is minimal, the lenses must be removed periodically for routine cleaning and to rest the cornea. Thus it is imperative that patients are able to handle and care for their lenses, and at the very least are competent themselves or have someone available to remove the lenses if problems such as unusual discomfort, redness or persistent blurred vision occur.

Extended wear hydrogel lenses are not without their disadvantages. As well as acute complications, which will be discussed in detail later, other less serious but troublesome problems may occur in some patients, including persistent deposit formation on lenses, poor vision due to lens flexure and undercorrected astigmatism, and lens damage during handling. Because the incidence of these problems is frequently related to the water content of the hydrogel lens material, the advantages and disadvantages of the various hydrogel lens types will be discussed below. Silicone elastomer lenses, although not hydrogels as they contain no water, will also be discussed in this section.

High water content lenses

The first hydrogel lenses used for extended wear were made from materials containing a high proportion of water (Permalens, 71%; Sauflon, 85%). Because oxygen is transmitted through the water contained in the polymer, it was thought at the time that these lenses could be made fairly thick (0.14–0.30 mm) and still transmit enough oxygen to be considered for extended wear. Current high water content lenses, however, are generally prescribed for extended wear in the thicknesses of about 0.12 mm, in order to maximize oxygen transmission.

The relative thickness of high water content extended wear lenses means that they retain their shape and are therefore easier to handle and to locate if accidentally dropped or dislodged from the eye. However, the fragility of some high water content polymers can lead to more frequent tearing and other damage than with low water content daily wear lenses.

Contamination and deposit formation on high water content lenses is also a significant problem. This is probably due to the large pore size in these polymers (Fatt, 1978), which allows small contaminating molecules to penetrate the polymer matrix (Refojo and Leong, 1979), and provides a more substantial 'toehold' for larger molecules to adsorb on to the lens surface. 'Jellybump' deposits, also known as 'mulberry' deposits, lens calculi or calcium deposits, are a particular problem with high water content lenses. These round nodular deposits, which are composed of calcium and lipid (Caroline *et al.*, 1985), can cause ocular irritation and poor visual acuity and, because they are difficult to remove without damaging the lens surface, lens replacement is usually necessary (*see also* Chapter 13).

Low water content lenses

Thin, low water content lenses became available in 1980 as an alternative to high water content lenses for extended wear. The thinness of these lenses allows sufficient oxygen to diffuse through the lens for them to be considered for extended wear. The first lenses of this type, the Bausch & Lomb 'O series' lenses, were made from HEMA (hydroxyethyl methacrylate) material (38.6% water content) with a centre thickness of 0.035 mm. Lenses in other materials with similar water content and centre thickness (for example, CSI-T and Permathin) also developed for extended wear applications.

The advantages of low water content lenses include increased durability of the polymer and less deposit accumulation within the lens due to the denser polymer matrix. However, the extreme thinness of these lenses for extended wear can make them difficult to handle, particularly in low powers, and also more vulnerable to damage such as tearing. In addition, the tendency of these lenses to 'drape' on to the cornea results in less lens movement than with thicker high water content lenses, which in some patients may hinder the flushing of debris from behind the lens. However, Holden and Sweeney (1987) suggested that as little as 0.2 mm movement may be adequate with these lenses provided it is maintained during lens wear.

Hydrogel alternatives

In an attempt to minimize the problems associated with high and low water content lenses, many extended wear lenses available today are made from medium water content materials (45–60%) with moderate centre thickness in the range 0.05–0.12 mm. As would be expected, the properties of these lenses provide a compromise between those of thin, low water and thick, high water content extended wear lenses.

Thin, high water content lenses have also been investigated for extended wear use. In theory, the high water content (70–75%) combined with a reduced centre thickness (0.03–0.08 mm) should greatly enhance the oxygen transmission characteristics of the lenses. In practice, however, the lenses are extremely fragile and difficult to handle, and may induce epithelial erosions (*Figure 15.4*)

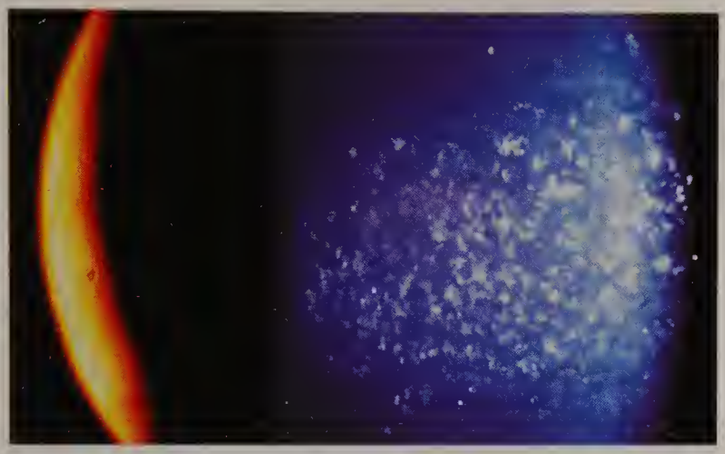


Figure 15.4 Epithelial erosions may occur when soft lenses dehydrate on the eye, such as this case of multiple confluent erosions following short-term wear of a very thin high water content hydrogel lens. It is postulated that small areas of dehydrated epithelial tissue become attached to th` lens and are torn away when the lens is removed. Erosions may also occur when mild degrees of punctate stain remain untreated for long periods or when debris builds up under a lens or adheres to its back surface. (From Holden, Sweeney and Seger, 1986, by permission)

due to on-eye dehydration which causes epithelial desiccation (Holden, Sweeney and Seger, 1986; Orsborn and Zantos, 1988).

Disposable lenses

At the time of writing, there are several types of extended wear disposable lenses on the market. These lenses generally fall into two broad categories: low water content non-ionic lenses (e.g. SeeQuence), and high water content ionic lenses (e.g. Acuvue and NewVues). Because the materials used for disposable lenses are fundamentally the same as those used for conventional extended wear lenses, their advantages and disadvantages are similar to those discussed above. In particular, it must be clearly understood that the oxygen transmission characteristics of these lenses do not differ from those of conventional extended wear lenses (Weissman *et al.*, 1991), and therefore the hypoxic effects of disposable lenses on corneal structure and function are the same as can be observed during conventional extended wear.

Further discussion of the advantages and disadvantages associated with the disposable lens modality can be found later in this chapter.

Silicone lenses

Silicone has been used for many years as a biomaterial for medical applications and, because of its inherent high oxygen permeability, there has been considerable interest in its use as a contact lens material. Silicone elastomer lenses have been available for aphakic and cosmetic extended wear use in Japan and Europe since the mid-1970s, but have gained FDA approval in the USA for paediatric and aphakic use only.

The high oxygen permeability of the silicone elastomer material is a major advantage for maintaining corneal function during extended wear. The lenses are also very durable and easy to handle, being approximately five times more rigid than an equivalent 50% water content hydrogel lens (Ruben and Guillon, 1979). However, despite their promise in terms of physiological performance, silicone elastomer lenses have failed to gain a significant share of the contact lens market, because of a number of unique and frustrating drawbacks.

Silicone is by nature hydrophobic; thus current-generation silicone elastomer lenses are surface-treated to render them hydrophilic. In spite of this, deterioration of surface wettability has been reported (Ruben and Guillon, 1979; Fanti, 1980; Josephson and Caffery, 1980) and, in general, silicone lenses have a life expectancy of about 6 months before requiring replacement. Lens deposits are also a problem (Ruben and Guillon, 1979; Fanti, 1980), possibly due to the hydrophilicity of the treated surface, although stronger cleaning solutions can be used with these lenses than with hydrogels (Josephson and Caffery, 1980).

Silicone elastomer lenses require a more discriminating fitting procedure than hydrogel lenses, in order to maintain lens movement during wear. Lenses should be fitted as flat as possible while maximizing patient comfort and vision. Fluoresccin can be used to assess lens fit without discolouring the lenses. As a consequence of the lens fitting required, however, patient awareness of silicone elastomer lenses is generally greater than with hydrogels, particularly during the adaptation period.

If adequate lens movement is not maintained, silicone lenses have a tendency to adhere or 'suck on' to the cornea (Fanti, 1980; Fanti and Holly, 1980; Josephson and Caffery, 1980). Fatt (1979) suggested that this phenomenon is due to the high modulus of elasticity of the material, which can store energy in the deformed state. When the lens is pressed by the lid against the cornea, a large positive pressure at the lens edge and a negative pressure or suction under the lens results, leading to lens adherence. Others have suggested that 'contact adhesion' between a hydrophobic lens surface and the bare cells of the epithelium, which are also thought to be hydrophobic, may contribute to this phenomenon (Fanti and Holly, 1980; Josephson and Caffery, 1980). Refojo and Leong (1981) also suggested water pervaporation through the lens as a possible mechanism for silicone lens adhesion, although other investigators (Kuriaki *et al.*, 1986; Fleming *et al.*, 1992) found little evidence to support this theory. Despite intensive research efforts, a reliable solution to this particular problem has not been identified.

Acute complications of hydrogel extended wear

Stromal oedema

Corneal stromal swelling or oedema during contact lens wear indicates that insufficient oxygen is being supplied to

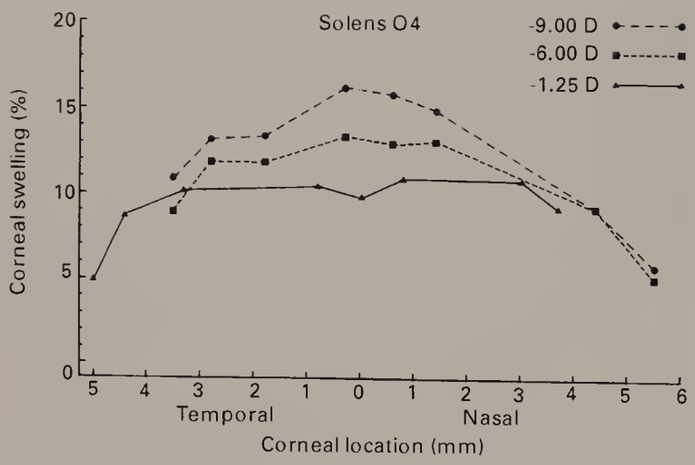


Figure 15.5 The topographical distribution of hydrogel lens-induced corneal oedema is shown in this graph of average overnight corneal swelling versus horizontal corneal location. Ten unadapted subjects wore Bausch & Lomb Soflens O4 series contact lenses continuously for a period of one week. All subjects wore –1.25 D lenses on one eye; half wore –6.00 D lenses and half wore –9.00 D lenses on the other eye. Significantly less swelling occurred in the peripheral cornea compared to the centre. (●) –9.00 D; (■) –6.00 D; (▲) –1.25 D. (From Holden, McNally *et al.*, 1985, by permission)



Figure 15.6 Striae begin to appear when approximately 5–6% corneal oedema occurs. They appear as fine, usually vertically oriented greyish-white, wispy lines in the posterior stroma. They need to be differentiated from nerve fibres, the latter being more regular in appearance and with obvious bifurcations. Striae are thought to represent a refractile effect due to fluid separation of fine, vertically oriented collagen fibrils in the posterior stroma. (From Zantos and Holden, 1978 by permission)

the anterior corneal surface to maintain normal epithelial metabolism. Thus stromal oedema is an important physiological indicator of epithelial hypoxic stress. Corneal oedema has been suggested as an aetiological factor in corneal neovascularization (Cogan, 1949), limbal injection (Tomlinson and Haas, 1980) and changes in corneal curvature (Mandell, 1975). In addition, chronic hypoxia, of which stromal oedema is an important index, can have a significant effect on corneal structure and function in the long term (Holden, Sweeney *et al.*, 1985). Thus it is desirable to attempt to eliminate or reduce contact lens-induced stromal oedema.

Stromal oedema accompanying hydrogel lens wear is evenly distributed across most of the cornea, although there is significantly less swelling in the extreme periphery than in the central cornea (Bonanno and Polse, 1985; Holden, McNally *et al.*, 1985), as shown in *Figure 15.5*. The lower swelling response of the peripheral cornea is thought to reflect a reduced swelling capability due to physical restraint in the limbal region.

The diffuse nature of hydrogel lens-induced stromal oedema makes it difficult to visualize with the slit lamp, as there is minimal light scatter in the stroma unless the oedema is severe. Moderate levels of stromal oedema are also unlikely to give rise to significant patient symptoms or reductions in visual acuity. However, when the stroma swells more than 4–6%, fine striae appear at the level of the posterior stroma and Descemet's membrane (Sarver, 1971; Polse and Mandell, 1976). The striae are usually vertical, but may be horizontal or oblique (*Figure 15.6*). The presence of these fine stress lines may therefore be used to infer the presence of stromal oedema. If the stromal oedema is severe (over 12–15%), dark lines resembling folds in Descemet's membrane may also be observed (Holden, 1977; *Figure 15.7*). Folds in Descemet's membrane represent a more severe buckling at the posterior stroma than striae, and usually indicate that stromal oedema has reached clinically unacceptable levels (*see also* Appendix D).

La Hood and Grant (1990) suggested that the percentage corneal oedema can be estimated by counting the number of striae and folds. They found that the presence of one stria correlated with a mean oedema response of approximately 5%, five striae with 8% oedema, and ten striae with 11% oedema. The presence of one fold suggests 8% oedema, five folds indicate 11% oedema and ten folds 14% oedema. By using this approach, the contact lens practitioner has an easy and clinically applicable method for estimating the individual patient's overnight corneal oedema response during extended lens wear, provided the patient is seen early in the morning after overnight lens wear.

The most direct and accurate way of quantifying stromal oedema is by measuring changes in corneal thickness using a pachometer. Although not widely used in clinical practice, pachometry provides a valuable means to detect and monitor subtle levels of stromal oedema which may not be detectable by slit lamp examination (*see* Chapter 6).

As mentioned previously, Efron and Carney (1979) showed that current-generation hydrogel lenses did not

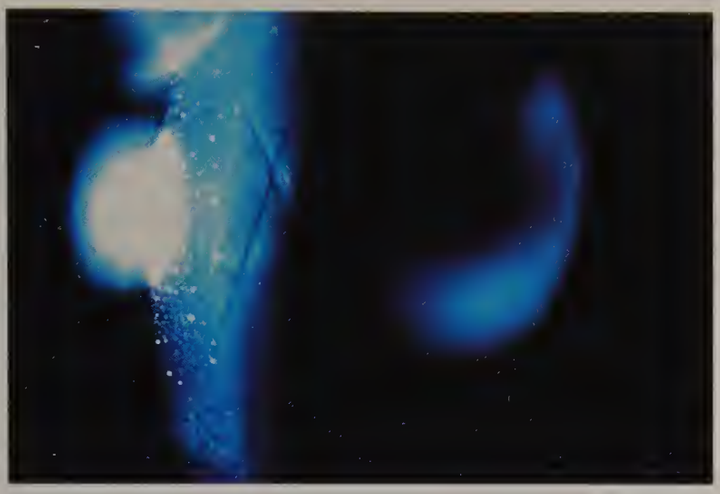


Figure 15.7 Stromal folds form in the posterior stroma and Descemet's membrane when corneal oedema reaches more than 10–12%. They are thought to represent a physical buckling of the posterior corneal layers, as in this case of a patient with 19.6% central corneal oedema induced by a tightly fitted soft lens. (From Zantos and Holden, 1978, by permission)

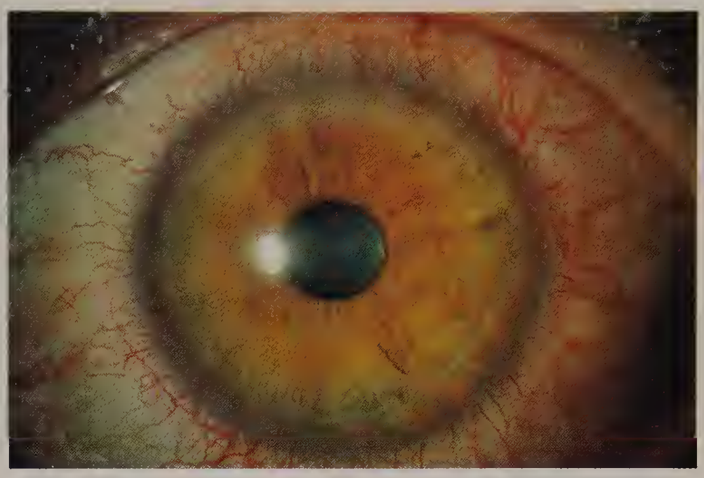


Figure 15.8 The contact lens-induced acute red eye (CLARE) reaction. (Courtesy of R. Terry)

provide enough oxygen during overnight wear to maintain normal epithelial functioning. Thus some corneal oedema is invariably present on eye opening during hydrogel extended wear. Holden, Mertz and McNally (1983) found average overnight oedema levels of 9.7–15.1% with a range of extended wear hydrogel lenses. They also found that the level of oedema reduced quite rapidly following eye opening to reach levels of 1.6–5.8% after 12 hours of open-eye wear. This 'oedema cycle', shown in *Figure 15.2*, of high overnight swelling, followed by partial recovery during the open-eye phase, is repeated with each overnight wear of lenses.

Zantos and Holden (1978) and Schoessler and Barr (1980) reported that corneal swelling accompanying extended wear reaches a peak during the first week of wear and declines thereafter, suggesting some adaptation to the reduced oxygen supply. However, Holden, Sweeney *et al.* (1985) suggested that stromal thinning due to chronic hypoxia may mask stromal oedema to some extent after long-term extended wear, and a period without lens wear is needed in order to determine the true level of contact lens-induced oedema.

Holden and Mertz (1984) derived the critical hydrogel lens oxygen transmissibility needed to limit overnight corneal oedema to 4%, the level experienced without a contact lens on the eye. This ideal level of oxygen transmissibility (*Dk/t*), based on published nominal Dk values for hydrogel lenses, was found to be 87×10^{-9} (cm ml O_2)/(s ml mmHg). This cannot be provided by current hydrogel lens materials, as average lens thickness would have to be reduced well below the limits of manufacturing feasibility. These authors therefore proposed an interim alternative criterion for acceptability of hydrogel lenses for extended wear. This compromise criterion of zero residual swelling, allowing 8% overnight oedema with subsequent recovery of normal corneal thickness during daytime wear, yielded a minimum desirable oxygen transmissibility of 34×10^{-9} (cm ml O_2)/(s ml mmHg). The lens thickness necessary to achieve this *Dk/t* appears to be feasible from a manufacturing point of view, at least for high water content lenses (> 75% water) where a maximum average lens thickness of 0.117 mm is indicated. However, as mentioned earlier, thin high water content lenses induce unacceptable levels of desiccation staining due to lens dehydration (Holden, Sweeney and Seger, 1986).

Contact lens-induced acute red eye (CLARE) reaction

The contact lens-induced acute red eye (CLARE) reaction, also occasionally called the 'tight lens syndrome' or non-ulcerative keratitis, is an acute complication of extended hydrogel lens wear, alarming for both patient and practitioner. The patient symptoms are characteristic – sudden onset, with the patient usually waking in the night with ocular pain and redness, tearing and photophobia. Clinical signs include marked conjunctival and limbal hyperaemia, and small patches of subepithelial infiltrates invading the cornea from the limbus. The typical clinical appearance of a CLARE reaction is shown in *Figures 15.8* and *15.9*. If the patient has not removed the lens, the lens may be relatively tight and immobile, although this is by no means a universal finding. In some cases, large flakes of debris may be observed apparently trapped behind the lens (Mertz and Holden, 1981). On lens removal, epithelial staining may be present, often corresponding to the pattern of tear debris. In severe cases a uveal response may be triggered, with aqueous flare and keratic precipitates.

Zantos and Holden (1978) suggested that this condition represents an inflammatory reaction to toxic substances released by the breakdown of cellular debris which has accumulated behind the lens (*Figure 15.3*). The presence of large numbers of inflammatory cells (neutrophils) together

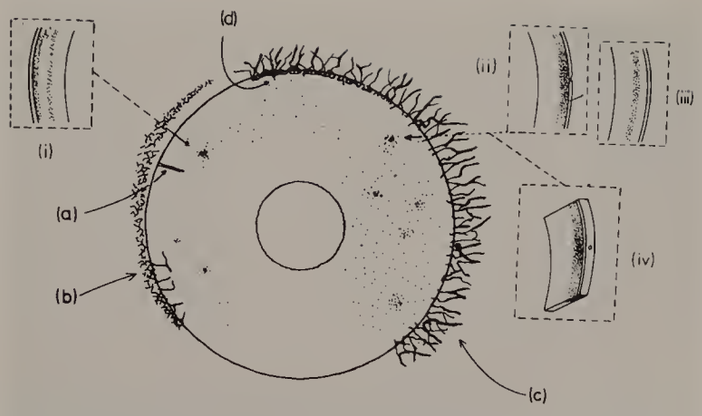


Figure 15.9 Composite diagram of some typical features of the external eye appearance in patients with a contact lens-induced acute red eye (CLARE) reaction during extended lens wear. (*a*) Midstromal blood vessel invasion; (*b*) perilimbal ring of vessel injection; (*c*) marked engorgement of bulbar conjunctival and ciliary blood vessels; (*d*) engorgement of limbal capillary plexus. Insets: (*i*) optic section near epithelial lesion, showing two distinct depths of stromal infiltrates separated by a layer of clear stroma; (*ii*) epithelial lesion with associated anterior stromal infiltrates; (*iii*) deeper stromal infiltrates adjacent to epithelial lesion in (*ii*); (*iv*) parallelepiped of section (ii) showing sharp demarcation between infiltrated and clear stroma. (From Zantos and Holden, 1977a, by permission)

with mucus and squamous epithelial cells in the post-lens debris recovered from a 'red-eye' patient, as reported by Mertz and Holden (1981), lends support to this hypothesis. The concurrent appearance of infiltrates, which indicates that leucocytes have been mobilized to invade the cornea from the limbal vessels (Josephson and Caffery, 1979), further underlines the inflammatory nature of this response. It is also possible that substances absorbed into or adsorbed onto the lens material may precipitate this acute inflammatory response (Kotow, Grant and Holden, 1987).

The role of bacterial lens contamination in CLARE reactions and other inflammatory responses has also received some attention. Baleriola-Lucas and colleagues (1991a,b) reported that patients who experience CLARE reactions form a subgroup of patients who repeatedly show high levels of Gram-negative bacteria on their lenses. While these bacteria may not cause frank corneal infection, it is possible that the release of endotoxin from the breakdown of the polysaccharide cell walls of these bacteria during eye closure may play a role in precipitating acute inflammation. Although Phillips *et al.* (1986) were unable to simulate a CLARE reaction in rabbits using endotoxin-coated lenses, this may reflect the selection of an inappropriate animal model. Further work in this area is being actively pursued.

The aetiology of the CLARE reaction may be further clarified in the light of more recent work on the nature of the tear film in the closed eye. During eye closure the tear film changes from a dynamic fluid layer rich in reflex tears to a relatively stagnant layer rich in secretory IgA (Sack *et al.*, 1992). This is accompanied by increases in albumin concentration, activation of complement and plasminogen, and the recruitment of polymorphonuclear cells into the tear film (Wilson *et al.*, 1989; Sack *et al.*, 1992; Vannas *et al.*, 1992; Tan *et al.*, 1993). Taken together, these changes in tear film composition suggest that the closed eye is in a state of subclinical inflammation. While this state may be important in protecting the vulnerable ocular surfaces from entrapped pathogens, it may also render the anterior ocular structures more susceptible to acute inflammatory responses. Thus it is possible that the presence of a contact lens and associated inflammatory stimuli in this environment may combine to precipitate an acute inflammatory reaction.

Extended wear patients should be advised to remove their lenses immediately if a CLARE reaction occurs, and to consult their practitioner promptly in the morning. Lens removal generally gives considerable relief from symptoms, although cold compresses may be helpful to relieve ocular discomfort. Patients should be seen as soon as possible in the morning, and again later in the day following the episode. If the epithelium has not healed at this time or if there are signs of a sustained uveal reaction, referral to an ophthalmologist is advisable. The patient may notice some ocular irritation, photophobia and tearing over the following 2 days, and infiltrates may take weeks to resolve. Lens wear should be discontinued during this period, and a new lens should be issued when lens wear recommences once the cornea is clear, preferably with more frequent lens removal (daily if possible).

The incidence of CLARE during hydrogel extended wear varies with lens type, wearing schedule, care and maintenance regimen, and lens replacement frequency. Undoubtedly, patient compliance is also a factor. At the Cornea and Contact Lens Research Unit (CCLRU), Sydney, we have recorded incidences of CLARE of approximately 30% and 15% per patient-year during conventional (non-replaced) extended wear of high and low water content lenses, respectively (Grant, 1991). This has been reduced to less than 6% per patient-year by instituting regular lens replacement or disposable extended wear. It should be noted that patients who have experienced a CLARE reaction have as much as a 50% chance of recurrence if they continue in extended wear (Sweeney *et al.*, 1993), suggesting that sensitization to precipitating stimuli may occur.

There are several ways in which the incidence of CLARE reactions can be minimized. It is essential to ensure that the lens moves freely over the cornea to facilitate the flushing of tear debris from behind the lens. It must be kept in mind that environmental changes under the closed lid will often tighten a lens fit leading to inadequate lens movement on awakening. Rigorous care and maintenance procedures, including frequent overnight lens removal, careful lens cleaning and disinfection, use of an enzymatic cleaner, and regular replacement or disposal of lenses, also reduce the incidence of CLARE reactions (Kotow, Grant and Holden, 1987; Grant, 1991). The former authors reported a disturbingly high incidence of CLARE reactions (56% after 12 months of extended wear) in patients using heat disinfection with high water content lenses, suggesting that heat is not an appropriate method for disinfecting these lenses. The

incidence of CLARE reactions generally appears to be greater with high water content lenses. This may be due to their propensity to absorb contaminants more easily than low water content lenses, and their more rapid ageing and spoiling.

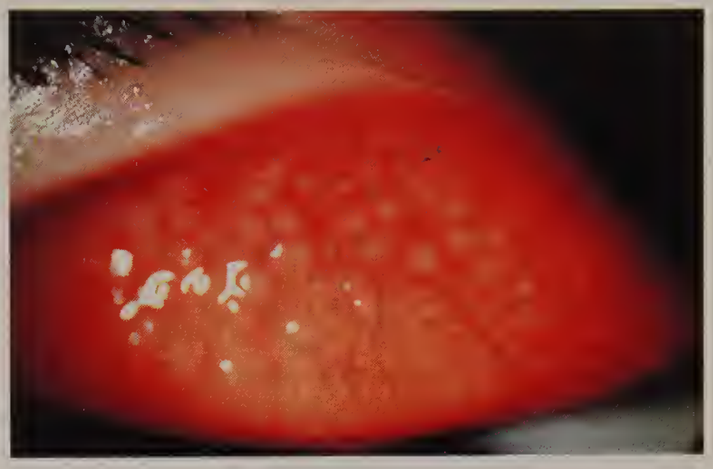
Contact lens-induced papillary conjunctivitis (CLPC) or giant papillary conjunctivitis (GPC)

Giant papillary conjunctivitis (GPC) is characterized by pronounced papillary hypertrophy and hyperaemia of the upper tarsal conjunctiva (*Figure 15.10*), with excess mucus discharge and ocular itching and discomfort. This condition has been likened to vernal conjunctivitis (Allansmith *et al.*, 1977; Collin, 1980, 1981), and may be precipitated by both hard and soft contact lens wear (Allansmith *et al.*, 1977), although it is much more likely to occur with soft lens wear. GPC has also been reported in association with ocular prostheses (Srivinasan *et al.*, 1979), protruding suture ends following anterior ocular surgery (Reynolds, 1978; Sugar and Meyer, 1981), tissue adhesive used to seal a corneal perforation (Carlson and Wilhelmus, 1987), and elevated corneal scarring (Dunn *et al.*, 1990).

GPC was first described by Spring (1974) who reported 78 cases in a population of 170 long-term daily wear soft contact lens wearers. Allansmith *et al.* (1977) described the condition in more detail and reported its occurrence with both hard and soft contact lens wear. There have since been many reports of GPC in association with extended soft lens wear (Mackie and Wright, 1978; Kotow, Grant and Holden, 1987).

Because patient symptoms and changes in the appearance of the palpebral conjunctiva during contact lens wear may be noted well before the condition reaches its terminal stage with the appearance of 'giant' papillae, it has been suggested (Barishak *et al.*, 1984; Kotow, Grant and Holden, 1987) that it is more appropriate to describe the condition, in association with contact lens wear, as 'contact lens-induced papillary conjunctivitis' or CLPC, a suggestion that we will follow. CLPC, shown in *Figure 15.10a*, may progress to the more severe condition of GPC (*Figure 15.10b*) if there is a failure to detect and appropriately manage the condition. In association with contact lens wear, CLPC generally causes reduced lens tolerance and may result in temporary or permanent discontinuation of lens wear. Although the condition may be unilateral, both eyes are usually affected. The incidence of CLPC during hydrogel extended wear studies conducted at the CCLRU is approximately 15–20% per patient-year during conventional (non-replaced) extended wear, reducing to less than 6% per patient-year during disposable extended wear studies.

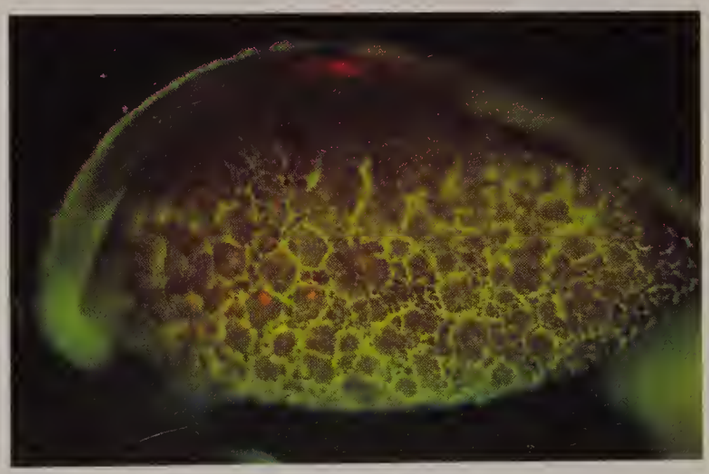
In its early stages, CLPC is characterized more by mild patient symptoms than by obvious clinical signs. Often direct questioning of the patient is necessary to elicit early symptoms which include mild mucus discharge evident in the nasal corner of the eye on awakening, and itching of the eyes on lens removal. As the condition progresses, however,



(a)



(b)



(c)

Figure 15.10 Giant (GPC) or contact lens-induced papillary conjunctivitis (CLPC) of the upper palpebral conjunctiva is a common complication of contact lens wear. The typical clinical appearance of CLPC is shown in (*a*) and the more severe condition of GPC is illustrated in (*b*). Instillation of fluorescein can aid in visualization of the condition (*c*), because the dye collects in the channels between the papillae. (Courtesy of T. Grant)

the patient will complain of increasing stringy mucus discharge and watering during the day, blurring of vision due to lens deposits or mucus, excessive lens movement, occasional lens displaeement, and intense itching and lens awareness after a period of lens wear, which may become severe enough to limit wearing times and eventually lead to complete lens intolerance.

The clinical signs of CLPC also follow a progressive course, although the severity of symptoms is not always related to the clinical picture. Eversion of the upper eyelid is necessary to detect CLPC in what may otherwise appear as a normal quiet eye. The instillation of fluorescein is often useful in revealing early papillary changes during slit lamp examination, because the fluorescein collects in the channels between the papillae (*Figure 15.10c*).

Allansmith *et al.* (1977) have categorized tarsal conjunctival appearance into four categories corresponding to stages in the development of the condition. In the early stages, the palpebral conjunctiva may retain its normal satin-smooth appearance free of papillary changes in the presence of mild symptoms. The next stage, which is accompanied by moderate symptoms of mucus discharge and itching, is characterized by the appearance of uniform small elevated papillae (4–8 per mm), and mild hyperaemia of the palpebral conjunctiva. In association with soft lens wear, the papillae are typically localized over the tarsus above the tarsal fold. As the condition progresses, larger non-uniform papillae develop, and increased lens awareness, mucus discharge and excessive lens movement or displacement are often reported. The appearance of 'giant' papillae, 1 mm or more in diameter, often covering all zones of the tarsal conjunctiva, marks the terminal stage in the development of GPC, and is associated with excessive stringy mucus discharge, ocular discomfort and complete intolerance to lens wear.

The aetiology of CLPC is not fully understood. Allansmith *et al.* (1977) suggest that the condition is immunological in origin and noted, on the basis of their histological findings, that it shows the characteristics of a cutaneous basophilic hypersensitivity reaction. They hypothesized that the antigen initiating the tissue response is a product of deposits on the lens surface rather than the lens material itself. Fowler *et al.* (1979b) noted that surface deposits on soft lenses worn by patients with CLPC were indistinguishable from those on lenses worn by asymptomatic patients, suggesting that individual patient susceptibility may be an important factor. Because the condition may also be stimulated by trauma from exposed suture ends following anterior ocular surgery for example (Reynolds, 1978; Sugar and Meyer, 1981), a mechanical component has also been suggested. It is possible, therefore, that irritation of the palpebral conjunctiva by the contact lens edge or deposits or irregularities on the lens surface allows access of the antigen to the mucous membrane, initiating the hypersensitivity reaction in susceptible individuals (Molinari, 1983).

A number of approaches to the management of CLPC have been proposed. Early recognition of the condition and prompt initiation of appropriate therapeutic measures are important factors in arresting its progression. Cessation of lens wear generally leads to relief of symptoms within 2–5 days (Allansmith *et al.*, 1977). However, clinical signs may persist for weeks or months, and resumption of lens wear without adopting an appropriate management strategy will frequently precipitate the return of symptoms.

Dispensing a fresh lens of the same material and design may allow resumption of lens wear in some patients in the early stages of the condition (Spring, 1974; Allansmith *et al.*, 1977). Grant *et al.* (1988) reported successful rehabilitation of CLPC sufferers through the use of a daily wear, daily disposal regimen for 6 weeks, followed by the gradual resumption of extended wear with weekly lens disposal. Others have reported successful management of early CLPC using a weekly disposal regimen while continuing with extended wear (Perryman, 1988; Strulowitz and Brudno, 1989). There is considerable evidence that the institution of a schedule of regular lens replacement or the use of disposable lenses from the beginning of lens wear reduces the incidence of CLPC (Grant, 1991; Boswall *et al.*, 1993).

Changing the solutions used to disinfect the lens, in particular avoiding preserved solutions (Molinari, 1981), and introducing regular use of an enzymatic cleaner (Allansmith *et al.*, 1977; Mackie and Wright, 1978; Kotow, Grant and Holden, 1987) may also interrupt progression of the condition. Resolution of symptoms has been reported with the use of systemic tetracycline (Mackie and Wright, 1978), or sodium cromoglycate ophthalmic solution (cromolyn sodium), a mast cell stabilizer (Meisler *et al.*, 1981; Molinari, 1991; Kruger *et al.*, 1992). Vitamin A drops have also been reported to alleviate the condition (Molinari and Rengstorff, 1988; Schultz, 1990).

Until the aetiology of the condition is more fully understood, management of CLPC in the clinical situation requires a trial and error approach to identify the most appropriate measures to relieve patient symptoms and encourage resumption of lens wear in each individual case. Although success rates as high as 90% have been reported (Schultz, 1990), a significant number of patients who develop CLPC are unable to resume lens wear at all despite intensive therapeutic measures. This emphasizes the importance of early detection and intervention in the clinical management of this condition (*see also* Chapter 18 and Appendix D).

Corneal infection (*see also Chapter 4*)

The acute complication of contact lens wear that causes the most concern is corneal infection (also termed ulcerative, microbial or suppurative keratitis). When corneal ulceration occurs involving the stroma, corneal scarring remains after resolution of the infection; if the scar is located in the central cornea, vision will be affected and keratoplasty may be required to restore useful vision.

Until the 1980s, microbial keratitis was rarely seen in normal healthy eyes, and was typically associated with trauma or corneal surface disorders. However, early reports

in the 1970s from the United Kingdom (Ruben, 1976) and Australia (Cooper and Constable, 1977; Zantos and Holden, 1978) warned of the potential for serious corneal infections in association with extended hydrogel lens wear. With the increasing popularity of this lens-wearing modality in the 1980s, the incidence of this complication soared, with a plethora of reports in the scientific literature (Adams *et al.*, 1983; Salz and Schlanger, 1983; Spoor *et al.*, 1984; Weissman *et al.*, 1984, to cite a few) and in the popular press (*Time*, 27 January, 1986, p. 57). It is now recognized that contact lens wear, and in particular extended hydrogel lens wear, is a significant risk factor in the development of corneal infection. Recent reports indicate that the majority of cases of microbial keratitis seen at major eye centres in the United States and United Kingdom are contact lens-related, and this trend appears to be increasing (Dart, 1988; Schein, Ormerod *et al.*, 1989; Dart *et al.*, 1991; Slack, 1993).

Fortunately, the incidence of corneal infections with contact lens wear is low. For cosmetic extended hydrogel lens wear, annualized incidences of approximately 0.2% have been reported from large-scale studies (Poggio *et al.*, 1989; MacRae *et al.*, 1991; Weissman and Mondino, 1993). Case-control studies have clearly demonstrated that hydrogel lens extended wear carries an increased risk of corneal infection compared to rigid lens extended wear, or rigid and hydrogel lens daily wear. The risk associated with cosmetic hydrogel extended wear has been estimated as up to 10–15 times greater than for daily wear of hydrogel lenses (Chalupa *et al.*, 1987; Schein, Glynn *et al.*, 1989; Dart *et al.*, 1991; Buehler *et al.*, 1992; Matthews *et al.*, 1992; Schein *et al.*, 1994).

Causative organisms

Corneal infection may be initiated by a variety of pathogens including bacteria, amoebae, fungi and viruses. One of the most feared organisms, however, is the Gram-negative bacterium *Pseudomonas aeruginosa*, because of the rapid course of the infective process and its devastating effects. *P. aeruginosa* is an opportunistic organism commonly found in water, sewage and soil, and is known to contaminate basins, sludge areas and toilets. It is generally considered that a break in the epithelium is required for the organism to gain entry to the corneal tissue (Stern *et al.*, 1982, 1985), although it is possible that the bacteria may invade superficial epithelial cells (Fleiszig *et al.*, 1994). The infective process after inoculation can be extremely rapid, with the potential for severe stromal scarring, corneal perforation and loss of the eye (Raber *et al.*, 1981). Pseudomonas spp. are the most common pathogens causing corneal infections in cosmetic soft extended lens wearers (Adams *et al.*, 1983; Galentine *et al.*, 1984; Weissman *et al.*, 1984; Derick *et al.*, 1989; Schein, Ormerod *et al.*, 1989). This contrasts strikingly with the predominance of Gram-positive corneal infections in the non-contact lens-wearing population (reviewed by Weissman and Mondino, 1993), and in association with therapcutic contact lens wear (Kent *et al.*, 1990).

Amoebic organisms of the genus Acanthamoeba have more recently gained prominence as potential pathogens in contact lens-related corneal infection (see reviews by Auran *et al.*, 1987; also Moore *et al.*, 1987). Although infections with these organisms are less common than are *Pseudomonas* infections, a survey by Stehr-Green *et al.* (1989) found that 85% of cases of *Acanthamoeba* keratitis recorded in the US since 1973 have been associated with contact lens wear. For soft contact lens wearers, significant risk factors for the development of Acanthamoeba keratitis include the use of home-made saline, wearing lenses while swimming and infrequent lens disinfection (Moore *et al.*, 1987; Stehr-Green *et al.*, 1987).

The clinical course of *Acanthamoeba* keratitis is prolonged, with periods of remission and resurgence. Unfortunately, the potential for eradication of the pathogen from the tissue by pharmacological intervention is moderate at best, and keratoplasty remains an important management option. This is because *Acanthamoeba* can exist as either active trophozoite or dormant double-walled cyst within the corneal tissue, and in its cystic stage the organism is particularly resistant to pharmacological agents.

The practitioner should be aware that corneal infection caused by other bacteria (including *Staphylococcus spp., Bacillus spp.* and *Serratia spp.*), fungi (such as *Candida spp.* and *Aspergillus spp.*) and viruses (such as Herpes simplex) may also occur in association with contact lens wear. Apart from the possibility that these infective organisms may be introduced to the eye via a contaminated contact lens, however, a clear aetiological link between contact lens wear and infections due to these organisms has yet to be established (*see* Chapter 4).

Predisposing factors

The cornea is normally protected from infection by antibacterial agents in the tears, including lysozyme, β-lysin and lactoferrin, and by the barrier properties of the epithelium. Corneal abrasion, erosion and trauma associated with contact lens wear compromise the epithelial barrier, providing an opportunity for pathogens to invade and infect the corneal tissue. This risk may be exacerbated by the reduced corneal sensitivity (Millodot, 1978), increased epithelial fragility (O'Leary and Millodot, 1981), and prolonged cell residence time before exfoliation (Lemp and Gold, 1986) associated with long-term contact lens wear.

In addition, more subtle compromise of epithelial function due to the effects of chronic hypoxia may impair the normal epithelial defence against invading organisms. Madigan *et al.* (1987) reported that soft contact lens-induced hypoxia can significantly reduce epithelial adhesion, by reducing the density of hemidesmosomes at the basal layer (Madigan and Holden, 1992). This may provide an explanation for the SLACH (soft lens-associated corneal hypoxia) syndrome (Wallace, 1986; Lindsay *et al.*, 1993), whereby there is spontaneous loss of large areas of epithelium during lens wear (*Figure 15.11*). Delayed epithelial wound healing under contact lenses (Mauger and

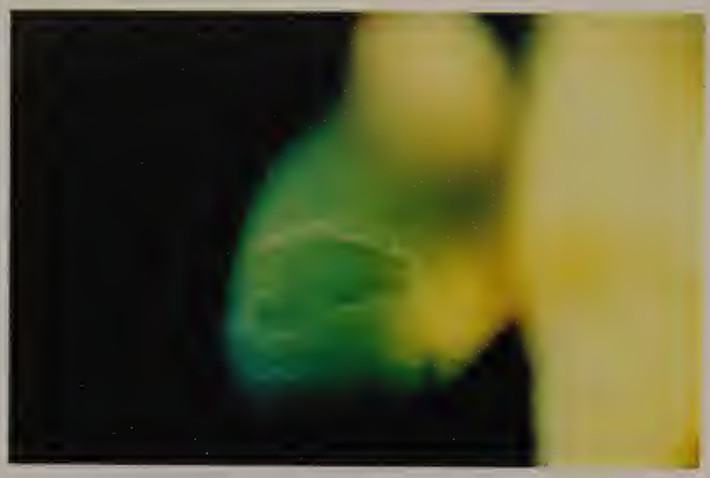


Figure 15.11 SLACH (soft lens-associated corneal hypoxia) syndrome where there is spontaneous loss of up to 40% of the epithelial surface during lens wear (From Holden and Swarbrick, 1991, by permission)

Hill, 1992) may also increase the risk of opportunistic infection.

There has also been some recent interest in the direct and indirect effects of contact lens wear on the integrity of the mucous layer of the tear film and the underlying glycocalyx, both of which are thought to play a key role in maintaining epithelial barrier function. For example, Fleiszig, Efron and Pier (1992) reported increased adherence of Pseudomonas organisms to corneal epithelial cells following extended lens wear; a similar effect was found for cornea stripped of its mucous layer by the application of mild acid or the mucolytic acetyl cysteine (Fleiszig, Fletcher and Pier, 1992). Imayasu and co-workers (1994) reported increased corneal adherence of *Pseudomonas aeruginosa* following 24 hours of lens wear. They found that the *Dk/t* of the lenses worn was inversely related to the level of bacterial adherence, and also to the extent of subtle epithelial damage induced by lens wear.

Not surprisingly, inadequate disinfection procedures and contaminated lens storage solutions and cases have been identified as the source of the invading pathogen in some cases of corneal infection (Cooper and Constable, 1977; Weissman *et al.*, 1984; Sweeney *et al.*, 1992). Bowden and co-workers (1989) reported non-compliance to lens care as a feature in 88% of patients with contact lens-related microbial keratitis in their series of 24 patients. However, the significance of this route during extended wear remains unclear. Controlled studies have failed to identify non-compliance to normal lens care as a significant risk factor (Schein, Glynn *et al.*, 1989; Dart *et al.*, 1991; Matthews *et al.*, 1992; Schein *et al.*, 1994). Furthermore, it would be expected that this route would be more significant during daily lens wear, where contact between lenses and contaminated solutions can occur more frequently. However, Bowden *et al.* (1989) suggested that extended lens wearers, who use less volume of solutions overall in their normal lens care, may continue to use old contaminated solutions rather than discard bottles with unused contents.

Handling of the lenses with unwashed fingers may also introduce pathogens to the eye (Cooper and Constable, 1977). Indeed, Adams *et al.* (1983) and Galentine *et al.* (1984) reported cases which suggest a direct association between recent lens manipulation and the onset of corneal infection during extended wear. However, it would be expected that contamination associated with lens handling would be more frequent during daily wear. Furthermore, it has been suggested that the normal antimicrobial action of tear components such as lysozyme can significantly reduce the microbial load introduced by lens handling (Mowrey-McKee *et al.*, 1992).

Studies at the CCLRU indicate that overnight eye closure is associated with an increase in normal conjunctival microbiota (Ramachandran *et al.*, 1995). Proliferation of entrapped pathogens during closed-eye lens wear may therefore play a role in extended wear infections. In addition, the low tear exchange behind hydrogel lenses during open-eye wear ensures that any introduced pathogens remain in proximity to the cornea (Galentine *et al.*, 1984). The ability of certain bacteria to create a protective biofilm (Slusher *et al.*, 1987) may also aid in their survival once introduced to the eye. Once established in a biofilm on a contact lens surface, it is unclear whether bacteria can then directly infect the tissue; however, if the bacteria proliferate, their progeny may be free to attach to and infect the corneal tissue.

A number of factors may exacerbate the severity of extended wear infections. Delay in removing lenses and in seeking treatment have been identified as particularly significant predisposing factors (Cooper and Constable, 1977; Salz and Schlanger, 1983; Lemp *et al.*, 1984). Unfortunately, in some cases this delay may be attributable to inadequate patient instruction and poor patient follow-up by practitioners. Furthermore, certain extended wear patients, such as elderly aphakes, have difficulty in handling lenses; indeed this is often the initial reason for prescribing extended wear lenses. As a consequence the lenses may not be removed immediately if problems such as discomfort, redness or blurred vision occur, increasing the risk of a severe outcome (Derick *et al.*, 1989).

It is not surprising that the use of extended wear lenses for therapeutic purposes carries an increased risk of corneal infection, due to the frequent presence of concomitant disease and epithelial compromise (Dohlmann *et al.*, 1973; Kent *et al.*, 1990). Elderly aphakic extended lens wearers are also at greater risk (Graham *et al.*, 1988), as they frequently show reduced corneal sensitivity and tear secretion (Salz and Schlanger, 1983; Galentine *et al.*, 1984), and concomitant diseases such as arthritis, keratoconjunctivitis sicca and blepharitis (Lemp *et al.*, 1984), which may act as predisposing factors for severe progression of the infective process.

Other factors which appear to increase the risk of a severe progression of corneal infection include diabetes (Eichenbaum *et al.*, 1982; Spoor *et al.*, 1984), concomitant immune disease (Chalupa *et al.*, 1987), lens wear in warm climates (Leisegang and Forster, 1980; Sjöstrand *et al.*, 1981), and

the initiation of inappropriate antibiotic (Galentine *et al.*, 1984; Derick *et al.*, 1989) or corticosteroid therapy (Eichenbaum *et al.*, 1982; Adams *et al.*, 1983; Chalupa *et al.*, 1987; Derick *et al.*, 1989).

Clinical detection and management

The clinical detection of corneal infection is usually initiated by patient symptoms, which may range from mild ocular discomfort and foreign body sensation through to severe ocular pain, redness and heavy discharge. Any corneal erosion accompanied by corneal infiltrates should be treated as a potential corneal infection, and should be presumed to be due to Pseudomonas until proven otherwise. In severe infections, corneal erosion with dense stromal infiltration, severe conjunctival hyperaemia and mucopurulent discharge may be noted. Hypopyon and aqueous flare may also be present, indicating a more severe anterior segment response.

Immediate (bilateral) lens removal and prompt referral for ophthalmological treatment, preferably by a corneal specialist, are imperative because of the frequent presence of highly virulent organisms. Treatment usually involves intensive and aggressive topical and subconjunctival antibiotic therapy, prescribed on the basis of culture of corneal scrapings, which will frequently determine the drug sensitivity of the infective organism. Corticosteroid treatment is strongly contra-indicated, because its use is associated with severe progression of the disease (Eichenbaum *et al.*, 1982; Adams *et al.*, 1983; Chalupa *et al.*, 1987; Derick *et al.*, 1989). Hospitalization may be necessary in severe cases, or where non-compliance is anticipated. The use of intravenous medication may be indicated if the integrity of the globe is threatened. Sequelae in the form of central or peripheral corneal opacities are to be expected if the stroma is involved, and further surgical intervention, such as keratoplasty, may be necessary after resolution of the infection in order to restore useful vision.

The risk of corneal infection can be reduced by careful patient management. It is important to emphasize to extended wear patients that lenses must be removed and the practitioner contacted immediately if any unusual redness, discomfort or blurred vision occurs, particularly in one eye only. The practitioner should ensure, in the case of elderly aphakic patients or children, that a competent companion or family member is available to remove the lenses under these circumstances. Rigorous patient instruction on lens disinfection and handling procedures is also necessary to reduce the risk of introducing pathogens into the eye.

Although it has previously been suggested that the risk of corneal infection may be reduced by limiting the frequency of lens removal and handling during extended wear (Adams *et al.*, 1983; Galentine *et al.*, 1984), the authors believe that regular overnight lens removal, at least once a week, for lens disinfection and to rest the cornea from hypoxia, is a more appropriate way of ensuring lens hygiene and maintaining corneal health. In fact, Grant *et al.* (1987) report that other lens-related complications are significantly reduced if hydrogel extended wear is limited to 1–2 nights per week. Certainly, it is recommended that extended wear should not exceed 6 nights of lens wear per week, in line with current FDA guidelines.

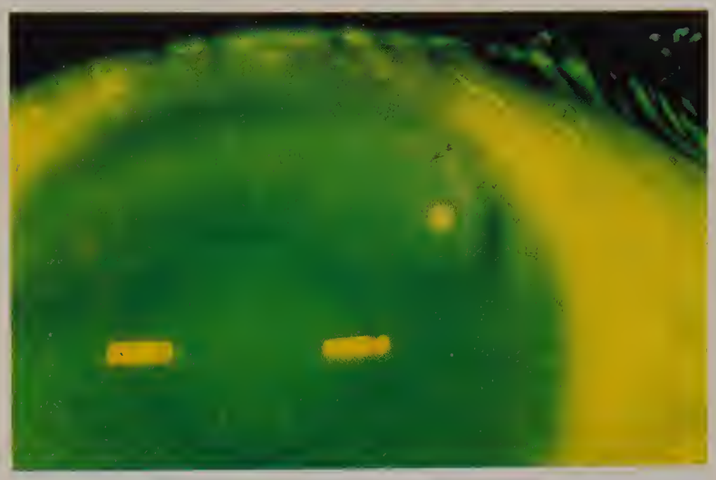


Figure 15.12 Culture negative peripheral ulceration (CNPU) epithelial lesion in the mid-periphery, at 2 o'clock position. (From Swarbrick and Holden, 1993, by permission)

Finally, minimizing the chronic hypoxic stress experienced by the cornea during extended wear will help to maintain epithelial integrity. This can be achieved with hydrogel lenses by fitting lenses with high *Dk/t* values, ensuring adequate lens movement and instituting a care regimen of frequent overnight lens removal and regular lens replacement. Alternatively, RGP lenses with high *Dk/t* values may be fitted to increase corneal oxygenation during lens wear.

Culture-negative peripheral ulceration (CNPU)

Culture-negative peripheral ulceration (CNPU), which we consider to be a sterile inflammatory response, is associated almost exclusively with hydrogel extended wear, but has received relatively little attention in the scientific literature. This response, which requires careful differentiation from potential or early microbial keratitis, is characterized by the presence of one, or occasionally two, small (<2 mm diameter) circular full-thickness epithelial lesions in the peripheral or paracentral cornea, associated with stromal infiltrates (*Figure 15.12*). In CCLRU studies, these ulcers have occurred at a rate of approximately 3% per patient-year. In all cases the ulcerative episode followed a benign course and resolved within 2 weeks without pharmacological intervention.

According to Stein *et al.* (1988), the differential diagnosis of sterile versus infected corneal infiltrates hinges on the presence, size and position of any epithelial lesion, the severity of patient symptoms and the presence or absence of ocular discharge and anterior chamber reaction. At the CCLRU, we have based our diagnosis of CNPU on the presence of one or two small circumscribed peripheral lesions without raised edges, and the absence of severe

ocular pain, mucopurulent discharge and anterior chamber reaction. Associated clinical signs have included increased conjunctival and limbal hyperaemia, and subepithelial or stromal infiltrates underlying and surrounding the lesion.

CNPUs often give rise to minimal patient symptoms. In several cases seen at the CCLRU, patients did not contact their practitioner at the time of the event because of the mild nature of the symptoms, and the occurrence of a CNPU episode was detected only at a routine after-care visit on the basis of residual scarring, which takes the form of a small white circular anterior stromal opacity in the corneal periphery. More frequently, however, the patient experiences some mild to moderate ocular discomfort or foreign body sensation associated with photophobia and excessive lacrimation.

The aetiology of CNPU is unclear. Although this condition bears some resemblance to staphylococcal peripheral ulceration, the two responses differ significantly in the typical location, size and shape of the lesion, associated clinical signs, clinical course and recurrence rate (Smolin and Okumoto, 1977; Mondino, 1988). However, it is possible that CNPU represents a hypersensitivity reaction to endotoxin or exotoxin released by bacteria contaminating the lens. Further work is needed to elucidate the mechanisms underlying this response.

It is important to stress that a prudent and conservative approach to the clinical management of suspected CNPU is recommended to avoid the risk of misdiagnosis, or subsequent infectious keratitis. If medical intervention is not pursued, extreme care must be taken in diagnosis, and close patient follow-up is essential to monitor resolution of the lesion. Typically, resolution of CNPU is rapid following lens removal, and the lesion resolves completely within 2 weeks, leaving a faint circular scar in the anterior stroma. Resumption of lens wear is usually successful and the chances of recurrence appear to be low (Sweeney *et al.*, 1993).

Other acute responses

Corneal neovascularization

The growth of new blood vessels into the normally avascular cornea is a sign that the cornea is under stress and may, in itself, threaten the integrity of the tissue. Corneal neovascularization has been reported in association with therapeutic (Schecter *et al.*, 1975) and aphakic extended wear (Stein and Slatt, 1977), but less frequently in association with cosmetic extended wear, possibly because the cornea is not compromised by an underlying abnormal condition or surgical intervention.

The aetiology of corneal neovascularization is not clear, and appears to be complex and multifactorial. A variety of predisposing or triggering mechanisms have been proposed, including peripheral corneal oedema, which reduces stromal tissue compactness at the limbus (Cogan, 1949); hypoxia (Knighton *et al.*, 1983) or byproducts of altered corneal metabolism under hypoxic conditions, such as lactate (Imre, 1972; Jensen *et al.*, 1986); vasostimulatory factors released by damaged epithelial cells (Eliason, 1978) or inflammatory cells (Fromer and Klintworth, 1976; Sholley *et al.*, 1978); or locally released vasoproliferative factors associated with inflammation (Klintworth and Burger, 1983), such as plasminogen activator (Berman *et al.*, 1982; van Setten *et al.*, 1990). These stimuli may all be present during hydrogel contact lens wear.



Figure 15.13 Increased limbal vessel proliferation and hyperaemia in association with extended hydrogel lens wear and certain other conditions. (Courtesy of C. McMonnies)

Extended lens wear appears to carry a greater risk of corneal neovascularization than daily wear. This may be because of the continual presence of the lens on the eye. The chronic increased limbal vessel injection and proliferation found in extended lens wearers (Holden, Sweeney *et al.*, 1986) may also increase the risk of new vessel growth in response to a precipitating stimulus, because of the presence of an established active vascular plexus immediately adjacent to the corneal tissue.

Increased limbal vessel proliferation and hyperaemia are normal, if undesirable, findings in association with extended hydrogel lens wear (Holden, Sweeney *et al.*, 1986). Limbal vessels may be distinguished from corneal vessels by locating the translucent limbal transition zone (*Figure 15.13*) using marginal retro-illumination with the slit lamp (McMonnies *et al.*, 1982). Vessels extending beyond this zone into the cornea, particularly if unlooped, should be viewed with concern, and cessation of lens wear is advised. According to McMonnies (1983), although established corneal vessels may empty to become ghost vessels, they rarely regress and may refill rapidly once the vasoproliferative stimulus reoccurs. Resumption of lens wear once the



Figure 15.14 Stromal infiltrates appear as hazy, grey areas which may be focal, as shown here, or diffuse. (Courtesy of H. Rypdal)

invading blood vessels have emptied, therefore, should be undertaken with caution, after elimination of all possible causes for the initial vessel proliferation, such as hypoxia, toxic effects from lens contaminants or solutions, or traumatic causes such as damaged or heavily deposited lenses (*see also* Appendix D).

Corneal infiltrates

Infiltrative keratitis is an acute inflammatory response of the cornea, in which inflammatory cells are released from the limbal vasculature and invade the corneal tissue; the tear film has also been suggested as a source of the invading cells (Josephson and Caffery, 1979). Infiltrates are thought to comprise predominantly polymorphonuclear leucocytes, although macrophages and lymphocytes may also be present. The chemotactic stimulus to leucocyte invasion may be traumatic, viral, allergic or toxic, and may be associated with solution preservatives, poor lens fit or condition, toxic environmental stimuli, or bacterial endotoxins or exotoxins (for example in chronic blepharitis due to Staphylococcus spp.). Infiltrates are a typical finding in association with a CLARE reaction, but may also occur in the absence of any identifiable stimulus.

Although infiltrative keratitis is a recognized clinical entity in non-contact lens wearers, its occurrence in association with hydrogel lens wear is of concern because of the exacerbating influence of the lens. Infiltrative keratitis has been reported in association with both daily and extended hydrogel lens wear (Josephson and Caffery, 1979; Gordon and Kracher, 1985), although it is certainly more common during extended wear, presumably because of the continual presence of the lens on the eye and the physiological compromise of the tissue due to chronic hypoxic stress. The incidence of corneal infiltrates in the hydrogel lens-wearing population has been estimated as 4–5% (Josephson and Caffery, 1979; Gordon and Kracher, 1985).

Infiltrative keratitis may occur in an otherwise quiet eye, or may be associated with other inflammatory signs and symptoms. Corneal infiltrates are usually subepithelial or stromal, although they may also occur in the epithelium (Zantos and Holden, 1977a, 1978; Josephson and Caffery, 1979). They may be focal or diffuse, but in extended wear they are typically focal and appear as round, well-demarcated, greyish-white areas, 0.5–2.0 mm in diameter, usually separated from the limbus by a clear zone (*Figure 15.14*). Infiltrates associated with extended lens wear have been reported to occur more frequently in the superior region of the cornea covered by the upper eyelid (Gordon and Kracher, 1985), although in association with a CLARE reaction they are generally more widespread (Zantos and Holden, 1977a). While infiltrates do not usually stain with fluorescein, positive staining suggests that the overlying epithelium is compromised, and this is cause for concern because of the possibility of concomitant or opportunistic corneal infection. In these cases it is prudent to presume the presence of corneal infection, particularly if the patient is symptomatic, and to refer for appropriate antibiotic therapy.

The presence of corneal infiltrates requires cessation of lens wear until the cornea is clear. Recovery time is related to the severity of the infiltration; severe stromal infiltrates, particularly those associated with viral infection, may take up to 3 months to clear (Josephson and Caffery, 1979), while mild infiltrates may resolve within 1–2 weeks (Zantos and Holden, 1977a). Before recommencing lens wear, it is advisable to attempt to identify and eliminate any predisposing factors such as a tight lens fit, excessive lens deposition or solution preservatives. In cases associated with chronic staphylococcal blepharitis, the institution of lid hygiene measures and antibiotic therapy is recommended before resuming lens wear. Dispensing a fresh lens is a recommended procedure, and the use of disposable lenses may also prevent recurrence.

Epithelial microcysts

Epithelial microcysts are a common clinical finding in hydrogel extended lens wearers and are best detected with the slit lamp using high magnification and marginal retroillumination (Zantos and Holden, 1978; Zantos, 1983; Holden and Sweeney, 1991). They appear as tiny translucent irregular dots, approximately 10–50 μm in diameter (*Figure 15.15*), and are usually distributed in an annulus in the corneal mid-periphery (*Figure 15.16*). Because they display reversed illumination, it is thought that microcysts comprise pockets of disorganized cellular material (Bergmanson, 1987) or dead (apoptotic) cells (Madigan, 1989). Microcysts are thought to form in the deeper layers of the epithelium, and move gradually towards the epithelial surface, where they may stain with fluorescein as they break through.

The level of microcystic development has proven to be a useful clinical index of the level of chronic hypoxic stress experienced by the cornea during extended wear (Holden,



Figure 15.15 Epithelial microcysts are small inclusions displaying reversed illumination, i.e. the distribution of light within the inclusion (darker on the left side) is opposite to that of the background (darker on the right side). Microcysts are seen best by indirect illumination at the highest magnification possible. (From Swarbrick and Holden, 1993, with kind permission)

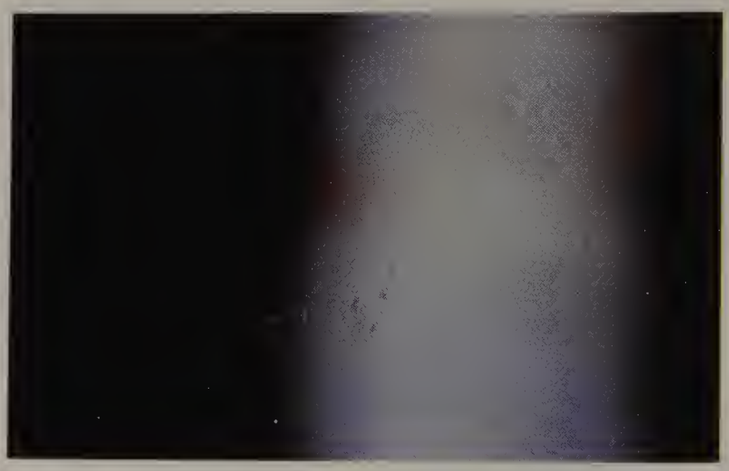


Figure 15.17 Epithelial vacuoles can be distinguished from microcysts by their more rounded shape, and their unreversed illumination, i.e. the light distribution within is the same as the background, which suggests that they represent fluid-filled inclusions. (From Terry *et al.*, 1993, by permission)

Grant *et al.*, 1987; Holden and Sweeney, 1991). Microcysts typically develop within 3 months of commencing extended lens wear, and their numbers may fluctuate thereafter, in some cases reaching as many as several hundred (Holden and Sweeney, 1991). Following cessation of lens wear, the number of microcysts increases temporarily, due to the resurgence of normal epithelial metabolic activity and the increased rate of elimination of metabolic waste products from the cornea (Holden, Sweeney *et al.*, 1985). As normal metabolism is re-established, the number of microcysts decreases, and complete recovery usually occurs within 3 months (Zantos and Holden, 1978; Holden, Vannas *et al.*, 1985; Holden and Sweeney, 1991). The slow rate of development and recovery of microcysts suggests that they represent fundamental changes in tissue synthesis processes in the epithelium.

Although microcysts indicate that the epithelium is compromised, they may be considered to be an inevitable consequence of hydrogel extended lens wear, and should not cause concern unless marked epithelial disruption or more than 50 microcysts are present (Zantos, 1983). In these circumstances it may be advisable to return the patient to daily wear until the epithelium regains a more normal clinical appearance. Recurrent excessive microcystic development is indicative of severe chronic hypoxic stress, and should be managed by refitting the patient with lenses of higher *Dk/t* value (Holden and Sweeney, 1991), reducing the number of nights of lens wear per week (Grant *et al.*, 1987), or returning the patient to a daily wearing schedule.

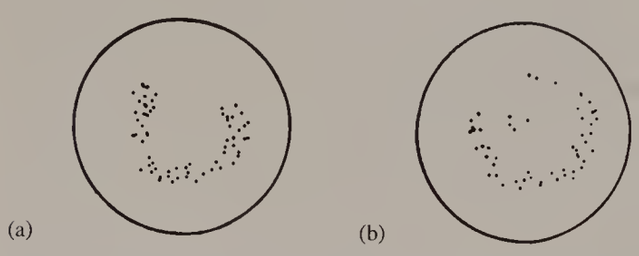


Figure 15.16 Schematic representation of the distribution of epithelial microcysts, in an annulus in the corneal mid-periphery, in one patient after 23 weeks of extended hydrogel contact lens wear. (*a*) Right eye; (*b*) left eye. (From Zantos and Holden, 1978, by permission)

Epithelial vacuoles may also occur during hydrogel extended wear, and can be distinguished from microcysts by their more rounded shape and unreversed illumination, which suggests that they represent fluid-filled bubbles or cysts in the epithelium (*Figure 15.17*). Although the aetiology of vacuoles is unclear, they occur more frequently during extended compared to daily wear, and are noted less frequently with lenses of higher oxygen transmissibility. Management of vacuoles parallels that for microcysts, with temporary discontinuation of lens wear a recommended strategy if the epithelial barrier is compromised.

Acute epithelial oedema, or microcystic oedema (*Figure 15.18*), should also be distinguished from the more chronic microcyst response. This acute response to hypoxia or hypotonicity of the tear film is usually transient, and represents intracellular accumulation of fluid due to an osmotically driven influx of fluid into the epithelium.

The endothelial bleb response

The transient endothelial bleb response was first reported in 1977 by Zantos and Holden (1977b), who observed the appearance of small dark spots distributed over the endothelium of an unadapted subject soon after the insertion of a thick soft contact lens. This observation has since been substantiated by a number of authors (Barr and Schoessler, 1980; Kamiya, 1980; Vannas *et al.*, 1981; Schoessler *et al.*, 1982). Both hard and soft lenses can induce this transient



Figure 15.18 In acute localized epithelial oedema, fluid collects in intracellular spaces throughout the epithelial layer. These 'cysts' move rapidly towards the surface where they rupture. (*a*) The general appearance of this response, sometimes called microcystic oedema, can be similar to superficial punctate keratitis. However, (*b*) by high magnification the small ruptured and non-ruptured 'cysts' can be clearly seen. (*c*) Empty (clear) and filled 'cysts' can be seen by using an endothelial camera but focusing at the level of the epithelium. (Courtesy of A. J. Phillips)

response, as can lid closure (Khodadoust and Hirst, 1984), and exposure to atmospheric anoxia (Holden and Zantos, 1981) and carbon dioxide (Holden, Williams and Zantos, 1985).

Endothelial blebs appear as small, dark, non-reflective areas scattered over the endothelial mosaic (*Figure 15.19*), and can be easily distinguished from guttata which appear as 'holes' in the endothelial mosaic (*Figure 15.20*). Endothelial blebs increase in size and number with continued exposure to the stimulus, reaching a peak after approximately 30 minutes. The bleb response then decreases to a steady level and disappears rapidly following



Figure 15.19 Endothelial blebs appear as black, non-reflecting areas of the endothelium, and are best observed using the highest slit lamp magnification and looking to one side of the specularly reflected light source. (From Holden, Williams *et al.*, 1985, by permission)



Figure 15.20 Endothelial guttata can be easily distinguished from blebs by their characteristic appearance which resembles 'holes' in the endothelial mosaic and by their persistence even without a contact lens on the eye. Guttata may occur as a congenital deformity, in certain dystrophic conditions, and associated with anterior segment inflammation.

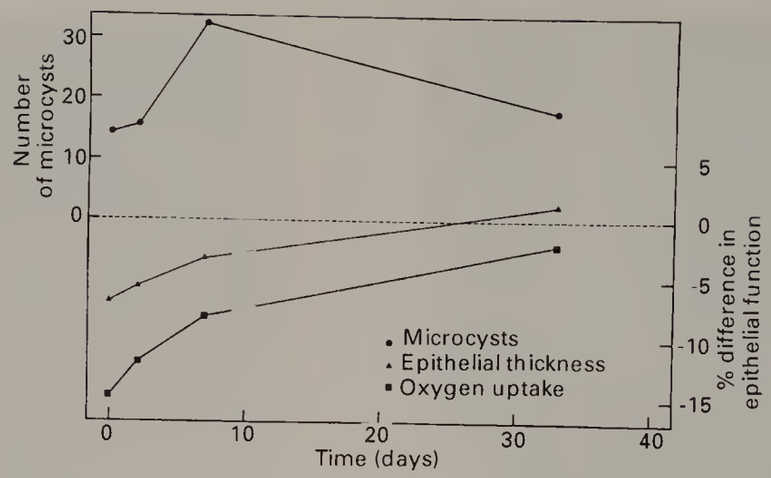


Figure 15.21 Long-term hydrogel extended wear causes significant changes in corneal physiology. This graph, taken from a study of unilateral hydrogel extended lens wearers, traces the recovery of epithelial oxygen uptake rate (■), epithelial thickness (▲) and epithelial microcysts (●) after cessation of long-term extended wear of high water content hydrogel contact lenses. Data on day 0 were obtained within 2 hours of lens removal. The dotted line represents the control (non-lens-wearing) eye data. (From Holden, Sweeney *et al.*, 1985, by permission)

removal of the stimulus. During extended lens wear, the bleb response shows a biphasic diurnal cycle, with a reduction in the number of blebs after eye opening, and a second phase of increased response in the late afternoon and evening (Williams and Holden, 1986). The bleb response also shows adaptation with continued lens wear (Barr and Schoessler, 1980; Kamiya, 1980; Williams and Holden, 1986).

The nature and aetiology of the bleb response are not fully understood. However, histological studies (Vannas *et al.*, 1984) indicate that the change in appearance of the endothelial mosaic is due to cellular oedema which causes bulging of the posterior endothelial cell membrane, altering its specular reflecting properties. Holden, Williams and Zantos (1985) have established that reduction in stromal pH due to carbon dioxide and/or lactate accumulation is the most likely cause for this response.

The clinical significance of the endothelial bleb response is not clear. It has been suggested that patients who exhibit a persistent bleb response to contact lenses may show poor adaptation to extended wear (Holden, 1983). However, the endothelial bleb response does not appear to affect the endothelial pump or barrier functions, at least in the short term, as blebs can be induced in the absence of corneal swelling, and no correlation between the amount of corneal oedema and the magnitude of the bleb response has been established (Holden, Williams and Zantos, 1985).

Long-term effects of hydrogel extended wear

Long-term hydrogel extended wear causes subtle changes in corneal structure and function. This was clearly established in the CCLRU – Göteborg study (Holden, Sweeney *et al.*, 1985), in which Holden and co-workers examined the corneas of 27 patients who had been wearing a high water content hydrogel lens in one eye only (because of amblyopia or anisometropia) on an extended wear basis for an average of 5 years. Compared to the non-lens-wearing fellow eye, the lens-wearing eye showed significant reductions in epithelial thickness and oxygen uptake rate, more epithelial microcysts, stromal thinning and increased endothelial polymegethism (variation in endothelial cell area). No interocular differences in endothelial cell density were found.

In order to investigate the time course of recovery from these corneal changes, patients in the study were asked to discontinue lens wear for one month. During this time epithelial thickness and oxygen uptake rate returned to levels found in the non-lens-wearing eye. The number of epithelial microcysts increased in the lens-wearing eye in the week following lens removal and subsequently decreased in number. This recovery of normal epithelial function is shown in *Figure 15.21*. The changes in epithelial characteristics after cessation of lens wear are thought to reflect the resurgence in epithelial metabolic activity which has been depressed as a result of chronic lens-induced hypoxia. The stromal and endothelial changes, however, were more long-lasting. Continued follow-up of several of the study patients over 6 months without lens wear showed little recovery in stromal thickness or endothelial cell regularity (Holden, Vannas *et al.*, 1985).

The clinical significance of these subtle alterations in corneal structure and function has yet to be clarified. Holden, Sweeney *et al.* (1985) have suggested that the lens-induced reduction in epithelial metabolic rate, as evidenced by epithelial thinning and decreased epithelial oxygen demand, may compromise the ability of the epithelium to withstand invading pathogens, thus predisposing the cornea to infection. Work by Imayasu *et al.* (1994) has indeed established a relationship between decreasing lens *Dk/t* and increased adherence of *Pseudomonas aeruginosa* to the cornea, following 24 hours of lens wear. The researchers also reported an increase in subtle epithelial surface compromise with decreasing *Dk/t*.

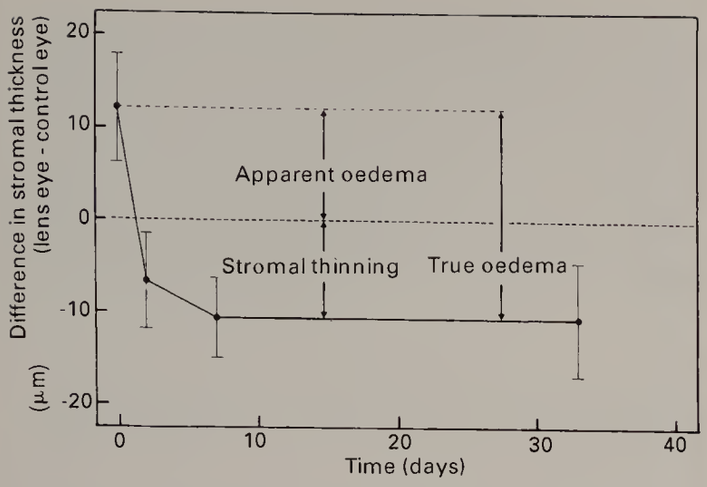


Figure 15.22 Stromal thinning is induced by long-term hydrogel lens wear, but may be masked immediately on lens removal by stromal oedema. This graph, taken from a study of unilateral hydrogel extended lens wearers, shows the change in stromal thickness of the lens-wearing eye, relative to the control (non-lens-wearing) eye (dotted line), after cessation of long-term extended wear of high water content hydrogel contact lenses. Data on day 0 were obtained immediately following lens removal. Error bars represent the standard error. The apparent oedema on lens removal, stromal thinning and true oedema are indicated. (Adapted from Holden, Sweeney *et al.*, 1985, by permission)

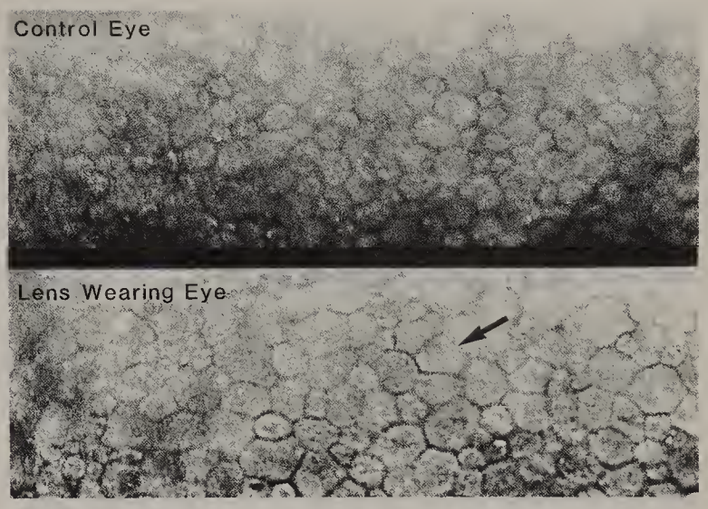


Figure 15.23 Endothelial photograph of the non-lens-wearing eye (*top*) and lens-wearing eye (*bottom*) of a patient who had worn a hydrogel lens on an extended wear basis in one eye only for 79 months. A greater variation in endothelial cell size (polymegethism) is evident in the lens-wearing eye. Also evident in that eye are a number of rosette formations (*arrow*); these are thought to occur following injury of a single endothelial cell, whereby neighbouring cells radiate towards the centre of the damaged cell. (Adapted from Holden, Sweeney *et al.*, 1985, by permission)

Other chronic hypoxia-related epithelial changes may also contribute to the enhanced corneal susceptibility to infection during extended wear by increasing the risk of trauma. These changes include reduced sensitivity (Millodot, 1978), increased fragility (O'Leary and Millodot, 1981), increased cell residence time before exfoliation (Lemp and Gold, 1986), reduced epithelial adhesion to the basement membrane (Madigan *et al.*, 1987), and delayed wound healing (Mauger and Hill, 1992).

In the CCLRU – Göteborg study (Holden, Sweeney *et al.*, 1985), the stroma of the lens-wearing eye was found to be 2.5% thicker than in the fellow non-lens-wearing eye immediately upon lens removal, due to contact lens-induced oedema. However, after 7 days without lens wear, the oedema had subsided to reveal stromal thinning in the eye that had been wearing the lens (*Figure 15.22*). The long-term significance of this stromal thinning is unclear. The amount of stromal thinning found after 5 years of extended wear was approximately 11 μm, which represents a thinning rate of only 2 μm a year. No structural abnormalities of the stroma were observed on biomicroscopic examination in patients exhibiting stromal thinning, nor was visual acuity affected. It is possible that stromal thinning may reflect a gradual leaching of glycosaminoglycans from the stroma due to chronic low-grade oedema, as described by Kangas *et al.* (1990). Stromal thinning may partially explain the apparent reduction in corneal oedema accompanying long-term extended wear, as reported by Zantos and Holden (1978) and Schoessler and Barr (1980), which has been interpreted by some as indicating an adaptation of the cornea to reduced oxygen levels.

Increased endothelial polymegethism in association with extended contact lens wear (*Figure 15.23*) was first reported by Schoessler (1983). Other studies have reported similar changes in endothelial morphology with long-term PMMA (Schoessler and Woloschak, 1981; Hirst *et al.*, 1984; Stocker and Schoessler, 1985; MacRae *et al.*, 1986) and daily soft lens wear (MacRae *et al.*, 1986). Interestingly, Schoessler *et al.* (1984) reported no increase in endothelial polymegethism in patients wearing silicone elastomer contact lenses, which have extremely high *Dk/t* values. Although this suggests that chronic lens-induced hypoxia plays a role in the aetiology of endothelial polymegethous changes, the mechanism may in fact be more complex. Holden, Williams and Zantos (1985) showed that the transient endothelial bleb response is most probably caused by a reduction in stromal pH due to either lactate accumulation under hypoxic conditions, or restriction of carbon dioxide efflux during lens wear. Indeed, such a reduction in stromal pH during eye closure and contact lens wear has been demonstrated by Bonanno and Polse (1987a,b,c) and Rivera *et al.* (1993). Because of the demonstrated sensitivity of the endothelium to changes in ambient pH *in vitro* (Fischbarg and Lim, 1974; Gonnering *et al.*, 1979; Bowman *et al.*, 1984; Lyslo *et al.*, 1985; Green *et al.*, 1986), it is tempting to speculate that chronic reductions in stromal pH during lens wear contribute to long-term changes in endothelial morphology, such as endothelial polymegethism.

The weight of current evidence indicates that contact lens-induced endothelial polymegethism is irreversible (Holden, Vannas *et al.*, 1985; MacRae *et al.*, 1986;

Yamauchi *et al.*, 1989). The apparently permanent nature of these changes is obviously cause for concern. However, there is conflicting evidence concerning the extent of functional compromise associated with these endothelial morphological changes.

Rao *et al.* (1984) reported that patients with high levels of preoperative endothelial polymegethism are significantly more likely to experience complications following intraocular surgery. This suggests that endothelial morphological changes compromise the functional reserve of the endothelium, making it more susceptible to added stresses such as surgery. However, a later study by Bates and Cheng (1988) failed to substantiate Rao's findings.

Some support for a link between endothelial polymegethism and functional compromise comes from work by Sweeney (1992), who described a 'corneal exhaustion' syndrome in long-term wearers of low *Dk/t* lenses. These apparently successful wearers demonstrated sudden intolerance to lens wear, blurred or fluctuating vision, and an excessive open-eye oedema response during lens wear. All patients described by Sweeney also showed moderate to severe endothelial polymegethism. Sweeney hypothesized that after many years of chronic hypoxic stress induced by wear of low *Dk/t* lenses the endothelium had suffered functional compromise.

Although the endothelium is the primary site for fluid pumping from the oedematous cornea, attempts to link contact lens-induced endothelial polymegethism with slower corneal deswelling rates have yielded equivocal results (Polse *et al.*, 1990). Fluorometric studies have shown that endothelial permeability is increased with long-term contact lens wear (Lass *et al.*, 1988; Dutt *et al.*, 1989). However, the nature of the structural changes that cause this increase in permeability has not been elucidated, and a direct link to endothelial morphological changes has not been established.

It is clear that the long-term consequences of endothelial changes have yet to be clarified, and the potential for endothelial functional compromise as a result of chronic stromal acidosis confirmed. It may well be that the full significance of contact lens-induced polymegethism will not be known until the present generation of contact lens wearers age, and their response to stresses such as those associated with intraocular surgery can be assessed.

Clinical management of hydrogel extended wear

Patient selection

Patients who may be considered for extended wear fall into the three broad categories shown below.

Patients who require therapeutic or 'bandage' lenses due to abnormal corneal conditions

Extended contact lens wear may be recommended to patients in this category where it is anticipated that the contact lens will promote corneal healing or alleviate ocular discomfort. Conditions that may benefit from application of a bandage lens include bullous keratopathy, indolent corneal ulcers, neuroparalytic conditions, exposure keratitis, penetrating corneal wounds and recent keratoplasty. Extended wear rather than daily wear is often indicated if regular manipulation of the lens may re-traumatize the healing cornea. As the use of contact lenses in ocular pathology is covered in detail in Chapter 20.7, this application of hydrogel extended wear will not be discussed further.

Patients who would benefit from contact lens correction, but have difficulty in handling lenses on a daily basis

Extended contact lens wear is a particular advantage for this reason for elderly aphakic patients, whilst young children with aphakia, anisometropia or high refractive errors can also be fitted with extended wear lenses; this is often essential if lens handling on a daily basis is a major problem. However, the risk of complications will be reduced significantly if lenses can be removed daily or at least 2–3 times a week (*see* Chapter 20.5).

Opinion was expressed in the early literature on extended wear that patients in this category could be left with the lens *in situ* for several months between practitioner visits for lens removal and cleaning. Considering the susceptibility of elderly patients to corneal insult due to concomitant external eye conditions such as reduced tear flow and chronic blepharoconjunctivitis, and reduced corneal sensitivity following cataract surgery, the authors feel that this approach to patient after-care is a recipe for disaster. Corneal surgery has been shown to decrease epithelial metabolic activity (Holden, Polse *et al.*, 1982; Vannas *et al.*, 1985), which may render the cornea more susceptible to infection. In addition, an elderly patient may not, for a number of reasons, appreciate the early warning signs of an acute corneal complication, and may be unable or unwilling to remove the lenses even if symptoms are recognized. There is, therefore, a risk of progression of the corneal insult before practitioner contact is initiated. As stated previously, patient delay in seeking treatment is a major factor in the development of vision-threatening corneal infections.

Patient selection for aphakic extended wear should therefore involve careful evaluation of the risk:benefit ratio in each individual case. The patient's mental alertness, manual dexterity, personal hygiene and social environment should be considered. If the patient has reduced mental competence, or is unable to manipulate the lenses if necessary, it is advisable that a relative or attendant be instructed to examine the patient's eyes periodically for unusual redness or discharge, and be trained to remove the lenses for regular cleaning or if signs or symptoms of corneal complications occur.

Following cataract extraction, many aphakic patients exhibit a certain amount of corneal astigmatism, which is not easily corrected by a hydrogel lens unless a toric fitting is attempted. However, in spite of the reduced visual acuity

due to uncorrected astigmatism, contact lenses provide many visual benefits over aphakic spectacle correction, including wider visual fields, and decreased distortion and prismatic effects. Provision of an appropriate spectacle over-correction to correct the cylindrical element, and/or to provide reading correction will often prove acceptable to the aphakic extended wear patient (*see also* Chapter 20.2). However, because most patients now undergo intraocular lens implantation at the time of cataract surgery, there has been a dramatic reduction in the number of patients requiring extended wear lenses for aphakia.

Contact lenses may prove beneficial for visual correction of high refractive errors, aphakia and anisometropia in very young children. However, careful consideration should be given to the physiological consequences of extended wear in this age group, particularly if high plus lenses are to be prescribed. In our opinion it is preferable to prescribe contact lenses on a daily wear basis if possible, to avoid the risk of the acute and chronic changes in corneal structure and function detailed earlier in this chapter. Neumann *et al.* (1993) reported considerable success with daily wear lenses in very young aphakic children.

If the decision is made to proceed with extended wear, care must be taken to ensure that the child's parents or guardians are thoroughly trained in handling the contact lenses and in detecting the early warning signs of acute complications. Parents should also be advised that the need for lens replacement, due to lens damage or loss, and also due to rapid changes in corneal curvature and diameter (Ellis, 1983), is more frequent in this age group, and the financial commitment will therefore be greater (*see also* Chapter 20.5). Children will normally revert to daily wear lenses once self-handling has been learnt or the child allows parental lens handling without objection.

Patients with moderate refractive errors who desire extended wear for cosmetic reasons

Most extended lens wearers fall into this category. A wide variety of refractive errors can be corrected with extended wear lenses, although undoubtedly the majority of these patients are myopic.

The convenience of extended wear is a major advantage in some occupational groups, such as military personnel, ambulance drivers and physicians on call, where time-consuming lens insertion under certain circumstances would be disadvantageous. Extended lens wear may also prove an advantage in certain leisure pursuits such as camping or ocean sailing where adequate provision for daily lens removal is awkward or inconvenient. Due to direct consumer advertising of the extended wear modality, however, most patients seeking cosmetic extended wear are attracted primarily by the prospect of not having to handle the lenses or perform care and maintenance procedures on a routine basis, and often anticipate trouble-free, comfortable, clear visual correction with these lenses for extended periods of wear of 30 days or more.

The primary responsibility of the contact lens practitioner, therefore, is to educate the prospective cosmetic extended wear patient in the risks, benefits and realities of extended wear. Potential acute complications and long-term effects should be clearly explained, and emphasis should be placed on the need for regular overnight lens removal, meticulous lens hygiene and disinfection procedures, and the importance of immediate lens removal and professional advice should unusual redness, discomfort or blurred vision occur. It is advisable to reinforce this preliminary discussion with a written summary detailing the patient's responsibilities and the risks involved. In particular, it is important that the patient realizes that extended wear does not mean continuous wear, and that by proceeding with extended wear, the patient is committed to a substantial continuing investment in terms of time and money.

Undoubtedly, some practitioners will be more willing to fit cosmetic extended wear lenses than others. This, of course, is a matter for the individual practitioner to decide, based on his or her perception of professional responsibility, personal competence and interest. The authors believe that, if a patient can be talked into daily contact lens wear or occasional overnight lens wear with frequent overnight lens removal, then this course should be followed in preference to extended wear. If the patient wishes to proceed with extended wear, the practitioner should carefully evaluate factors such as the patient's mental alertness, manual dexterity and personal hygiene before proceeding with lens fitting. A careful slit lamp examination of the external eye and a detailed history including previous ocular complications, allergic conditions and general health are essential to exclude patients with contraindications for extended wear, such as reduced tear flow, ocular allergy, structural abnormalities of the lids, diabetes or the use of ocular medications. Care should be taken when recommending extended wear to patients with moderate or high degrees of hyperopia, as the greater thickness of plus lenses will reduce oxygen transmission through these lenses. Higher water content lenses should invariably be used in these cases (*see below*).

Attempts to predict which individual patients are more likely to suffer acute complications or long-term effects during extended wear have generally been inconclusive. An analysis of data collected during the CCLRU–Göteborg study (Holden, Swarbrick *et al.*, 1987) indicated that long-term lens-induced changes in corneal structure and function were less apparent in patients with thinner corneas and structurally regular endothelium prior to commencing extended lens wear. Sarver *et al.* (1983) and Efron (1986) have suggested that hypoxic stress testing of prospective extended lens wearers, either by 3 hours' wear of thick hydrogel lenses or short-term exposure to gaseous anoxia, may identify those individuals more susceptible to excessive corneal oedema during contact lens wear; however, these measures are unlikely to be viable in practice. In the short term, the most direct way of evaluating an individual patient's response is to monitor the corneal response closely during the first weeks of extended lens wear.

Lens fitting

The fitting of soft contact lenses is discussed in detail in Chapter 11. There are no major differences in the approach to fitting hydrogel extended wear lenses compared to daily wear lenses, except in two areas.

First, consideration must be given to maximizing the oxygen transmission characteristics of the lenses. Thus selection of either a high water content lens or a very thin low water content lens is indicated. The refractive error of the patient may influence this choice. Because of their greater average thickness, plus lenses or high-minus lenses will transmit less oxygen than the more commonly prescribed low-minus lenses. Holden, McNally *et al.* (1985) found that high-minus lenses in a low water content material induced greater mid-peripheral corneal swelling than in a high water content material, presumably because of the greater *Dk/t* differential with low water content lenses between centre and periphery. Thus high water content lenses are preferable for patients with higher degrees of refractive error.

Secondly, the provision of adequate lens movement is considered to be an important factor in avoiding inflammatory complications such as CLARE reactions. More specifically, the lens should not fit tightly or become tight with wear, and should move across the cornea with ease when pushed up by the eyelid. With high water content lenses, lens movement on a blink should be in the region of 0.4 mm. Thin low water content lenses move less on the eye because they tend to 'drape' on to the cornea; however, lens movement of approximately 0.2 mm on blinking is desirable. It must be kept in mind that lenses often tighten up with wear. This tends to be a greater problem with high water content lenses due to their more rapid ageing. It is therefore recommended that the practitioner should attempt to fit the flattest possible lens consistent with acceptable patient comfort and stable vision.

Care and maintenance

Rigorous care and maintenance procedures are a key factor in maximizing extended wear success. As well as maintaining good patient comfort and vision, the removal of lens deposits and regular lens disinfection ensure that bacteria and other pathogens are less likely to adhere to and survive on the lens surface, thus reducing the risk of corneal infection. In susceptible individuals, deposits on the front surface of the lens may also precipitate papillary changes in the upper palpebral conjunctiva; maintenance of a clean front lens surface, therefore, may avoid or halt the progression of this tissue response.

Regular overnight lens removal of extended wear lenses is essential, in order to carry out lens cleaning and disinfection procedures, and to rest the cornea from chronic hypoxic stress. The authors recommend that extended wear lenses should be removed for a minimum of 16 hours, including a period when the eyes are open, at least once a week. In fact, from a physiological point of view it is preferable to limit overnight wear with current hydrogel lenses to 1–2 nights per week if possible (Grant *et al.*, 1987). Establishment of a routine timetable for overnight lens removal will reinforce regular lens cleaning and disinfection habits.

Table 15.1 Recommended minimum care and maintenance regimens for hydrogel extended wear lenses

Conventional extended wear		*Disposable extended wear*
High water content	*Low water content*	
Weekly removal	Weekly removal	Weekly removal
*Surfactant cleaner	*Surfactant cleaner	*Surfactant cleaner
*Unpreserved saline rinse†	*Unpreserved saline rinse†	*Unpreserved saline rinse†
Enzymatic cleaner	Enzymatic cleaner	
Repeat surfactant cleaner	Repeat surfactant cleaner	
*Peroxide or chemical‡ disinfection	*Peroxide, chemical‡ or heat disinfection	*Peroxide or chemical‡ disinfection
16-hour rest period	16-hour rest period	16-hour rest period
Replacement every 1–3 months	Quarterly replacement	Weekly replacement

* To be performed whenever the lens is removed from the eye.
† Aerosol or single dose saline.
‡ Multipurpose chemical systems with low preservative concentration. Chlorine-based systems are not recommended.

Recommended care and maintenance regimens for high and low water content lenses used for conventional extended wear, and disposable lenses, are summarized in *Table 15.1*. In addition to routine care and maintenance, surfactant cleaning, rinsing and disinfection of lenses should be performed whenever the lenses are removed from the eye. A surfactant cleaner should be used to remove loose surface deposits and debris, followed, on a weekly basis, by enzymatic cleaning to remove persistent deposits (except when lenses are disposed of on a weekly basis). The lenses should then be disinfected, preferably using peroxide or a multipurpose chemical system with low preservative concentration, to destroy contaminating bacteria and other pathogens. CCLRU studies suggest that the use of peroxide results in a lower adverse response rate than heat disinfection, particularly for high water content lenses (Kotow, Grant and Holden, 1987). Because of the possibility of allergic or toxic reactions to preservatives, the authors recommend that non-preserved saline (unit dose or aerosol) be used to rinse the lenses during the cleaning process. Scrupulous attention should be paid to cleanliness of the hands to avoid recontaminating the lenses during handling. It is also advisable to review lens care procedures routinely during after-care visits to ensure patient compliance.

Regular lens replacement

There is considerable evidence to suggest that regular replacement of extended wear lenses may reduce the risk of both acute complications (Kotow, Holden and Grant, 1987) and long-term effects (Holden, Sweeney *et al.*, 1985). Replacement of lenses helps to avoid problems related to the build-up of stubborn deposits, and lens ageing and spoiling. Although frequent lens replacement may increase the patient's financial commitment, the authors recommend that fresh extended wear lenses should be issued routinely at least every 6 months, and as often as every 1–3 months, depending on the material used, for those patients who show persistent stubborn deposits or rapid lens ageing.

Disposable lenses

The introduction of disposable extended wear lenses in the mid-1980s has led to a revolution in patient management practices. For this reason, a more detailed discussion of this lens modality is warranted.

Lens deposits

The rationale behind the regular replacement and disposable lens philosophies stemmed from the role of lens deposits in many contact lens-related complications. Deposits on the lens surface are thought to provoke both mechanical and immunological complications, in particular GPC and CLPC. As discussed earlier, the pathogenesis of these palpebral conjunctival changes is believed to involve both mechanical trauma to the tissue (Reynolds, 1978; Sugar and Meyer, 1981) and a delayed hypersensitivity response to antigens associated with front surface lens deposits (Allansmith *et al.*, 1977). It has also been suggested that deposits may provide attachment sites for bacteria (Fowler *et al.*, 1979a; Stern and Zam, 1986; Butrus *et al.*, 1987), implicating lens deposits as a contributory factor in contact lens-related corneal infections. In theory, by replacing the lens before deposits build up to a point where they can trigger an adverse response, many contact lens complications should be avoided.

Most currently marketed disposable lenses fall into two FDA categories: low water content non-ionic lenses (Type I; e.g. SeeQuence), and high water content ionic lenses (Type IV; e.g. Acuvue and NewVue). It is well established that Type IV lenses show a greater affinity for protein deposits, in particular lysozyme, than Type I lens materials (Minarik and Rapp, 1989), and the increased deposition on Acuvue compared to SeeQuence lenses has been demonstrated by Lin and co-workers (1991). These researchers also commented on the significant individual variation in deposition rates in their subject group, a finding which is familiar to practitioners.

In addition to the variability in individual deposition rates, individual susceptibilities to challenge from lens deposits are also highly variable. This has been well known since the early work of Fowler *et al.* (1979b), who found no difference in deposits on lenses from patients with and without palpebral conjunctival changes. Taken together, these observations suggest that some patients may develop upper eyelid changes in spite of regular replacement or disposal of lenses. This has been confirmed by a number of investigators. For example, Grant (1991) reported an incidence of 5% CLPC with disposable extended wear (compared to 19% with conventional extended wear). Others have also reported the development of CLPC or GPC during disposable lens extended wear (Donshik *et al.*, 1988; Maguen *et al.*, 1991, 1992).

The problem of lens deposition may be compounded if compliance with lens replacement schedules is poorly maintained (Maguen *et al.*, 1991). For example, a 1989 survey of disposable lens patients found that only 54% *always* replaced their lenses according to their prescribed schedule, while 22% usually wore the lenses longer than recommended (Anon., 1989). Thus, it is not surprising that although disposable lenses are associated with a significantly reduced incidence of CLPC and GPC, they do not eliminate this complication. In addition, the mechanical factor in the pathogenesis of CLPC should not be ignored. It may be that even a 'non-deposited' lens can induce CLPC in some patients.

Lens ageing and solution sensitivities

A major potential advantage of the disposable lens regimen is avoidance of complications associated with ageing of lens materials and lens deposits, and sensitivities to lens care solution preservatives which may be absorbed by the lens polymer over time.

As a hydrogel lens ages it may discolour, lose flexibility and develop surface and edge defects. In addition, lens parameters may change, resulting in a tightening of the lens fit. These changes reduce vision and comfort, and may predispose the wearer to complications associated with a tight lens fit such as limbal compression conjunctival staining (Grant *et al.*, 1990), neovascularization (McMonnies, 1984), and inflammatory responses to debris trapped behind the lens (Mertz and Holden, 1981). By replacing lenses before ageing changes occur, these problems can be avoided. However, because of the 'single fit' approach originally employed with disposable lenses, problems associated with tight lens fitting have been reported occasionally in clinical studies of disposable lenses (Maskell, 1989; Nilsson and Lindh, 1990; Maguen *et al.*, 1991).

Because disposable extended wear lenses are not routinely exposed to lens care solutions which may contain preservatives, problems associated with solution preservative sensitivities are avoided. Complications such as superior limbic keratoconjunctivitis (which has been associated with thimerosal sensitivity; Sendele *et al.*, 1983) and allergic or toxic keratitis attributable to lens care products have not been reported during disposable lens extended wear.

Unfortunately, it is possible that the promotion of the disposable lens system as 'care-free' may have its dis-

advantages. Inevitably, extended wear patients will occasionally have to remove their lenses for cleaning or rinsing, for example in dusty environments, when swimming in chlorinated water, or because of foreign bodies. More importantly, extended wear patients should be instructed to remove their lenses promptly if unusual unilateral redness, pain or reduced vision occur. If contact lens solutions and cases are not provided to the patient, or if the patient incorrectly perceives that lens removal and cleaning are not appropriate in this regimen, minor problems may progress to more serious and vision-threatening sequelae. If disposable lenses are removed and reused, it is essential that they undergo careful mechanical surfactant cleaning and rigorous disinfection before reinsertion in the same way as any other hydrogel lens.

Hypoxia

Because disposable lenses are manufactured from the same polymers as are used for conventional (non-disposable) hydrogel lenses, the oxygen transmissibility of these lenses is no different from conventional extended wear lenses. This point has been clearly demonstrated by Weissman and colleagues (1990), who measured oxygen permeability of Acuvue material as 18, NewVues as 15, and SeeQuence as 9×10^{-11} (cm^2 mlO_2)/(s ml mmHg). This means that disposable lenses in standard thicknesses have oxygen transmissibilities in the range of $9–18 \times 10^{-9}$ (cm mlO_2)/(s ml mmHg) (Weissman *et al.*, 1991). This level of oxygen transmissibility gives rise to overnight corneal oedema levels of between 10 and 14%, equivalent to those induced by conventional extended wear hydrogel lenses (La Hood *et al.*, 1988; Grant, 1991).

It must be stressed, therefore, that disposable lenses worn for extended wear induce similar chronic hypoxic and hypercapnic changes in corneal structure and function as conventional extended wear lenses. Thus epithelial microcysts, reduced epithelial adhesion, endothelial polymegethism and other subtle hypoxia-induced corneal changes occur with the same frequency as with conventional extended wear (Donshik *et al.*, 1988; Grant and Holden, 1988; Maskell, 1989; Grant, 1991; Maguen *et al.*, 1991, 1992; Port, 1991). Indeed, CCLRU studies have shown that only 6% of patients seem unaffected physiologically after three years extended wear of even the highest *Dk/t* disposable hydrogel lenses (Holden, 1992a).

Corneal inflammation

Corneal inflammatory responses such as infiltrative keratitis and the CLARE reaction have been documented during disposable lens extended wear (Grant and Holden, 1988; Serdahl *et al.*, 1989; Nilsson and Lindh, 1990; Grant, 1991; Maguen *et al.*, 1991, 1992; Port, 1991). However, regular replacement of lenses has been shown to reduce significantly the incidence of CLARE reactions (Kotow, Grant and Holden 1987; Kotow, Holden and Grant, 1987). Grant (1991) reported a 3% incidence of CLARE reactions with disposable extended wear, compared to an annual incidence of 15% during conventional extended wear. It is likely that regular disposal of lenses lessens the exposure of the cornea to factors which may provoke these inflammatory responses, such as preservatives absorbed by the lens polymer, bacterial toxins and lens deposits.

There have also been several reports of sterile corneal ulceration associated with infiltrates during disposable extended wear (Grant and Holden, 1988; Dunn *et al.*, 1989; Harris *et al.*, 1989; McLaughlin *et al.*, 1989; Parker and Wong, 1989; Serdahl *et al.*, 1989; Mertz *et al.*, 1990; Grant, 1991). We have termed this condition CNPU (culture-negative peripheral ulceration), and believe it to be inflammatory rather than infectious in aetiology. Grant (1991) found that the annual incidence of CNPUs (approximately 2–3%) is similar for different types of disposable lenses and less frequently replaced conventional extended wear hydrogel lenses. In contrast, Boswall *et al.* (1993) and Poggio and Abelson (1993) suggest that this type of 'benign' peripheral corneal ulceration may in fact be more frequent with disposable compared to conventional extended wear. Further studies of the incidence of this complication are needed to clarify this issue.

Corneal infections

Corneal infection is the most serious complication of hydrogel extended wear. It was hoped that the use of disposable lens regimens would reduce the frequency of corneal infection, because the lenses would have little chance of becoming contaminated through exposure to contaminated lens cases or care solutions. Because lenses are replaced before significant lens deposits accumulate, it has also been suggested that there should be less bacterial attachment to lens surfaces. However, there have been a number of reports of corneal infection during disposable lens extended wear, including severe infections with *Pseudomonas aeruginosa* (Dunn *et al.*, 1989; Glastonbury and Crompton, 1989; Harris *et al.*, 1989; Kent *et al.*, 1989; Kershner, 1989; Killingsworth and Stern, 1989; Rabinowitz *et al.*, 1989; Capoferri *et al.*, 1991; Cohen *et al.*, 1991) and Acanthamoeba spp. (Ficker *et al.*, 1990; Heidemann *et al.*, 1990). Current evidence therefore suggests that the use of a disposable lens regimen does not reduce the risk of corneal infection during extended wear. Although recent case-control studies present some evidence that the risk might be enhanced compared to conventional extended wear (Buehler *et al.*, 1992; Matthews *et al.*, 1992), a re-analysis of the data from one of these studies (Schein *et al.*, 1994) has established that the over-riding risk factor for corneal infection is the overnight use of hydrogel lenses; no influence of lens type (disposable versus conventional) was found.

Several reasons can be advanced for the continuing problem of corneal infection during extended wear of disposable lenses. Poor patient compliance to wearing and

disposal schedules (Dunn *et al.*, 1989; Kershner, 1989; Cohen *et al.*, 1991; Matthews *et al.*, 1992), and use of contaminated care solutions (Rabinowitz *et al.*, 1989; Matthews *et al.*, 1992), have been implicated in a number of cases of corneal infection with disposable lenses. It may well be that marketing strategies which have promoted disposable lenses as 'care-free' have tended to attract a group of patients who are less meticulous about lens hygiene and reporting of initial symptoms. As discussed previously, delay in seeking treatment is a major risk factor in the progression of corneal ulceration. This stresses the importance of careful patient selection, instruction and education for all forms of extended lens wear.

The role of lens replacement in reducing bacterial attachment to lens surfaces is also uncertain. Although some studies have reported that bacteria preferentially attach to deposits on the lens surface (Fowler *et al.*, 1979a; Stern and Zam, 1986; Butrus *et al.*, 1987), other studies have questioned this finding. Duran *et al.* (1987) showed that bacteria can attach avidly to unworn lenses, while Dart and Badenoch (1986) found no difference in bacterial adherence between worn and unworn lenses. These findings suggest that replacement of lenses before significant deposits have accumulated may do little to reduce the chances of bacterial adherence to the lens surfaces.

Hypoxia has also been implicated as a major contributing factor in contact lens-related corneal infection. As discussed previously, chronic hypoxic stress reduces corneal sensitivity, increases epithelial fragility and compromises epithelial adhesion. More subtle effects on the epithelium, the primary barrier to invasion of pathogens, may also result from the continual presence of the lens and the absence of the blink-activated cleansing of the ocular surface. Because disposable extended wear lenses induce similar levels of chronic hypoxia as conventional hydrogel extended wear lenses, and are present on the eye for similar periods, these risk factors are not reduced with a disposable lens regimen.

Finally, there have been several reports of lens imperfections in disposable lenses, particularly the Acuvue lenses (Seger and Mutti, 1988; Maskell, 1989; Wodis *et al.*, 1990; Lowther, 1991; Efron and Veys, 1992). These imperfections, mainly at the lens edge, arise because of the manufacturing process in which lenses are moulded in a hydrated state, resulting in occasional excess material (flashing) at the lens edge. Efron and Veys (1992) have provided some evidence for slight compromise of ocular integrity associated with wear of imperfect disposable lenses, and suggested that this compromise may be related to the development of severe ocular complications during extended wear. However, the clinical significance of these findings has been questioned (Guillon, 1992; Holden, 1992b; Levy, 1992), as no clear evidence has been presented to support these claims.

In summary, the use of disposable lenses for extended wear appears to result in fewer complications than conventional extended wear (Boswall *et al.*, 1993; Poggio and Abelson, 1993). Acute and chronic inflammatory ocular responses, which are triggered by ageing of lenses and deposits, are significantly reduced. However, complications which are attributable directly or indirectly to chronic hypoxic stress are not reduced in frequency, because current disposable lenses have similar oxygen transmission characteristics to conventional hydrogel extended wear lenses. Furthermore, the continuing problems of corneal inflammation and infection with disposable lens extended wear clearly indicate that careful patient selection, rigorous instruction in lens care, and compliance with lens replacement and after-care schedules may not be sufficient to avoid the inevitable problems associated with hydrogel extended wear.

Patient advice and management

As previously discussed, before any type of extended wear lens is dispensed, it is important to ensure that the patient is competent in lens handling or at the very least, where handling difficulties are apparent, that a family member or companion is trained to insert and remove the lenses. In many cases, a daily wear adaptation period is not essential as adaptation is generally rapid. However, if there is any question about the patient's ability to handle the lenses or adapt to lens wear, or if the lens fitting requires further evaluation, it may be appropriate to institute an initial period of daily wear until confidence in lens management and performance is achieved.

It is important to examine the extended wear patient early in the morning following the first overnight wear of the lenses, in order to assess the patient's response to overnight hypoxic stress. A careful slit-lamp examination should be performed to evaluate the corneal oedema response; the presence of striae or folds more than 2 hours after eye opening should be taken as a warning sign of high levels of overnight corneal swelling. The fitting characteristics of the lenses should also be assessed to ensure that adequate lens movement has been maintained.

Follow-up visits after 3 days, 1 and 2 weeks and 1 month of extended wear are then advised. At these visits, discussion and reinforcement of lens handling techniques, care and maintenance procedures, and disposal or replacement regimens are suggested in order to emphasize to the patient the importance of these procedures. If no problems are apparent, 3-monthly after-care visits should follow. However, patients should be advised to consult their practitioner if problems arise between scheduled after-care visits. Provision of an after-hours contact telephone number for use in emergencies is also recommended.

Yamane and Kuwabara (1987) suggest that extended wear patients should be encouraged to check their eyes daily to ensure that they 'feel good, look good, and see good'; if these criteria are not met, the patients should remove their lenses and consult their practitioner.

From clinical studies at the CCLRU, the following measures have been found to lead to safer extended wear (Holden, 1986).

Patient advice

- Remove the lenses and consult your practitioner if there is any unusual redness, irritation or blurred vision, especially in one eye only.
- Instil sterile unpreserved saline drops in the morning and evening.
- Remove lenses during a cold, influenza or hospitalization.
- Wear swimming goggles when swimming in fresh water, and in salt water remove the lenses.

Patient management by the clinician

- If corneal erosions occur, remove the lenses and refer for ophthalmological attention.
- A corneal erosion with infiltrates may well indicate a corneal infection, and urgent referral to an ophthalmologist with experience in contact lens-related problems is imperative.
- If significant corneal staining is noted, remove the lenses for at least 48 hours and review.
- If asymptomatic infiltrates are present, remove the lenses for 3 days and review. No lens wear is advised until the infiltrates disappear. Fresh lenses should be issued.
- If corneal striae or folds are present 2–3 hours after waking, return the patient to daily wear or try lenses with higher oxygen transmissibility.
- A drop in visual acuity of one line or more requires an over-refraction and a check of lens condition. Replace the lenses if necessary.
- A CLARE reaction warrants immediate lens removal (if the eye is painful, cold compresses may help). Infiltrates must be resolved before recommencing lens wear. New lenses should be issued when resuming lens wear.
- The development of CLPC requires lens removal and review every 3–4 weeks. The use of disposable lenses may be indicated. Refitting with RGP lenses for extended wear may be more successful in avoiding progression of CLPC than refitting with a new soft contact lens, or a different hydrogel material.

RGP extended wear

Historical review

Rigid gas permeable (RGP) lenses have been available for daily wear since the mid-1970s. The first rigid oxygen-permeable material, cellulose acetyl butyrate (CAB; marketed initially as RX-56, Meso and Cabcurve), provided little additional oxygen by diffusion through the lens material, and was soon replaced by a new generation of RGP materials made of co-polymers of silicone and methyl methacrylate. The first of these was the Polycon material, developed by Leonard Seidner, and approved for daily wear in the USA in January 1979. New silicone acrylate materials were soon to follow, including the Boston material (Polymer Technology Corp.) and the Calgary and Alberta materials (Corneal Contact Lens Co., Canada). More recently, fluorosilicone acrylate materials have been developed, such as the Equalens and Fluoroperm family of materials. Today many RGP materials of various compositions are available for daily wear.

Although there are anecdotal reports of patients achieving continuous wear with oxygen-impermeable PMMA lenses (reviewed by Young, 1985), it is now well known that the cornea requires oxygen during closed-eye lens wear in order to maintain its integrity in both the short and long term. The use of RGP lenses for aphakic extended wear was first reported by Garcia in 1976, but the development of hydrogel extended wear lenses effectively stifled interest in this modality for several years. However, with increasing reports of adverse acute and chronic effects with hydrogel extended wear, and with the development of new RGP materials with oxygen transmission characteristics rivalling those of hydrogel extended wear materials, interest in RGP extended wear was revived.

In 1983, Levy reported the successful use of RGP lenses for cosmetic extended wear in an elderly myope, and commented that 'preliminary results indicate that rigid gas permeable materials are a viable alternative to the high water content hydrophilic materials currently in use for extended wear'. The following year, Fonn (at the Eighth European Research Symposium, Interlaken, Switzerland) reported a pilot study in which 10 subjects were fitted for extended wear with a hydrogel lens in one eye and an RGP lens in the other. He found that the acute adverse response rate and physiological effects were less in the RGP lens-wearing eye; these findings were confirmed in a follow-up study with a further 30 subjects (Fonn and Holden, 1988). Following these reports, the interest in RGP extended wear grew rapidly, and stimulated the development of many new RGP materials which combine increased oxygen transmission properties with improved wettability, stability and deposit resistance. RGP extended wear lenses are now in clinical use in many parts of the world, and received FDA approval in the USA late in 1986.

Materials currently available for RGP extended wear can be broadly classified as silicone acrylate or fluorosilicone acrylate polymers. Silicone acrylate materials contain siloxane units to enhance oxygen permeability, methacrylic acid or HEMA for wettability, and methyl methacrylate to give good mechanical and optical properties (Caroline and Ellis, 1986). Crosslinking agents are added to the polymer to give the material additional strength and dimensional stability. In general, differences between materials in the silicone acrylate family arise from variations in the proportions of these monomers in the polymer matrix.

The more recently developed fluorosilicone acrylate materials comprise co-polymers of siloxane, fluorinated monomers and methyl methacrylate. The incorporation of fluorine, which is an efficient oxygen transmitting substance, is designed to enhance oxygen permeability, wettability and deposit resistance of the polymer by allowing a reduction in the proportion of silicone, a hydrophobic substance, in the polymer. Other co-monomers are also

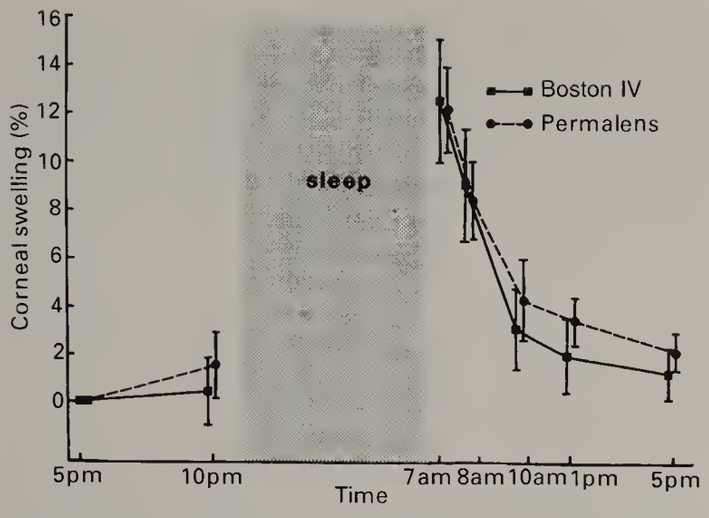


Figure 15.24 Due to their greater tear exchange and smaller diameter, RGP lenses provide more corneal oxygenation than hydrogel lenses of similar *Dk/t* during open-eye lens wear. This is shown in this graph of average corneal swelling versus time for 10 unadapted subjects wearing an RGP (Boston IV) lens (■) on one eye and a soft (Permalens) lens (●) on the other eye over a 24-hour wake/sleep cycle. More rapid corneal deswelling is apparent in the RGP lens-wearing eye following eye opening. (From Holden *et al.*, 1988, by permission)

added to enhance strength and wettability; the ratio of these co-monomers can be manipulated to alter the physical and physiological properties of the material (*see* Chapters 3 and 10).

Advantages and disadvantages

The interest in RGP extended wear was spurred primarily by the potential of RGP lenses to transmit more oxygen to the cornea than is possible with current-generation hydrogel materials. Early studies of overnight corneal swelling responses with RGP lenses utilized lenses with oxygen transmissibilities equivalent to those provided by hydrogel extended wear lenses (Sweeney and Holden, 1983; Kenyon *et al.*, 1985; Zantos and Zantos, 1985). Not surprisingly, similar levels of overnight corneal oedema were obtained as with hydrogel lenses, and Sweeney and Holden (1983) cautioned that RGP lenses should have a *Dk/t* value of at least 25 in order to be considered for extended wear. It was found, however, that the cornea could eliminate overnight oedema at a faster rate with RGP lenses than with hydrogel lenses, due principally to the oxygenation provided by the tear pump on eye opening (*Figure 15.24*) (Andrasko, 1986; Holden, Sweeney *et al.*, 1988). Thus, during extended wear, the cornea is likely to experience less chronic hypoxic stress with RGP compared to hydrogel lenses of comparable *Dk/t* value.

Early clinical studies of RGP extended wear reported a low incidence of acute complications, such as acute inflammatory reactions, excessive oedema and corneal infection, compared to hydrogel extended wear (Benjamin and Simons, 1984; Levy, 1985; Zantos and Zantos, 1985; Zabkiewicz *et al.*, 1986; Polse *et al.*, 1987; Fonn and Holden, 1988). However, these studies identified some of the unique complications which we now associate with the overnight wear of rigid lenses, including lens adherence or 'binding', corneal moulding and reduced toricity, and exacerbation of peripheral 3 and 9 o'clock staining. In addition, hypoxia-related corneal changes such as striae and epithelial microcysts were also noted in these early studies.

Developments in the field of polymer chemistry soon resulted in RGP materials with higher Dk values than hydrogel extended wear materials. Overnight corneal oedema appeared to be considerably reduced with these lenses; levels in the range of 5–7% were reported initially (Mandell and Liberman, 1985), comparing favourably with the normal overnight corneal swelling response of 3–4% without lens wear. These encouraging initial reports, however, were based on study protocols which significantly under-estimated the true level of overnight oedema present on eye opening. Holden, La Hood *et al.* (1985) found that overnight oedema levels with these materials were in fact closer to 10% when measured immediately on eye opening. Further work by Seger and Mutti (1986) and La Hood *et al.* (1988) confirmed this higher oedema response.

Clinical trials with these second-generation moderate Dk materials, termed 'super-permeables', have given encouraging results (Henry *et al.*, 1987; Polse *et al.*, 1988; Key and Mobley, 1989; Levy, 1991; Rivera and Polse, 1991; Young and Port, 1992). Hypoxia-induced corneal changes, such as striae and epithelial microcysts, are less frequent than with lower Dk RGP and hydrogel materials. However, it has also become apparent that complications such as adherence, corneal moulding and peripheral staining are not reduced by increasing the Dk of the RGP material (Rivera and Polse, 1991).

Technological developments are now providing RGP lenses with far higher *Dk/t* values, thus further reducing the hypoxic stress on the cornea during extended wear. Although long-term clinical reports have been few, it is clear from our experience at the CCLRU that these high *Dk/t* lenses ($> 50 \times 10^{-9}$ units) provide sufficient oxygen to the cornea, even during closed-eye lens wear, to avoid most of the hypoxia-related complications associated with hydrogel extended wear. Results from long-term RGP extended wear trials conducted at the CCLRU using high *Dk/t* lenses are discussed below.

As clinical trials of RGP extended wear have progressed, other advantages of this modality have become apparent. Compared with hydrogel extended wear, there appears to be a much lower incidence of serious complications such as CLARE reactions, CLPC and corneal infection (Henry *et al.*, 1987; Polse *et al.*, 1987; Fonn and Holden, 1988; Young and Port, 1992). In RGP clinical studies conducted at the CCLRU, we have observed only two CLARE reactions, both associated with an adherent lens and occurring in previous soft lens problem patients. The incidence of CLPC during RGP extended wear is also low, and this complication tends to occur in previous soft lens wearers with CLPC

prior to commencing RGP extended wear (Douglas *et al.*, 1988; Schnider *et al.*, 1988). In addition, there have been very few reports to date of corneal ulceration during RGP extended wear (Levy, 1985; Schnider *et al.*, 1988; Ehrlich *et al.*, 1989; Terry, Holden and Schnider, 1989). In most cases, corneal ulcers associated with RGP extended wear appear to be more benign than hydrogel-related infections, being typically peripheral in location and consequently less vision-threatening.

There are a number of reasons for the low incidence of acute complications with RGP extended wear. First, because of the efficient tear pump with rigid lenses, tear debris and contaminants are readily flushed from behind the lens. This may explain the very low rate of CLARE reactions, which are thought to be triggered in part by breakdown products of retained back surface debris. Secondly, RGP lenses attract less deposition and are more easily cleaned, and therefore build up fewer stubborn deposits on the lens surface than hydrogel lenses; thus inflammatory reactions to lens deposits, such as CLPC, are minimized. Bacteria and other pathogens are also less likely to be retained on the lens surface, thus reducing the risks of corneal infection. In addition, the lower hypoxic stress experienced by the cornea during RGP as compared to hydrogel extended wear probably reduces compromise of epithelial metabolism, and the epithelium is therefore more able to withstand invading organisms.

Because of their rigidity, RGP lenses generally provide better vision than hydrogel lenses; corneal astigmatism of up to 2.5 D can be corrected with these lenses, depending on the lens thickness and flexibility. The greater ease of cleaning and maintenance, combined with enhanced deposit resistance compared to hydrogel lenses, is also of benefit for many patients in terms of improved vision, comfort and convenience. In general, RGP lenses are more durable than hydrogels, more stable under varying environmental conditions, and are able to be modified or polished.

RGP extended wear is not without its drawbacks, however. Potential problems include corneal distortion or moulding, lens adherence or 'binding', and corneal staining (*see below*). As with hydrogel extended wear, CLARE reactions, CLPC and corneal infections may also occur in association with RGP extended wear, although much less frequently. Other minor complications have also been identified. Initial lens discomfort and intolerance have been noted in some patients, and appear to be the major reasons for discontinuation from this lens-wearing modality (Key and Mobley, 1989; Sigband and Bridgewater, 1994). However, once adaptation has been achieved comfort is usually very good, and may be superior to that with hydrogel lenses (Fonn and Holden, 1988). The edge profile of the lens appears to be a significant factor determining RGP lens comfort, with a rounded front edge being the most important factor in providing good subjective comfort (La Hood, 1988). Abrasions due to foreign bodies, lens mishandling or dislodgement also occur with greater frequency than with hydrogel lenses. Careful patient instruction may circumvent these problems to some extent.

Fonn and Holden (1986) have also reported the development of eyelid ptosis in association with RGP extended wear, a finding which has since been confirmed by others (Gauthier *et al.*, 1992; Fonn *et al.*, 1996). It is thought that the ptosis is caused by lid oedema or inflammation due to chronic irritation of the eyelid by the lens edge or deposits on the lens surface.

Acute complications of RGP extended wear

Stromal oedema

As with hydrogel extended wear, overnight wear of low or moderate *Dk/t* RGP lenses may give rise to significant levels of overnight corneal oedema. Because the oedema accompanying RGP lens wear is usually localized in the central 6 mm of the cornea (Fonn *et al.*, 1984), it may be detected with the slit lamp using the technique of sclerotic scatter (*see* Chapter 6). However, oedema associated with RGP overnight lens wear resolves rapidly following eye opening due to the circulation of oxygenated tears behind the lens; unless the patient is seen within one hour of eye opening, there may be little evidence of residual oedema. As with hydrogel lens-induced oedema, the presence of striae or folds in the posterior stroma which persist for more than 2 hours following eye opening can be used to infer the occurrence of clinically unacceptable levels of overnight corneal swelling.

The selection of an RGP lens material which will provide adequate corneal oxygenation during sleep is usually based on the clinician's knowledge of the Dk value of the material and the lens thickness. At the CCLRU, RGP lens materials that have been assessed to date can be classified as either low Dk [$< 40 \times 10^{-11}$ (cm^2 mlO_2)/(s ml mmHg)], moderate Dk (40–100) or high Dk (> 100). The authors believe that, while consideration must be given to other lens properties, it is advisable to prescribe only high Dk RGP lens materials for extended wear, in order to maximize oxygen availability to the cornea during sleep, and thus reduce the chronic hypoxic stress experienced by the cornea in the long term. Certainly, there are now a number of RGP lens materials available which meet this criterion.

Information on the nominal Dk value of RGP materials is generally supplied by the marketing company and, until the mid-1980s, was based on Dk measurements performed by the polarographic technique described by Fatt (1984). It became apparent, however, that these early estimates of the *Dk/t* of RGP lenses overestimated the true *Dk/t* values of the lenses on the eye. For example, Holden, La Hood and Sweeney (1985) observed that Paraperm EW, a silicone acrylate material with a nominal Dk value of 56×10^{-11} units, in a thickness of 0.17 mm (i.e. nominal *Dk/t* of 33×10^{-9} units), induced 10% overnight oedema, equivalent to the level induced by a hydrogel lens with a *Dk/t* of 22×10^{-9} units. This implied that the on-eye or 'effective' Dk value of this RGP material is closer to 37×10^{-11} units. The resultant controversy (Guillon, 1985; Hamano *et al.*, 1985;

Brennan *et al.*, 1986; Fatt, 1986a,b) stimulated a re-examination of both the measurement of *Dk/t* and the derivation of Dk from these measurements. The importance of barrier and surface effects (Hwang *et al.*, 1971), edge effects (Fatt *et al.*, 1987; Brennan *et al.*, 1987) and other factors affecting both *Dk/t* measurement *in vitro* and prediction of *Dk/t in vivo* has been recognized, and correction factors have been incorporated into Dk measurement protocols. It is also clear that high Dk materials are more appropriately measured using the coulometric method (Winterton *et al.*, 1987). Fortunately, there now appears to be general consensus regarding the Dk of RGP materials available on the market (Holden, Newton-Howes *et al.*, 1990) (*see also* Appendix B). However, the uncertainty which arose as a result of this controversy emphasizes the importance of monitoring individual patient responses to RGP extended wear in order to identify those patients who may be susceptible to excessive overnight corneal swelling.

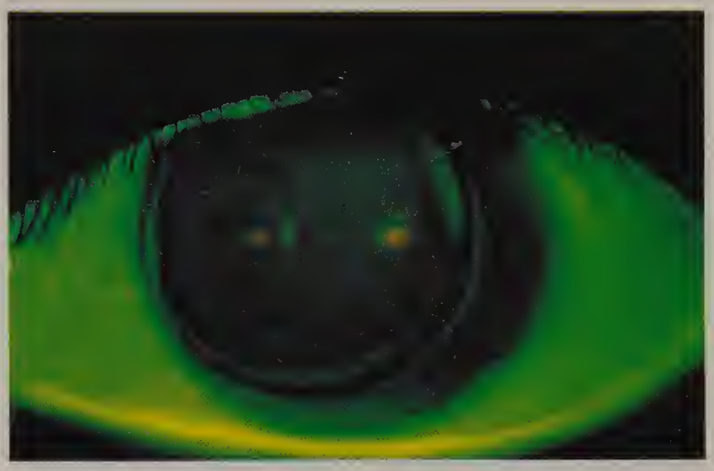


Figure 15.25 Lens adherence or binding occurs with extended wear RGP lenses after overnight wear. (From Swarbrick, 1988, by permission)

Corneal moulding and distortion

Because of the rigidity of RGP compared to hydrogel lenses, corneal distortion or moulding of corneal curvature may result from overnight wear of these lenses, due to the sustained pressure exerted by the eyelid on the lens and the cornea beneath it. Distortion of the cornea under these circumstances may possibly be facilitated in a 'softened' or swollen cornea during closed-eye lens wear.

Clinical investigators have consistently reported slight corneal moulding with RGP extended wear. The trend appears to be towards a slight flattening of corneal curvature, which occurs to a greater extent with more astigmatic corneas. In general, the steeper corneal meridian appears to be more affected, resulting in a trend towards reduced corneal toricity (Benjamin and Simons, 1984; Zabkiewicz *et al.*, 1986; Henry *et al.*, 1987; Polse *et al.*, 1987; Key and Mobley, 1989; Rivera and Polse, 1991; Young and Port, 1992; Sigband and Bridgewater, 1994). Corneal moulding may be reduced with higher *Dk/t* lenses (Polse *et al.*, 1988), although the lens fitting characteristics also play a role (Rivera and Polse, 1991).

The long-term significance of these subtle changes in corneal curvature is unclear, and further work is needed. However, slight corneal moulding does not appear to cause detectable structural changes in the cornea and, in general, corrected visual acuity is unaffected.

Temporary localized corneal distortion and spectacle blur have been reported in association with lens adherence, and other physiological disturbances such as corneal oedema, vacuoles and staining (Zabkiewicz *et al.*, 1986; Young and Port, 1992). Appropriate clinical management of the underlying condition is likely to eliminate the distortion in these cases.

Lens adherence

A number of researchers have described the phenomenon of lens adherence or binding in association with RGP extended wear, whereby the lens is tightly adherent to the cornea on eye opening (Zantos and Zantos, 1985; Seger and Mutti, 1986; Polse *et al.*, 1987; Swarbrick and Holden, 1987, 1989; Kenyon *et al.*, 1988, 1989; Swarbrick, 1988, 1991; Lin *et al.* 1989. The lens is typically decentred, usually in the nasal position and often overlapping the limbus, and causes little discomfort or subjective symptoms (Swarbrick and Holden, 1989). Spontaneous lens movement generally occurs within the first hour after eye opening due to increased tear secretion and lid action, although in some cases the lens may remain bound to the cornea for many hours (Swarbrick and Holden, 1987). On lens removal, a complete or partial indentation or compression ring (*Figure 15.25*) corresponding to the lens edge is usually observed, and the epithelium may display some central punctate staining (Kenyon *et al.*, 1988). The compression ring rarely stains with fluorescein; more typically fluorescein pools in the indentation, or appears to thin in this area if the indentation is shallow. Lens adherence has been estimated to occur in approximately 50% of RGP extended wearers on any one night of lens wear (Seger and Mutti, 1986; Swarbrick and Holden, 1987, 1989; Kenyon *et al.*, 1988), although higher incidence figures have been reported in some studies (Lin *et al.*, 1989).

Lens adherence is a significant complication of RGP extended wear for a number of reasons. First, epithelial compression by the adherent lens edge causes significant localized corneal distortion (*Figure 15.26*), which may persist for some hours. Because some patients bind lenses frequently (Swarbrick and Holden, 1989), and often in the same position (Swarbrick, 1991), there is a potential for long-term compromise of the underlying epithelium and stroma. However, the significance of this repeated localized pressure has yet to be determined.

Lens adherence also exacerbates peripheral 3 and 9 o'clock staining, which can sometimes show alarmingly rapid progression to dellen formation and peripheral corneal ulceration. Levy (1985) was the first to report the development of bilateral peripheral corneal ulceration in



Figure 15.26 Photokeratoscopic image showing corneal distortion associated with a corneal indentation or compression ring induced by the edge of an adherent RGP lens. The photograph was taken immediately following lens removal. Recovery is usually complete within 8 hours. (From Swarbrick and Holden, 1987, by permission)

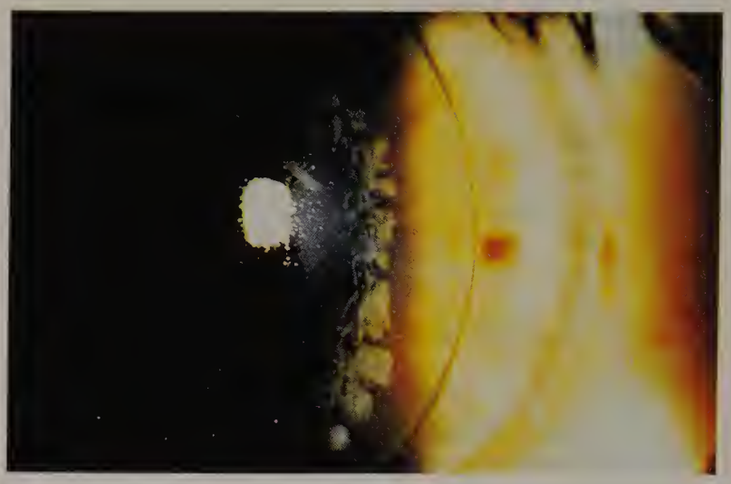


Figure 15.27 Tear debris and mucus remain trapped behind the lens, typically collecting in a ring behind the midperiphery of an RGP lens, as shown here, and centrally under a soft lens (*see Figure 15.3*). This trapped debris has the potential to provoke an acute inflammatory response, such as the CLARE reaction. (Courtesy of R. Terry)

one of his subjects in association with lens adherence; fortunately the ulcers healed without affecting vision. Schnider *et al.* (1988) also reported a case of peripheral corneal ulceration precipitated by severe 3 and 9 o'clock staining which developed in association with a bound lens. Swarbrick (1991) found that 3 and 9 o'clock staining in association with lens adherence showed progression only if the lens remained adherent for some time after eye opening. She postulated that tear film disruption at the intersection of the limbus and the edge of the stationary lens is the major contributing factor. Typically, 3 and 9 o'clock staining resolves rapidly once the adherent lens becomes mobile.

A further cause for concern with lens adherence is that, while the lens is adherent, there is no circulation of tears behind the lens. Consequently corneal deswelling after overnight hypoxic stress may be impeded, although this may not cause significant problems with high *Dk/t* lenses. More importantly, however, tear debris and mucus remain trapped behind the lens, typically collecting in a ring behind the mid-periphery of the lens (*Figure 15.27*; Zantos and Zantos, 1985). This trapped debris has the potential to provoke an acute inflammatory reaction; such a course of events has been noted in two RGP extended lens wearers participating in CCLRU clinical studies (Schnider *et al.*, 1988). Fortunately, however, this consequence appears to be rare.

In a retrospective analysis of factors influencing lens adherence, Swarbrick and Holden (1987) reported that lens adherence was more frequent with large diameter, flat base curve lenses with little edge lift. Lenses fitted on-*K* or slightly flatter than central *K*, or which showed insufficient lens movement before eye closure, were also more likely to bind. In further controlled prospective studies, Swarbrick and Holden (1996a) found that changes in lens diameter and edge fitting of lenses did not in fact influence the incidence of lens adherence. However, lenses fitted flatter than *K* were associated with a significant increase in the incidence of lens adherence, while steeply fitted lenses bound with the same frequency as those fitted in alignment with the cornea.

Swarbrick and Holden (1987, 1989, 1993) also noted that some patients have a markedly greater propensity to exhibit repeated lens binding, suggesting that individual patient factors may influence this phenomenon. An analysis conducted by Swarbrick (1991) suggested that ocular rigidity may be a significant factor influencing lens adherence, although of poor predictive value in identifying those prone to frequent adherence. They suggestsed that corneal flexure or moulding towards the back surface of the adherent lens during eye closure may contribute to the phenomenon.

Several theories have been advanced to explain RGP lens adherence, based on mechanisms proposed to explain silicone elastomer lens adhesion. The negative pressure or 'suction cup' effect proposed by Fatt (1979) has been discussed in relation to RGP lens adherence. However, steeply fitted RGP lenses in fact show a lower incidence of lens adherence compared to those fitted flatter than *K* (Swarbrick and Holden, 1987, 1996a), and lens fenestration, which would be expected to reduce any suction effect, appears to have little effect on lens adherence (Polse *et al.*, 1987; Swarbrick, 1988; Kenyon *et al.*, 1989).

Contact adhesion between the back surface of the lens and the corneal epithelium, as discussed by Fanti and Holly (1980) in relation to silicone elastomer lens adhesion, has also been proposed as a mechanism for RGP adherence. According to this theory, hydrophobic attraction between the epithelium and the silicone-containing lens material precipitates direct lens-to-cornea adhesion.

One would anticipate that such intimate contact would induce significant epithelial staining. However, although central punctate staining may accompany lens adherence, it is not a necessary finding even after prolonged periods of adherence (Swarbrick, 1988), and is rarely observed in the area of indentation, where contact between lens and cornea is heaviest. Further evidence against this theory comes from the observation of a high incidence of adherence of hydrogel lenses (which contain no silicone) immediately on eye opening after overnight lens wear (Kenyon *et al.*, 1988; La Hood and Holden, personal communication).

Swarbrick (1988, 1991) proposed that lens adherence is precipitated by gradual expulsion of the aqueous phase of the tear layer from between the lens and cornea due to the light, but prolonged, pressure of the eyelid on the lens during eye closure. The resultant very thin, highly viscous layer of mucus-rich tears then acts as an adhesive which sticks the lens to the cornea. On eye opening, the force required to initiate lens movement may exceed that exerted by the eyelid on blinking, and the lens will remain adherent until the retained mucus layer is thickened and diluted by gradual penetration of aqueous tears behind the lens. Corneal moulding towards the back surface of the rigid lens during sleep may also play a role in thinning the tear film between the lens and cornea.

Because of the potential for serious consequences with repeated or prolonged episodes of lens adherence, clinicians should schedule examinations of RGP extended wear patients as early as possible in the morning following overnight lens wear. Although an adherent lens will rarely be observed, as spontaneous lens movement after eye opening is generally rapid, the presence of a corneal indentation ring should be considered a positive diagnostic sign (Kenyon *et al.*, 1988).

Reliable strategies for controlling lens adherence have yet to be determined, although the work of Swarbrick and Holden (1996a) suggests that flat-fitting lenses should be avoided. However, attempts to manage the consistent lens binder can prove frustrating. Various clinical approaches have been advocated, including manipulation of the edge design (Quinn, 1990), increasing or decreasing optic zone diameter, changing lens back surface design, blending the peripheral curves and the use of in-eye wetting drops (Bennett and Egan, 1986; Henry *et al.*, 1987). Increasing lens thickness to reduce lens flexure has also been advocated (Bennett and Egan, 1986; Morgan and Bennett, 1989), although this will reduce the *Dk/t* value of the lens (Polse *et al.*, 1987), and appears to be relatively ineffective (Kenyon *et al.*, 1989). Alerting the patient to the phenomenon, so that lens movement can be initiated soon after eye opening by irrigation with sterile saline solution and gentle lens manipulation with the lid margins, may reduce the risk of complications, in particular progressive 3 and 9 o'clock staining. However, in many cases the most practical and successful clinical option is to return the persistent lens binder to a daily wearing schedule (*see also* Chapter 10).

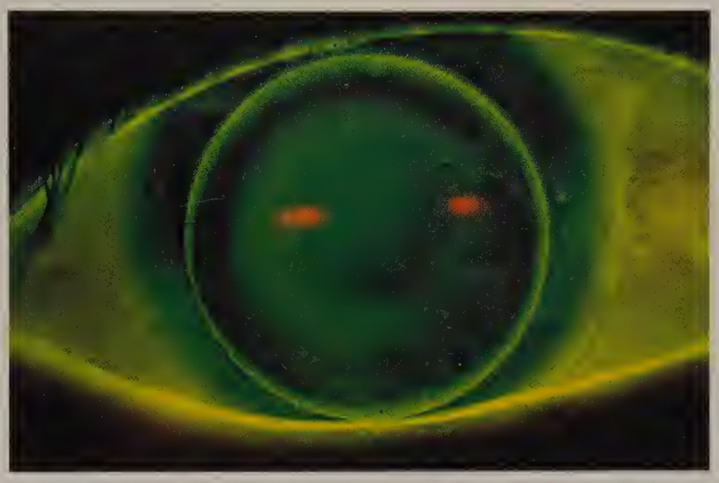


Figure 15.28 During extended wear, inadequate edge clearance and associated restricted lens movement may also induce 3 and 9 o'clock staining. (Courtesy of R. Terry)

Corneal staining

Significant corneal staining, in particular 3 and 9 o'clock staining (*Figure 15.28*), may occur in association with RGP extended wear (Zantos and Zantos, 1985; Seger and Mutti, 1986; Zabkiewicz *et al.*, 1986; Schnider *et al.*, 1988; Key and Mobley, 1989). If 3 and 9 o'clock staining is persistent and severe, the localized drying of the cornea may lead to dellen formation and corneal thinning (Seger and Mutti, 1986) and, in extreme cases, epithelial erosion, neovascularization or corneal ulceration may ensue. Vascularized limbal keratitis, as described by Grohe and Lebow (1989), may represent an exacerbation of persistent peripheral desiccation staining.

In general, 3 and 9 o'clock staining can be attributed to peripheral corneal desiccation resulting from inappropriate lens design and fitting, rather than to the lens material itself. During open-eye lens wear, this type of staining is due to excessive edge lift of the lens, which creates a pool of tears under the lens edge that draws tears from adjacent areas, leading to localized drying. Excessive edge lift or thickness also causes a bridging effect whereby the eyelid cannot properly resurface the cornea adjacent to the lens edge with mucin and tears, leading to localized drying and desiccation (Schnider *et al.*, 1988). This situation may be exacerbated by a low-riding lens with small diameter and inadequate lens movement, or by incomplete blinking, low tear secretion or short tear break-up times (Hamano *et al.*, 1989).

During extended wear, it is now clear that insufficient edge clearance may also precipitate 3 and 9 o'clock staining, due to reduced tear flow under the periphery of the lens or restricted lens movement (Schnider, Terry and Holden, 1987; Andrasko, 1990). Thus during extended wear, a compromise must be reached in lens edge design to avoid both excessive and insufficient edge clearance. On the basis of CCLRU studies, an on-eye edge clearance of approximately 70–80 μm and edge width of approximately

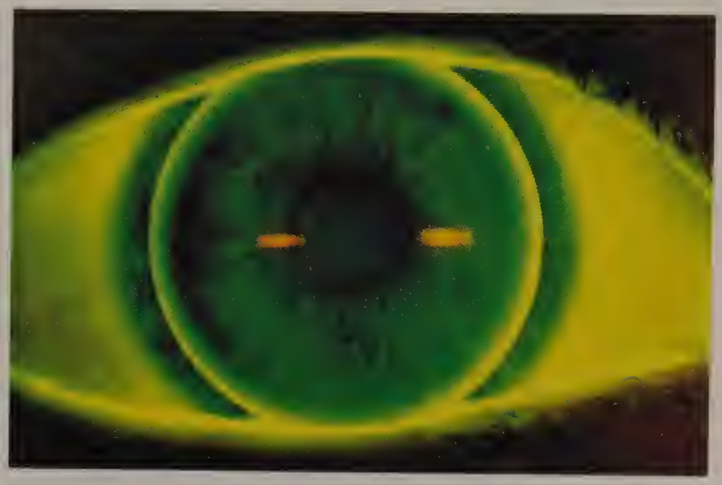


Figure 15.29 Fluorescein photograph of an acceptable RGP lens fitting for extended wear. Slight apical clearance is apparent, with light mid-peripheral bearing and a moderate edge width and clearance. (Courtesy of R. Terry)

0.4–0.5 mm has been recommended for extended wear (*Figure 15.29*) (Cornish *et al.*, 1988).

The development of severe 3 and 9 o'clock staining also appears to be a patient-dependent phenomenon. Patients who are more prone to develop this type of staining tend to show higher levels of baseline conjunctival hyperaemia, more tear debris and lipid, faster lens drying, and poor lens centration and movement (Schnider, Terry and Holden, 1996).

Successful daily wear without the development of more than slight 3 and 9 o'clock staining should be a prerequisite for commencing RGP extended wear. Although mild 3 and 9 o'clock staining is not unusual during RGP extended wear, severe cases must be managed promptly by reducing wearing time until the staining resolves, and by altering the lens edge design to avoid peripheral desiccation. Avoiding persistent lens adherence following eye opening will also help to minimize 3 and 9 o'clock staining, as will altering lens design to maintain lens centration and adequate and sustained lens movement during open-eye lens wear (*see also* Chapters 10 and 18).

Another type of corneal staining, termed the Fischer–Schweitzer polygonal mosaic, is also occasionally noted immediately upon lens removal following RGP extended lens wear (Benjamin and Simons, 1984; Levy, 1985; Zantos and Zantos, 1985; Zabkiewicz *et al.*, 1986). This phenomenon does not generally involve true staining of the epithelium, but rather manifests itself as a polygonal meshwork of fluorescein pooling in the central or superior regions of the cornea. The aetiology of the phenomenon was described by Bron and Tripathi (1969), who considered that external pressure exerted on the cornea causes ridges to form in Bowman's layer as the cornea flattens. Following removal of the pressure, Bowman's layer regains its normal curvature, leaving grooves where epithelial cells have been compressed above the ridges during flattening. The corneal mosaic normally disappears within 10 minutes following removal of the lens. Although not of concern in itself, the appearance of this corneal mosaic pattern in RGP extended lens wearers suggests that the contact lens may be exerting undue pressure on the cornea during wear, possibly indicating an excessively flat fit.

Corneal staining due to foreign bodies, lens mishandling or dislodgement, lens adherence or damaged lenses may also be noted during RGP extended wear. In severe cases, it is wise to discontinue lens wear until the epithelial defect has resolved. Appropriate clinical management and patient education may reduce the incidence of these complications.

Long-term effects of RGP extended wear

Relatively little has been published regarding the long-term effects of RGP extended wear on corneal physiology. It is thought that the long-term corneal changes accompanying hydrogel extended wear are induced directly or indirectly by chronic hypoxic stress on the corneal tissue (Holden, Sweeney *et al.*, 1985). Therefore, it would be anticipated that similar changes would occur with long-term extended wear of RGP contact lenses of comparable *Dk/t* value. As RGP lenses of higher *Dk/t* value become used increasingly for extended wear, it might be expected that changes such as epithelial thinning and microcystic development, reduced epithelial oxygen uptake, stromal thinning and endothelial polymegethism, would be less apparent.

Indeed, results from RGP extended wear studies at the CCLRU and elsewhere indicate that epithelial microcysts, which are invariably seen in hydrogel extended lens wearers after 3 months of wear, are infrequent in high *Dk/t* RGP lens wearers (Terry *et al.*, 1986; Holden, Grant *et al.*, 1987; Schnider, Holden *et al.*, 1987; Rivera and Polse, 1991). A number of investigators have also reported minimal induction of endothelial polymegethism with moderate or high *Dk/t* RGP lenses, although the periods of observation have generally been less than 12 months (Orsborn and Schoessler, 1988; Polse *et al.*, 1988; Rivera and Polse, 1991). It should be noted, however, that polymegethism accompanying hydrogel extended wear may be noted after as little as 2 weeks of lens wear (Holden, Vannas *et al.*, 1985).

Long-term clinical studies of high Dk RGP extended wear conducted at the CCLRU (reported by Cornish *et al.* at the 7th International Contact Lens Congress in Queensland, Australia, 1990) provide some further information concerning the long-term viability and safety of this lens-wearing modality. A total of 135 patients were enrolled in these studies, and fitted with lenses with *Dk/t* values greater than 50×10^{-9} units. The patients were put on an extended wear schedule which specified overnight lens removals as desired by the patient. Patients were told to clean their lenses as frequently as required, and there were no scheduled lens replacements. The cleaning regimen, which was tailored to each patient, included the use of an alcohol-based cleaner in cases of lipid deposition, and a textured cleaning pad for removing heavy deposition. An enzymatic cleaner was not used.

Lens-related discontinuations were highest in the first year, with 30% of patients leaving the study. By far the most frequent cause of discontinuation was discomfort (24%), and the majority of discontinuations for this reason (87%) occurred in the first month. In the first year, CLPC was confined to previous soft lens wearers with pre-existing upper lid changes. Discontinuations were less frequent in subsequent years. Notably, some patients developed CLPC associated with lens deposits in the third and fourth years of the study. However, after 3 years, 54% of patients entered in the study (excluding non-lens-related discontinuations) were still successfully wearing the lenses. Adverse responses during this period were rare. One patient developed idiopathic infiltrates, and another experienced an eruption of vacuoles; both successfully resumed extended wear after resolution. No CLARE reactions or corneal infections were recorded during the 3-year period.

However, some other interesting clinical findings were noted. There was a slight increase in the incidence of microcysts, despite the high *Dk/t* of the lenses. It should be noted, however, that the increase averaged less than 10 microcysts over a 3-year period, and thus could be considered of only marginal clinical significance. This finding may mean that even with high oxygen levels reaching the cornea, a slight reduction in oxygenation may provoke a hypoxic response in the long term. Alternatively, chronic corneal acidosis or mechanical factors may play a role in the microcyst response. Further work is needed to clarify this finding.

The other interesting clinical finding was an increasing incidence of upper eyelid changes. Both upper eyelid hyperaemia and papillae increased significantly over the 3-year period, and three patients were ultimately discontinued from lens wear due to CLPC. The development of CLPC during RGP extended wear has also been reported by others (Zabkiewicz *et al.*, 1986; Douglas *et al.*, 1988; Terry, Schnider and Holden, 1989; Sigband and Bridgewater, 1994). The eyelid changes are different from those seen during hydrogel lens wear, being more localized in the central portion of the eyelid, and less marked than the typical hydrogel-induced CLPC in both extent and roughness.

Possible factors which may precipitate these eyelid changes include the mechanical effect of the lens itself, and either mechanical or antigenic effects of lens deposits. The latter seems more likely, as a significant increase in lens deposition was noted during the study. Annual lens replacement and enzymatic cleaning may prove successful for management of deposits, and may thus reduce the incidence of upper eyelid changes during long-term high Dk RGP extended wear.

The significance of other potential chronic effects, such as reduced corneal and lid margin sensitivity, and eyelid ptosis (Fonn and Holden, 1986) has yet to be determined. Further long-term studies are needed to detail the extent of these and other chronic changes which may be induced by RGP extended wear, and to ensure that the extended wear of high Dk RGP materials continues to be a safe and efficacious means of vision correction.

Clinical management of RGP extended wear

Patient selection

Because RGP lenses do not cover the cornea completely, and may induce mechanical trauma to a compromised cornea, the use of these lenses for bandage purposes is unlikely to be beneficial, and is therefore not recommended. However, RGP lenses have been used successfully for both aphakic (Benjamin and Simons, 1984; Garcia *et al.*, 1990) and cosmetic extended wear (Levy, 1985, 1991; Henry *et al.*, 1987; Polse *et al.*, 1987, 1988; Key and Mobley, 1989; Rivera and Polse, 1991; Young and Port, 1992). Kastl and Johnson (1989) also reported success with this modality for patients with high astigmatism and keratoconus.

The criteria for patient selection for hydrogel extended wear have been outlined in a previous section; these criteria also apply to the selection of potential patients for RGP extended wear. As with hydrogel extended wear, the risk:benefit ratio for each individual patient should be considered carefully before proceeding with RGP extended wear. Thorough patient education and instruction are essential in order to emphasize the realities of extended wear, including the need for regular lens cleaning and maintenance, frequent overnight lens removal to rest the cornea, and prompt contact with the practitioner should unusual redness, discomfort or blurred vision occur.

More latitude is available for correcting corneal astigmatism with RGP lenses compared to hydrogel lenses, although the centre thickness of the lenses may have to be increased to minimize on-eye flexure which may cause fluctuating vision on blinking (*see* Chapter 10). It must be remembered that increasing lens thickness will reduce the *Dk/t* value of the lenses.

Patients with dry eye problems or poor blinking habits may have poor success with RGP extended wear, particularly if the lens fit is less than optimal. It has been suggested that hydrogel extended lens wearers who are forced to discontinue lens wear due to the development of CLPC may be successfully re-fitted with RGP lenses for extended wear. However, it has been the experience at the CCLRU and elsewhere that although patient symptoms may be reduced initially, there is frequently a recurrence of CLPC after a period of RGP lens extended wear (Douglas *et al.*, 1988; Schnider *et al.*, 1988).

Lens fitting

Techniques for fitting RGP lenses are discussed in Chapter 10, and therefore will not be considered in detail in this section. In general, RGP lens fitting for extended wear requires more care and expertise than hydrogel lens fitting.

For high Dk materials, large diameter lenses can be used as less reliance needs to be placed on tear exchange for provision of oxygen to the anterior corneal surface. Lens diameters of 9.4–10.2 mm can be employed. These large diameter lenses allow for greater back optic zone diameters, in the range 8.0–8.2 mm, giving the advantages of improved

comfort, and less flare in younger patients with large pupils, particularly under conditions of low illumination.

It is advisable to aim for an alignment fitting which minimizes the bearing pressure on any particular corneal location, especially the mid-periphery, in order to encourage an even tear flow beneath the lens and minimize lens-induced corneal distortion. Multi-curve back surface designs with well-blended transition zones, or aspheric lens designs, can be used to achieve this type of fitting, which is best verified using fluorescein fitting techniques. Flat-fitting lenses should be avoided because of the increased potential for lens adherence (Swarbrick and Holden, 1996a). A tapered edge design incorporating two or three peripheral curves is suggested; on fluorescein evaluation the edge should be approximately 0.4–0.5 mm wide and 70–80 μm deep (Cornish *et al.*, 1988; *Figure 15.29*). Excessive or insufficient edge lift may exacerbate 3 and 9 o'clock desiccation staining.

Lens movement or lag following a blink should be smooth, without apical rotation or excessive lens–lid interaction. Although there is less dependence on the tear pump for corneal oxygenation with higher *Dk/t* lenses, lens movement following a blink should be in the order of 0.75–1.50 mm in order to permit efficient flushing of debris and waste products from behind the lens. Good centration of the lens between blinks is also desirable; it may be necessary to steepen the back optic zone radius slightly in some cases to achieve this.

The choice of RGP material will influence the long-term physiological performance of the lens for extended wear. In the short term, moderate Dk materials, such as Equalens and Quantum 1, appear to perform reasonably well for extended wear for many patients, but are not likely to stand the test of time in physiological terms. We believe that the oxygen requirements of the cornea during extended wear can be fully met only with RGP materials with a Dk of at least 100 $\times 10^{-11}$ units, and that these materials should be used in preference to low or moderate Dk materials which are more likely to induce long-term changes in corneal physiology. However, other aspects of on-eye lens performance are also critical for long-term extended wear success, including lens wettability and deposit formation. These characteristics appear to vary between individual patients, and should be evaluated carefully before a final decision on lens material is made.

Lens centre thickness will also influence the physiological performance of the lens. However, a balance must be achieved between enhancing the oxygen transmission characteristics of the lens and minimizing on-eye flexure, particularly on astigmatic corneas. An increase in lens thickness of 0.02 mm for every dioptre of uncorrected corneal cylinder has been suggested as a rule of thumb (Bennett, 1985; *see also* Chapter 10).

Care and maintenance

Because of the non-porous nature of RGP lens materials, contaminants are unable to penetrate the polymer matrix. Thus the care and maintenance procedures for RGP lenses are considerably less complicated and time-consuming than those required with hydrogel lenses. Contaminants and deposits which adsorb on to the lens surface are usually easily removed using a surfactant cleaner. Cleaning solutions incorporating a fine particulate suspension may prove advantageous for the removal of stubborn surface deposits through friction, as may the use of textured cleaning pads. Because of the propensity of some RGP materials to adsorb tear proteins, some practitioners also recommend the use of enzymatic cleaners to enhance lens cleanliness in those patients with significant deposit problems. Other alternatives, such as the use of hydrogen peroxide disinfection (Boltz *et al.*, 1993), are also useful to maintain lens surface cleanness in some cases.

Overnight lens storage solutions should be used when the lenses are off the eye to maintain lens hydration and enhance surface wettability. An antibacterial agent is generally incorporated in the storage solution to inhibit bacterial contamination. Although it has been suggested that the preservative benzalkonium chloride may bind to the surface of silicone acrylate materials (Rosenthal *et al.*, 1986), it does not appear to reach concentrations which are toxic to the eye, at least for low Dk materials (Wong *et al.*, 1986). Wetting solutions can be used to maximize lens wetting and patient comfort on lens insertion. The current trend appears to be towards combination storage/wetting solutions, which considerably simplify lens care for the patient. In-eye 'comfort' drops for re-wetting and cleaning the lenses on the eye may also be used to maintain patient comfort during lens wear (*see* Chapter 4).

Because we believe that a conservative approach to extended wear is advisable, we recommend that patients be advised to remove their lenses overnight at least once a week to rest the cornea from hypoxic stress. Within this framework patients should be encouraged to remove their lenses as often as they desire. As with hydrogel extended wear, occasional overnight wear is preferable to continuous wear for long periods without lens removal, although with very high Dk materials, true continuous wear remains a possibility (Terry *et al.*, 1986).

Regular lens replacement is probably not as necessary as with hydrogel extended wear, because RGP lenses do not absorb contaminants or age as rapidly as do hydrogel lenses. Obviously, replacement of damaged, deposited or scratched lenses is essential to avoid corneal or lid trauma.

Patient advice and management

As with hydrogel extended wear, it is essential that patients are able to handle their RGP lenses competently before these are dispensed. A period of daily wear of 1–2 weeks is often useful to reinforce the patient's lens handling techniques, and is advisable if there are any doubts about the lens fit, which must be optimal before an extended wear regimen is initiated. During the daily wear adaptation period, problems with lens wettability and deposit forma-

tion may also be identified and changes in lens material or care and maintenance procedures instituted before extended wear begins. In addition, patients prone to excessive peripheral desiccation staining can be identified and discouraged from progressing to extended wear, which will exacerbate this problem. Adaptation to RGP lenses is generally rapid, and full-time daily wear is often possible from the first day. However, there will be greater lens awareness during the first few days than with hydrogel lenses and previous hydrogel lens wearers should be warned of this.

Patients should be seen early in the morning following the first overnight wear of their RGP lenses. At this visit, the practitioner should examine the cornea carefully for signs of residual corneal oedema (striae and folds) and lens adherence (compression ring). Follow-up visits after 3 days, 1 week, 2 weeks, 1, 2 and 3 months of extended wear are then advised, and if no problems are apparent, 3-monthly aftercare visits should follow.

Patient advice and management procedures are similar to those suggested for hydrogel extended lens wearers. It is essential to emphasize to the patient that if unusual redness, discomfort or blurred vision develops, particularly in one eye only, the patient should remove the lenses and consult the practitioner immediately.

The future of extended wear

Extended or continuous wear is the desired mode of contact lens wear for the majority of prospective contact lens patients. A CCLRU study (Holden, 1989) found that, if it were possible, 41% of prospective contact lens patients would prefer to wear lenses on a continuous basis (without lens removal), 35% were happy with 6 nights of wear per week, 21% desired occasional extended wear, and only 3% wanted daily lens wear.

The development of safe, comfortable lenses for extended or continuous wear depends on a number of factors. Clearly such lenses must satisfy basic prerequisites such as the provision of adequate oxygen to the cornea during sleep, maintenance of fluid movement behind the lens during waking hours, and physical and biological compatibility of the lens with the ocular tissue. RGP lenses are now available which satisfy corneal oxygen requirements in the majority of patients during both open- and closed-eye lens wear. These lenses also provide adequate tear exchange, good mechanical performance and excellent biocompatibility for the majority of wearers, and give an extremely low adverse response rate. In addition, long-term changes in corneal structure and function, which are inevitable with current hydrogel extended wear lenses, appear to be minimal with lenses made from high Dk RGP materials. Although these results are promising, discomfort, 3 and 9 o'clock staining, lens adherence and changes in corneal shape remain as significant problems with this lens-wearing modality, and have limited the clinical acceptance of RGP lenses for extended wear.

High Dk flexible lens materials are an obvious area for development in the search for a truly successful continuous wear lens, and a number of promising materials are now entering preliminary clinical trials. While these and similar lens materials may go a long way towards solving the problems of lens-induced hypoxia and patient acceptance in terms of comfort, it is not yet clear whether the inflammatory and infective problems associated with current hydrogel extended wear lenses will be reduced. Continuing research is clearly needed to elucidate the mechanisms underlying these adverse responses, and to develop strategies which will reduce their incidence and improve the safety and acceptance of extended lens wear.

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Chapter 16

Bifocal and multifocal contact lenses

J. T. de Carle

Introduction p. 540
History p. 540
Theory of bifocal contact lenses p. 544
Types of bifocal contact lenses p. 545
Monovision p. 547
Choice of bifocal type p. 548
Extra measurements needed when fitting bifocal lenses p. 549
Fitting procedures for rigid lenses p. 549
Scleral bifocal lenses p. 559
Hydrophilic bifocal contact lenses p. 560
Fitting sets p. 563
Conclusion p. 563

Introduction

Presbyopic patients present difficulties to contact lens practitioners and it is important to discuss the available options with the patient at the initial visit. Such patients may be fitted with:

- single vision contact lenses, corrected for distance, and wear a pair of additional glasses for near vision (this correction could be made up in the form of plano distance bifocal spectacles);
- single vision lenses correcting one eye for distance and the other eye for reading (monovision);
- bifocal or multifocal contact lenses.

Possibly the biggest problem occurs with early presbyopes who are just becoming aware of the fact that they are experiencing difficulty with near vision and have only been wearing single vision spectacles or contact lenses. It is sometimes difficult to convince such patients that it is necessary to change from single vision spectacle lenses to single vision contact lenses plus spectacles, or to bifocal contact lenses. In these cases, it may be preferable to fit them with contact lenses with +0.50 D added to aid near vision, at the same time explaining that presbyopia happens to everybody and that these changes occur whether or not they have contact lenses. Also it should be explained that this solution is only temporary and one of the above options will eventually become necessary.

Generally, patients who are able to wear single vision lenses should be suitable for bifocals, but care must be taken with some patients who may manage single vision lenses but would prove unsuitable for the more complicated bifocal lenses. Also, most types of bifocal contact lenses will reduce contrast sensitivity (Collins *et al.*, 1989).

History

The first reference to bifocal contact lenses is credited to Feinbloom of New York, who showed diagrams of bifocal and trifocal segments in the optic zone of scleral contact lenses in a patent specification in 1938 (*Figure 16.1*).Williamson-Noble (1951), a British ophthalmologist, mentioned his own work on bifocal contact lenses when he gave the presidential address to the Contact Lens Society in 1950. He had become interested in the possibility of these lenses after seeing a patient aged 71 years who could read small print easily, both with and without a +2.25 D near addition. Slight lens opacities had made the crystalline lens, in effect, bifocal and it occurred to him that something similar might be possible with a contact lens. A lens was made with a central portion 2.00 D more convex than the remainder of the front surface (*Figure 16.2*). This lens was tried on his own eye but at first did not work in the way he had hoped. However, he found that if he kept his eye open for some time the print gradually became clearer. This was thought to be due to the front surface of the lens becoming dry and then allowing the near addition to have its proper effect; also that an accumulation of tear liquid around the small near addition prevented the lens from working properly. It was therefore suggested that a fused bifocal would probably be the answer.

Pinhole lenses have been suggested as a means of giving a presbyopic patient clear vision from distance to a normal near working position (Freeman, 1952). This can be easily achieved with contact lenses, half the normal near addition being added to the distance prescription (*Figure 16.3*). The diameter of the aperture is between 1.00 and 2.00 mm, according to the near addition: the higher the near addition the smaller the aperture needs to be, in order to achieve an acceptable degree of vision by reducing the size of the blur circles. Unfortunately, this cannot be done without a number of disadvantages as follows:

- Considerable loss of light. A 1.00 mm aperture is the equivalent of a very dark-tinted spectacle lens.
- Reduced field of view; this could be as little as 15°, depending on the depth of the anterior chamber, i.e. the distance of the lens from the eye's entrance pupil.

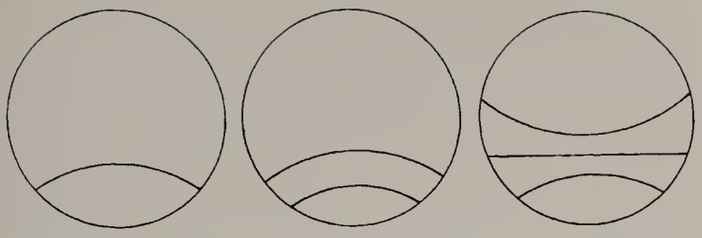


Figure 16.1 Bifocal and trifocal constructions in the optic portion of scleral lenses as suggested by Feinbloom (1938)

- Poor cosmetic appearance.
- A lens with a minimum of movement is essential. This is often difficult to achieve without sacrificing comfort and upsetting corneal metabolism.

De Carle (1959) considered these experimental lenses in 1957 and, because of the difficulties involved in making a fused bifocal, decided that a similar effect could be achieved by putting the bifocal surface on the back of the lens so that the partial neutralization effect of the tears would be constant. De Carle also reversed the positions of the near and distance portions so that there was now a distance portion in the centre (*Figure 16.4*). Provided that the distance portion was small (2.00–4.00 mm was usual), the fact that the back central curve was much steeper than the cornea did not create problems. (Large distance portions, particularly with the higher near additions, were found to be impractical as a bubble or bubbles would form between the lens and the eye.) In this type of concentric bifocal lens, the patient looked through both the distance and near portions at the same time.

The de Carle bifocal may best be visualized as a near vision contact lens with a small portion in the centre of the back surface, ground and polished to a much steeper radius for distance vision use. This creates a positive tear lens between the central portion of the lens and the cornea. The power difference in air between the distance portion and the near portion is just over three times the near addition actually required (*see* Chapter 5), for example:

Distance Rx +2.00 D
Near addition +2.50 D
Distance BCOZR 6.92 mm
Near BPOZR 7.80 mm
Distance BVP of lens in air –3.50 D
Near BVP of lens in air +4.50 D



Figure 16.2 Bifocal scleral lenses suggested by Williamson-Noble (1951) with a small convex central near portion on the front surface



Figure 16.3 Cross-section of a pinhole contact lens with opaque areas of the lens shown in black

To some extent most multi-curve corneal lenses act as back surface bifocals, since the back vertex power (BVP) through the periphery of the lens is more positive, or less negative, than through the optic zone, due to the back surface peripheral flattening.

In 1957–58, Wesley and Jessen of Chicago (Jessen, 1960) were also working on a concentric bifocal lens with a central distance portion. The difference between their bifocal and the de Carle bifocal was that the bifocal surface was worked on to the front surface and that the distance portion was larger (*Figure 16.5*). The Wesley-Jessen bifocal had the same power difference in air between the distance and near portions as the near addition actually required.

As the difference in radii on the de Carle bifocal was three times greater than that on a Wesley-Jessen bifocal, the manufacturing problems were slightly less as there was less tendency for the two curves to blend together when being polished. Also any errors of this nature were two-thirds eliminated by the tear liquid on the de Carle bifocal.

The main effect of the difference in sizes of the distance portions of these two lenses conveniently illustrates the two ways in which bifocal contact lenses work. The average distance portion of the de Carle bifocal was 3.00 mm and the lens was fitted so that this completely centred over the pupil with only a small amount of movement. The distance portion diameter was determined by the pupil size so that

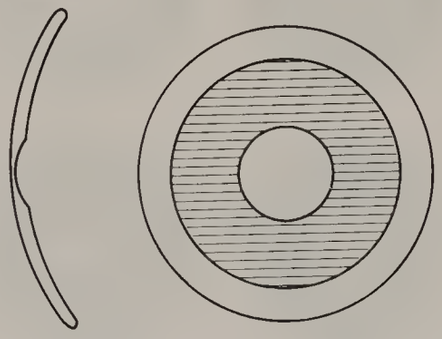


Figure 16.4 De Carle concentric back surface bifocal (1957) with a 2.0–4.0 mm central distance portion surrounded by the near portion used as a bearing surface

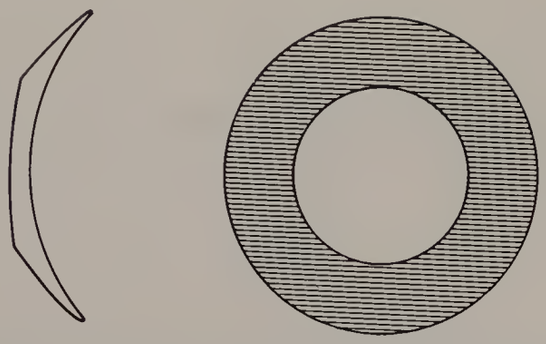


Figure 16.5 Wesley–Jessen concentric bifocal with a relatively flat distance portion on the front surface surrounded by a more convex near portion

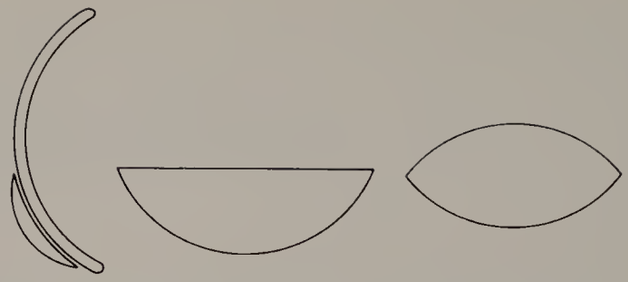


Figure 16.7 McKay Taylor additive bifocal. A small supplementary additional lens is placed on top of the carrier lens *in situ*. Two suggested shapes for additive lenses are shown on the right of a cross-section through carrier and additive lens (*left*)

approximately the same amount of light entered the eye through the distance portion as the near portion. This is the 'bivision' principle. When viewing distant objects, there is a sharp image from the distance portion and, superimposed over it, a very blurred image from the near portion, and *vice versa* when the patient reads or does close work. This has the advantage that the patient does not have to hold the reading matter in any particular position to read. The main disadvantage is that the vision is not as sharp because of the side-effects from the superimposed images. However, this is not as bad as might be expected and proved to be quite acceptable to many patients. The Wesley-Jessen bifocal originally had a 6.00 mm distance portion, but this was later reduced to 5.00 mm to increase the near portion. The near portion on this lens can only cover the pupil by movement of the lens – the 'alternating vision' principle. This normally occurs by the patient looking down to read and the lens being pushed upwards by the lower lid. The advantage is sharper image formation with less visual side-effects – the disadvantage being that some lower lids are very loose, so that the lens tends to slide between the lid and the eye and is therefore not pushed upwards sufficiently.



Figure 16.6 Multiple aperture lenses for distance and near vision use suggested by Wesley in 1967

In 1967, Wesley announced another ingenious lens to achieve a bifocal effect (Plastics Contact Lens Company, 1970). Essentially, it has a small central distance portion with a plurality of light-transmitting apertures in the opaque remainder (*Figure 16.6*). This corrected one of the major objections to pinhole lenses namely, the restricted field of view. Many different patterns of apertures were tried, the average width of the slits being 0.8 mm. The central transparent portion was made as large as 3.00 mm. The distance correction was the same as would be prescribed for a single vision distance lens, the near vision focus being achieved by the reduced blur circles from the peripheral apertures. One of the drawbacks of these designs was the multiple images formed with large pupils.

A further type of bifocal lens was suggested by McKay Taylor (1962) and consisted of a small lens placed on top of a contact lens *in situ* (*Figure 16.7*). The lens was held in place by the surface tension of the tears and was made with a single back surface curve slightly flatter than the front radius of the carrier lens to allow a certain amount of movement of the additive lens. When the parent lens was a corneal contact lens, it was necessary to flatten the peripheral curve of the front surface slightly to prevent the additive lens from sliding off entirely. The combined weight caused the corneal lens to rotate in the same way as a prism ballasted lens. When the patient wished to see only in the distance, the small additive lens was removed with a suction holder.

From about 1960, bifocal contact lenses resembling spectacle bifocals became increasingly popular. The segment shapes were mostly similar to their spectacle lens counterparts. Nearly all the lenses were prevented from rotating and kept in their correct position by the use of a prism which settled base-down. *Figure 16.8* shows two of the first of these lenses, both worked on the front surface. *Figure 16.9* shows a decentred de Carle bifocal incorporating prism with the distance portion decentred upwards relative to the base of the prism. *Figure 16.10* shows some solid bifocal lenses designed by Hodd (1967) that are theoretically excellent visually but extremely difficult to make in practice. In fact, all these lenses and variations of them suffer from some disadvantages.

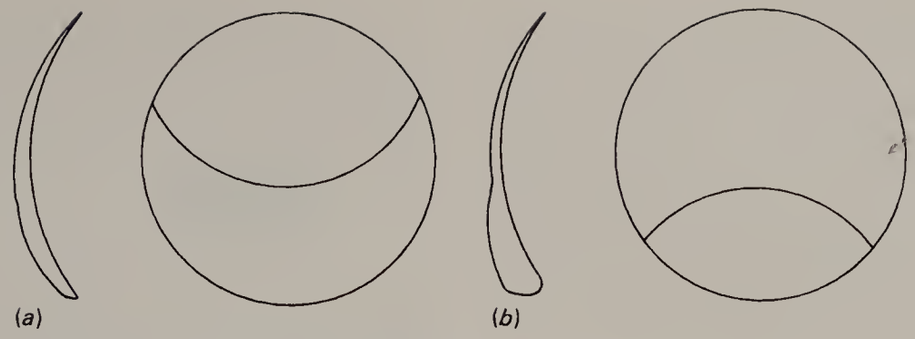


Figure 16.8 Two early suggested front surface solid prism ballasted bifocals

Because the two front surface curves were so similar, it used to be difficult to ensure a sharp focimeter image right up to the transition, with no blending of the curves. This is no longer a problem with modern computer controlled lathes. One of the difficulties found with front surface bifocals was that the vision was not always as clear as with single vision lenses.

As previously mentioned the accumulation of tear liquid prevents the bifocal from working properly. Back surface bifocals do not have this disadvantage, but the type shown in *Figures 16.4* and *16.9* must either have a small distance portion to avoid bubbles becoming trapped or be fitted so that the radius on the back surface for the near portion is flatter than the cornea. This results in the transition touching the cornea, which could cause corneal abrasion. Corneal abrasion from the edge of the recessed portion of the lens, shown in *Figure 16.10a*, could be a problem, the segment needing to be recessed as the radius of curvature of the near portion has to be flatter than the distance portion. Blending is undesirable as it creates an area of blurred vision.

Mandell (1966) was commissioned by a laboratory (Kontur Kontact) to design a prism ballast bifocal to try and eliminate the problems encountered with earlier front surface bifocals. The result was the Mandell 'No-Jump' 'monoconcentric' bifocal (*Figure 16.11*) which at the time was probably the most successful of the front surface bifocals. The near portion was cut into the front surface so that there is a slight 'ledge' between the distance portion and the near portion (similar to a semi-visible centre controlled spectacle bifocal, but on the front surface). The amount of this ledge increases towards the edge of the lens and was absent in the centre. The ledge does not appear to cause irritation of the upper lid.

Monocentric fused bifocals gave an equal performance and had the advantage that the front surface can, within reason, be repolished or have a small power change carried out. Due to the very precise nature of the front surface of the Mandell bifocal, repolishing was not



Figure 16.9 De Carle back surface concentric bifocal incorporating prism ballast and with the distance portion decentred upwards relative to the base of the prism

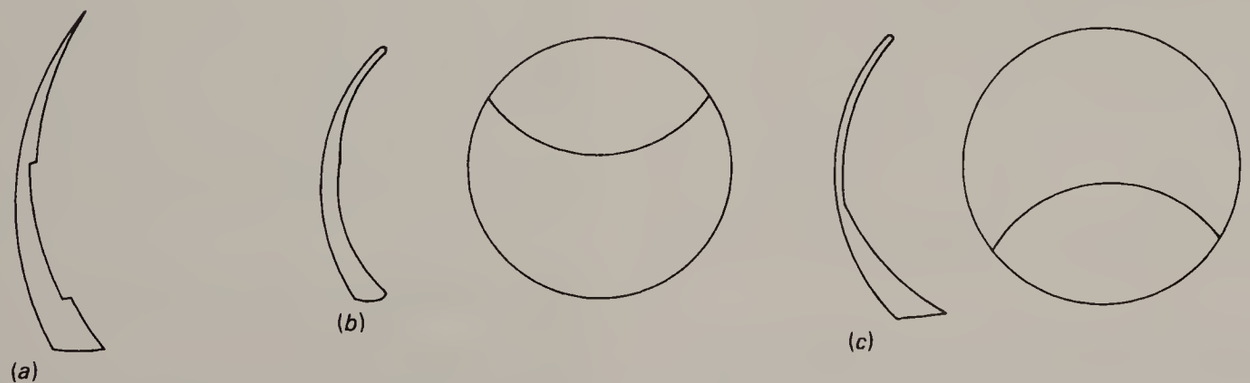


Figure 16.10 Some solid bifocal contact lenses suggested by Hodd (1967). (*a*) With recessed near portion on the back surface; (*b*) an upcurve prism ballasted back surface bifocal; (*c*) a downcurve prism ballasted back surface bifocal

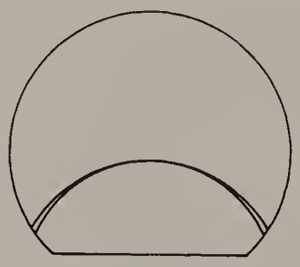


Figure 16.11 Mandell 'No-Jump' front surface bifocal lens

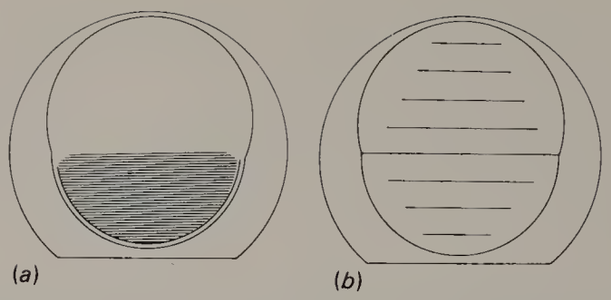


Figure 16.13 (*a*) Front view of the Ysoptic inserted fused bifocal; (*b*) Ysoptic measuring lens for determining segment height

advised. A current lens of this type is the Tangent Streak bifocal (*see* p. 557), having a flat top. These lenses can be repolished when necessary.

A bifocal with an inserted segment of a higher refractive index, or a fused bifocal as shown in *Figure 16.12* would overcome the objections to the back and front surface solid bifocals. The French company of Ysoptic made an inserted segment type of lens (Guilbert, 1969a,b). This lens had a unique back surface. The distance and near portions had the same radius but were set at a slight angle to each other so that the lens could rock on the cornea. This was intended to anchor the lens more firmly for distance or near use (*Figure 16.12b*). Ysoptic also made a bifocal measuring lens for determining segment heights (*Figure 16.13*)

The first multifocal contact lens, to the author's knowledge, was made by accident. In 1958, Jessen, of America (personal communication), suggested that it should be possible to make and fit a concentric back surface bifocal by fitting a single vision corneal lens corrected to the patient's near vision and then setting this up on a lathe and cutting a small steep central curve on the back surface. This necessitated removing approximately 0.01–0.02 mm of material, which was extremely difficult. Polishing this area was even more difficult. When the final lenses were checked, it was found that the focimeter target remained in focus over a range of 8 D, although fainter than normal. By blending the two curves together, a multifocal lens had inadvertently been produced with a range of focus from infinity to about 25 cm. Unfortunately, the side-effects

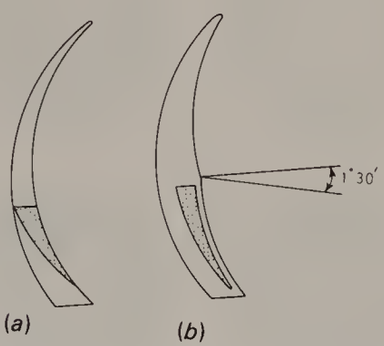


Figure 16.12 (*a*) Fused 'no-jump' bifocal (cross-section). (*b*) Inserted segment fused bifocal (Ysoptic Laboratories) with a double back optic surface to help locate the lens with the desired optic portion in front of the pupil

experienced with this lens were so great that it was not a practical proposition.

In 1972, Wesley, of America, suggested a new lens that was almost identical in concept to the one described above. The idea had been forgotten and by strange coincidence, was re-invented by Dr Jessen's partner Newton K. Wesley. This lens was the result of research into fitting using the photoelectric keratoscope.

In 1959, Jessen (personal communication) produced a lens which was a combination of a back surface concentric bifocal and a front surface concentric bifocal. By making the diameter of the distance portion on the back surface smaller than the distance portion on the front surface, a trifocal effect was achieved.

Söhnges (1962, 1963) developed a blended multifocal lens on the front surface consisting of a small central distance portion and concentric rings 0.50 mm wide, each ring 0.50 D more positive in power than the one before it, so that the positive addition increased gradually towards the edge of the lens.

Aspheric contact lenses, where either the anterior or posterior surfaces are non-spherical, were developed for two purposes: to try to correct the natural spherical aberration of the eye and to create a bifocal or multifocal lens. William Feinbloom developed an elliptical posterior surface lens in 1961, followed by Joe Goldberg's, Ellip-See-Con and V.F.L. aspheric designs, manufactured under a Volk patent. Wesley-Jessen introduced the Autofocal, an aspheric simultaneous bifocal. In all these lenses the posterior surface became progressively flatter from the centre to the edge.

Kaplan (1967) used models to show that a front aspherical surface would help to correct presbyopia and astigmatism. The CALS soft lens was developed using this principal, the lens becoming progressively less positive towards the periphery. This lens was the result of work by Carl and Thomas Evans (Evans and Evans, 1981; Evans, 1983) of Canada. (*See also* Nissel PV200 lens below).

Theory of bifocal contact lenses

Retinal image quality

It is far more difficult to design a bifocal contact lens than a bifocal spectacle lens. For the most part the contact lens

moves with the eye; the spectacle lens does not, so it is easier for the patient to choose which part of the spectacle bifocal to look through. The retinal image quality of both simultaneous and translating bifocals is affected by some out-of-focus light entering the eye. This can be serious, particularly, for example, when driving in busy streets at night.

Earlier diagrams of translating bifocal contact lenses usually showed the pupil completely covered by the distance or near portion, often overlapping the pupil over the entire area. In practice this is not achievable, since unless the patient has extremely small pupils the lens would have to move too much.

A good idea of the potential side-effects can easily be demonstrated by asking a patient wearing bifocal contact lenses to look at a bright spot of light in both a darkened and normally lit room. Remember that when driving at night the patient may be looking at multiple spots of light and the problems will be compounded if it is raining. (If possible, practitioners should try bifocal contact lenses on their own eyes to better understand the problems caused by the lenses they are fitting and the patient's complaints. It is not necessary to be presbyopic to see these effects.)

Types of bifocal contact lenses

Bifocal contact lenses can be divided into five different categories. Some designs incorporate features from two categories and many are available in both rigid and soft materials

1. Simultaneous vision or bivision bifocals.
2. Translating or alternating vision bifocals.
3. Monovision.
4. Multizone bifocals
5. Non-refractive bifocals
   (a) pinhole lenses
   (b) spherical aberration correcting lenses:
   (c) concentric aspheric 'multifocal lenses'
   (d) diffractive lenses

1. Simultaneous vision or bivision bifocals

Light enters the eye from both the distance and near portions at the same time. When viewing distance objects, there is a sharp image from the distance portion and, superimposed over it, a very blurred image from the near portion, and *vice versa*, when the patient reads or does close work. This has the advantage that the patient does not have to hold the reading matter in any particular position to read. The main disadvantages are that the vision is not as sharp as with a single vision lens because of the side-effects from the superimposed images, although this is not bad as might be expected. Also the ratio of light entering the eye from the two portions varies with different pupil sizes and thus different lighting conditions.

Lenses with separate portions can be made with the central portion for either distance or near. However, a near central portion can be a disadvantage during bright lighting conditions, when good distance vision is essential, for example, when the sun comes from behind a cloud while driving. In this situation the pupil constricts thereby limiting vision to the near portion and making distance vision blurred. This can be improved by wearing sunglasses.

Breger (1980) suggested that if the central portion is small, between 1 mm and 2 mm in diameter, the blur circle from the out-of-focus image will be reduced. The writer believes that the ideal diameter of the central portion is determined by the pupil diameter and the distance from the anterior surface of the cornea to the pupil. Light entering the eye should be divided as nearly as possible so that there is 50% from the distance portion and 50% from the near portion. In normal lighting conditions this results in an average size of 3.00 mm for the central portion. Erickson and Robboy (1985) found that the best diameters for simultaneous vision with a central distance portion were from 2.25 mm to 3.00 mm.

Variations of simultaneous bifocal lenses are possible using either front or back aspherical surfaces.

Aspheric bifocals

These are lenses where either the anterior or posterior surface is non-spherical. The type of aspheric surface is determined by the degree of departure from a spherical curve, the eccentricity value. The degree of eccentricity (*e* value) can be calculated and all aspherics have a mathematical definition (*see* Chapter 10). For example, a spherical curve has a value of 0, ellipsoidal curves have a value of 0.7 to 1.0. Hyperbolic curves with an *e* value from 1.0 to 1.6 (a curve with an *e* value of 1.0 is a parabola) are interesting from a multifocal point of view as they can create reading additions of up to +5.00 D. (The Aqualine MF200 lens is an example of such a lens (*see* p. 551).

2. Translating or alternating vision bifocals

Theoretically, these bifocals provide alternating vision, the patient looking through the distance portion for distance vision, the lens moving upwards for close work through the near portion. A prism ballast of approximately 1.5△ base-down is often incorporated to orientate the lens correctly and in addition the lens is sometimes truncated. The lens must move up easily when the eye looks down for close work but the lens must not be so loose that the lens rides up when looking straight ahead causing the near portion to cover the pupil.

The Tangent Streak bifocal and the Fluoroperm ST bifocal are examples of alternating vision (*see* pp. 557–559).

3. Monovision (*see also* p. 547)

Although strictly speaking not a bifocal technique, monovision is the generally accepted name for the method of

correcting presbyopia by using a distance contact lens for one eye and a near contact lens for the other eye. It has proved popular over the years due to the simplicity of the system, the minimal additional cost involved and its reasonable success rate, compared with difficulties experienced when fitting some bifocal lenses.

The monovision principle does not work well with spectacles due to the difference in prismatic effects on version movements and the difference in magnification between the two eyes. These problems are minimal with contact lenses.

An investigation by Loshin *et al.* (1982), using contrast sensitivity, revealed that as the power of the near addition is increased, the binocular contrast sensitivity is reduced until it is almost a monocular function. In practice, it is found that most patients have little difficulty in accepting an addition of +1.00 D in the non-dominant eye. As the addition is increased further, the blur becomes more noticeable and they sometimes feel giddy and unbalanced. An interesting legal situation might arise for a car driver who had a road accident while driving wearing monovision contact lenses, although many uncorrected ametropes are effectively in a similar binocular refractive situation.

4. Multizone bifocals

Some of the lenses in this section are either obsolete or only of academic interest but are included for the sake of completeness.

The one factor that causes the most difficulties with the fitting and success of bifocal contact lenses is the pupil size. In recent years there have been several attempts to design and make a lens where the optical effects would not be influenced by either the difference in pupil size from one presbyope to another, or variations in the pupil size due to different lighting conditions.

One theoretical way of overcoming this problem is a bifocal lens with a large number of distance and reading portions, the advantage being that as the pupil size varied, more or less portions would be used and the 50:50 ratio maintained. Little or no lens movement would be ideal. Good centration would be preferable but, in theory, the 50:50 ratio could be maintained even if the lens was badly decentred.

In 1977, Cohen, in the USA applied for a patent for a zonal bifocal contact lens. This consisted of concentric rings, alternately powered for distance and near, the adjacent zones interfaced continuously so that there were no steps. The bifocal surface was on the lens front surface and he suggested that the partial neutralization of this surface by tears could be corrected by changing the relationship of one zone with the next, so that an overlying tear layer would form a surface matching the distance and near curvatures as closely as possible. The patent does not state if this would be achieved by blending the junctions.

In 1983, de Carle in the UK, applied for a patent for a multizone bifocal contact lens. He was unaware of the work of Cohen, and as well as applying for a similar design

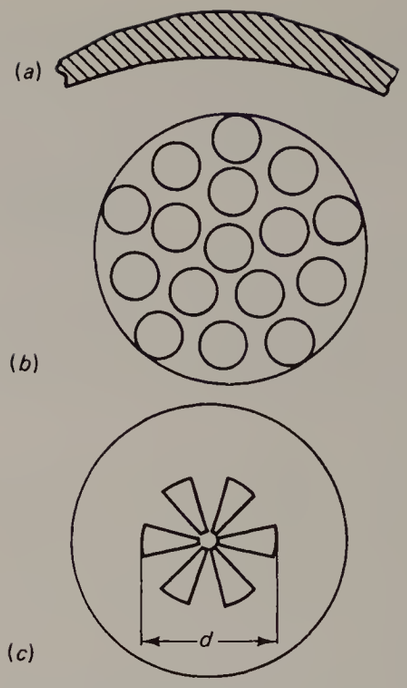


Figure 16.14 De Carle multizone bifocal lens design. (*a*) Multizone front surface bifocal; (*b*) multizone design to maintain an approximately equal ratio of distance to near power in front of the pupil during lens movement. (*c*) As (*b*) with diameter *d* intended to be larger than the pupil diameter to allow for lens movement

(*Figure 16.14a*) he also applied for two other designs as shown in *Figure 16.14b,c*. Appreciating the problems that can be created by tears on the anterior surface and not being convinced that changing the design of the front surface would be sufficient to eliminate them, as the quantity of tears can vary from second to second, he suggested that the designs could also be made in fused form or on the front surface.

The advantages are that they are easy to fit. The practitioner is then only concerned with obtaining the correct near addition, good centration and minimum movement. Also there should be no side-effects from a fluctuating pupil size. With experimental lenses, rings around lights were noticed corresponding to the number of distance and near portions on the lens.

5. Non-refractive bifocals

A non-refractive lens is a lens that acts as both a distance and near correction with either no corrective power in the lens or only a single vision prescription.

(a) Pinhole lenses

The simplest non-refractive 'bifocal' is the pinhole lens, as described earlier (*see Figures 16.3* and *16.6*). Pinhole lenses are really therefore of only academic interest but could, on the rare occasion, be useful.

(b) Spherical aberration correcting lenses

These lenses are aspherical but should not be confused with aspheric bifocals. The theory behind the lenses is entirely different.

A good camera lens is corrected for spherical aberration. The human eye is not. A cheap camera lens that has not been corrected for spherical aberration produces an image which is not perfectly sharp. Rays refracted through the periphery of such an 'uncorrected' lens focus in front of the rays from the centre of the lens. It follows that if a contact lens can be produced which will correct the spherical aberration of the eye (and also, in higher powers, the spherical aberration of the contact lens itself), then the retinal image should be sharper. This should have the effect of increasing the depth of focus and therefore of effectively increasing amplitude of accommodation, but if the pupil size is too large or the eye suffers from irregular aberrations the effect may be negated.

This effect was attempted in aspheric lenses such as the CALS lens (Evans *et al.*, 1988) and is currently available as the N5 lens from Cantor and Silver England, and the Nissel PV200 lens (*see* p. 561 and *Table 16.6*).

A front aspheric surface will help to improve presbyopia and astigmatism (Kaplan, 1967). Whereas the positive power of most aspheric bifocal lenses (e.g. Hydrocurve II) increases towards the periphery, it decreases with spherical aberration correcting lenses. It should be emphasized that these lenses are not an attempt to make a bifocal lens by a method which is the reverse of the aspheric bifocal. In fact these lenses are not bifocals at all, but by reducing spherical aberration the visual acuity of presbyopic and astigmatic patients, as well as some patients with visual problems, should be improved. The central power of the lens, which can only be accurately checked with a very small aperture (e.g. 1.5 mm) on the focimeter, should be that required for a point dioptrically halfway between the distance and near powers.

Evans (1983) referred to the blur circle tolerance range (BCTR). It has been suggested that the BCTR of the eye is 2.00 D, and if that is so the lens prescription would be +1.00 D added to the distance power. The best focus should then be at 1 metre from the eye, where the blur circle should be so small as to be almost non-existent. At infinity and 50 cm from the eye the blur circle would be at its largest within the range considered to be 'in focus'. As the pupil size affects the depth of focus, it is doubtful whether a presbyope with a large pupil would agree that objects at infinity and 50 cm were both in focus.

These lenses should be useful for early presbyopes needing a near addition of up to +1.50 D. Their usefulness in patients needing a higher near addition probably depends on their pupil size and occupational vision requirements.

All bifocal contact lenses have some side-effects. Some of these could be reduced if they employed this principal of having an aspherical front surface to reduce spherical aberration.

Concentric aspheric 'multifocal lenses'

A variation from the aberration correcting lens is available as the Nissel PV200 or PV250 lens. These have a greater degree of asphericity than the original lens design by Carl Evans and the fitting is therefore different (*see* p. 561).

(d) Diffractive bifocals

A diffractive lens is one which breaks up each ray of light into dark and light bands or into colours of the spectrum. A ray of light normally travels in a straight line but can be bent by diffraction; the longer the wavelength the more it is bent. Red light which has the longest wavelength of the visible spectrum is therefore deviated more than blue. This is the opposite way round to the chromatism produced by a prism or lens or, for that matter, the eye itself.

In 1981, Freeman in the UK, applied for a patent for a contact lens with a transmission hologram providing diffractive power on a wavelength and/or amplitude selective basis, whereby light from both distance and near objects could be focused on the retina of a presbyopic wearer. This permits an equal amount of light to be used for distance vision and near vision whatever the pupil size.

He suggested several ways in which this could be achieved. The hologram could be on either surface or on a layer inside the lens. The hologram could be generated by using two lasers, the effective near addition being created by the distance of the light sources. For example, if one beam was at infinity and the other at 33 cm they would have a divergence of 3D. The laser beams would interfere within photosensitive material in or on the lens, creating interference fringes.

A Fresnel zone plate uses a similar principle, the zones being alternately clear and opaque, and a lens could be made in this form. Such a lens would suffer the same disadvantages as a multiple pinhole. However, the opaque zones can be changed into transparent ones if the thickness of the optical path has been increased by a half wavelength, Freeman, took this a step further by changing this extra thickness smoothly across the width of each zone from nought to one wavelength (or some fraction of a wavelength depending on the colour). The power of the superimposed zones provides the diffractive near addition. The near addition varies for different colours. For example, if the addition is +2.00 D with a wavelength of 400 nm (blue), it will be approximately +3.50 D with a wavelength of 700 nm (red). Fortunately, the majority of this effect is neutralized by the chromatic aberration of the eye but is apparent on a focimeter with the lens in air (*see* Chapter 12). The Hydron Echelon lens uses this principle (*see* p. 561). Pilkington–Barnes–Hind used to supply the Diffrax RGP lens, which used this principle, but it is no longer available.

Monovision

Any single vision lens, whether rigid or soft, can be used for monovision. Erickson (1988) stated that contact lens monovision patients can theoretically attain a well-focused

image for any intermediate viewing distance when the reading add is less than 2.00 D. Aniseikonia with monovision contact lenses is inherently much less than that of the same correction with spectacles.

Critics of monovision argue that monocular central suppression occurs, that contrast sensitivity is depressed and stereopsis is reduced (Koetting, 1970; Back *et al.*, 1987; McGill and Erickson, 1988; Erickson and McGill, 1992). It is not uncommon for patients to complain of imbalance or disorientation after trying monovision for a day or two. This will reduce in time but many patients are not willing to persevere long enough for this to occur. Many practitioners are worried about the ethical aspects of monovision. They feel it is contrary to their basic training.

The author prefers to fit monovision only for early cases of presbyopia and use modified monovision or bifocal contact lenses when the reading addition is over 1.50 D

Before trying monovision it is necessary to determine which is the dominant eye. It is usually the right eye if the patient is right handed and *vice versa*, but it must not be assumed that this is the case. Testing for dominancy is quick and simple: ask the patient to clasp both hands together interlocking the fingers but leaving a hole between the thumbs and first fingers, then, without closing one eye, ask the patient to raise the arms with hands as far away as possible and to sight an object such as the large letter at the top of the distance chart in the centre of the hole. Occluding one eye soon shows which eye is dominant. If this test is done with one hand only there is sometimes a tendency to turn and sight the target on the same side.

The strength of the near addition should be as low as possible commensurate with visual needs. Too weak a near addition, however, may cause problems as the patient will then read at arm's length and may become visually confused as to which eye should be used. The 'reading' addition can often be found by refraction in the normal way, adding plus power slowly to the non-dominant eye with a pair of single vision contact lenses in place. The effect on both distance and near vision binocularly can be assessed. It is essential to explain exactly how monovision works and what is being done (Josephson *et al.*, 1990). Despite doing this, comments such as 'when I shut my right eye my distance vision is all blurred' are quite common, both at the time of explanation and later!

If the patient is still interested a 'reading' lens of the indicated power should be tried in the non-dominant eye. Ask patients to walk outside as a lens which is acceptable in the consulting room may prove unacceptable in a busy street. Phillips (A. J., 1987, personal communication) has stated that approximately 50% of monovision wearers require supplementary single vision or bifocal spectacles to balance vision for concentrated visual tasks, especially for driving.

A form of modified monovision can be utilized when monovision is not visually acceptable to the patient and there are problems in prescribing two bifocal lenses. A compromise would be to prescribe one single vision lens and one bifocal lens. If the patient is disturbed by the quality of the distance vision, a single vision distance lens in the dominant eye and a simultaneous vision bifocal lens in the non-dominant eye may be visually acceptable if the patient's near vision requirements are not too demanding.

A compromise between differing types of bifocals can also work well. For example, by using centre distance concentric bifocal lenses with different distance portions, the dominant eye can be fitted with a larger distance area than the non-dominant eye. This would result in enhanced distance vision in the dominant eye and enhanced reading vision in the non-dominant eye. Alternatively, if centre near concentric bifocals are used the dominant eye could be fitted with a smaller reading area than the non-dominant eye, giving a similar result.

Choice of bifocal type

The patient's occupation is an important consideration which should help to determine whether or not to supply bifocal contact lenses and also the type of lens and whether a soft or a rigid lens is required. This is an area where the practitioner's skill and experience are invaluable. It is important that the practitioner realizes that there is no one design of bifocal lens that is ideal for every patient. By choosing the correct type of lens, the majority of patients should be successfully fitted. It is important to question the patient carefully regarding visual requirements and, if necessary, give a demonstration of these requirements. These should fall into one of the following categories.

- Good distance vision essential (for flying, driving etc.)

  When good peripheral vision at distance is required, concentric lenses with a small distance portion in the centre should be avoided. Diffractive bifocals and some aspherical lenses give good distance vision and may be better. Alternatively, a prism ballasted rigid bifocal might be tried and, to ensure that the near portion does not ride up or rotate on the eye when the patient is using distance vision, slightly more prism ballast should be given and the near portion fitted slightly lower than average. This latter situation is not possible if the patient insists on very good near vision.

- Very good near vision required for long periods of time (for example a copy editor)

  A rigid concentric bifocal with a small distance portion can be tried and compared to a prism ballasted bifocal with the largest possible near portion. The latter should be fitted so that the near portion is as high as possible without interfering with the distance vision.

  An alternative is to specify the lens for the non-dominant eye biased towards the near vision so that the distance vision is reduced by approximately one line whilst fitting the dominant eye with a bifocal lens giving optimum distance vision. This is usually preferable to the much greater effect upon distance vision that monovision would have.

- Good intermediate vision at, or slightly below, eye level (for example a word processor operator or a musician)

  An aspheric bifocal should be considered for this group. Alternatively, a lens with the addition for the intermediate focus in the dominant eye and for the near focus in the non-dominant eye may be successful. However, fitting bifocal lenses with the near portion suitably powered for intermediate vision does not usually give a satisfactory result.

- Good intermediate vision required above eye level (for example a chemist)

  A chemist may need to look at bottles on high shelves. In this case, a concentric lens with the addition for the intermediate focus in the dominant eye may be successful or aspheric lenses to both eyes.

- Good near vision required above eye level (for example a librarian)

  Usually, a concentric bifocal with a peripheral near portion fitted to give alternating vision is the most satisfactory lens, particularly if it tends to settle below the central position on the cornea. Again aspheric lenses to both eyes may give the best results.

- Lenses required mainly for social reasons

  In such cases, long-sustained critical near vision is not usually carried out with the bifocal contact lenses. Possibly, nothing more critical than reading a menu or theatre programme is required. Monovision or an aspheric bifocal lens to both eyes will usually be adequate. Alternatively, a concentric bifocal, or, if the patient is a keen bridge player, two different powered additions (intermediate and near), one for each eye, may be the answer.

Extra measurements needed when fitting bifocal lenses

Two anatomical features are of importance with bifocal contact lenses that are of lesser importance with single vision lenses. These are the pupil diameter and the position and tightness of the lower lid, the latter being of importance in rigid lens fitting. The pupil diameter may be a problem if it fluctuates considerably between bright and dark conditions especially when considering aspheric or concentric bifocals. It has sometimes been stated that patients with small pupils are not suitable for rigid bifocal contact lenses; but back surface concentric bifocals with distance segments as small as 1.50 mm have been successfully fitted. The larger the pupil diameter, the greater the difficulty in fitting prism ballasted bifocals because the possibility of achieving good alternating vision becomes harder and some degree of bivision has to be accepted.

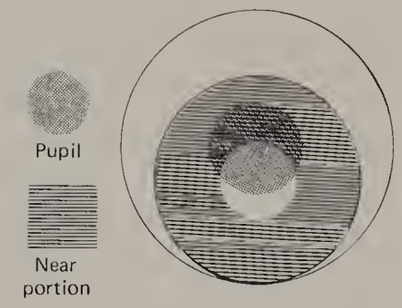


Figure 16.15 A low fitting concentric bifocal interferes with good distance vision and makes near vision difficult unless looking above eye level

The lower lid should be carefully examined, particularly if prism ballasted bifocals are being considered. The lower lid raises the lens when the eyes are lowered for near vision. If the lower lids are loose or situated below the limbus they may be unable to raise the lenses sufficiently. In such cases, a soft lens or a concentric rigid bifocal fitted on the bivision principle will probably be the lens of choice.

Fitting procedures for rigid lenses

Back surface concentric bifocals with central distance portion

Utilizing the simultaneous vision method these lenses (*see Figure 16.4* and p. 545) must be fitted so that they centre well with the minimum amount of movement that is acceptable to the patient and practitioner. This can be done by fitting the lenses larger, steeper or thinner than usual. All three methods could result in an uncomfortable lens, so considerable care is required by the practitioner. Using a high Dk RGP material will ensure that there is enough oxygen transmission through the lens. A lens that rides up very slightly is preferable to one that settles below centre. A low fitting lens makes near vision difficult, although patients may be able to read quite well if they hold reading matter above eye level (*Figure 16.15*).

The back peripheral optic zone radius (BPOZR) is the main fitting radius and together with the front surface radius determines the near portion power. The back central optic zone radius (BCOZR) is calculated to determine the correct distance portion power (*see* Chapter 5) and has a negligible effect on the fit. The back peripheral optic zone diameter (BPOZD) needs to be between 7.50 and 8.00 mm, and the back peripheral radii and total diameter are selected to achieve good centration with adequate tear exchange, as when fitting a large single vision gas permeable lens (*see* Chapter 10).

With the advent of very high Dk gas permeable materials, specialist laboratories are able to manufacture lenses of this design, much larger in diameter than before. The advantage is that they centre better and move very little which helps to

Table 16.1 Recommended diameter of the distance portion in concentric bifocals related to the pupil diameter

Pupil diameter (mm)	*Distance portion diameter (mm)*	*Pupil diameter (mm)*	*Distance portion diameter (mm)*
4.5	3.20	3.2	2.25
4.4	3.10	3.1	2.20
4.3	3.05	3.0	2.10
4.2	2.95	2.9	2.05
4.1	2.90	2.8	2.00
4.0	2.80	2.7	1.90
3.9	2.75	2.6	1.85
3.8	2.70	2.5	1.75
3.7	2.60	2.4	1.70
3.6	2.55	2.3	1.65
3.5	2.45	2.2	1.55
3.4	2.40	2.1	1.50
3.3	2.30	2.0	1.45

stabilize the vision. Lenses as large as 12.50 mm can be made and worn successfully.

The diameter of the distance portion or the BCOZD is mainly dependent upon the pupil diameter and should cover approximately half the area of the pupil. One method is to measure the pupil in low illumination and order the distance portion according to *Table 16.1*. The pupil is difficult to measure with a scale in low illumination (although ultraviolet light is useful as the crystalline lens fluoresces). The most accurate method is by photography. A scale – preferably divided into 0.1 mm graduations – is held in approximately the same plane as the iris and photographed, using a flash gun. The pupil does not contract until immediately after the flash has taken place.

Another method is to measure the pupil diameter when a bright light is shone into the patient's eye and order the distance portion of the same diameter. Where both methods are used, some practitioners order a distance portion diameter half way between the two measurements. A laboratory can usually slightly reduce the diameter of the distance portion on the finished lens, if necessary, but cannot increase the diameter satisfactorily. *Figure 16.16* shows how a well-fitted lens can move approximately 1.00 mm and still have all the distance portion over the pupil and the same percentage of the pupil area covered by the near portion.

Trial lenses with different sized distance portions are useful as an added check on these calculations. However, with the advent of other types of bifocal, back surface bifocals are now seldom fitted, so the outlay on a fitting set may not be justified. Nevertheless, these lenses can still be useful when a prism ballasted type has been found unsatisfactory because of a loose lower lid and soft lenses have been ruled out.

The distance portion diameter can also be varied according to the patient's visual requirements. For example,

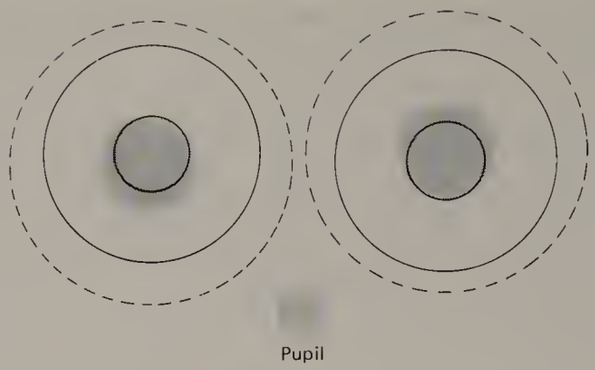


Figure 16.16 A well-fitting concentric bifocal can move up to 1.0 mm and still have all the distance portion in front of the pupil (shaded)

a person who needs bifocals only to see to read a menu or a theatre programme can be given a larger distance portion than a person who needs to read small print for long periods of time.

Although, in theory, this type of lens could be fitted flatter and used as an alternating vision concentric bifocal, the larger distance portion required would, in practice, lead to an increased risk of central bubble formation or a stagnant pool of tears likely to cause central corneal oedema.

Front surface concentric bifocals

The alternating vision type of concentric bifocal is better fitted where the near addition is worked on the front surface. *Figure 16.5* shows an example of one of these lenses and the fitting principles are discussed on pp. 541 and 545.

This type of lens is normally fitted on the flattest keratometer reading (*K*). If the BOZR is fitted flatter than this, the lens may have a tendency to ride slightly high on the cornea so that the distance portion is displaced upwards. Conversely, if the BOZR is made steeper the lens may tend to remain in a central position making it difficult to use the near portion.

The BOZD should be as large as possible, with the intermediate and peripheral curves sufficiently flat to allow a moderate amount of lens movement. The thickness is approximately 0.05 mm thicker than the equivalent single vision lens except with higher powered negative lenses. Most positive lenses should be made in a lenticular form to prevent very thin edges as the lower lid must move the lens slightly upwards when the patient is looking at a near object.

The diameter of the distance portion or the front central optic zone diameter (FCOZD) must be carefully measured. If the distance portion is too large, the lens will not be able to move sufficiently to allow the patient to look through the near portion. If the distance portion diameter is too small, the patient will have a noticeable blur surrounding distant objects and this becomes aggravating when the lens moves during blinking. The FCOZD should not be smaller than the pupil size in a normal artificially lit room. If the pupil is

larger than 5 mm, it is preferable to fit these lenses steeper by the simultaneous vision method; but with smaller pupils, they are normally fitted using the alternating vision principle, although a certain amount of simultaneous vision invariably occurs.

One method of arriving at the distance portion diameter is to measure the distance from the bottom edge of the lens (or lower lid margin) to the bottom edge of the pupil, then double this value and subtract it from the total diameter (TD) of the lens. For example, if the bottom edge of the lens is 2.50 mm from the lower edge of the pupil, the number doubled equals 5.00 mm and subtracted from a trial lens of 9.50 mm TD it gives a distance portion diameter of 4.50 mm.

Aspheric bifocals

Aspherical lenses, with a posterior surface that is progressively flatter towards the periphery, produce a multifocal lens with distance in the centre progressing to the reading portion, where the outer edge of the optical area has the maximum reading addition. Like the back surface concentric bifocals, aspheric bifocals have the same optical problems from the partial neutralization effect of the tears. Theoretically, the reading addition in air will need to be three to four times the actual reading addition required. (depending upon the refractive index of the plastic used).

Examples of aspheric bifocals

One example of this type of lens is the Nissel Aqualine MF2OO (UK). It is fitted on flattest *K* and can give an effective add of up to +2.00 D. The total diameter is 9.50 mm.

A second example is the V/X–2 (C-rite) lens, made by GBF Contact Lenses Inc., of Virginia Beach, USA. It has an eccentricity value of 1.4. The lenses are fitted so that the tear lens at the centre of the lens, for a diameter of only 1.00 mm, is between +4.50 D and +5.00 D.

A third example is the MF19 (MF194 +2.00 D add, MF195 +2.25 D add, and MF196 +2.50 D add) by Contex (Sherman Oaks, California) which have both front and back aspheric surfaces.

If the eccentricity is carried to the edge of the lens the degree of flattening will be far greater than that of the cornea. As good centring with minimal lens displacement on blinking is required, the lenses may need to be fitted up to 0.80 mm steeper than flattest *K*. Some manufacturers lessen the *e* value beyond the optical area such that the lenses do not need to be fitted as steeply. Whatever lens is fitted, it is essential that trial lenses are used, to assess the fitting and also the vision obtainable at both distance and near.

An innovative posterior aspherical design is the Lifestyle Hi-Rider lens, designed by Leonard Seidner and manufactured by Permeable Technologies Inc., USA. This lens is fitted so that the normal position of the lens is above centre. It is particularly useful for patients who use a computer.

The fitting technique for fitting these lenses for simultaneous vision is the same as for back surface concentric bifocals with centre distance portion (p. 549).

Alternating or translating, and prism ballasted bifocals

These lenses can be either solid or fused. They are only rarely fitted as custom-made lenses nowadays, but the following is included for those occasions where no other lens will suffice. *Figures 16.8–16.13* illustrate the early versions of these types of bifocal. The fitting requirements are the same whether the lens is a front surface, back surface or fused bifocal and it is easier to use a fitting set to achieve a satisfactory fit. Patients with a very low or flaccid lower lid are unlikely to succeed with this type of lens.

In addition to all the information required when ordering a single vision lens, the practitioner also needs to calculate the following:

1. Near addition.
2. Size and shape of segment.
3. Height of segment above the lower edge of the lens.
4. Amount of prism ballast and thickness of the lower edge.
5. Vertical total diameter.
6. Stabilization

These are examined in detail below.

1. Near addition

This varies according to the type of lens being ordered. With solid back surface bifocals of every design, it is necessary to allow for the fact that the tears neutralize just over two-thirds of the difference in power between the two areas with PMMA material and even more with most gas permeable materials, as illustrated in the previous section (*see also* Chapter 5).

For front surface solid bifocals and for fused bifocals, the near addition should be the same as that ordered for spectacle bifocals.

2. Size and shape of segment

Fused bifocals are nearly always made so that the segment is worked from the back surface and can be made slightly thinner than lenses with an inserted segment as depicted in *Figure 16.12a,b*. The construction and manufacture of PMMA fused bifocals was described by Bryant (1973).

A variety of segment shapes can be made as shown in *Figure 16.17*. The first segment (*a*) has the disadvantage that near vision becomes blurred if the lens slips slightly to one side. The second segment (*b*) largely overcomes this problem, but the optical centre of the near portion is a greater distance from the optical centre of the distance portion so that a 'jump' is created as the visual axis passes from one portion to the other. The third segment (*c*) is theoretically monocentric so that there should be no 'jump', and the width of the segment is therefore exactly twice the

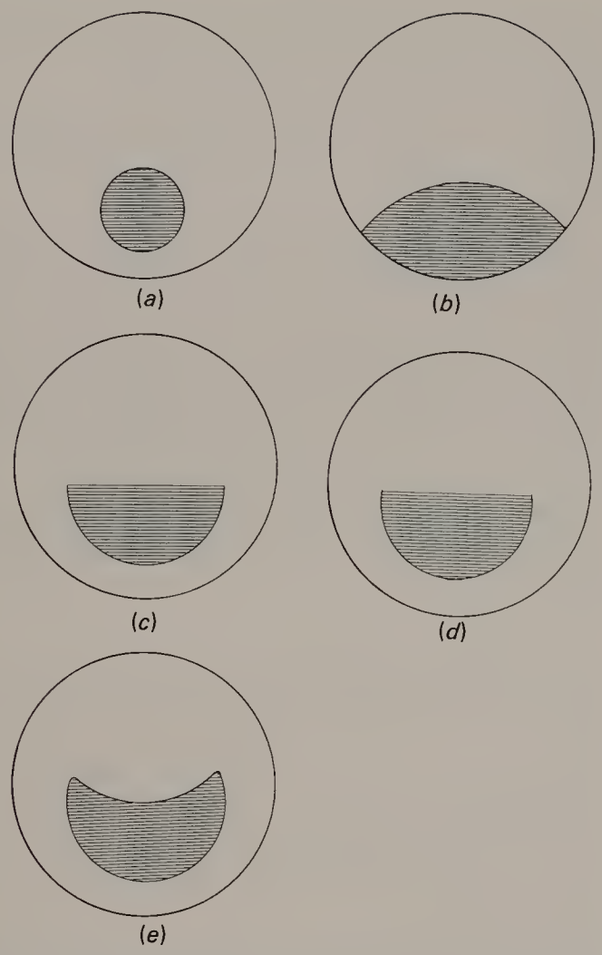


Figure 16.17 Segment shapes which have been used for fused bifocal lenses

height. This sometimes limits the height of the segment as an increase in size would increase the thickness, which might be undesirable in negative lenses. A lens of this type is the Fluoroperm ST bifocal lens (*see* p. 559). The fourth segment (*d*) is a good compromise, not theoretically monocentric – because the vertical height of the segment is slightly greater than half the width – but the 'jump' is so slight that it is no problem in practice. The fifth segment (*e*) is also monocentric, the aim of the up-curved top of the segment being to ensure that the centre of the segment top is always in the same position in relation to the pupil if the lens swings slightly in a pendulum manner on the eye (Goldberg, 1969). Theoretically, the radius of curvature of the top of the segment should be the same as half the overall lens size. The disadvantage of this type of segment is the possibility of slight peripheral blur at the sides when using distance vision.

Where lenses are to be made to order (instead of using trial sets), the segment should normally be the largest possible without increasing the thickness. However, there is no point in having a segment that is so large that it extends beyond the back optic zone diameter or is cut into by the lower edge of the lens. This particularly applies to fused bifocals.

Table 16.2 Minimum central thicknesses recommended for fused bifocals according to segment width (or diameter) and near addition

Near (reading) addition (D)	*Minimum central thickness (mm)*					
	Segment widths (mm)					
	5.00	*5.50*	*6.00*	*6.50*	*7.00*	*7.50*
+1.50	0.12	0.14	0.17	0.20	0.23	0.28
+1.75	0.14	0.16	0.19	0.23	0.27	0.32
+2.00	0.16	0.18	0.22	0.26	0.31	0.37
+2.25	0.17	0.20	0.25	0.29	0.35	0.42
+2.50	0.19	0.23	0.27	0.33	0.40	0.47
+2.75	0.21	0.25	0.30	0.36	0.44	0.52
+3.00	0.22	0.27	0.33	0.40	0.48	0.57

Occasionally, it is necessary to increase the thickness of a lens slightly to obtain a sufficiently large segment. This could occur, for example, with the combination of a large pupil, a high near addition and myopia (i.e. with a flat top segment and the thickest part of the segment coinciding with the thinnest part of a negative lens). *Table 16.2* gives the suggested minimum thicknesses of fused bifocals for certain segment widths and near additions. If this table is used in conjunction with *Table 16.3*, it may easily be determined if a particular reading addition and segment width are possible without increasing the central thickness.

The segment shape is usually determined by the type of lens which the practitioner has decided is likely to give the best performance. As the lens moves with the eye, many of the criteria that are used to determine the size and shape of spectacle bifocal segments do not apply to contact lens bifocals. For instance, whether a book-keeper can see books on both sides of the desk will depend as much on whether the lenses are stable and remain over the pupil area as on the segment width. It is interesting to note that patients complain far less about seeing the segment when they walk, go up stairs etc., than those with bifocal spectacles. The author's preference is for slightly upcurved fused segments, the particular dimensions being calculated for each case.

3. Height of segment above the lower edge of the lens

The height of the segment can be stated in two ways:

(a) in relation to the centre of the lens (with a truncated lens this is taken as that of the round lens prior to truncation);
(b) as the height above the lower edge of the finished lens.

The author strongly recommends the second method.

The higher the segment without having any noticeable effect on the distance vision the better. In this way, the

Table 16.3 Minimum central thicknesses for prism ballasted lenses of 9.00 mm total diameter according to back vertex power (and prism ballast in negative powered lenses)

Positive lenses, 9.00 mm total diameter; all 1.5 △ prism ballast		*Negative lenses, 9.00 mm total diameter*		
BVP (D)	*Central thickness (mm)*	*BVP (D)*	*Central thickness (mm)*	Prism (△)
+0.50	0.34	–0.50	0.31	1.5
+1.00	0.35	–1.00	0.30	1.5
+1.25	0.35	–1.00	0.30	1.5
+1.50	0.36	–1.50	0.29	1.5
+2.00	0.37	–2.00	0.27	1.5
+2.50	0.39	–2.50	0.26	1.5
+3.00	0.40	–3.00	0.25	1.5
+3.50	0.41	–3.50	0.24	1.5
+4.00	0.42	–4.00	0.25	2
+4.50	0.44	–4.50	0.25	2
+5.00	0.45	–5.00	0.24	2
+5.50	0.46	–5.50	0.23	2
+6.00	0.47	–6.00	0.22	2
+6.50	0.49	–6.50	0.25	2.5
+7.00	0.50	–7.00	0.24	2.5
+7.50	0.51	–7.50	0.23	2.5
+8.00	0.52	–8.00	0.22	2.5
+8.50	0.54	–8.50	0.25	3
+9.00	0.55	–9.00	0.24	3
+9.50	0.56	–9.50	0.23	3
+10.00	0.57	–10.00	0.22	3
+10.50	0.59	–10.50	0.25	3.5
+11.00	0.60	–11.00	0.24	3.5
+11.50	0.61	–11.50	0.23	3.5
+12.00	0.62	–12.00	0.22	3.5
+12.50	0.64	–12.50	0.25	4
+13.00	0.65	–13.00	0.24	4
+13.50	0.66	–13.50	0.23	4
+14.00	0.67	–14.00	0.22	4

amount by which the lens has to rise to allow good near vision is reduced. It has been found, in practice, that the top of the segment can be one-quarter of the pupil diameter above the lower edge of the pupil without causing visual annoyance. In other words, if the pupil diameter is 4.00 mm, the top of the segment can be 1.00 mm above the bottom of the pupil when the patient is looking straight ahead (*see Figures 16.23* and *16.24* and (5) Vertical total diameter and pupil coverage below).

It is therefore necessary to measure the distance from the lower lid to the bottom of the pupil and then add one-quarter of the pupil diameter. When the lower lid is below the limbus, a prism ballasted lens – not necessarily a bifocal, but one of approximately the correct thickness – should be placed on the eye so that the practitioner may observe the lowest point that the lower edge reaches. The position of the lower edge in relation to the edge of the iris should be noted to aid this measurement. Due to the added weight of a prism ballasted lens, and the fact that a tight lens is unlikely to move sufficiently for a satisfactory visual result, prism ballasted lenses normally rest on the lower lid if this is on or above the limbus. (Occasionally, they will actually depress a flaccid lower lid and an allowance for this may have to be made.) However, it is not easy to measure this with a scale as the eye does not keep still. An accuracy of 0.50 mm is as much as can normally be attained. The height of the segment is one of the most important factors in the successful fitting of prism ballasted bifocals and an accuracy of 0.10 mm is desirable. Photography is the most accurate method. An ordinary camera with an auxiliary lens may be used at 25–35 cm from the eye, with a scale divided into 0.10 mm divisions placed close to the eye. It is important that this is held at the same distance from the camera as the pupil and iris. The photograph is taken in ordinary room illumination with a flashlight. Fortunately pupil contraction occurs after the photograph has been taken, so that the normal pupil diameter is recorded. The ideal camera for such photographs is a Polaroid (*see* Chapter 7). The author has had such a camera specially made so that it takes a photograph of the eye, five times the normal size. The camera is adapted to ensure that the eye is exactly the correct distance from the camera lens when the photograph is taken; even an error of 1.00 mm would make an appreciable difference in the measurements (*Figure 16.18*).

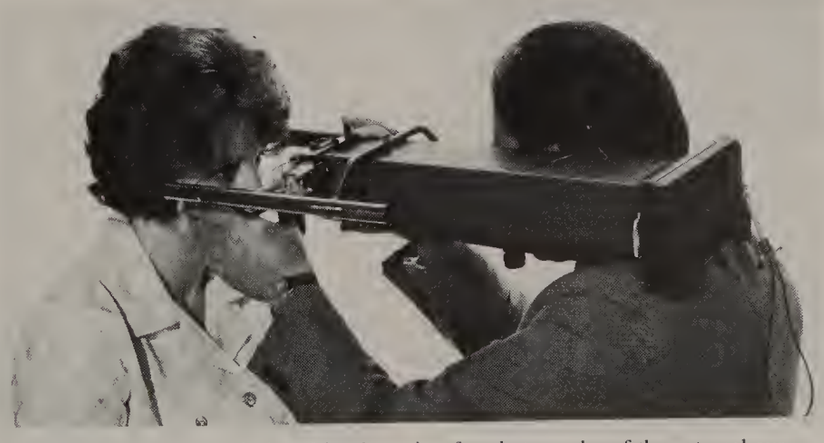


Figure 16.18 Camera designed by the writer for photography of the external eye

Bifocal trial lenses are an easier method of assessing the segment height, as well as other factors. However, unless an extremely large trial set is available, estimation is still needed in deciding the segment height. The use of trial lenses also enables a subjective visual check on the segment height to be carried out. It is not possible with trial lenses to adhere exactly to the rule of the segment top being one-quarter of the pupil diameter above the bottom of the pupil, but the segment height may be varied by pushing the lens upwards with the lower lid. If the vision with the trial lens is reasonably good, the patient should be able to make valuable comments on the effect of the near portion on the distance vision. At the same time trial spectacle lenses can be held in front of the eye to improve distance acuity. In most cases, the segment may be lowered by pulling down the lower lid. It is essential for the practitioner to be able to see the top of the segment, and this may be done by marking the top line with instant drying waterproof ink or a grease pencil. The entire segment area may also be coloured in with waterproof ink, which has the advantage of permitting the patient to notice a colour change, as soon as the visual axis enters the segment area, thus checking the segment position. This is particularly useful if the trial lens segment is of insufficient power (or even when a single vision trial lens – without a segment – is used). A fluorescent mark may also be used. (One advantage of fused PMMA bifocals is that the whole segment may be made slightly fluorescent (Bier, 1965), although an ultraviolet lamp is needed to show it up.) The top of flat-top fused bifocal segments can also be seen quite easily with an ophthalmoscope or slit lamp. It has been suggested that a scale placed in the focal plane of the eyepiece of a slit lamp biomicroscope would be a useful way of determining the segment height. Such graticule eyepieces are available as accessories to most slit lamp biomicroscopes (*see Figure 11.16*).

If in doubt, it is best to err on the high side when ordering the segment height – but not excessively so. The segment may usually be lowered by removing material from the bottom of the lens (i.e. by truncating the lens) but material cannot be added to raise the segment. The segment height may be as little as 2.50 mm above the lower edge, if the lower lid is tight or well above the lower limbus, or as much as 5.00 mm on a large eye with a loose or low lower lid. Giving an average in every case will result in many failures.

4. Amount of prism ballast and thickness of the lower edge

These can usually be left to the laboratory. *Table 16.3* gives details of average centre thicknesses and prisms. They may need to be modified, for example, if ordering negative lenses for a patient where there is a considerable prescription difference between the two eyes. The prism should normally be the same for the two lenses.

The thickness of many bifocal lenses is more than that of single vision lenses. This helps prevent the lens from riding up every time the patient blinks, which can be annoying visually. Extra unnecessary thickness usually reduces the comfort and may give rise to corneal oedema. Concentric RGP lenses usually have the same thickness as single vision lenses.

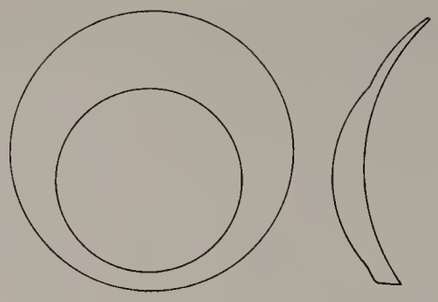


Figure 16.19 Positive lens with a prism ballasted convex carrier peripheral portion and decentred downwards with respect to the base of the prism. Such a lens has a sufficiently thick lower edge to rest on the lower lid without being excessively heavy and may therefore be made in bifocal form

The portion of the edge just below the segment is of extreme importance. It is this part of the lens that is pushed upwards by the lower lid when the patient looks down to read. Positive lenses obviously create the biggest problem of how to increase the lower edge thickness, without increasing the overall thickness and weight more than is absolutely essential. Unless the patient has a very tight lower lid most positive lenses are better made with a decentred lenticular carrier (*Figure 16.19*). This keeps the weight down but increases the lower edge thickness.

It is preferable to have a larger prism than the alternatives of either a very thick lens or a lens which does not ride up when the patient is reading but slips under the lower lid. For the same reason, no lower edge thinning should be attempted except on very high negative lenses. The edge is similar to the one shown in *Figure 16.20* which would seem to be highly undesirable to those who have studied edge



Figure 16.20 (*a*) Diagrammatic representation of the ideal inferior edge shape in a prism ballasted lens to be made in bifocal form. (*b*) The 'square' edge shown in (*a*) rests on the lower lid (shown in cross-section) and moves upwards and downwards on the cornea as the eye is depressed or elevated. (*c*) Excessive rounding of the inferior edge enables the lens to pass behind the lower lid and the near portion may not then move in front of the pupil on depression of the gaze

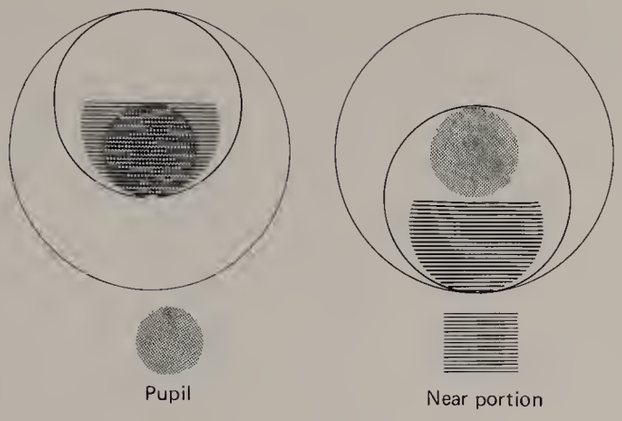


Figure 16.21 The theoretical ideal for a bifocal contact lens where the entire distance portion is centred before the pupil for distance (*right*) and the entire near portion centred for close work (*left*)

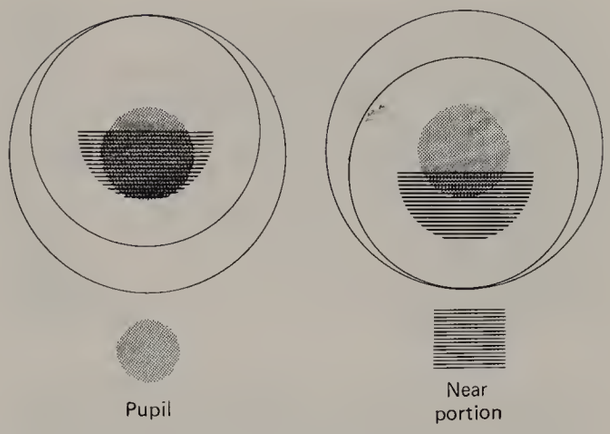


Figure 16.23 A compromise is usually found to be the ideal so that 80% of the pupil area is covered by the distance portion of the lens during distance vision (*right*) and a similar proportion is covered by the segment during near vision (*left*). (*see also Figures 16.22* and *16.26*)

forms for single vision lenses (Shanks, 1966). In practice, it is found that, provided that this unusual edge does not continue right around the lens and there is a normal corneal lens edge at the top, the lens is perfectly comfortable to wear and, when inserted, quickly rotates to the correct position.

5. Vertical total diameter and pupil coverage

The factors determining the vertical total diameter are quite different from those that determine the total diameter of a single vision lens. The lens must be able to move vertically by not less than half the pupil diameter. This is to enable the lens to rise upwards from the position where the segment covers one-quarter of the pupil diameter to covering three-quarters of the pupil diameter (*see Figure 16.24*). Trial lenses can help in assessing the vertical total diameter.

The practitioner new to prism ballasted bifocals usually visualizes them moving as illustrated in *Figure 16.21*. On closer examination, it can be seen that this is not normally possible. A lens of 8.00 mm total diameter on an 11.50 mm diameter cornea can move approximately 4.00 mm, allowing for the fact that it is on a curved surface. However, if the pupil diameter is 4.00 mm, an average size for a presbyopic patient, it will be seen that the pupil can only be covered entirely by the distance or near portions if the lens has moved from the extreme lower area of the cornea to the extreme upper area; also there is no room on this lens for peripheral and intermediate curves so that a situation of completely alternating vision is only possible when the pupil is very small. For most patients, we must accept the fact that there will be a combination of 'alternating vision' and 'bivision'.

Figure 16.22 shows a larger lens where the upper edge of the near portion coincides with the lower edge of the pupil. However, the lens is only able to move vertically by 2.00 mm, and on a 4.00 mm pupil this means that only half the pupil area is covered by the near portion when the patient looks down for near vision.

In *Figures 16.23* and *16.24*, the top of the near portion covers 1.00 mm of the 4.00 mm pupil when the lens is in the low position. When the lens rises by 2.00 mm, the near portion covers 3.00 mm of the 4.00 mm pupil. It can be shown mathematically that when this lens is in the position for maximum distance vision, 80% of the pupil area is covered by the distance portion of the lens. Similarly, when the lens is in the near position, 80% of the pupil area is covered by the near portion. This method of fitting provides both optimum lens fitting and adequate vision.

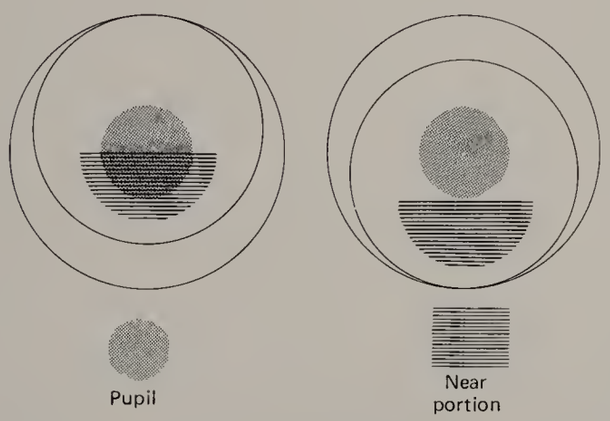


Figure 16.22 In practice, a lens made with the top of the near portion level with the bottom of the pupil (*right*) usually only covers half of the pupil when the gaze is depressed (*left*)

6. Stabilization

Prism ballasted bifocals can be truncated, but this does not necessarily keep them in their correct position. In fact, some lenses of this type can rotate through 180°, showing no tendency to return to the normal position (Cohen, 1976). One advantage of a truncation is to increase the area of edge



Figure 16.24 (*a*) A straight top fused bifocal lens correctly positioned for distance vision with the top of the segment slightly overlapping the lower margin of the pupil. (*b*) Fused bifocal moving up as the patient looks down to read. (Courtesy of D. Westerhout)

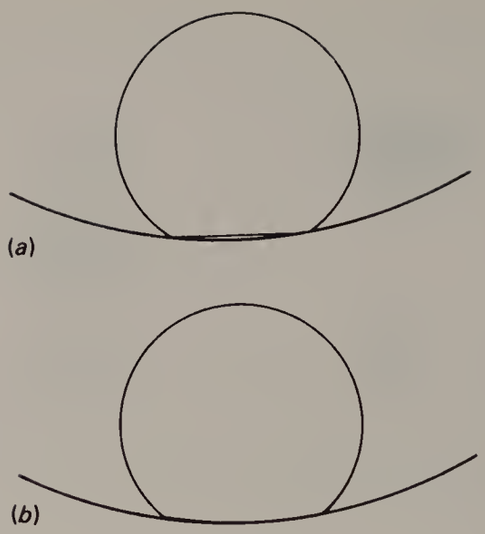


Figure 16.25 The lower edge of a truncated prism ballasted lens should not be straight as shown in (*a*) but curved to match the line of the lower lid as shown in (*b*)

to be raised by the lower lid, but edge thickness and shape are probably of greater importance. The truncation should preferably not be straight but slightly curved to match the radius of curvature of the lower lid (*Figure 16.25*). Examination of photographs of the eye has shown this radius to be between 15.0 and 21.0 mm. A radius of 18.0 mm is a good average.

Lenses may be stabilized by other means (Gates *et al.*, 1961), the principal methods are as follows:

- An oval lens or a double truncation. The BOZR should be approximately the same as the *K* reading at 180° if it is intended to keep the long axis horizontal. It must be remembered that there is a strong tendency for the long axis of the lens to settle along the meridian of the cornea with a similar curvature and for this reason the method is unsuitable in cases of oblique or 'against-the-rule' astigmatism.
- A spherical BOZR combined with toroidal peripheral curves on the back surface occasionally helps stabilize the lens on a toroidal cornea.
- Theoretically, a small metal weight could be embedded in the plastics near the edge, which should rotate to the 6 o'clock position. This is never used as it is unhygienic.

These methods all lose the advantage of the prism ballasted lens for bifocals, namely, increased thickness at the lower edge to enable the lower lid to raise the lens. The first two methods also have the disadvantage that the lenses can fit in two positions at 180° to each other, so that a bifocal near portion would be correct in one position but upside down in the other.

Adjusting prism ballasted bifocal lenses

A number of adjustments are possible to these lenses. Despite accurate measurements, it is often necessary to adjust them to obtain satisfactory results. The following are the most common problems and the adjustments that will usually correct them.

Good distance vision with poor near vision

Assuming that the reason is not an incorrect prescription, this problem is usually due to the near portion not covering the pupil sufficiently when the patient looks downwards. This may be caused by loose lower lid, or a lower lid 1.00 mm or more below the corneal limbus, or a combination of both factors. The lens may then settle below the normal position when looking straight ahead and not translate sufficiently when the patient looks down. A larger lens or a lens with a steeper back surface could make it centre properly, but the vertical movement might then be reduced so that it did not translate sufficiently when looking down for close work. A lens with the near portion closer to the geometric centre or even above it should then be tried.

If the lens is unable to move up sufficiently when the patient's gaze is directed downwards, the adjustment would be to remove material from the top of the lens in order to reduce the vertical total diameter to allow the lens to ride up higher or, if the lens is not moving up to the



Figure 16.26 A fused bifocal which rises too high on the depression of gaze causes the patient to look through the distance portion below the segment as well as partly through the segment

upper limbus, to flatten the back surface intermediate and peripheral curves at the upper part of the lens. It is not essential – and, in fact, is often inadvisable – to flatten these curves all the way round the lens. By carefully masking the lower portion of the lens on the back surface with thin tape and then holding the lens on to the appropriate tool of the adjustment kit, it is possible to flatten the curves only at the top of the back surface of the lens. Sometimes, a reduction in both total diameter and flattening of the curves is needed.

If the near portion rises too high when the patient looks down, the patient will look partly through the near portion and partly through the area below the segment (*Figure 16.26*). This tends to happen particularly if the patient's lower lid is well above the lower limbus. In this case, it is important to have as little non-optical area below the near portion as possible. The method of rectification is to remove material from the bottom of the lens, but not so much that the lower edge actually cuts into the near portion. This is usually done by a slightly curved truncation, and it is recommended that no more than 0.50 mm is removed before trying the lens again. If necessary, more can be removed, but if too much material is removed, a new lens will have to be ordered. The vertical height of the near portion may be less than or equal to the pupil diameter. It is important that this is positioned as closely as possible over the pupil area when the patient looks down to the normal position for near work. Altering the segment 0.50 mm up or down can make a great deal of difference. As the horizontal width can be considerably larger than the pupil diameter, a little movement laterally is usually of small consequence visually. It is also surprising that the lens can twist considerably on the cornea and the patient is still able to obtain good vision. The critical factor seems to be how much of the pupil area is covered by the near portion when it is required to see at near.

Good near vision with poor distance vision

This is almost certainly caused by the near portion being too high and covering too large an area of the pupil. First, it is important to determine whether this is due to the near portion height being too great or to the lens settling above the lower lid when the gaze is directed straight ahead. If it is the former, the only adjustment possible is to remove material from the lower edge so that if the lens continues to rest on the lower lid the segment height will be lowered by the amount that is removed from the lower edge of the lens. If it is the latter, there is no one answer. High-riding single vision lenses often settle higher still if the intermediate and peripheral curves on the back surface are flattened, and a steeper lens is required to achieve better centration. This may apply to bifocals; but generally, the increased weight due to the prism helps the lens to settle low so that flattening the intermediate and peripheral curves may have the desired effect. If not, re-ordering a lens with an increased prism is indicated.

Poor vision due to excessive lens movement

Thinning the edge on the front surface, being careful not to reduce the lower edge thickness, may help. However, it is usually necessary to order a larger lens by at least 0.50 mm. (The total diameter can always be reduced later.)

General discomfort

It would be wrong to assume that a prism ballasted bifocal is far more uncomfortable than a single vision lens. The edge should be checked with a microscope (*see* Chapter 12) to make sure that there are no sharp areas. Although a truncated edge is flat, its intersection with front and back surfaces should be well polished and the lateral limits of the truncation should be well rounded. The intermediate and peripheral back surface curves should be adjusted if necessary; but care must be taken to ensure that the BOZD is not reduced. It is always advisable to make several small adjustments – trying the lens on the eye in between – rather than one large adjustment.

Some alternating vision bifocals

The Tangent Streak bifocal is an example of an alternating bifocal. It has the reading segment worked on to the front surface and is similar to the 'Executive' spectacle bifocal lens having a straight line at the top of the segment. As the two optical centres coincide there is no 'jump' when shifting the gaze from one segment to the other (Romba, 1988). One disadvantage is that the segment extends across the entire lens, consequently plus lenses cannot be made in lenticular form and the peripheral areas of the lower field will be blurred. The lens is available in 70 Dk gas permeable Fluorex material.

The manufacturers (G.T. Laboratories, Chicago, USA) make the lenses in the following parameters:

Total diameter	8.00 mm to 10.50 mm
BOZR	6.50 mm to 8.50 mm
BVP range	+12.00 D to –20.00 D
Reading add	+0.75 D to +5.00 D
Prism	1.75△ to 4.00△
Centre thickness	0.20 mm to 0.80 mm

A centre thickness of 0.80 mm is excessive but is inevitable for high plus powers in larger diameters.

Although the lenses can be made to prescription within this range, it is important to use a trial set when fitting. Trial lenses are usually made with a TD of 9.40/9.00 mm, a segment height of 4.2 mm and a prism of 2.00△. The BOZD is 7.80 mm but this can be altered, if necessary. The BOZR is fitted flatter than usual for single vision lenses. This enhances the movement necessary as the eyes move between distance and near vision.

The initial BOZR chosen should be:

0.2 mm flatter than *K* for a spherical cornea
0.1 mm flatter than flattest *K* for 0.5 D of corneal astigmatism
Up to 0.05 mm steeper than the flattest *K* for more than 1.00 D of corneal astigmatism.

Although the lens is truncated, prism is necessary to orientate the lens correctly and also to increase the weight of the lens so that it sits in a low position on the eye providing a thick 'ledge' to be comfortably pushed up by the lower lid when looking down to read. The amount of prism varies from a minimum of 1.75△ for a +10.00 D lens to 3.50△ for a –10.00 D lens; higher reading additions requiring slightly more prism than lower ones.

In order to decide on the segment height it is important to measure accurately the visual axis to the lower lid and then subtract 1.3 mm for lower lids on or above the lower limbus and up to 2.0 mm for lower lids below the lower limbus. This critical measurement is best taken using a graticule on the microscope. Alternatively, with a trial lens *in situ*, the height of the segment should be 1.5 mm below the visual axis. Again using a graticule on a slit lamp this measurement can be made and added to or subtracted from the trial lens segment height (of 4.2 mm).

The vertical lens size depends on the palpebral aperture with smaller lenses being used where the lower lid is at or above the lower limbus and larger lenses being necessary where the lower lid is situated below the lower limbus.

The power of the lens is assessed with a trial lens, with adequate segment height, *in situ*. Where possible, a lens nearest to the final power should be used.

The Tangent Streak lens is also available as a trifocal, incorporating a 1.00 mm intermediate zone above the reading zone.

The NC bifocal is another lens with a straight top segment made by Nu Contacts Laboratories of Adelaide, Australia. This lens is made of Boston RXD material and has the bifocal worked on the back surface. Another difference is that with the Tangent Streak lens, material is removed to form the reading area, whereas with the Nu Contacts lens material is removed to form the distance area (*Figure 16.27*)

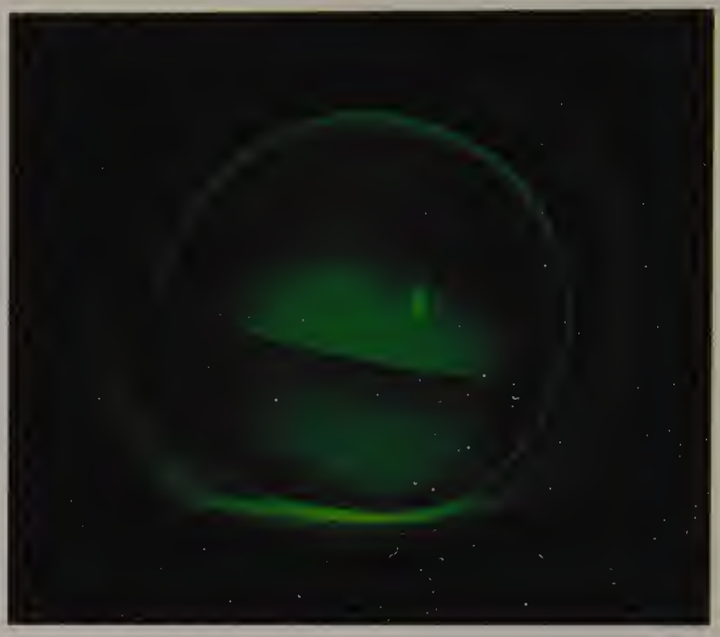


Figure 16.27 An inset distance portion RGP bifocal (NuContacts, Adelaide, South Australia) showing fluorescein pooling in the distance zone. Careful differentiation should be made from the front surface Tangent Streak bifocal. (Courtesy of A. J. Phillips)

The NC bifocal lens will suffer from the same limitations on segment size as the de Carle bifocal developed in 1957. If the segment is too large bubbles will be trapped at the centre of the lens where the gap between the lens and the cornea is greatest. As the refractive index of the Boston RXD material is lower (1.435) than the PMMA material (1.49) used in the original de Carle lens, the problem will be worse.

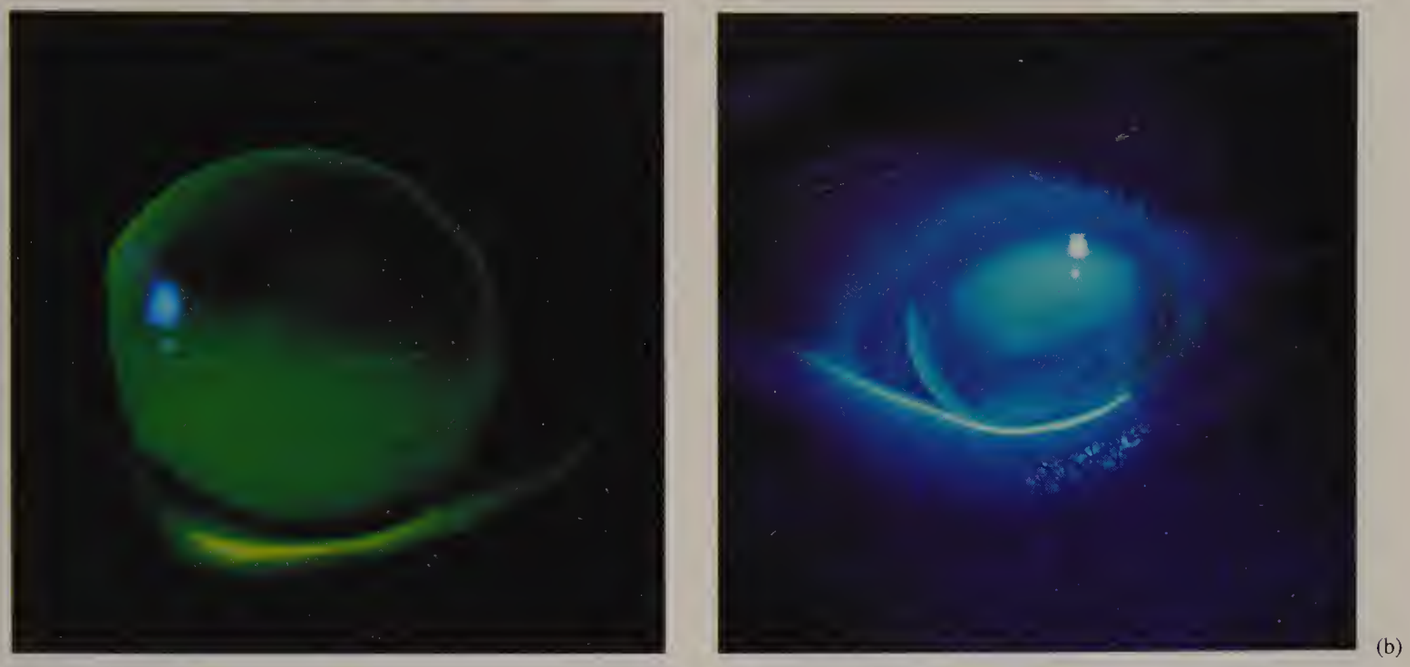
For example, a lens with a BOZR of 8.00 mm, a reading addition of +2.50 D and a segment width of 6.00 mm will have the following measurements:

Inner radius of distance portion:
PMMA 7.08 mm Boston RXD 6.66 mm

Dioptral difference between distance and near portions:
PMMA 7.96 D Boston RXD 10.99 D

Sag difference between the distance portion and cornea:
PMMA 0.0832 mm Boston RXD 0.1301 mm

Although the design of the lens is good, the use of such a low refractive index material will seriously limit the diameter of the distance portion if bubbles or frothing are to be avoided for the higher addition lenses. If technically possible, it would be preferable to remove material to make the reading portion, then any bubbles would be at the outer edge of the reading portion as the radius would be flatter than the BOZR.



(a) (b)

Figure 16.28 A well-fitting Fluoroperm ST bifocal lens in (a) the straight ahead position and (b) moving up to cover the pupil when looking down. (Courtesy of D. Ruston)

The **Fluoroperm ST** (Paragon Vision Sciences) is a fused rigid gas permeable bifocal that is available from Paragon Vision Sciences. It is manufactured from Fluoroperm 60 with an encapsulated D-shaped segment. The Dk of the main lens is 60 with a refractive index of 1.45, but the segment, which has a refractive index of 1.60, is not permeable to oxygen. The lens is an alternating bifocal with a monocentric design, where the distance and near optical centres are coincident so there is no image jump when looking from distance to near.

The lens is manufactured in the following parameters:

Total diameter:	8.00 to 10.50 mm
BOZR:	7.00 to 8.30 mm
Back vertex power:	–20.00 to + 12.00 D
Addition:	+1.50 D, +2.00 D, +2.50 D
Prism:	1△ to 3△
Centre thickness:	0.3 to 0.7 mm
Segment size:	6 mm wide by 3 mm deep
Segment height:	3.00 to 5.00 mm

The first trial lens should be 0.15 mm flatter than *K* for a spherical cornea and 0.05 steeper than flattest *K* for 1.50 D of corneal astigmatism. This allows the lens to sit low on the cornea in the primary position (*Figure 16.28a*) and to translate smoothly for down gaze (*Figure 16.28b*). The vertical diameter of the lens is decided by measuring the distance from the lower lid to the superior limbus and subtracting 2 mm. The amount of prism is dependent on the power of the lens, a +4.00 D lens requiring 1.5△ and a –4.00 D lens requiring 2.25△ (Ruston and Meyler, 1995).

Scleral bifocal lenses

These are now almost of historic interest only. However, it is possible that the advent of rigid gas permeable materials will lead to their reintroduction.

All the forms of corneal lens bifocals are theoretically possible with scleral lenses. The type recommended by the author is an upcurved near portion worked on the back surface. This design was suggested by Hodd (1967) for corneal lenses but has the disadvantage that the back surface may be unacceptable in contact with the cornea. However, as the back optic surface of a scleral lens clears the cornea, this does not apply and there is a major advantage in that the lens can be made in distance form first. The BOZR should be up to 0.25 mm steeper than would normally be ordered but with the usual apical clearance, so some slight limbal touch can be expected. The lens can be adjusted, if necessary, and a line then marked on the front optic surface one-quarter of the pupil diameter above the lower pupil margin. The lens is returned to the laboratory for a second back optic radius (BOR) to be cut and polished, decentred inferiorly (*Figure 16.29*). For example:

BOZR	8.00 mm
Near add	+2.25 D
Second BOR	9.05 mm

This will ease the limbal touch considerably. The lens should be fitted and allowed to settle before any further adjustments are considered. Adjustments to aid the comfort of the lens at this stage may affect the visual performance.

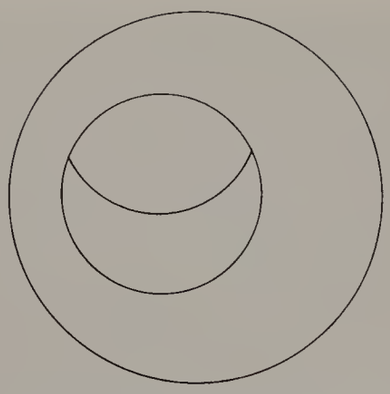


Figure 16.29 Upcurve back surface solid bifocal scleral lens

If the lens is not being raised sufficiently for the patient to obtain good near vision when the direction of gaze is lowered, the vertical total diameter should be reduced by removing material from the upper edge. Not more than 1.00 mm should be removed at a time. Increasing the inferior limbal clearance may also help slightly.

If the near portion is too high and affecting the distance vision, removal of material from the lower edge should help to lower the lens slightly. Care must be taken, because if too much material is removed it is possible for the lower edge to rise above the lower lid on upward gaze and to hold the lower lid down when looking normally again. Removing material from the lower back scleral surface or increasing the superior limbal clearance should also help to lower the lens slightly.

Hydrophilic bifocal contact lenses

With the increased use of hydrophilic materials has come the development of various soft bifocal contact lenses and as with single vision lenses, soft bifocals are frequently the first lens of choice. A fused hydrophilic bifocal lens has not been made but all the solid designs that have been made in rigid materials have been made in hydrophilic form. One advantage is that the larger total diameter enables the practitioner to achieve better control of centration and lens movement. Most soft bifocal lenses are fitted from trial lenses so various types are discussed here.

Simultaneous vision bifocals

These are concentric bifocals with one distance portion and one reading portion. They rely for their success on good centration with the minimum movement consistent with a good fitting (McGill *et al.*, 1987). The **Ciba Weicon 38E Bisoft** has a distance zone diameter of either 3.20 mm or 3.80 mm and a reading zone diameter 8.00 mm. The TD is available in either 13.00 mm or 13.80 mm and the elliptical back surface can be either 'Steep' or 'Flat'.

The range of BVPs is from +7.00 D to −10.00 D in 0.25 D steps and the reading add ranges from +1.00 D to +4.00 D in 0.25 D steps.

Initial trial lens selection is a 13.80 mm TD lens with a 'Flat' base curve and larger (3.80 mm) distance FOZP lens in the dominant eye and the smaller (3.20 mm) distance FOZP lens in the non-dominant eye. After allowing the lenses to settle there should be between 0.50 mm and 1.50 mm of movement on blinking. If there is too much movement, the 'Steep' base curve should be tried. If the lens shows no movement, the smaller TD can be tried.

Over-refraction should be carried out monocularly, then if binocular distance vision is inadequate the 3.20 mm distance zone lens should be changed to the 3.80 mm lens in the non-dominant eye and *vice versa* if binocular reading vision is poor. If binocular vision is still poor, a different type of bifocal lens should be considered.

Breger Mueller Welt, Chicago, USA, have developed the **Bullseye bifocal**. It has a small diameter distance portion of 1.00 to 2.00 mm. The reason for the small diameter is to use the theory of pinhole vision. However, flaring around lights at night can be a major problem with this lens.

The author has used small specialist laboratories to make concentric bifocals with distance portions varying from 2.20 to 4.00 mm. Lenses with unusual dimensions can also be ordered to try and improve the visual result. For example, if a lens settles inferiorly, the patient may find reading in the normal position difficult but excellent above eye level. A larger or steeper lens can often help achieve better centration.

An alternative simultaneous vision lens has the reading portion in the centre surrounded by the distance portion. The **Alges bifocal** was the first lens of this type to be made generally available and was, of course, the same design as the lens first tried in 1951 by Williamson–Noble. The diameters originally available for the near portions were small, 2.12 mm and 2.35 mm, probably to avoid the dangers from poor distance vision. Unfortunately, some patients found that their vision for close work was not helped because their pupils were too large. To overcome this problem three larger near portions were made, 2.55 mm, 3.00 mm and 3.50 mm. Obviously, it is better to fit the smallest satisfactory near portion and when driving, for example, patients should be advised to wear sunglasses, where appropriate, to avoid the situation of sudden pupil constriction and blurred distance vision should the sun shine on the drivers' eyes.

The Alges lens was available with BOZR values of 8.60 mm and 8.90 mm with a total diameter of 14.00 mm. Although the Alges bifocal is no longer available, various similar types of bifocal can still be obtained from laboratories made to prescription (*see* Simulvue lens, *Table 16.6*).

One lens of each design can be fitted to the same patient: a concentric lens with a central distance portion on the dominant eye and a central near portion on the non-dominant eye. This overcomes some of the criticisms of monovision, and of bifocals with central near portions.

The **Hydron Echelon bifocal** is a hydrophilic diffractive lens with the concentric diffractive portion on the inner surface. The lens is cast-moulded in HEMA (38.6% water). Theoretically, the main advantage should be good optics independent of pupil size. Unfortunately, the lenses suffer from the problem that the distance and near vision are superimposed and that the diffractive zone sizes are too small. They are 4.21 mm for the +2.00 D addition lens and 4.55 mm for the +1.50 D addition. However, patients with small pupils usually report excellent vision both at distance and near.

With the Echelon lens there is a reduction in contrast sensitivity. This is attributed to the fact that the incident ray of light is split between two images. Forty per cent of the light goes to the distance image, 40% to the near image and 20% to higher order diffractive images.

Only a 13.80 D mm TD is available with a BOZR of 8.70 mm. It is essential that the diffractive zone is well centred in front of the pupil for minimal side-effects. This is best checked with a slit lamp microscope, the diffractive zone can usually be seen quite easily but high molecular weight fluorescein can be used if necessary. If part of the distance area beyond the diffractive zone can be clearly seen over part of the pupil it is doubtful whether the patient will achieve acceptable near vision with this type of lens.

Translating or alternating vision bifocals

Madden & Layman Ltd manufacture a segment lens, the **R-type bifocal**, in which the segment top may be specified at any position. It is normally fitted 0.50 mm flatter than the flattest *K* reading and can be supplied in 38% or 65% material, but the higher water content material is recommended because the lenses have to be made thicker than normal lenses of similar power, which can lead to problems of oedema (*see Figure 16.30*).

The fitting requirements of such a lens are as follows:

- The lens must move upwards easily when the patient looks down.
- The lens must resume the normal position immediately upon looking straight ahead.
- The vertical lens movement when looking straight ahead must be minimal.
- The lens must settle quickly in the correct position and not rotate.

Concentric 'multifocal' lenses

The original lenses of this type of lens had an aspherical back surface to produce a lens that was distance in the centre with a progressively stronger near power towards the periphery. The first two lenses of this type were the Pilkington Barnes–Hind (now Wesley-Jessen) Hydrocurve II soft bifocal (Ivins, 1987) and the Bausch & Lomb PA1 lenses which had a nominal +1.25 D addition. For most purposes the reading add was not strong enough but was adequate for social use.



Figure 16.30 (*a*) Soft R seg bifocal (Madden & Layman, England) with top segment marked, showing it to be in the correct position at the lower pupil margin with the eye in the primary position. (*b*) The segment has moved up as the wearer looks down to read. (Courtesy of D. Westerhout)

Wesley-Jessen also make an aspheric lens, **Hydrocurve II Multifocal**, of BOZR 9.00 mm and TD 14.80 mm. Because the lens increases in power from the centre to the periphery, the useful addition can range from +1.50 D for a 3.00 mm pupil to +3.00 D for a 7.00 mm pupil. Being a one-fit lens makes this lens suitable for only a limited number of patients.

Nissel manufactures the **PV 200** (+2.00 D add) and **PV 250** (+2.50 D) lenses (originally called the PS45) aspherical hydrophilic lens for presbyopes. At first it appeared that this lens was almost identical to the CALS lens (*see* page 547): a diagram in their brochure showed the lens on an eye with no spherical aberration. Work by Charman and Saunders (1988) suggested that the lens had overcorrected spherical aberration. This need not be a bad thing. Correcting the spherical aberration of the eye is an ingenious idea but if it has been fully corrected, and is still insufficient to give an adequate bifocal effect, then further correction will obviously be impossible.

The PV200 and PV250 lenses are made of HEMA and are available in three base curves: 8.30 mm, 8.70 mm and 9.10 mm; a TD of 14.00 mm, and two reading additions of +2.00 D and +2.50 D. The design has reducing plus power peripherally, unlike the Hydrocurve II aspheric lens, and is therefore a centre-reading lens. For patients with average *K* readings the 8.70 mm lens is the first lens of choice with the

Table 16.4 Basic fused bifocal fitting set

BOZR (mm)	*BOZD (mm)*	*BPR_1 (mm)*	*TD* (mm)	
7.20	7.00	7.80	8.80	BPR_2 12.25 mm
7.35	7.00	7.95	8.90	All lenses round
7.50	7.00	8.10	9.00	Segment on datum
7.65	7.25	8.35	9.10	Suggested Rx Distance plano
7.80	7.25	8.50	9.20	Near addition +2.50 D
7.95	7.25	8.65	9.30	Prism: 2△ base-down
8.10	7.50	8.90	9.40	Upper edge as thin as possible
8.25	7.50	9.05	9.50	Lower edge as shown in *Figure 16.20a*
8.40	7.50	9.20	9.60	

8.30 mm and 9.10 mm lenses for patients with steeper or flatter corneas.

The lenses should be fitted to both eyes to achieve optimum binocular vision and over-refraction should never show more than +0.50 D residual error as the overall effect on the vision can be dramatic even with small amounts of overcorrection.

Essilor of France manufactures the **Variations** lens (marketed by Lunelle). It is a moulded front surface aspherical lens with a water content of 78%. The lens is available in four reading additions, +1.50 D, +2.00 D, +2.50 D and +3.00 D but in only one fitting, a monocurve posterior surface and a TD of 14.00 mm (Baude and Miege, 1992).

The **Lifestyle** bifocal lens (Microturn Laboratories) is manufactured under licence by Contact Lens Precision Laboratories, England. The lenses are described as having an aspheric front surface geometry which creates a simultaneous vision bifocal lens with a central near addition. They are made in either HEMA (38.6% water) or a 55% material. Three BOZRs are available (8.40 mm, 8.70 mm and 9.10 mm), with one TD of 14.00 mm. Two reading additions are available (+1.00 D and +2.00 D).

Many variations of these designs are possible and unless inspected carefully appear identical, for example:

- A lens with a central reading portion, having both distance and reading portions spherical but the transition blended.
- A lens with a central spherical reading portion, a blended transition and an aspherical distance portion.
- A lens where the degree of asphericity is constant from the centre to the periphery.
- Lenses where the degree of asphericity varies from the centre to the periphery.

The permutations are almost endless.

Fitting sets

The large successful contact lens practice will have no difficulty in purchasing a variety of sets so that many different types of bifocal lenses can be offered (*Tables 16.4–16.6*). For the practitioner with a small contact lens practice the financial outlay would not be justified. How then can bifocal contact lens fitting be started?

One way is to order one or a pair of bifocals basing the specification on the best fitting single vision lens of a similar material and total diameter. One advantage of using this method is that the prescription should be correct, giving

Table 16.5 Additional truncated fused bifocal fitting set

BOZR (mm)	*BOZD (mm)*	*BPR_1 (mm)*	*Horizontal TD (mm)*	*Truncation*	
7.20	7.00	7.80	9.00	0.70	BPR_2: 12.25 mm
7.35	7.00	7.95	9.10	0.75	Radius of truncation 18.00 mm as
7.50	7.00	8.10	9.20	0.80	shown in *Figure 16.25b*
7.65	7.25	8.35	9.30	0.85	Segment on datum before truncation
7.80	7.25	8.50	9.40	0.90	Suggested Rx Distance plano
7.95	7.25	8.65	9.50	0.95	Near addition +2.50 D
8.10	7.50	8.90	9.60	1.00	Prism: 2△ base-down
8.25	7.50	9.05	9.70	1.05	Upper edge as thin as possible
8.40	7.50	9.20	9.80	1.10	Lower edge as shown in *Figure 16.20a*

Table 16.6 A selection of various types of hydrophilic bifocal fitting lenses

Wesley-Jessen Hydrocurve II Multifocal				
BOZR (mm)	*TD (mm)*	*Distance Rx (D)*	*Near add (D)*	
9.00	14.80	−3.00	Fixed	
9.00	14.80	+3.00	Fixed	
Ciba Weicon 38E Bi-soft				
BOZR (mm)	*TD (mm)*	*Distance Rx (D)*	*Near add (D)*	
8.30	13.80	−3.00	+2.50	
8.60	13.80	−3.00	+2.50	
8.60	13.80	+3.00	+2.50	
8.90	13.80	+3.00	+2.50	
Alges type, e.g. Simulvue lens from No. 7 Laboratory (UK)				
BOZR (mm)	*TD (mm)*	*Distance Rx (D)*	*Near add (D)*	*Front Central Optic Diameter (mm)*
8.70	14.50	−3.00	+2.50	2.35
8.70	14.50	−3.00	+2.50	2.35
9.00	14.50	+3.00	+2.50	2.35
9.00	14.50	+3.00	+2.50	2.35
Hydron Echelon				
BOZR (mm)	*BOZD (mm)*	*Distance Rx (D)*	*Near add (D)*	
8.70	13.80	−3.00	+2.00	
Nissel PV 200 and PV 250				
BOZR (mm)	*BOZD (mm)*	*Distance Rx (D)*	*Near add (D)*	
8.30	14.00	+3.00	+2.00, +2.50	
8.70	14.00	−3.00	+2.00, +2.50	
9.10	14.00	−3.00	+2.00, +2.50	

the patient a much better idea of the visual performance than a fitting lens with an additional lens held in front. Lenses not used will form the basis of a useful fitting set.

Rigid bifocal fitting sets

A fitting set of fused bifocals (*Table 16.4*), although not essential, is most useful as the top of the segment shows very clearly, which helps considerably in judging both the correct segment height and the correct amount of lens movement. If necessary the lens may then be ordered in two different forms, for example, the two lenses shown in *Figure 16.17d,e*. It is suggested that the basic fitting set should consist of round lenses only, but truncated lenses are sometimes required for patients with high lower lids, and a second set of truncated lenses would certainly be very useful, as shown in *Table 16.6*.

Most lenses, these days, are not custom made and it is advisable to have the relevant manufacturer's fitting sets.

Hydrophilic bifocal fitting sets

If only one set of lenses can be afforded it would be preferable to make up a set with a few lenses of several types rather than a full range of one type. For suggestions of such hydrophilic bifocal lenses, see *Table 16.6*.

Conclusion

It is impossible in a chapter of this type to include all the available lenses and to comment on each mode of fitting. The Further Reading list at the end of the Reference section therefore provides the reader with a sample of such information.

It is important to use lenses from several manufacturers. With rigid lenses many adjustments are possible and can often make the difference between a successful and an unsuccessful fitting. With hydrophilic lenses no adjustments are possible. Fitting becomes a matter of trial and error and

the more different lenses which are available the greater the chance of success.

Aspheric multifocal lenses have improved considerably over the past few years thanks to modern computer-controlled lathes. In the author's opinion the centre reading addition lenses are preferable and hold considerable promise for the future. However, claims made by some manufacturers such as 'One lens fits all' and particularly that 'The eye will automatically choose which image to concentrate on so that only one optic design is required' are largely untrue. The visual result *must* be different for a patient who has a minimum and maximum pupil diameter of 2 to 3 mm, than for a patient with a pupil diameter varying between 3 mm and 5 mm. The author believes this is the main reason for some patients finding these lenses good in all lighting conditions and others being so disappointed.

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Chapter 17

The role of scleral lenses in modern contact lens practice

K. W. Pullum

Introduction p. 566
Principles of scleral lens fitting p. 569
Controlled clearance RGP scleral lens fitting p. 576
Eye impressions p. 580
Manufacture of the finished lens p. 594
Solutions and maintenance of scleral lenses p. 597
Scleral lenses in pathological conditions p. 597
Problems and complications with scleral lens wear p. 605
Conclusion: the role of scleral lenses p. 606

This chapter is an amalgamation and update of two chapters in the Third Edition written by E. Geoffrey Woodward and Kenneth W. Pullum.

Introduction

Anterior ocular anatomy relevant to scleral lens fitting

The technique of designing and fitting a scleral lens requires a knowledge of the configuration of the orbit, the positions of the extraocular muscle insertions, and the conjunctival, corneal and scleral topography.

The sclera

Observations of normal eye casts (Marriott, 1966) showed that the contour is not spherical or symmetrical about the visual axis of the eye. The temporal sclera is usually steeper, and the centre of curvature is contralaterally offset, giving a far less pronounced limbal sulcus (*Figure 17.1*).

The orbit and recti muscle insertions

Figure 17.2 shows the position of the recti muscles insertions. The superior, inferior and lateral recti do not have a significant effect, but a scleral lens may overly the medial rectus. The origins of the medial and lateral recti (*Figure 17.3*) are at the apex of the orbit. The medial rectus lifts away from the globe just posterior to its point of insertion, separating further with nasal gaze (*Figure 17.4*). The effect is a flattening of the nasal scleral contours, which is further accentuated by the bunching of the nasal conjunctiva against the caruncle.

Corneal curvature and flattening

The normal cornea flattens towards the periphery, which affects the choice of back optic zone radius (BOZR) in scleral lens fitting. *Figure 17.5* represents the extrapolation of the central corneal curvature compared to the actual contour of a cast of a normal eye. The relative flattening is greater at the steep end of the range compared to the flat end (Kiely *et al.*, 1982).

Advantages of scleral lenses

Scleral lenses retain a special place in contact lens practice because they have a number of unique advantages which are not always fully appreciated.

- They are held in place by the eyelids and bear on the sclera, and do not depend on capillary attraction to the cornea. Therefore:
  - it is less of a problem to fit eyes with irregular corneal topography because close alignment between the corneal surface and the lens is not necessary;
  - toric back central optic zones are unnecessary;
  - they are not affected by lid traction or by the position of the centre of gravity with higher powered lenses;
  - there is less lid sensation.
- There are no areas of the cornea which are not covered by the lens. Therefore:
  - foreign bodies are rarely trapped behind scleral lenses;
  - there are no localized exposure areas due to a disrupted blink mechanism.
- Maintenance is straightforward.
  - Dry storage is normal, and seems to be satisfactory even with RGP materials.
  - Polishing is less likely to cause distortion.
  - There are none of the problems of spoilation and dehydration associated with hydrogel lens wear.

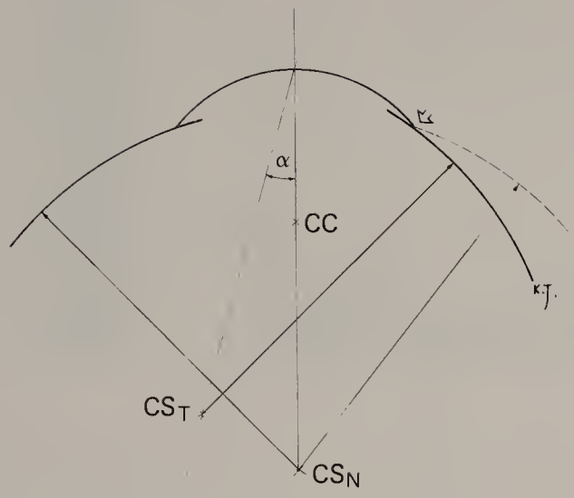


Figure 17.1 Diagrammatic representation of the difference between the nasal and temporal scleral contours. The limbus is less pronounced on the temporal side because the centre of curvature of the temporal sclera is contralaterally offset. In this diagram, the nasal and temporal radii have been made equal to show the effect. Sometimes the nasal scleral radius is actually flatter, which accentuates this. CC, centre of curvature of cornea; CS_T, centre of curvature of temporal sclera; CS_N, centre of curvature of nasal sclera; α = angle of offset; ⇓ = temporal limbus. The dotted line indicates the continuation of the nasal sclera on the temporal side

- Inserting is easier for less dextrous patients, who have difficulty with rigid corneal or soft lenses because the lens is held between the thumb and a finger rather than balanced on one finger. Removal rarely presents any problem once the technique is learned.

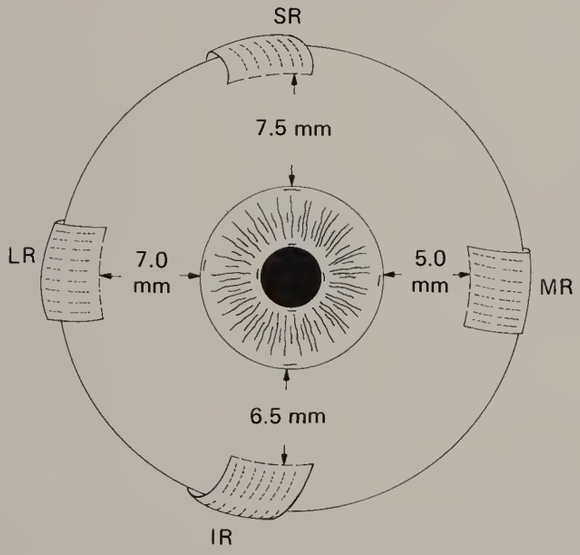


Figure 17.2 Diagrammatic representation of the extraocular muscle insertions showing their positions in relation to the limbus. LR, lateral rectus; MR, medial rectus; IR inferior rectus; SR, superior rectus. The oblique muscle insertions are not included as they do not have a significant effect. A scleral lens may overly the medial rectus

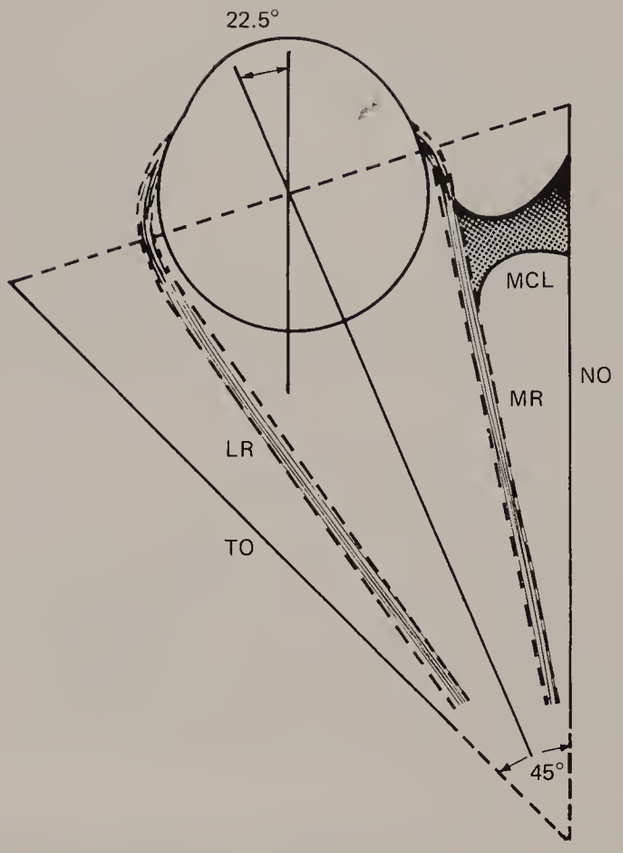


Figure 17.3 Configuration of the lateral and the medial rectus muscles in the orbit (left eye seen from above). The origins of the medial and lateral recti are at the apex of the orbit. As this is situated nasally relative to the globe, the lateral rectus wraps itself around the globe, remaining in contact during all eye movements. LR, lateral rectus; MR, medial rectus; NO, nasal orbital wall; TO, temporal orbital wall; MCL, medial check ligament

- Scleral lenses cover most of the anterior eye and retain a pre-corneal tear reservoir, enabling some therapeutic uses.

Scleral lens materials and types

Scleral lenses were first described almost simultaneously by Fick (1888), Kalt (1889) and Muller (1889). These early attempts were produced from blown glass and endeavoured to address the same clinical problems that still exist today (*see also* Chapter 1). In 1938, Obrig described the use of PMMA, which had excellent machinability and thermoplastic properties, enabling greater precision and versatility. Some patients are still wearing scleral lenses which were issued in the 1940s and 1950s. Following the introduction of corneal and hydrogel lenses the application of scleral lenses reduced mostly to special needs. However, even today, scleral lenses remain the lens of choice under some circumstances (Foss *et al.*, 1994, Tan *et al.*, 1995a).

Preformed and impression PMMA scleral lenses

Scleral lenses can be made to specifications derived from preformed fitting sets or produced from eye impressions.

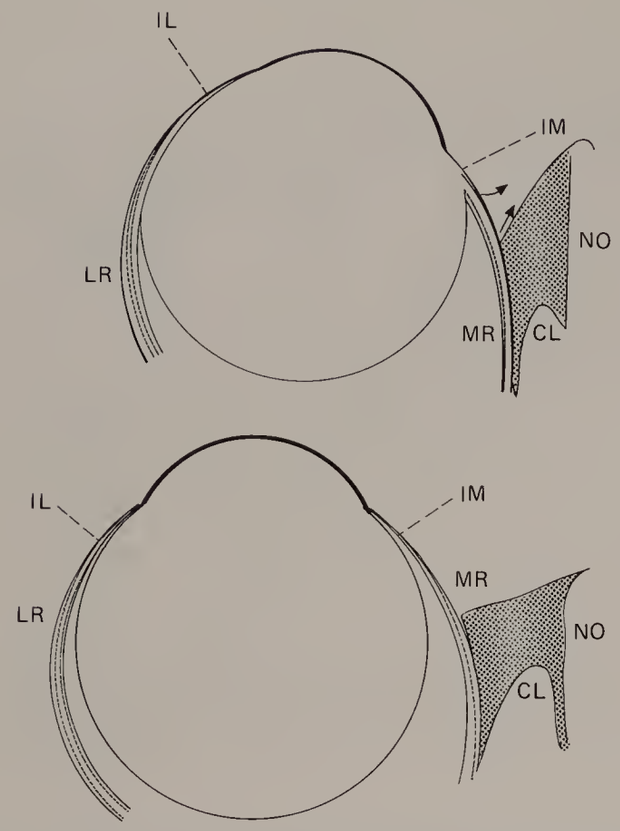


Figure 17.4 Effect on the scleral contours during gaze movements to the nasal side, when the medial rectus departs from the globe. The upper diagram shows the eye turned nasally and the lower diagram the eye in the primary position. IM, medial rectus insertion; IL, lateral rectus insertion; MR, medial rectus; LR, lateral rectus; NO, nasal orbital wall; CL, medial check ligament

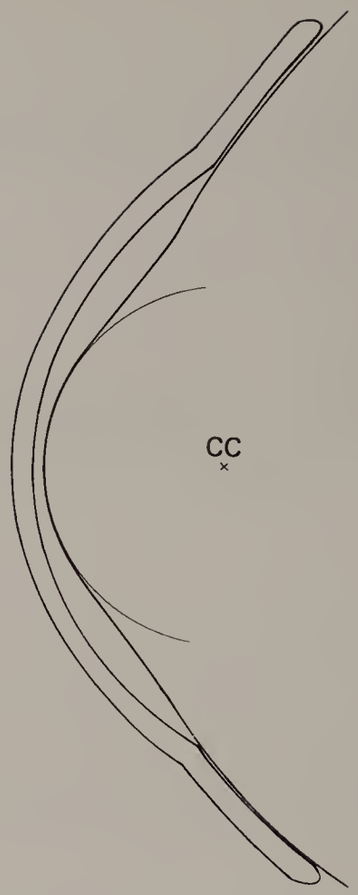


Figure 17.5 The back optic zone radius is flatter than the central corneal curvature, but the two curves become nearly concentric in the periphery where the cornea is flatter. CC, centre of curvature of the cornea; fine line = continuation of spherical central corneal curvature

Both systems were developed in tandem prior to the widespread use of corneal and hydrogel lenses. Preformed PMMA lenses are either lathe-cut from suitably sized large diameter buttons or heat softened from sheet material and pressed over master moulds. Impression lenses are pressed over casts of eyes, and the optic zone fabricated according to the individual contour. Preformed PMMA scleral lenses can be used satisfactorily for most topographically normal eyes but less readily for irregular eyes, while eye impressions can always be used equally well irrespective of topography. Josef Dallos was an advocate of a fitting system using 'type' casts and shells (*see* Chapter 1). He would select a cast from a huge bank with a shape similar to the patient's eye and use it to produce a shell. In this way he moved towards the idea of preformed fitting while retaining some of the benefits of impression techniques.

Corneal and hydrogel lenses largely meet the requirement for topographically normal eyes today, so the majority of scleral lens fittings are for irregular corneal topographies. Consequently, most scleral lens practitioners have preferred the extra versatility of impression fitting in recent years.

Rigid gas permeable (RGP) scleral lenses

The introduction of RGP materials has changed this emphasis dramatically. The materials are not sufficiently thermoplastic to heat mould so it has become necessary to review preformed techniques in order to maximize the potential of RGP materials. Production of RGP preformed scleral lenses is essentially the same as PMMA, given that buttons of sufficient size can be made, and was first described by Ezekiel in 1983. Alternatively, they can be polymerized over master moulds to reproduce a range of back surfaces.

While not possible to heat mould, it is still possible to use eye impressions as a starting point for RGP scleral lens fitting. There are two methods by which RGP impression scleral lenses can be made and fitted. A fitted impression PMMA scleral lens is cast with a suitable moulding compound, and the back surface is duplicated by a process of individually cast polymerizing to produce an RGP blank (Pullum, 1987).

Sapp (Lyons *et al.*, 1989) described a method making use of the scleral zone glove fit achieved by impression. The optic zone of a fitted PMMA shell is cut out, an RGP button

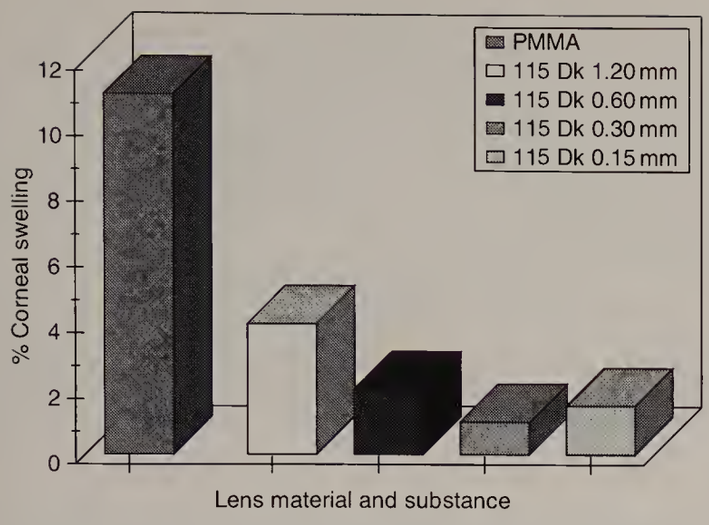


Figure 17.6 Bar chart to show the comparative swelling with PMMA and 115 Dk scleral lenses of substance varying between 1.20 mm and 0.15 mm. (Reproduced from data published in the *BCLA Journal*, 1991)

is reduced to the same diameter as the hole and cemented into the PMMA scleral zone. The back optic zone surface is lathed to the spherical equivalent curve of the original PMMA lens and the front optic zone is lathed to the appropriate power. Some materials can be fused into the PMMA scleral zone but the material must contain a high proportion of PMMA, which limits the permeability to a very low Dk.

Transmissibility through RGP scleral lenses

The substance required for scleral lenses is much greater than for corneal lenses, so there was initially some doubt that RGP materials would have sufficient transmissibility. An evaluation of the corneal oxygen uptake with RGP preformed scleral lenses *in situ* using various thicknesses (Ruben and Benjamin, 1985) showed that there was an improvement in the EOP at the corneal surface beneath a scleral lens using materials of approximately 20 Dk. Bleshoy and Pullum (1988) showed that central corneal swelling was significantly lower in RGP scleral lenses compared to PMMA. A 24 Dk material with substances between 0.18 mm and 0.50 mm was used, indicating an improvement in transmissibility with thinner lenses. Further studies (Pullum *et al.*, 1990, 1991) verified a significant improvement with a Dk over 100 compared to PMMA, and confirmed that the improvement tended to reduce as the substance was reduced (*Figure 17.6*). Clinical trials or reports (Ezekiel, 1983; Pullum *et al.*, 1989; Visser, 1990; Schein *et al.*, 1990; Ezekiel, 1991; Kok and Visser, 1992; Tan *et al.*, 1995b) have all indicated encouraging results with RGP materials, in cases where scleral lenses had been fitted for a variety of visual and therapeutic conditions.



Figure 17.7 A scleral lens in cross-section to illustrate the increasing clearance at the limbus compared to the central cornea. The central optic is flatter than the cornea, but the two curves tend towards concentricity in the periphery, giving a limbal clearance approximately twice that over the apex of the cornea

Principles of scleral lens fitting

Fitting systems have changed dramatically with the introduction of RGP materials, but it is still necessary to view this development against the background of traditional fitting methodology. The aim is as near as possible alignment to the sclera with clearance over the cornea and limbus. *Figure 17.7* shows a scleral lens *in situ* to illustrate an optimal matching of the corneal surface with the BOZR.

Fitting by preformed methods

Preformed scleral lens designs have been documented fully in previous texts, and have not changed appreciably since their original development. The finer points of fitting vary from type to type, but the principles are similar. A bibliography for further more specific information on preformed lens design is given at the end of this chapter.

Four interdependent variables – the back optic zone radius (BOZR), the back optic zone diameter (BOZD), the scleral zone radius (SZR) and total diameter (TD) – influence the final fitting of scleral lenses (*see* p. 577). There is no established accurate method to assess scleral topography other than by taking an impression. Keratometry is a measurement of the central 3 mm only, giving little information about the periphery or the projection of the cornea. Even topographical mapping provides no reliable information about the limbal region. Hence the optimum parameters can only be decided upon after inspection of the lenses *in situ*. There are two fundamentally different methods: fitting the scleral and optic zones separately, or using sets which integrate both simultaneously.

Separate optic and scleral zone fitting

Scleral zone fitting

To fit the scleral zone, the optic zone must be steep enough to avoid corneal contact (*Figure 17.8*). Corneal contact (*Figure 17.9*) may cause the scleral zone to lift off the globe. A glove fit on the sclera is rarely achieved because it

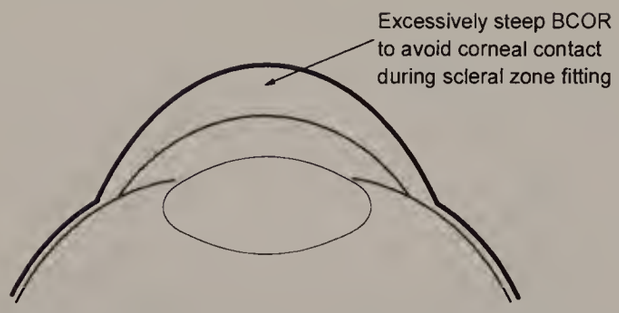


Figure 17.8 The optic zone must be steep enough to avoid contact with the central cornea. The BOZR must be no flatter than 8.00 mm with a BOZD of 13.00 mm to clear the cornea when fitting the scleral zone only

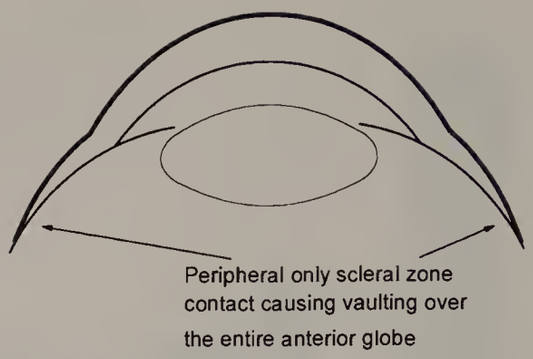


Figure 17.10 An excessively steep scleral radius vaulting the cornea during scleral zone assessment

is not symmetrical about its axis, but the fact that preformed lenses have been successful in many cases indicates that it is not a prerequisite. The optimal fitting is alignment to the anterior sclera with corneal clearance which has full liquid coverage extending 2–3 mm beyond the limbus. The lens should not impinge on the inferior fornix or the inner canthus and should not occlude the conjunctival blood vessels. Movement on the globe should be minimal. Rotation can cause the fenestration (*see* p. 589) to be covered by the lids, thereby obstructing tear flow to the pre-corneal space. Two or three lenses should be enough to establish the optimum fit, or to show that preformed lenses are not suitable.

Scleral zone radius (SZR)

The SZR is usually between 12.50 mm and 14.50 mm, which is a larger radius than half the diameter of the globe to allow for the flatter scleral regions. A usual increment in traditional fitting sets is 0.25 mm, but as the difference between the steepest section and the flattest section of a normal sclera is more than this amount, it is doubtful whether 0.25 mm is clinically significant. The bulbar conjunctiva is easily compressed, which further masks minor imperfections in the scleral zone fit. A more appropriate step is 0.5 mm.

If the SZR is too steep (*Figure 17.10*), the lens may vault the whole anterior eye from its periphery and is easily seen with fluorescein. There also may be some blanching of the peripheral conjunctival vessels. Vaulting may be a result of a localized flat scleral region, which may also cause tilting or decentration of the whole lens (*Figure 17.11*). If too flat, the scleral zone stands off the globe allowing fluorescein to encroach under the periphery, and may occlude the limbal blood vessels. There may be more settling back because of the narrow bearing surface (*Figure 17.12*).

Total diameter

The TD may be anything larger than peri-limbal to as much as 25 mm. A lens which is too small may show excessively at the inner and outer canthi, and may catch on the lower lid. If too large, the lens impinges on the inner canthus or the inferior fornix, lifting the whole lens off with nasal or downward eye movements. *Table 17.1* shows the minimum scleral fitting set specifications.

As a scleral lens is nearly a hemisphere, a small increase in the diameter gives rise to a relatively large increase in the scleral bearing surface (*Figure 17.13*). If the peripheral sclera flattens significantly, increasing the TD without flattening the SZR may cause vaulting. It may be necessary to flatten the SZR or to add a second flatter peripheral scleral zone curve if the TD is increased, but only if it can be seen that the larger TD has affected the fit. In practice, it is usually unnecessary to use a TD

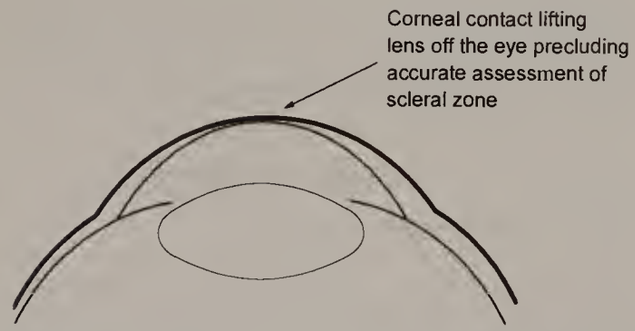


Figure 17.9 Apical contact may lift the lens off the sclera during scleral zone assessment

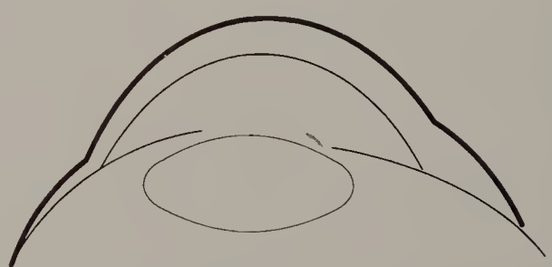


Figure 17.11 Vaulting and tilting of a scleral lens as a result of a localized flat scleral region

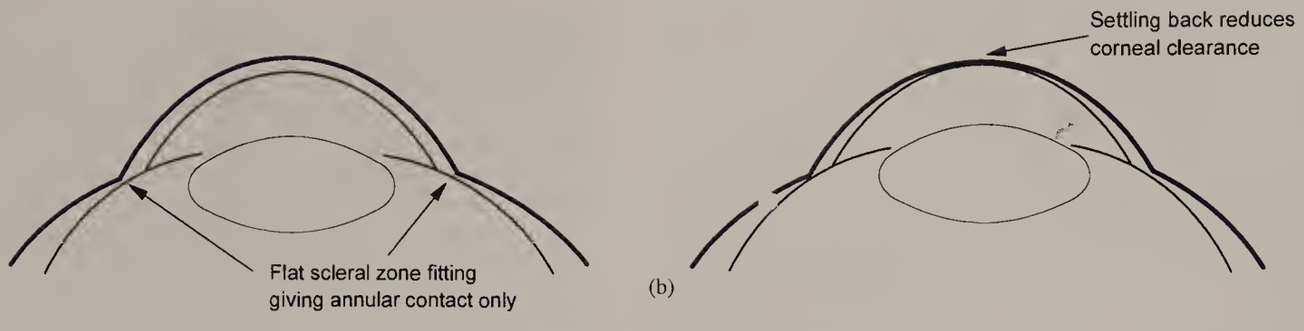


Figure 17.12 Scleral lens *in situ* with SZR too flat. (*a*) There is an annular bearing surface only with the scleral zone standing off towards the periphery, but the optic zone clearance is not affected unless the lens settles back excessively. (*b*) The narrow bearing surface may cause settling back on to the globe which reduces the optic zone clearance

greater than 23 mm, but if needed, a special trial lens can be made for assessment purposes prior to a final decision. This is preferable to using a comprehensive but excessively cumbersome fitting set.

Decentration of optic

It is usually beneficial to decentre the optic 1–1.5 mm towards the nasal side in order to reduce the width of the nasal scleral zone (*Figure 17.14*). This helps to prevent the edge impinging on the inner canthus on nasal gaze movements, and reduces rotation of the lens.

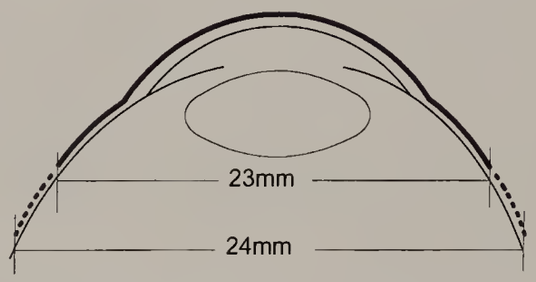


Figure 17.13 A small increase in the TD gives rise to a large increase in the scleral bearing surface

Optic zone fitting with FLOMs

Fitting the optic zone requires use of fenestrated lenses for optic measurement (FLOMs), which were first described by Bier in 1948. The BOZR range is between 8.00 mm and 9.50 mm in 0.25 mm steps and the BOZD 13.0 mm to 14.75 mm in 0.25 mm steps. A 1.5 mm fenestration hole is drilled in each lens. The scleral zone is a narrow annulus, approximately 2 mm wide and 13 mm radius, which is flat enough at the peri-limbal region to exclude vaulting. The transition is deliberately left sharp to give a precise BOZD but makes these lenses uncomfortable, so a local anaesthetic may be necessary to reduce reflex lacrimation before the fit can be assessed properly. *Figure 17.15* illustrates a FLOM *in situ*; *Table 17.2* shows the parameters of a 30 unit FLOM fitting set which omits the flat radii with small diameters and steep radii with large diameters.

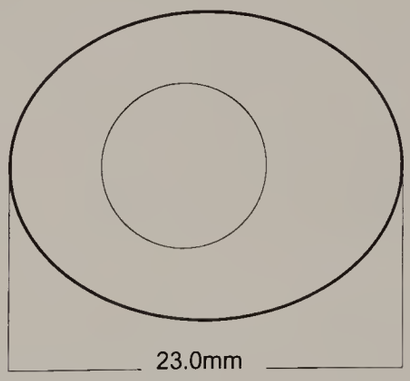


Figure 17.14 Decentration of optic zone

Table 17.1 A scleral zone fitting set.

TD (mm)	SZR (mm)				
22.50	12.50	13.00	13.50	14.00	
24.00		13.00	13.50	14.00	14.50

Such parameters would be sufficient to order a suitable lens, which if not actually seen *in situ*, would be near enough to make an estimate

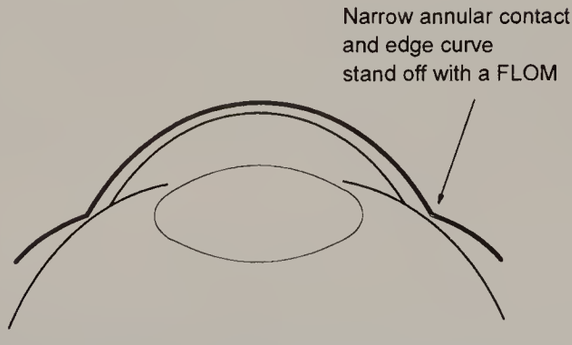


Figure 17.15 A FLOM *in situ*. Note the narrow, flat scleral zone to avoid too steep a scleral radius vaulting the cornea

Table 17.2 Specifications for a FLOM fitting set

BOZR (mm)	BOZD (mm)							
8.00	13.00	13.25						
8.25	13.00	13.25	13.50	13.75	14.00			
8.50		13.25	13.50	13.75	14.00	14.25		
8.75			13.50	13.75	14.00	14.25	14.50	
9.00			13.50	13.75	14.00	14.25	14.50	14.75
9.25				13.75	14.00	14.25	14.50	14.75
9.50							14.50	14.75

Optic zone clearance

The optimum apical and limbal clearance is achieved by varying the BOZR and BOZD independently or simultaneously. The primary sagitta for the typical values encountered in FLOM fitting remains constant if the BOZR and the BOZD are increased by the same amount. However, a lens fitted to an eye is not resting on a flat surface but on a curved surface of uncertain radius, hence the relationship between the lens parameters and the apical clearance is much less predictable.

First trial FLOM

The first lens should be in the middle of the range for both BOZR and BOZD, such as an 8.50 mm BOZR/13.75 mm BOZD (8.50/13.75) or an 8.75/14.00. Approximately 2.0 mm larger than the horizontal visible iris diameter (HVID) is a guide to the BOZD. Keratometry is of limited value for the reasons described earlier but the optimum BOZR would be approximately 0 mm to 0.5 mm flatter than the mean keratometry reading for corneas at the flat end of the range, and 0.6 mm to 1.0 mm flatter for normal steeper corneas. The lens is placed symmetrically on the cornea as if inserting a large corneal lens. A 5-minute period is allowed for settling back, after which fluorescein is instilled to observe the depth and extent of the pre-corneal reservoir using a UV lamp.

Too much apical clearance allows a spherical air bubble to form behind the lens. Correct apical clearance with excessive limbal clearance gives a long crescent-shaped bubble extending too far around the limbus. Insufficient limbal clearance produces no bubble or there may be an annular contact at the limbus. The end point of fitting is when there is fluid coverage over the whole cornea, approximately 0.1 mm in depth, extending 2 or 3 mm beyond the limbus with any air bubble crescent shaped at the limbus only, extending no more than one-third of the limbal circumference.

Alteration of BOZR independently

Steepening the BOZR while retaining a constant BOZD increases both the apical and limbal clearance. Flattening the BOZR reduces both.

Alteration of BOZD independently

Increasing the BOZD while retaining a constant BOZR increases the apical and limbal clearance. Decreasing the BOZD reduces both.

Reducing, i.e. steepening, the BOZR would have approximately twice the effect on the apical clearance as the same increase in the BOZD. Given a similar increase to the apical clearance effected by an alteration to either, the corresponding change in the depth of the limbal clearance is greater with a BOZD change. The extent of the fluid reservoir beyond the limbus is increased by increasing the BOZD while this feature of the fit is unaffected by a change to the BOZR.

Alteration of BOZR and BOZD simultaneously

Changing both together may be additive or subtractive and changes the extent of the fluid reservoir beyond the limbus. Reducing the BOZR while increasing the BOZD is additive, giving a large increase in apical and limbal clearance and the extent of the reservoir. Increasing the BOZR while reducing the BOZD gives a large reduction in apical and limbal clearance.

Clinical equivalents

A subtractive effect is achieved by increasing or decreasing both values simultaneously. Two lenses with different parameters having the same apical clearance are referred to as *clinical equivalents*. This is achieved for a 'standard' eye by altering the BOZR by an amount equal to half the alteration made to the BOZD, e.g. by increasing the BOZR by 0.25 mm and increasing the BOZD by 0.50 mm. The clearance at the apex remains constant, but the depth of the limbal clearance and the extent of the fluid reservoir beyond the limbus are increased.

Limitations of FLOM fitting

Changing the BOZR while retaining a constant BOZD gives a change to the optic zone clearance which can be precisely calculated. However, changes to BOZD, including clinical equivalents, are dependent on the scleral curvature which cannot be measured accurately, hence the effect is less predictable. There may be a large difference between the settling seen with a FLOM compared with a finished lens due to the unequal bearing surfaces. Also, most scleral lens fittings derived from FLOM fitting would include a transition curve in the final specification to blend the junction between the scleral and optic zones which may cause further discrepancies. Finally, because the scleral zone of an FLOM stands off the sclera, the effect of vaulting from the finished lens due to any scleral flat regions cannot be taken into account. *Figure 17.16* and *Table 17.3* summarize the principles of FLOM fitting. *Figure 17.17*

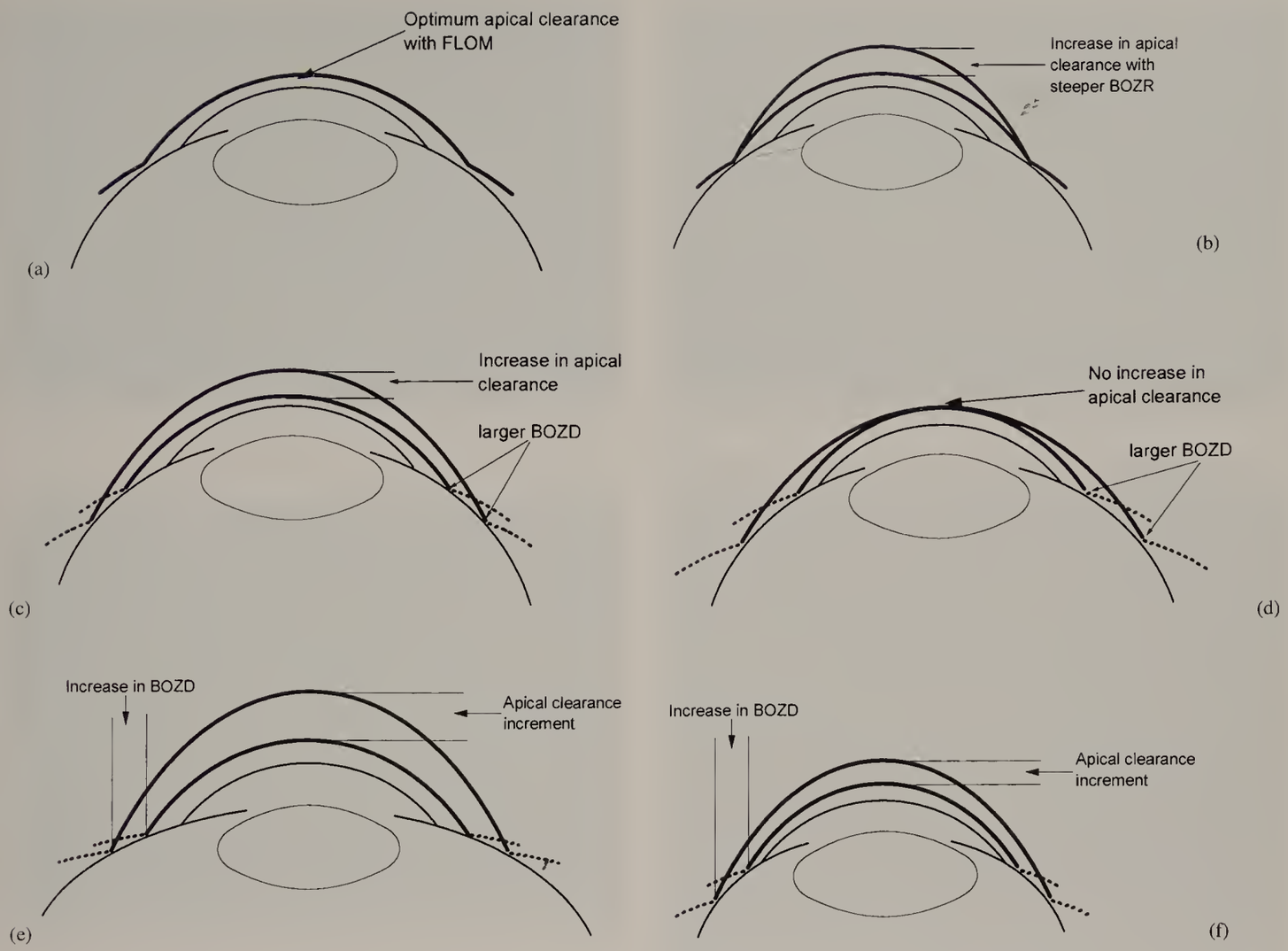


Figure 17.16 Summary of the principles of FLOM fitting. (*a*) Optimal apical and limbal clearance; (*b*) alteration of BOZR while retaining a constant BOZD; (*c*) alteration of BOZD while retaining a constant BOZR; (*d*) clinical equivalent effect; (*e*) changing the BOZD on a relatively flat sclera; (*f*) changing the BOZD on a relatively steep sclera

Table 17.3 Summary of essential FLOM fitting procedures

Selection of first lens	
Either: Add 1.0 mm to mean keratometry for corneas steeper than 7.80 mm or 0.5 mm for corneas flatter than 7.80 mm for initial BOZR, and add 2.0 mm to the HVID for the initial BOZD. Or: A mid range FLOM can simply be chosen in all cases as first choice	
Fluorescein and white light appearance	
Central touch	*Central bubble*
↓	↓
Steepen BOZR or Increase BOZD	Flatten BOZR or Decrease BOZD
Optimal apical clearance with Peripheral bubble	*Optimal apical clearance with* Tight periphery
↓	↓
Clinical equivalent smaller BOZD	Clinical equivalent larger BOZD

shows the effect in a clinical equivalent, of flattening the BOZR and of increasing the BOZD.

Integrated scleral and optic zone fitting

Fitting the scleral and optic zones simultaneously is simpler and more predictable because the final lens is much closer in appearance to the fitting lenses. Lenses can be made to specification varying the SZR, the BOZD and BOZR, but a very large set is required to cover all the permutations possible.

Wide angle lenses

Wide angle lenses were introduced by G. Nissel in 1947 in order to simplify integrated fitting. Their characteristic feature is a conical transition having a tangential junction at the corneal chord. The terms limbal and corneal chord are



Figure 17.17 Illustration of FLOM fitting. Keratometry 7.75 mm spherical. (*a*) BOZR 8.25 mm, BOZD 13.00 mm (abbreviated to FLOM 8.25/13.00); (*b*) clinical equivalent FLOM 8.50/13.50. The apical clearance is virtually unchanged but the limbal bubble has enlarged as the limbal clearance has been increased; (*c*) FLOM 9.00/13.50, i.e. the BOZR has been flattened by 0.50 mm, retaining a constant BOZD. The apical clearance is reduced leaving a broad area of central corneal contact; (*d*) FLOM 9.00/14.00 i.e. the BOZD has been increased by 0.50 mm while retaining a constant BOZR, thereby increasing the apical and limbal clearance. However there still remains some apical contact. The next stage would be to reduce the radius to 8.75 mm retaining the same diameter of 14.00, but this is a clinical equivalent of the second lens, namely FLOM 8.50/13.50. This lens trapped a large bubble, which had increased from the smaller diameter clinical equivalent FLOM 8.25/13.00

used rather than the normal nomenclature, referring respectively to the base of the conical transition and the junction of the transition with the optic curve. *Figure 17.18* illustrates the principle of the wide angle design.

There are two parameters, the SZR and the BOZR. The BOZD can be calculated but is unimportant as it cannot be varied. The corneal chord is standardized at 11.5 mm and the limbal chord at 16 mm. The cone angles vary from 45° to 54° in 1.5° steps for each 0.25 mm change in BOZR. The full BOZR range is from 7.50 mm to 9.00 mm, but 8.00 mm to 8.75 mm is more usual. Each BOZR has been paired with the appropriate cone angle in order to create the tangential junction. For example, a 7.50 mm back optic zone radius is joined by a transition of cone angle 45°, a 7.75 mm radius with 46.5°, and so on. The TD can be altered as desired, but a standard set variously includes 23 mm round or 23 × 21 mm oval lenses. This introduces an additional problem that two adjacent lenses in the system may have an extra variable. In the author's opinion, a single diameter of 23 mm round would be preferable with ovals ordered as specials if required. *Table 17.4* lists the parameters for a comprehensive wide angle set.

Selection of first lens

The lack of a definitive indicator for the selection of the initial trial lens applies also to integrated fitting. A lens in the mid range is a reasonable first option, hence a 13.50 mm

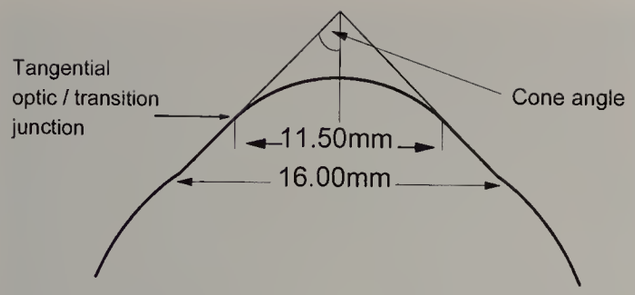


Figure 17.18 The principle of the wide angle design. The scleral and optic curves are linked by a conic transition. The cone angle is selected to give a tangential junction at the corneal chord (11.50 mm)

SZR and 8.50 mm BOZR is worth inspecting *in situ*. The option of 8.25 mm for corneas at the steep end of the normal range or 8.75 mm at the flat end would be appropriate alternatives. All parameters are assessed together. The optimum SZR is chosen according to the same criteria as previously described. Care must be taken to ensure that the BOZR is not excessively flat as this may lift the lens off the eye to some extent affecting the scleral zone fitting. The apical clearance is increased or decreased by steepening or flattening the BOZR respectively. *Figure 17.19* illustrates the change to the fluorescein appearance from two successive increments of 0.25 mm. *Table 17.5* is a suggested scaled down wide angle fitting set.

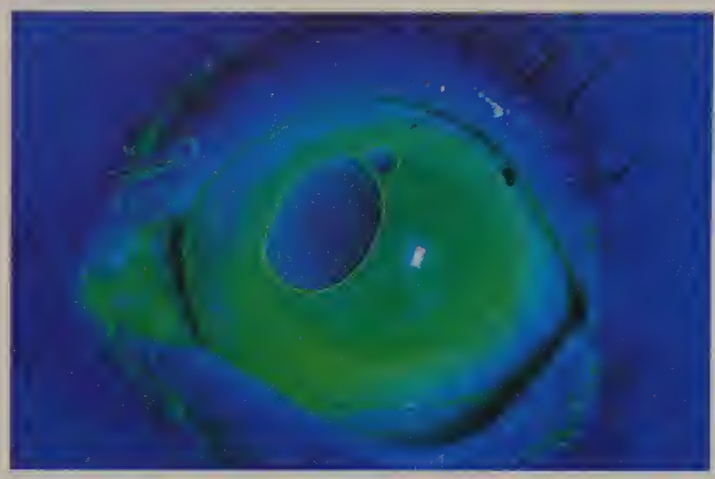
The concept of wide angle lenses was a very good one at the time of its introduction, and proved to be simple and quick to fit. Most normal topographies can be fitted from the wide angle set. Those which cannot be fitted can be tried with FLOMs and scleral sets, or an impression can be taken. They do not lend themselves well to RGP materials because the lenses are pressed over master moulds rather than lathe-cut. It would require a complex lathe specially designed to produce the conic transition. However, the lens design was good, and formed the basis of a system from which it is possible to produce RGP scleral lenses.

Transcurve lenses

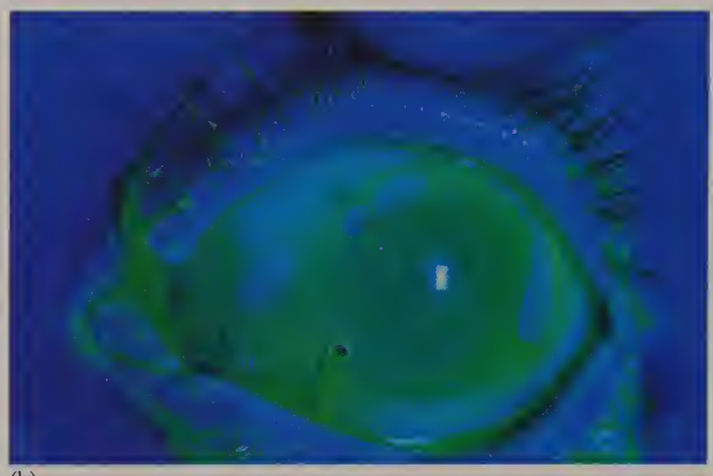
Transcurve lenses incorporate an extra transitional curve with a radius approximately mid-way between the BOZR

Table 17.4 A comprehensive wide angle fitting set with 30 lenses

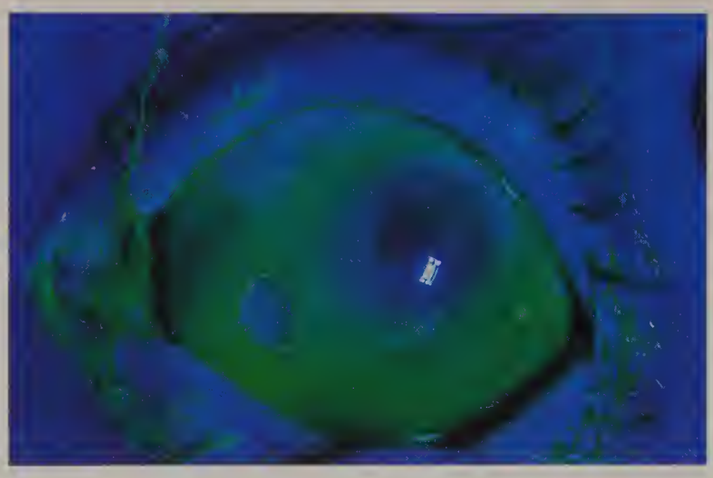
SZR (mm)	BOZR (mm)				
12.50	8.00	8.25	8.50		
12.75	8.00	8.25	8.50		
13.00	8.00	8.25	8.50	8.75	
13.25	8.00	8.25	8.50	8.75	9.00
13.50	8.00	8.25	8.50	8.75	9.00
13.75		8.25	8.50	8.75	9.00
14.00			8.50	8.75	9.00
14.25			8.50	8.75	9.00



(a)



(b)



(c)

Figure 17.19 Effect of flattening the BOZR with an optimally fitting scleral zone using wide angle lenses. (*a*) BOZR 8.00 mm SZR 13.50 mm (8.00/13.50). Note the deep limbal clearance. The apical clearance is slightly too much as a spherical bubble is admitted into the pre-corneal reservoir; (*b*) 8.25/13.50. The apical clearance is reduced, leaving a small crescent shaped bubble at the periphery. This is as near to an ideal fit as could be expected with preformed scleral lens fitting. The lens has rotated so that the fenestration has traversed to the nasal side but this had no significant effect on the lens fit; (*c*) A further flattening using 8.50/13.50. There is unacceptable corneal contact. Note also the fluorescein under the inferior scleral zone probably caused by some degree of lifting as a result of the contact

Table 17.5 A suggested scaled down wide angle fitting set of just 10 lenses that should be sufficient to establish whether or not wide angle lenses can be used in any particular case

SZR (mm)	BOZR (mm)				
12.75	8.00	8.25			
13.50	8.00	8.25	8.50	8.75	
14.25		8.25	8.50	8.75	9.00

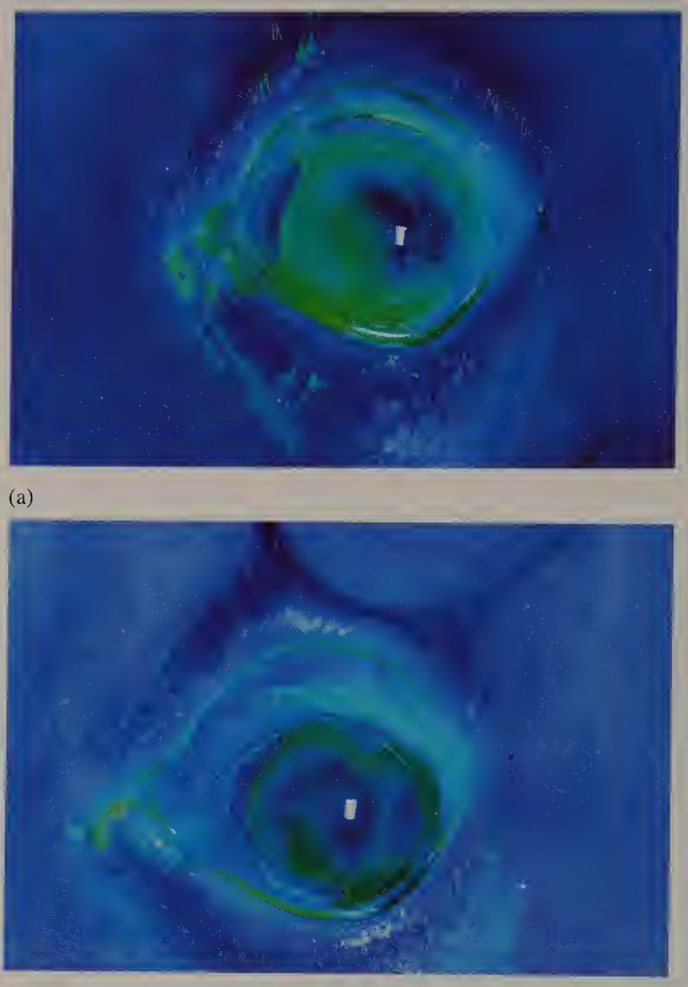
and the SZR. The apical clearance is unaffected unless the reduced bearing surface increases settling back. A selection of transcurve lenses could be compiled into an integrated fitting set. In order to maintain a manageable sized set, the variable of BOZD would probably be best eliminated, i.e. all lenses ordered would have the same BOZD, or the BOZD could increase with flatter BOZRs. One advantage of a transcurve set over a wide angle set is that it is possible to order lathe-cut lenses in an RGP material. *Table 17.6* shows the parameters of a minimum working transcurve set.

Lens verification

It is simple to check the BOZR, but verification of the BOZD can only be prior to blending at the optic/scleral zone junction. Even if within manufacturing tolerance, errors in the BOZR and BOZD could have a significant effect on the sagittal depth if additive. Furthermore, it is possible to alter just the central area of the optic zone during the manufacturing process to give the specified radiuscope (optical microspherometer) reading. The lens may be presumed made to specification but in fact has a sagittal depth which differs from the fitting set lens. Conversely, the radiuscope reading may differ from the specification, but the apical clearance may be comparable to the fitting set lens. This can quite easily happen with lenses pressed from master moulds. It would be inappropriate for the manufacturer to alter the BOZR to make the lens conform to the prescription as this influences the apical clearance. Against this background, it is not surprising that preformed scleral lens fitting can be confusing. Scleral lenses should be checked as far as possible before issue, but the final verification should be made *in situ*.

Table 17.6 A suggested transcurve set mimicking the layout of the wide angle set in *Table 17.5* but with the addition of a specified BOZD. The transcurve radius would be set mid way between the BOZR and the SZR

SZR (mm)	BOZD (mm)	BOZR (mm)				
12.75	13.00	8.00	8.25			
13.50	13.50	8.00	8.25	8.50	8.75	
14.25	14.00		8.25	8.50	8.75	9.00



(a)

(b)

Figure 17.20 (*a*) Slotted PMMA fitted to penetrating keratoplasty photographed immediately following insertion of the lens. There is a small contact zone just at the superior nasal donor/host junction but otherwise the lens is fully clear of the cornea. (*b*) After less than one hour the lens has settled back to give an unacceptable contact zone over nearly the whole donor cornea and the limbus is occluded, illustrated by the static bubbles trapped just inside the limbus

Controlled clearance RGP scleral lens fitting

RGP materials allow sealed designs to be used as an option to fenestrated scleral lenses because the oxygen transmissibility reduces the need for ventilation. There are two major advantages. First, excluding air bubbles is easier without fenestrations. Second, settling back on the globe is reduced because the pre-corneal reservoir is not disrupted. An explanation of the forces influencing settling back appears later in this chapter (*see* p. 593, and *Figures 17.49*, *17.50*). *Figure 17.20* illustrates settling back with PMMA slotted lenses.

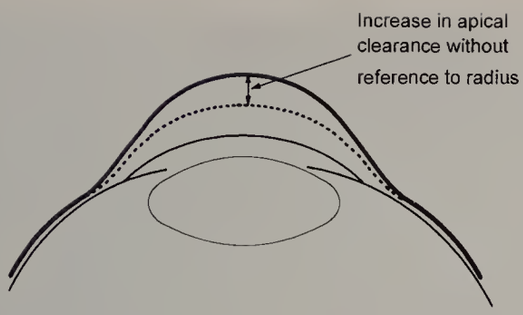


Figure 17.21 Controlled clearance scleral lens fitting. A simple increment in optic zone projection without reference to BOZR or BOZD gives an increase in corneal clearance

Sagittal depths

A combination of the BOZR and BOZD gives the optic zone sagittal depth, and hence the corneal clearance which is the critical feature of scleral lens fitting. The SZR is also a contributing factor if there is some scleral vaulting. *Figures 17.10, 17.16, 17.17* and *17.19* illustrate how corneal clearance is affected by variation of the BOZR, BOZD and SZR.

Visser (1990) and Schein *et al.* (1990) described an integrated scleral and optic zone fitting system with trial transcurve lenses including combinations of BOZRs and BOZDs to vary the sagittal depth for RGP sealed lenses. The blending between the curves in more recent designs has a smoother and less demarcated transition, but a nominal value for the BOZD is stated. The set includes a table of sagittal depths for each lens to indicate the difference in expected apical clearance between two lenses.

Controlled clearance using optic zone projection

An alternative method is to use a system with moulded lenses having progressive increments in the projection of the optic zone without reference to the BOZR or BOZD diameter. This controls the clearance in a simple, direct manner (*Figure 17.21*), and can be used for fenestrated designs or sealed gas permeable lenses. Between 0.10 mm and 0.30 mm apical corneal clearance usually allows an air-free pre-corneal reservoir with sealed lenses compared to a maximum of 0.10 mm with fenestrated lenses.

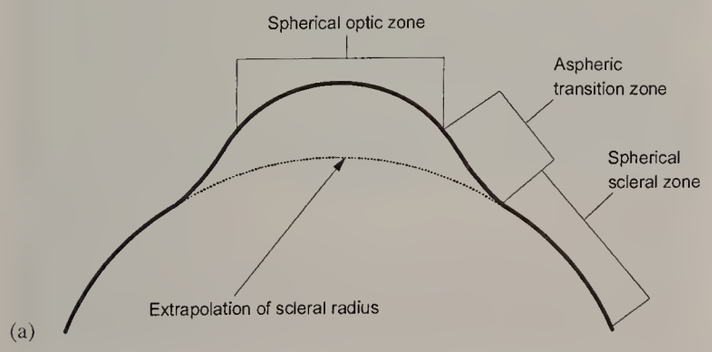
Lens specification

There are three zones on the lenses: a peripheral spherical scleral curve, a broad aspheric transition overlying the peri-limbal region and limbus, and a spherical central optic zone, as in *Figure 17.22a*. The transition between the scleral and optic zones is an aspheric continuous curve. Each lens is defined by three parameters; the SZR, together with the optic zone projection (OZP) from the extrapolation of the scleral curve measured in two places, just inside the limbus and at the apex, as *Figure 17.22b*. All lens parameters are interdependent: the system enables assessment of the scleral radius, the limbal clearance and the apical clearance simultaneously.

Scleral zone radius

As the scleral topography of a normal eye may be quite different along a single meridian, it is debatable whether small changes to the SZR are clinically significant. Therefore, the SZR options have been simplified to steep or flat; 13.50 or 14.50 mm, from which the majority of eyes can be fitted. The sclera is not easy to assess by observation, and the only reliable measuring technique is to inspect a scleral lens in situ, the suitability of which is immediately apparent. If the 13.50 mm radius is acceptable, there is no need to investigate the effect of the flat scleral fitting range which only serves to add conflicting information to the fitting process.

Choice of the flatter or steeper scleral curve may be determined in part by the appearance of the underlying conjunctival blood vessels, but also by the most favourable optic zone appearance, which is affected by the degree of



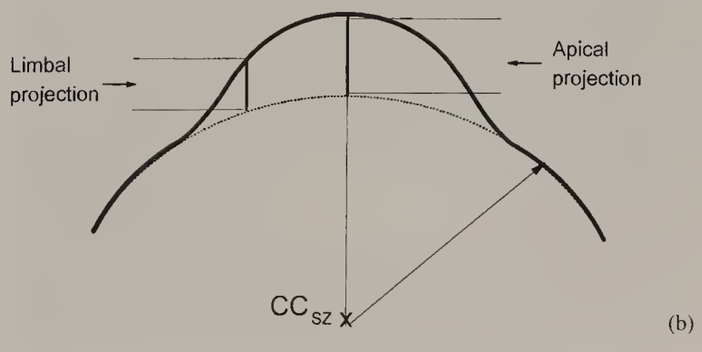


Figure 17.22 (*a*) Controlled clearance scleral lens fitting. The three zones on the lenses: a peripheral spherical scleral curve, a broad aspheric transition overlying the peri-limbal region and limbus, and a spherical central optic zone; (*b*) Controlled clearance scleral lens fitting. Each lens is defined by three parameters: the SZR, and the optic zone projection (OZP) from the extrapolation of the scleral curve measured in two places, just inside the limbus and at the apex. CC_{SZ} = centre of curvature of scleral zone



Figure 17.23 Controlled clearance scleral lens fitting. Partial vaulting from the mid-periphery may be quite acceptable and can contribute to the apical clearance

vaulting from the scleral zone. Vaulting from the very edge as illustrated in *Figure 17.10* is rarely tolerable, but partial vaulting from the mid-periphery is quite acceptable, and may aid the optimum apical clearance, as shown in *Figure 17.23*. *Figure 17.24* shows how the width of limbal clearance can be varied by steeping the SZR. A moderately toroidal sclera may be satisfactorily fitted with flat spherical lenses giving stand off in the steeper meridian. This may not necessarily cause a problem, and could even provide some tear exchange to the pre-corneal reservoir.

Optic zone projection (OZP)

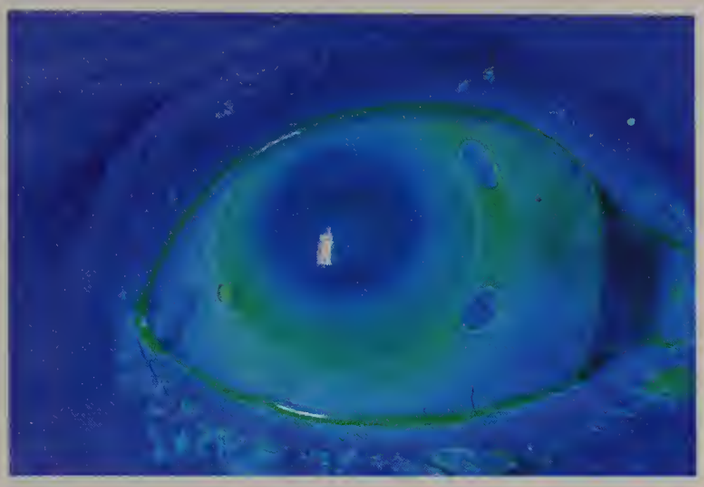
A change to the apical OZP changes the corneal clearance by the same amount. Part of the design process analysed the parameter changes so that differences between lenses are clinically significant but ensure that fitting sets are not too cumbersome. A suitable apical increment for normal topographies is 0.16 mm, which is about half the average apical clearance increment effected by a steepening of the BOZR by 0.25 mm with the wide angle fitting method. *Figure 17.25* demonstrates decreasing apical contact with two apical OZP increments of 0.16 mm. The most protrusive of normal profiles could need an OZP up to 2.50 mm to avoid apical contact, although the usual range is more like 1.0 mm to 2.0 mm.

Keratoconic and keratoglobic corneal profiles (*see Figures 17.54–17.56*), are more varied, requiring an OZP range from 2.00 mm to 4.00 mm to clear the cornea. The irregular topography causes excessive variations in the depth of the pre-corneal reservoir, hence it is often impossible to avoid large air bubbles or apical contact zones with fenestrated preformed lenses, especially if the cone apex is decentred. However, sealed RGP scleral lenses inserted, filled with saline, usually give an air-free pre-corneal reservoir. Use of a controlled clearance system provides a relatively simple method for establishing the optimum OZP.

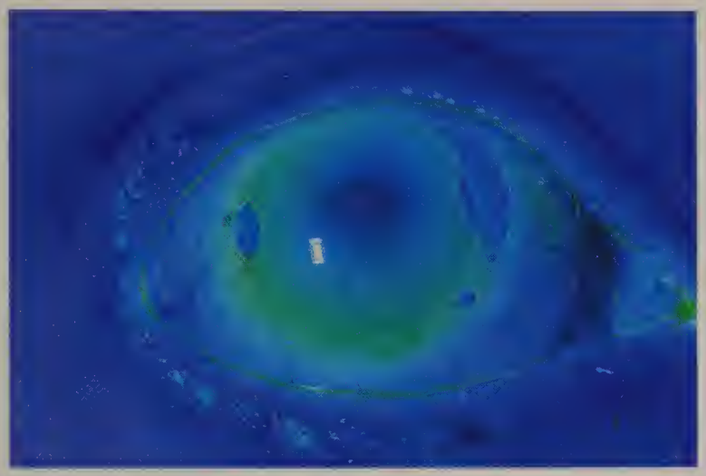
While more protrusive, keratoglobic corneas have a broader ectatic base and assume greater symmetry about the central axis (*see Figure 17.57*), fitting with fenestrated lenses may be easier compared to the more irregular keratoconus with a shallower overall corneal profile. However, establishment of the optimum apical OZP alone is still the paramount consideration and fitting with sealed RGP lenses is still quicker and the reduced settling back may improve the comfort of finished lenses. Apical OZPs in excess of 4.0 mm are necessary for a comprehensive scleral lens fitting set.



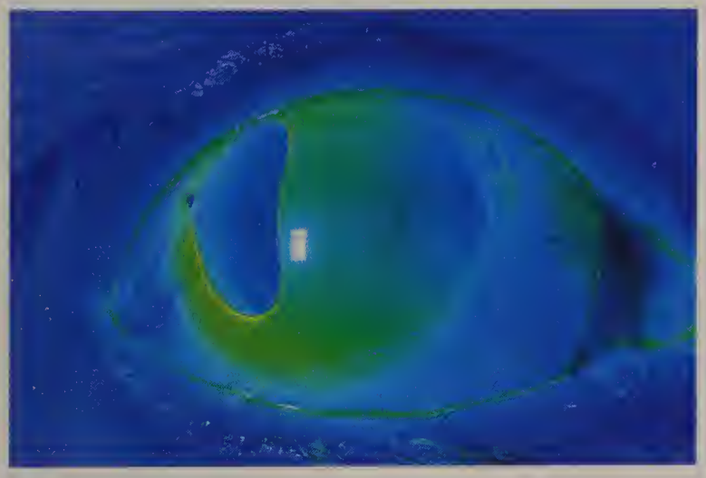
Figure 17.24 Controlled clearance scleral lens fitting showing how the width of limbal clearance can be varied by (*a*) steepening or (*b*) flattening the SZR



(a)



(b)

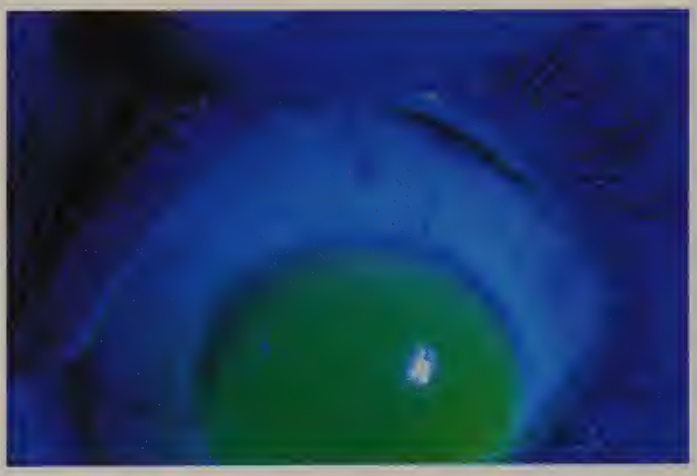


(c)

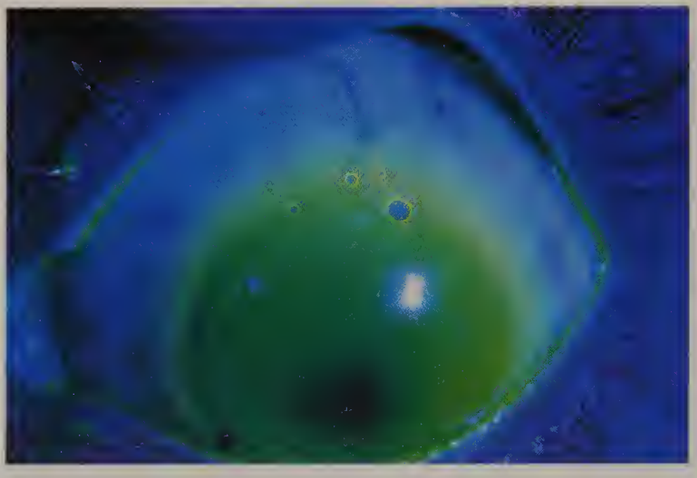
Figure 17.25 Controlled clearance scleral lens fitting. Fluorescein photographs demonstrating decreasing apical contact with two apical OZP increments of 0.16 mm. The lenses in this example were fenestrated and the cornea was of normal topography, not keratoconic

Special parameters

Sometimes it is necessary to design a back surface shape that varies the relationship between the apical and limbal OZP. If air cannot be eliminated or enters the pre-corneal fluid reservoir subsequent to the initial insertion of the lens, it may be necessary to reduce the limbal OZP or the apical and limbal OZP simultaneously, even if this leaves a light corneal contact with the final lens. If the cornea has an abnormally high limbal projection, it may be necessary to increase the limbal OZP for a given apical OZP to clear fully the peripheral cornea (*Figure 17.26*). Increasing the limbal clearance removes some substance from the scleral zone. This may cause the lens to settle back more on the globe, thereby reducing both apical and limbal clearance.

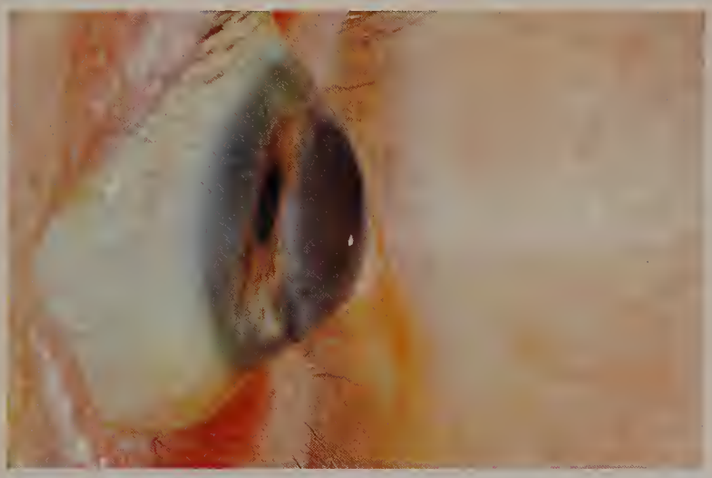


(a)

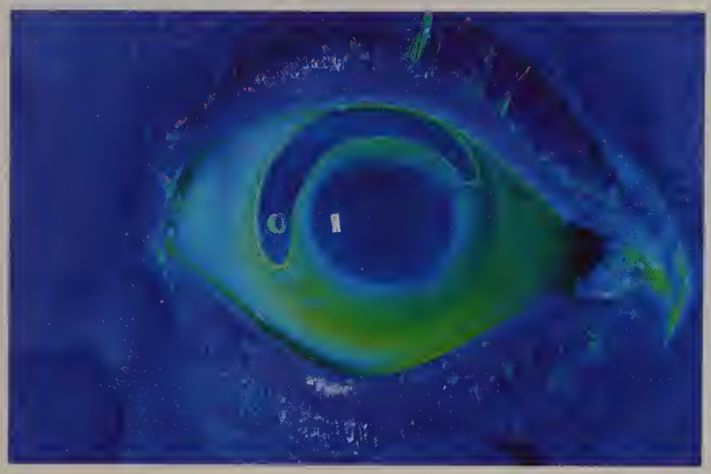


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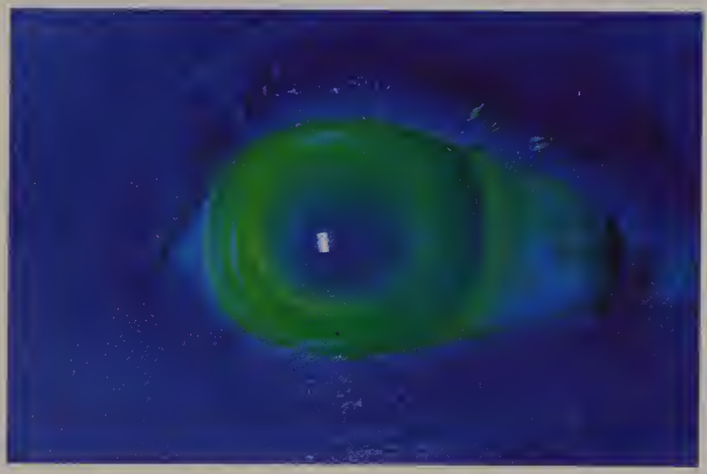
Figure 17.26 Controlled clearance scleral lens fitting. Fluorescein photographs of a keratoconic eye fitted with a sealed RGP scleral lens. The annular limbal contact zone is completely eliminated and fluorescein extends well beyond the limbus when the limbal OZP is increased by 0.24 mm. Note that the contact zone is increased slightly when the limbal clearance is increased. This is due to a small amount of settling back after removal of substance from the scleral bearing surface just beyond the limbus



(a)



(b)



(c)

Figure 17.27 (*a*) Highly protrusive corneal profile following an attempted epikeratophakia procedure on an already protrusive keratoconus; (*b*) best fenestrated PMMA fit leaving heavy contact over the central apex. The bubble is an acceptable size and shape, but the contact zone is not. If the central touch were to be eased by trying a grind-out, the bubble would be massive; (*c*) the central contact is virtually eliminated with a controlled clearance lens, apical projection 3.72 mm from the extrapolation of the scleral curve of 13.50 mm

Selection of optic parameters

Keratometry

Flat corneas would usually have less corneal projection than steep eyes, but as previously discussed, keratometry provides insufficient information about the corneal projection. It gives an idea whether the eye is at the flat or steep end of the range, but this becomes self-evident by inspecting the ocular profile.

Empirical selection

A better indicator is a simple assessment of the corneal profile, which is not difficult with practice. The first lens can be used to assess the apical clearance irrespective of the corneal curvature, with the choice of subsequent lenses dependent on the observations. The depth of the pre-corneal reservoir can be estimated in slit lamp optical section by comparison to the corneal thickness. It is more difficult to assess by how much the OZP should be increased to give clearance if the first trial lens is in contact with the cornea. A lens with an OZP of 1.8 mm to 2.0 mm should be clear of the cornea in most instances where the topography is normal. Keratoconus profiles may need an OZP up to 4.0 mm in advanced cases. With a dedicated preformed fitting system, most advanced keratoconus or highly protrusive corneal topographies can be successfully fitted with a sealed preformed gas permeable scleral as shown in *Figure 17.27.*

Eye impressions

The greater latitude possible with RGP materials has shifted the emphasis away from impression techniques. However, impressions are still necessary from time to time, for example if the sclera is excessively toroidal or irregular. The principal advantage of impressions is scleral zone alignment so that the optic zone is made according to the corneal topography alone and is not subject to influence from the fit of the scleral zone.

Taking impressions

Some dental alginates and polyvinyl siloxanes can be used to take impressions of eyes. They are soft enough to minimize abrasion of the cornea and separate easily from moist surfaces. There is less than a minute available from the start of the process to the end so all the necessary items must be readily to hand.

Alginates

Kromogel* has been the most commonly used alginate for contact lens work in recent years. Mixing 2 g powder with 7 ml of fresh distilled water in soft sided rubber or plastic bowls gives a homogeneous cream which gels in about

*Wright Dental Co. Ltd, Dundee, UK.

40–60 seconds. Sterile non-preserved saline can be used, but buffering agents in some aerosol salines upset the gelling process. The colour changes from purple to pink and finally white, indicating the progress of gelling.

Polyvinyl siloxanes

Storey (1987) described the use of Panasil C, a silicone-based dental moulding compound, for eye impressions. Water is not needed for mixing so it does not dehydrate and has a virtually indefinite shelf-life. A measured length of Panasil is squeezed from the tube and spatulated with the hardener to initiate gelling. Delayed or repeated casting is possible, hence may be preferable to Kromogel if impressions are carried out only occasionally. Panasil C has been discontinued but Panasil light body grade* is similar.

At the time of writing the manufacturers of Kromogel have refused to sanction its use outside dentistry. It is possible that the same could be applied to all dental moulding compounds. This would cause a problem as there is not a product specifically manufactured for eye impressions.

Establishing correct visual fixation

The impression of the cornea must be reasonably well centred, preferably with a wider scleral portion superiorly and temporally, but as it is occluded at the time, this has to be confirmed by the position of the fellow eye prior to the moulding. The fellow eye fixates on the patient's own index finger which is moved until the eye to be moulded is looking slightly in and down. The eyelid immediately below the pupil of the fixing eye is marked with a waterproof fibre pen. During moulding, the patient looks at their finger, which is moved until the pupil is lined up with the mark on the eyelid. If fixation with the fellow eye is not possible, the eye to be moulded is positioned before moulding in the same manner, with fixation maintained using the function of innate hand–eye proprioception.

Preparation for impression

The patient should be seated, with a straight back and the head comfortably supported in an upright position. Three or four drops of local anaesthetic are instilled into the conjunctival sac. A guide to adequate anaesthesia is that the stinging sensation of the final drop should not be noticed.

Impression trays

The largest tray that can be inserted and removed easily is selected, cleaned and marked 'R' or 'L' with a waterproof fibre pen at the top. The back radius should be steeper than the sclera so that it is clear of the eye except at its extremities, as shown in *Figure 17.28*. A suitable radius is range 12–14 mm, and between 21 mm and 25 mm for the diameter. About 20 counter-sunk holes, 1–1.5 mm in diameter are drilled in the tray. A tubular handle, about 25 mm long and 5 mm in diameter, is attached to the front. The tray should be 0.8 mm to 1.0 mm thick to avoid distortion. The temporal and superior sectors of the tray should both be about 2 mm larger than the nasal and inferior. Special large, small, steep or flat trays can be made if required. *Figure 17.29* illustrates an impression tray.

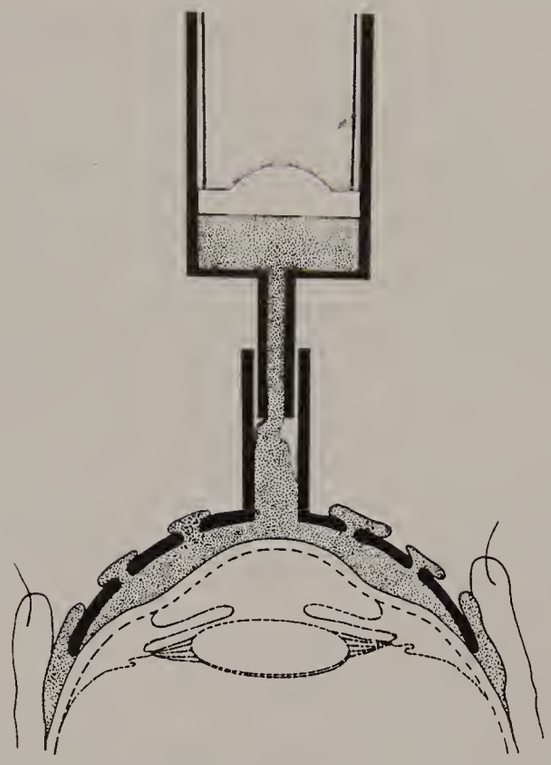


Figure 17.28 An impression tray *in situ* during the process of injection. The paste extrudes through the holes in the tray to lock the gelled impression in place. Note also the back radius of the tray is steeper than the sclera so that it is in contact at the extremities only, with the maximum thickness of the impression over the cornea

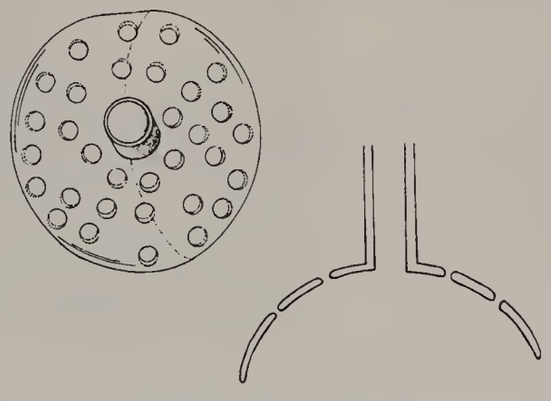


Figure 17.29 Back view and cross-section of an impression tray showing the large fenestrations and tubular handle

*Kettenbach, Eschenberg, Germany.

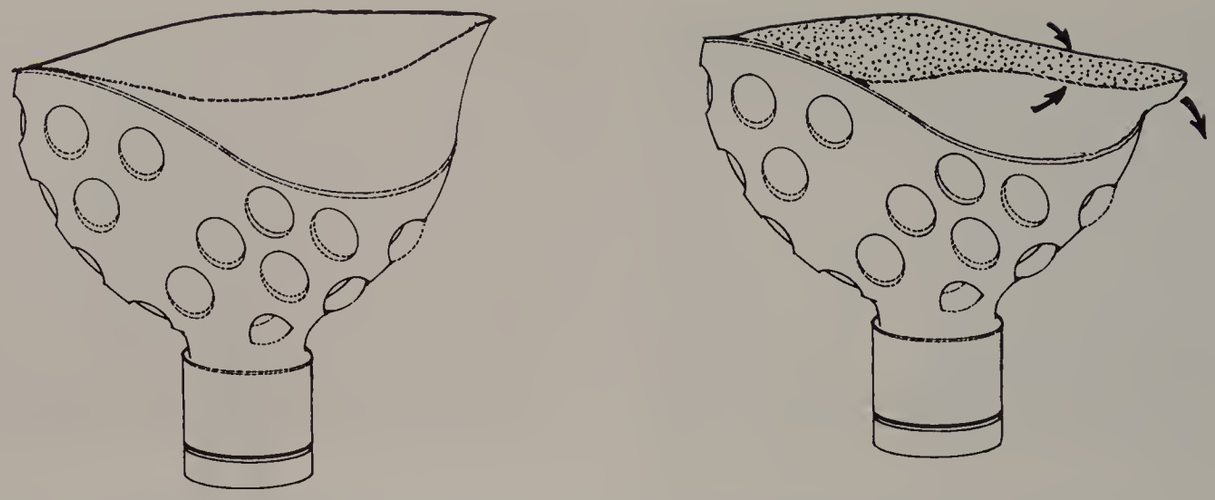


Figure 17.30 Diagram to illustrate how an inadequately supported impression can become distorted. The unsupported impression collapses outwards in its central section and inwards towards its edge. This results in an area of loose scleral zone fitting bordered on both sides by a tight area. (→ indicates the collapsed area of the impression)

Application of impression material

The impression material is transferred to a 10 ml syringe and injected continuously through the tubular handle of the tray. Holding the tray slightly away from the globe and moving it up, down, left and right as the plunger is pressed helps to cover the eye fully with the impression material. If held upright and the plunger depressed slowly, the free-flowing homogeneous paste passes unmixed alginate particles which are easily visible as they do not change colour as quickly. *Figure 17.28* shows an impression tray *in situ* during the process of injection.

Alternatively, the tray can be inserted already filled with impression material. The patient's head has to be facing downwards to prevent the impression material dropping away from the upper part of the tray on insertion. The method of choice is a matter of personal preference. There is a greater risk of distorting the cornea with injecting but it is possible to use a larger tray and there is more time available as the tray is inserted before spatulation. Insertion eliminates the risk of introducing an excessive amount of material and is usually preferred for polyvinyl siloxanes as the consistency is stickier than Kromogel.

Removal of the impression

The top should be re-marked and excess material removed from the lids. The impression and the tray may separate if it is pulled too rapidly away from the globe. To prevent this happening, the lower lid is pulled down below the impression and pressed gently underneath to relieve the suction, allowing the impression to slide out.

Post-impression examination

Inspection of the cornea using the slit lamp and fluorescein reveals any abrasions. If significant, a prophylactic antibiotic may be indicated. The conjunctival sac should be examined for any residual slivers of impression material. Irrigation of the eye helps to flush out small particles.

Casting

An alginate impression must be cast with dental stone within a few minutes before dehydration and shrinkage takes place. Cold water and dental stone powder in approximately a 1:5 part ratio are stirred in a flexible bowl to give a homogeneous cream which is lowered gently into the impression. Agitating helps to eliminate air bubbles. Most types of stone set after about one hour. The cast is separated from the impression, identified with the patient's name, the top marked R or L, and the nasal and temporal sides indicated. Surplus material and conjunctival folds or vessels recorded on the cast are removed by scraping lightly with the plaster knife. A plaster of Paris base added afterwards provides a solid foundation.

Sources of error in impression taking

- There is very little pressure on the cornea with free-flowing impression material but the risk of corneal distortion should be borne in mind when the corneal rigidity may be reduced.
- The impression may distort under the weight of the liquid dental stone if inadequately supported, as shown diagrammatically in *Figure 17.30*.
- The liquid dental stone adheres to any particles of unmixed alginate on the surface of the impression leaving an irregular cavity in the final cast. Incomplete coverage leaves proud areas. Small defects can be filled in or scraped away as appropriate. There may be a marked Bell's reaction on taking an eye impression when the whole superior or temporal sclera may be missed.



Figure 17.31 Typical handpiece tools required for scleral lens modification

- Alginates deteriorate with storage due to their hygroscopic nature, lengthening the gelling time and reducing the quality of the impression. Gelling is quicker in warm, humid conditions, when it may be necessary to use refrigerated water. If in doubt it is useful to carry out a trial mix. Polyvinyl siloxanes are less affected by ambient conditions but incomplete mixing results in a dimensionally unstable impression.

Production and fitting of PMMA shells

As much handwork as possible should be carried out on PMMA shells by the practitioner or under his or her immediate supervision so that the effect of any modification can be seen immediately.

Equipment for production and modification of shells

- Variable speed hand motor or one with a flexible drive attachment capable of 15 000 rev/min.
- A selection of dental tools mounted on mandrels or on fixed mounts designed to fit the flexible drive: rose burrs of various sizes from 0.3 mm to 2 mm in diameter, fissure burrs or cutters, flat discs about 25 mm in diameter and 5 mm wide, conical shapes about 12 mm long and 8 mm wide tapering to a blunted point, hard packed felt wheels for polishing, loose rag wheels for buffing. *Figure 17.31* illustrates some of these tools.
- Block of PMMA polish.
- Powerful bench motor or a dental lathe. A two-speed model of approximately 1200 rev/min and 2500 rev/min is preferable.
- Rag wheel buffs both tightly and loosely packed, fitted to the bench motor.
- Eye protectors, which should be worn at all times when using high velocity wheels on both types of motor.
- 1.0 mm, 1.5 mm and 2.0 mm clinical quality PMMA sheets.
- A device for heating and pressing PMMA sheets over the cast (*Figures 17.32–17.34*).*
- A contact lens thickness gauge (*see Figure 12.17*).
- A range of diamond-coated lapping stones (*Figure 17.35a*).
- Vertical bench spindle (*Figure 17.35a*).
- Polishing tools (*Figure 17.35b*). Brass or Delrin polishing tools are covered with absorbent fabric, e.g. zinc oxide plaster tape or silk, which is better for polishing

*Vacformat, available from Panadent, London.

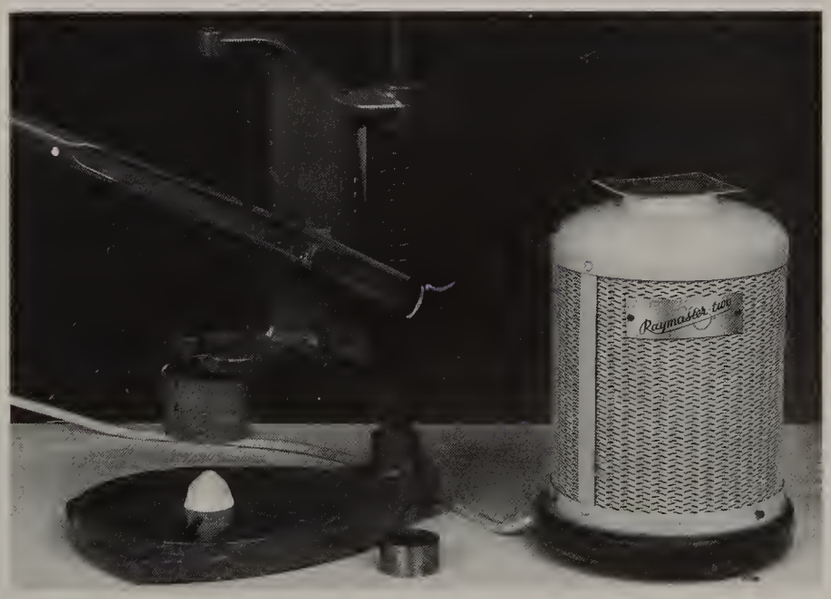


Figure 17.32 A cylinder mounted on a drill stand and a rigid cylinder just larger than the cast. A simple heating unit and a cylinder comprise adequate inexpensive equipment for occasional use. The cylinder can be mounted on a mechanical device with a levered downward motion, such as a drill stand, to improve reproducibility when pressing

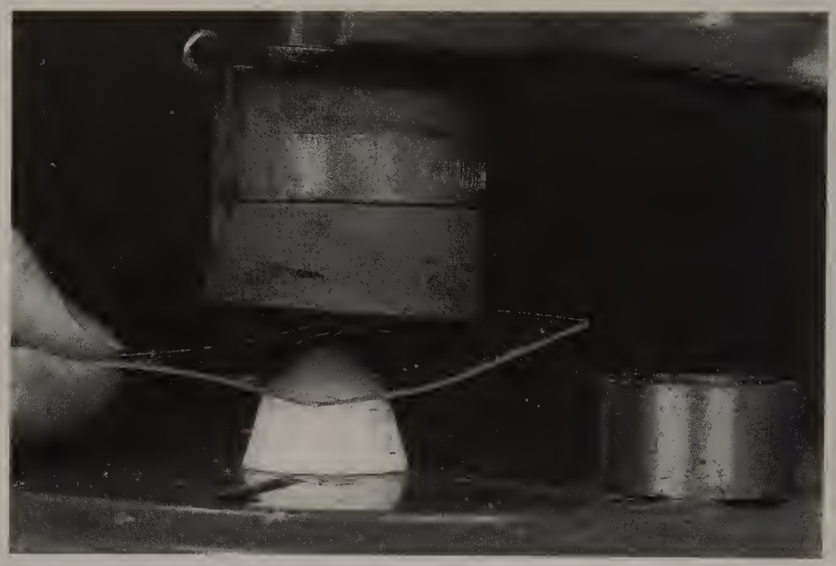


Figure 17.33 Heated PMMA sheet about to be pressed over a cast using a cylinder mounted on a press

RGP materials. An allowance must be made for the thickness of the cloth which makes the radius slightly greater when in use. Erring on the flat side polishes more towards the periphery of the back optic zone, on the steep side more towards the centre. Individually made wax polishing tools can be cut to the desired radius by using a female gauge (*Figure 17.36*), or preferably lathe-cut.

- Polish. Specially formulated RGP material polish is necessary because ammonia-based silver polish cannot be used for RGP scleral lenses.
- Riders for holding the shell (*Figures 17.37*).

Three stages of production and fitting procedures now follow: production of the flush fitting shell, working the primary optic zone and shell fitting.

The flush shell

Clinical quality PMMA sheet is selected, approximately 1.5 mm or 2.0 mm thick for high powered lenses and 1.0 mm for low minus powers, or to copy a lens. The sheet is softened by heating to about 140°C and pressed over the cast. Overheating causes bubbling in the PMMA sheet.

The perimeter of the shell is marked with a waterproof fibre marker, cut to size and edged using handpiece tools mounted in a flexible drive motor. Conical shaped tools enable working the inside edge of the shell as well as the outside. A dental lathe is good for the edge and front surface polish because the surface velocity is much faster and the contact area greater. Polish-laden handpiece-mounted rag wheels are better for the final edge and surface polish.

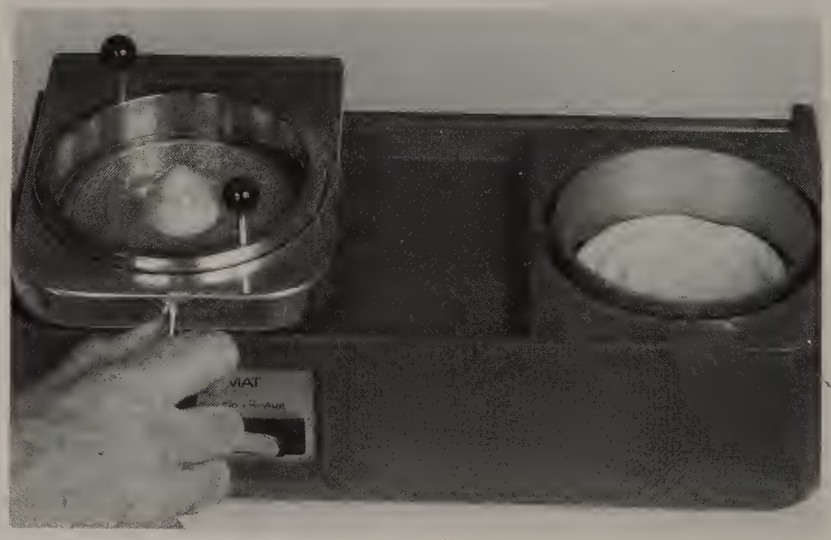
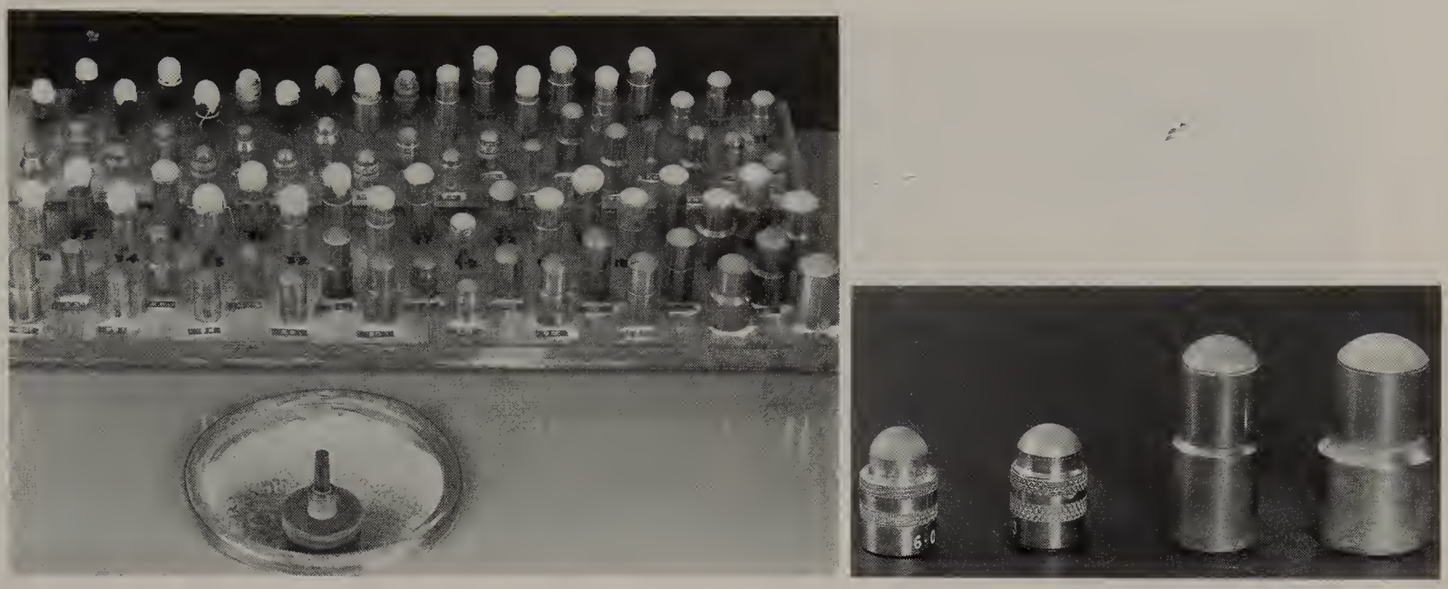


Figure 17.34 Purpose designed vacuum press with integrated heating element



(a) (b)

Figure 17.35 A vertical spindle and a range of diamond-coated lapping stones with corresponding polishing tools made from brass or Delrin are required for grinding a back optic zone radius. Radii of 6.00 mm to 10.00 mm in 0.25 mm increments is the minimum workable range. It is better to have 0.10 mm steps, and is also useful to have coarse and fine grit stones available

Figure 17.38 demonstrates the processes. The result at this stage is a flush-fitting shell with no optic clearance, but of good enough quality to put into the eye for initial inspection.

The sealed shell

The second stage of manufacture involves creating an optic zone clearance to give a sealed shell. Assessment of the scleral zone fitting is better at the sealed shell stage than at



Figure 17.36 Cutting a wax polishing tool with a female gauge

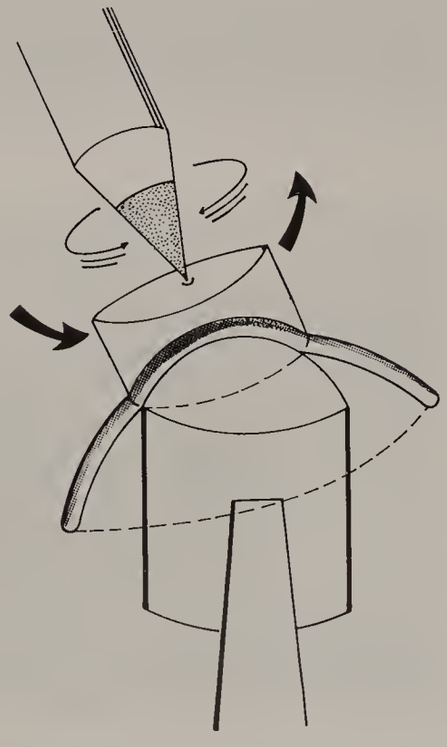


Figure 17.37 Illustration of a shell mounted on a rider spinning on a lapping stone. Corneal lens buttons with one concave surface can be attached to the front of the shell with double-sided adhesive tape. It is held down using a pencil point in the hollow in the rider. The graphite assists lubrication

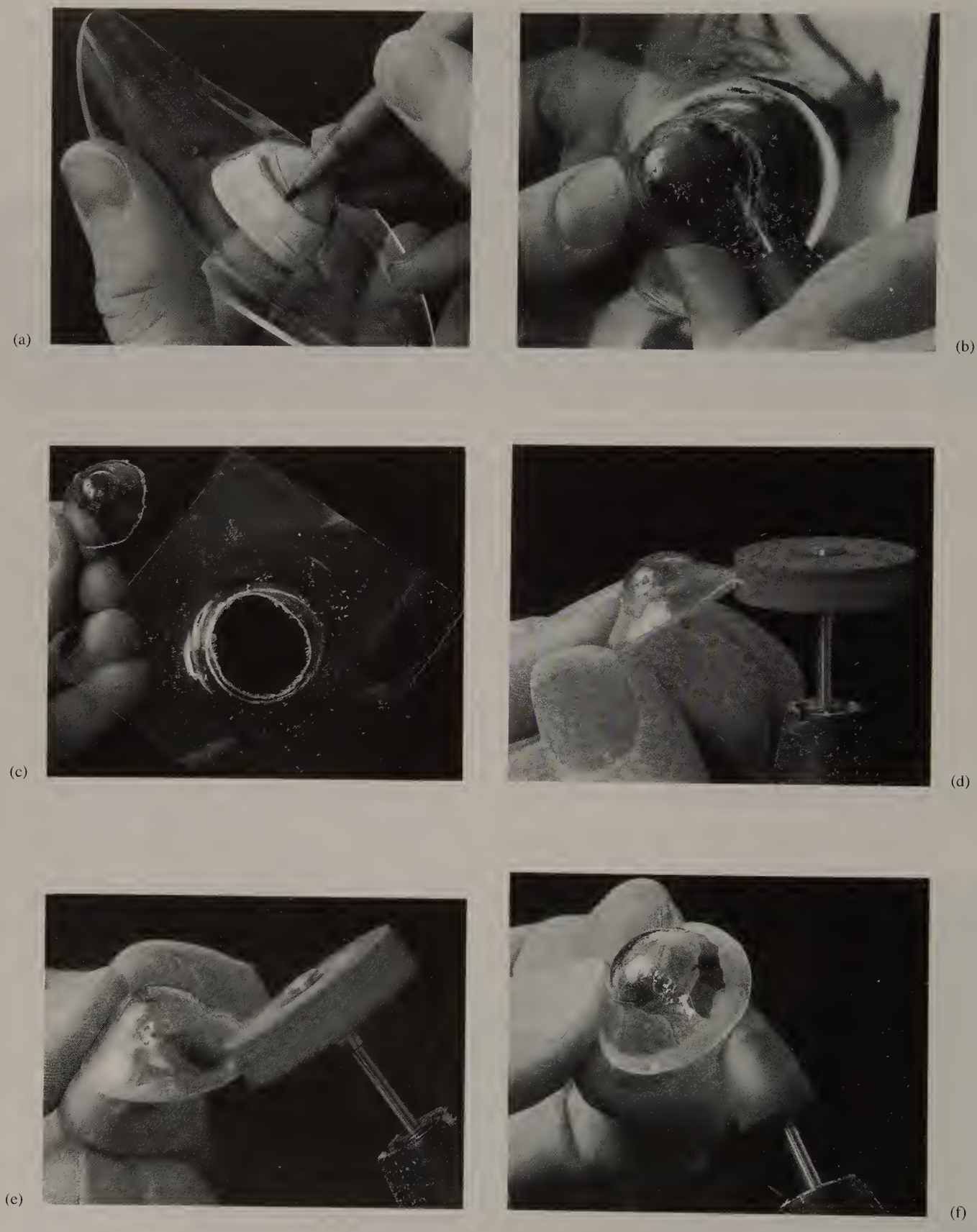


Figure 17.38 (*a*) Marking the periphery of the shell according to marks made on the cast; (*b*) use of cutting tool or fissure burr mounted into the flexible drive on a suspension motor to cut the shell from the moulded sheet of PMMA; (*c*) the rough-edged shell taken from the moulded PMMA sheet; (*d*) use of a disc-shaped abrasive tool to give the desired size of the shell; (*e*) use of a disc-shaped tool to begin the thinning down and final profiling of the edge; (*f*) use of a conical-shaped tool to round the inside surface or the edge (continued opposite)



(g)



(h)



(i)



(j)



(k)



(l)

Figure 17.38 (cont.) (*g*) A carborundum-impregnated rubber tool with mild abrasive quality used to continue the edge shaping and commence the polishing process; (*h*) polishing the surface and edge using a polishing mop mounted on a bench motor. This gives a faster and more even polish than if rag wheels are mounted into a flexible drive of the suspension motor; (*i*) polish-laden rag wheel being used to polish the back surface of the lens; (*j*) polish-laden rag wheel being used to polish the front surface; (*k*) loose rag wheel being used to give a final buff to the front surface; (*l*) loose rag wheel being used to give a final buff to the back surface

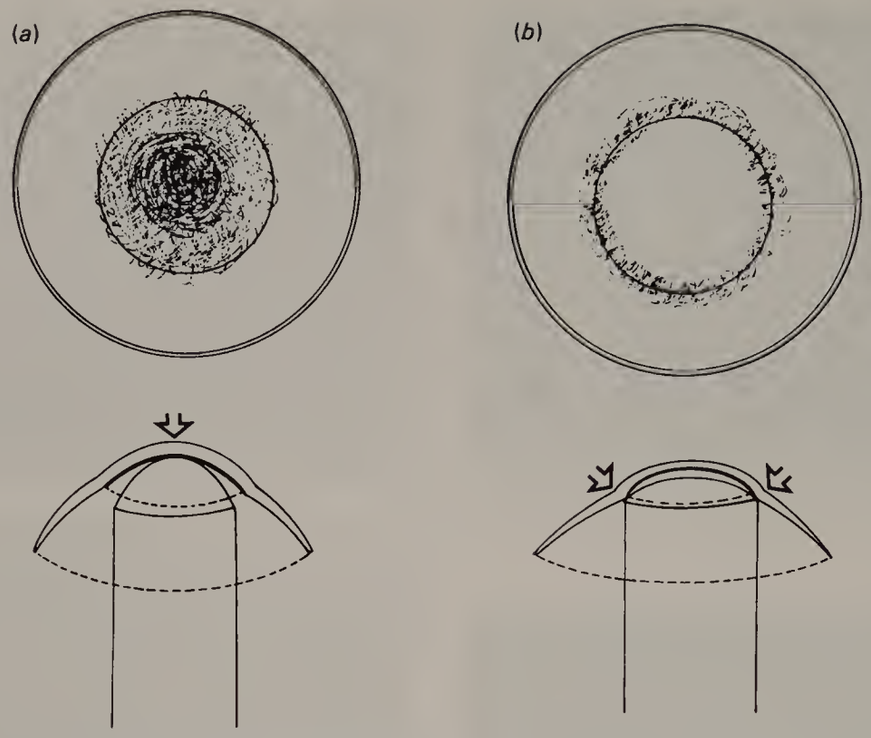


Figure 17.39 Diagrammatic representation of (*a*) steep and (*b*) flat lapping tools in use showing the comparative areas where they cut into the substance of the shell. The arrows show the points of contact during the process of working the back optic zone radius and the upper diagrams show this as viewed through the shell

the flush shell stage because the corneal contact of the flush shell may influence the scleral zone fitting.

Empirical selection of the primary back optic curvature

The normal corneal curvature is flatter towards the periphery, so a BOZR which is flat relative to the central cornea tends towards concentricity nearer the periphery. Lightly grinding the flush shell with trial lapping stones on a vertical bench spindle is the ideal way to select the primary BOZR. A tool which is too steep cuts more towards the centre and one too flat more towards the periphery. *Figure 17.39* represents steep and flat cuts into the back surface of the primary shell. The optimal lapping tool cuts at first in the mid-periphery, and then simultaneously towards the centre and the outer periphery. More than one may have to be tried, and sometimes a bi-curve or even a multi-curve may be necessary. Spherical polishing tools are necessary to true up the BOZR.

The shell is now inserted filled with saline, and with the patient leaning forward facing the floor to ensure that the saline is not lost from the shell. The corneal clearance can be most easily assessed if fluorescein is added to the saline prior to insertion but ventilating may subsequently change the appearance completely.

Keratometry

Kiely *et al.* (1982) showed that steeper corneas have a greater flattening factor so that the rule of thumb relating the BOZR to the keratometry readings is not constant across the whole range of corneal curvatures. If the topography is irregular, keratometry is of little value (*see* Chapter 20.1) but may be used as a guide to the selection of the BOZR if the corneal contour is reasonably normal. Lewis (1969) and Marriott (1972) described their favoured use of keratometry measurements where possible as a baseline for impression scleral lens fitting.

Alternative methods of constructing the primary optic zone clearance

Two alternative methods have been documented: taking the impression with a hydrogel lens *in situ* (Westerhout, 1975), and the use of laminates (Marriott, 1970).

Hydrogel lens *in situ*

The eye impression can be taken with a low minus hydrogel lens of –3.00 D to –4.00 D with t_c 0.15 mm *in situ*. This method produces a flush-fitting scleral zone with an optic zone clearance comparable to the thickness of the lens. t_c 0.15 mm is sufficient to allow for settling back whilst the

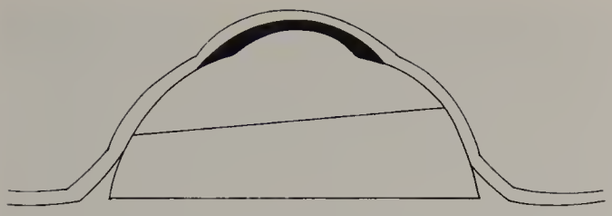


Figure 17.40 The laminate method of establishing apical clearance. PMMA sheet pressed over the cast which has been built up with the laminate to provide automatically for the required corneal and limbal clearance. (Not to scale)

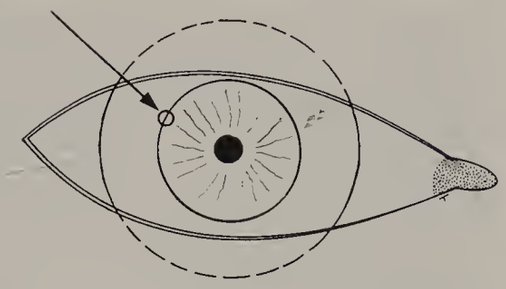


Figure 17.41 A single fenestration at the maximum depth of the pre-corneal reservoir at the limbus on the temporal side

thicker edge of the negative lens provides for greater limbal clearance. There is an added advantage that there may be less superficial post-impression epithelial trauma. The main drawback is that the lens may dislodge completely, thereby spoiling the impression.

Laminates

An acrylic laminate of thickness equal to the desired apical and limbal clearance is stuck on the cast to give the optic zone clearance when the PMMA sheet is pressed (*Figure 17.40*). The theory is attractive, but laminates are time-consuming to produce. If the clearance is not correct, another laminate has to be made and the whole process repeated.

Boat varnish painted on to the optic zone of the cast could be used as an alternative to rigid laminate (Rigby, P.C., personal communication, 1993). As it is a viscous liquid it tends to flow into the limbal sulcus giving greater final limbal clearance. Another layer can easily be added if the clearance is insufficient rather than a new laminate made or another impression taken.

All have been shown to work and are worth keeping in mind, but lack the precision, versatility and speed of the diamond lapping tool method. Settling back is an unpredictable feature of scleral lens fitting, therefore some substance has to be removed from the optic zone if the final clearance is insufficient. Even if it is correct, the BOZR has to be trued up optically with whichever method.

Ventilation of scleral lenses

The success of PMMA scleral lens wear is dependent on a flow of fresh tears to the corneal surface. All methods of ventilation disrupt the static pre-corneal fluid reservoir and may admit air bubbles, so this should be done before any further modifications are made.

Ventilating impression PMMA scleral lenses

Fenestrations

Bier (1948) described fenestrations in scleral lenses. A single fenestration between 0.5 mm and 0.7 mm in diameter is made at the limbus on the temporal side (*Figure 17.41*). A fenestration is made with a fine drill, counter-sunk with a larger diameter rose burr, blended with a more pointed burr and polished with a fine pointed wooden stick dipped in liquid polish (*see* Chapter 22). If the fenestration is too small, blockage with mucus may occur, but if too large, there is a tendency for frothing. Multiple limbal fenestrations may be an aid to some extra tear flow in some instances.

Ideally, a fenestration should allow a full air-free fluid coverage, approximately twice as deep at the limbus compared to the apex. Marriott and Woodward (1964) measured the apical clearance in satisfactorily fitting finished scleral lenses to be between 0.06 mm to 0.08 mm. In practice a crescent-shaped bubble is acceptable if it does not encroach over the visual axis and remains mobile (*Figure 17.42*).

Slotted scleral lenses

Enhanced tear exchange was a feature noted as a result of the wide opening in Trodd type ptosis props (Trodd, 1971, *see Figure 17.63*). Hence a slot cut into the annulus of clearance circumjacent to the superior limbus for ventilating was applied to other scleral lenses (Pullum and Trodd, 1984a). A slot enables greater limbal clearance because of the improved tear catchment, maximizing the free-flowing fluid reservoir. *Figure 17.43* diagrammatically shows a front and side view. *Figure 17.44* shows a slotted lens *in*

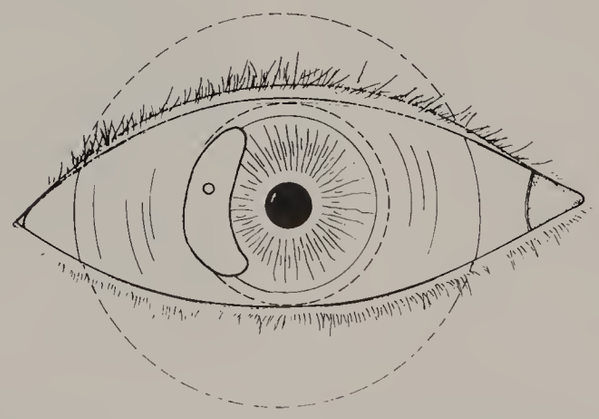


Figure 17.42 The usual size, position and shape of a single fenestration in a scleral lens with a crescent shaped air bubble at the limbus

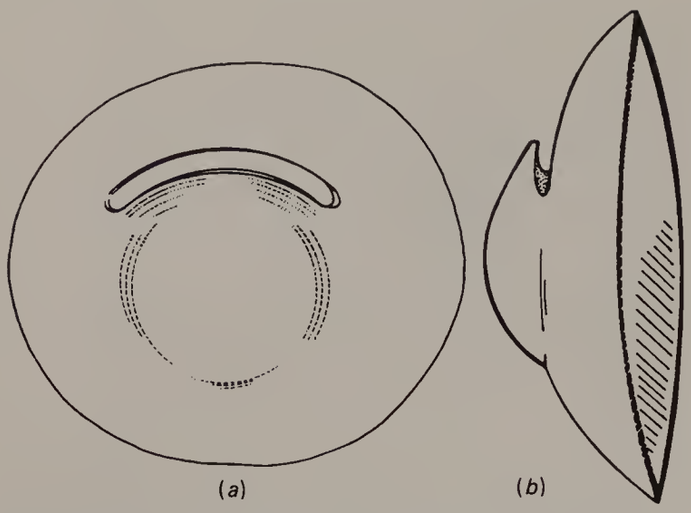


Figure 17.43 (*a*) Front view and (*b*) cross-section of a slotted scleral lens. The edges of the slot must be well rounded so that there is no lid sensation. Peripheral air bubbles are more mobile because of the greater depth of fluid overlying the limbal sulcus

situ, illustrating the slot profile. Without the deep extra-limbal clearance, cutting a slot may be counterproductive because the conjunctiva may herniate into the slot (*Figure 17.45*). *Figure 17.46* shows the process of creating and profiling a slot.

Truncations

Trodd (personal communication, 1986) also described a process of truncating the superior scleral zone from some PMMA impression lenses to give a comparable tear

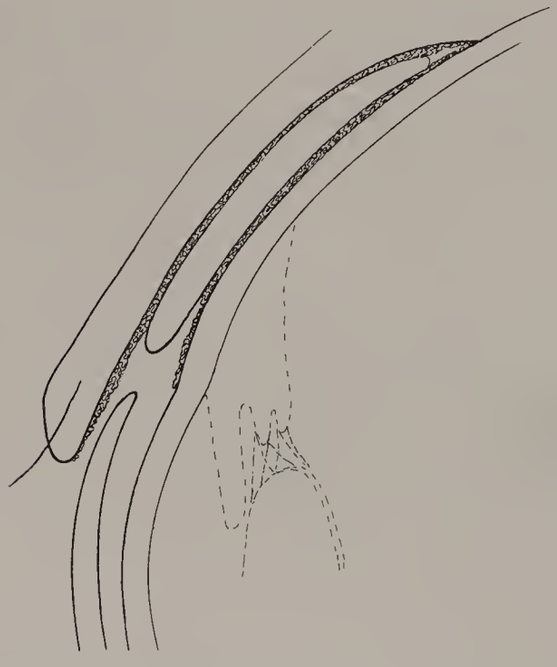


Figure 17.44 A slotted lens *in situ*, illustrating the slot profile. (Conjunctiva shown shaded)

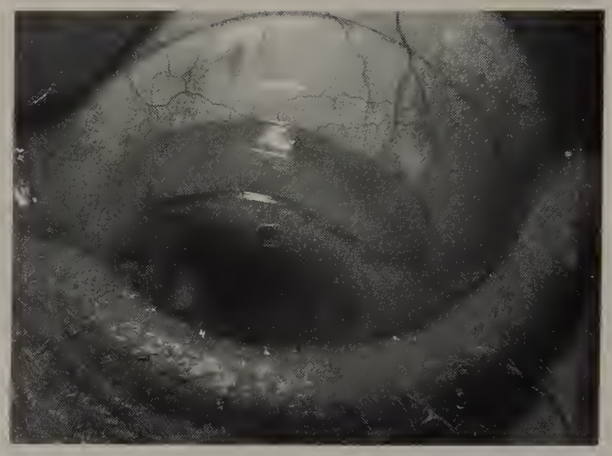


Figure 17.45 Herniation of the conjunctiva into a slot with inadequate limbal clearance

exchange. Some material is left on each side of the truncation to allow the upper lid to slide over the edge of the truncation. The tear exchange properties are similar to slots, but the bearing surface is reduced in area, increasing the potential for settling back.

Channels

A channel can be worked on the back of the scleral zone linking the optic zone to the edge (*Figure 17.47*). *Figure 17.48* shows a front view. The depth is quite critical: if too deep, air bubbles may be admitted and collect under the central area, if too shallow it occludes when the lens settles back. Channels are worked with spherical or disc-shaped abrasive tools and polished with polishing rag wheels, requiring an extra 0.5 mm thickness of the PMMA sheet. Alternatively, metal foil is stuck on cast where the channel is to be placed and another shell pressed but this leaves sharp junctions which require blending. Siting may be in any scleral zone sector but the author's preference is for a broad superior channel blended into the space overlying the limbus.

Channelled and slotted lenses enable greater limbal clearance while fenestrated lenses have to be made with less peripheral clearance to reduce intrusion of air bubbles. Movement of fresh tears via a channel is slower but less likely to admit air compared to either fenestrations or slots so may be especially useful for gross irregular topography.

It must be emphasized that the preceding text refers to impression lenses only. As the optic zone is shaped empirically from a basis of a flush-fitting shell, with impression fitting there is a better prospect of a sufficiently even pre-corneal reservoir depth, compared to preformed fitting in cases of irregular topography. Slots are virtually ruled out with preformed lenses because any lens rotation brings them into the palpebral aperture producing a poor cosmetic effect and irritation of the upper lid. Working a channel leaves a localized thin zone, so the front surface cannot be lathe-cut concentrically without penetrating

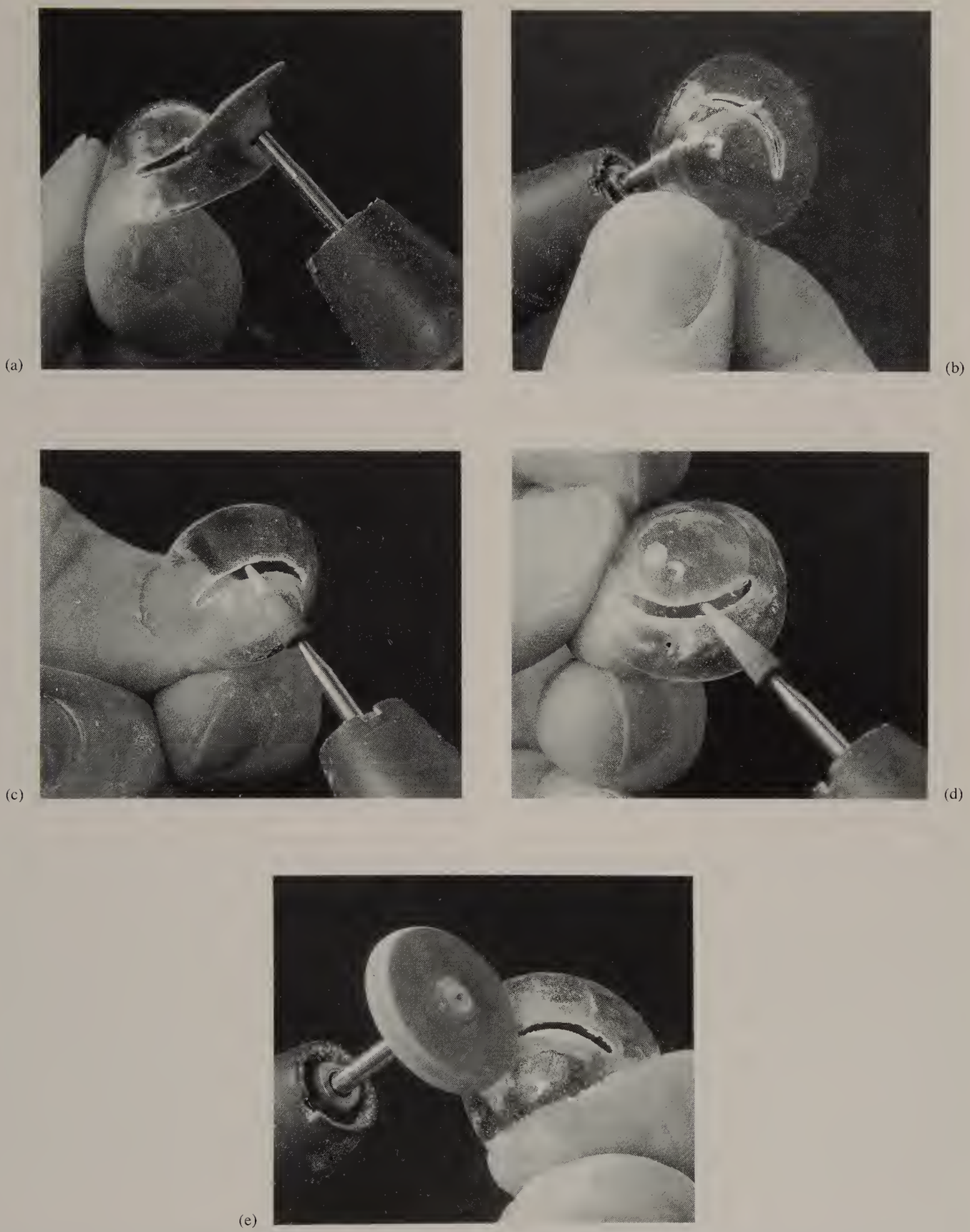


Figure 17.46 The successive stages of cutting and profiling the slot using specially shaped abrasive tools mounted into the flexible drive of a suspension motor. (a) The slot can be cut using thin fissure burrs or sharpened abrasive discs. (b), (c), (d) Conical carborundum points are used for widening and removal of the very rough edges. (e) Finally, the profile is shaped and polished with specially shaped carborundum tools of various grades of abrasiveness and polish-laden felt or rag wheels

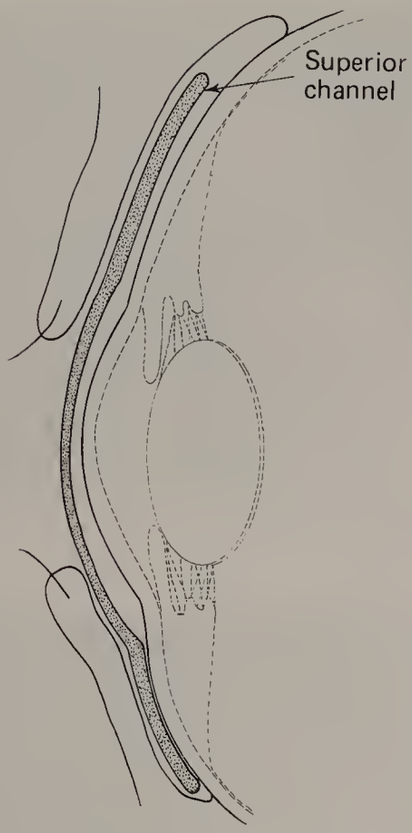


Figure 17.47 Cross-section of a superior channel in situ

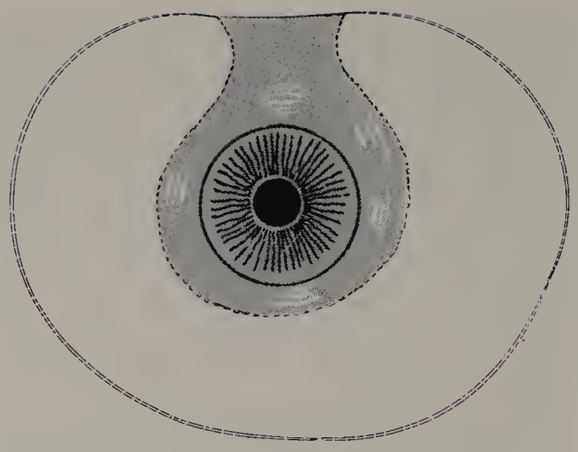


Figure 17.48 Front view of a broad superior channel. The shaded area represents the clearance from the eye over the limbus and to the channel itself

through the material at the site of the channel. Hence a fenestration is the only feasible option for ventilating preformed scleral lenses.

Ventilating RGP scleral lenses

Some patients have successfully been fitted with a duplicate of a channelled or a slotted PMMA lens but the process of thinning down the scleral zone is labour-intensive. Slotting RGP materials carries a high risk of breakage, and working a smooth finish to the slot profile is technically difficult. The hybrid PMMA scleral/RGP optic can be used to incorporate either but as the back optic is the best spherical approximation to the original tailored shape, a channel is preferable.

Sometimes the superior sclera is depressed with respect to the other sectors of the sclera, resulting in an unintentional patent channel. This may admit troublesome air bubbles even when the lens has settled back fully. If this is an intractable problem, a duplicated PMMA impression lens or an RGP insert into a PMMA scleral zone may be indicated.

Fenestrating RGP scleral lenses is possible, but still carries a risk of breakage. Most recent workers (Visser 1990; Schein *et al.*, 1990; Pullum *et al.*, 1990, 1991; Kok and Visser 1992; Tan *et al.*, 1995b) have come to the conclusion that sealed RGP scleral lenses appear to work satisfactorily, although Ezekiel (1991) considers that fenestrations are still necessary to maximize corneal oxygenation, and recommends three sited around the limbus to ensure that one is in the palpebral aperture at all times.

The author's opinion is that fenestrated designs should be considered optional for RGP scleral lenses, but it is emphasized that fitting is much more difficult and time-consuming. The almost invariable introduction of air bubbles into the pre-corneal reservoir, especially with irregular corneal topography and the increased settling back with consequent corneal contact are definite disadvantages compared to sealed RGP lenses. However, if there is an unusually high oxygen requirement such that hypoxic changes become apparent during the course of wear of a sealed RGP scleral lens, the option of fenestrating should be examined.

In addition, insertion with the head facing downwards is necessary to retain the fluid in a sealed lens. This is sometimes impossible for elderly or disabled patients with back disorders that may restrict bending. Removal is often more difficult because of the increased suction. Fenestrated lenses can be inserted with the head upright. A fenestration could be tried when it is impossible to exclude air bubbles as it may facilitate an outlet for an entrapped bubble, but increased rather than reduced air bubbles under the lens is a more likely outcome. The fitting of fenestrated lenses requires much more precision because it depends on a pre-corneal fluid reservoir with a maximum depth of 0.10 mm. It should be clearly understood that the chances of a satisfactory result from simply fenestrating a functional sealed lens are not high.

Modification

Modifications may be necessary to ease corneal contact or tight areas at the limbus subsequent to full settling back. However, with sealed RGP scleral lenses the need for post-issue modification has been considerably reduced. In

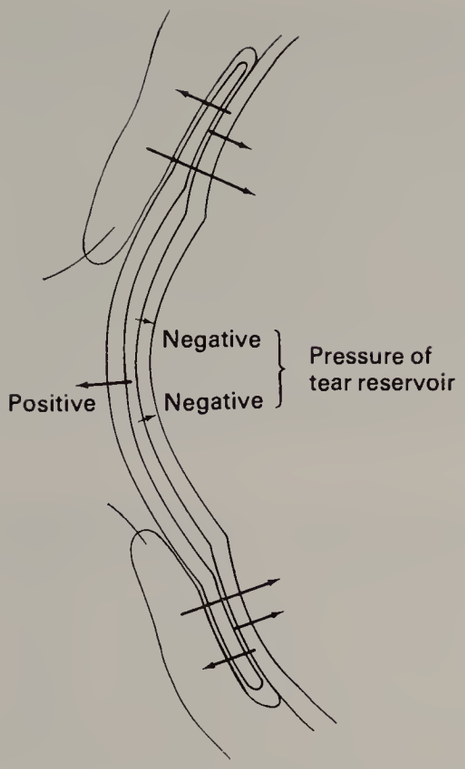


Figure 17.49 Vector representation of the forces involved during settling back of a scleral lens or shell

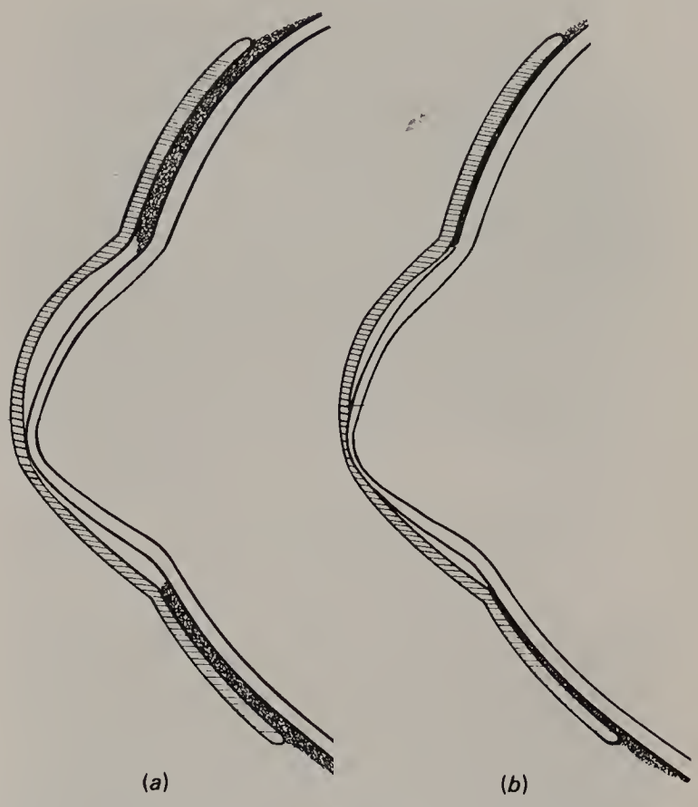


Figure 17.50 Diagrammatic representation of a possible outcome of removal of centre substance using a steeper BOZR. If the corneal contact is a factor limiting settling back, the result may be further settling with no reduction of apical touch and an unwanted reduction of the limbal clearance. (*a*) Apex of cone tangentially in contact with the back surface of the lens; (*b*) the back optic zone of the lens has been steepened in an attempt to reduce apical touch. Apical touch now covers a larger area and the limbal clearance has been obliterated following further settling back

addition, modifications of any kind to the back surface of RGP scleral lenses are not recommended. The likelihood of subsequent distortion due to the reduced dimensional stability of the materials is so high that it is preferable to refit rather than to modify.

Forces affecting settling back

Both the central apical and the limbal clearances are reduced when a lens settles back. The capillary attraction of the tears, the weight of the lens and the pressure exerted by the lids are the forces inducing settling back. The resisting forces are the rigidity of the sclera and cornea, if there is significant corneal touch, and the pressure of the pre-corneal reservoir (*Figure 17.49*). A rapid tear exchange, for example with a slotted design, brings the positive pressure of the pre-corneal reservoir to equilibrium quickly, reducing the resistance to settling back. Channels with just a slow percolation of tears disrupt the reservoir much less, with consequent reduction in settling. Less still would be expected with sealed RGP scleral lenses, to the extent that it is sometimes virtually eliminated. This appears to be an advantage that outweighs the loss of tear exchange with a fenestration.

Alteration to the back optic zone curvature

Modifications to the central curvature are made using diamond lapping tools in the same way as the primary optic zone is cut. Steepening the curve removes substance from the central region increasing the apical clearance. Flattening the curve removes substance from the periphery increasing the limbal clearance, but the central region may remain unchanged.

Steepening the BOZR should be undertaken with caution as apical touch is a factor that may limit settling back. If so, more settling back may take place if central substance is removed (*Figure 17.50*). An apical contact zone with a PMMA lens is a less likely cause of intolerance compared to an occluded limbus. Flattening the BOZR may extend the optic further into the scleral zone which could precipitate further settling back as the bearing surface is reduced. Hence every possible modification procedure may increase the settling back. If in doubt, the intended adjustment can be made on a copy shell to test the effect because adverse changes, as described above, are not easily rectified.

Modifying the scleral zone

In theory, modifications to the scleral zone of impression lenses should not be necessary, but in practice tight areas may be present, blanching the conjunctiva. They can be



(a)



(b)



(c)

Figure 17.51 Grinding and polishing the transition. (*a*) Grinding the transition; (*b*) polishing the transition; (*c*) shell with transition ground

eased by removing lens substance using disc-or spherical-shaped abrasive tools. Polish-impregnated felt wheels and clean loose rag tools are substituted to give the final finish to the surface prior to re-insertion. Transitional grind-out modifications are carried out in the same way. *Figure 17.51* shows the process of opening out the transitional zone. Loose areas stand off the surface and are easily seen after instillation of fluorescein. Any relatively tight areas in the remainder of the scleral zone can be eased to even out the fit of the shell as a whole, but this action almost certainly reduces the optic zone clearance. It may be better to start again from a new impression.

Modifications to the scleral and transition zones of preformed lenses can only be carried out on a co-axial basis, unless some feature of the design, e.g. making the lens oval, or decentring the optic, prevents rotation. Also, as preformed lenses are lathe-cut there is more control over the thickness, so they tend to be thinner leaving less latitude for removing substance.

Total diameter reductions

A larger lens is usually cosmetically preferable because the edge is largely concealed, but local reductions in diameter should be made if the shell impinges against the inferior fornix or the inner canthus. The superior scleral zone may be reduced if it is too large, and causing difficulty removing the lens. Reducing the TD reduces the bearing surface, which may lead to further settling back and may cause the edge to catch on the lower lid. RGP scleral lenses can be reduced in diameter, but it is better carried out on a lathe rather than using handpiece-mounted abrasive tools. Decentring is possible if the diameter is reduced on a lathe. If an oval or an irregular shape is required, use of handpiece tools is unavoidable, but it must be carried out with caution with RGP materials to minimize the risk of breakage.

Manufacture of the finished lens

Ordering finished impression lenses

The practitioner may send a flush shell, a fitted shell or a cast to the laboratory. With a cast or a flush shell, it is necessary to decide on the BOZR, the apical clearance and the degree of blending between the optic and scleral zones. These all depend upon the peripheral corneal and limbal topography, so it is only possible to hazard an educated guess at what is required by keratometry or even topographical mapping. It is necessary to specify apical clearance, but experienced scleral lens manufacturers are specialists in their own right, and should select the primary optic radius as previously described. Accurate refractive data for the power can be taken from a refraction over an Apex lens (*see* Chapter 20.2) or preferably a scleral lens. The BOZR does not have to be identical to that of the final lens as an appropriate allowance can be calculated. It is sound practice

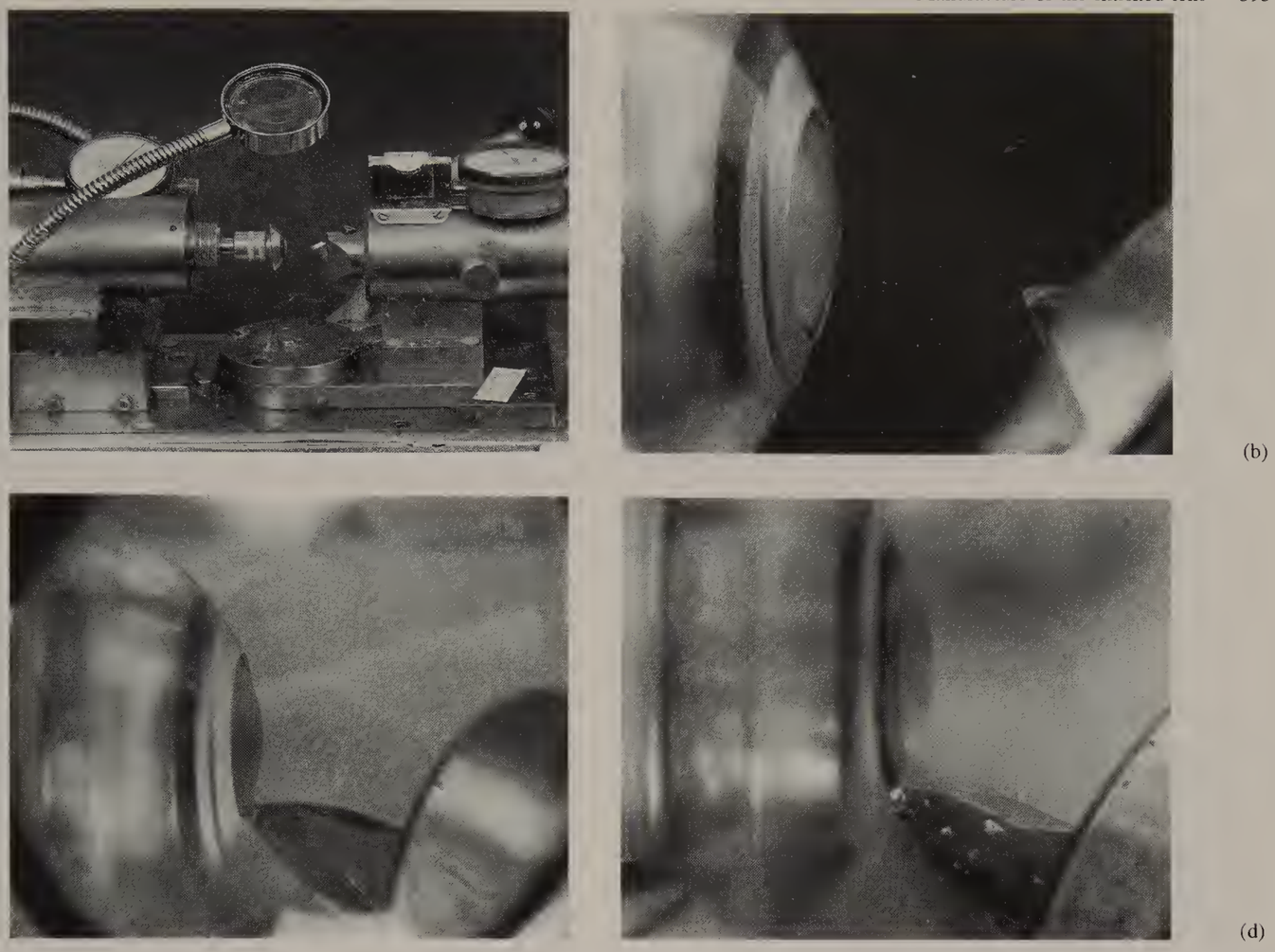


Figure 17.52 The process of lenticulating a positive lens. (*a*) The lens mounted on a lathe; (*b*) after the central front surface has been cut. The central front curve is steeper than the front radius or the shell, therefore there is a well-defined groove at the extremities of the front surface. The diamond point is withdrawn from the surface of the lens and set to a flatter radius. (*c*) The diamond point is replaced back into the groove; (*d*) the carrier curve is cut using a much flatter radius, perhaps as much as 3–4 mm flatter than the central curve

to check lenses *in situ* before they are returned to the laboratory for re-powering so that the number of alterations can be minimized.

Cutting the front optic

The same principles apply to scleral lenses as to corneal lenses when calculating and cutting the front surface, which are described in Chapter 21, but there are some points relating specifically to scleral lenses.

Front optic curve junction

The uncut front curve of an impression shell is approximately equal to the corneal curvature, i.e. the keratometry reading, plus the thickness of the original flush shell. Concentric front and back curves produce a BVP of approximately –4.00 D for normal scleral lens thicknesses. If the FOZR is steeper than the sum of the BOZR and the substance, there is a risk of leaving the periphery too thin or even of cutting through the lens. The FOZD is determined by the FOZR and the centre substance, which can be controlled precisely as the front surface is lathed. *Figure 17.52* illustrates the process of powering and lenticulating a scleral lens mounted on a lathe.

High positive powers on scleral lenses

High positive powered lenses are more difficult to cut than negative lenses, requiring much more care during the lathing process. The power of the finished lens is better if it errs on the plus side, both to improve intermediate vision and because it is easier to add minus rather than plus. In addition, the negative liquid lens can be up to –3.00 D or –4.00 D requiring extra positive power to compensate for this, so an aphakic scleral lens is typically between +18.00 D and +20.00 D. An error in calculating or setting the steeper FOZR of the positive lens produces a much greater difference in the power. There is also a greater positive power addition per unit thickness of a positive lens. The front vertex power of the lens blocked on a hollow chuck can be checked during the process of lathe-cutting.

There is hardly any difference between this and the back vertex power of a minus lens, but the difference can be over 2 D with a high plus lens (*see* Chapter 5 for relevant calculations).

High Dk RGP scleral lenses

These require a powering process which produces a high quality surface following lathing. Polishing must be kept to a minimum in order to retain a good quality optic zone. This is not an important issue with PMMA, which lends itself much better to polishing. High Dk corneal lenses are usually powered using closed chucks, but the extra substance of scleral lenses allows use of open chucks, as with PMMA. If the front and back surface co-axial configurations can be fully specified in *x/y* co-ordinate form, scleral lens manufacture lends itself well to computer numeric controlled lathing processes. The position of the cutting point is defined not by the radius of the curvature, but by co-ordinate geometry on a two dimensional matrix.

Power changes with alterations to BOZR of finished lenses

Changing the BOZR of a finished lens also alters the BVP. Approximate rules and examples are given in Chapter 5. However, scleral lenses are made with a large range of BOZRs, so there is a difference depending upon whether the BOZR is at the steep or the flat end of the range.

Four factors affect the power of a scleral lens *in situ* after BOZR modification: change in BOZR of the lens, change in front radius of the liquid lens, reduction of thickness of the lens, increase in thickness of the liquid lens.

Steepening the BOZR

- Adds negative power to the back surface of lens.
- Adds positive power to the front surface of liquid lens.
- Reduces the thickness of the lens, reducing positive power.
- Increases the thickness of the liquid lens, increasing positive power.

Removal of substance using an unchanged BOZR

- Has no effect on surface powers of lens or liquid lens.
- Reduces the thickness of the lens, reducing positive power.
- Increases the thickness of the liquid lens, increasing the positive power.

The changes as a result of both tend to cancel each other out, but the overall effect is to reduce positive power. An equal change in radius or thickness has a greater effect on the contact lens than on the tear lens because its refractive index is greater.

Flattening the BOZR

- Has the reverse effects to steepening BOZR on the powers of the lens and liquid lens.
- Would not necessarily alter paraxial thicknesses of lens and liquid lens.

The overall effect is to add positive power, but less for a given change in the radius if the thickness is unaffected.

The intricacies are best illustrated by examples. Using the surface power formula $F = \frac{1000(n'-n)}{r}$

where F = surface power, r = surface radius, n' = 1.336 (tears), n = 1.490 (PMMA); approximate rule (3) (*see* Chapter 5, p. 183) gives a –0.12 D power addition for every 0.10 mm of substance removed, allowing for a comparable increase in the thickness of the liquid lens.

Example 1

BOZR steepened from 6.00 mm to 5.70 mm with the lens thickness reduced by 0.1 mm.

F = –25.67 D when r = 6.00 mm and –27.02 D when r = 5.70 mm

Power change due to alteration of BOZR: 25.67 D – 27.02 D	–1.35 D
Power change due to reduction in thickness of lens:	–0.12 D
Total power change:	–1.47 D

Example 2

BOZR steepened from 9.00 mm to 8.70 mm with the lens thickness reduced by 0.1 mm

F = –17.11 D when r = 9.00 mm, and –17.70 D when r = 8.70 mm.

Power change due to alteration of BOZR, 17.11 D –17.70 D	–0.59 D
Power change due to reduction in thickness of lens	–0.12 D
Total power change	–0.71 D

In the opposite situation, flattening the BOZR from 5.70 mm to 6.00 mm would give rise to a power change of +1.351 D and flattening from 8.70 mm to 9.00 mm would give a power change of +0.59 D, assuming no substance is removed at the centre

When substance is removed from the back optic zone using an unchanged radius, the only variable is the thickness difference of the lens and liquid lens with no change to either surface power. Therefore the only change is to add –0.12 D for every 0.10 mm removed. However, as previously mentioned, it is not constant across the range of powers, positive lenses being more affected by a change in thickness.

The reduction in lens substance is not necessarily equal to the increase in thickness of the liquid lens because central corneal touch may remain after a back optic grind-out, especially in advanced keratoconus. If so, –0.25 D is added for each 0.10 mm removed. This adds significantly to the total minus power if a steep BOZR is further steepened. The concept of tear lens neutralization holds good for normal corneas, but not necessarily for keratoconus because a PMMA/cornea interface regularizes the corneal surface. Even though the difference between the refractive indices of the cornea and tears is only 1.376 – 1.336, the improvement in vision with a PMMA/cornea interface is often quite marked in keratoconus compared to a tears/cornea interface.

One final consequence of corneal contact is that the axial length of the globe may be reduced when a scleral lens is *in situ*. If so, more minus power may have to be added to the contact lens if the globe resumes its original shape when the central touch is eased. Corneal lenses fitted with apical touch would not have a comparable effect as the pressure on the cornea is much less.

Solutions and maintenance of scleral lenses

PMMA scleral lenses

These are the easiest and least expensive of all contact lenses to maintain. Dry storage is normal, although wetting agents may aid cushioning just prior to insertion. Some scleral lens wearers do not like the increased viscosity, hence sterile non-preserved saline may also be necessary. Others prefer to insert their lenses dry and appear to have no adverse effects.

RGP scleral lenses

RGP lenses are more difficult than PMMA to keep clean because the surface attracts more lipid and protein. RGP corneal lenses should be stored in soaking solution to retain dimensional stability, but even high Dk scleral lenses are not subject to such changes because of their greater substance and rigidity. Many RGP scleral lens wearers achieve a satisfactory result if they clean and rinse the lens after wear, store dry and apply wetting solution prior to insertion. A further application of a cleaning solution and rinsing with saline before wetting may be necessary. Soaking solutions can be added to the regime if the surface does not wet adequately, but in the author's experience it is not often required.

Sealed RGP lenses

Sealed lenses retain a pre-corneal reservoir for long periods, hence any preservatives in solutions are kept in contact with the eye. Therefore wearers may have favourite solutions, or solutions which they have to avoid (*see* Chapter 4). Aerosol salines tend to be gassy which is a problem when filling a sealed RGP scleral lens prior to insertion. They also appear to sting more than unit dose salines, possibly due to the lower pH commonly found. Ultrafiltered unit dose saline* can be used for up to week if the cap is replaced and the tube stored in a refrigerator. This departs from the strict recommendations for unit dose, but is a modality of use which is in keeping with preservative-free ophthalmic preparations (Moorfields Eye Hospital Formulary, 1992).

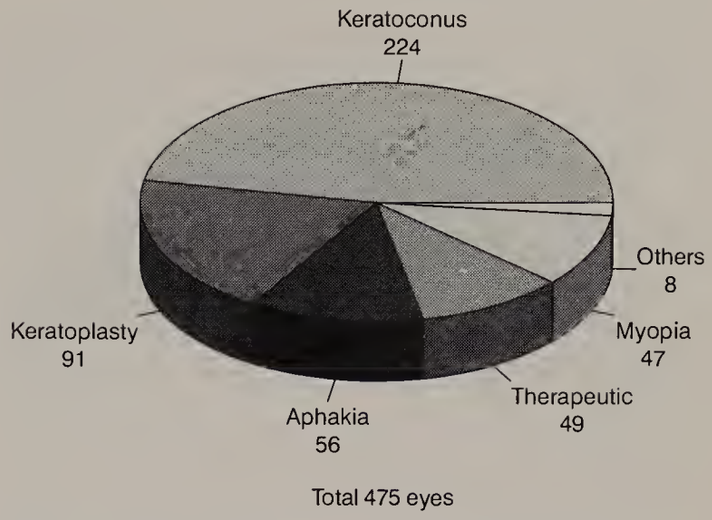


Figure 17.53 Pie chart to show the spread of indications for contact lenses seen in scleral lens referral clinics (Tan *et al.*, 1995a)

Scleral lenses in pathological conditions

Scleral lenses have a particularly important place in the management of some pathological conditions with irregular corneal topography or high refractive errors. Tan *et al.* (1995a) analysed the indications for referrals to a scleral lens clinic, with a breakdown as in *Figure 17.53*.

Keratoconus and other primary corneal distortions

Keratoconus or other primary corneal distortions form nearly 50% of the total number referred for scleral lens fitting (*Figure 17.53*). The implication of the name keratoconus is that the corneal topography resembles a cone, but there are forms of the condition with markedly varying topography.

Topographical classification using casts of eyes

An area of thinning in the central third of the cornea gives rise to a relatively symmetrical protrusion of the affected cornea (*Figure 17.54*). This is the only example of the cornea bearing any resemblance to a cone. *Figure 17.55* illustrates the topography when the ectasia is mid-peripheral and displaced downwards. Pellucid marginal dystrophy is an ectasia affecting the periphery of the cornea (*Figure 17.56*). Keratoglobus is consequent to a larger area of

*Amidose saline, Abatron, Sandy, Bedfordshire, UK.



Figure 17.54 Nearly central cone apex (*a*) from above and (*b*) from the side. This is the only example of the cornea bearing any resemblance to a cone

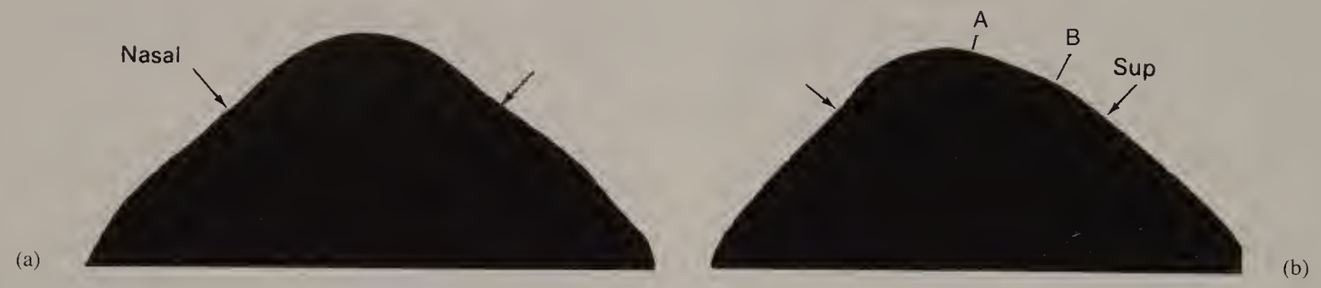


Figure 17.55 Mid-peripheral cone apex, displaced downwards (*a*) from above and (*b*) from the side. Note the gross irregularity at the visual axis as the contour becomes re-entrant between points A and B



Figure 17.56 Pellucid marginal dystrophy (*a*) from above and (*b*) from the side, illustrating the high astigmatism in the central region. In this instance there was 15.00 D of regular astigmatism with the negative cylinder axis 90°



Figure 17.57 Keratoglobus (*a*) from above and (*b*) from the side. Note the remarkable sphericity and symmetry in both meridians, not present with the other kinds of keratoconus. The resultant refractive error can be in the region of 30–40 D of myopia because of the combination of the steep cornea and the increased axial length

thinning in the central region. Advanced cases may be almost hemispherical (*Figure 17.57*).

Indications for scleral lenses in keratoconus

Irregular topography

Scleral lenses do not depend on capillary attraction to the corneal surface so can be fitted in cases when corneal lenses dislodge or are simply impossible to fit. When PMMA was the only choice of material, most advanced or highly irregular keratoconus would have required fitting by impression. However, RGP sealed preformed lenses have become an acceptable and arguably first choice option.

Poor tolerance to corneal lenses

Tolerance to corneal lenses may be poor due to the extra mobility and greater peripheral clearance typical of keratoconus fitting. RGP materials have enabled use of scleral lenses at a lower level of pathology than before. It is wrong to consider scleral lenses only when corneal lenses are physically unfittable. Use of both types can maximize total daily contact lens wearing time.

The alternative to corneal transplant

Davies *et al.* (1977) showed that the prognosis for keratoplasty is favourable when keratoconus is the underlying indication. However, there remains a 5% failure rate, so it is still necessary that all contact lens management options, including scleral lenses, are available and fully investigated. A corneal transplant may be contraindicated or not advised when:

- the cone is steep but there is good visual potential with a contact lens;
- the patient wishes to avoid or postpone surgery;
- there is an increased chance of rejection due to pre-existing corneal neovascularization, or because a very eccentric cone apex requires a large diameter donor button which increases the proximity to the limbal vascular arcades and hence the likelihood of transplant rejection;
- there has been a previous failed transplant in the other eye.

Constructing the optimal back surface shape of a PMMA impression lens in keratoconus

The objective for the final lens is an uninterrupted fluid coverage across the cornea without apical touch, occlusion of the limbus or air bubbles, but these criteria are rarely met to complete satisfaction when fitting keratoconic eyes. The large variations in the depth of the pre-corneal reservoir due to the irregular corneal topography leads to apical contact zones and intrusion of air bubbles.

Substance of up to 0.20 mm can be removed from the limbal region of a flush-fitting shell while the apex is just skimmed, giving a starting point for the shell fitting. A bi-curve or blended multi-curve construction using lapping stones of progressively steepening radius may be needed to give a shell with uniform clearance. However, if there is significant cone apex eccentricity, co-axially cut curves do not end up in a concentric configuration until so much substance has been removed that there is no longer any resemblance to the original corneal shape. *Figure 17.58* illustrates the incompatibility of the two resultant curves cut about the cone apex and the geometric axis. Part of the back surface may have to be shaped using a handpiece-mounted polish-laden rag–wheel buff which removes some substance from the central portion fairly evenly but must be trued up prior to powering. *Figure 17.59* illustrates an example of an eccentric cone apex fitted with a slotted PMMA scleral lens which has been worn successfully 16 hours a day for 15 years.

RGP scleral lens fitting in keratoconus

The introduction of gas permeable materials has revolutionized fitting concepts. Even with the greater substances required for scleral lenses, they appear to transmit enough oxygen to retard the onset of hypoxia for considerably longer periods compared to PMMA (*see Figure 17.6*). Tan *et al.* (1995b) showed that PMMA scleral lens induced neovascularization can be reversed in long-term PMMA scleral lens wearers when they are switched to RGP materials, so it seems reasonable to presume that onset of neovascularization may be retarded.

Apical clearance and contact zones

The author's early experience with gas permeable scleral lenses seems to indicate that an increased problem of discomfort and corneal staining results from corneal contact zones when using RGP materials compared to PMMA. Apical clearance, even with the most advanced cones, is possible using sealed controlled clearance lenses but is much more difficult with fenestrated fitting methods. Settling back is reduced with sealed lenses, and so it is easier to achieve a balance between providing a contact zone that gives better vision and one that is sufficiently light to maintain a reasonable level of comfort.

Management of aphakia with scleral lenses

Corneal and hydrogel lenses are widely used in aphakia, but maintenance and handling may be difficult for elderly aphakes. Extended wear hydrogel lenses are convenient but Graham *et al.* (1986) identified a high risk of sight-threatening infection. Where problems occur with other lens types, the improved stability, simple maintenance and relative ease of handling of scleral lenses can be advantageous.

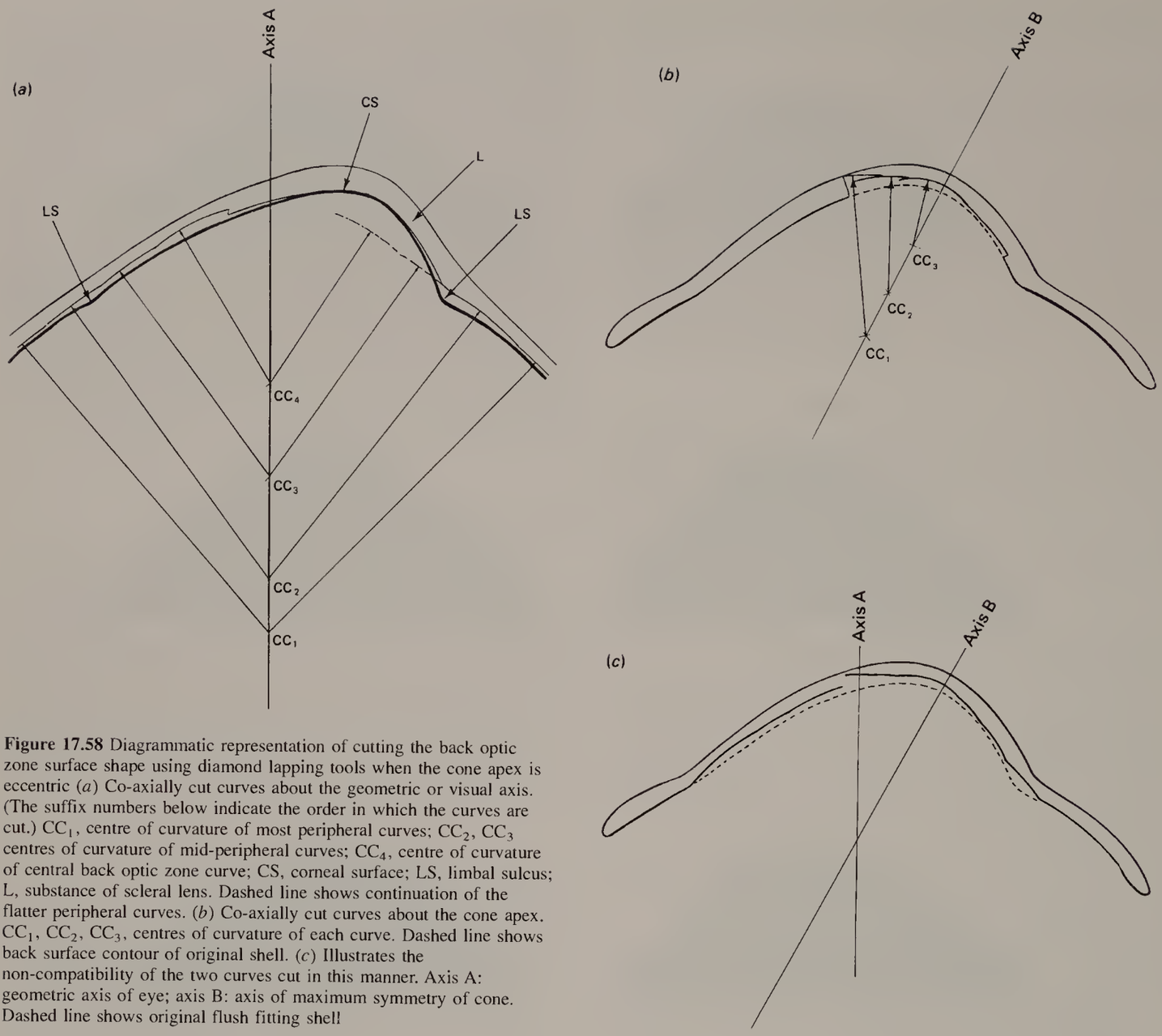
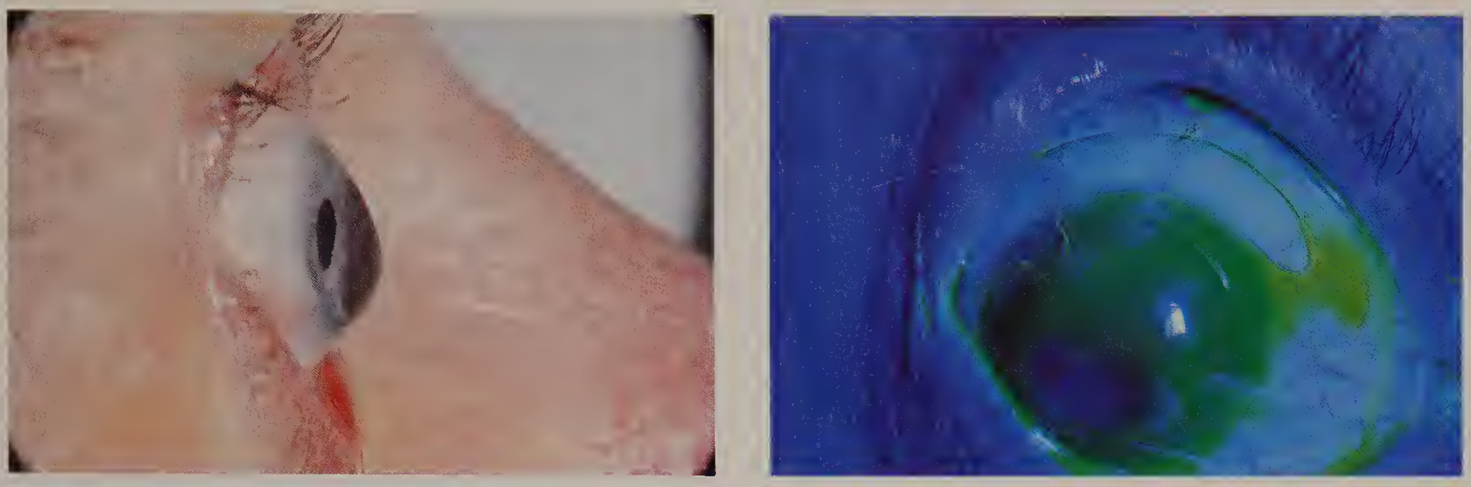


Figure 17.58 Diagrammatic representation of cutting the back optic zone surface shape using diamond lapping tools when the cone apex is eccentric (*a*) Co-axially cut curves about the geometric or visual axis. (The suffix numbers below indicate the order in which the curves are cut.) CC_1, centre of curvature of most peripheral curves; CC_2, CC_3 centres of curvature of mid-peripheral curves; CC_4, centre of curvature of central back optic zone curve; CS, corneal surface; LS, limbal sulcus; L, substance of scleral lens. Dashed line shows continuation of the flatter peripheral curves. (*b*) Co-axially cut curves about the cone apex. CC_1, CC_2, CC_3, centres of curvature of each curve. Dashed line shows back surface contour of original shell. (*c*) Illustrates the non-compatibility of the two curves cut in this manner. Axis A: geometric axis of eye; axis B: axis of maximum symmetry of cone. Dashed line shows original flush fitting shell

Lid sensation is minimal with scleral lenses and may be further reduced with age-related loss of sensory nerve function. Holden *et al.* (1980) showed that the cornea of an aphakic eye has a lower oxygen requirement. In any event, long-term lens-induced ocular changes are less of a problem as the life expectancy is generally less in aphakia than any other group.

RGP scleral lenses have been shown to be beneficial in aphakia if PMMA is not tolerated (Tan *et al.*, 1995b), but PMMA allows greater precision in manufacture, versatility in fitting and easier maintenance. Aphakes may find spectacles satisfactory for reading and watching television, activities which account for much of their waking hours. Scleral lenses may be useful for activities when mobility is important, requiring short wearing spells only, in which case RGPs may not be necessary.

Traumatic cataract may result from an impact liable to also cause other ocular injuries. Scleral lenses may be indicated if contact lens fitting is complicated by corneal irregularity, scar tissue, iris loss or pupil displacement. Photophobia and glare from iris loss can be significantly reduced with a full diameter front optic zone which completely covers the pupil. A painted iris can be incorporated, but the anterior repositioning of the entrance pupil restricts the visual field. Alternatively, PMMA scleral lenses can be surface tinted over the whole optic zone. At present, it is not possible to use an RGP material if a painted iris is required.



(a) (b)

Figure 17.59 Eccentricity of a cone apex fitted with a PMMA slotted scleral lens. Note that the position of the cone apex conforms to the contact zone when the lens is worn

Scleral lenses in high myopia

As with aphakia, high myopia is adequately managed with corneal or hydrogel lenses in most cases. However, it is worth remembering the potential advantages of scleral lenses for high myopia.

- They are more easily found when patients have poor unaided vision.
- There is no problem of lid traction. Much greater powers can be worked onto a scleral lens. Powers over –40 D are possible except when the BOZR is very flat.
- There is a significant negative liquid lens which reduces the power necessary to work on to the lens.

Established successful scleral lens wearers usually do not like the increased mobility and lid sensation of corneal lenses or the more complex and expensive maintenance of hydrogel lenses. The visual acuity may also be better with scleral lenses compared to hydrogel lenses if there is corneal astigmatism. For these reasons, switching to corneal or hydrogel lenses may not be feasible, so continued supervision of scleral lens wear is needed. From a clinical standpoint there is no reason to refit if there are no adverse reactions.

Keratoplasty

Improved surgical techniques have reduced the incidence of high corneal astigmatism or protrusive corneal profiles, reducing the need for scleral lenses compared to the 1960s and 1970s. However, there remain some cases where they are preferred because of the irregularity of the corneal surface or for any of the other general indications previously covered. Postoperative astigmatism in excess of 20.00 D has been reported in some scleral lens clinics. In addition, there are patients who were successfully fitted with scleral lenses up to 30 years ago and need periodic after-care appointments or refitting.

There can be a considerable variation in the postoperative corneal topography. The donor cornea may spring forward at the time of removal of the sutures, even if they are left in place for over a year. However, there is usually a greater symmetry about the visual axis compared to keratoconus. Channelled PMMA scleral lenses may be preferable to fenestrated or slotted lenses if the topography is irregular. Sealed RGP scleral lenses also offer a good prospect of ensuring full fluid corneal coverage as well as ensuring an increased level of oxygen to the cornea compared to PMMA.

The corneal metabolism is compromised following keratoplasty due to the loss of endothelial cells (Bron and Brown, 1974; Olsen, 1981), so it is possible but unproved that a reduced level of corneal oxygen may be a factor contributing to rejection episodes. The reduced postoperative corneal sensation may allow early subjective indications of oedema, i.e. discomfort, to pass unnoticed by the patient. Misty vision is an early symptom of rejection as well as being a symptom of contact lens hypoxia, so the scleral lens practitioner should be alert to the problem of rejection when fitting transplanted corneas (*see also* Chapter 20.3).

Outcome of scleral lens fitting in ocular pathology

The criteria for success are that the visual advantages of scleral lens fitting enable the patients to conduct their normal occupation, and that any scleral lens-induced ocular changes are within acceptable limits. Pullum and Trodd (1984b) showed that keratoconus constituted about a third of the total number referred for continuing management or

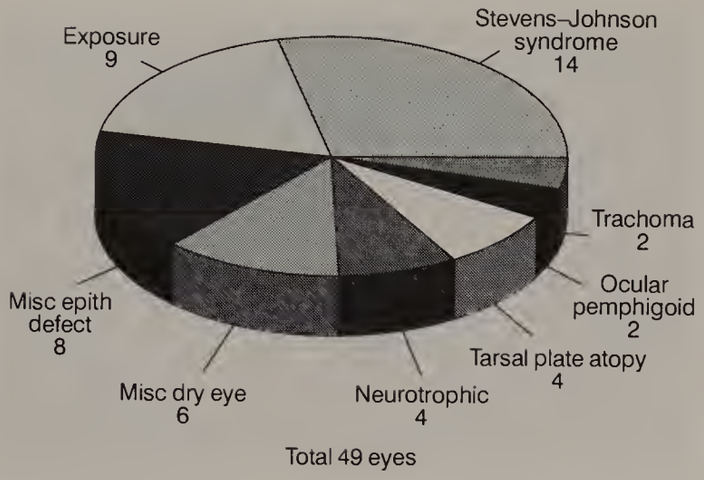


Figure 17.60 Pie chart showing the spread of ocular disorders that have been managed with scleral lenses (Tan *et al.* 1995a)

new fitting of scleral lenses. The analysis showed that the majority were successful to varying degrees, evenly spread between those patients who totally succeeded, partially succeeded or totally failed. The authors' impression was that they took up much more than a third of the time allocated for scleral lens practice, putting a strain on the resources available but reflecting the greater occupational needs of this group. Tan *et al.* (1995a) indicated that closer to 50% of scleral lens wearers were keratoconic.

Results of fitting corneal transplants showed that successful wearers were spread in a similar fashion to the keratoconus sample (Pullum and Trodd, 1984b). Corneal oedema with PMMA lenses was the principal reason for failure or a reduced wearing time, often without discomfort. This was presumed to be due to endothelial cell loss during and soon after the operative procedure. When the cornea remained clear, the result was usually a good one. Early results with RGP scleral lenses indicate that corneal oedema is less of a problem compared to PMMA.

The aphakes were polarized between two groups: one doing quite well and the other finding scleral lenses no improvement and giving up (Pullum and Trodd, 1984b). The patients who were successfully fitted required less subsequent follow-up than any other group and it was also technically easier and quicker to fit the lenses because of the relatively normal topography. Most of the myopes in the study were existing wearers with relatively few new referrals. Therefore most were already successfully wearing their lenses and were attending for routine follow-up.

Therapeutic and protective applications of scleral lenses

Scleral lenses have a unique therapeutic role to play under certain circumstances because they cover the whole cornea while retaining their rigidity. Chapter 20.7 covers therapeutic applications of contact lenses, but the following specifically describes the conditions requiring therapeutic scleral lenses. *Figure 17.60* illustrates the spread of ocular disorders managed with therapeutic scleral lenses in a study by Tan *et al.* (1995a).

Protective and tear retentive therapeutic function

Corneal exposure

Impaired lid closure disrupts the pre-corneal tear film and results in exposure keratitis. The aetiology may be ectropion, coloboma of the lid, loss of lid tissue, exophthalmos, lid retraction after surgery or neurological, e.g. VIIth nerve, lesions. A contact lens helps to provide fluid coverage and prevent evaporation, but as hydrogel lenses have a tendency to dehydrate, there is a significant role for silicone rubber (Woodward, 1984) or scleral lenses. Neither dehydrates, but there are problems of surface deterioration with silicone rubber.

Silicone rubber lenses can be worn overnight for therapeutic purposes, but scleral lenses would usually be advised for day wear only, with the lids held closed at night by secure padding. Overnight use of RGP scleral lenses has yet to be tested, but on occasion, e.g. in cases of major lid loss, scleral lenses are worn continuously to alleviate severe exposure keratitis. There were occasions prior to the introduction of RGP scleral lenses when continuous wear of a PMMA scleral lens was necessary. Buckley (R. J., personal communication, 1994) described the use of RGP scleral lenses to prevent lid action from removing cells while the basement membrane is reforming.

Neurotrophic keratitis

Denudation of the epithelium may occur as a consequence of degeneration of the nerve supply to the cornea, for example in diabetes. The pre-corneal reservoir may assist reformation in some cases.

Anaesthetic cornea

An anaesthetic cornea is at risk of injury through foreign bodies lodging in the epithelium or because of abrasions caused by tarsal plate foreign bodies. Scleral lenses can give excellent protection in these circumstances. However, the anaesthetic eye is very tolerant, so the patient probably would not report discomfort which is normally attendant with hypoxia in its early stage.

Retention of a pre-corneal fluid reservoir with a scleral lens

This may be the only way to maintain corneal hydration in some serious dry eye conditions. Ocular cicatricizing pemphigoid is a progressive atrophy of the mucous membrane. The adenoid layer becomes fibrotic with secondary effects on the secretory cells and fornix shrinkage. Stevens–Johnson syndrome is caused by systemic drug sensitivity, especially associated with sulphonamides. The acute phase involves a severe mucopurulent conjunctivitis with ultimate loss of the fornix, symblepharon and acute

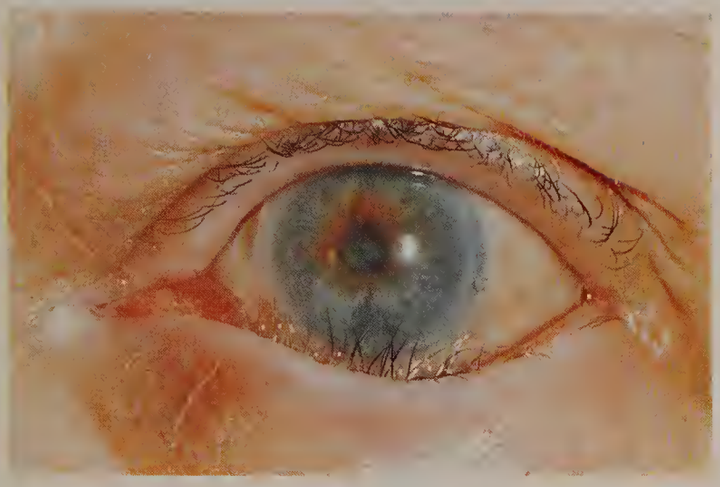


Figure 17.61 Fenestrated PMMA scleral lens fitted in a case of age related entropion

tear dysfunction. Severe dry eyes can also occur in some cases of rheumatoid arthritis.

Disfiguration of the sclera can be an additional complication which may preclude fitting preformed RGP scleral lenses. In addition, the poor quality of the tears fluid may render the surface of an RGP scleral lens unwettable, hence an impression PMMA scleral lens may be better under some circumstances. Hypoxic changes are possible, but cessation of contact lens wear would almost certainly result in more serious damage as a consequence of the dry eye condition. Sealed RGP or channelled PMMA lenses minimize the chance of introducing air into the pre-corneal reservoir, while slotted PMMA designs maximize tear exchange behind the lens. Scleral lenses have been used in conjunction with continuous perfusion apparatus to provide a constant supply of fluid or drugs to the cornea (Ruben, 1975).

Prevention of fornix shrinkage and symblepharon

Symblepharon may also be the result of burns, particularly from alkaline chemicals. Normal blinking is affected with adverse corneal sequelae due to exposure or entropion and trichiasis. Shells or scleral rings to avoid corneal occlusion may help to prevent symblepharon re-forming after surgical separation.

Entropion and trichiasis

A therapeutic hydrogel or silicone rubber contact lens used as a protective barrier may alleviate the discomfort and reduce the threat of long-term erosion of the corneal epithelium. However, the lashes may be pushed under the edge of hydrogel lenses, or may erode the surface. Scleral lenses are not subject to these drawbacks and provide the most effective protection, as shown in *Figure 17.61*. Trichiasis may be treated by removal of the lashes, either by repeated epilation or electrolysis. However, if the lid is inverted so that keratinized tissue instead of lid margin mucous membrane is in contact with the cornea, persistent abrasion can still occur.

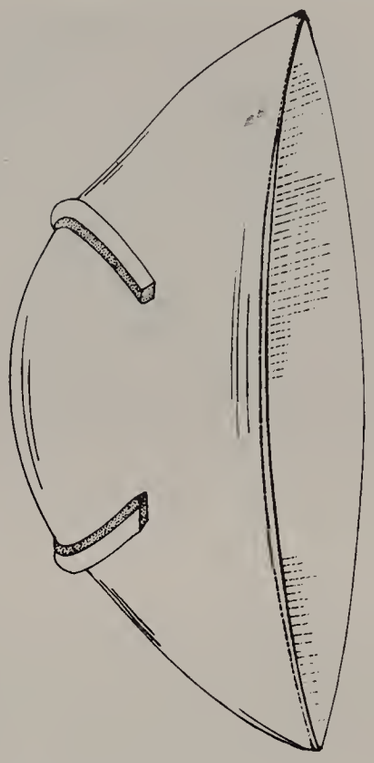


Figure 17.62 Double ledged ptosis prop

Ptosis

Ptosis may be present following lid trauma, IIIrd nerve palsy, as part of general myasthenia gravis or in ocular myopathy when the condition is specific to the levator muscle. Scleral lens ptosis props can be offered but there is usually some extra discomfort and frequent wiping of the front surface with a damp tissue may be necessary as blinking becomes impossible.

A ledge can be cemented on to the front to hold the upper lid open. Sometimes a second ledge may be added to rest on the lower lid to prevent lens depression (*Figure 17.62*). Nelson (K., 1993, Personal communication) has described an alternative method using a row of small dumb-bell shaped studs cemented to the front scleral zone surface.

Trodd (1971) constructed a ptosis prop by cutting through a thick shell. The shelf is easily lowered by cutting away more of the shell, and the front optic portion can be cut at the end of the fitting procedure. Repositioning a cemented ledge is more difficult, and the optic zone has to be cut before a ledge can be cemented on. It is also easier to construct a solid shelf that is highly polished and free from imperfections. *Figure 17.63* shows an example of a Trodd type ptosis prop *in situ*. Partially cutting through the shell, as shown in *Figure 17.64*, enables fenestrated or channelled lens designs. Occasionally, a thick finished shell may open the lids enough to uncover the pupil (*Figure 17.65*).

The positioning of the ledge is very critical. If placed at the upper limbus the downward force exerted on the shelf is increased and pushes the lens down. This may introduce a

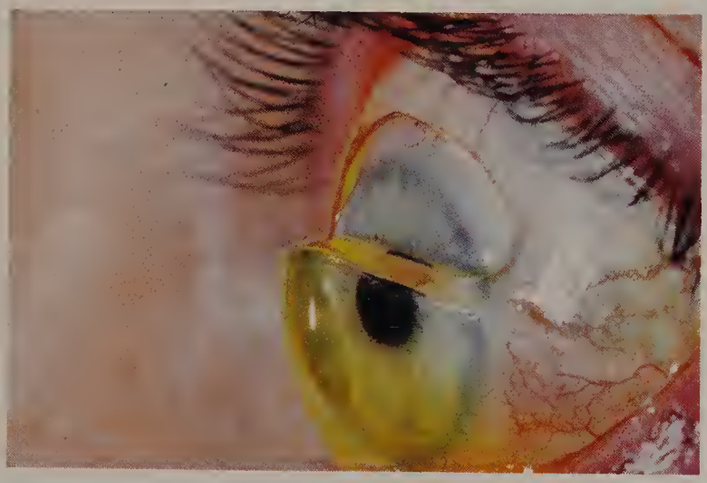


Figure 17.63 Trodd-type ptosis prop worn successfully 16 hours a day for over ten years

bubble over the inferior part of the cornea with a corresponding area of contact in the upper half (*Figure 17.66*). The correct height is the lowest that raises the lid sufficiently to allow unobstructed vision. Spectacle frame-mounted props may be quite effective, but the forced opening of the eye may lead to corneal exposure. A protective contact lens may be indicated which may have to be a scleral lens as a hydrogel would dehydrate.

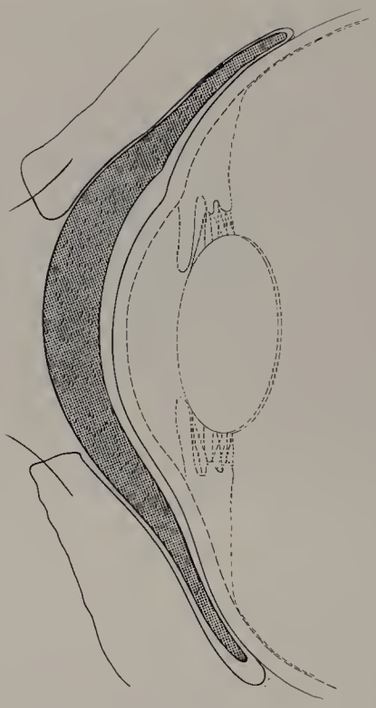


Figure 17.65 Thick shell used for ptosis prop. A very thick shell must be used in order to have any significant effect as the lid is being stretched rather than lifted up

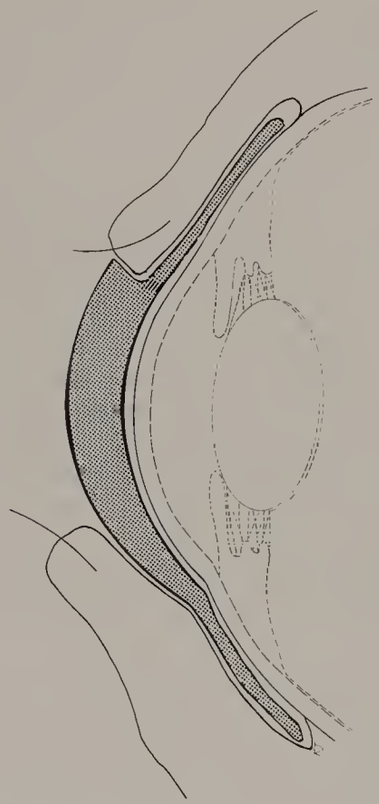


Figure 17.64 Partially penetrating shelf

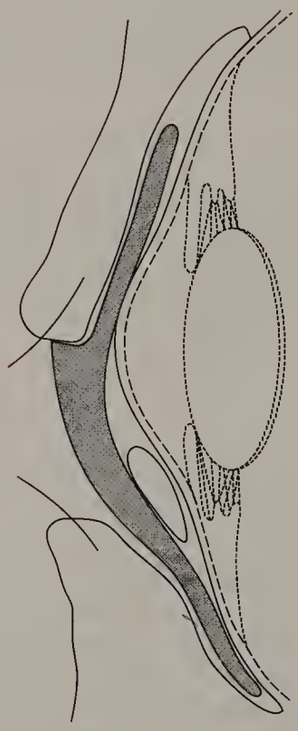


Figure 17.66 Ptosis prop (partially penetrating shell in this diagram) with the shelf placed too high. It is pushed down by the upper lid and causes an inferior bubble

Cosmetic shells

Cosmetic shells are difficult and time-consuming to fit, but last many years with virtually no maintenance costs. The whole anterior eye is covered and any iris and scleral features, such as conjunctival blood vessels, can be included for the best possible match with the fellow eye. The appearance of unsightly phthisical eyes can be improved by building up the thickness of a cosmetic shell. The exception to the general rule that shells are the best cosmetic option is if the eye is proptosed when the extra bulk may be unfavourable. Chapter 20.6 covers in greater detail the various types of cosmetic contact lenses available to mask scarred or disfigured eyes.

Problems and complications with scleral lens wear

Bubbles

Air bubbles trapped beneath the peripheral optic zone cause reflections. Small frothy bubbles easily encroach across the visual axis and may disrupt vision completely. Elimination of air is not always possible, especially with irregular corneal topography causing variations in the depth of the pre-corneal reservoir. Removal of the lens and re-inserting with more wetting solution or instillation of a viscous eye drop directly into the fenestration, slot or channel may have the desired effect for a short while. A second fenestration into an area retaining a permanent bubble may reduce its size, or removal of substance from the whole of the scleral zone may be attempted to reduce the corneal clearance. However, like many other scleral lens modifications, the result of either is far from predictable. Remaking the lens with reduced optic zone clearance may be preferable. Sealed RGP lenses can usually be inserted air free, hence the problem of air bubbles and frothing are much less common. However, when a bubble is admitted via an unintentional channel due to a depressed superior sclera, it often increases in size remaining permanently under the optic zone. Clicking sounds are caused by air bubbles entering the space behind the lens. They can be very annoying, but there is little chance of eliminating them with fenestrated lenses. The problem does not exist with sealed RGP lenses.

Accumulation of mucus beneath scleral lenses

Scleral lenses sometimes seem to generate over-secretion of mucus which may be trapped in the pre-corneal space. This is more of a problem with slotted lenses because of the wider opening and deeper space behind the lens, although it occurs even with sealed RGP lenses. Removal and re-insertion with fresh saline in the lens is necessary or mucolytic drops such as acetylcysteine may be considered.

Conjunctival hyperaemia

This problem may accompany scleral lens wear. If this is localized it may indicate an area of tight scleral zone fitting. The limbus should be watched carefully for early signs of limbal arcade vessel engorgement which may be the precursor of corneal neovascularization, but otherwise some hyperaemia is not a threat and may be impossible to alleviate.

Compression of conjunctival flap

Compression of the conjunctival flap over the limbus and peripheral cornea can occur with sealed RGP scleral lenses if there is insufficient limbal clearance. It does not cause a serious problem, but patients sometimes report it as they notice the unsightly effect when looking in a mirror.

Discomfort

Discomfort from scleral lenses is usually a consequence of apical corneal contact zones, limbal occlusion, or an ill-fitting scleral zone. It may also be an early symptom of corneal hypoxia in PMMA scleral lenses in which case it could be reduced by re-fitting with an RGP lens.

Settling back

This has been discussed at length earlier in this chapter. Further elaboration is not necessary, but it should be remembered that the fitting of scleral lenses should always be assessed both immediately after insertion and after a period of settling back. Use of sealed RGP lenses minimizes settling back.

Complications

Abrasions

Abrasions can be caused by clumsy insertion or due to heavy central touch on a fragile corneal apex, especially in keratoconus when corneal touch cannot always be eliminated. Unusual discomfort after a period of wear is an early symptom. As a scleral lens is the only means by which some keratoconus patients see adequately there is a tendency to exacerbate the situation by continuing to wear the lens. Observations by the author suggest that there is more discomfort and corneal staining in some cases if there is a contact zone with RGP scleral lenses compared to PMMA. This could be because there is more friction between the lens and the corneal surface with RGP materials if there is no pre-corneal reservoir.

Exposure keratitis

Exposure keratitis can be caused by static bubbles behind the lens resulting in dehydration and epithelial desiccation. In some advanced cases there may be corneal neovascular-

ization corresponding to the area not covered by the precorneal reservoir.

Dealing with unwanted bubbles is a constant problem in scleral lens practice, but the application of sealed RGP lenses has made a significant improvement.

Exacerbation of corneal scarring

Corneal scarring is part of the disease process of keratoconus. Persistent central corneal contact may make this worse although there is no way of being sure that the scarring would not have progressed in the absence of a lens. If there are justified visual indications it may be necessary to proceed irrespective of the possibility of increased scarring.

Compression of the anterior chamber or blebs

If there is a predisposition to angle closure, or if there is a drainage bleb following a trabeculectomy, care is necessary to avoid compression which may obstruct drainage. There is also a risk of intraocular infection if the bleb is ruptured as pathogens would have direct access into the globe. Blebs are most often located at the superior limbus, which is typically the position where a lens may be slotted. It may be necessary to relocate a slot to prevent the conjunctiva herniating into the slot which would obstruct the tear flow or restrict the aqueous outflow.

Giant papillary conjunctivitis (GPC)

GPC does not often appear to cause the typical discomfort described by hydrogel lens wearers, presumably because there is no contact between the tarsal conjunctiva and a lens edge or spoiled surface during blinks. In addition, protein does not adhere to PMMA and is easily cleaned from RGP materials. The issue is rather clouded as there is a high percentage of keratoconics who have atopic lid changes as part of the condition.

Hypoxic changes

Oxygen deprivation accounts for the most common and serious complications of scleral lens wear. Corneal oedema with attendant discomfort and misty vision may cause reduction of wearing time, but the onset of oedema and misty vision may be retarded after a period of adaptation. Misty vision due to corneal oedema may not be obvious in the presence of other ocular pathology such as disease process opacities or lenticular changes.

Neovascularization

This is a long-term complication of chronic corneal oedema, but a small amount may be an acceptable complication if the visual indication for scleral lens wear is significant. It is possible that neovascularization may be self-limiting if it compensates for a corneal oxygen deficit. In the absence of evidence to support or refute this, each case must be judged individually. If it appears that the rate of new vessel growth is unlikely to encroach across the pupil margin in the patient's lifetime, lens wear should be maintained with careful monitoring of changes.



Figure 17.67 Lipid keratopathy in a patient aged 55 from a long-standing fine new vessel which crossed the pupil margin. The VA was reduced to 6/36 but improved back to 6/12 after six months with reduced lens wear and switching to an RGP sealed scleral lens

Neovascularization in keratoconus

Here a different criterion applies because there is a risk that only very slight neovascularization may increase the risk of any future corneal transplant rejection. The risk is particularly applicable to more eccentric cone apices which would require larger donor buttons. Most cones are decentred downwards and a common origin of major new vessels seen in keratoconic eyes fitted with scleral lenses is from the inferior sector of the cornea. It is therefore essential that regular liaison with the ophthalmologist who may carry out a future transplant is a part of scleral lens after-care in keratoconus.

Lipid keratopathy

New vessels *per se* do not always cause a major visual loss, even if across the visual axis, but the vessels have a tendency to leak lipid. This can occur without much warning even if the vessels are apparently quite fine in calibre, and can cause a dense opacity (*Figure 17.67*) with sudden onset visual loss. Some absorption is possible after a time, but the rate is slower for older patients.

Conclusion: the role of scleral lenses

Today's requirement for scleral lenses constitutes the smallest of all lens types. However, there is often the greatest visual or clinical contact lens indication and so it is necessary to continue to preserve the art of scleral lens practice in an effective way. A scleral lens can provide a feasible conservative management option which may avoid

hazardous surgery, especially since the introduction of RGP materials. Scleral lens practice requires ongoing mutual support between contact lens practitioner and ophthalmologist.

While there is such a small demand for the service, it must be carried out as efficiently as possible to avoid discredit due to too many unsatisfactory results, so careful patient selection is crucial. There is a need for a small number of practitioners to develop skills in manufacturing and fitting but contact lens practitioners who may not wish to undertake the work personally should still familiarize themselves with the theory and application of scleral lenses to enable recognition of suitable patients and referral to colleagues who are specialists in the area.

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Chapter 18

After-care symptoms, signs and management

C. W. McMonnies

Introduction p. 609
Interviewing and history taking p. 610
Symptom analysis p. 610
After-care glossary p. 612
Conclusion p. 650

Introduction

Contact lens after-care is the key to developing and sustaining good lens performance. During this period of intermittent patient contact, the initial prescribing of lenses and maintenance methods can be modified according to individual patient experience so that optimum results are achieved and sustained. For this reason, it is sometimes referred to as **continuing care**. After-care is a time-consuming and demanding challenge for contact lens practitioners. The task can be difficult and draws, at various times, on all aspects of optometric and contact lens knowledge since the symptoms and signs require differential diagnosis from ocular pathology that is unrelated to contact lens wear. Successful practice depends on a thorough and responsible approach to after-care that results in correctly identifying or predicting problems, so that appropriate management and remedial steps are taken. An after-care examination should be based on the following structure:

- History of contact lens use, including hours per day, days per week and any limitations on wearing that are experienced.
- Symptom analysis in regard to prevalence, onset, duration and associated provocative circumstances.
- Evaluation of vision performance including visual acuity and over-refraction using retinoscopy and subjective methods.
- Examination of lens fitting in regard to centring, movement, tear circulation and appropriate lens/cornea alignment.
- Examination with low magnification using a hand-held ultraviolet and white light, and with higher magnification using a biomicroscope. Lens and tissue changes should be noted including the use of stains. Further examination of lenses off the eye may be indicated, including additional microscopic examination for signs of degradation, and re-assessment of lens parameters.
- Non-routine tests and measurements such as keratometry, tear film analysis, corneal sensitivity and assessment of ocular health.

This structure is not intended to imply a rigid examination sequence. Usually symptom analysis continues throughout the examination when additional information is sought from the patient in the search for a conclusive diagnostic assessment. Skilled interviewing and observation techniques need to be supported by a thorough base of pre-fitting assessment, and a knowledge of normal and abnormal tissue appearances including the pathological and physiological responses to contact lens wear. An observer who is unaware of particular tissue or lens changes is unlikely to look for them, nor to appreciate their significance if they are observed. Under these circumstances, the correct basis for good management will be absent. It is always important to remember that a patient's symptoms may not result from contact lens wear and a full eye examination may be indicated.

An analysis of 600 contact lens consultations and examinations (McMonnies, 1987) showed how after-care consumes the greatest proportion of contact lens fitting time. It was found that, within the first year of prescribing contact lenses, after-care visits occurred at the rate of at least 4.2 per fitting in the case of rigid lenses and 4.4 per fitting in the case of soft lenses. A detailed analysis of a second series restricted to 600 after-care visits, indicated the wide range of problems encountered (126 subtypes), and remedial strategies employed (64 subtypes). At 32% of after-care visits, there were no significant symptoms and yet adverse signs (conjunctival hyperaemia, surface deposits, oedema, epitheliopathy etc.) were recorded at 81% of those visits and resulted in remedial action being taken. This finding indicated a significant problem-preventing mode of practice; also 32% of the management procedures recorded involved controlling lens surface deposits or some other feature of maintenance technique, even though surface deposits were recorded as a problem at only 10% of visits. Within the first year of prescribing, 74% of remedial action was *not concerned* with lens modification. Beyond the first year, 67% of after-care management is concerned with areas *other than* the technical aspects of lens and fit modification. For example, additional instruction and counselling accounted for 36% of all remedial and prophylactic actions.

The findings revealed numerous insights into current contact lens practice showing that, for example, significant corneal oedema accounted for only 2% of after-care problems and severe over-wear oedema was not encountered at all during the period of survey. Overall, the findings serve as a guide to developing practice management techniques that are appropriate for particular types of problem, according to their prevalence. In undergraduate teaching there needs to be an emphasis on the management of problems, especially in regard to their prevention. The findings indicated the potential to improve after-care management in many areas, but especially surface deposit control and methods used for patient instruction and re-instruction.

This chapter is as much concerned with describing methods for adapting and organizing contact lens and eye-care knowledge in the interests of effective after-care as it is about particular problems and optimum management.

The problem areas dealt with herein are not exhaustive and there is no way of anticipating the problems that face us in the future. A systematic approach to the after-care examination sequence, as described in this chapter, will provide a firmly based pool of information for correct identification of problems and their causes. In the early stages of fitting the concern is to determine how adaptation can be facilitated and tolerance improved. The practitioner can usefully analyse findings in order to separate the patient's limitations from those of the lens. When problems develop in adapted patients the same analysis structure is equally productive. Is lost tolerance due to changes in the eye's receptivity, changes in the lenses' wearability or changes in the circumstances under which the lenses are worn? Deductive analysis leads to remedial action which in turn leads to remedial strategies being discovered from accumulated personal experiences.

Interviewing and history taking

Patient interviewing is a key skill of after-care and the efficiency of this process should derive in part from the trust, confidence and rapport developed between practitioner and patient at prescribing visits (Enelow and Swisher, 1972). Interview technique will vary depending on whether the visit is prompted by an emergency, a particular problem, or a routine appointment with or without symptoms.

Open-ended questions are appropriate at the initial stages, but questions should become increasingly more direct as specific details are sought. 'What kind of troubles have you been having?' is not open-ended enough to start, because it assumes that there have been some difficulties. A preferred start is 'How have you been getting on with your lenses?' and, as will be necessary with the reticent patient, a follow-up may be employed along the lines, 'Do you wear your lenses routinely?', and then, if necessary, 'Are there any restrictions on wear?'. If reduced or occasional wear is reported, the more direct, 'Could you wear them longer or more often if you needed to?', which allows for reports of casual use.

According to the patient's personality or mood (co-operative, angry, paranoid, evasive, embarrassed, shy, guilty etc.), an interviewer should vary approaches across the range between an active authoritarianism, through a guiding and cooperative mode, to one of mutual participation between patient and practitioner as the clues are sought that lead to a solution to a particular problem. Mutual participation is of most value when discussing a patient's compliance with handling and maintenance instructions. A patient's embarrassed attitude may correctly indicate problems in following instructions and an aura of shared responsibility needs to be engendered as, through mutual participation in discussion, the reasons for non-compliance will become apparent. Some humour may help, combined with an acknowledgement that lack of strict discipline is a common failing, and the use of the euphemistic 'casual approach' rather than 'incorrect' may help expose the need for changes in the patient's attitude. Conversely, when changes are needed, stronger authoritarian terms such as 'dangerous procedures' may be required in the case of a high risk of infection when negligence prevails. Thus the tone of the interview is adjusted between excessively authoritative at the risk of prompting an unproductive defensive patient attitude, and excessively passive at the risk of promoting a non-problem-solving ambience. It may help to acknowledge that the nature of a patient's tear composition may be responsible for lens deposits but that only through increased patient effort will further problems be avoided. Blaming tear quality may not be valid if patient negligence is suspected, but if the outcome is desirable (greater maintenance effort and compliance), then making such an assumption is justified, even if incorrect.

Interviewing is time-consuming but there is no completely satisfactory alternative. Despite limitations of language, intelligence and literacy, questionnaires may be useful (McMonnies, 1978, 1986a; McMonnies and Ho, 1987a,b), especially when they can be completed without supervision. However, the precision of a questionnaire increases with the narrowness of the area of enquiry, and may be best suited to pre-fitting visits. Problem-orientated interviews frequently need great skill in handling so that progress to appropriate emphasis on the nature of the problem can be achieved rapidly.

Symptom analysis

Although symptoms related to vision and comfort may occur together, it is instructive to consider them separately.

Vision symptoms

A report of poor vision requires careful analysis and consideration of numerous possibilities. Is the problem a blur that suggests incorrect lens power, or a distortion that

suggests faulty optical quality or residual astigmatism? Is the problem a ghost image that suggests incomplete pupil coverage or faulty optical quality? Does the problem only occur at near distances because the patient is a presbyope, or because of the nature of the near vision task, such as typing or using a visual display unit, that leads to inefficient blinking? Do symptoms occur intermittently because of flexure of a thin lens or rotation of an unstable toric lens? Do difficulties increase during the day as surface deposits accumulate, and is the problem relieved by removing the lenses for cleaning? Does increased blinking improve vision because the lenses are soiled or unwettable? Does the difficulty only occur with reduced illumination because of a myopic shift under these conditions? Reference to established findings may help identify causal factors, for example, the patient's age, occupation and hobbies. Have poor blinking habits previously been noted? Was the lens found to have doubtful optical quality or power when checked prior to delivery? Is the lens too thin, and easily flexed by lid pressure? Did the lens previously give good vision and has it become accidentally warped in handling?

Tests, such as retinoscopy or front surface keratometry, may be needed to detect lens flexure. Is the lens inside out, or have right and left or old and new lenses been mixed? Ophthalmoscopy may indicate cataract development, retinal changes or other pathology. Further questions may be needed. Does the problem become more apparent when reverting to spectacles after lens wear? Have there been systemic health changes and possible ocular side-effects of medications or general anaesthesia? Has there been an increase in near vision possibly due to examinations or a change in work practices such as more VDU use?

Symptom analysis should proceed as tests of visual performance are conducted. In most cases, a systematic approach to visual symptoms and associated tests of visual performance lead to the identification of the important factors in each case. Simple explanations should always be sought first and, if over-refraction indicates antimetropia, the possibility of lenses being reversed between right and left eyes should be considered. Variations from expected acuity should be noted and the difference between quantitative and qualitative vision performance should be recognized when good letter reading acuity is achieved but complaints of poor vision persist. Contrast sensitivity or low contrast acuity tests may be useful. Retinoscopy may indicate an irregular residual astigmatism that could be due to a distorted lens or one with poor optics. Biomicroscopy may reveal a soiled and/or non-wetting lens surface. The parameters and cleanliness of the lens being worn for over-refraction should always be checked before reordering or carrying out modifications. Even when a patient presents a copy of their lens prescription issued by their previous practitioner, it is wise to remember that the prescription only tells you what the lenses are supposed to be, whereas the actual parameters are often found to be different. Your own patients may present wearing a lens or lenses from an earlier fitting, forgetting or not realizing that they are not wearing the pair most recently prescribed.

Symptoms of discomfort

When some degree of discomfort is reported, further questioning and consideration of possibilities are again required to discriminate between various possible causes. Is it a chemical sting or a gritty, foreign body sensation? How is it rated in intensity: 1 – lens awareness; 2 – irritation; 3 – pain? Is there associated headache and/or visual phenomena suggesting migraine? Is the discomfort an itch (allergy)? Does it occur after lens removal? Is discomfort present prior to lens insertion and eliminated when lenses are inserted (suggesting trichiasis, retained foreign body or extruding concretion of the upper palpebral conjunctiva)? Is the lens damaged or ill fitting, and does localized limbal hyperaemia or corneal epitheliopathy give a clue to the cause? Is the lens inside out or mixed (left with right or old with new)? Is the cornea significantly oedematous and does the discomfort occur some hours after lens removal (over-wear (3 a.m.) syndrome)? Is the discomfort constant – only on insertion, only after several hours wear, only when reading, only in glare situations? Are rigid lens back surface transitions smooth? Is the edge shape satisfactory? Is the lens too thick? Was this lens previously comfortable? Has a duplicate lens been incorrectly made with or without lenticulation, fenestration, truncation etc.? Are different maintenance products being used? Are the lenses being over-worn? Are the lenses being worn in a harsh environment? Is the discomfort associated with the use of certain cosmetics? Does lens insertion require multiple attempts that cause irritation? Are there 'psychological' reasons for the patient to exaggerate or fabricate discomfort symptoms? For example, is the patient trying to justify not paying his or her account? Is the patient unhappy with the choice of tint? Is this a case of an industrial compensation claim that is yet to be settled? Has the patient lost the motivation for wearing contact lenses? Has the patient been subjected to adverse comments about his or her appearance without spectacles?

Again a systematic examination sequence combined with symptom analysis provides an effective base of information from which the correct cause(s) of discomfort can be identified. Examination may reveal hyperaemia, lacrimation, lid oedema, photophobia and other generalized responses to discomfort. Localized hyperaemia or epitheliopathy are strong clues, as is a degraded or damaged lens. Stereomicroscopic or slit lamp examination of the lens off the eye may reveal defects not evident with on-eye inspection. Fit evaluation may reveal excess looseness, tightness, heavy or harsh bearing areas or truncated edges that cause abrasion. The lens surface may be excessively soiled or seen to dry rapidly, suggesting inefficient blinks or an unwettable surface. Other evidence of tear deficiency may be present and blepharitis, chalazion, hordeolum, acne rosacea, or other external eye condition, may be present.

Summary and conclusions

The analysis of lens-wearing history and symptoms should continue during the visual assessment, evaluation of lens

fitting and the examination of the eyes. For example, changes in refraction may prompt questions regarding general health, use of medications and recent alteration to visual demands. When a degraded lens condition is encountered prematurely, it is necessary to ask questions about maintenance procedures. When the symptoms are not specific and the cause of problems remains uncertain, caution regarding alterations to an apparently successful fitting is advised. The after-care study discussed previously (McMonnies, 1987), found that two-thirds of after-care management was unrelated to the technical aspects of lens fitting and design and unnecessary lens changes may compound the difficulties. The patient does not need another pair of lenses that cannot be worn successfully. When the cause of problems remains uncertain, and both eyes have the same or similar prescriptions, it is frequently useful to switch lenses, left with right where appropriate, or old with new, as the outcome is often very informative. If the problem of discomfort occurs in the same eye, even when the comfortable lens from the other eye or the old pair is worn, then the eye appears to be the problem, not the lens. If the problem of discomfort transfers to the other eye, now wearing the suspect lens, then the lens appears to be the problem, not the eye. Sometimes visual problems associated with suspected inferior quality optics can be resolved by switching the lenses, left with right, as poor results with the suspect lens on both eyes help to confirm suspicions of poor optical quality.

When a patient reports new symptoms in relation to contact lenses that have previously been worn successfully, a useful problem-solving strategy can be based on the following questions.

- Has the patient become less tolerant (e.g. medication side-effects, reduced tear function, allergy etc.)?
- Have the lenses become less wearable (e.g. lens or case contamination, lens damage, surface deposits etc.)?
- Have the conditions under which the lenses are worn changed significantly (e.g. increased exposure to air conditioning or glare, work-related increase in visual demand etc.)?

The discipline of routinely asking these questions (Is it the eye, the lens, or some aspect of the lens wearing environment?) will help to avoid taking inappropriate action. After-care problem prevention and amelioration also depend on good record keeping (*see* p. 639). Reference to pre-fitting information can be crucial to successful after-care.

Whether after-care visits are complicated or not, it is not possible to understate the value of biomicroscopic examination. The after-care glossary that completes this chapter cites numerous examples of the need for a comprehensive biomicroscopic technique. However, the most important lesson to be gained from the glossary concerns the need for a wide-ranging and thorough approach to after-care.

After-care glossary

The entries in this glossary are chosen according to their relevance to after-care consultations rather than contact lens fitting in general, and reference to other chapters of this book is made where appropriate. Cross-referencing is used to limit repetition, and to broaden the usefulness of individual entries. The distinction between rigid gas permeable and PMMA lenses is only made when necessary and other references to rigid lenses include both types. Similarly, entries in this glossary refer to rigid and soft lenses unless otherwise stated.

Variations in terminology used may cause some problem in locating information within the glossary. It is suggested to the reader that reference to the major index should facilitate the search for particular entries.

Cross-references in bold type refer to other entries within the glossary.

Advice

Advice regarding the use of contact lenses in a variety of sport, work and leisure situations is frequently required at after-care visits so that problems can be avoided by inexperienced wearers (*see* **Flying; Swimming; Travelling; Toxic fumes; VDU**).

After-care examination sequence and structure

See the introduction to this chapter.

Allergies

These may be a complicating factor of contact lens wear (*see also* Chapters 4 and 8). Although sensitivity to lens material is difficult to confirm, circumstantial evidence for it is strong in those uncommon instances when a change of lens material results in a resolution of symptoms and signs of sensitivity. Similarly, sensitivity to cosmetics occurs occasionally (*see* **Cosmetics**), the complication being unsuspected after long periods of successful use of a particular product in cases of delayed reactions. The evidence for solution hypersensitivity (*see* **Preservative reaction**) is convincing and, like other allergies, is managed by recognition and elimination of suspected products. If a history of allergies (atopy) predisposes patients towards contact lens-related allergies, it may be only in cases when the eye has been the primary response organ in previous episodes of hypersensitivity (McMonnies, 1978).

Signs: Oedematous lids, watery discharge, conjunctival hyperaemia and oedema. General corneal superficial punc-

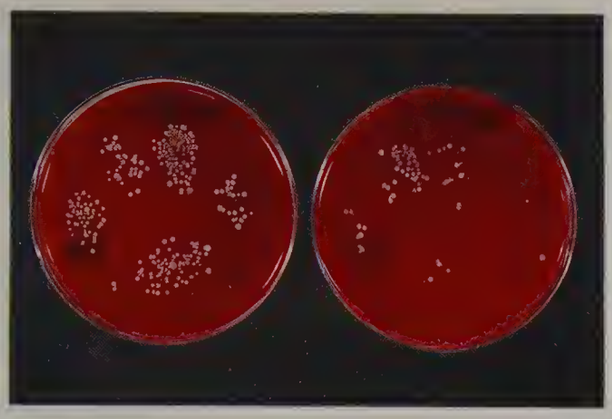


Figure 18.1 Hygiene and hand-washing. Two agar plates are shown with a practitioner's fingers and thumbprint before (*left*) and after (*right*) hand-washing. The reduction but not complete elimination of bacterial colonies is clearly visible. (Courtesy of C. Copley)

tate keratitis may be the sign of a material allergy, and grey stromal infiltrates the signs of a solution (especially thimerosal) allergy (*see* **Fit evaluation**; **Vascularization**; *Figure 18.28*).

Symptoms: Burning, itching and irritation.

Management: Trial and error to eliminate suspected antigenic factors such as maintenance solution preservatives, cosmetics, soaps and the contact lens material. Antigens encountered independently of contact lens wear should also be considered, especially in spring, when treatment with systemic or topically administered antihistamines may be indicated.

Bacterial conjunctivitis

This is more likely to occur in contact lens wearers who are negligent regarding hygienic lens handling and maintenance.

Risk factors: Failure to wash hands effectively prior to insertion and removal (*see* **Hand washing**; *Figure 18.1*), failure to prevent case and storage solution contamination (*see* **Case contamination**), and a predisposition towards chronic external eye conditions such as tear deficiency or blepharitis (*see* **Reactive eye**; Chapter 8; *Figures 18.18, 18.49*).

Signs: Watery, mucoid or purulent discharge, crusted exudate on lid margins, conjunctival hyperaemia and oedema, and lid oedema.

Symptoms: Irritative/foreign body sensation (monocular initially) and photophobia (Wilson, 1979a; Stapleton *et al.*, 1992). Often the cornea becomes involved, when, for example, discrete punctate epithelial keratitis may develop.

Management: Discontinue contact lens wear. Consider adnexal, lid and conjunctival cultures as well as cytology of conjunctival scrapings. Antibiotic sensitivity results may be needed for treatment choice. Delayed resumption of lens wear is indicated along with review of hand washing and lens maintenance, espeeially in regard to case contamination. Consider replacing lenses and case as well as reinforcing continuing lid hygiene and other risk-reducing procedures to lessen chances of recurrences (*see* **Bacterial corneal ulcers; Infection**).

Bacterial corneal ulcers

These can be a consequence of contact lens wear. Extended wear is a predisposing factor additional to those described for bacterial conjunctivitis (Lippman, 1986; Stenson, 1986; Matthews *et al.*, 1992; Dart, 1993; *see* **Bacterial conjunctivitis**).

Signs: Rapid development of a necrotic, greyish, stromal infiltrate in the bed of an epithelial injury, attended by surrounding epithelial oedema, radiating posterior corneal folds, endothelial plaque (fibrin) and flare and/or cells in the anterior chamber. An abundant mucopurulent discharge may also be present. In *Pseudomonas* keratitis the discharge is often yellowish-green in colour (Wilson, 1979b). Prompt medical treatment is indicated and often hospitalization of the patient may be required for effective treatment (*see* **Infection**).

Management: Discontinue lens wear. A laboratory work-up is required, including culture scrapings from the advancing and the central deeper areas of the ulcer. Cytology of scrapings is indicated. Antibiotic sensitivity results may be needed in treatment choice. Delayed resumption of lens wear is indicated for corneal recovery along with review of hand washing and lens maintenance, especially in regard to case contamination. Consider replacing lenses and case as well as reinforcing continuing lid hygiene and other risk-reducing procedures to lessen chances of recurrences. Soft lens wearers may be advised to change to RGP lenses (*see* **Bacterial conjunctivitis; Infection**).

Biomicroscopy

During after-care, biomicroscopy is directed towards lens condition and fit, as well as tissue changes which can be compared with a baseline record of pre-fitting observations (*see also* Chapters 6, 7 and 8).

After-care biomicroscopy is the key to determining the cause of symptoms but must be broadly based so that signs indicating the need for prophylactic management are also detected. Biomicroscopy is more informative if preceded by a lens-wearing history and an analysis of symptoms, especially as this interview period allows for general observations of the patient's response to contact lenses to be made, including blink patterns, head position, hyperaemia and lacrimation. General room illumination sources that

favour natural skin tone appearance, for example a Philips fluorescent tube number TLD 36/84, is recommended. An examination of lens centration and movement with low magnification and white light before tear volume and lens movement is altered by the instillation of fluorescein (*see* **Hand UV or Burton lamp**), can usefully precede biomicroscopy especially as changes to the adnexa or lid margins, or localized hyperaemia, can be detected at the same time. The combination of symptoms and preliminary observations helps to identify areas of special interest with the biomicroscope. Essential areas for detailed inspection are tear quality, lens condition and fit, and corneal integrity. Corneal integrity is further assessed after lens removal, especially as removal affords an opportunity to use stains in the case of soft lens wear.

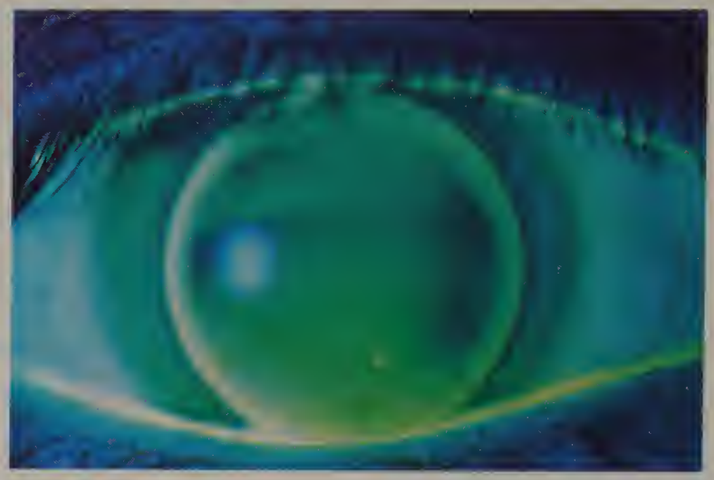


Figure 18.2 An interrupted tear layer (prowline) across the lens front surface indicating that the blink prior to the photograph was partial or incomplete

Blinking efficiency

This may be found to be reduced at after-care visits, the most common problem being an excess of partial blinks compared with full, complete blinks (Korb, 1974). Both partial and complete blinks are normal, but the unadapted wearer may be seen to produce an excessive number of the partial, hesitant, incomplete type. It is likely that contact lenses increase the blink frequency during adaptation or when discomfort is present but, when lenses are worn comfortably by adapted patients, the frequency of blinks is determined by factors such as the patient's personality, mood, fatigue level, visual task, state of alertness and ambient atmosphere conditions etc. Thus frequency of blinking is predetermined by prevailing conditions and the quality of blinks (the ratio of complete to partial) is the area in which efficiency can be improved. Efficient, complete blinks help to position lenses correctly, promote tear circulation, eliminate debris from under lenses and prevent deposits from forming.

Helping the patient understand these various blink functions, and the nature of their problem, is a key factor in motivating them to make the effort required to develop more efficient blinks. An instruction period is needed for the patient's appreciation of a full or complete blink (when the top lid lightly touches the bottom lid) which is also relaxed (does not involve facial muscles). Facial muscles become involved in blinking to either increase the force of closure (blepharospasm) and/or increase the widening of the palpebral aperture. Thus facial muscle involvement will cause blinks to appear forced and unnatural and cannot be justified, irrespective of how much such blinks might help contact lens performance. Patients should be asked to practise relaxed complete blinks that do not involve the facial muscles, but should only involve the 'muscles of the lid' (the levator and the palpebral portion of the orbicularis). They should be warned against developing slow blinks while practising, as these will look unnatural, reduce efficiency and attract the wrong kind of comments from friends. Thus, an efficient blink is complete, relaxed and rapid and the ratio of these to incomplete, blinks can be increased by frequent periods of practising voluntary blinks with these characteristics. Sessions of 20 blinks, 20 times per day for a week should be sufficient, but patient motivation to achieve this is of paramount importance. A full explantation of the problems associated with inefficient blinking should be given using any aids such as photographs, to help establish understanding. Without these explanations it is not possible to motivate the patient to do the exercises both properly, and often enough, to achieve the required changes. The matter may be crucial as inefficient blinking may be the only barrier to complete success with contact lenses (*see also* Chapter 8).

Signs: Interrupted tear layer (prowline) across the pupil region of the lens front surface (*Figure 18.2*), excess tear debris under lenses, and superficial punctate epitheliopathy on the inferior area of the cornea exposed by partial blinks, may be observed in soft lens wearers. Another important clue is the observation of excess drying and deposits on the inferior, exposed area of lenses. These deposits are particularly noticeable on lenses that do not rotate (toric and/or prism ballast etc.) (*Figures 18.3, 18.25 and 18.26*).

Management: Maximize contact lens comfort when blink inefficiency is due to contact lens irritation; remove contact lenses for extended reading periods, especially in air conditioning/central heating; use tear supplements; prescribe blink efficiency exercises (*see* **Tear deficiency**).

Bubbles of air

When trapped under lenses, bubbles may form a froth. An excessively steep lens fitting may trap a bubble of air at the time of insertion (*Figure 18.4*), or during lens displacement with eye movements, and successive blinks cause the bubble to break up into a froth. In the case of rigid lenses a flatter fitting is indicated. However, in some keratoconus fittings, excess para-apical or inferior peripheral clearance will lead to froth formation (*Figure 18.5*) and, although a



Figure 18.3 A partial blink allows the inferior portion of the lens to dry, increasing the deposition of tear residues

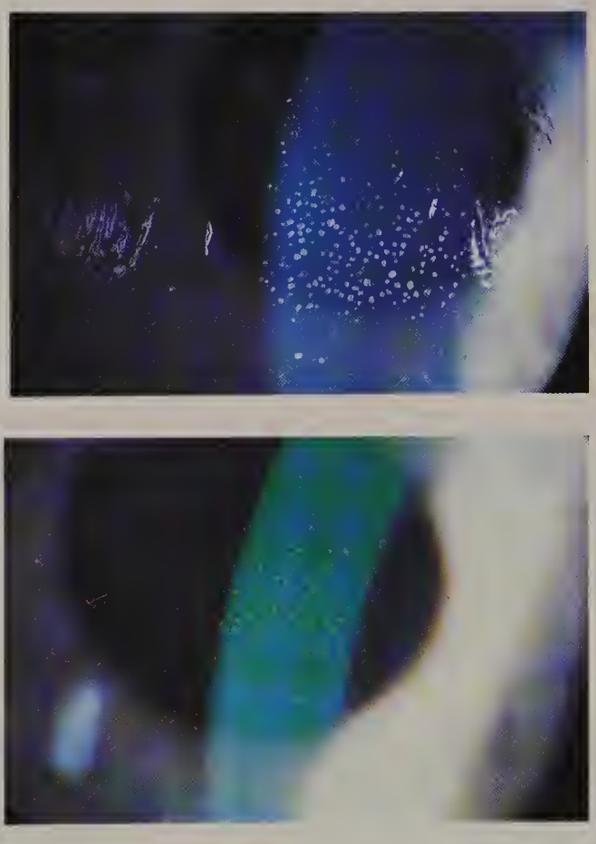
fenestration can relieve the problem, it should be noted that, in some cases, the fenestration itself allows the bubble to form. Repeated fluorescein observation during blinking and eye movements will reveal whether a fenestration is desirable. Conversely excessive edge lift will allow the entry of bubbles under the edge and possibly into the back optic portion. Bubbles under soft lenses (*Figure 18.6*) can form a finer froth that is usually observed in association with stationary tear debris. These findings may indicate a fitting with insufficient lens movement. Centrally located froth is likely to reduce vision only slightly, if at all, but can cause increased flare due to light scattering. Froth may



Figure 18.4 Excess apical clearance can permit bubble formation



Figure 18.5 In keratoconus, bubble formation can easily occur



(a)

(b)

Figure 18.6 Dimple staining can occur with both rigid (*see Figure 18.7*) and soft lenses. (*a*) Here lipid droplets are shown beneath a soft lens. With rigid lenses the dimples are more often caused by the break-up of a bubble into froth. On immediate removal fluorescein collects in the dimples or hollows left where lid pressure through the lens has compressed the droplets or bubbles into the epithelium shown in (*b*). Dimpling can be recognized by its bright staining and sharply defined edges. Staining lasts no more than a few minutes as normal blink action (or irrigation) will remove the fluorescein from the hollow since true staining has not occurred. Even with no staining the dimples may be seen by indirect slit-lamp illumination both against the dark pupil and the light iris background (retroillumination). If severe enough, they may produce blurring of vision known as 'dimple veil'. (Courtesy of A. J. Phillips)

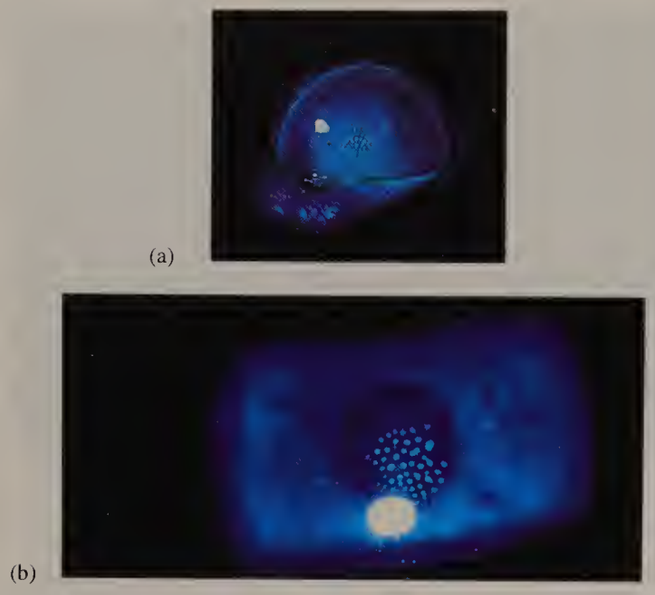


Figure 18.7 (*a*) Small bubbles trapped under a corneal lens have caused furrows and dimples in the epithelium during lens movement; (*b*) fluorescein has collected in these furrows and dimples. The resultant deterioration in vision is known as dimple veil (*see also Figure 18.6*). (Courtesy of A. J. Phillips)

cause epithelial indentation that generally disappears within an hour of lens removal. Such 'dimple stains' fill with fluorescein (*Figure 18.7*) but the corneal surface may not actually be stained unless the epithelial cells are damaged. The areas of fluorescence are typically larger, brighter and have sharply defined edges compared to punctate keratitis staining. The long-term effects of froth indentation on epithelial integrity have not been recorded. However minor, non-central froth in keratoconus fittings does not appear to harm the cornea and may be acceptable in advanced cases, if attempts to eliminate the froth by fitting modification are not successful (*Figure 18.8*) (*see also* Chapters 10, 11, 17 and 20.1).

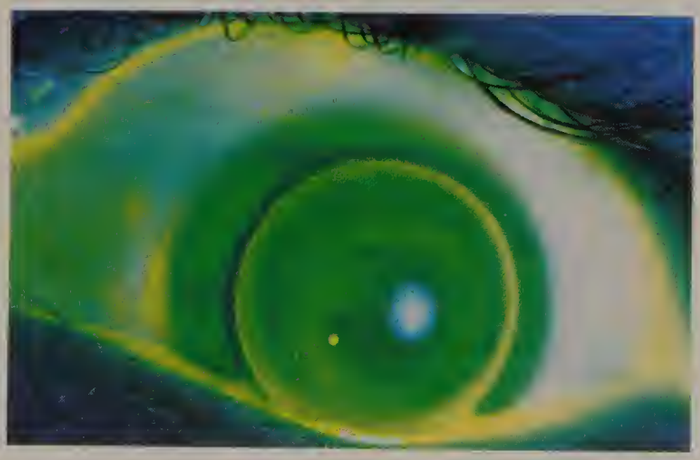


Figure 18.8 In some cases of keratoconus, minor frothing can be regarded as acceptable



Figure 18.9 The soiled case (*below*) contrasts with the new case (*above*). Dark coloured cases are not ideal because they conceal dirt and biofilm

Symptoms: Possible deteriorating vision and increased flare/glare later in the wearing day (dimple veil).

Management: Refit flatter RGP lenses or looser soft lenses. In keratoconus, a steeper fitting with a smaller back optic zone diameter may be indicated or a steeper and/or toroidal BPR_1 depending upon clinical observation.

Case contamination

This is a common suspicion at after-care visits when the external and internal appearance indicates lack of attention to routine cleaning. Cases with white or light-coloured lens wells are essential because dark colours conceal accumulated biofilm and are more likely to lead to high levels of contamination (*Figure 18.9*). Re-instruction on this aspect of lens care is frequently needed and many patients benefit from having a clear plastic pouch as a case retainer for their pocket or bag, so that dust and dirt is prevented from soiling the case exterior. Soiled cases provide a nutrient for colonies of microorganisms that may cause infection or other problems. Case contamination is presumed or suspected when infection occurs (*see* **Infection**; *see also* Chapters 4 and 9).

Management: Advise patient of association between case contamination and infection. Improve maintenance compliance; advise more frequent case replacement.

Case design problems

See **Scratches**.

Chronic hyperaemia

This may be evident at after-care visits (McMonnies *et al.*, 1982; McMonnies and Chapman-Davies, 1987a). Some patients will have been noted to present with chronically

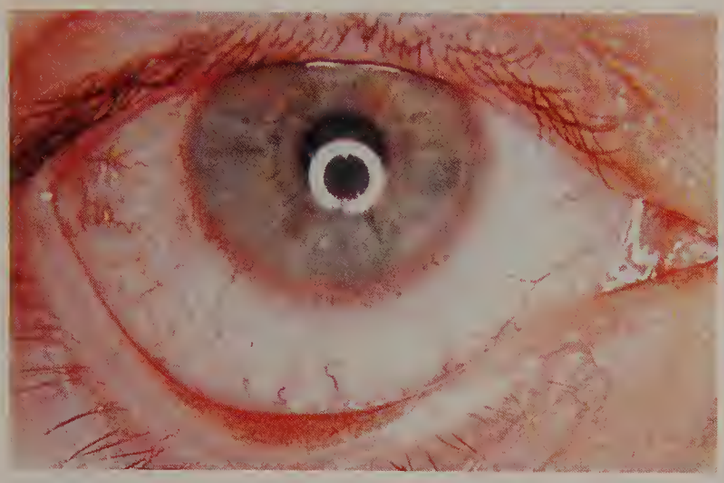


Figure 18.10 Conjunctival hyperaemia may be due to lack of sleep, eye rubbing, exposure to dust or any other occasional cause. Alternatively, conjunctival hyperaemia may be caused by contact lenses and become chronic

hyperaemic eyes at pre-fitting visits (see **Reactive eyes**; *Figure 18.10*) and contact lens wear can be expected to increase the hyperaemia. Wearing history may reveal patterns of lens wear under harsh conditions of smoke, smog, wind, dust or glare. Systemic conditions such as hay fever may be relevant. Frequently, little can be done about atmospheric or systemic factors that are unrelated to contact lenses, although they should be discussed with the patient. In the case of soft lenses, tight fittings that restrict blood flow in limbal vessels to cause passive 'limbal flush' hyperaemia should be improved. However, hyperaemia is a very common response to all kinds of contact lens trauma and looking for multiple causes is necessary if improvements in chronic levels are to be achieved (*Figure 18.11*). (*See* **Three and nine o'clock peripheral staining**; *see also* Chapters 11 and 15.)

Risk factors: Poor fitting, allergy, solution toxicity, overwear, soiled lenses, damaged lenses, excess reading/VDU work, tear deficiency, chronic low grade infection, lack of sleep, excess wind/dust/glare/smoke/smog, and poor lens maintenance compliance.

Management: Assess and monitor, preferably using a photographic reference scale (*see Figure 18.11*). Remove, treat or reduce risk factors. Improve lens fit. Reduce wear. Counselling is particularly relevant to people with reactive eyes (*see* **Reactive eyes**). Differentiate from general ocular pathology.

Compliance with instructions

Lens care and maintenance compliance cannot be assumed during after-care examinations. For example, soiled lenses serve as a prompt for having the patient recount their usual maintenance routine. Despite good initial instruction (*see* Chapter 9) that recognizes optimum teaching conditions (McMonnies, 1974a), departures from recommended techniques are common (Collins and Carney, 1986), sometimes because of laziness but sometimes because of misunderstanding or incorrect advice from other sources. In the latter case, simply eliminating the confusion is all that is required but a defensive patient may wish to deny having been taught correctly and/or having been negligent (*see* **Informed patient**). Motivating the patient towards the development of a responsible attitude will necessitate a discussion of infection risk and consequences. Also the risk of increased hyperaemia and discomfort, reduced quality of vision and shortened lens life can be described as consequences of poor compliance. Repeated or additional hand-out literature may be helpful but, depending on the patient's attitude, it may have to be read and discussed with the patient for it to have the desired effect. (*See also* Chapters 8 and 9.)

Concretions

These develop from retention cysts in goblet cells or accessory lacrimal glands in the palpebral conjunctiva, resulting in the formation of discrete white aggregates of sebaceous material and crystals (*Figure 18.12*). The formation stage is characterized by a clear vesicle that traps the gland production. The accumulated secretions form a hardened core that is gradually extruded on to the conjunctival surface.

Symptoms: Concretions are benign and associated with chronic hyperaemia, but at the stage of extrusion they may cause symptoms of a foreign body sensation (*see* **Foreign body sensation**) that could be attributed to a contact lens. Alternatively, an extruding concretion in the superior palpebral conjunctiva may cause symptoms when the cornea is exposed on lens removal, but which are not present when the contact lens is worn and serves to protect the cornea from irritation. The same finding may occur in the case of a foreign body retained under the upper lid or a trichiasis-related lash irritation (*Figure 18.13*). (*See also* Chapter 8.)

Management: Counsel patient to expect symptoms to disappear as concretion naturally extrudes.

Corneal fatigue/exhaustion

This is a non-specific term which is used to describe a phenomenon of lost tolerance to contact lens wear. Often the mechanism of lost tolerance is not evident, especially when the patient is examined after a period of forced abstinence from lens wear, but may be caused by chronic corneal hypoxia and acidosis together with endothelial dysfunction (Sweeney, 1992). Usually there are no symptoms until contact lenses are re-worn but then the findings can be hyperaemia, photophobia, lacrimation, sting and discomfort. The patient is frustrated because of the previous record of satisfactory tolerance, and the practitioner finds attempts to relieve symptoms, at best, only moderately successful.

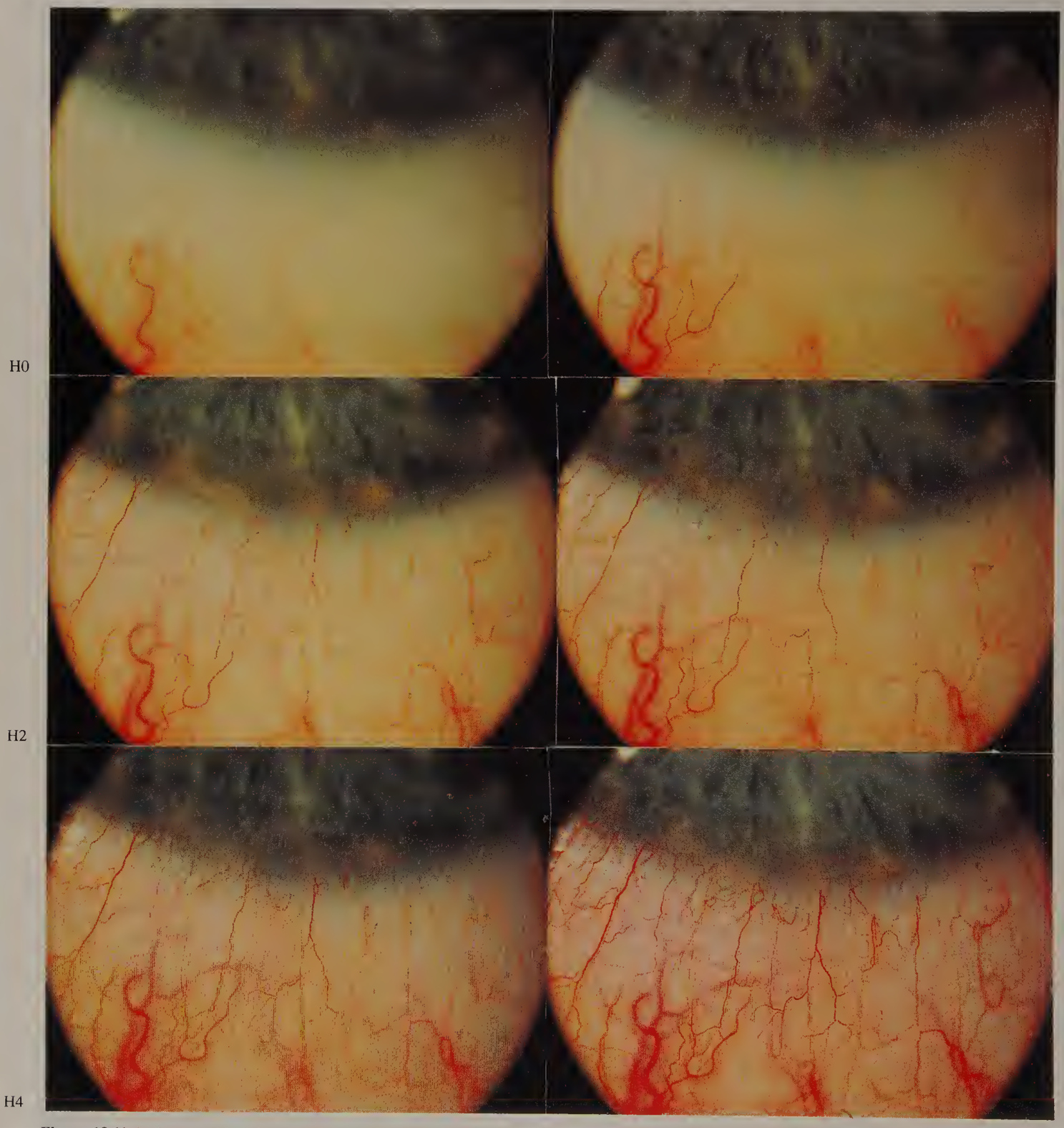


Figure 18.11 A photographic reference scale can be used to assess hyperaemia associated with contact lenses, reactive eyes, over-wear, infection, allergy irritation, cosmetics, preservatives, tear deficiency etc. These may be graded from H0 (top left) to H5 (bottom right). (From McMonnies and Chapman-Davies, 1987b, by permission of the *American Journal of Optometry and Physiological Optics*). (*see also* Appendix D)

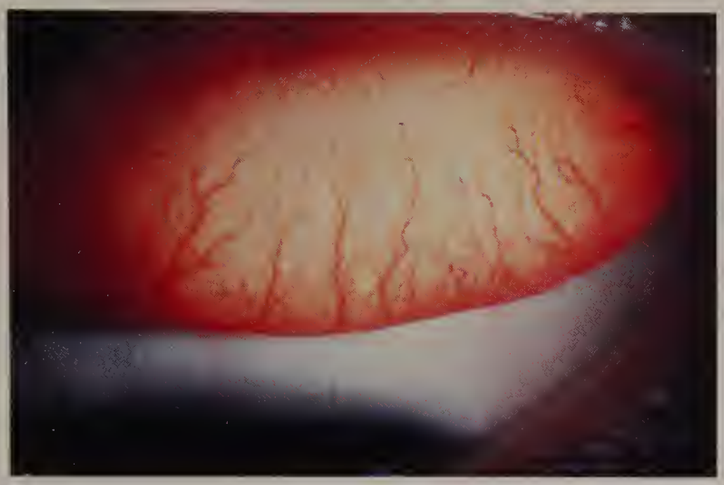


Figure 18.12 Retention cysts in goblet cells or accessory lacrimal glands in the palpebral conjunctiva may result in the formation of discrete white aggregates of mucus, sebaceous material and crystals. These concretions may cause irritation when they extrude to the surface

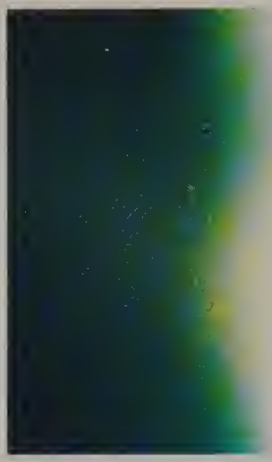


Figure 18.14 Endothelial bedewing observed in the region of the inferior pupil margin 3 days after the intense oedema from an over-wear episode had cleared. Bedewing is thought to represent inflammatory cells adhering to the endothelium

Signs: History of chronic over-wear or fittings that provide barely adequate oxygen transmission and tear circulation. Possible history of conjunctivitis where careful biomicroscopy reveals residual infiltrates in the cornea which suggest that a viral infection may have been the initial problem (*see* **Corneal infiltration**). Endothelial bedewing (*Figure 18.14*), epithelial basement membrane dystrophy, endothelial guttata and polymegathism (*see Figure 15.23*), fine pigmentary keratic precipitates and tear deficiency may be evident. There may be systemic factors associated with corneal fatigue, such as chronic fluid retention and hormonal imbalance or emotional physical stress (e.g. overwork) (*see also* **Hormonal factors**).

Management: Discontinue lens wear. Refit with very high gas permeable material when corneal integrity and transparency is fully recovered, including regularity and stability of keratometric readings. Limit wearing time.



Figure 18.13 Severe entropion and trichiasis associated with blepharitis. The use of a bandage soft lens allowed regeneration of damaged corneal epithelium and prevented further disturbance prior to surgery. (Courtesy of D. Westerhout)

Corneal infiltration

Infiltration of the cornea with inflammatory cells may occur in response to solution preservatives or another immune stimulus associated with contact lenses. Such infiltrates should dissipate on removal of the contact lenses and differential diagnosis with the chronic phase of a viral infection needs to be made for effective management. A history of a recent red eye episode, that cleared with or without treatment, is a clue to a viral aetiology for infiltrates that do not disperse with lens removal. In some cases many weeks may be needed before contact lens wear can be resumed. Premature resumption of lens wear may result in no symptoms on day 1, but on day 2 or 3 the patient will be very disappointed to experience a red eye episode that indicates the need for an additional and greater period of abstinence from lens wear. Subepithelial infiltrates do not stain and may only be detected with careful marginal retroillumination or sclerotic scatter. In nummular keratitis, corneal scarring that is apparent in direct focal illumination may remain after infiltrates have cleared. Cautious resumption of contact lens wear is possible in these cases. In all cases of resumption following infection or immune response, lens purging (*see* **Purging**) or lens replacement is indicated as toxic contamination with staphyloccus toxins, viral extract or inflammatory by-products should be suspected (*Figure 18.15*).

Management: Abandon lens wear until the cornea is clear. Consider improvement in lid hygiene and other treatment for blepharitis. Suspect contaminated lenses and solution toxicity. Resume wear cautiously following purging or replacement.

Corneal oedema

This is a common response to contact lens wear (*see* **Over-wear syndrome**). For some patients low levels of corneal



(a) (b)

Figure 18.15 Stromal infiltrates may occur in association with a variety of adverse reactions to lens wear, such as the acute red eye reaction, contact lens-induced superior limbic keratoconjunctivitis, stromal vascularization and corneal ulceration. Infiltrates appear as hazy, grey areas which (*a*) may be focal, or (*b*) diffuse. They typically occur near the limbus and the adjacent conjunctiva is often hyperaemic. Infiltrates are most probably leucocytes or monocytes lying between collagen fibres in the stroma. ((*a*) Courtesy of T. Grant; (*b*) courtesy of A. J. Phillips)

oedema are a normal response to sleep, and this factor needs to be taken into account when evaluating contact lens oedema symptoms that are exaggerated in the first hours of waking, especially for extended wear patients (*see* Chapter 15). Biomicroscopy permits objective evaluation of epithelial oedema (*see* Chapter 6) (Schoessler and Lowther, 1970). Epithelial oedema will be observed when hypotonic tears are provoked by contact lenses that cause a foreign body sensation (*see* **Foreign body sensation**), especially in the early stages of adaptation to rigid lenses when corneal and lid margin sensitivity have not reduced significantly. A similar epithelial oedema can be induced by prolonged emotional tearing or exposure to hypotonic water when swimming. Stromal oedema is a common response to contact lens-induced hypoxia and increased corneal thickness is evident using a pachometer.

Signs: The appearance of vertical striae in direct observation of a parallelepiped slit lamp beam (*see* Chapter 6 and *Figure 15.6* and Appendix D). These wispy white lines lie in the posterior stroma and do not have the discrete appearance of lines of Vogt seen in keratoconus, or more anterior nerve fibres observed in normal corneas. Higher levels of stromal oedema cause folds in Descemet's membrane to appear as dark lines that traverse the specular reflection from the endothelium (*see Figure 15.7* and Appendix D). Very high levels of stromal oedema result in loss of corneal transparency (*see* Chapters 11 and 15). Corneal oedema shows loss of transparency of the epithelium evident with an optic section or marginal retroillumination as well as some limbal and conjunctival hyperaemia (*see also* Chapters 6, 10 and 11).

Symptoms: Photophobia, haloes, spectacle blur, stinging, burning and pain.

Management: Refit thinner lenses and/or more gas permeable materials; reduce wearing times. Consider cyclical influence of menstrual factors or pregnancy (*see* **Hormonal factors**).

Cosmetics

Cosmetics need not cause problems for contact lens wearers if used sensibly, but advice may be required when problems are noted. The main difficulties are accidental soiling of lens surfaces (*Figure 18.16*) and chronic irritation associated with cosmetic contamination of lashes, lid margins and tears, that leads to physical and/or allergic reactions. It is better to apply eye make-up after the lenses have been inserted. For presbyopic hyperopes, special cosmetic application spectacles with hinged lenses may be necessary to ensure accurate application, and good illumination and a magnifying mirror also help increase the precision of application. Mascara that releases particles onto the conjunctiva should be avoided in favour of non-particulate types, and preferably a type that is not water-based, so that lacrimation associated with contact lens wear (e.g. dust under a rigid lens) does not become an embarrassment. However, grease-based cosmetics can increase the oil in the tear film. Having lashes tinted is a safer and satisfactory alternative to mascara for some contact lens wearers. A cream eye shadow that smudges easily should be avoided if

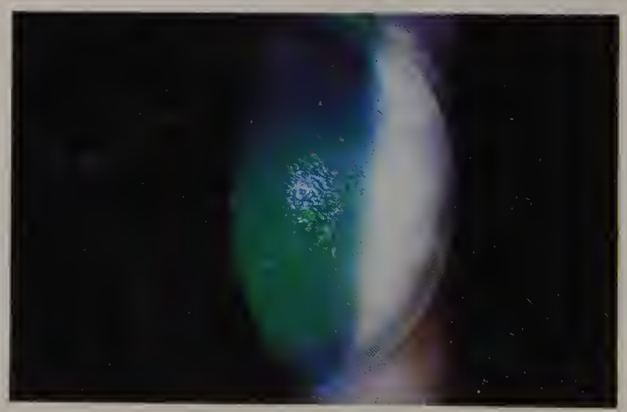


Figure 18.16 Poor surface wetting of an RGP lens due to residual hand cream, following failure to wash hands adequately. A similar appearance is seen on lenses coated with excess lipid secretion

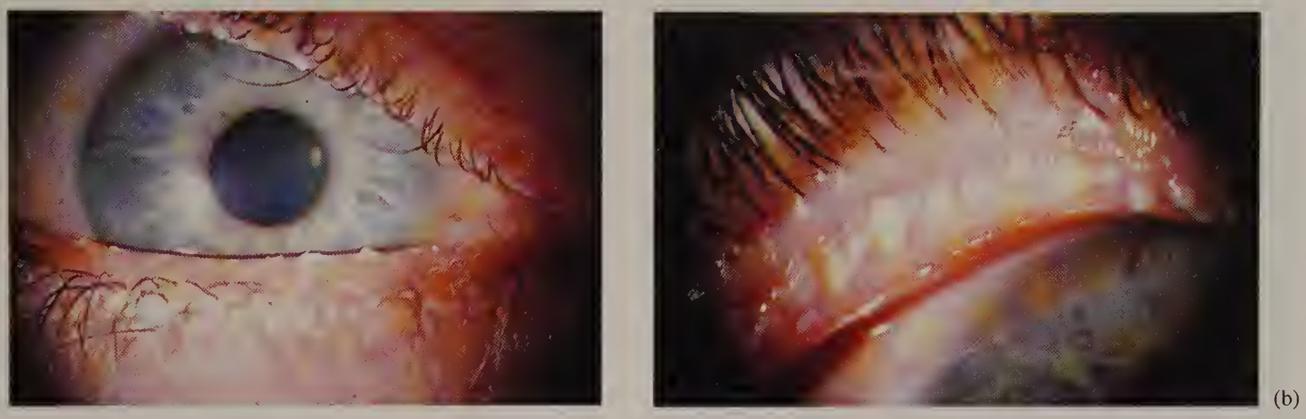


Figure 18.17 Severe meibomian hypersecretion. (a) The excess cloudy secretion contrasts with normal clear gland products. (*b*) The upper lid margin shown in more detail

lid manipulation is required, but powders can cause different problems. Hypoallergenic brands are preferred, especially for the atopic patient, as sensitivities can develop, particularly because cosmetics and cosmetic containers become increasingly contaminated with use. Additionally, cosmetics should be regarded as a possible source of infection or as potential causal factors in a chronically infected and irritated eye, especially when applied excessively. Eye liner applied to the lid margin can easily be a source of irritation and interference with meibomian gland function.

Hyperaemia and irritation may also develop from agents used to remove cosmetics or from false eyelash glue, skin conditioners and soaps. Trials by elimination of suspected factors may lead to a cause of irritation or reaction being identified. Over-frequent application of suntan lotions and anti-wrinkle creams to the lids and adnexa is sometimes associated with tear lipid that is excessive and/or contaminated. Careful counselling will be required when a desire to wear inappropriate cosmetics outweighs a common-sense approach from the patient (*see also* Chapters 8 and 9).

Counselling

Counselling patients at after-care visits may be an important component in contact lens management. The most common circumstances requiring counselling involve patients with chronic tolerance problems (chronic hyperaemia and symptoms) associated with a life-style that creates high demands on time and causes excessive stress. Common factors in this syndrome are over-work complicated by study and/or frequent and demanding social activities that lead to a chronic pattern of insufficient sleep and contact lens overwear. Advising such patients to reduce demands on their eyes and contact lenses is not usually productive without an examination of the underlying causes of their high stress levels. To this end, careful counselling is required (*see* Interviewing and history taking at the beginning of this chapter). (*See also* Chapters 8 and 9.)

Dermatological conditions

These can be associated with reduced contact lens tolerance reported at after-care visits. Any evidence of a deteriorated adnexal or facial skin condition should be considered as a potential causal factor in symptom analysis. Medical treatment may be indicated and reduction in, or cessation of, lens wear could be necessary until elimination or control of the dermatological condition is re-established. Signs of these conditions include erythema and pustules of acne rosacea, oiliness, scales or crusts of seborrhoea, erythema and various localized eruptions, including exudative lesions associated with eczema and dermatitis (*Figures 18.17* and *18.18*) (*See also* Chapter 8).

Diabetics

Such patients may be predisposed to contact lens intolerance, although published studies provide conflicting evidence (*see also* Chapter 8). The corneal endothelium in diabetes has been found to be both normal (Pardos and

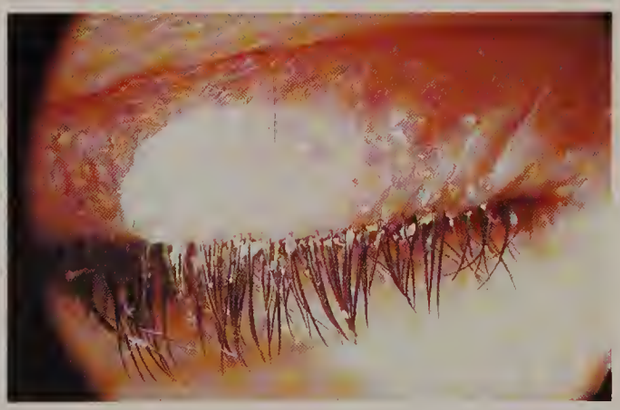


Figure 18.18 Blepharitis indicating the need for treatment and sustained lid hygiene to improve the chances of good contact lens tolerance. Dead epithelial tissue accumulates around the base of the lashes. This material is a nidus for infection and is irritating in the tear film

Krachmer, 1980) and morphologically abnormal (Schultz *et al.*, 1984). Healing rates for the epithelium were found to be the same for diabetics and non-diabetics (Snip *et al.*, 1980), although the same study found a tendency towards recurrent epithelial defects in diabetics, a finding that is supported by a study that showed that diabetic corneas have increased epithelial fragility (O'Leary and Millodot, 1981). Diabetic corneas have also been shown to have depressed touch sensitivity (O'Leary and Millodot, 1981). Variation in sampling criteria in these studies may explain the different results found (Snip *et al.*, 1980). Some diabetics show good tolerance to contact lenses and individual response to contact lens trauma may depend on age of onset of diabetes, whether there is insulin dependency and whether the response to insulin is satisfactory. A diabetic patient may be predisposed to epithelial fragility or other form of contact lens intolerance, and this possibility should be considered at after-care examinations, even if the patient has not been previously diagnosed as diabetic.

Dimple veil

See **Bubbles of air**.

Diplopia

This may present as a symptom of unstable binocular vision, for example, during the adaptation phase of a fitting for an intermittent strabismus or aphakia (especially monocular). Vision training to develop binocularity may be needed to aid adaptation to the new relationship between retinal image sizes, accommodation and convergence that prevails with the change from spectacles to contact lenses. However, a patient who has been able to maintain single vision with decentred spectacles may develop diplopia as soon as contact lenses are fitted. A complaint of double vision may be a monocular symptom in the case of poor pupil coverage, especially in the case of bifocals, occurring when secondary ghost images are seen (*see* **Ghost images**) and are described as double vision. (*See also* Chapters 5, 10 and 16.)

Discoloration

This usually occurs as soft lenses degrade with use, although the reasons for these changes are not completely understood. Possibly the selective adsorption of amino acids or other by-products of the protein-denaturing process on the lens surface, leads to gradual loss of transparency (Wardlaw and Sarver, 1986). Lenses may perhaps adsorb substances from the skin of the hands during surfactant use and it is possible that some patients have tear chemistry that causes increased discoloration in association with particular systemic medication (*see* Chapter 4). Sometimes maintenance methods lead to discoloration. Heat disinfection and certain preservatives, such as sorbic acid, cause the discoloration of higher water content lenses (Wardlaw and Sarver, 1986). However, mild to moderate degrees of discoloration do not seem to have clinical consequences, although some patients demonstrate a



Figure 18.19 Soft lens discoloration of unknown aetiology. (Courtesy of A. P. Gasson)

capacity to cause severe lens discoloration over short periods of time, leading to a need for replacement because lenses are cosmetically unsatisfactory (*Figure 18.19*). (*See also* Chapters 11 and 13.)

Management: Usually discoloration can be ignored. If discolored lenses give rise to a poor appearance they can sometimes be improved using a hydrogen peroxide disinfection procedure or intemittent sodium perborate cleaning (*see* Chapter 4) or else they can be replaced. A change to disposable or frequent replacement lenses may be indicated. (*See also* Chapter 4.)

Discomfort symptoms

For details, *see* Symptoms of discomfort at the beginning of this chapter and also **Concretions**; **Irritation**; **Itch**; **Lid twitch sensation**; **Stinging**.

Disposable lenses

Many after-care problems can be prevented or reduced by the use of disposable or frequent replacement lenses. For example, most surface deposit problems are relieved using these types of lenses and giant papillary conjunctivitis may be helped. Inexpensive disposable lenses can be useful when trying to answer the fundamental after-care question: 'Is the problem due to an intolerable lens or an intolerant eye?' A short-term trial with a disposable lens may help resolve the dilemma. If the symptoms persist with a disposable lens, an intolerant eye is probably a correct diagnosis. If the symptoms are relieved with a disposable lens, then suspicions about an intolerable lens are probably confirmed.

Distortion

Distortion or warpage of rigid lenses may ocur due to lens ageing or accidental stress in handling, and can lead to alterations in lens performance. When a lens flattens,

steepens or develops toricity, there will be effects at both front and back surfaces, as well as in the shape of the tear lens. For this reason over-refraction results through a patient's lens should not be used for re-prescribing without checking lens parameters. Distortion of soft lenses is apparent if they do not show a regular edge contour when placed on a fingertip and when focimeter readings show distortion. Retinoscopy is a superior means of examining for lens distortion and/or poor optical quality, especially in the case of soft lenses (*see* Chapter 11). When the quality of visual acuity is reduced, the retinoscopic reflex may show evidence of a refractile disturbance that is not detectable by any other objective means (clinical or laboratory). (*See also* Chapters 5, 10 and 12.)

Dry eyes

For dry eyes *see* **Tear deficiency**; **Tear deficiency management; Three and nine o'clock peripheral stain**.

Duplicate lenses

These can be the source of many problems, especially when manufacturing tolerances result in a lens that is significantly different from the one it replaces. This problem may occur when the same laboratory is involved, but is more likely if a second laboratory attempts to duplicate the original prescription (*see also* Chapters 12 and 13). Apart from variations in quantifiable parameters, problems arise with features of lens manufacture (peripheral flattening of the back surface, front optic zone diameter, edge shape etc.) that cannot always be quantified. The older the prescription, the greater the chance of problems arising from attempts to produce a duplicate, especially if the original lens was modified to improve performance, or has undergone age-related changes, such as a flattening of curvature, prior to its loss. The potential for problems with duplicate soft lenses is not as great as found with rigid lenses because BOZR variations are not as critical.

Edge shape

Adaptation to RGP lenses may be made more difficult if there is an unsatisfactory edge shape (*Figure 18.20b*). Adapted patients are sometimes capable of wearing lenses with unsatisfactory edges without discomfort but a new duplicate lens can cause problems. Persistent awareness of lenses may result from a poor edge shape and suspicions can be confirmed using a ×20 hand-held magnifier and a point source of light or its equivalent (McMonnies, 1986c) (*see* Chapter 12). Practitioners may choose to modify edge shape themselves (*see* Chapter 22) or they may prefer to send the lens to the manufacturer for this purpose. A shape similar to that shown in *Figure 18.20a* will reduce lens awareness. It shows a good balance between edge thickness, roundness and taper. Variations from this model may be indicated when matching the shape of a patient's previous lens which has proved to be comfortable.

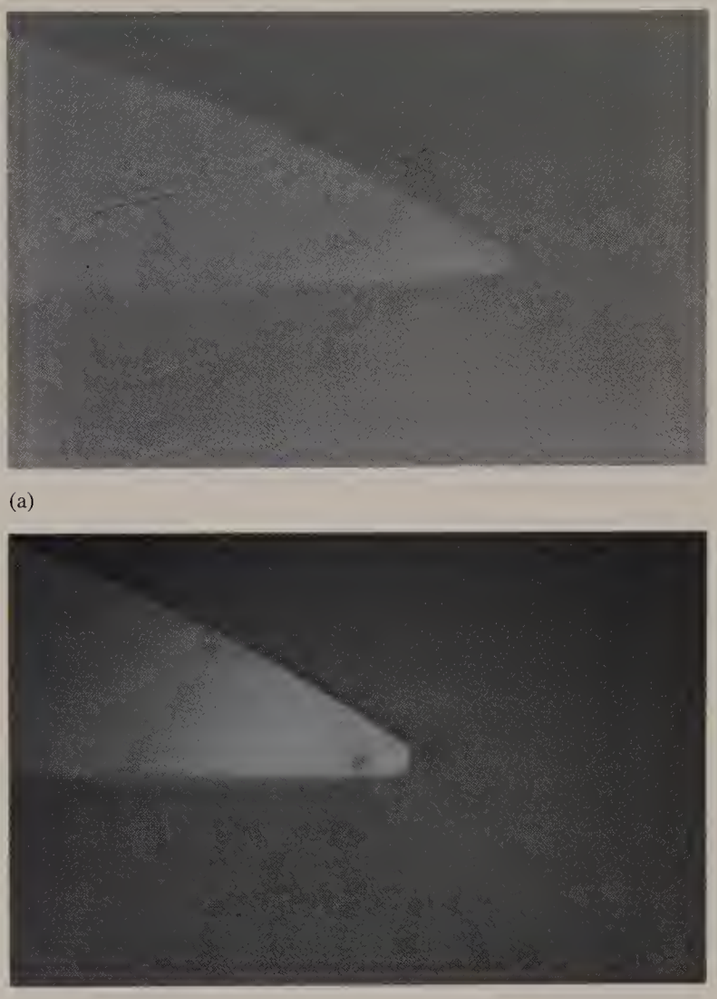


Figure 18.20 (*a*) Example of a desirable edge shape showing good taper, rounding and thickness. (*b*) Poor rounding on the anterior edge may cause increased awareness of the lid margin

Emergency examinations

These are not usually true emergencies as the drama may be more in the patient's mind than real, but the patient's problem must still be handled sympathetically. For example, depending on the patient's personality, a lost lens can be a greater crisis for the low ametrope than for one with a very high refractive error. A lens that cannot be retrieved from under the lid is a greater problem if there is fear of the lens 'lodging in the brain'. True emergencies are not common. Severe over-wear oedema may occur with PMMA lenses (*see* **Over-wear**), but is seldom encountered with gas permeable materials. Patients should be instructed to report marked symptoms of photophobia and irritation, especially when associated with conjunctival injection and increased lacrimation or exudative secretions and always to remove the lens in such cases. The pathology may not be contact lens-related, however, and care should be taken to differentiate the signs and symptoms from those of other ocular emergencies, for example acute glaucoma or retinal detachment. Often a patient needs to be reminded to remove the contact lens and some might resist this advice. The earliest

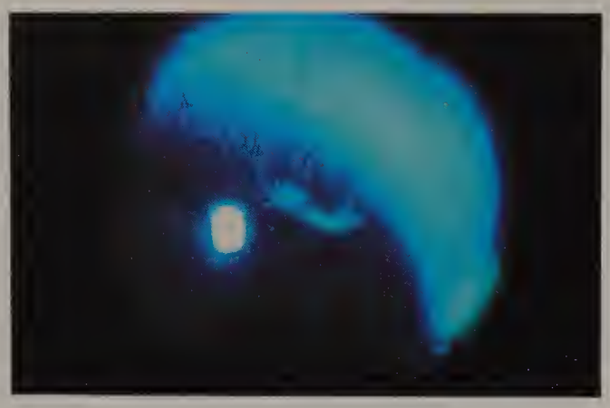


Figure 18.21 Symptomless superior limbal epithelial splitting and hypertrophy stained with fluorescein and showing vascularization. (Courtesy of A. P. Gasson)



Figure 18.22 Superior limbal epithelial split found in a hydrogel lens wearer causing pain, dense staining and diffusion of the stain into the underlying stroma, with increased vascularization as compared with *Figure 18.21*

re-examination should be arranged and medical treatment given when appropriate. (*See* **Out of Hours Emergencies**; *see also* Chapter 9.)

Endothelial bedewing

This appears as a cluster of drop-like particles on the endothelial surface, usually located near to the inferior pupil margin, and is normally only visible using marginal retro-illumination (*see* Chapter 6) and at least ×25 magnification. This finding may occur in association with marked contact lens-induced corneal oedema and represents cellular keratic precipitates without obvious exudate (McMonnies and Zantos, 1979). After the oedema subsides and the cornea has regained transparency, the observation of endothelial bedewing may indicate that a limited uveal response occurred in association with the corneal oedema. It has been reported that chronic contact lens intolerance can be associated with endothelial bedewing in a cornea that otherwise appears to be normal (McMonnies and Zantos, 1979). Physiological endothelial bedewing will show amoeboid movement of particles and this observation may be an important indication of recovery when attempting to re-establish contact lens tolerance following a severe oedema response (*see* **Over-wear**) (*see Figure 18.14*).

Management: Detection of endothelial bedewing following over-wear oedema indicates the need for greater caution before resuming contact lens wear, preferably with a material of higher Dk, as difficulty re-establishing routine lens wear may be experienced. In the absence of adverse lens performance, endothelial bedewing can be regarded as non-diagnostic.

Endothelial response

This response to contact lens wear consists of dark areas of non-reflecting individual cells (blebs) when observed by specular reflection (*see Figure 15.19*). A normal finding is characterized by bleb formation that peaks approximately 30 minutes after insertion, and then falls back towards a normal continuous endothelial reflection and appearance (Williams and Holden, 1986). For daily wear patients, care should be taken not to confuse these changes with corneal guttata (*see* **Guttata**), and observations after at least 1 hour of wear may be more reliable. However, in the adapting stage of extended wear, bleb responses show peaks at eye opening and 6 hours later. These responses are not detected after about 5 days of extended wear (Williams and Holden, 1986). (*See also* Chapters 6, 7 and 15.)

Epithelial basement membrane dystrophy

See **Recurrent corneal erosion syndrome** and Chapter 20.7.

Epithelial dimpling

See **Bubbles of air**.

Epithelial splitting or SEAL (superficial epithelial arcuate lesion)

This is characterized by a horizontal lesion, usually adjacent to the superior limbus and occurring in soft lens wearers especially those wearing thick periphery high water content lenses (*Figures 18.21, 18.22*; *see also* Chapters 11 and 15). Depending on the stage of repair or splitting, the split will show diffuse stain into the surrounding cornea. The cause of this response is not known but may be related to predisposing epithelial fragility factors. Precipitating factors may include tightening of lens fittings through tear hypotonicity, localized drying associated with the upper lid tear meniscus or overall lens dehydration. The split may occur during lens removal or during blinking when lid shear forces may be increased by surface deposits, palpebral conjunctival thickening or tear deficiency. Any combination of these proposed causal factors may be associated with prolonged periods of reading as an additional factor. The finding is sometimes symptomless, but usually is associated

with irritation leading to intolerance. In mild cases, superficial healing can occur overnight and cautious wear can be resumed if there are no obvious fitting problems. In some cases, however, healing takes longer and care should be taken to ensure that the various risk factors are eliminated to avoid recurrence.

Management: If possible, abandon lens wear until the epithelium heals with the expectation that healing of the basal cell layer takes much longer than superficial healing (indicated when staining has disappeared). It may be found that resumption of wear in the existing fitting is possible but refitting lenses with improved movement characteristics or a different water content may be necessary or refitting with RGP lenses (*see* **Superficial punctate epitheliopathy).**

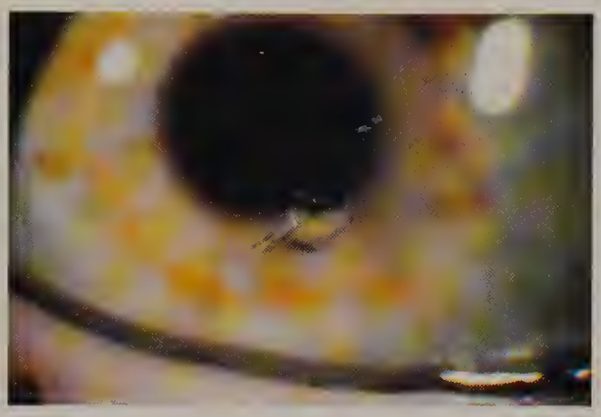


Figure 18.23 Damaged soft lens, with central nick possibly caused by a foreign body or fingernail, or due to folding a partially dehydrated lens. (Courtesy of A. J. Phillips)

Epithelial staining

See **Superficial punctate epitheliopathy**.

Fenestrations

Fenestrations are seldom used with RGP lenses but if they are necessary they should have polished bevels to avoid epithelial abrasion. Sometimes they can become plugged with a solid core of mucus and tear debris that requires removal with a sharpened/splintered soft match wood or a brush bristle, because use of a metal pin or needle will risk lens damage. Where possible, care should be taken not to position a fenestration over the pupil area as this can lead to visual interference.

When fenestrations facilitate tear circulation, oxygen-dependent metabolism is promoted and oedema levels are reduced. In addition, fenestrations may aid the elimination of metabolic waste products that could otherwise accumulate and cause tissue disturbance. For example, red eye reactions in extended wear may be reduced if fenestrations increase tear circulation.

The value of placing fenestrations in current generation soft lenses is minimal, although there appears to be an advantage gained in reducing peripheral oedema with a fenestration 3 mm from the edge (Brennan *et al.*, 1986). (*See also* Chapters 10, 17, 18, 21 and 22.)

Management: Sharpened match wood or a fine nylon bristle from a hair brush can be used to clear blocked fenestrations. Poor or unpolished fenestration holes can be improved using contact lens polishing liquid and a sharpened match (*see* Chapter 22).

Fingernails

These may be a source of eye and soft lens damage depending on their length, condition and the technique for lens removal employed. Jagged nicks and gouge marks should be suspected of being caused by accidental fingernail contact (*Figure 18.23*). Occasionally a patient with long nails will accept advice that the fingernails of at least one index finger and thumb need to be kept shorter to allow for safe removal. Otherwise a technique that recognizes the possible danger to lens or eye tissue should be taught. However, the problem may recur intermittently when nails grow beyond manageable length. (*See also* Chapter 9.)

Fit evaluation

Patients should wear their lenses for after-care examinations, even in the presence of symptoms, because useful evaluations will depend on seeing lens position, axis location and movement when lacrimation and blinking have stabilized. Soft lenses appear tight when bound to the ocular surface by osmotic forces in the presence of hypotonic excess tears. Tight soft lenses show little or no movement with upward gaze blinks and can cause limbal conjunctival indentation. However, limbal indentation can occur with a well-fitted lens that shows good movement with upward gaze blinks, when the conjunctiva is oedematous and susceptible to indentation. Movement and centring of rigid lenses should first be assessed with white light because the instillation of fluorescein can invalidate the evaluation by significantly altering tear volume. Fluorescein assessment should follow to allow for evaluation of the lens/cornea relationship and tear circulation. (*See also* Chapters 10, 11, 14–17 and 20.)

Flare

This occurs with inadequate pupil coverage by the optic zone of the lens. Large pupils, rigid lenses, small optic zone diameters on either front or back surface and lenses that decentre are all factors likely to induce flare. Bifocal designs with small central optic zones are commonly associated with flare. Flare is most apparent when light sources are seen against a dark field and at night with dilated pupils. This problem may be insurmountable with bifocal lenses but reasonable flare levels can become progressively acceptable because new patients report the symptoms less frequently with the passage of time,

presumably as lacrimation reduces, blink efficiency improves and lens centration is maintained more effectively. (*See also* Chapters 5, 10, 11, 14 and 16.)

Management: For patients new to contact lenses, flare can be expected to subside significantly during the first month of wear. If flare persists, lens designs with larger central optic zone diameters are indicated (front and/or back surface). Improving lens centration will help, or refitting with soft lenses.

Flexure

This is seldom a problem with soft lenses that wrap around the cornea but thin rigid lenses can flex with lid pressure during blinks, depending on corneal astigmatism and the material used (*see* Chapter 3). The cornea/BOZR fitting relationship is also important. Steep lenses flex more and the least flexure is found with lenses fitted in alignment (about 0.08 mm flatter than the flattest corneal meridian) (Herman, 1983). The critical centre thickness for PMMA lenses is about 0.12 mm, but RGP materials may vary from this guideline figure and usually need to be slightly thicker to reduce flexure (*see* Chapter 10). Changes in residual astigmatism due to lens flexure should be considered as a possible cause of altered acuity noted at after-care visits.

A critical aspect of flexure measurement using a keratometer concerns the effect of patient blinking. The mire images are easily distorted by an irregular pre-lens tear layer and repeatability of measurements is increased by making measurements immediately after a blink that improves mire image quality. Unfortunately, blinking is likely to increase lens flexure, especially when a patient blinks consciously on request. As a consequence, it is reasonable to expect that keratometric assessment quantifies maximum lens flexure. Lenses may recover their manufactured shape during inter-blink intervals so that patients may have improved vision just before a blink. Conversely, blur due to residual astigmatism resulting from lens flexure could be maximum immediately following a blink. Very thin lenses may become permanently flexed into a toric shape that aligns with corneal astigmatism. Although distorted from their manufactured shape such lenses may give satisfactory performance if they are meridionally stable on the eye (*see* Chapters 5 and 10).

Management: Ignore flexure that does not cause significant fluctuation or deterioration in vision. Change to a thicker design if necessary, preferably using a material with more stable characteristics, but be aware of reduced oxygen permeability (*see* Chapter 10).

Fluorescein

Use of fluorescein is limited by lens materials that absorb ultraviolet so that the appearance of fitting patterns is not evident when an ultraviolet lamp is used. For these types of materials, it is necessary to use a cobalt blue filter on a biomicroscope or appropriate filters over a white hand UV or Burton lamp to obtain a satisfactory evaluation of fit (Pearson, 1986) (*see* Chapters 4, 10 and 23). Fluorescein should be used to examine soft lens patients after lens removal with the precaution of irrigating the eyes with a tear supplement or physiological saline prior to reinsertion, especially for patients with reduced tear flow. Residual discolouration of soft lenses is not usually permanent and if necessary can be removed with hydrogen peroxide or sodium perborate.
(*See also* **Tear deficiency**.)

Flying

Flying can create problems when reduced oxygen levels become critical in cases of borderline contact lens tolerance, especially when systemic oedema develops during a long flight. Window glare is frequently excessive and contact lens-induced oedema exacerbates the discomfort. However, even for short flights in pressurized cabins, the principal difficulty is likely to be the dehumidified air, and tear supplements may be necessary. Contact lenses should be removed before boarding for long flights, especially if there is a long period of wear during the day prior to boarding for an evening flight. Even for extended wear lenses, sleep will be complicated by the adverse conditions on board and the very unsatisfactory circumstances for handling contact lenses in flight.

The use of contact lenses by aircrew is covered in Chapter 8.

Foreign body sensation

This may be otherwise described as a gritty or 'lash in the eye' sensation. A real foreign body sensation occurs when solid matter is trapped under a lens (soft or rigid) and causes epithelial abrasion. Instantaneous lacrimation should wash the foreign matter away in the case of rigid lenses but a soft lens needs to be deliberately displaced with an index finger, to one side of the cornea, to allow the foreign body to be displaced from under the lens. Voluntary eye movements in the opposite direction to the lens displacement will exaggerate the lens excursion relative to the cornea, and increase the chance of success. If the foreign body sensation persists, lens removal and rinsing is indicated. The 'lash in the eye' sensation associated with adaptation to rigid lenses is also sometimes called a foreign body sensation (in this case the lens is the foreign body). As adaptation proceeds, lid and corneal sensitivity reduce, together with lens awareness, until the lens causes either no sensation or only a mild awareness that is easily ignored. Any lens that causes persistent awareness in an adapting patient may be found to have a poorly formed edge (*see* **Edge shape**), even with a soft lens (especially if fitted very loosely and/or too small and/or with truncation so that limbal irritation occurs). Apart from poor edge shape, rigid lenses cause a foreign body type of sensation when the back surface is made with harsh/unblended transitions (*see* **Transition quality in**

rigid lenses; *see also* Chapter 12). A foreign body sensation that occurs with a previously comfortable lens may be due to a lens split, chip or other form of damage or deposit (*see Figures 18.32, 18.34* and *18.39*). A foreign body sensation can occur in eyes that develop a variety of external eye conditions and recognition of this possibility may help avoid unnecessary and unproductive lens alterations (*see* **Concretions**; **Dermatological conditions**; **Tear deficiencies**). (*See also* Chapters 8, 9, 10 and 11.)

Management: Is the problem due to an intolerable lens or due to an intolerant eye? Are previous (old) lenses more comfortable? Try switching lenses (right and left or new and old), especially if the problem is monocular. Consider possible causes described above. (*See* **Irritation**.)

Frequent replacement lenses

See **Disposable lenses**.

Front surface keratometry

This may be used to assess the image-forming properties of the contact lens front surface. However, with some lens powers, supplementary lenses are needed to extend the effective range of the keratometer (*see* Chapters 6, 12 and 13). Frequently, surface deposits degrade the mire image quality so that reliable readings are not possible. Excess lens movement with blinks also reduces the reliability of measurements. Mire image quality improves with blinks and readings are more reliable when voluntary blinks are encouraged. Complete voluntary blinks help to stabilize lens position for more reliable readings, but it should be noted that readings derived from repeated blinks measure maximum lens flexure (*see* **Flexure**). Usually the type of information yielded by front surface keratometry can be derived with other methods of assessment (such as retinoscopy and biomicroscopy), which are more convenient and are adequate for most clinical purposes.

Ghost images

These are secondary images adjacent to the primary image. Ghosting may occur momentarily due to tears, poor lens wetting and lens displacement, but will occur more consistently when due to incomplete pupil coverage, a distorted lens or one with faulty optics. Ghosting is a monocular symptom, although it can occur simultaneously in both eyes and will be most obvious when a bright image is viewed in a relatively dark field. It is a common symptom with bifocal contact lenses. (*See also* Chapter 16.)

Management: Like flare, ghost images may disappear with adaptation. If due to a lens with poor optic quality, replace the lens. If due to poor pupil coverage, change design to increase lens centration and/or increase central optic diameter(s). If present in bifocals, try an alternative design: for example, changing from an alternating design to a simultaneous vision design may help. If due to surface deposits, lens reconditioning or replacement is indicated.

Giant papillary conjunctivitis (GPC) or contact lens-induced papillary conjunctivitis (CLPC)

This is an extreme form of a range of palpebral conjunctival responses to contact lens wear (Allansmith *et al.*, 1977).

Symptoms: The first (pre-clinical) stage is characterized by a mild increase in mucus that accumulates at the inner canthus during sleep (morning mucus), and mild symptoms of itchiness on lens removal. The second stage involves a moderate increase in mucus discharge, mild blurring, increased lens awareness and mild itch late in the day, that increases on lens removal. The third stage includes moderate to severe mucus discharge and accumulation on lens surfaces and increased lens awareness throughout the day. Lens wearing time begins to decrease, there is mild to moderate itch during wear and moderate to severe itch on lens removal. Additionally, there is some increase in lens movement (soft lenses appear to loosen). The fourth (or terminal) stage is characterized by morning mucus discharge being sufficient to cause the lids to stick together; lenses are uncomfortable, surface deposits are excessive, mucus production during wear accumulates excessively at the inner canthus, wearing times are very restricted, itch is mild to severe and lens movement is excessive.

Signs: Conjunctiva shows progressive changes that correspond approximately with the symptoms just described (Allansmith *et al.*, 1977). In the pre-clinical stage there are no signs associated with the mild symptoms. In the second stage, normal papillae show some elevation and the thickened conjunctiva shows a hyperaemic appearance. Stage three includes loss of translucency of the conjunctiva and the giant papillae begin to form from a combination of several smaller papillae, producing a clover-like appearance. Stage four involves giant papillae of increased size and elevation with flattening of the top surfaces that show fluorescein staining during active development. At later stages, scar tissue at the top of papillae obscures the characteristic papillary blood vessel stalk (glomerulus). The observation of papillae on the non-tarsal palpebral conjunctiva is not relevant to contact lens-induced changes which are restricted to the tarsal area (Allansmith *et al.*, 1977). Frequently, signs of papillary conjunctivitis exist without significant symptoms and prophylactic management is usefully applied at any stage. Aetiologies such as vernal conjunctivitis or chlamydial infection should always be considered in cases of giant papillary conjunctivitis, especially when no progress is made with contact lens management methods. (*See Figure 18.24* and Appendix D; *see also* Chapters 4 and 15.)

Management: Improve lens maintenance. Change to disposable lenses. Change to a different material. Change maintenance products and include a protein removal tablet.

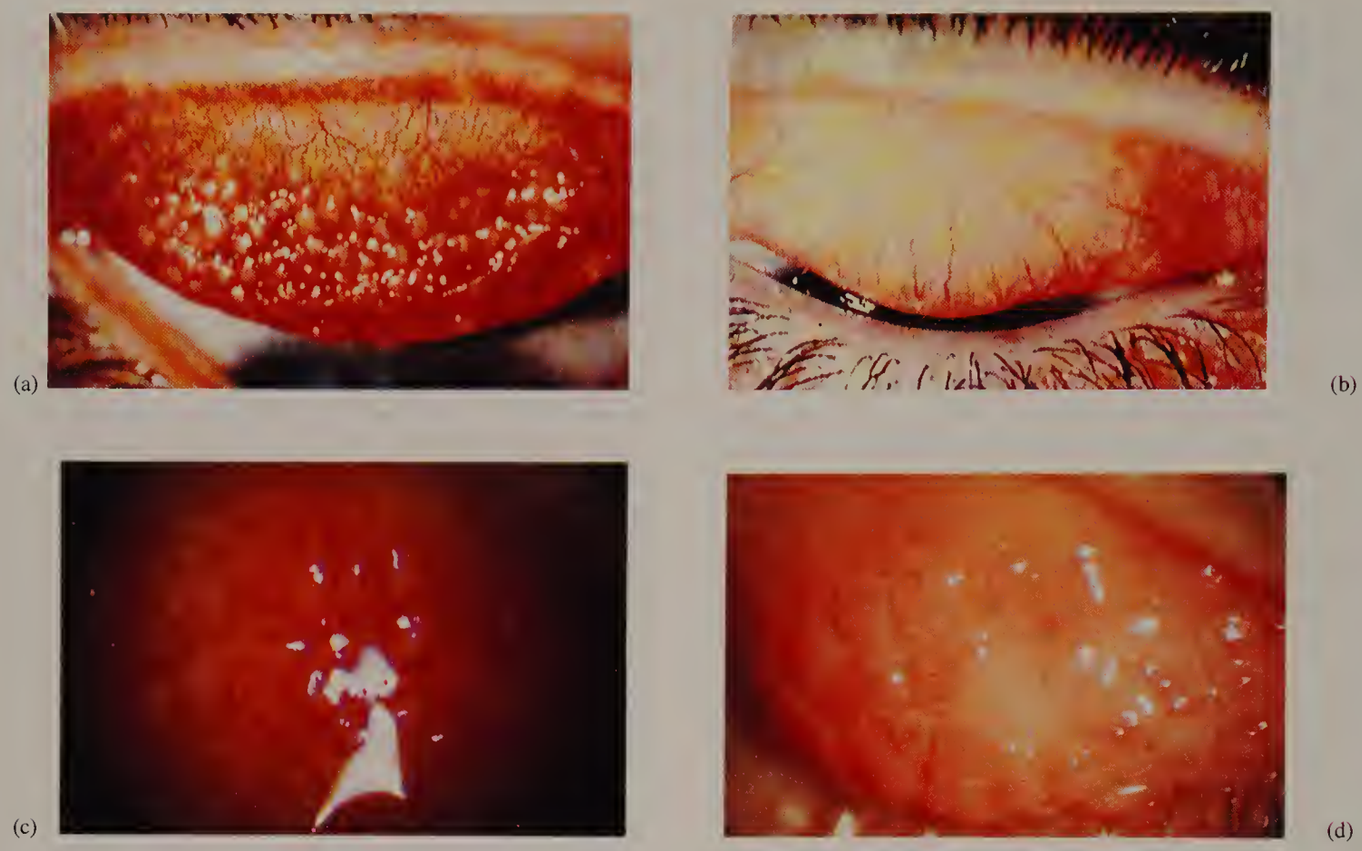


Figure 18.24 Giant (GPC) or contact lens-induced papillary conjunctivitis (CLPC) of the upper palpebral conjunctiva due to contact lens wear shown in (*a*) and compared to the normal conjunctiva in (*b*). Shown in (*c*) is the early 'tapioca' granule appearance of early GPC compared to the more advanced papillary formations shown in (*d*). ((*a, b*) Courtesy of M. R. Allansmith and (*c, d*) courtesy of D. J. Coster)

Reduce wear. Change from soft to RGP lenses with well-rounded edges. Try sodium cromoglycate or weak steroid drops. In severe cases cease lens wear for a time until symptoms and acute signs subside (possibly for as long as 3–6 months). (*See* **Surface Deposits**.)

Glare

Glare or photophobia was once a universal symptom of contact lens wear but occurs less frequently with RGP lenses because of the larger diameters commonly used and reduced hypoxia. The principal types are discomfort glare and, to a lesser extent, disability glare.

Depending on climate and oedema levels that develop, sunglasses may be needed by contact lens wearers, especially during periods of adaptation. Increasing the contact lens tint is not indicated as reduced transmission is a disadvantage at night. The problem is exacerbated if the patient's habit has been to wear tinted prescription spectacles prior to starting with contact lenses. Glare is worse in the mornings and evenings, when higher levels of oedema may be present and when sunlight is oblique to the earth's surface. Glare symptoms in adapted patients may signal loss of tolerance or corneal pathology associated with ciliary injection. The possibility of cataract development or other changes in the transparency of ocular media should be considered when glare is a presenting symptom at after-care. (*See also* Chapters 9 and 10.)

Management: When due to oedema resulting from hypoxia, check fit and change to a more gas permeable material. Where no oedema is evident, recommend good quality sunglasses, which can include a correction for residual astigmatism if indicated.

Glaucoma treatment

This can usually continue without interruption of contact lens wear. Morning and evening instillations of drops can be performed before and after lens wear so that associated lacrimation does not influence lens performance. A mid-day instillation may necessitate lens removal, depending on a balance between patient convenience and consideration of the possibility of soft lens discoloration or possible accumulation of preservative; daily disposable lenses will overcome this problem. Soft lenses can be used as a means of achieving greater anterior segment penetration for protracted periods, when the lens acts as a constant reservoir for slow release of the therapeutic agent. However, except in some cases of secondary glaucoma, the practical approach to soft

lens glaucoma therapy is limited by cost and annoyances that are far greater than the general need for such systems (Galin, 1978). (*See also* Chapters 4, 20 and 23.)

Guttata

These are usually observed in the corneas of middle-to-older age groups and are wart-like excrescences on Descemet's membrane. On specular reflection, guttata are seen as dark spots and are regarded as a normal finding in the peripheral cornea, even in young individuals, when they are sometimes referred to as Hassall–Henle bodies. When located in the central cornea in sufficient numbers, endothelial function may be compromised. Stromal oedema develops followed by epithelial oedema and bullous keratopathy as found in Fuchs' endothelial dystrophy (Grayson, 1979). The significance of corneal guttata in contact lens wearers is greater when seen in the central cornea (usually older female patients). In these cases, contact lens tolerance may be limited by significant oedema developing over short wearing times. Corneal guttata need to be distinguished from the transient endothelial bleb response to contact lens wear (*See* **Endothelial response**; *see also* Chapters 6 and 15.)

Management: The presence of significant guttata can be a contraindication for contact lens wear or an indication to limit contact lens use. Prescribe highly gas permeable materials. Change from soft to RGP lenses.

Hand UV or Burton lamp

Evaluation of lens fittings with white and ultraviolet light has several advantages not available with the biomicroscope. It is convenient to make rapid evaluation with the Burton or similar contact lens fitting lamp prior to trial lens refraction, more complete evaluation being made after trial lenses have settled because *both* eyes are visible within the field of the magnifier. This type of lamp permits rapid alternation between fittings on each eye so that repeated comparisons of movement and centration can be made over a period of several successive blinks. The patient's head should remain in a natural position during these observations and, when required, lid control can be used to compare fit characteristics for both static and dynamic blinking situations. The biomicroscope can be used for more detailed examination, although without the convenience of the hand ultraviolet lamp and without freedom of patient head position. The hand UV lamp is also ideal for low magnification bright white light illumination observations of adnexal skin, lid margin, lower palpebral and bulbar conjunctival conditions. (*See also* Chapters 8 and 10.)

Hand washing

This needs to be stressed when a negligent approach to lens maintenance is evident from case contamination and poor lens condition. If previous advice regarding hygienic lens handling appears to have been disregarded, compliance can be improved by anecdotal discussions of the risks caused by negligence and by providing information on the prevalence of contact lens-related infection (Lippman, 1986; *see* **Infection**). Patients who work in occupations that lead to greater amounts of hand soiling, car mechanics for example, need to wash their hands two or three times (lather/rinse cycles) before lenses can be handled safely. Telling the negligent patient that repeated washing is necessary when hands are more than normally soiled, might help increase compliance under routine conditions. Discuss the potential for natural skin secretions or hand creams to disturb contact lens surfaces and the need to rinse hands thoroughly after washing to avoid stinging on insertion. The negligent patient may be impressed by the fact that the practitioner takes hand washing seriously. (*See Figures 18.1, 18.16*; *see also* Chapters 4, 8 and 9.)

History taking techniques for after-care

See Interviewing and history taking at the introduction to this chapter.

Hormonal factors

Many women experience significant systemic oedema as part of their menstrual cycle. Systemic fluid retention increases the risk of contact lens induced corneal oedema (*see also* **Over-wear**). It is prudent to suspect the possibility of menstrual factors being relevant when women present with symptoms that occur occasionally. An association with menstruation may be confirmed during subsequent cycles and will greatly help in management. If there is no association, the need to look for another causal mechanism is clearly indicated. If an association is confirmed then systemic signs that indicate general fluid retention (weight gain, ring tightness, breast soreness, tightness of clothes that are normally comfortable etc.) can become a signal for the need to moderate contact lens use during that phase of each cycle (Serrander and Peek, 1993; Guttridge, 1994).

Hormonal changes during pregnancy may also affect contact lens wear as tear volume and corneal sensitivity reduce, corneal curvature steepens and cornea thickness increases. The latter can lead to oedema developing much earlier than usual when contact lenses are worn (Imafidon and Imafidon, 1991). (*See also* **Oral contraceptives**.)

Infection

This is sometimes encountered in association with contact lens wear. Apart from medical treatment, resumption of contact lens wear should be conditional on a complete re-assessment of patient hygiene. Case disinfection (*see* **Case contamination**) or replacement is a fundamental step followed by changes to disinfection methods, especially in regard to compliance. That extended wear patients are at greater risk is indicated by the finding that corneal ulcers reported to the US Food and Drug Administration (FDA)



Figure 18.25 Non-rotating RGP lens with an inferior deposits on the exposed area of the lens



Figure 18.26 Non-rotating hydrogel lens with an inferior deposits apparently due to habitual incomplete blinks

occur at a seven to one ratio in extended wear compared with daily wear (Lippman, 1986). (*See also* Chapter 4.)

Management: Discontinue lens wear and carry out appropriate culturing, cytology and treatment. Consider replacement of lenses. Delayed resumption of wear is necessary along with review of hand washing, lid hygiene and lens maintenance, especially with regard to case contamination (*see* **Bacterial conjunctivitis; Bacterial corneal ulcer; Corneal infiltrate**; *see also* **Hand washing**).

Inferior front surface deposits

These form on the area of lens exposed by inefficient blinking and/or lagophthalmos. The problem is less apparent on lenses that rotate because the deposits occur around the entire annulus of lens periphery. Non-rotating lenses show these deposits more obviously because they are concentrated in the area of lens surface that is exposed by the lower half of the palpebral aperture (*Figures 18.25, 18.26*).

Management: Improve blink efficiency. Improve maintenance, especially with particular emphasis on surfactant cleaning the inferior portion of the front surface, i.e. the area of prism ballast or the portion that does not fold as easily when the lens is buckled gently between finger and thumb (*Figure 18.26*). If possible consider changing to frequent replacement lenses (*see* **Blinking efficiency**; **Surface deposits**).

Informed patients

Those patients with a complete understanding of contact lens wear and management are the exception rather than the rule. (*See* **Advice; Compliance; Counselling**; **Re-instruction**.) Priluck *et al.* (1979) found that, although 97% of patients presenting for retinal detachment surgery acknowledged the thorough preoperative discussion that they were given, overall retention of disclosures was only 57%. When patients failed to remember particular aspects of the preoperative discussion, more than half the time there was denial of having discussed that particular aspect previously. Written confirmation of advice was not used in the study of retinal surgery patients but, judging by experience in contact lens practice, the issue of handouts would not guarantee that they would be read or that receipt would be acknowledged at a later time. (*See also* Chapters 8 and 9.)

Departures from recommended maintenance methods are commonly found (Collins and Carney, 1986). A major problem in contact lens practice is the large amount of information that needs to be taught at the initial stage of lens use. Balance should be attempted by spacing the delivery of instruction and new information throughout the after-care period, according to need. For example, instruction regarding the use of protein-removing enzyme tablets need not be given at the initial delivery visit, but can be given at a subsequent examination when lens deposition can be assessed, and the expected rate of use of enzyme tablets can be appropriately recommended.

Inside out lenses

These may be unwearable in higher powered soft lenses (especially plus), but, in low powers, only small degrees of reduced vision performance and/or increased lens movement and/or lens awareness may occur (*See* Chapter 11). The more difficult it is to judge whether a soft lens is inside out or not when off the eye, the smaller the effect of wearing it inside out. Mild symptoms in a previously comfortable low power lens, warrant suspicion that the lens is inside out.

If patients control the orientation of their lenses during removal, cleaning and rinsing then they can be placed in the

storage case with a known orientation. This control removes the need to determine whether the lens is inside out prior to insertion.

Very thin rigid lenses can invert and this results in irreversible changes in parameters.

Interviewing technique for after-care; history taking

See Interviewing and history taking in the introduction to this chapter.

Irritation

This is a general term used for symptoms that are reported in response to a range of problems. It is helpful to ask the patient to discriminate between a chemical sting and a foreign body sensation and also when the irritation occurs; for example, when lenses are inserted, later in the day etc. If the irritation only occurs at the time of insertion, it may be due to clumsy insertion technique or lens contamination from unwashed hands. If the irritation develops as the lenses are worn, it may be due to the onset of oedema, the increase in surface deposition during wear or the progressive drying of the lenses. If irritation is intermittent, it may be due to a damaged lens that only causes abrasion when located in a particular position. Adverse response to maintenance solutions can cause an acute irritation on insertion or a lower intensity chronic hotness and burning. When irritation occurs monocularly, switching lenses (right with left where appropriate and old with new) may help demonstrate whether the lens or the eye is the problem.

Management: Consider that the lens might be at fault (damaged, soiled, poorly manufactured etc.), or that eyes may be less tolerant (epithelial split, tear deficiency, infiltrates etc.), or a sensitivity to the lens material or solutions being used and take appropriate action. (*See* **Foreign body sensation** and **Sting**.)

Itch symptoms

These may be associated with allergic conditions but need not be derived necessarily from contact lenses or solutions. A day without contact lens wear may be necessary to determine if the itch occurs independently of lens wear. Often itch symptoms are mild but prompt a vigorous eye rubbing episode immediately on lens removal. Patients should be persuaded to avoid eye rubbing, especially those with keratoconus, but simply advising them not to rub their eyes is poor management. An alternative means of relieving the itch symptoms is required and, when convenient, hot and/or cold compresses offer the best alternative, especially as suspected or potentially antigenic matter can be removed from the lids and lashes at the same time (*see* **Lid hygiene**). Itch symptoms that develop after lens removal are a possible indication of giant papillary conjunctivitis (*see* **Giant papillary conjunctivitis**).



Figure 18.27 One of the best methods of viewing deposits on contact lenses is by dark field microscopy. Shown above are protein deposits with superimposed calcium deposits centrally and lower right. (Courtesy of R. Payor)

Management: Suspect an allergic response and, if possible identify and remove/avoid allergic stimulus. Change to different maintenance method; replace soiled lenses; change cosmetics etc. If an allergic stimulus cannot be avoided, try anti-histamine or mast cell stabilizing drops, e.g. sodium cromoglycate (*see* **Allergies**).

Lens condition

This is best assessed after lens removal because re-wetting by blink action masks the appearance of deposits during biomicroscopy. The deposits become increasingly apparent when the lens surface is allowed to dry and is illuminated with an external spot source. Additionally, lens damage is more easily detected with intense transillumination that can be achieved with off-the-eye inspection, as a background of even light-coloured irides may obscure small splits or nicks during biomicroscopy. Off-eye examination is possible with a slit lamp, but a stereomicroscope with transillumination facilities is preferable and will allow for accurate estimation of depth of lens changes. Even a monocular microscope with transillumination facilities is superior to on-eye inspection. The advantage of transillumination is that refractile changes in the lens material, including most forms of damage, will become evident with this method. The microscope transillumination mirror can be rotated to achieve useful dark-field effects for the examination of surface deposits (*Figure 18.27*) but, again, direct illumination with an oblique external spot source is ideal for assessing surface scratches and deposits as the lens dries. Magnification between ×20 and ×40 is adequate for clinical purposes. (*See Figures 18.19, 18.23, 18.27, 18.32, 18.39–18.46.*)

Lens insertion

Insertion sometimes remains a problem during after-care and recourse to the fundamentals of lid and eye control through fixation control is required (*see* Chapter 9). The most

common problems associated with insertion are poor fixation control, inaccurate lens positioning (aim) and failure to maintain a wide palpebral aperture due to lack of lid control. It is often useful to teach patients with insertion problems to place the lens on their eye by approaching along the visual axis. If a target is fixed carefully and head position controlled so that the cornea is centred in the palpebral aperture, patients with binocular vision can learn to appreciate that correct lens placement can be achieved by maintaining fixation *through* the fingertip on which the lens has been placed for insertion. The patient will experience an apparent 'X-ray vision' providing both eyes are kept open and, with this form of control, accuracy of placement can be achieved. An additional advantage of this method is that the need to keep the contralateral eye open helps reduce the muscle tonus and blepharospasm of the lid of the eye receiving the lens. Additional lid control is usually needed and patients with strong blepharospasm can be taught to restrain the lashes of the upper lid against the supraorbital margin, so that a non-traumatic, effective control can be maintained. A finger of the hand holding the lens can be usefully placed on the lower lid to steady the control of placement and to increase the palpebral aperture. When eye position, lid separation and placement accuracy are controlled, there is a good chance of successful placement. (*See* **Patient management and instruction**; *see also* Chapter 9.)

Lens parameters

These require re-assessment when there is suspicion of change. Usually, soft lenses do not require inspection for parameter changes because significant loss of shape or change in optical quality can be detected on the eye from fit and retinoscopy observations. Rigid lenses should be re-measured when over-refraction results are used for re-prescribing or when parameters considered to be just within tolerance at pre-delivery checks are suspected of being the cause of after-care problems. Pre-delivery findings can be recorded in pencil on record cards, adjacent to the ink record, and question marks used to indicate doubtful readings. For example, a power reading that is correct quantitatively can be given a pencilled question mark if focimeter image quality is doubtful and, during after-care, attention will be drawn to this factor if visual results are poor. The same approach is useful for all quantitative and qualitative assessment but it is vital that re-assessment should be convenient and rapid so that after-care consultation time is not wasted. By far the most suitable method for consulting room assessment of edge shape and other qualitative features is obtained with hand magnifiers (McMonnies, 1986c). It should be remembered that laboratories may have difficulty in maintaining objectivity when re-assessing doubtful quality lenses at the request of a practitioner. Skill in the assessment of lens parameters and quality are a vital asset to a practitioner throughout after-care. (*See* **Transition quality in RGP lenses**; **Edge shape**; *see also* verification of rigid and soft lenses in Chapters 12 and 13.)

Lid hygiene

This may need to be recommended to contact lens wearers with chronic blepharitis and/or meibomian gland dysfunction and/or palpebral conjunctivitis (*see* **Reactive eye**; **Tear deficiency**). Apart from normal ablutions, about which nothing should be assumed, recommending hot compresses on waking and before retiring will frequently improve lid condition and contact lens performance. A steaming hot face cloth, as hot as the hands can accept, should be held against closed lids so that gentle massage and manipulation of the lashes can remove the dust that has collected during the day (evenings), and remove the discharge that accumulates during sleep (mornings). This simple hygiene measure will be all that is required to improve cases of mild meibomian gland dysfunction and will be appropriate as a maintenance regimen for more serious cases that have initially responded to stronger measures (*see* **Tear deficiency management**). Chronic blepharitis is improved by removing the crusts that form at the base of the lashes and by providing a cleaner environment that is less conducive to the proliferation of *Staphylococcus spp.* (Catania, 1987). Additionally, hordeola will resolve more rapidly with this form of lid hygiene and the chances of recurrence are reduced. To avoid patient embarrassment it may be more acceptable to refer to lid hygiene euphemistically as lid management when instruction is given (*see Figures 18.17, 18.18*). (*See also* Chapter 8.)

Management

- Recommend hot compresses on waking and before going to bed, with particular emphasis on clearing all dust and debris from the lid margin, lashes and canthi.
- Lid scrubs (bicarbonate of soda solution, diluted baby hair shampoo or Lid Care (Ciba Vision): dip a cotton wool bud into the solution and thoroughly clean around the base of the lashes.
- Expression of the meibomian glands: using a cotton wool ball dipped into a solution of the above and pressing downwards on the upper lid, and upwards on the lower lid before wiping the lid margin with a solution-soaked cotton wool bud, will improve lens comfort in cases of meibomitis.
- Consider antibiotic treatment.

See **Tear deficiency management**.

Lid twitch sensation

This is a minor but annoying symptom that may be attributed to contact lenses. The innervation to lid muscle fibres (of Riolan) discharges haphazardly to cause minor flexing of the surrounding tissue including the skin of the lid margin. It has been suggested that twitching eyelid symptoms are related to diet, for example, lowered concentration of calcium ions at myoneural junctions (Hall and Cusack, 1972). Under conditions of fatigue, stress and/or debility, haphazard discharge causes a nuisance symptom which is unlikely to be related to contact lens wear.

Management: Counsel patient with explanation of possible causes of the symptoms. Reassure patient that the symptoms pass with time. (*See* **Counselling**.)

Limbal indentation

See **Fit evaluation; Vascularization**.

Lost lenses

These may be retained in the eye without the patient's awareness or with minimal symptoms. Rigid lenses may be displaced and retained in the superior fornix as can ultrathin soft lenses that crumple into a folded shape. Large eyes and lids with loose tonus may complicate finding and retrieval procedures. Eversion of the upper lid is usually sufficient to disclose the lens position, if combined with extreme downward gaze and lateral eye movements. Fluorescein may aid discovery and is useful if pieces of a soft lens are suspected to be retained after a broken lens is removed. Biologically inert contact lens materials have been unwittingly retained for months and a concerned patient will require careful management. (*See* **Emergency examinations**; *see also* Chapter 9.)

Low vision

If associated with myopic retinal degeneration, the need for power changes should be based on subjective assessment rather than the number of additional letters read with over-correction, because it is not uncommon for a highly valued improvement to be realized in the dominant eye with a power change that does not alter measured acuity significantly. In the case of the non-dominant eye having much lower acuity than the dominant eye, the possibility of wearing a lens of the same power as the dominant eye should be considered as that lens would then serve as a useful spare for the dominant eye in the case of lens loss. Many low vision myopes would prefer to read unaided rather than with a contact lens and a low vision aid. The reading distance may be similar, but preference for reading without cosmetically disabling spectacles will often be shown.

Filing a tactile groove in the storage case, or marking one end with clearly visible nail polish, will aid low vision patients in keeping their lenses on the correct eyes. Tinted lenses aid handling and lens location. Using different colours to identify left and right lenses should be employed when cosmetically acceptable (patients with moderate to dark iris colours). (*See also* Chapters 20 and 23.)

Maintenance of contact lenses

See **Case contamination**; **Compliance**; **Discoloration**; **Fenestration**; **Finger nails**; **Hand washing**; **Inferior surface deposits**, **Informed patients**; **Lens condition**; **Paper tissue**; **Polishing**; **Preservative**; **Purging**; **Reconditioning**; **Re-instruction**; **Scratches; Surface deposits**.

Medication

Medication taken for systemic conditions may induce ocular side-effects that interfere with contact lens performance or are mistaken for contact lens symptoms. Usually these effects only occur in susceptible individuals on high and/or prolonged dosage treatment. For example, tear production may be reduced by antihistamines, diuretics, sleeping tablets, tranquillizers and oral contraceptives (*see* **Oral contraceptives**) and medication for duodenal ulcer, digestive problems or high blood pressure. Current medication use should be considered when signs and symptoms of tear deficiency are encountered. Some systemic medications may alter accommodation function and lead to near vision difficulties (loss of accommodation) or to transient myopia (spasm of accommodation). Conditions for which medication may induce accommodative disorders include psychiatric disorders, depression, insomnia, anxiety, tension headaches, hypertension, cardiac and vascular conditions, malaria, rheumatic disorders, epilepsy, diabetes, fluid retention, painful muscular conditions, cramps, torticollis and infections (O'Connor Davies, 1972). Thus, unusual changes in refraction, especially loss of near vision, should prompt consideration of medication side-effects as a contributing cause. Additionally soft lenses may discolour in response to systemic medication (*see* Chapter 4). Finally, some patients may experience a delayed recovery to normal accommodation function after general anaesthesia, and this change may be confused with medication side-effects (*see* Chapter 4).

Meibomian gland dysfunction

See **Lid hygiene**; **Tear deficiency**; **Tear deficiency management**; *Figure 18.17.*

Mixed lenses

Mixed lenses (left on right eye and *vice versa*, or old with new) are frequently encountered at after-care visits (McMonnies, 1987). Often lens prescriptions are very similar so that wearing them on the wrong eyes is of little or no consequence. For some patients, the only reason that their lenses are not mixed is because they have unwittingly switched them an even number of times. However, when prescription differences are significant, an induced antimetropia will be evident from over-refraction results, when one eye accepts plus and the other eye requires a similar amount of minus, indicating that lenses are mixed. Also the fit of the lenses may be completely wrong; steep on one eye, flat on the other.

Management: Have right and left lenses engraved R and L or have the right lens engraved with a single dot (coloured is better) and the left lens with two dots (*see* Chapter 10). For patients with darker irides consider colour coding (different colours for each lens). Reaffirm rigid sequencing of insertion and removal procedures to minimize risk of confusion.

Modifications

Those that can be carried out on rigid lenses during the course of an after-care visit greatly facilitate management. Simple procedures such as polishing surfaces, re-shaping edges, adding posterior edge curves, or making small power changes can be completed within a few minutes (*see* Chapters 21 and 22). Sending lenses to a laboratory causes inconvenience to the patient and removes the advantage of being able to assess the influence of a modification immediately on its completion, so that further change can be made if needed. Modification of RGP materials requires ammonia-free polishing compounds and very wet conditions in order to minimize over-heating which is likely to distort the lens. Soft lens modification is extremely difficult and unreliable (*see* Chapters 14 and 22) and is therefore best avoided.

Monovision

Sometimes after-care visits reveal a situation in which a presbyopic patient is corrected for distance in one eye and for a nearer focus in the other. A common reason is a monocular increase in myopia. In most cases the patient is unaware of one eye being superior for distance and the other for near. This type of refractive change yields a fortuitous monovision and the patient is likely to be disappointed if restoration of full distance correction in both eyes causes increased near vision difficulties (*see also* Chapter 16).

Neovascularization

see **Vascularization**.

No symptoms

No symptoms reported at after-care visits allows for an emphasis on the detection of signs of short- or long-term impending difficulties. Findings such as hyperaemia, surface deposits, oedema etc. may be symptomless in early stages, but improvement in lens fitting and advice regarding better lens management and maintenance are warranted in order that future problems can be prevented.

Management: If significant signs of potential difficulties are evident, take extra time to gain the patient's cooperation to carry out prophylactic measures.

Ophthalmoscopy

This may be aided by not removing contact lenses in cases of high myopia, astigmatism or corneal irregularity. However, compared with soft lenses, the smaller optic zone diameter and instability of rigid lenses may restrict the patient's eye movements so that viewing the peripheral fundus is restricted. Direct ophthalmoscopy through contact lenses may be disturbed by contact lens surface conditions and the lenses may need to be cleaned and/or the patient may need to be reminded to blink so that a clean, wet surface is maintained during the examination.

Using a Volk lens or equivalent in conjunction with a slit lamp makes the fundus view easier regardless of the condition of the lens surface.

Oral contraceptives

These have been reported to be associated with contact lens intolerance, but the evidence for a causal relationship is circumstantial and not very strong. Studies that compared contact lens tolerance in groups of users and non-users of oral contraceptives did not detect any significant differences (Ruben *et al.*, 1976; de Vries Reilingh *et al.*, 1978). However, while those results showed there was no general effect, they do not discount the possibility of individual adverse reactions to oral contraceptives, a view supported by anecdotal case reports of relief from symptoms after abandoning this medication. The prevalence of oral contraceptive-related contact lens symptoms may have reduced with increasing use of low dosage formulations, and current experience supports that view. A readiness to blame oral contraceptives may delay the identification of the real cause of after-care symptoms (*see* **Hormonal factors**; *see also* Chapters 4 and 8).

Out of hours emergencies

Difficulty removing a lens, a lost or broken lens, or a lens displaced (or suspected of being displaced) under the upper lid, can be crises depending on the patient's reaction to each situation. Reassurance is required in large measure. However, more obvious emergencies, such as red eye, loss of vision or failure to neutralize a lens soaked in hydrogen peroxide, all indicate the importance of an out of hours contact number. In some countries, such as the UK, practitioners are required to provide patients with such a number.

Over-refraction

This is performed with contact lenses on the eye. If the expected visual acuity and binocular balance are achieved, then the only interest may be to determine whether any additional plus will be accepted. A hand-held +0.50 D spectacle trial set lens should blur distance acuity slightly if the contact lens power is correct. This procedure provides adequate over-refraction in many cases and confirms that the contact lens power is correct. If the expected acuity is not achieved and plus blurs and minus does not give any improvement, retinoscopy may indicate excess surface deposits, poor wetting, residual astigmatism and/or poor lens optical quality. Lenses may be on the wrong eyes or a lens may be distorted by handling or have been supplied to give a monocular near vision correction, and these alternatives should be explored before a decision is made to alter lens power. Additionally, it is always necessary to consider the possibility of ocular pathology being the cause of

reduced acuity noted at after-care visits. (*See also* Chapters 5, 10, 11 and 14–17.)

Over-spectacles

See **Supplementary spectacles.**

Over-wear

The over-wear syndrome, involving significant oedema and symptoms that develop a few hours after PMMA lens removal, is becoming increasingly less frequent with greater use of RGP lenses. This syndrome is also known as the '3 a.m. syndrome' because onset of the severe symptoms is often around that time in the morning after the patient has been sleeping for a few hours.

Symptoms: intense pain may be experienced depending on the degree of oedema and disturbance to the epithelium. The morning brings intense photophobia and continued pain and lacrimation.

Examination is difficult because of photophobia, but symptoms and the history of lens use, together with the obvious gross signs, permit the syndrome to be diagnosed without detailed biomicroscopic examination. If necessary, a local anaesthetic will allow a more detailed examination. Usually lenses have been over-worn, or worn all day after a period of abstinence. Even well-adapted patients can experience this response when lens wear is resumed after a period of abstinence or when reverting to a spare non-gas permeable lens. There may be systemic factors, such as fluid retention, that help predispose towards the over-wear syndrome. The presumed mechanism is greater than usual corneal swelling due to increased oxygen deprivation associated with over-wear. The thickened cornea then becomes mechanically abraded. Apparently sufficient corneal anaesthesia develops for symptoms to be minimal at the time of lens removal. However, as the corneal sensitivity returns, the rapid eye movement phase of sleep results in intense irritation through lid movements over a swollen cornea. The patient requires maximum reassurance that vision is not permanently impaired and that the symptoms will dissipate slowly during the course of the following day. Oral analgesics may help as well as avoiding light. Prophylactic drops may be used to minimize risk of secondary infection. Apart from avoiding the circumstances that lead to this response, re-fitting lenses with increased oxygen supply is indicated. Cautious lens wear can be resumed within a few days in most instances, but a clear biomicroscopic appearance of the cornea is not sufficient evidence that the cornea has completely recovered. The abraded epithelium may require several weeks for complete recovery. When the corneal oedema and epithelial damage have cleared, endothelial bedewing may be detected, indicating that an anterior uveal response may have occurred in association with the corneal insult (*see Figure 18.14*; **Endothelial bedewing**). (*See also* Chapter 10.)

Management: Use brief examination procedures and low light levels (e.g. thin slit lamp beam). Counsel patient to expect major resolution of symptoms on the first day. Recommend analgesic for relief of pain and irritation. Reassess next day if necessary or within three days to monitor corneal recovery. Delay return to lens wear well beyond superficial epithelial healing, especially if endothelial bedewing is apparent. Recommend limited lens use initially on resumption of lens wear. Refit lenses with a higher Dk material (*see also* **Endothelial bedewing; Hormonal factors**).

Paper tissue

This can be recommended for use with rigid lenses under certain circumstances and can give significant advantages. Provided that a lens is wet first, and then wiped dry with a soft, lint-free tissue, the mildly abrasive effect of wet tissue will remove almost all unbound deposits. When used in this way, the surface is not scratched and a surfactant cleaner can be much more effective when used to remove the residual deposits that remain after tissue use.

It is essential that paper tissue is not used on a dry lens, because scratching may result, and static electricity that builds up on the surface of the dry lens can attract dust particles.

The more abrasive 'wet-strength' or 'extra-strength' tissues should be avoided.

Photophobia

See **Glare**.

Polishing

Polishing of rigid lenses may be required more than once per year in some cases, but usually annual repolishing is sufficient. Convex surfaces show the greatest need because they attract the larger quantity of deposits and scratches, but polishing the inside surface can be important as a degraded surface may cause discomfort. However, it is not always possible to polish the inner lens surface as it may alter the lens fit or power. It may not be possible completely to remove significant scratches by polishing, but it is an advantage to reduce them so that their capacity to collect mucus is lessened. Thus, polished lenses are cleaner, stay cleaner longer and are easier to clean, but if lenses show advanced degradation, polishing is of little value and replacement is necessary. High Dk RGP materials do not react well to polishing and it may be advisable to replace the lenses every 6 months (Woods and Efron, 1996). (*See also* Chapters 17, 21 and 22.)

Pregnancy

See **Hormonal factors**.

Presbyopia

This may take up a large amount of after-care consultation time (McMonnies, 1987). The simplest solution of an over-correction for near work is often as appropriate as the sophisticated approach of bifocal contact lens fitting (*see* Chapters 5 and 16). Between these two extremes of difficulty, other solutions such as monovision or near contact lenses and distance over-spectacles may be found to be more appropriate. All these techniques involve some compromise of visual efficiency, and the most careful pre-prescribing consultation may not lead to the most suitable method of correction. Once presbyopes start to use their new correction, they may become aware of previously unsuspected visual requirements that necessitate an alteration in method of correction. For example, in theory it is possible to determine the most appropriate eye to be corrected for near when monovision is prescribed (McMonnies, 1974b). However, in practice, it is often only when monovision has been experienced in a variety of circumstances that the choice of dominant eye and the success or otherwise of this form of correction is determined. Trials with alternate eyes corrected for near are sometimes needed to determine the most suitable combination, if monovision is acceptable at all.

Understanding the presbyope's complex needs and variable capacity to accept a visual compromise is the cornerstone to success, even if sometimes laboriously achieved. Power changes, that increase distance vision at the expense of near, are a step that should not be taken without a full discussion of the consequences. (*See* **Reading difficulties; Monovision**.)

Management: Consider all alternatives: distance contact lenses plus reading over-spectacles, near contact lenses, near contact lenses plus distance over-spectacles, near contact lenses as well as distance contact lenses, monovision as either an occasional system or as an everyday system, bifocal contact lenses etc. Remembering that hyperopes need to accommodate less in contact lenses, while myopes need to accommodate more in contact lenses, can be important in successful management (*see* Chapter 5).

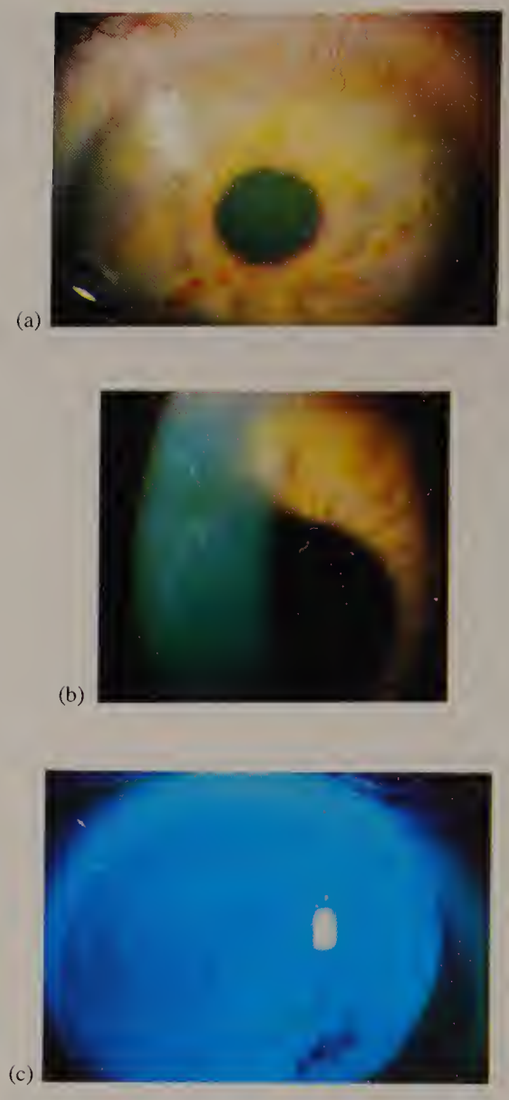


Figure 18.28 Toxic keratitis may arise from several sources but is commonly due to a hypersensitivity or toxic reaction to the preservative in a lens storage solution which leaches onto the cornea when the lens is inserted. The pattern is that of a diffuse to heavy punctate keratitis over a large area or the whole area of the cornea. The limbal area is also commonly injected. (*a, b*) Low and high magnification white light photographs respectively; (*c*) low magnification blue light photograph showing long-term thimerosal toxicity with diffuse fluorescein staining of the epithelium and a pronounced dark dry spot. (Courtesy of T. Grant)

Preservative reaction

This may be suspected if symptoms of stinging and burning occur on lens insertion (*see* Chapter 4). In chronic responses, however, symptoms may be mild and only increased lens awareness may be reported.

Signs: Hyperaemia of the limbal, bulbar and palpebral conjunctiva, conjunctival oedema, punctate epithelial stain and corneal infiltration with inflammatory cells.

Evidence of hypersensitivity may be obtained from a positive ocular reaction to a provocative test with a suspected preservative or from a skin patch test, or if cytology results show eosinophils. However, management can proceed on the basis of a presumed diagnosis, by a trial elimination of suspected preservative from storage, cleaning and 'in eye' solutions. Usually lenses can be purged successfully (*see* **Purging**) and wear resumed. However, corneal infiltrates should be given time to disperse because early resumption may cause symptoms to recur (*see* **Corneal infiltrates**). Careful examination using marginal retro-illumination and sclerotic scatter may be necessary to detect residual infiltration. Because of their capacity to bind preservatives, soft lenses are more likely to be associated with adverse preservative responses and a greater level of limbal hyperaemia has been found in soft lens wearers who

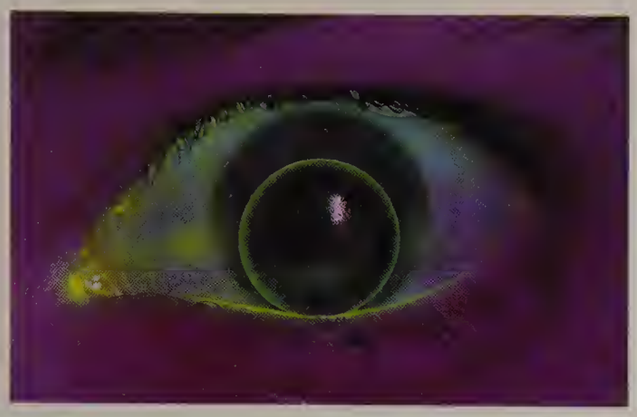


Figure 18.29 Three and nine o'clock corneal staining here shown associated with a dry and lipid-coated rigid lens. This type of staining only occurs in those areas exposed to the atmosphere between blinks. If the lower lid is very low then similar staining may also occur in the six o'clock position. (Courtesy of D. Westerhout)

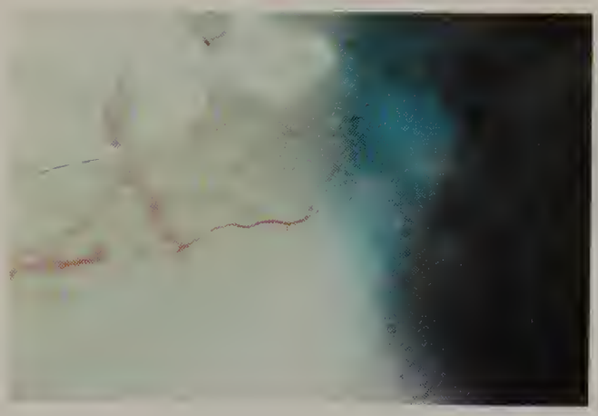


Figure 18.30 A case of pseudopterygium in an RGP lens wearer. This is the sequel to chronic nine o'clock epithelial desiccation, staining and erosion.

use preserved storage solutions compared with those who use unpreserved storage solution (McMonnies and Chapman-Davies, 1987a). (*see Figures 18.10, 18.28*).

Management: Adverse reactions to preservatives may present with delayed and insidious or immediate and acute responses. Purging suspected lenses may not be successful. Consider preservative allergy/toxicity as a possible component in any abnormal vascular response.

Pseudopterygia

These appear to be a sequel to chronic epithelial erosion (*see* **Three and nine o'clock peripheral stain**) occurring in hard lens wearers (Stainer *et al.*, 1981). The temporal and/or nasal limbal cornea can become scarred and vascularized superficially, leading to subepithelial opacities that give the appearance of corneal involvement from a pterygium, except for a diffuse leading edge. Initially, there are no symptoms but later increased lens awareness, burning and stinging occur. Predisposing factors are over-wear, inferiorly locating lenses, superiorly locating lenses with low lower lids, tear deficiency, lenses with excess peripheral clearance, lenses with thick edges and inefficient blinking. (*See Figures 18.29* and *18.30*.)

Management: Change to soft lenses. Refit thinner, better centred RGP lenses with reduced edge clearance and smaller lens diameter. Improve blink efficiency and treat any tear deficiency. Reduce concentrated close work in contact lenses. Prescribe in-eye rewetting drops.

Pterygia and pingueculae

These may become injected (*Figure 18.31*) during contact lens wear. Because these lesions are highly vascularized, any stimulus to conjunctival injection will result in a greater hyperaemic response in these exposed scar tissues. Contact lenses add to the list of potential causes of injection but, when well cleaned and fitted, do not appear to cause significant problems. However, a contact lens may be incorrectly regarded as the cause of pterygium growth activity when other factors, such as exposure to excessive sunlight, are more significant. It is possible that soft lenses, especially with a UV inhibitor, help by acting as a bandage for the head of the pterygium and preventing epithelial drying that is associated with increased growth and corneal involvement. Changes in corneal astigmatism may be caused by a pterygium requiring surgical treatment and could be confused with contact lens-induced changes. (*See* Chapters 8 and 11.)

Management: Refit unstable RGP lenses that might mechanically irritate vascularized scar tissue. Monitor corneal astigmatism and consider need for surgical intervention if advancing pterygium alters corneal shape. Recommend effective sunglass protection from ultraviolet radiation (*see* **Ultraviolet protection**).



Figure 18.31 Because they are highly vascularized and exposed, pterygia can become injected in response to a wide range of irritants, including degraded or ill-fitting contact lenses

Purging

Purging lenses suspected of being contaminated with toxic materials may be required when stinging, hyperaemia and lacrimation develop with lenses that were previously comfortable. Soft lenses especially are susceptible to adsorbing irritant substances from storage solutions and toxic gases, vapours or sprays (*see* **Toxic fumes**). Purging of these substances is slow and requires multiple cycles of soaking in unpreserved saline. Purging efficiency is improved with use of larger volumes of fluid (a lens vial is better than a lens case), and with agitation to circulate the purging fluid. If unlikely to affect the lens, heating the saline will help speed up the process. The suspected toxic contamination is confirmed if 4 × 12-hour soaking cycles with heat and occasional agitation result in a significant reduction in symptoms. (*See also* Chapter 4.)

Quality control

For lens manufacture, quality control depends on the laboratory observing satisfactory tolerances for accurate radii, power, edge shape, back surface transitions etc. (McMonnies, 1986c).

Practitioner time spent in assessing lenses prior to delivery is justified when significant errors can be corrected before delivery that will reduce after-care problems. A difference in acuity between the two eyes, for example, might be explained by one lens being 0.12 D strong and the other being 0.12 D weak. The powers read at the pre-delivery check can be recorded in pencil next to the record card prescription, so that the probable cause of the difference in acuity is immediately apparent when unequal acuity results are encountered. Questionable quality of optics could be indicated on the record card by a question mark over the lens power, and this information would again shorten the problem-solving process when the eyes yield different acuity results (*see* Chapters 12 and 13).

Management: Routinely check all RGP lenses qualitatively and quantitatively prior to delivery to patient. Check hydrogel lenses prior to delivery as required. (*See* **Edge shape; Transition quality in RGP lenses**.)

Reactive eye

This is a general term for those eyes that have a greater propensity to react to many ordinary, everyday stimuli, and contact lenses in particular (McMonnies, 1978). These eyes show chronic conjunctival hyperaemia and injection of episcleral vessels and may have pterygia or pingueculae. Other signs and findings associated with the reactive eye syndrome include lid conditions such as blepharitis; skin conditions such as acne rosacea; tear deficiency, chronic follicular or papillary changes in the palpebral conjunctiva and meibomian gland dysfunction. There may be a history of allergies such as hay fever, as well as a propensity for reactive eyes to respond adversely to normal stimuli such as wind, dust, glare, smoke, smog, lack of sleep, eye strain and food allergies, such as an ocular hyperaemia response to alcohol consumption.

Steps taken to ensure lens care and lid hygiene can help to reduce the response to the physical, chemical, physiological and immunological stimuli provided by a contact lens. After-care visits are the opportunity to re-emphasize the key management factors for these patients. *Figures 18.17, 18.18* and *18.31* illustrate some of the above-mentioned conditions.

Management: Identify features of reactive eyes before fitting and, depending on degree of reactivity, recommend moderation of contact lens usage to minimize adverse responses. Remind patients that their eyes might react adversely to excess contact lens use. Ensure rigorous cleaning with a surfactant cleaner and protein remover tablets. Recommend use of disposable or frequent replacement lenses and avoidance of solution preservatives. Take steps to control meibomian gland dysfunction and blepharitis. (*See* **Chronic hyperaemia; Lid hygiene**.)

Reading difficulties

Some myopic patients will report difficulty with reading when wearing contact lenses because myopes need to accommodate more than when they are wearing spectacles. Incipient presbyopes are, therefore, likely to be disappointed if reading over-spectacles are required with contact lenses when they could read quite well with single vision spectacles. This accommodative disadvantage is greater for higher degrees of myopia. Even younger myopes can experience difficulty if their habit was to read unaided prior to being fitted with contact lenses; a 2 dioptre young myope requiring very little accommodative effort for reading when uncorrected, may take many weeks to learn to accommodate for near focus when wearing contact lenses. The closer this type of patient is to presbyopia, the more difficult the adaptation will be. Happily, hyperopic patients experience an accommodative advantage when wearing contact lenses. In the case of higher degrees of hyperopia, the need for supplementary reading spectacles in early presbyopia is usually delayed. (*See also* Chapter 5.)

Management: Apart from accommodative/focusing problems, consider blink efficiency and associated lens drying as contributing factors (*see* **Monovision; Presbyopia**).

Reconditioning

Reconditioning of lenses may be performed for patients whose lenses have become degraded, but do not necessarily need replacing. Patients should be encouraged to accept responsibility for maintaining their lenses in satisfactory condition. If patients think that their poor compliance with maintenance instructions can be absolved by occasional recovery operations performed by the practitioner, there is reduced incentive for them to look after their lenses.

However, when considered appropriate, more powerful cleaning measures can be performed 'in office' (*see* Chapter 4), but care should be taken to avoid accepting responsibility for the outcome. The more degraded the lenses are the stronger the measure required for improvement, and the stronger the indication for replacement rather than reconditioning. (*See also* **Polishing**.)

Record keeping

This requires a balance between filling cards with unnecessary details of after-care visits and not recording sufficient information for effective problem-solving. For example, it is unnecessary to record that the patient *is* complying with maintenance instructions although any departure from recommended technique should be noted so that future visits can include a follow-up discussion. Again, if a trial with lenses reversed – right switched with left – is not recorded, confusing results may be obtained at the subsequent visit. Economy of detailing findings is achieved through the use of abbreviations. An uncomplicated soft lens visit might show the record:
WT 12, No S, R&L 6/6, No O/R, R&L (o, o) M1, B-ve Rep 12/12
indicating that wearing time is 12 hours average each day, there are no symptoms, both eyes read 6/6 with neither eye having significant over-refraction, both lenses centre and move 1 mm on upward gaze blink, biomicroscopy results are unremarkable, and the patient is to report for the next after-care visit in 12 months. Many observations are readily rated on nominal or ordinal scales that can be described economically. For example, rigid lens/corneal curvature relationships can be described by the following shorthand system: AL– for borderline flat, AL for alignment, AL+ for slight clearance, AL++ for definite clearance etc. (A. J. Phillips, 1987, personal communication). The recording of conjunctival hyperaemia is another example, where a photographic reference scale allows six grades of hyperaemia to be determined (McMonnies and Chapman-Davies, 1987b) and these can be recorded as H0 through to H5 so that time and record card space is conserved (*see Figure 18.11*).

A Grading Scale of commonly observed conditions is shown in Appendix D at the end of this book.

Re-fitting contact lenses

Re-fitting contact lenses to an existing wearer is indicated when changes in refraction and/or a degraded lens condition indicate a potential for significant improvement with new lens prescription, design or material. Degraded rigid lenses show accumulated surface scratches and/or significant changes to the back optic radius, including warpage. Degraded soft lenses also show surface scratches and deposits, as well as loss of shape, deposits and discoloration. A gradual loss of lens performance (comfort and vision) over a number of years is often not appreciated by patients with good tolerance until the change is made to a new fitting. It is part of the responsibility of after-care to advise that re-fitting is required when sufficient indicators are encountered. (*See also* Chapters 10, 11 and 14–20.)

Refractive changes after wearing contact lenses

Ideally patients should be able to alternate between contact lenses and spectacles, with a similar visual performance being obtained from either form of correction. The ability to do this is one criterion for measuring the success of a contact lens fitting. Patients with higher levels of ametropia are likely to experience difficulty when changing from contact lenses to spectacles. Myopes, although having a larger field of view in spectacles, experience a smaller retinal image size and peripheral distortion. Astigmats find everything is distorted in spectacles, while hypermetropes have a reduced field of vision but do gain a benefit in the increase in retinal image size afforded by spectacles. (This may be very useful for hypermetropes or aphakes with poor acuity who may see better in spectacles than contact lenses.) Habitual contact lens wearers, therefore, may experience spatial disorientation and other perceptual problems when they wear spectacles. Their world may appear to be 'out of shape' and their ability to judge distance may be significantly altered.

For any contact lens wearer, the change to spectacle correction may be more difficult when corneal oedema and corneal curvature changes have altered refractive error (Rengstorff, 1978). Greater difficulties are encountered when contact lenses induce higher levels of hypoxia due to increased thickness and/or lower oxygen permeability. The problem is compounded when lens design and lens location combine to induce corneal shape changes, especially when the same lens design is worn for many years. For example, long-term PMMA wearers may have great difficulty with spectacles (*see* **Spectacles**). Over a period of often many months, these patients can be rendered more correctable by spectacles if refitted with highly gas permeable materials. A measure of successful rehabilitation is found when spectacle refraction yields a decisive end-point that indicates correcting powers similar to those required in contact lenses (after allowing for vertex distance in powers over 4 dioptres). (*See* Chapter 5.)

Desirable corneal curvature changes may be induced using the principles of orthokeratology to achieve transient or even permanent reduction in refractive error (*see* Chapter 19).

Management: Counsel patients about potential problems when changing to spectacles. Try to establish realistic expectations for variation in performance of spectacles depending on how recently contact lenses have been worn (on removal, on waking etc.) (*see* **Spectacles**).

Re-instruction

Re-instruction of handling and maintenance techniques is sometimes needed at after-care. Occasionally, amazing

departures from recommended methods are encountered, not necessarily due to ineffective instruction, but because patients may have taken incorrect advice from other sources. In either case, re-instruction is needed. Additional instruction may be needed at after-care that cannot be anticipated at the delivery visit; for example, after-care patients may require instruction regarding blink efficiency, lid hygiene, cleaning the inferior portion of non-rotating lenses, tear supplement use, tissue use on the removal of rigid lenses etc. Written hand-outs can be issued for home reference to reinforce consulting room discussion (McMonnies, 1974a) (*see* Chapter 9).

Reports

These are needed by patients who require after-care from another practice when travelling or moving house. A copy of the latest keratometry findings, spectacle prescription and contact lens prescription, including recommended maintenance products, are the most useful basic information. Other significant details can be added if necessary to facilitate the transfer of after-care responsibility.

Residual astigmatism

This is suspected when expected acuity is not obtained with spherical over-refraction, and can be confirmed by retinoscopy, which allows the assessment of varying lid position and lens movement. A decentred lens, especially with high power, will induce an astigmatic effect and variations in lens flexure may be induced with changes in palpebral aperture and lid tonus. After retinoscopy, the degree and axis of residual astigmatism can be refined with subjective refraction, but allowance should be made for the variation in subjective responses that occurs from blink to blink. Reliability of responses can be increased by removing any lens surface deposits and ensuring an even wetness of the front surface. In addition, greater viewing time of the alternatives should be allowed during subjective refraction so that blinking can clear vision and stabilize lens position. Even with these precautions, retinoscopy should be regarded as the principal finding. In the case of rigid lenses, residual astigmatism induced by flexure can sometimes be eliminated by varying centre thickness and lens/cornea fitting relationship (*see* **Flexure**).

Sometimes lens flexure fortuitously compensates for residual astigmatism that would occur if a non-flexing lens was fitted, and this phenomenon may explain some of the differences in visual performance found with lenses of the same prescription made with different centre thickness or in a different material. For either rigid or soft lenses, front and/or back toroidal surfaces can be used to compensate for residual astigmatism, or supplementary spectacles can be prescribed for occasional use. (*See also* Chapters 5, 10 and 11 and 14.)

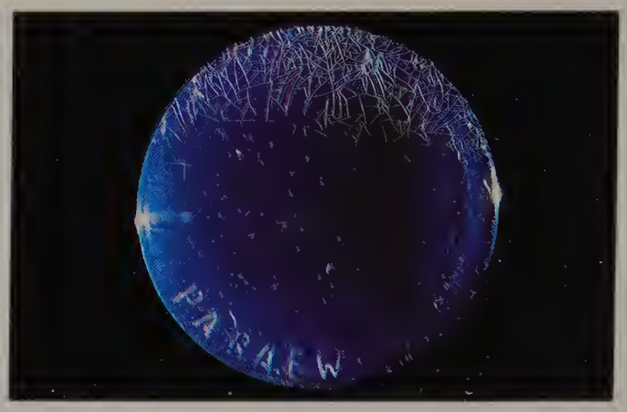


Figure 18.32 Surface crazing and cracking of high oxygen permeable silicone–acrylate lenses is often seen as the lenses age. Symptoms can range from slight loss of vision if occurring centrally, to some loss of comfort. Removal of the cracks is not possible and lens replacement is the only answer, but in the early stages of surface crazing it may be possible to repolish the surface. (Courtesy of A. J. Phillips)

Management: Custom toric soft lenses are indicated if stock lenses result in significant residual astigmatism. If the use of toric RGP lenses to compensate for residual astigmatism is not indicated (e.g. in keratoconus) consider supplementary over-spectacles to correct residual astigmatism. These can be photochromic to expand their usefulness. Consider including a correction for residual astigmatism in reading over-spectacles.

Rigid lens verification

For rigid lens verification, *see* Chapter 12; *see also* **Lens parameters**; **Quality control**.

Scratches

Scratches that develop earlier than expected should be noted at after-care visits, and can be due to faulty case design, rough skin on hands, from a ring on a finger, or the lens dropping on to a hard surface.

When the lens convex surface matches a smooth or basket-type case surface, the lens will usually be removed by sliding. This action provides a daily opportunity for dust or degraded plastic surfaces to scratch the lens. Soft lens case wells should be ribbed and/or flat bottomed to minimize this problem. Some lens cases allow for the lens to be suspended, free from flexure stress, by soft plastic holders that project from the case ends into the storage fluid. However, a large diameter lens may be come warped if lens flexure is induced by this method and the cases are difficult to clean. Chapter 22 describes the technique for polishing out scratches on rigid lenses. Incorrect retrieval of a dropped lens can result in lens scratching. The appearance of deep scratches may in fact be surface crazing (*Figure 18.32*) in which case the lens will need to be replaced. (*See also* Chapters 10, 12 and 13.)

Management: Ignore minor scratches. Repolishing RGP lenses yearly will reduce scratches and restore a relatively deposit-free surface but a small reduction in thickness occurs on each occasion and if possible replace high Dk lenses (Woods and Efron, 1996). Avoid storage case designs that increase scratch damage. Replace excessively scratched lenses that soil too easily or which cause irritation. If rough skin is the problem suggest the use of a clean, lint-free tissue.

Sequential stain

This occurs with multiple instillations of fluorescein over a period of several minutes and is associated with contact lens intolerance, but can be observed in mild forms in successful wearers (Korb and Herman, 1979). Several instillations of 2% liquid fluorescein at 5-minute intervals may be necessary to identify at-risk patients, or to detect signs consistent with poor contact lens tolerance. Absence of fluorescein stain upon sequential instillation suggests normal epithelial integrity.

Silicone rubber lenses

These may be found to adhere tightly to the ocular surface because of pervaporation, i.e. the tears vaporize and the vapour passes through the silicone rubber material reducing the volume of liquid beneath the lens causing lens adherence to the cornea (Refojo and Leong, 1981). Attempted removal may lead to corneal abrasion unless the depleted tear layer under the lens is supplemented with isotonic saline. Frequent instillation with head tilted back is required. When lens movement is restored, removal can be completed safely. However, the lens can usually be safely removed without instilling saline by using the edge of a rubber suction holder to lift the edge of the lens away from the eye. If lenses still prove resistant, removal can be effected with round-ended forceps, after instillation of a local anaesthetic drop. (*See also Figure 11.33* and Chapters 9 and 11.)

Slit lamp biomicroscopy

For this, *see* Biomicroscopy; Chapters 6–8.

Spectacles

For contact lens wearers, spectacles are usually most appropriately prescribed after a 12-hour break overnight from lens wear, providing the lenses have not been overworn the previous day. Prescribing spectacles immediately after lens removal may give less reliable results (especially for astigmatism) and a myopic over-correction (or hypermetropic under-correction). Some practitioners like to obtain a mid-afternoon refraction, immediately after lens removal and another first thing in the morning, after no contact lens wear overnight. The correction given is a compromise between the two results. Waiting days or weeks for keratometry findings to stabilize is not practical or necessary with RGP materials. If poor results are obtained after a 12-hour break from lens wear, keratometry will indicate corneal changes that necessitate improvement in the contact lens fitting and management. For the PMMA lens-wearing patient who has no spectacles, wearing times cannot be reduced without some form of correction for the non-contact lens periods. In these cases, an initial prescription of approximate spectacles is needed, which allows for reduced contact lens wearing times while concurrently refitting with RGP lenses. (*See* **Refractive changes after wearing contact lenses; Supplementary spectacles**.)

Striae

See **Corneal oedema**.

Stinging

This is usually reported on lens insertion or soon after. Possible causes include an adverse reaction to the pH, buffering, tonicity or preservative in a storage or rinsing solution, or hydrogen peroxide that has not been effectively neutralized. The sensation and associated hyperaemia and lacrimation should pass after a few minutes if the stimulus is mild. Other possible causes include lens contamination from unwashed hands or misapplied cosmetics. New lenses may sting if not completely leached of toxic substances introduced during manufacture, and in mild cases a few minutes immersion of the lens in fresh saline will allow for comfortable re-insertion. (*See also* Chapter 4.)

Suction holders

Suction holders intended for contact lens removal should only occasionally be recommended. If after-care visits reveal continuing problems with lens removal (loose lids that do not dislodge a rigid lens, or long fingernails that inhibit soft lens removal), further instruction should be given before suggesting a suction holder. These devices can become contaminated and are potential sources of corneal abrasion if removal is attempted after a lens has become displaced onto the conjunctiva. A patient who is dependent on a suction holder is in an awkward predicament if it is lost. Nevertheless, a suction holder may provide a feeling of security for a patient who lacks confidence in lens removal techniques, even if it is never used.

Suction holders are generally essential for removing silicone rubber and flexible gas permeable (FGP) lenses but do not work well with Softperm lenses. (*See also* Chapters 9 and 10.)

Superficial epithelial arcuate lesions (SEALS)

See **Epithelial splitting**.

Superficial punctate epitheliopathy (SPE)

SPE is a common corneal finding in contact lens wearers, being caused by many factors including surface deposit

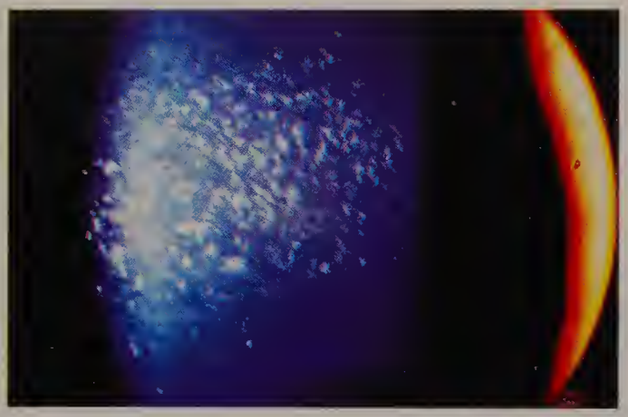


Figure 18.33 Epithelial erosions may occur when soft lenses dehydrate on the eye, such as this case of multiple confluent erosions following short-term wear of a very thin high water content hydrogel lens. It is postulated that small areas of epithelial tissue become attached to the lens and are torn away when the lens is removed. They may also occur when mild degrees of punctate stain remain untreated for long periods or in cases of sterile ulceration, also when debris builds up under a lens or adheres to its back surface. (From Holden, Sweeney and Seger (1986), *Clin. Expl Optom.*, **69**, 103, with kind permission)

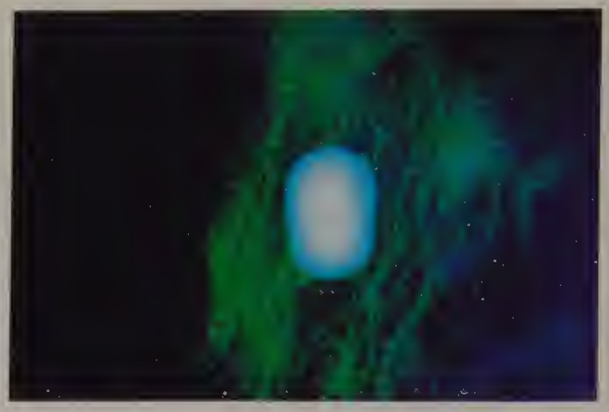


Figure 18.34 Multitrack foreign body corneal abrasion and staining seen under high magnification

abrasion, incomplete tear distribution, tear deficiency, lens damage abrasion and toxic or sensitivity reactions to solution preservatives etc. (*see* Chapters 4, 6, 10, 11, 14 and 15). Additionally, corneal pathologies that are not contact lens-related can cause changes that must be correctly identified (*see* **Corneal infiltrates**). Increased visibility of punctate epithelial lesions suggests associated infiltration with inflammatory cells that reduce transparency rendering them visible with direct focal illumination. Infiltrative lesions may stain better with Rose Bengal than fluorescein, but will not stain at all when superficial healing takes place and the infiltrates become subepithelial. However, abrasive and desiccation aetiologies result in lesions that stain better with fluorescein and these are translucent when viewed with marginal retro-illumination. Haphazard linear distributions of SPE suggest a foreign body abrasion whereas a damaged lens, especially a non-rotating fitting, will cause a localized or arcuate lesion. When only the lower (exposed) area of cornea is involved, inefficient blinking and tear deficiency are indicated as causal factors. Sensitivity and toxic reactions lead to generalized SPE in contact lens wearers, as may the lesions due to multiple causes. Superiorly located SPE suggests superior limbic keratitis. (*See Figures 18.21, 18.22, 18.28, 18.29, 18.33, 18.34, 18.35.*)

Management: Most contact lens-related epitheliopathy heals rapidly after the cause is removed. Greatest concern is indicated with deeper lesions, especially if necrotic, greyish stromal infiltrates are observed in the bed of an epithelial injury that appears to be ulcerating. This type of change is rare but is an indication for immediate action. Concern should always be greater when there is conjunctival inflammation local to the epithelial lesion.

Superior limbic keratitis (SLK)

SLK is characterized by localized bulbar conjunctival injection beneath the upper lid and, as a contact lens-related condition, usually occurs unilaterally in soft lens wearers (*see* Chapters 11 and 15). Aetiology may include prolonged hypoxia, mechanical irritation from the lens edge, an immunological response from protein deposits or solution preservatives.

Symptoms: Vary with severity and include irritation, photophobia and lacrimation.

Signs: Apart from localized injection, the superior limbal epithelium shows various combinations of dulling, infiltration and opacities, and the palpebral conjunctiva shows hyperaemia.

Management: Abstinence from contact lens wear is the principal factor in management, and successful resumption

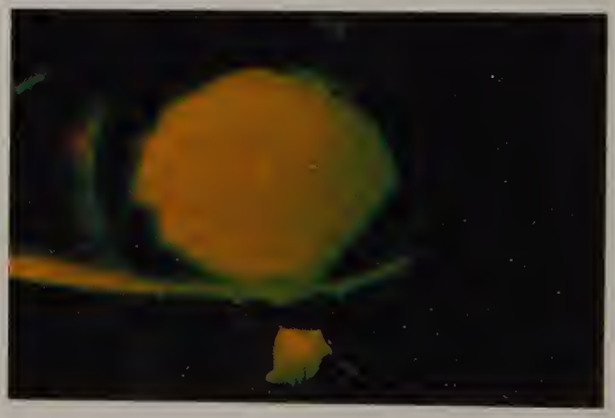


Figure 18.35 Prolonged soft contact lens-induced hypoxia can significantly reduce epithelial adhesion. This may provide an explanation for the SLACH syndrome (soft lens associated corneal hypoxia syndrome) where there is spontaneous loss of up to 40% of the epithelial surface during lens wear. (Courtesy of B. Holden and D. Sweeney)

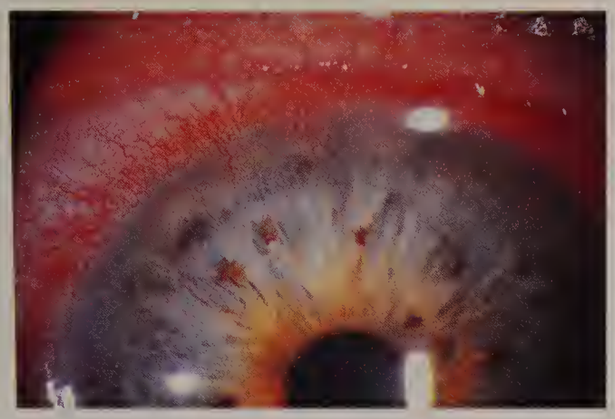


Figure 18.36 Contact lens-induced superior limbic keratitis shows hyperaemia of the superior limbus and adjacent conjunctiva, stromal infiltrates, a fibrovascular micropannus, epithelial haziness and corneal and conjunctival staining to fluorescein (*see also Figures 18.21* and *8.22*). (Courtesy of A. J. Phillips)

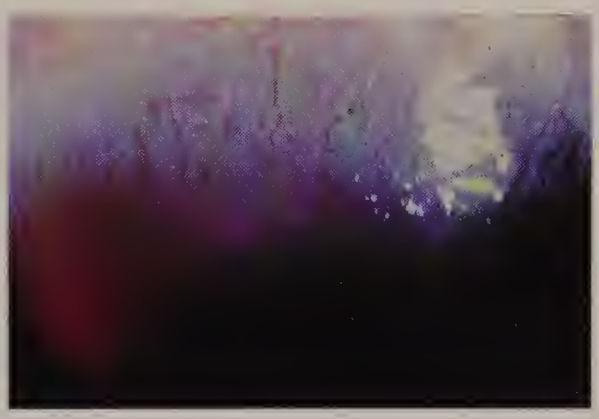


Figure 18.37 The same type of contact lens-induced superior limbal keratitis as in *Figures 18.21, 18.22, 18.36*, showing Rose Bengal staining of the damaged epithelium. This should be differentiated from that in *Figure 18.38*. (Courtesy of A. J. Phillips)

can occur when signs have resolved in most cases, although sometimes recovery takes several months. However, because thimerosal toxicity has been a common factor in some reports (Stenson, 1986), resumption with new or thoroughly purged lenses is indicated together with, when necessary, a change of maintenance products to avoid thimerosal. If soft lens intolerance recurs, re-fitting with rigid lenses is indicated. SLK may occur independently of contact lens wear, sometimes in association with thyroid disease – this is Theodore's SLK. In some of these cases, treatment with bandage soft lenses is required to reduce abnormal lid friction (shear forces) on the superior bulbar conjunctiva. In contact lens wearers, routine examination under the top lid allows for early signs to be detected, and localized hyperaemia should prompt the use of Rose Bengal stain. (*See Figures 18.36–18.38.*)

Supplementary spectacles

These are usually required as a reading correction (*see* **Presbyopia**), but there are other indications. When residual astigmatism is encountered, but a toric lens is an unwanted complication to the fitting (for example in keratoconus), a supplementary pair of spectacles worn over the contact lenses is indicated. These may be prescribed with photochromic lenses so that their usefulness is increased. Additionally, 'monovision' patients may require supplementary spectacles for concentrated distance or close work purposes that require optimum binocular vision (*see* Chapter 16). (*See also* Chapters 10, 11, 14–17 and 20.)

Surface deposits

These form on some types of lenses more than others and develop excessively for some patients despite their best efforts in following maintenance instructions. The reasons for susceptibility of particular materials and particular patients are not known with certainty, but the numerous assoeiated problems must be dealt with at after-care visits.

Management: A simple remedial approach is to recommend an increase in lens cleaning time so that if 10 seconds per lens surfactant cleaning was recommended, an increase to 20 seconds is suggested. Another technique is to simply repeat the surfactant–rinse cycle. Increased frequency of use of enzyme tablets may help as will the use of a surfactant cleaner prior to using the enzyme tablets, so that unbound deposits (the most recently formed) are removed. This procedure exposes the bound (older) deposits to a greater concentration of enzyme. Use of surfactant cleaner immediately after enzyme tablet exposure will help to remove deposits partly broken down by enzyme action (as well as helping to remove the residual enzyme itself, so that the risk of an adverse reaction to the enzyme is reduced). Problem levels of deposits observed at after-care visits may be due to inappropriate product recommendations. Changes

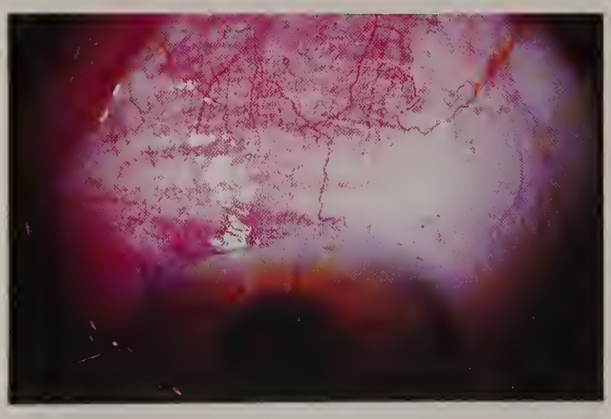


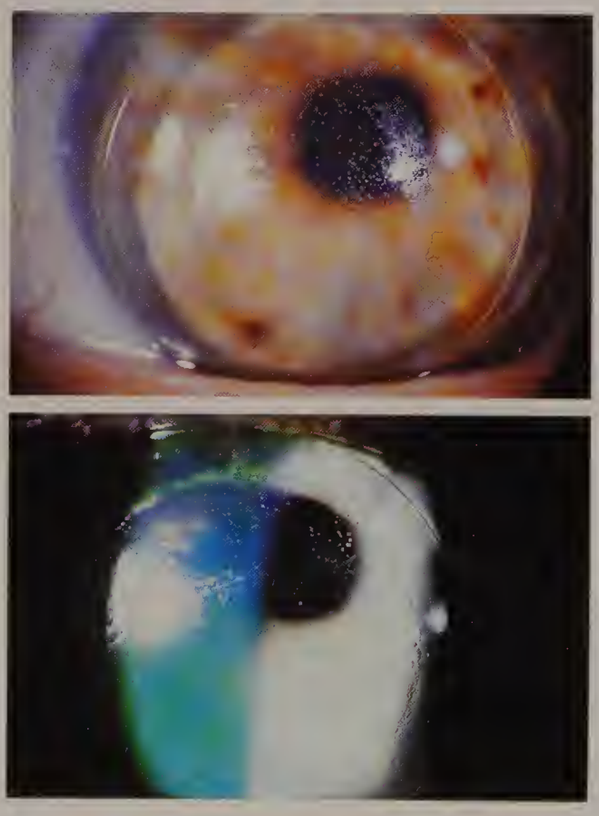
Figure 18.38 Superior limbic keratitis (SLK) or Theodore's SLK occurs when there is abnormal frictional force between lid and globe. The condition is commonly associated with thyrotoxicosis. Epithelial staining to Rose Bengal can be seen in the area above the globe and a fold of loose or stretched conjunctiva hangs over the upper limbal area. The condition often responds to the use of an extended wear bandage lens, ocular lubricants and, of course, the treatment of any underlying condition. True SLK should be differentiated from contact lens-induced SLK (*see Figures 18.21, 18.22, 18.36, 18.37*) which also stains similarly with Rose Bengal. (Courtesy of A. J. Phillips)



Figure 18.39 Grease and mucus on the scratched front surface of a corneal lens. (Courtesy of A. P. Gasson)

to more powerful surfactants that contain abrasives for more effective cleaning (emulsion cleaners) may be indicated. Because enzyme action is specific to certain types of protein, it may be found that a different type of enzyme (for example, animal- or vegetable-derived) is indicated. The comparative performance of enzyme cleaners can sometimes be determined by suggesting that two different types are used on alternate weeks, so that the patient can assess, by estimation of relative comfort levels, which product is the more effective. By a similar process, it may be found that a patient is better off to continue alternating brands of enzyme weekly, as this procedure will expose deposits to a greater range of enzymes, and may result in cleaner lenses. Dealing with a deposit problem effectively may require consideration of factors other than maintenance procedures. When tear deficiency leads to increased lens soiling, any step to improve tear function will help relieve the deposit problem. Use of tear supplements may be indicated along with improvement in blink efficiency for example. Excessively oily deposits may be noted at after-care visits, indicating abnormal meibomian gland function that requires attention to lid hygiene (*see* **Lid hygiene; Tear deficiency management**). Non-rotating lenses show greater deposits on the inferior convex surface in patients with inefficient blink patterns. These patients need to be taught special methods that emphasize more efficient cleaning of this area (*see* **Inferior surface deposits**). Most importantly, compliance with recommended techniques is essential for achieving a sustained optimum level of lens maintenance (*see* **Compliance with instructions**). Chapter 4 should be consulted for additional information on lens maintenance. (*See Figures 18.16, 18.27, 18.39–18.46* and Appendix C.)

After maximizing lens maintenance and compliance consider changing to disposable or frequent replacement lenses. Treat tear deficiency and blink inefficiency. Polish RGP lenses more frequently. Reduce lens wear when reading in air conditioning/central heating. Lens prescribing should include choice of material least likely to soil (e.g. avoid high water content ionic materials).



(a)

(b)

Figure 18.40 (*a*) Protein deposition on an RGP lens seen by direct, indirect and specular reflection illumination with the slit lamp. (*b*) Deposits occurring in the lenticular junction shown by indirect illumination. These build up because of the lack of the normal sweep action of the lid into this area combined with a similar effect in lens cleaning. (Courtesy of A. J. Phillips)

Swimming

Swimming in rigid lenses may lead to lens loss. Goggles can be worn over rigid lenses but are seldom effective enough to be completely safe. For snorkelling and diving, a

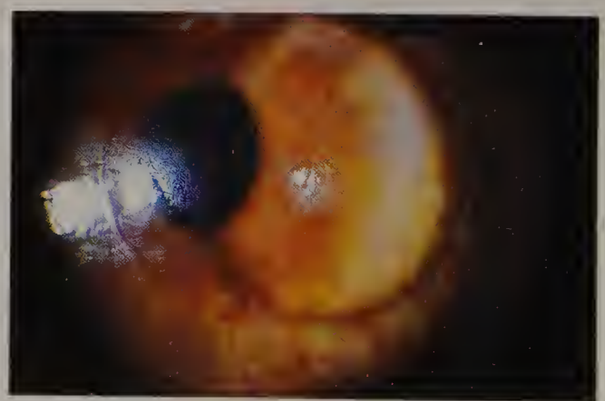


Figure 18.41 Deposits on a lenticulated soft lens are shown here largely by specular reflection. As the surface dries out between blinks the deposits are more readily visible. Deposits may be seen by direct, indirect or specular reflection methods of slit-lamp illumination and all three methods should normally be employed. (Courtesy of A. J. Phillips)

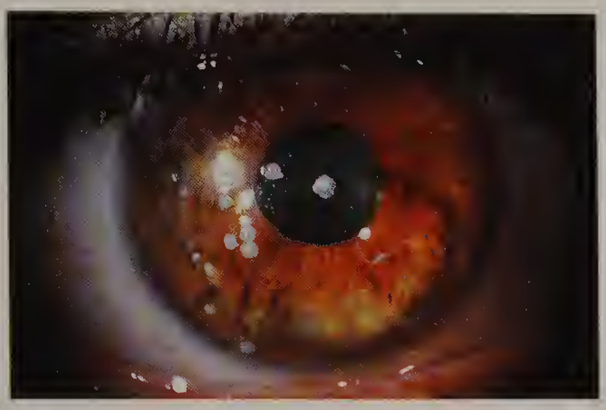


Figure 18.42 Lens calculi or mulberries or jelly bumps represent localized areas of lipid build-up with calcium salts sometimes also present. The calculi build up around the edge of dry spots on the lens surface until they eventually break through the tear film. Because of their interaction with the lid on blinking the lens is often rotated until the majority of calculi lie in the lower half of the lens when on the eye, severely affecting vision. (Courtesy of A. J. Phillips)

face mask offers satisfactory protection as water that leaks in can usually be eliminated by an experienced lens wearing diver, without lens loss. It is advisable to remove soft lenses or use swimming or diving goggles. In the event of contamination with swimming pool water, lenses should be disinfected by a method considered active against possible Acanthamoeba contamination (*see* Chapter 4).

(a)



(b)

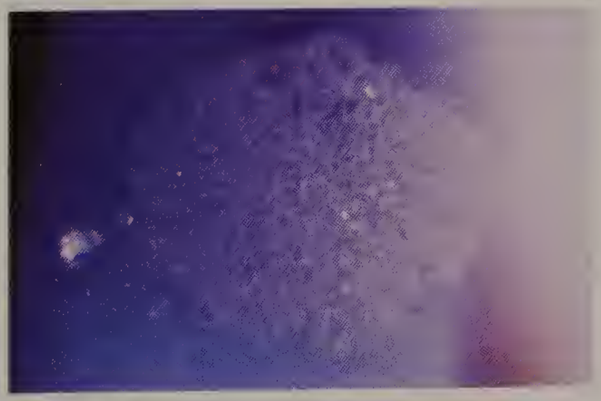


Figure 18.43 Fungal growths can occasionally be seen in inadequately disinfected soft lenses. Few symptoms are reported by the patient unless the growth is central when vision may be affected. The fungal hyphae can be detected (*a*) at low magnification and are clearly visible (*b*) at high magnification. (Courtesy of A. J. Phillips)



Figure 18.44 Calculi stained for lipid with Oil-Red-O showing the crater or doughnut effect as they build up around the edge of dry spots. (Courtesy of A. J. Phillips)

Tear circulation

Tear circulation is most effectively evaluated at after-care visits when lenses have fully settled. Indications of poor circulation include delayed movement of fluorescein-stained tears under a rigid lens, or the accumulation of stationary tear debris under either rigid or soft lenses. Lack of lens movement with blinks is another clue to this potential problem which may predispose towards red eye responses, especially with extended wear (*see* Chapter 15). Poor tear circulation will lead to oedema with any type of fitting. (*See also* Chapters 10, 11, 14–17.)

Management: Sometimes fenestrations help tear circulation in rigid lens fittings (*see* **Fenestration**). Avoid matching toric RGP back optic radii to corneal curvature too exactly. Increase edge lift (*see* Chapter 10). Alter design of hydrogel lenses to improve lens movement and tear circulation.

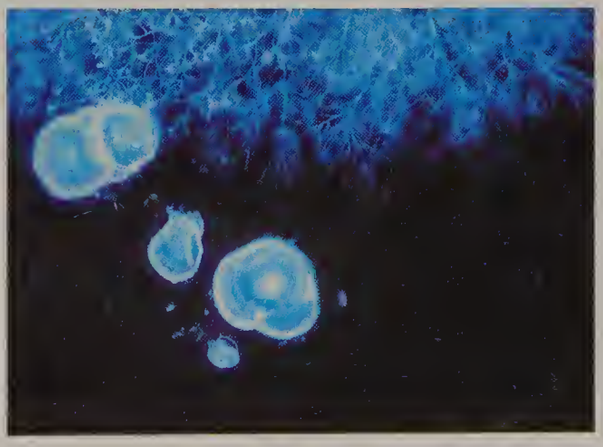
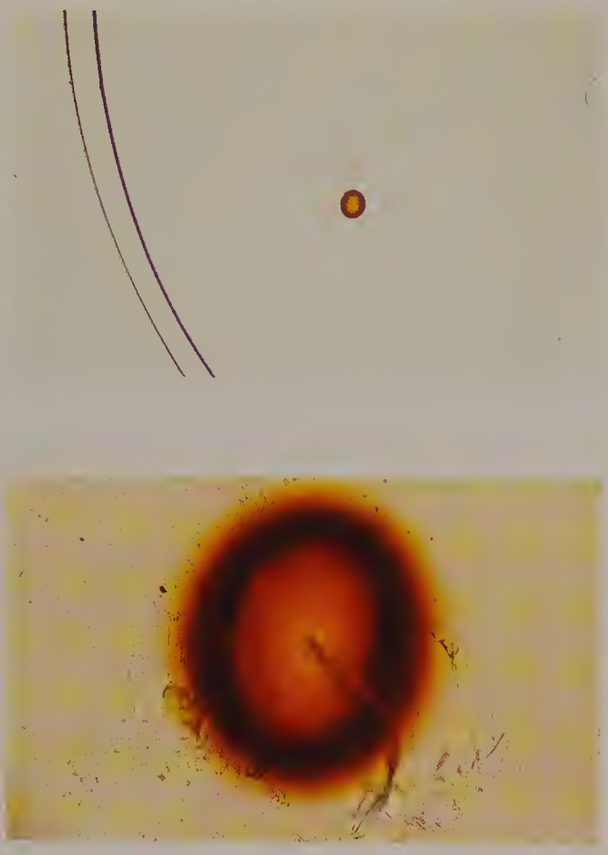


Figure 18.45 The doughnut nature of many soft lens calculi is clearly shown here by dark field microscopy. Fungal growth is also visible at the top of the picture. (Courtesy of A. J. Phillips)



(a)

(b)

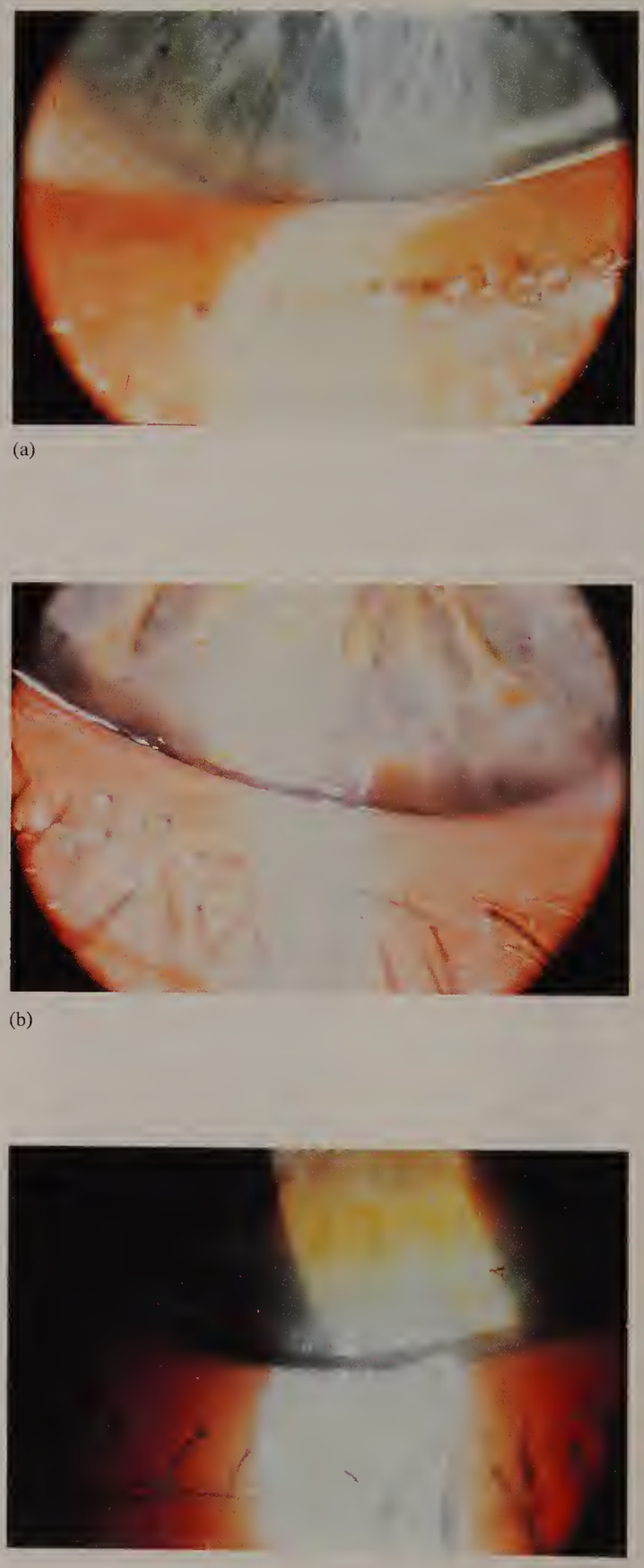
Figure 18.46 (*a*) Small pin-point red dots seen in hydrogel lenses are usually rusting metallic particles. Careful differential diagnosis from small fungal growths should be made. Most rust spots create no subjective or objective problems. (*b*) Under high magnification the split in the lens surface where the foreign body entered can easily be seen. The rust stain from the centre of the particle has diffused out through this split. (Courtesy of A. J. Phillips)

Tear deficiency

This may cause contact lens intolerance. Although the prevalence of established dry eye conditions is low for populations wearing contact lenses for the correction of refractive error (McMonnies and Ho, 1986), patients with marginal dry eye conditions may be susceptible to tear deficiency problems when contact lenses are worn. It has been shown that a dry eye questionnaire and biomicroscopy can be used to identity these patients (McMonnies and Ho, 1987a,b) as well as slit lamp examination together with the Tearscope (*see* Chapter 6) (McPherson, 1993; Guillon and Guillon, 1993).

Signs: Contact lens surface drying and associated surface deposits. Other signs include:

- Conjunctival hyperaemia.
- Reduced height, irregular or excessively viscous marginal tear prism (*Figure 18.47*).
- Excessive precorneal tear debris (*see Figure 18.48*).
- Dull specular reflection from a desiccated bulbar conjunctiva.



(a)

(b)

(c)

Figure 18.47 Tear prism height is one method of estimating tear volume. (*a*) deficient; (*b*) normal; (*c*) excess. Ectropian may significantly invalidate this type of observation



Figure 18.48 Rose Bengal staining of a dry eye: note tear debris. (Courtesy of A. J. Phillips)

- Meibomian gland secretion that is excessive (indicated by oily lid margins) may be exacerbated by frequent application of suntan oil or cosmetic preparations (*see Figure 18.17*).
- Meibomian secretion that is contaminated and deficient in association with blockage of the gland orifices with waxy plugs of abnormal secretion (Henriquez and Korb, 1981). The interference pattern caused by the lipid layer with corneal specular reflection will be disturbed or not present when meibomian gland secretions are deficient (Josephson, 1983). Sometimes the deficient meibomian glands are obviously infected with *Staphylococcus spp.*, when purulent plugs occlude the orifices in meibomitis, or hordeola are present that lead to contaminated tears and symptoms. Also, meibomian gland dysfunction may be indicated by a froth formation at the canthi and along the lid margins. (*See* **Lid hygiene**.)
- Fluorescein and Rose Bengal stains may facilitate the observation of excess mucus, and will reveal epitheliopathy, although Rose Bengal stain of devitalized cells is often not seen until dry eye pathology has advanced past the marginal stage (*see Figure 18.49*). Reduced aqueous volume is indicated by dull fluorescein appearance (hypofluorescence) and by delayed elimination of the stained tears (necessitating extra irrigation before soft lenses can be re-inserted).
- Superficial punctate epitheliopathy may be apparent, especially in the inferior areas of the cornea exposed by inefficient blinking.
- Tear instability may be indicated by rapid break-up time that suggests deficiency and/or poor lid apposition to the globe during blinks. Tear break-up observed during normal interblink intervals is more significant than that induced by having the patient refrain from blinking (Andres *et al.*, 1987).
- Stain at 3 and 9 o'clock with rigid lenses (*see* **Three and nine o'clock peripheral stain**), and superficial punctate epitheliopathy in the exposed area of the cornea with soft lenses (especially torics) may both be manifestations of tear deficiency.

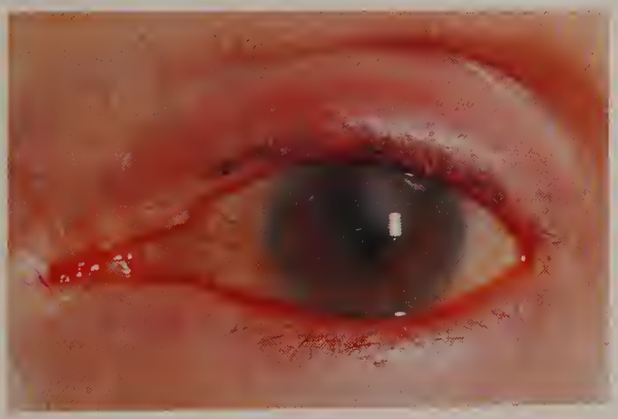


Figure 18.49 Keratoconjunctivitis sicca associated with chronic blepharitis where both aqueous and lipid layers of the precorneal tear film are affected. (Courtesy of D. Westerhout)

See Figures 18.29, 18.47, 18.48, 18.49 and *see also* Chapters 4, 8 and 9.

Symptoms: Dryness and grittiness for rigid lens wearers, and dryness and soreness for soft lens wearers (Bron and Quinlan, 1993). Soft lens wearers report these symptoms significantly more than hard lens wearers (McMonnies and Ho, 1986).

Management: The prescribing of tear supplements can help alleviate the problem of dry eyes and various different products are available. Preservative-free supplements are often found to be the most beneficial (see Appendix C).

Meibomian gland dysfunction in which the orifices become plugged with waxy secretion can be treated with expression of the blocked glands, hot compresses, lid massage and the scrubbing of the lid margins with a cotton bud, using either a diluted shampoo that is not irritant to the eyes, or bicarbonate of soda dissolved in cooled boiled water or Ciba Vision Lid Care (Henriquez and Korb, 1981). Scrubbing and expression are required when the orifices are plugged but, as the gland condition improves, simple lid hygiene involving hot compresses and massage should be sufficient to maintain the improved function. Treatment for blepharitis and seborrhoea control helps to maintain the improved meibomian gland condition. When meibomian gland secretion is excessive and causes lens surface oiliness and non-wetting, lid hygiene measures (*see* **Lid hygiene**) assist, but advice to reduce the application of suntan oil or cosmetic creams such as skin conditioning and anti-wrinkle preparations may be necessary. Tear deficiency associated with exposure (partial blinks and inferior location of deposits etc.) is managed through improvement in blinking (*see* **Blink efficiency**) and by avoiding wearing lenses in provocative drying conditions whenever possible. For example, removal should be recommended during prolonged periods of intense vision (reading or visual display unit activity etc.), especially when the patient is fatigued

and/or exposed to heating systems that dehumidify the air (Anon., 1994) (*see also* Chapters 4 and 20.7).

Summary: Identify vocational risk factors (central heating/air conditioning, VDU use). Consider tear supplements appropriate to specific patient needs. Trial and error is usually necessary to determine the most suitable product. Advise lid hygiene procedures (compresses, scrubs etc.) where meibomian gland dysfunction and/or blepharitis indicate need. Improve blink efficiency and modify lens use to avoid difficult lens wear conditions. Consider prescribing materials least likely to soil (e.g. avoid high water content ionic materials). Consider punctal occlusion trial (Anon., 1992; Bockin, 1993) (*see also* **VDU problems**).

Three and nine o'clock peripheral stain

This localized staining and desiccation only occurs in areas exposed to the atmosphere between blinks. It has been more common since the introduction of RGP materials (Bennett and Egan, 1986). It presents as a chronic condition for many patients, progressing to scarring and vascularization of the cornea in some cases (*see* **Pseudopterygium**). Possible causes include inability of eyelid to properly resurface the cornea with mucin due to lid-bridging over the contact lens edge, and abrasion due to lens movement. These factors may combine with predisposing conditions such as a hot dry climate, tear deficiency and inefficient blinking (Sarver *et al.*, 1969) (*see Figures 18.29, 18.30*).

Management: Refit lenses with reduced edge clearance and/or smaller or larger total diameters. Ensure edge is not too thick and is well polished. Improve blink efficiency and treat tear deficiency. Ensure rigorous surfactant lens cleaning. Reduce lens wear for prolonged periods of reading or high vision demand. Consider a change to soft lenses (*see* **Pseudopterygium**; *see also* Chapter 10).

Tonometry

Tonometry through contact lenses is not advisable. However, McMonnies (1986b) showed that using a non-contact tonometer over soft lenses with a centre thickness of less than 0.15 mm can be considered reliable. Soft lenses of greater thickness will increase readings significantly. It is possible that these conditions of measurement apply with other types of tonometer such as the Mackay–Marg, Schiötz and Alcon pneumotonometer, but readings with the Goldmann applanation tonometer have been found to be unreliable due to inadequate mire pattern quality (Deluca *et al.*, 1974).

Toric lenses

These may not give expected visual results because of incorrect prescribing of power or axis, inaccurate manufacture, poor fit, or meridional mislocation that is either constant or variable. In the case of toric soft lenses, it is useful to rotate the lens in 2.5° steps to find the axis of maximum acuity. A cotton bud provides a hygienic and convenient method of altering axis location in a controlled manner for this purpose. If satisfactory acuity cannot be achieved by this technique then it can be concluded that the lens is incorrectly made in regard to power or quality of optics. A lens that gives good acuity intermittently or when rotated to the correct axis, is probably a correctly prescribed and accurately made lens that requires a tighter fit and/or increased prism or truncation to stabilize axis location (*see also* Chapter 14).

Management: When vision results are poor consider change in refraction, accuracy of prescribing, accuracy of manufacture (for powers, axis and optical quality) and accuracy of meridional location on the eye.

Toxic fumes

These may contaminate soft lenses and lead to symptoms and loss of tolerance. Industrial sites that expose workers to fumes and vapours from paint, glue, plastic, solvents, cleaning agents or any other source of air-borne contamination, need to be identified so that the patient can be advised accordingly. Anti-splash protective goggles worn when toxic liquids are handled are not enough protection against adsorption from the air. Goggles need to be air-tight for adequate protection. Apart from vocational risk, it is necessary to remember that hobbyists (e.g. model makers) and home renovators may also be exposed to toxic fumes intermittently. Such exposure may be forgotten when a cause for symptoms is sought at an after-care visit. Purging may be successful in reducing contamination (*see* **Purging**), but sometimes suspect lenses must be replaced and advice given about avoiding future exposure. (*See also* Chapters 4, 8, 9, 11 and 15.)

Transition quality in rigid lenses

Lack of continuity in an elongated fluorescent tube image formed by reflection from the back surface of a rigid lens, indicates a poor transition between optic zone and periphery (*see Figure 18.50*). This type of lens may require modification (*see* Chapter 22) or remaking.

Additionally (*see Figure 18.50*), the non-paraboloidal shape of the image towards the edge indicates unsatisfactory formation of the most peripheral curve and its transition to the posterior edge. In contrast, *Figure 18.51* shows a fluorescent tube image that has a satisfactory shape and smooth transition between optic zone and periphery. Also the paraboloidal shape of the peripheral part of the image indicates a well-formed transition between flattening peripheral curves and posterior edge (*see* Chapter 12). This catoptric image of a fluorescent tube formed by the posterior lens surface can be viewed using a 7× to 10× hand-held magnifier (McMonnies, 1986c).

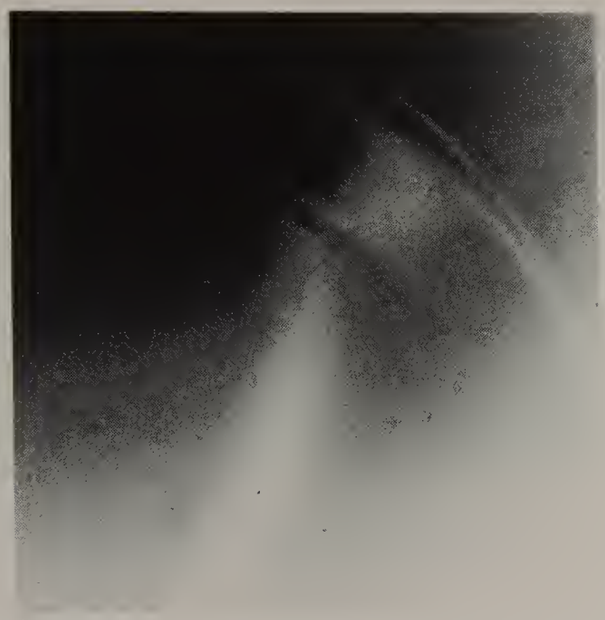


Figure 18.50 Lack of continuity in a fluorescent tube image followed by reflection from the back surface of a rigid lens indicates a poor transition between optic zone and periphery. Additionally, the non-paraboloidal shape of image towards the edge indicates unsatisfactory formation of the most peripheral curve and its transition to the posterior edge. This image can be viewed using a ×7 to ×10 hand-held magnifier (*see Figure 18.51*)



Figure 18.51 The fluorescent tube image from the back surface of this rigid lens has a satisfactory shape. Smooth transition between optic zone and periphery is evident. Also the paraboloidal shape of the peripheral part of the image indicates a well-formed transition between flattening peripheral curves and posterior edge (*see Figure 18.50*)

Travelling

Travelling in contact lenses may be complicated by restrictions on the amount of baggage that can be carried so that contact lens accessories must be limited. Unit dose and other small quantity containers, such as sample bottle sizes, are preferred. Contact lens wearers may encounter hygiene problems in some countries, depending on the availability and quality of water supply. Spectacles should be worn under these circumstances as the availability or standard of contact lens after-care in these countries may be limited. Heat disinfecting units may not be operable on voltages available overseas and conversion plugs that give access to different outlet configurations are often required, even when there is no voltage difference. (*See* **Flying**; *see also* Chapter 8.)

Ultraviolet protection

Sometimes conjunctival injection observed at after-care visits is associated with exposure to excess levels of ultraviolet radiation. Contact lens materials that absorb ultraviolet radiation (*see* Chapter 23) will help to protect the internal eye structures and the cornea (to the extent that such lenses cover the cornea). However, the use of ultraviolet absorbing contact lenses does not remove the need to use protective sunglasses in order that the conjunctiva and unprotected cornea are shielded from excess damaging radiation. For example pterygia and pingueculae that are normally quiescent may become actively inflamed after exposure to ultraviolet if sunglasses are not worn.

Vascularization

Vascularization of the cornea may occur in contact lens wear with both acute and chronic injection of limbal vessels (McMonnies, 1983). Factors that may predispose towards this complication include over-wear, adverse reactions to preservatives, oedema, loss of epithelial integrity, such as 3 and 9 o'clock stain, tight lenses which trap debris and metabolic waste and which cause passive hyperaemia by restriction of limbal blood flow, poorly finished edges and any environmental cause of ocular irritation and injection. These risk factors occur more frequently in soft lens fittings (McMonnies, 1984). Criteria for the assessment of suspected corneal vascularization include the following:

- Terminal limbal capillaries should be at least partly empty and should be seen to lie in translucent conjunctival tissue no more than 1 mm beyond the limit of visible iris (2 mm superiorly where the transitional conjunctiva encroaches over the transparent stroma to a greater extent). A biomicroscopic eyepiece scale can be used to measure the degree of incursion of vessels beyond the limit of visible iris.
- New vessel growth is indicated by spike vessel development projecting from normal limbal loops. During development these will be blind-end capillaries surrounded by inflammatory exudate, but, once established, new spikes can be seen to consist of arterial and venous portions when viewed under high magnification. Adjacent spikes may be seen to join to form a new arcade. Stromal vessels are not continuous with the conjunctival

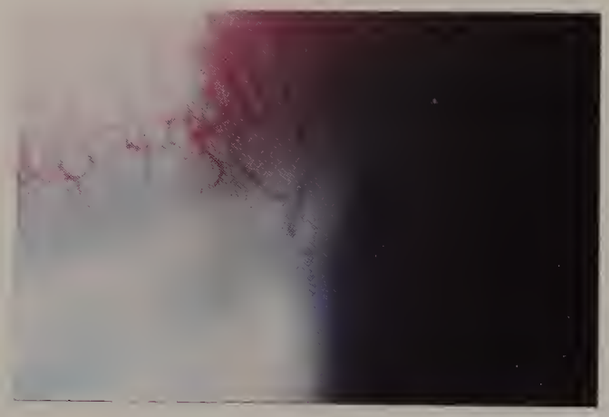


Figure 18.52 Active stage of new limbal vessel growth showing a new spike projecting from an existing arcade and surrounded by exudate



Figure 18.53 Red-free illumination may help detect stromal vessels (seen around 8 o'clock) that are partly obscured by inflammatory lipid exudate when examined with white light

vessels and their growth should be regarded as a more serious complication as they indicate a deeper pathology.

(*See Figures 18.36, 18.37, 18.38, 18.52, 18.53* and *11.36*; *see also* Chapters 6 and 15 and Appendix D.)

Management: Consider risk factors for corneal vascularization. Avoid tight lenses that cause conjunctival indentation and conditions that promote chronic hyperaemia. Refit soft lens wearers with thinner lenses or higher water content materials and consider changing them to RGP lenses. Refit RGP wearers with smaller lenses of higher Dk value.

Vasoconstrictors

Whereas occasional use of vasoconstrictors is not potentially harmful, and helps to relieve intermittent periods of hyperaemia, patients should understand that redness is a sign of ocular stress and, if contact lens-induced, vasoconstrictors do not remove the underlying cause. It is preferable that the cause of increased hyperaemia is treated rather than attempting to mask the problem with a vasoconstrictor, especially as frequent use may lead to rebound (permanent) hyperaemia. (*See also* Chapter 4.)

Vision symptoms

For visual symptoms, *see* discussion at the beginning of this chapter; and *see also under* **Diplopia; Flare; Ghost images; Glare; Over-refraction; Presbyopia; Residual astigmatism; Spectacles**.

Visual display unit problems

The combination of air conditioning or central heating and an intense visual task that tends to reduce blink efficiency will increase the risk of contact lens-related symptoms for people who work at visual display units (VDUs) or terminals (VDTs) for extended periods (Patel and Port, 1991). Reference to **Blinking efficiency** is relevant; however, the increased problems associated with VDU use may require additional action. Most VDU users intermittently employ function keys that involve several seconds delay. Such time lapses can provide an opportunity for the VDU operator to employ some ocular 'pause gymnastics'. Instead of staring at the screen during these prolonged operations, waiting for an indication that work can continue, contact lens wearers, especially those that experience work-related symptoms, can be taught to use delayed function keys as a prompt for them to look away from the screen, preferably into the far distance, and to blink consciously while making exaggerated versional eye movements. These ocular gymnastics will help to clean and rewet lenses as well as to promote lens movement. If repeated intermittently throughout the work day they will help to prevent and/or ameliorate symptoms. Patients may need to be advised to abandon wear or use re-wetting drops during VDU use if symptoms persist.

Visual field examination

The validity of a visual field examination may be increased when a patient wears contact lenses so that field obstruction due to spectacle lens correction is avoided. This advantage is greater for higher refractive errors and when contact lenses are worn during the examination of fields beyond 30°. It is important to encourage a normal blink pattern throughout the examination so that consistent vision and comfort levels are maintained and the patient's ability to maintain fixation and attention to the test demand are not compromised.

Conclusion

There is a critical need to monitor ocular tissue responses during after-care, so that prophylactic management procedures can be employed. The current approach to after-care

appears to be very sophisticated. However, as observation techniques have evolved to reveal contact lens responses in much greater detail, so has come the realization that many gaps exist in after-care knowledge. The need for optometrists and ophthalmologists to continue searching for a greater understanding of contact lens adaptation is clear, and those involved can look forward to the fascination of a complex mystery that unravels on many fronts.

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Chapter 19

Orthokeratology

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Historical perspectives p. 653
Controlled studies of orthokeratology p. 655
Modern orthokeratology p. 656
A specific approach to fitting the OK series p. 665
Is orthokeratology predictable? p. 677
Corneal rheology p. 683
Anatomical considerations p. 685
Clinical experience with accelerated orthokeratology p. 687
Refractive surgery and orthokeratology compared p. 690
Summary and conclusions p. 691

The advent of radial keratotomy and, more recently, photorefractive keratectomy has reawakened optometric interest in orthokeratology as a non-surgical method of myopia reduction. The many documented adverse responses to both surgical procedures, as well as the uncertainty of the stability of the refractive changes in the long term, have been part of the reason for this (Ajamian, 1986; Binder, 1986; Gartry *et al.*, 1992). Also, the development of radically different contact lens designs with the ability to produce rapid alterations to corneal curvature in a short period of time has added to the viability of orthokeratology as an alternative to refractive surgery. The effects of long-term hard contact lens wear on corneal topography have been well documented, especially the tendency for flat fitting lenses to flatten the cornea (Dickinson, 1957; Morrison, 1958; Hodd, 1965; Rengstorff, 1965).

Orthokeratology takes this as its basic premise and extends the effect by progressively flattening the lens fit as the cornea responds, thus reducing myopia and improving unaided visual acuity. Once the desired level of unaided visual acuity has been achieved, a programme of retainer lens wear is initiated until the cornea reaches a level of stability in the 'new' shape. Lens wear is then gradually reduced to the minimum required to attain good functional vision throughout the day.

Orthokeratology is therefore defined as the '*reduction, modification or elimination of a visual defect by the programmed application of contact lenses*'. The correction of hypermetropia by orthokeratology is as yet not considered a viable or stable alternative to current techniques.

The history of orthokeratology is somewhat controversial, with extravagant claims of a 'cure' for myopia in the early 1960s to the largely negative reports from controlled studies in the late 1970s and early 1980s. However, the procedure has its strong adherents who have continued the practice and refined the technique with more advanced lens designs.

Historical perspectives

Jessen (1962) was the first to present the results of his 'orthofocus' technique at the conference of the International Society of Contact Lens Specialists. His technique was to use the liquid lens as the correction for the refractive error, which resulted in quite unstable flat fitting lenses for the higher degrees of myopia. Neilsen *et al.* (1964) are credited with the development of a more controlled technique, which is still in use today. The lenses were fitted up to 0.20 mm flatter than the flattest corneal meridian, with the BOZD equal to the flattest keratometer value and the TD 1.30 mm larger than K_f (Grant and May, 1970).

The periphery was either a well-blended bicurve or aspheric curve. Centration was of prime importance as high riding lenses tended to induce unwanted with-the-rule astigmatism. Further refinement of the technique led them to fit lenses much less flat than before, usually on K or up to 0.10 mm flatter, and changing by small increments in response to corneal flattening, improved unaided visual acuity and reduced myopia. Gates (1971) advocated fitting lenses much flatter, up to 0.30 mm, as did Carter (1977) and Ziff (1976), whilst Fontana (1972) preferred a bifocal lens with the central BOZR 0.10 mm flatter than K_f and surrounded by a peripheral zone fitted on K. Nolan (1972) fitted lenses 0.20 to 0.30 mm 'steeper' than K_f using small TD lenses designed from the information gained from the photoelectric keratoscope (PEK).

Tabb (Coon, 1984) used a different approach. Instead of flattening the BOZR he reduced the BOZD by very small percentages, thereby causing small reductions in lens sag and effectively flattening the fit of the lens in order to cause corneal flattening.

Numerous papers were published about the different techniques, but all appeared to have the same overall effect irrespective of the fitting philosophy – the reduction of myopia. The somewhat contradictory nature of the results

led to the controlled studies of Kerns (1976–78), Coon (1984) and Brand *et al.* (1983). These studies concentrated on two methods of orthokeratology: the May–Grant and the Tabb techniques.

The May–Grant technique

A large trial lens fitting set forms the basis of this technique, with 370 lenses of specific radii, BOZD, peripheral curves and thicknesses. The BOZR range is from 7.20 mm to 8.90 mm in 0.05 mm steps, with powers from +0.50 D to −4.00 D in 0.25 D steps. The initial lens is fitted from 0.075 mm to 0.10 mm flatter than K_f with the TD 1.30 mm larger than the K_f reading in millimetres, and the BOZD equal to the flattest keratometry reading in millimetres. Lenses are supplied from inventory as the cornea flattens.

Centre thickness is determined by lens power but, in general, is thicker than that normally used in order to add weight to the lens as an aid to centration. The impetus for lens changes is the level of change in unaided visual acuity and keratometer readings. Once the unaided visual acuity ceases to improve and the keratometer readings are stable, the limit of the procedure has been reached and retainer wear is initiated.

The course of active treatment ranges from 6 to 12 months depending on the original refractive error, with a further 6 months for fine tuning the retainer lens fit, stability of the corneal shape and visual acuity. Grant (1981) reported on a two-year study of 100 patients undergoing orthokeratology. The age range was from 11 to 50 years (mean 21years) with myopia ranging from 0.25 to 8.75 D (mean 2.50 D). The results were as follows:

Group 1: 0 to 2.00 D: 90% 6/6 unaided acuity; 73% emmetropic.
Group 2: 2.00 to 4.00 D: 65% 6/6 unaided acuity; 36% emmetropic.
Group 3: >4.00 D: 36% 6/6 unaided acuity; 22% emmetropic.

The practical limits, according to May, were 4.00 D myopia, and 2.00 D of astigmatism. The aim was to attain a level of 'functional vision' for the patient which, in general terms, could be considered to be 6/12 uncorrected. The uncorrected acuity usually bears no direct relationship to the refractive error, so the exact specification of the reduction of myopia is somewhat anecdotal.

The Tabb technique

Jenkin and Tyler-Jones (1962) found that lenses fitted slightly steeper than the flattest corneal meridian caused far less distortion and yet were still quite suitable for orthokeratology. Tabb agreed with these findings and refined the technique. His routine is to fit the lens either on K or 0.05 to 0.075 mm steeper depending on the degree of corneal astigmatism, with the TD equal to the flattest keratometry reading plus 1.00 mm. The peripheral curves are each 1.00 mm flatter than the preceding curve, 0.20 mm wide and well blended to mimic an aspheric curve. The BOZD is calculated such that the BOZ area constitutes 70% of the total lens area. The peripheral curves make up the remaining 30% and are termed the 'tear reservoir'. The standard orthokeratology techniques used by other workers are based on flattening the BOZR of the lens as the cornea flattens. Tabb's reasoning is that reducing the BOZD by small increments, thus gradually decreasing the sag of the lens, will cause more subtle and controllable changes in corneal curvature without the distortion-inducing effects of larger, flat, heavy central touch lenses.

An initial tear reservoir of 30% of the back surface area is used as it gives the best balance between lens centration and the positive and negative forces of the lens cornea relationship. If the initial tear reservoir is less than 30% a tight lens will ensue, causing the cornea to steepen. As the tear reservoir increases from 30% to 45%, the net balance changes, causing a positive pressure distributed evenly across the cornea.

Tabb states that his technique does not cause oedema, with-the-rule astigmatism or corneal distortion, mainly because the lens design gives good centration and tear exchange without heavy mechanical pressure. The formula for Tabb's design is given as:

$$BOZD = 2\sqrt{(1 - TR/100).(TD/2)^2}$$

where BOZD = back optic zone diameter (mm); TR = tear reservoir(%).
TD = total diameter = K_f + 1.00 mm
BPR_1 = BOZR + 1.00 mm; BPR_2 = BPR_1 + 1.00 mm; BPR_3 = BPR_2 + 1.00 mm
BPD_1 and BPD_3 are each 0.20 mm wide. BPD_2 is obtained from the TD less the combined BPD_1 and BPD_3, i.e. BPD_1 = BOZD + 0.20 mm and BPD_3 = TD − 0.20 mm.

Orthokeratology by the Tabb technique is initiated with the BOZR 0.05 to 0.075 mm steeper than K_f and a tear reservoir of 30%. As the cornea flattens, the unaided visual acuity improves. If, after two successive visits, the unaided acuity remains unaltered, the tear reservoir is increased in increments of 2.5%, from 30% up to 45%, keeping the BOZR and TD unchanged. This decrease in lens sag effectively flattens the lens fit. As the tear reservoir approaches the 40% level, the lenses tend to become very unstable, and a flatter BOZR is then used with the reservoir reduced to the lower level again. Although largely superseded by the Accelerated Orthokeratology technique of Wlodyga (*see below*), Tabb design lenses still have their place, primarily as retainer lenses.

The main drawback of the design is the relatively small diameter of the lens that results from the calculations above and which causes flare and discomfort, as is common with small, mobile lenses.

Controlled studies of orthokeratology

There have been three major studies of the effects of orthokeratology. Their findings are summarized below.

Kern's study

Kern's study (1976–78) at the University of Houston compared three groups, consisting of spectacle wearers, conventional contact lens (PMMA) wearers and an orthokeratology group. The method used for the latter group was a modified May–Grant technique (0.05 to 0.125 mm flatter than K_f).

Kern's results can be summarized as follows.

- The spectacle group increased slightly in myopia.
- The conventional and orthokeratology groups both decreased in myopia, but the orthokeratology group showed a greater degree of change that was statistically significant.
- The initial shape factor of the cornea determined the magnitude of myopic change, positive shaped corneas being more responsive to change than spherical corneas, as determined by PEK analysis.
- Once the shape factor of a cornea became spherical no further reduction in myopia, even with aggressive lens therapy, was possible.
- There was no correlation between the refractive error and the unaided visual acuity in the orthokeratology group.
- The procedure produced an average reduction in myopia of 1.00 D.
- Regression to near baseline levels occurred within a few months of the cessation of lens wear.

Kerns concluded that although the procedure was safe, the results were variable, unpredictable and uncontrollable.

The Berkeley orthokeratology study

Polse *et al.* (1983a) conducted a controlled study comparing the efficacy of orthokeratology with conventional contact lens fitting over an average of 444 days of treatment. They found an average decrease in myopia of 0.54 D in the control group and an average of 1.01 D in the orthokeratology group. The changes in refractive error tended to occur in the first 132 days with little or no further gains over the rest of the study, even with aggressive therapy. After cessation of lens wear, both groups regressed to near baseline levels in about 95 days. The safety of the procedure was also assessed by monitoring corneal thickness, refractive astigmatism, corneal astigmatism, correctable spectacle acuity, corneal oedema, corneal staining and endothelial cell density.

The differences between the treatment and control groups were not statistically different, leading to the conclusion that orthokeratology was a safe procedure requiring more after-care time than normal contact lens fitting. The overall reduction in myopia was, however, felt to be 'modest' from a clinical viewpoint, but the fact that 5 of the 31 experimental subjects achieved a 2 D or greater reduction in myopia, when compared to the control group, indicated that the procedure could have a clinical significance if the response variations could be made more stable.

Coon's study

Coon (1982, 1984) investigated the efficacy of Tabb's orthokeratology technique. This study differed from the previous studies in that clinical and technical guidance was given by practising orthokeratologists. Once again there were control, treatment and spectacle groups. Variables studied were refractive error change, unaided visual acuity, corneal shape, peripheral and central corneal thickness, anterior chamber depth, crystalline lens thickness, axial length and tonometry.The results showed no statistically significant change for the spectacle group, but a marked difference in the treatment and control groups. There was no statistical difference or change in axial length, crystalline lens parameters, intraocular pressure, anterior chamber depth or corneal integrity. However, unaided acuity, refraction, corneal topography and corneal thickness showed a statistically significant difference between the treatment and control groups. Unaided visual acuity changes showed a 195% (5.5 lines) increase in the orthokeratology group compared to an 82% (3 lines) increase in the control group. Refractive error changes between the two groups also varied. The orthokeratology group had a mean maximum reduction in myopia of 1.30 D (range +0.25 D to +5.00 D improvement: s.d. 0.89 D) whilst the control group had a mean reduction of 0.96 D (range −1.25 D to +3.35 D: s.d. 0.95 D). The 'average' change for the treatment group, however, was much lower (0.56 D).There was no significant increase in with-the-rule astigmatism in the orthokeratology group compared to an increase of 0.48 D for the control group, thus supporting Tabb's claim that his technique did not cause an increase in with-the-rule astigmatism.

The corneal curvature and shape measurements showed a 'relative' steepening of the peripheral cornea as the centre flattened. Both groups showed an average decrease in corneal asphericity, tending towards a more spherical corneal shape ('sphericalization'). As with the other studies, there was no correlation between unaided visual acuity and refractive error. Keratometry changes accounted for approximately 50% of the refractive changes. This was felt to be due to the fact that the keratometer only measures an area 3.00 mm in diameter around the corneal apex. Corneal thickness measurements showed a statistically significant level of central thinning in the experimental group compared to the control group. Peripheral thickening occurred in both groups. Coon believed that this was part of the reason for the increased unaided visual acuity in the orthokeratology group as an overall increase in corneal thickness was unlikely to produce a refractive change.

All three studies indicated that the average decrease in myopia was approximately 1.00 D, and that the maximum effect was gained after six months of treatment. The gains

were then eroded slightly over the following six months irrespective of the aggressiveness of the therapy. Binder *et al.* (1980) reviewed the results of a group of patients who had undergone orthokeratology at May and Grant's practice. The fitting philosophy was more aggressive, with lenses being fitted from 0.15 to 0.50 mm flatter than K_f. Their results were similar to the other three studies, with an average reduction in myopia of 1.54 D.

All studies reported a regression back to near pre-fitting levels of myopia once lens wear was discontinued. Maintenance of the induced changes required lens wear for at least 8 hours each day (Polse *et al.* 1983a; Coon, 1984).

All of the above studies took place in the late 1970s and early 1980s, and all used PMMA lenses, although Polse *et al.* (1983b) used Polycon I when corneal oedema did not resolve. Orthokeratology survived despite the modest results achieved by Kerns, Polse and Coon as most practitioners involved in the procedure at the time had severe reservations about the design and execution of the controlled studies, as the results did not correlate with their own experiences (Grant, 1993; Wlodyga, R.A., personal communication, 1993).

The studies all found that the procedure was safe with the exception of unwanted distortion and induced with-the-rule astigmatism. That it was unpredictable, and that there appeared to be a relationship between initial corneal shape factor and refractive change. Corneal sphericalization indicated the end point of the procedure.

Little further research into orthokeratology has appeared in the literature since, the Berkeley study being considered by most as the final word on the subject.

Modern orthokeratology

Accelerated Orthokeratology

Accelerated Orthokeratology (Accelerated Ortho-k) refers to a fitting philosophy and lens design system developed by Richard Wlodyga, a Michigan optometrist and Nick Stoyan, a contact lens specialist and designer who felt that the procedure would be more predictable and controlled if a lens could be used that was steeper in the periphery than the optic zone. By allowing the steepening peripheral cornea produced by orthokeratology a greater flexibility of movement,* they felt greater control of centration would ensue, thus helping to avoid the unwanted effects of induced astigmatism. Clinical research over the next few years by Wlodyga led to further refinement and expansions on the basic design. Wlodyga found that not only did the lenses centre well, even when fitted up to 0.40 mm flatter than K_f, but also produced very rapid and stable corneal curvature changes. Refractive changes that had previously taken months to produce using standard orthokeratology techniques could be achieved in a matter of days and weeks with the new design lenses. It was because of these rapid changes that the epithet 'Accelerated' was applied to the procedure.

*As the central cornea is flattened, the peripheral cornea becomes relatively steeper. This is thought to be due to a displacement of corneal tissue (Soni and Horner, 1993).

The OK series of lenses

The OK series of rigid gas permeable lenses (Contex, Sherman Oaks, California) are produced from fluorosilicone acrylate materials with Dks of 88 (DW) and >120 (EW). Routine inspection shows the lenses to be of a consistently high standard of quality and reproducibility. OK lenses have BOZDs of 6.00, 6.50, 7.00, 7.50 and 8.00 mm with a BPD_1 that varies from 0.50 to 1.80 mm wide (depending on the TD) and BPR_1 0.20 to 1.80 mm *steeper* than the BOZR. The edge curve band width (BPD_2) is 0.50 mm and is a flat aspheric curve that is approximately 0.60 mm flatter than the BOZR. The parameters of the various OK designs are shown in *Table 19.1*. These are the 'standard' designs, which consist of purely spherical central and secondary curves. The 'A' series OK lenses differ from the standard design in that the back surface peripheral geometry consists entirely of aspheric curves. The stated advantages of the 'A' scries are less flare and a lesser tendency for the lenses to bind as the cornea changes shape. The disadvantage is that the rate of corneal change is slower than the standard design. Therefore, in the majority of cases, the standard OK designs are the lens of first choice. The basic geometry of the groups remains constant except that the 'A' series lenses have *aspheric* BPR_1 and BPR_2 curves compared to the standard designs, and are always followed by the 'A' suffix, e.g. OK603 refers the standard design (6.00 mm BOZD, 0.60 mm BPR_1 and spherical BOZR and BPR_1) and OK603A refers to the aspheric version of the lens.

The asphericities used in the lens design are unknown, but the BPR_1 *gradually* becomes 0.60 mm steeper than the BOZR (e.g. 603A) as the limits of the BPD_1 are reached. The overall effect is a decrease in lens sag between the two designs such that the 'A' series are a looser fit than the standard design, and the BOZR must be steepened in order to maintain an equivalency of fit. The standard and 'A' series OK lenses have a constant axial edge lift of 0.12 mm. The axial edge lift can be altered by nominating four variations: XL (extra low), L (low), H (high) and XH (extra high) with each step representing an approximate change of 0.02 mm in AEL. The nomenclature used to describe the lens is a numeric code based on the BOZD/BPR_1 relationship, e.g. an OK 603 has a BOZD of 6.00 mm and a BPR_1 3.00 D steeper than the optic zone radius. The BPR_1 is expressed in dioptres.

Examples:

Name	BOZD (mm)	BPR_1 steeper than BOZR by:
605	6.00	5.00D (1.00 mm)
651	6.50	1.00D (0.20 mm)
704	7.00	4.00D (0.80 mm)
758	7.50	8.00D (1.60 mm)
809	8.00	9.00D (1.80 mm)

Table 19.1 Design characteristics of OK lenses

Lens design	*BOZD (mm)*	*TR (mm) (D)*	*Corneal change rate*	*Comments*
OK601	6.00	0.20 (1 D)	Minimal	Retainer
OK602	6.00	0.40 (2 D)	Moderate to fast	Useful as a retainer or as cornea becomes more spherical. Night therapy
OK603	6.00	0.60 (3 D)	Fast	Lens of first choice in the majority of cases, but is interchangeable with the OK704 (*see text*)
OK604	6.00	0.80 (4 D)	Fast	Useful for centration as the cornea becomes more spherical. Deep TR
OK605	6.00	1.00 (5 D)	Fast	Very deep TR. Small area of central touch **TD: 8.00 mm (minimum), 9.60 mm (average), 12.20 mm (maximum)**
OK651	6.50	0.20 (1 D)	Minimal	Larger optic zone for large pupils; 10 mm minimum diameter. Low myopia?
OK652	6.50	0.40 (2 D)	Moderate	Retainer
OK653	6.50	0.60 (3 D)	Fast	Aids in centration. Larger BOZD to reduce distortion in pupil zone
OK654	6.50	0.80 (4 D)	Fast	Aids in centration. Deep TR
OK655	6.50	1.00 (5D)	Fast, assoc. central distortion	Aids in centration. Deep TR **TD: 8.50 mm (minimum), 10.00 mm (average), 12.20 mm (maximum)**
OK701	7.00	0.20 (1 D)	Low	Retainer
OK702	7.00	0.40 (2 D)	Low to nil	Retainer; night therapy
OK703	7.00	0.60 (3 D)	Slow	Retainer; low myopia; large pupils
OK704	7.00	0.80 (4 D)	Fast	Deeper and wider TR than the OK603; ideal as first lens; centration
OK705	7.00	1.00 (5 D)	Distorts centrally	Deep TR **TD: 9.00 mm (minimum), 10.00 mm (average), 12.20 mm (maximum)**
OK751	7.50	0.20 (1 D)	Rarely used	Retainer?
OK752	7.50	0.40 (2 D)	Rarely used	Retainer; excellent for post-graft corneas
OK753	7.50	0.60 (3 D)	As above	As OK752
OK754	7.50	0.80 (4 D)	As above	As OK752
OK755	7.50	1.00 (5 D)		Post graft **TD: 9.50 mm (minimum), 10.00 mm (average), 12.20 mm (maximum)**
OK801	8.00	0.20 (1 D)		Post-graft
OK802	8.00	0.40 (2 D)		As OK801
OK803	8.00	0.60 (3 D)		As OK801
OK804	8.00	0.80 (4 D)		As OK801
OK805	8.00	1.00 (5 D)		As OK801 **TD: 10.00 mm (minimum), 10.50 mm (average), 12.20 mm (maximum)**

Notes: Prism can be incorporated into any OK lens, but is of little clinical use as an aid to centration. TR refers to the degree of steepening of BPR_1 to form the tear reservoir. The diameters in bold type refer to the indicated diameter range for the group of OK lenses with the same BOZD. The 'A' series lenses are based on the same design as standard OK lenses, except that they are composed entirely of *aspheric* curves, and are mainly used as retainers.
The steeper TR curves (1.20 mm to 1.80 mm) are not used for orthokeratology (see text) and are mainly used for post - refractive surgery and post penetrating keratoplasty cases.
AEL variations are described as XL (extra low), L (low), H (high) and XH (extra high) and are each approximately 0.02 mm variations from the standard 0.12 mm AEL.
Materials are given three designations: nil for standard Dk 88 (blue, green and grey) material, 'R' for Dk 88 (red) deposit-resistant material and 'Y' (yellow) for the high Dk (> 120) EW material.
A wider edge curve, of width 1.10 mm, is designated 'c'.

The specification of lens material and edge lift is by the use of letters where a prescription is written as:

8.25/ 10.60/ OK704/ XL describes an OK704 with an 'extra low' edge lift

Soni and Horner (1993) postulated the mode of action to be that the steep secondary curve (BPR_1) acts as a tear reservoir (TR) that aids in lens centration and supplies the fluid force that induces corneal flattening. The width and depth of the tear reservoir are therefore critical to the performance of the lens, and will be discussed in greater detail later.

General outline of the fitting philosophy of the OK series

Even though the design of the OK series differs radically from all previous lenses, the same basic concept of a sequential set of lenses that is altered as the cornea changes shape followed by a period of retainer lens wear, is still used as the treatment model. The following section describes the 'traditional' approach used in conjunction with the OK series.

Background

Orthokeratologists have historically used the 'shape factor' of the cornea to predict the potential level of myopia reduction (Wlodyga and Bryla, 1989). The formula is:

Projected myopia reduction $\Delta Rx = 2(K_c - K_t) + 1.00\,D$

where K_c is the central keratometry and K_t the temporal keratometry in dioptres measured by asking the patient to fixate on the mire target on the nasal side of the keratometer. This estimates the curvature of the cornea at approximately 4.00 mm from the corneal apex.

The extra 1.00 D is added to allow for axial length reduction due to corneal flattening, even though the controlled studies had previously proved this was not the case. Therefore a difference in the two K readings of 2.00 D indicates a potential reduction of 5.00 D myopia. These suppositions will be dealt with in greater detail later.

A 'positive shape factor' cornea exhibits a steeper central K reading than temporal K reading ($K_c > K_t$)* and will therefore respond better to orthokeratology than a spherical cornea ($K_c = K_t$: shape factor zero), or a cornea with a 'negative shape factor' ($K_t > K_c$) (Kerns, 1976–78; Binder *et al.*, 1980; Coon, 1984). The level of corneal astigmatism is also relevant in the selection of the initial lens BOZR. The greater the difference in the two meridians, the steeper the lens of first choice, as the aim is to reduce the corneal astigmatism before initiating the orthokeratology. A guideline is shown in *Table 19.2*.

*In the orthokeratology context, the terms K_c (central K reading) and K_t (temporal K reading) are expressed in dioptres. K_f (flattest K reading) and K_s (steepest K reading) are expressed in millimetres radius of curvature.

Table 19.2 BOZR indicated with varying astigmatism

Astigmatism:
<0.75 D: BOZR 0.30 to 0.40 mm flatter than K_f
0.75 to 1.50 D: BOZR 0.20 to 0.30 mm flatter than K_f
1.50 to 2.00 D: BOZR 0.10 to 0.20 mm flatter than K_f
2.00 to 2.50 D: BOZR on K_f

The fitting of OK lenses requires precision, is difficult and time-consuming and should only be attempted by those who have a thorough knowledge of rigid lens dynamics. There is no general formula, as every case must be treated individually due to the largely unpredictable level of response and variations in corneal shape (*see below*). Also, the limitations of the keratometer when compared to the wealth of information available from the computer-generated corneal topography instruments currently available makes these instruments obsolete in the context of orthokeratology where active, accurate manipulation of corneal shape is the aim. A large set of trial lenses is necessary as corneal changes occur rapidly and, to a certain degree, unpredictably. It therefore becomes essential to be able to fit correctly the next lens in the series and assess and modify the lens parameters before ordering. Lens diameter is a major factor in centration, so the addition of a series of trial lenses of a different diameter is advisable (*Table 19.3*).

The initial expenditure required to start accelerated orthokeratology is high, but the savings produced by the efficient use of chair time and adequate and correctly fitting trial lenses makes it worth while.

Patient selection

Those patients interested in undergoing orthokeratology, usually express an interest in becoming less dependent on their habitual use of spectacles or contact lenses. Also, there may be the underlying psychological desire to do something 'positive' about their constantly increasing level of refractive error. These patients are usually highly motivated and therefore make good candidates. The absence of any active or chronic disease of the eye or adnexa is, as with all contact lens fitting, of prime importance. The degree of refractive error is important, in that the currently accepted maximum level of correctable ametropia is between 3.00 and 4.00 D myopia and 1.50 D astigmatism, although there can be

Table 19.3 Suggested trial lens set

Lens design	*BOZR (mm)*	*Total diameter (mm)*
OK704C*	7.50–9.00 0.05 steps	10.6 and 11.2

*See p. 675 for description of the 'C' designated peripheral curve

individual variations. The practitioner's aim may be to achieve uncorrected visual acuity of 6/5, which may not be possible, whereas the patient may be quite happy with an improvement in unaided acuity from 2/60 to 6/12, and this must be taken into account.

Previous soft contact lens wearers must, of course, be advised of the differences between the two modalities, and that their previous experience with soft lenses will not make the change to RGP wear any easier. Finally, pupil diameter in normal light must also be considered in assessing a patient's suitability for the procedure. Orthokeratology flattens the central cornea and, for the effect to be useful, an area of 5.4 mm in diameter must be affected in order to compensate fully for variations in pupil size under varying illumination, induced aberration and the Stiles Crawford effect (Holladay *et al.*, 1991).* Therefore, those patients with large pupils in normal illumination should be excluded as their visual acuity in dim illumination will be adversely affected by aberrations induced in the cornea by the procedure.

Fitting routine

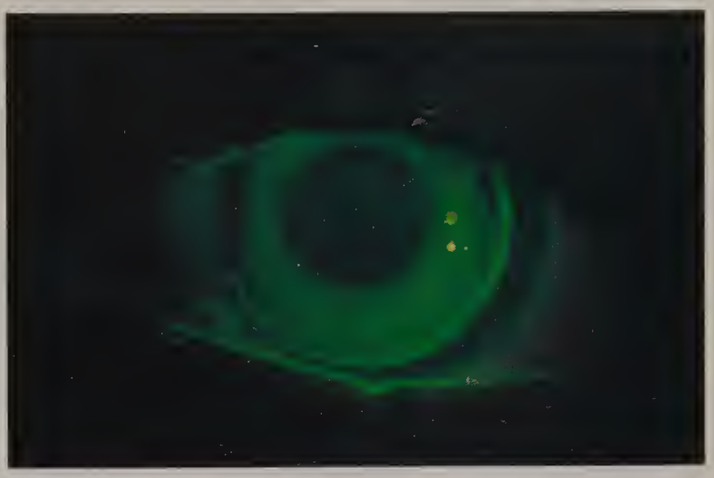
The patient, after a full pre-fitting ocular assessment (*see* Chapter 8), is scheduled for a trial fitting and wearing appointment, with an interval of at least 6 hours between lens insertion and reassessment. This allows the practitioner to determine the probable chances of success for that patient. If there is little or no change in refractive error or unaided visual acuity after approximately 6 hours with the trial lenses in place, then the patient should be advised that the procedure is unlikely to be successful (*see below*). The choice of the first trial lens is critical to the level of corneal response. If the lens is initially too steep, the degree of corneal flattening will be reduced (*see below*).

The first lens is typically 0.30 to 0.60 mm flatter than K_f depending on factors that will be discussed more fully later. The ideal lens exhibits 3.00 mm of central touch, a wide, deep tear reservoir, 1–2 mm of movement and good centration of the area of touch over the pupil zone (*Figure 19.1a*). The Contex fitting manual (1996) advocates flatter than the indicated 0.30 mm if the difference between the K_c and K_t is greater than 2.00 D.

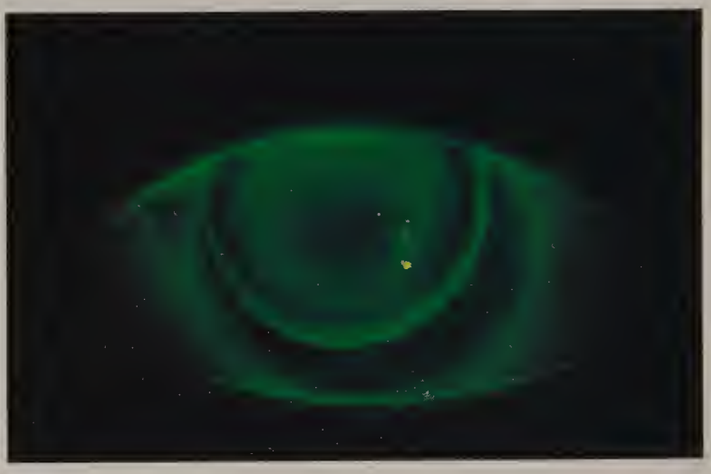
Other fitting guidelines are:

- The larger the BOZD, the looser the fit.
- The steeper the Tear Reservoir (BPR_1) the tighter the fit.
- The larger the TD the tighter the fit.
- Use base down prism as an aid to centration if lenses locate superiorly.

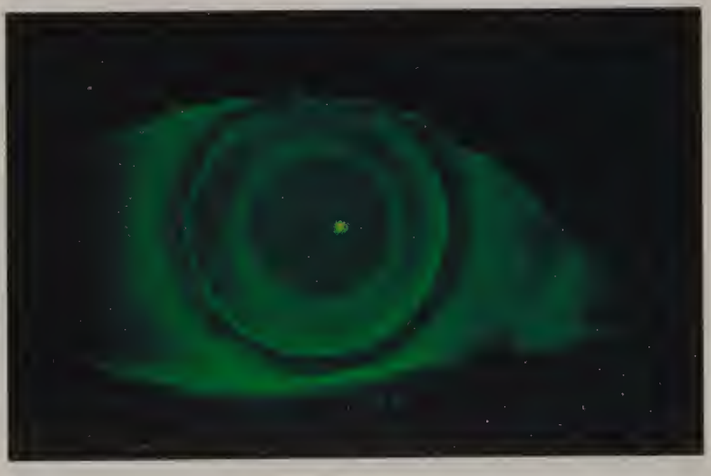
*The relationship between visual acuity and pupil size is dependent on the interactions of defocus, diffraction and optical aberrations. At pupil diameters between 3.00 and 5.40 mm the main factors are defocus, aberration and the Stiles Crawford effect. In both RK (Radial Keratotomy) and OK the degree of positive spherical aberration increases towards the peripheral cornea. The combination of these aberrations, the Stiles Crawford effect and pupil dilatation in dim illuminations causes a reduction in visual acuity (Holladay *et al.*., 1991)



(a)



(b)



(c)

Figure 19.1 (*a*) Fluorescein pattern of an optimum OK603 fit. Note central touch area, deep tear resevoir, minimal peripheral contact and edge lift. (*b*) Appearance of an OK603 after 8 hours wear, showing a relatively steeper fit. Note slight apical clearance, superior position and wide intermediate contact band. (*c*) Tightening of an OK603 after 6 hours wear caused by the initial lens being fitted too steeply. The central touch is still obvious, but the TR is thin and shallow and the peripheral contact band too wide. The central cornea has flattened and the peripheral cornea steepened to fill the TR

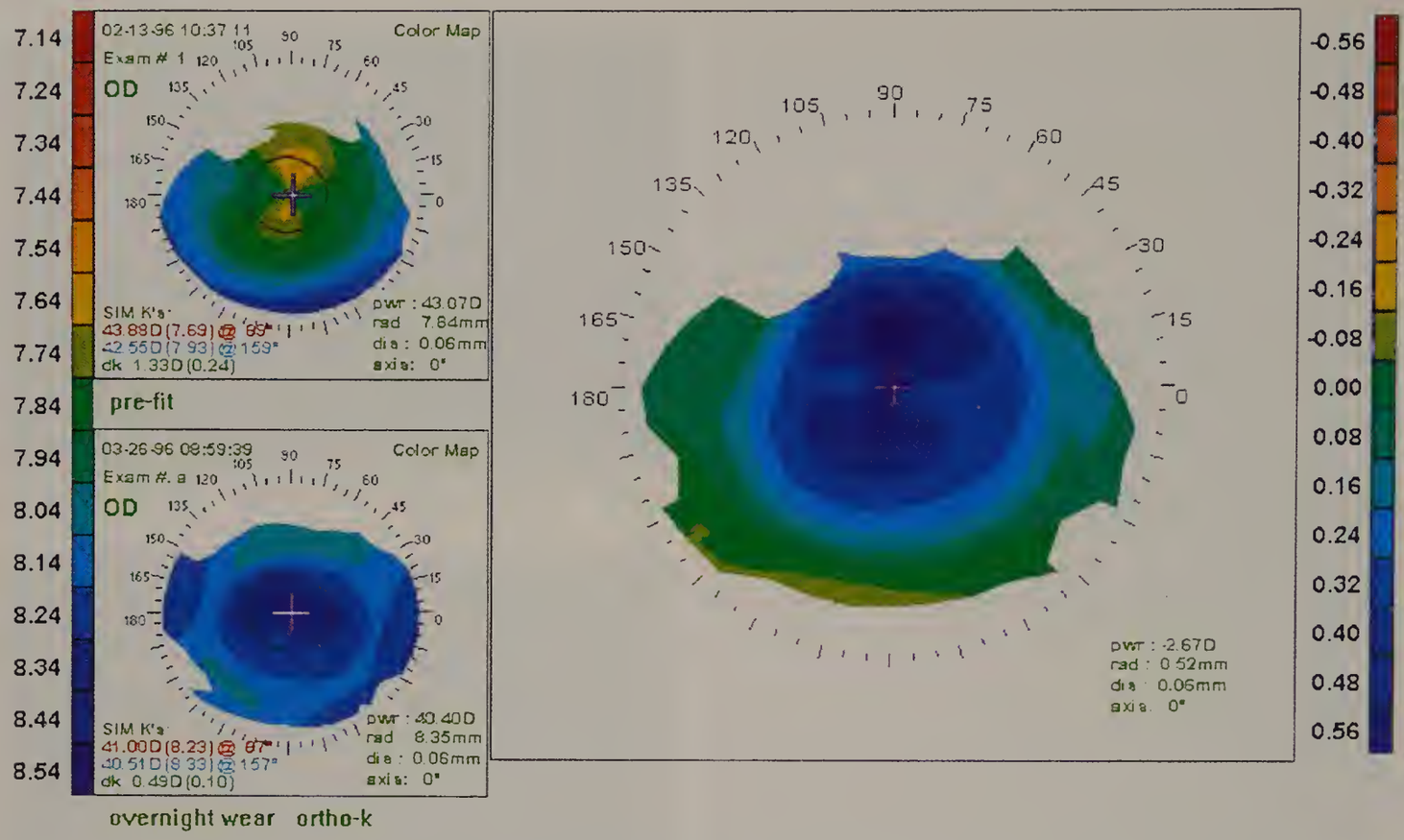


Figure 19.2 Subtractive plot of pre-fit cornea and the same cornea following lens removal. The reference cross is at the pupil centre and represents the apical radius r_0. The original R_x was −2.75 / −1.00 × 160; final R_x was plano. Note the greater flattening of the vertical meridian compared to the horizontal. The altered corneal shape is mildly oblate

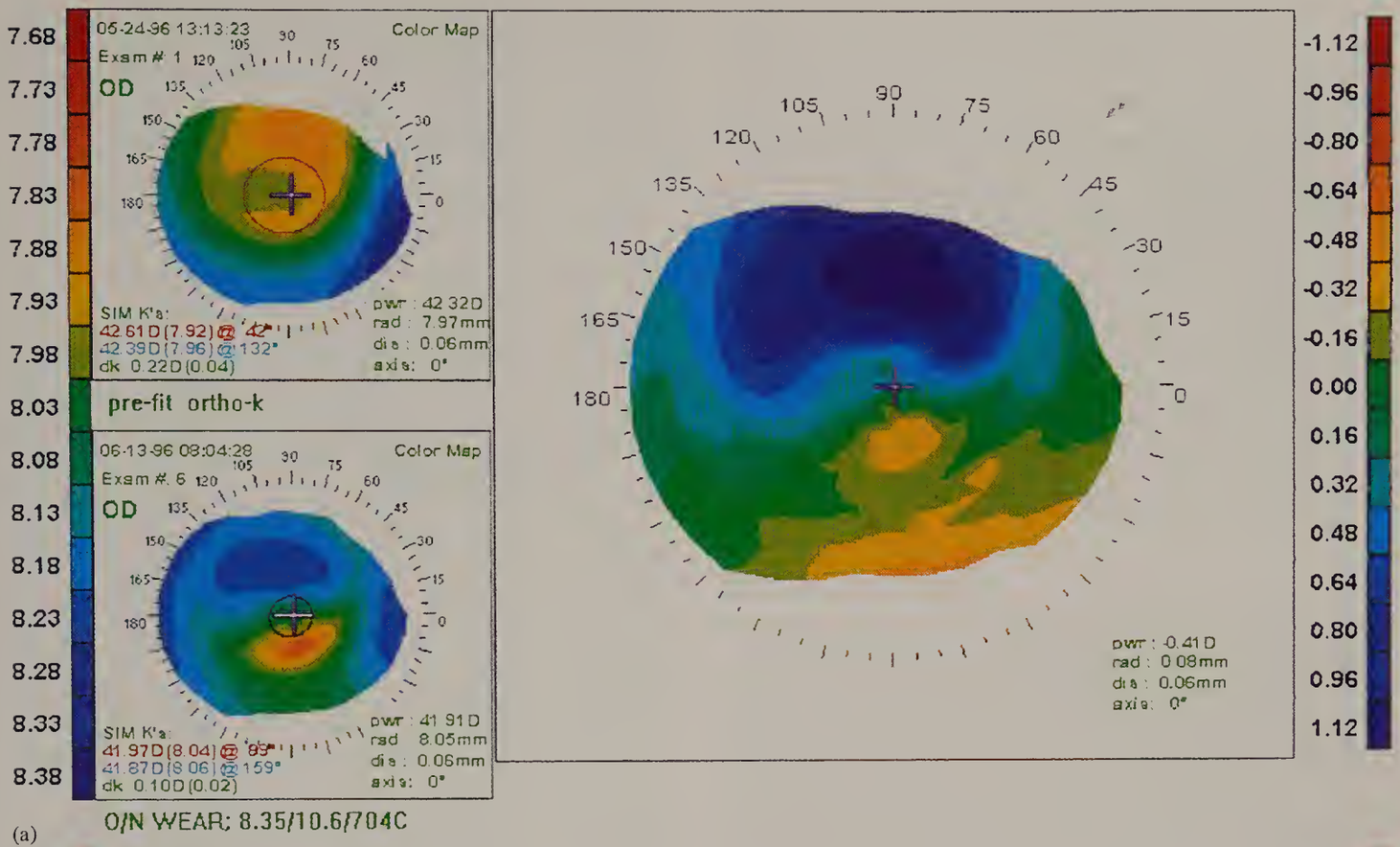
In the majority of cases, the cornea responds dramatically to the lens with changes of from 0.75 to 3.00 D of myopia reduction evident after 6 hours of wear. The initial assessment of the lens fit after the wearing period is done prior to the instillation of fluorescein. This is in order to determine lens movement, as a sluggish lens may loosen up considerably with the introduction of the dye.

Once lens movement has been assessed, fluorescein is instilled and the pattern observed. At this stage the fluorescein pattern will typically show either apical clearance or minimal corneal touch together with a shallow TR, sluggish movement and possible decentration. In other words, the central cornea has flattened and the peripheral cornea relatively steepened, producing a tight fitting lens (*Figure 19.1b,c*). The lens may have become bound and immobile, indicating a rapid alteration in corneal shape to the extent that the trial lens has become so relatively steep that adhesion has occurred. If this is the case the patient must be rescheduled for another fitting with a flatter lens and reviewed on an hourly basis to ascertain the rate of corneal change.

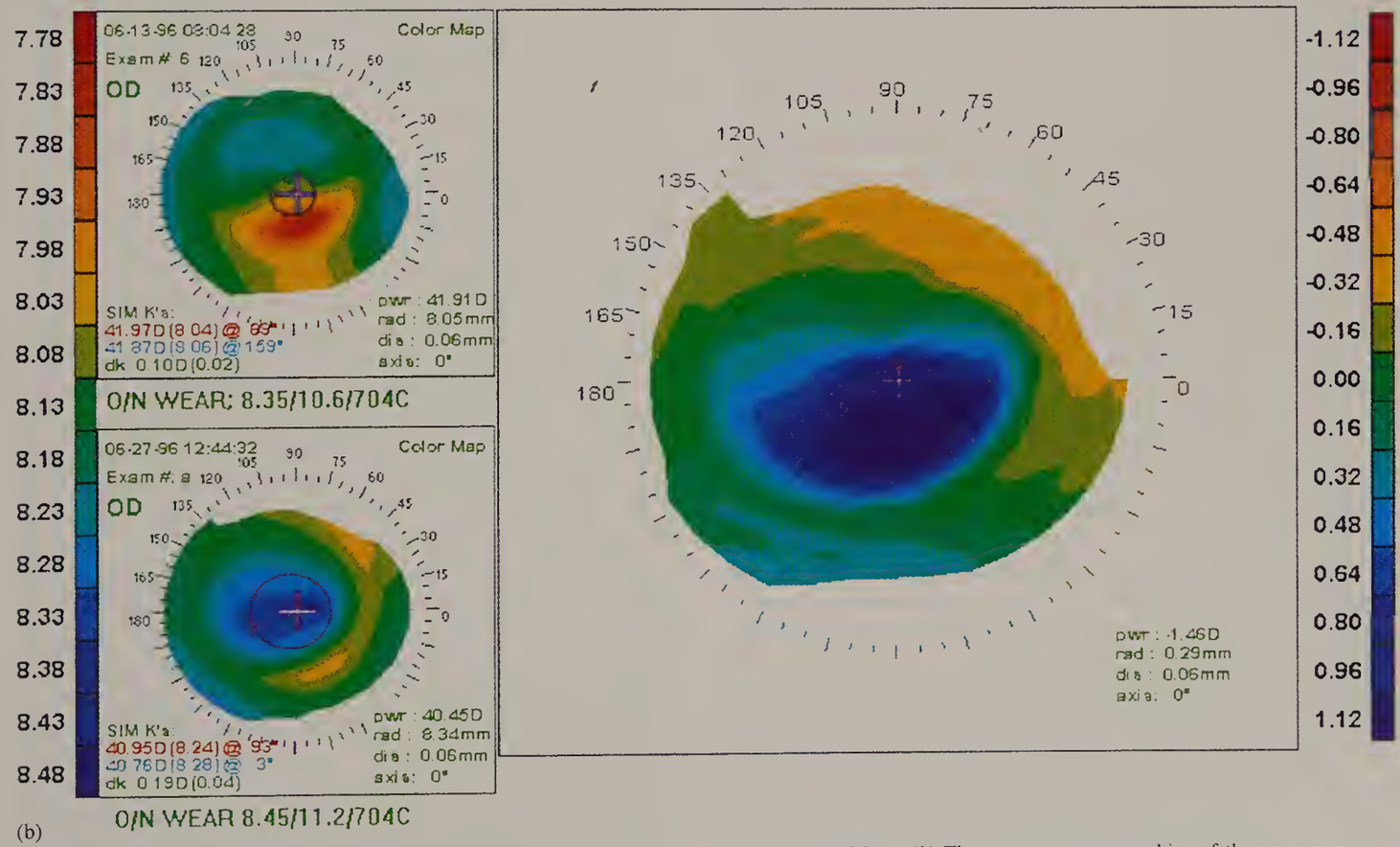
Once the desired fluorescein pattern of minimal corneal touch or slight apical clearance is reached, over-refraction is performed. The lens is then removed and refraction, corneal topography or keratometry, and unaided visual acuity measured. Retinoscopy is an invaluable tool in that inferior corneal distortion in the pupil area from a high riding lens is easily detected. Computerized corneal topography is also invaluable as the second reading can be subtracted from the initial reading and the exact degree of corneal change measured (*Figure 19.2*).

The next lens is then inserted and the fit assessed. This is usually 0.20 mm flatter than the initial lens, but can vary depending on the degree of corneal flattening. The most important aspect when assessing the second lens is centration. The depth of the TR is also important as it appears to play an important role in lens movement and tear exchange, a shallow reservoir indicating a high probability of lens adherence, often with the lens off centre, resulting in unwanted corneal distortion over the pupil area. If the second lens does not behave in the desired manner, then either a design with a deeper TR (OK604), 1 to 3 base down prism or a larger BOZD (6.50 or 7.00 mm) should be tried.

The importance of correct centration and movement is essential in controlling unwanted distortion (Wlodyga and Harris, 1993). Topographical plots (*Figure 19.3*) show that in cases of lens decentration upwards, the superior cornea flattens and the inferior steepens and, if this occurs over the pupil zone, the uncorrected vision suffers from ghost images. Also, the flat central optic zone will tend to centre over the flattened superior cornea, so that all subsequent lenses will do the same. This must be controlled in the early



(a)



(b)

Figure 19.3 (*a*) Superior corneal flattening with inferior corneal distortion from a decentred lens. (*b*) The post-wear topographies of the same eye following a separate trial wear period with a correctly centred lens. Note the superior flattening and the inferior distortion produced by the initial lens. The second lens caused central flattening and resolved the inferior crescent distortion.

Table 19.4 Typical after-care schedule

Visit	*Procedure*
1	Delivery: check 6 h later and change if indicated
2	1 day later: change to set 2
3	1 week later: trial fit set 3 and deliver when ready
4	1 week after delivery of set 3: check fit etc.
5	1 week later: trial fit set 4 and deliver when ready
6	3 weeks after delivery of set 4: trial fit set 5
7	1 month after delivery of set 5. Fit retainers if cornea has stabilized
8	Overnight wear of retainer
9	After 1 week of extended wear*
10	1 month later*
11	Check 4 h after retainer removal in morning
12	Review at indicated intervals until retainer wear schedule is finalized

*Check fit and alter retainers as necessary.

stages, otherwise the design variations and the number of lenses required for a final retainer fit are increased.

The first and second pairs of lenses can now be ordered, with the second pair typically 0.10 to 0.20 mm flatter than the first. The third and subsequent pairs of lenses are usually 0.10 mm flatter than the preceding lenses, with power compensatory changes based on the standard calculations (Wlodyga and Harris, 1993) (*see* Chapter 10). The initial pair of lenses may need to be replaced with the second set within 1–3 days, depending on the rate of corneal flattening and lens tightening. It is for this reason that both the first and second pairs are ordered at the initial visit. The second set will usually take one to two weeks to alter corneal shape to the extent that the fit requires modification. As the treatment proceeds, the rate of change slows, and a longer period of wear with the same pair of lenses is required. A general outline of the usual after-care and lens replacement schedule is shown in *Table 19.4*. It should be noted that at each after-care visit the lenses for the next visit are ordered in advance. This means that once the practitioner is satisfied with the progress of myopia reduction, the next pair of lenses is immediately available for issue. Because of the importance of lens centration, it is vital to assess the fit of the next set of lenses before they are ordered. The next flatter BOZR will often behave differently from the preceding lens and it is usual to find that not only is a change in BOZR necessary, but also a change in design and diameter (*Tables 19.5*, *19.6*).

As lenses are changed throughout the procedure, the previous sets are retained by the practitioner for future use as trial lenses. If the unaided visual acuity, refractive error, or corneal topography show no alteration over two consecutive monthly reviews, then the maximum amount of change possible has taken place in the cornea, although small changes may still occur over the following few months. The treatment phase of orthokeratology is now considered complete and the retainer phase is commenced.

Table 19.5 Problem solving

Problem	*Possible cause*	*Possible correction*
Tight lens	BOZR steep. Rapid corneal response, diameter too large TR too deep	Flatten BOZR, decrease diameter Add 3 fenestrations in TR at 120-degree intervals
Loose lens	BOZR too flat; TD too small	Steepen BOZR. Increase TD
Decentration		
1 High	1. BOZR too flat. TD too small; high minus	1. Steepen BOZR, Increase TD Deeper TR; 'C' edge
2 Low	2. TD too small; loose lid; corneal apex low; BOZR too steep	2. Increase TD, flatten BOZR
3 Lateral	3. Lid force; corneal apex off centre	3. Larger BOZD; increase TD
Central staining	Lens too loose; trapped debris under lens; BOZ scratched	Steepen BOZR; clean and polish lens or replace
Inferior distortion	Lens decentred superiorly	OK 704C (10.6 or 11.2)
Poor unaided VA	Distortion from decentred lens; lens changes too rapid; tight lens	Re-centre lens; revert to previous lens until cornea settles; loosen fit
Rapid regression	Poor retainer design, lens changes too rapid	Re-design retainer or use final OK lens; revert to previous lens; increase wearing time

Retainer lenses

Ideally by this stage the patient should have attained uncorrected visual acuity of 6/6 and slight hypermetropia of +0.50 D. If this has not been possible and the VA is only 6/9 to 6/12 or worse, then lens wear will still be necessary for the majority of waking hours, and the last set of OK lenses become the retainers. The aim of orthokeratology is to correct vision to the stage where constant lens wear and dependence on either contact lenses or spectacles is no longer necessary. In order to achieve this, retainer lenses must be worn to a schedule that allows at least 16 hours of clear vision after lens removal. Overnight lens wear is the logical solution to this problem.

The majority of patients will achieve unaided visual acuity levels that will allow them to function normally during waking hours. The retainer must therefore be designed not only to keep the cornea in its altered shape, but also to even out any remaining areas of corneal distortion and to be safe for extended wear. Once the lenses have been designed, they are worn on an all-waking hours schedule for one week and the results assessed.

If the visual acuity and refraction results are acceptable then the patient is advanced into an extended wear programme of seven days and six nights for up to the next few weeks or months. This is intended to stabilize the

Table 19.6 Variation in BOZR with lens diameter, design and corneal shape

Cornea	*Lens design*	*Lens diameter (mm)*						
		9.50	*9.60*	*9.80*	*10.00*	*10.20*	*10.50*	*10.60*
r_0 = 7.40 mm	OK602	7.90	7.90	7.95	7.95	8.00	8.05	8.05
e = 0.70	OK603	8.00	8.05	8.05	8.10	8.10	8.15	8.20
	OK604	8.15	8.15	8.20	8.25	8.25	8.30	8.35
	OK653	7.95	8.00	8.00	8.05	8.10	8.15	8.15
	OK652	7.90	7.95	7.95	8.00	8.05	8.10	8.10
	OK702	7.85	7.85	7.85	7.90	7.95	8.00	8.00
r_0 = 7.40 mm	OK602	7.70	7.75	7.75	7.75	7.80	7.80	7.85
e = 0.45	OK603	7.85	7.85	7.90	7.90	7.95	7.95	7.95
	OK604	7.95	8.00	8.00	8.05	8.05	8.10	8.10
	OK653	7.80	7.85	7.85	7.85	7.90	7.95	7.95
	OK652	7.75	7.75	7.80	7.80	7.80	7.85	7.85
	OK702	7.65	7.65	7.70	7.70	7.75	7.80	7.80
r_0 = 7.40 mm	OK602	7.60	7.65	7.65	7.65	7.65	7.70	7.70
e = 0.20	OK603	7.75	7.75	7.75	7.80	7.80	7.85	7.85
	OK604	7.85	7.90	7.90	7.95	7.95	8.00	8.00
	OK653	7.70	7.70	7.75	7.75	7.75	7.80	7.80
	OK652	7.65	7.65	7.65	7.70	7.70	7.75	7.75
	OK702	7.55	7.55	7.60	7.60	7.60	7.65	7.65
r_0 = 7.80 mm	OK602	8.25	8.30	8.30	8.35	8.35	8.40	8.40
e = 0.70	OK603	8.40	8.40	8.45	8.45	8.50	8.50	8.55
	OK604	8.50	8.55	8.55	8.60	8.65	8.65	8.70
	OK653	8.35	8.35	8.40	8.45	8.45	8.50	8.50
	OK652	8.30	8.30	8.35	8.35	8.40	8.45	8.45
	OK702	8.20	8.20	8.25	8.25	8.30	8.35	8.35
r_0 = 7.80 mm	OK602	8.10	8.10	8.15	8.15	8.15	8.20	8.20
e = 0.45	OK603	8.25	8.25	8.25	8.30	8.30	8.35	8.35
	OK604	8.35	8.35	8.40	8.40	8.45	8.45	8.50
	OK653	8.20	8.20	8.20	8.25	8.25	8.30	8.30
	OK652	8.10	8.15	8.15	8.20	8.20	8.25	8.25
	OK702	8.05	8.05	8.05	8.10	8.10	8.10	8.15
r_0 = 7.80 mm	OK602	8.00	8.00	8.00	8.05	8.05	8.10	8.10
e = 0.20	OK603	8.15	8.15	8.15	8.15	8.20	8.20	8.20
	OK604	8.25	8.25	8.30	8.30	8.35	8.35	8.35
	OK653	8.10	8.10	8.10	8.15	8.15	8.20	8.20
	OK652	8.05	8.05	8.05	8.05	8.10	8.10	8.10
	OK702	7.95	7.95	7.95	8.00	8.00	8.00	8.05
r_0 = 8.20 mm	OK602	8.65	8.65	8.70	8.75	8.75	8.75	8.80
e = 0.70	OK603	8.75	8.80	8.80	8.85	8.85	8.90	8.95
	OK604	8.90	8.90	8.95	9.00	9.00	9.05	9.05
	OK653	8.70	8.75	8.75	8.80	8.85	8.90	8.90
	OK652	8.65	8.65	8.70	8.75	8.75	8.80	8.80
	OK702	8.55	8.60	8.60	8.65	8.70	8.75	8.75
r_0 = 8.20 mm	OK602	8.50	8.50	8.50	8.55	8.55	8.60	8.60
e = 0.45	OK603	8.60	8.60	8.65	8.65	8.70	8.75	8.75
r_0 =	OK604	8.75	8.75	8.75	8.80	8.85	8.90	8.90
	OK653	8.55	8.55	8.60	8.60	8.65	8.70	8.70
	OK652	8.50	8.50	8.55	8.55	8.60	8.60	8.60
	OK702	8.40	8.40	8.45	8.45	8.50	8.55	8.55
r_0 = 8.20 mm	OK602	8.40	8.40	8.40	8.45	8.45	8.50	8.50
e = 0.20	OK603	8.50	8.50	8.55	8.55	8.55	8.60	8.60
	OK604	8.65	8.65	8.70	8.70	8.70	8.75	8.75
	OK653	8.45	8.45	8.50	8.50	8.55	8.55	8.55
	OK652	8.40	8.40	8.45	8.45	8.50	8.50	8.50
	OK702	8.30	8.35	8.35	8.35	8.40	8.40	8.40

Note: The charts represent the sagittal equivalents of the different OK designs but this does not mean that the fits are equivalent, e.g. if the indicated lens is an 8.65/9.80/OK603(r_0 = 8.20, e = 0.45 above) but the TR appears shallow, then the next option is the 8.75/9.80/OK604. If this lens fails to centre properly but the TR and central touch appear correct, then increasing the TD may aid in centration and the equivalent fit would then be an 8.85/10.20 OK604.
The same sag relationships also apply to the 'A' series lenses.

induced corneal changes. The length of time required for this to occur depends upon the individual patient response and the practitioner's assessment of the case. The long-term effect of retainer lens wear is to further reduce myopia, so small amounts of 0.50 D myopia still present at the start of the retainer programme need not cause concern. Unacceptable levels of hypermetropia are reduced by slightly steepening the retainers or reducing the wearing time (Wlodyga, R.J., personal communication, 1993).

At the appropriate stage, the patient is advised to remove the lenses at least one hour after waking and record the length of time that vision remains clear. When vision blurs to an unwanted level the lenses are re-inserted until the next morning. This continues until the vision remains clear for the entire day. Eventually, the lenses need only be worn for as little as once every third night depending, again, on the individual patient response.

Retainer lens design

As stated above, if the lenses are still required for the majority of waking hours, then the last pair of OK lenses are ideal retainers. However, the deeper TR lenses (OK603,4,5 and 655 [*see Table 19.1*]) are not really suitable as night retainers as they tend to accumulate debris behind the lens and adhere to the cornea. Also, the small optic zones of these lenses tends to cause ghosting from corneal distortion near the pupil zone, especially if the lenses mislocate off-centre during the night. The other alternatives are to use either the 3.00 D (0.6 mm steeper) TR designs, particularly in the 'A' series, or else a custom-designed contour or aspheric lens. Clinical experience has shown that the OK lenses give a longer retainer effect and take less time to reach stability than normal lenses, but the overriding concern must be the corneal response. If standard lenses give a more regular corneal surface with less ghosting than the OK lenses, then they will be the lens of choice and time considerations become of secondary importance.

Tabb design lenses fitted 0.05 D steeper than the flattest corneal meridian function well as retainers, except when the TD is less than 9.20 mm. This is primarily due to the discomfort of the smaller lenses when compared to the larger OK lenses. Also, the greater degree of lens movement often causes concern to patients. Once again, centration is of prime importance. The optic zone must be well centred over the pupil area to 'smooth out' any residual distortion, and the apical touch should be minimal. Oxygen permeability is also a vital factor when considering extended wear of retainer lenses. The Dk of current OK lenses is 88 and 120, but with the centre thickness being between 0.20 and 0.24 mm due to the back surface geometry the *Dk/t* is reduced to lower than optimal levels unless the higher Dk material is used. This could still reduce the total oxygen transmissibility of the lens to borderline levels for extended wear (Terry *et al.*, 1993). The incorporation of prism ballast as an aid to centration will reduce this even further, and makes extended wear an unadvisable option. There are other materials with much higher Dk values and these, combined with alternative

designs, may be the more prudent approach. Nevertheless, it should be emphasized that in the majority of orthokeratology cases, lenses are not worn on an extended wear basis but in the overnight mode only (*see below*).

Lens binding can be another problem. By the time retainer wear is reached, the cornea is either nearly spherical or oblate in shape and this, combined with the minimal apical clearance and tear reservoir design of the OK series, leads to sluggish lens movement and tear exchange. The incidence of lens binding can be quite high and is, as reported by Swarbrick (1988) and others (*see* Chapter 15), usually asymptomatic with the lens decentred nasally. The tear reservoir becomes an ideal trap for debris and mucus. Adequate tear exchange and lens movement are essential in order to minimize these adverse responses. Punctate epithelial erosions are a good indication of poor tear exchange and chronic lens binding and should alert the practitioner to the need to redesign the retainer lenses. Tear exchange can be enhanced by the use of three 0.25 mm fenestrations placed at the BOZD/TR junction at 120-degree intervals. Lens binding overnight is the main reason for removing the retainer one hour after waking. If the lenses are removed immediately, the distortion produced by a bound lens will degrade the quality of vision, whereas leaving the lenses *in situ* until movement recommences reduces the distortion significantly. Also, the incorrect removal of bound lenses can lead to central corneal staining, and patients must be instructed in the correct technique in order to minimize the problem.

In conclusion, the requirements for a successful retainer design hinge on the final corneal shape, good centration, evenly distributed pressure over the pupil area, a large optic zone and high oxygen transmissibility.

Reduction of corneal distortion due to lens decentration

Sometimes, despite a concerted effort, the lens continues to decentre superiorly and cause inferior corneal steepening (*see Figure 19.3*). This can be a most frustrating situation as the distortion effects can ruin what would otherwise be an excellent result. The aim, therefore, is to recentre the lens without allowing the cornea to regress, and without adding significantly to costs. Stoyan (1992) and Wlodyga and Harris (1993) suggest using lenses with a larger BOZD (OK702, 752 or 803), a steeper BOZR (often the previous lens), or a larger TD. Alternatively, prism ballast has been suggested in conjunction with any of the OK series which in some cases can aid in centration. However, the tendency for prism ballast lenses to centre inferiorly is due mainly to the 'watermelon seed' phenomenon, where the lens taper from top to base combined with lid forces makes the lens ride low. The important factor is the presence of a thin upper lens edge that tapers to the base. The design characteristics of the OK series limits this effect as the thickness of the top of the lens is governed by the junction thickness at the BOZD/BPD_1 interface. In practice, the addition of prism ballast to OK lenses in order to control centration has been found to be of little practical value. The only viable means of reducing distortion induced by lens decentration is to control lens centration by the use of other lens design variations, and these will be discussed in greater detail later.

Astigmatism

Earlier studies into orthokeratology (Kerns, 1976–78; Binder *et al.*, 1980) all noted the tendency of flat, non-centring lenses to increase with-the-rule astigmatism, although Coon did not find this to be the case with Tabb design lenses. Patterson (1975) found a 60% retention of the original astigmatism in patients undergoing the Fontana technique of orthokeratology.

The general trend for astigmatic corneas that did change was:

- against-the-rule to sphere or with-the-rule
- with-the-rule to sphere
- sphere to with-the-rule.

Kerns (1976–78) found that more than half the subjects showed an increase in astigmatism which was mainly with-the-rule due to flat, poorly centring lenses. The greater control of centration with the OK series limits the incidence of induced with-the-rule astigmatism (Soni and Horner, 1993). Anecdotal evidence by Wlodyga and Harris (1993) indicates that astigmatism should be reduced prior to the active flattening of the cornea. They recommend fitting the initial lens steeper than usual which has the effect of making the cornea more spherical. As has been shown to occur with normal contact lens fitting, against-the-rule astigmatism is reduced to a greater extent than with-the-rule astigmatism (Bailey and Carney, 1977).

However, this is not the case with reverse geometry lenses which tend to flatten the vertical meridian faster than the horizontal, leading in some cases to induced against-the-rule astigmatism (*see Figure 19.2*). Patients presenting with against-the-rule astigmatism are not good candidates for orthokeratology using OK design lenses. Another approach (Wlodyga and Harris, 1993) is to reduce the myopia until a condition of mixed astigmatism results. Retainer lenses based on a 'split-*K*' (i.e. mid-*K*) rationale are then fitted which tend to induce a more spherical surface. The literature on the effects of orthokeratology on astigmatism is extremely vague, with little or no attempt to define the nature or axis of the astigmatism or the results of treatment. As a result there are no defined or predictable methods of approaching the problem, but the following guidelines may be useful:

- OK lenses will successfully reduce with-the-rule astigmatism by approximately 60% (Soni and Horner, 1993).
- OK lenses will increase against-the-rule astigmatism.
- May–Grant lenses will reduce against-the-rule astigmatism by inducing with-the-rule astigmatism.
- The degree of residual astigmatism must be taken into account prior to initiating a course of treatment.

Current research

Harris and Stoyan (1992) reviewed the results of a 4-month trial of the OK603 lenses on 86 patients. The average reduction in myopia was 2.75 D, due mainly to the selection of patients with moderate levels of myopia, although they reported that up to 6.00 D had been achieved in other cases. Wlodyga (1992) used the OK603 in the successful management of an unsuccessful RK patient, with initial unaided acuity of R 6/18, L 6/120 improving to R 6/6 and L 6/12 after 5 months of treatment. Riley *et al.* (1992) fitted five subjects with a conventional design lens in Polycon II in one eye and an OK603 design in the other. Both lenses were fitted 0.30 to 0.375 mm flatter than K_f and the same diameter used in each eye. Each subject wore the lens for a period of 2 hours. The spherical equivalent refraction showed an average reduction in myopia of 0.69 D for the OK603 lens and 0.25 D for the conventionally designed lens. The claimed centration properties of the OK603 were verified by comparing corneal topography results between the two designs. The conventional lenses induced inferior corneal steepening and distortion, which was not evident with the OK design.

Horner *et al.* (1992) studied the recovery rates of corneas exposed to specific wearing periods of the OK603. After wearing times of 1, 2 and 4 hours the ranges of myopia reduction were: 0.1 to 2.37 D (1 hour); 1.015 to 1.81 D (2 hours); 1.34 to 2.56 D (4 hours). Following lens removal, the corneas recovered to 95% of baseline after 4.21, 6.57 and 8.22 hours respectively. The rate of recovery expressed as a percentage per hour decreased with increased wearing time, e.g. 1 hour: 50.9%/h, 2 hours: 36.6%/h, and 4 hours: 30.5%/h. There was no correlation between the rate of recovery and the degree of initial induced flattening. The variability was thought to be due to intrinsic elastic corneal properties that determine the individual corneal response to induced stress. Wlodyga and Harris (1993) state that in general, those corneas that respond faster to the orthokeratology procedure with OK lenses tend to lose the effect at a faster rate and require a longer period of retainer wear to reach stability. Joe *et al.* (1993) fitted 15 subjects with OK603 lenses and followed them for a minimum of 16 weeks. Corneal topography, tonometry and subjective and auto-refraction changes were studied in an attempt to find a correlation that could be used as a predictor of the amount of change induced by the procedure. Their results, through regression analysis, showed no correlation between corneal eccentricity and improvement in visual acuity. However, there was a correlation between lower intraocular pressure and refractive change, and also eccentricity and refractive change. They also addressed the predictive value of the differences between measurements of central (K_c) and peripheral (K_t) keratometry (ΔK). This was found to have no correlation with any of the observed results. Previous studies (Polse *et al.*, 1983a,b; Coon, 1984) had also shown no change in axial length with orthokeratology, so the supposition that the degree of expected myopia reduction can be calculated by the ΔK measurements, plus an allowance for axial length reduction, is shown to be groundless.

Joe *et al.* (1993) concluded that eccentricity and lower IOPs may be predictors of the changes that could be achieved with orthokeratology but advised that a larger sample and longitudinal study was required in order to determine if this were the case. Soni and Horner (1993) found, in retrospective and prospective studies on the OK603 design, that the degree of myopia reduction in 120 patients with very low (< 2 D), low (2–3 D), moderate (3–5 D) and high (>5 D) myopia was a spherical equivalent of 1.12, 1.86, 2.15 and 2.48 D respectively. Orthokeratology achieved a level of myopia reduction approximately 60% of that produced by radial keratotomy. The results indicated that twice the level of myopia reduction was possible with OK design lenses as compared to the older orthokeratology techniques, and in half the time. The corneal shape predictions of Wlodyga and Bryla (1989) were also examined with results similar to those of Joe *et al.* (1993) and a more accurate model was found to be:

$$\text{Myopia reduction} = 0.85\ (K_c - K_t)$$

A specific approach to fitting the OK series

The Contex fitting manual advocates fitting the first lens 0.30 mm flatter than K_f and varying the fit depending on the fluorescein pattern. Also, the simple guidelines as to what tightens or loosens the fit do not in any way adequately describe the variations in BOZR/Flat-K relationships between the 360 variations in lens design available. For example, the fitting rules in no way describe accurately the differences in behaviour and effect between an OK603 or an OK754.

The main problem with this approach is that it totally depends on the practitioner's ability to assess the fluorescein pattern accurately, which with such a radical lens design and so many variations requires both a high degree of skill and experience. The ideal lens (*see Figure 19.1a*) exhibits a central area of approximately 3.00 mm benign touch surrounded by a wide, deep tear reservoir that tapers rapidly to a narrow band of peripheral touch at the edge of the secondary curve, with an even edge lift that is approximately 0.20 mm wide. Soni and Horner (1993) alluded to the clinical importance of an active tear flow between the tear reservoir and the edge lift as an aid to centration and that it could play a critical role in the displacement of central corneal tissue. If the peripheral bearing zone is too wide or exhibits too much touch, then the tear reservoir is too shallow and the lens too tight. Conversely, if the area of central touch is small and the peripheral bearing zone narrow, then the fit is considered to be too flat and the lens will decentre. Because this method relies totally on the practitioner's expertise, a more accurate and predictable approach is required.

Modern contact lens design is based on the interaction of corneal shape, tear layer thickness and axial edge clearance

(*see* Chapter 10). The combination of corneal sag, tear layer thickness and lens sag are integral factors in the calculations which are used to design lenses that show predictable fitting characteristics. Corneal shape is determined not only by the keratometer readings, but also by the level of eccentricity (Guillon *et al.*, 1986; *see also* Chapter 10). Corneal topographical systems such as the EyeSys (EyeSys Technology, Texas) and TMS (Computed Anatomy, New York) give clinically accurate information on corneal curvature and eccentricity (Heit *et al.*, 1992; Wilson *et al.*, 1992; Mandell and Horner, 1993), and can be used to calculate the sag of the cornea over a given chord using the formula:

$$z = \frac{r_o - \sqrt{r_o^2 - y^2 p}}{p}$$

where p = shape factor = $1 - e^2$; y = chord/2; z = corneal sag; r_o = apical corneal radius and e = eccentricity.

Both r_o and e are computed by the EyeSys and TMS from the topographical data and the chord determined by the diameter of the lens to be fitted. The ideal OK lens is assumed to have a minimal tear layer under the centre of the lens and touch at the edge of the tear reservoir. Therefore, for a given lens, the chord is equal to the BOZD plus the secondary curve (BPD_1) width; e.g. a 9.80 mm OK603 lens with a 6.00 mm BOZD will have a secondary curve width of 1.4 mm, and the total chord will be 8.60 mm (i.e. 1.00 mm less than TD).

The sag of the lens is given by:

$$p = I + (x - y)$$

where p = primary sag
I = sag of BOZR at BOZD
x = sag of BPR_1 at BPD_1
y = sag of BPR_1 at BOZD

The formula used for the computer calculations of the sag of the OK lenses is as follows:

$$\text{Sag} = \text{BOZR} - \sqrt{\text{BOZR}^2 - (\text{BOZD}/2)^2} + \sqrt{(\text{BOZR} - \text{BPR}_1)^2 - (\text{BOZD}/2)^2} - \sqrt{(\text{BOZR} - \text{BPR}_2)^2 - (\text{TD}/2)^2}$$

Therefore, the sag of an ideal fitting initial OK lens will be equal to the sag of the cornea at the edge of the tear reservoir plus a minimal tear layer thickness of 0.010 mm. The fitting characteristics will also change as the corneal eccentricity (e) changes (*see Figure 19.1b*).

Examples:

For a cornea with the following eccentricities at a chord of 8.80 mm:

r_o = 7.80	e	Corneal sag	Equivalent OK603
	0.60	1.311	8.35/9.80
	0.50	1.325	8.30/9.80
	0.40	1.337	8.25/9.80
	0.30	1.347	8.20/9.80

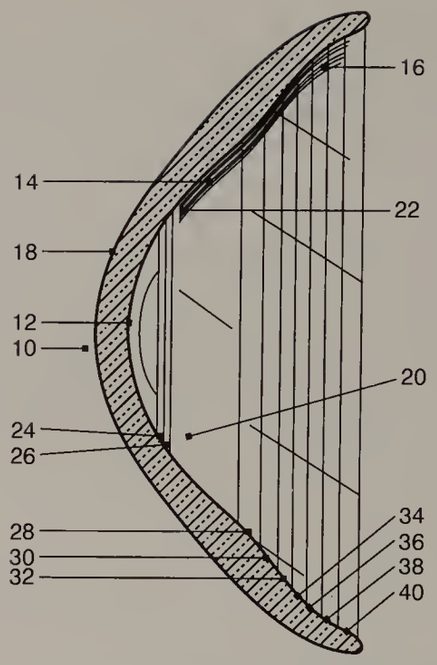


Figure 19.4 A part extract from the Contex patent for the orthokeratology lens. This shows the BOZR (12), the steeper secondary curve (14) and aspheric periphery (16)

If the K_f value for this cornea was assumed to be 7.80 mm; according to the rule of thumb (K_f + 0.30 mm), the indicated lens would be 8.10 mm. This would result in a tight lens unless the corneal eccentricity is in the order of zero. In general, fitting the lens a standard 0.30 mm flatter than K_f only applies if the corneal eccentricity is zero (spherical). Since the 'average' corneal eccentricity is 0.50 the initial trial lens as chosen by the 'rule of thumb' technique will be too steep in the majority of cases. As can be be seen by the above example, the BOZR of the lens flattens as the asphericity of the cornea increases. The corneal topographer calculates the apical radius (r_o) as an *average* curvature at the corneal apex, therefore astigmatism is automatically taken into account in the calculation of the indicated lens.

The calculations do make two assumptions: first, the eccentricities produced by the videokeratoscope are clinically accurate, and second the tear reservoir of the standard OK series is spherical and not aspheric and remains constant over the entire width of the curve.

The patent application shows a small transition zone between the BOZD and the tear reservoir and a multiple curve peripheral curve system (*Figure 19.4*). The small transition zone would have a minimal effect on the sag calculations and the peripheral curve is not considered as it plays no part in the actual fitting calculations. However, the asphericities used in the 'A' series lenses have a marked effect on lens fit. The standard lens calculations are based on a chord that is 1.00 mm less than TD and a TLT of 0.010 mm, whereas the 'A' series calculations are based on the following approximations:

- a TLT of 0.015 mm;
- a chord of 1.20 mm less than TD for BOZDs of 6.00 to 7.00 mm;
- a chord of 1.50 mm less than TD for 7.50 mm BOZD;
- a chord of 2.00 mm less than TD for 8.00 mm BOZD.

Fitting philosophies compared

In order to assess the differences between the 'rule of thumb' principle and the sag fitting principle, a retrospective study of 23 patients was performed. Thirteen patients (Group 1: 13 eyes) were fitted according to the Contex fitting guide (0.30 to 0.40 mm flatter than K_f) and 10 patients (Group 2: 10 eyes) fitted according to corneal eccentricity and sag (0.30 to 0.65 mm flatter than r_o). The change in central corneal power was measured by using the subtractive plot function of the EyeSys. An initial, pre-fitting topographical plot was taken on all subjects and another after 6 hours of lens wear. The two plots were then subtracted and the plot of the difference obtained.

Measurement of the change in apical corneal curvature and power was made by placing the cursor at the cross representing the centre of the pupil zone (*see Figure 19.2*).

Group 1 had a mean decrease in apical corneal power of 0.91 D (sd 0.36 D)* and Group 2 had a mean decrease of 1.38 D (sd 0.58 D). An ANOVA statistical analysis showed these results to be highly significant (P = 0.0024; F = 10.373).

Changes in corneal sag were also calculated from the apical radius and eccentricity values. Group 1 had a mean *increase* of 0.008 mm (se 0.005; sd 0.023), whereas Group 2 showed a mean *decrease* in corneal sag of –0.0187 mm (se 0.008; sd 0.034).* These results were also highly significant (P = 0.0066; F = 8.283). Neither group had any individual eye exhibit a steepening of the central corneal curve, so it would be natural to assume that a decrease in curve would lead to a drop in sag. This is obviously not the case, and the difference in sagittal change could be due to the following causes:

- Differences in induced pressure forces between the relatively steep fitting lenses worn by Group 1 as compared to the flatter lenses worn by Group 2.
- The effect of the relationship, if any, between the pre- and post-lens wear eccentricities.
- The 'Law of Conservation of Corneal Power', which states that 'corneal power can never be created or destroyed but can only be redistributed' (Caroline and Campbell, 1991).

If the initial trial lens is too steep, then insufficient pressure on the corneal apex combined with compression forces at the peripheral contact band may limit the movement of corneal tissue and result in a change of central radius and eccentricity that leads to an increase in sag. The greater degree of myopia reduction in the sag fitting group therefore indicates that the accuracy of the fitting technique has a direct bearing on the corneal response to the lens.

Orthokeratologists have noted that the keratometry changes were always approximately half the value of the refractive change. Erickson (1978) showed that this was due to the limitations of the keratometer and calculated a linear regression equation that would predict the relationship between refractive change and keratometry changes. The equation is:

$$\Delta Rx = 0.72 + 0.68\Delta K \ (r^2 = 0.63)$$

where ΔRx = change in refractive error; ΔK = change in average K readings.

Analysis of the corneal power change versus refractive change for 35 randomly chosen eyes undergoing orthokeratology gave the following relationship:

$$y = 0.967x + 0.087 \quad r^2 = 0.823: \ p < 0.001$$

where y = refractive change and x = apical corneal power change.

This is illustrated graphically in *Figure 19.5*. Therefore, measurement of the central corneal power change will give a more accurate and objective estimation of refractive change than the relationship derived by Erickson. Joe *et al.* (1993) found less of a decrease in mean refractive error when measured by autorefraction as compared to subjective refraction and felt that patient/practitioner bias may have accounted for the difference. The above relationship between central corneal power and refractive change may also be influenced by the same bias, so that a comparison of central corneal power change and autorefraction could conceivably produce an even more dependable relationship.

The second lens

The results of the above analysis raise serious doubts about the validity of the assumption that the second and subsequent lenses follow a predictable pattern of 0.10 mm flatter than the preceding lens. Two individual case histories will be used as examples. The standard design of the OK series was used in these cases and the lenses functioned optimally with a TLT of 0.010 mm.

Patient 1

r_o (pre-fit) = 7.76 mm; e = 0.42; sag = 1.3420 mm (8.80 mm corneal chord); r_o (post wear) = 7.87 mm; e = 0.02; sag = 1.3448 mm (8.80 mm corneal chord).

The initial lens – 8.20/9.80/OK603 – has a sag of 1.3545 mm (0.010 mm tear layer thickness, TLT*) at a chord of 8.80 mm. If the next lens is assumed by the rule of

*'se' or standard error refers to the differences between the means of the two groups, and 'sd' (standard deviation) refers to the spread of the results.

*TLT = lens sag – corneal sag over the common chord. For a lens matching corneal shape or with benign touch, this has been shown to be 0.01 mm. For a very heavy pressure, the value may approach zero.

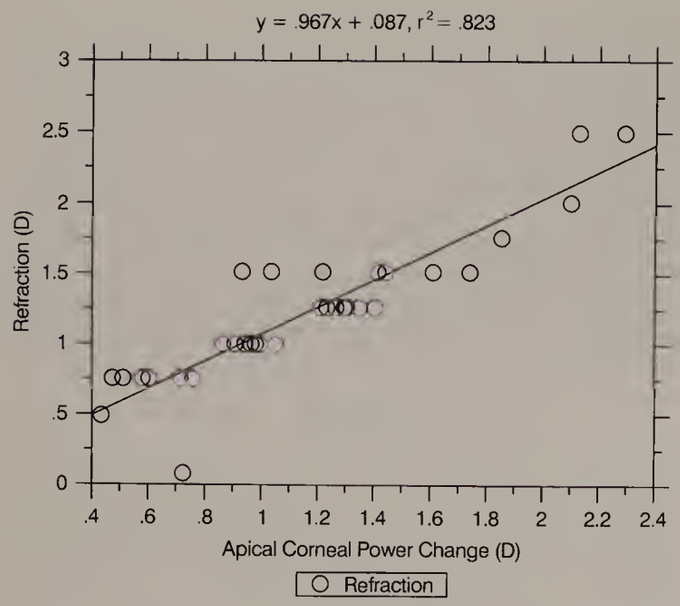
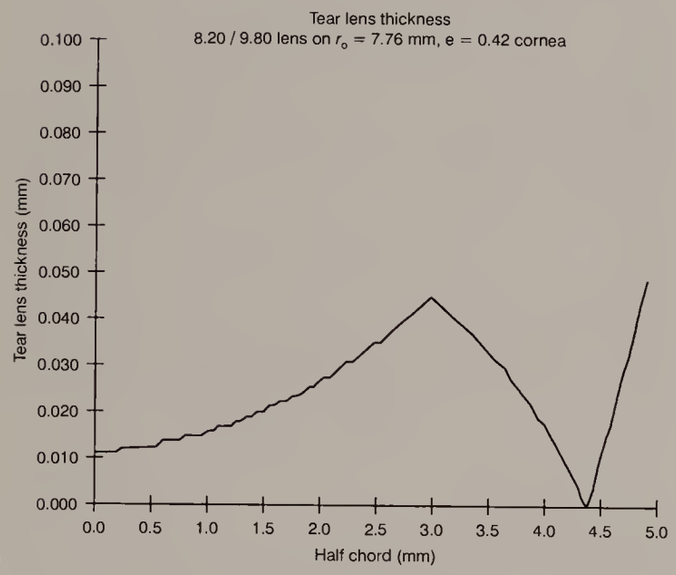
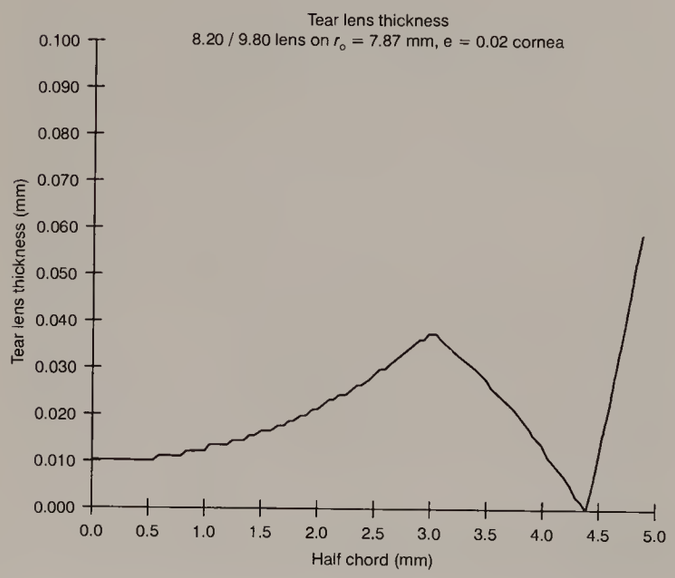


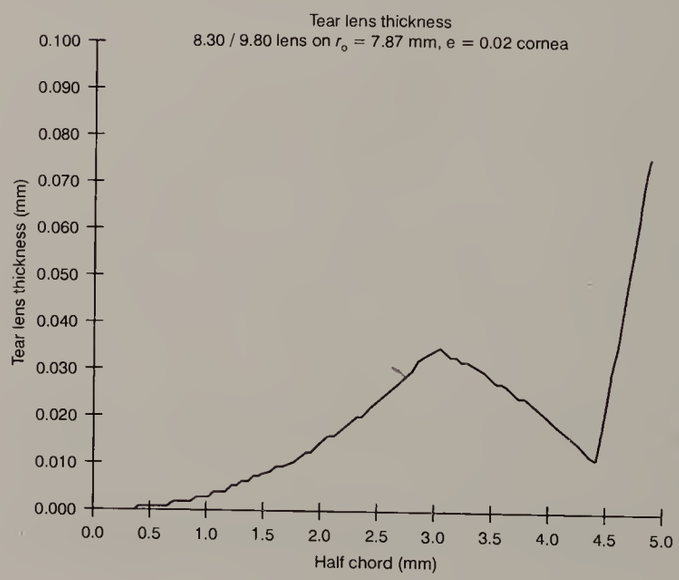
Figure 19.5 Relationship between apical corneal power as measured by the EyeSys and refractive change for a randomly chosen group (p = 0.001; r^2 = 0.823; n = 35)



(a)



(b)



(c)

Figure 19.6 Patient 1: (a) Axial tear lens thickness of indicated lens on pre-fit cornea (*b*), lens on altered cornea and (*c*) the next lens in series on altered cornea. The fluorescein pattern shown in *Figure 19.1* (*c*) is similar to the tear layer thickness graph shown here in (*b*). Note that there is little change in the actual fit of the lens, even though the cornea has changed shape. The next lens in the series would exhibit exessive central touch and no peripheral bearing to aid in centration

thumb to have a BOZR of 8.30 mm, it will be flatter in sag than the altered cornea and will be too loose.The TLT of the initial lens on the pre-wear cornea, the same lens on the altered cornea and the second lens on the altered cornea are shown in *Figure 19.6a–c*.

There is little difference in the tear layer thickness centrally in both the original and altered corneal shapes (*Figure 19.6a,b*), but this changes significantly at the 3.00 mm chord (TLT_1 = 0.040 mm; TLT_2 = 0.034 mm), indicating some relative steepening of the cornea under the lens in this area. Note that there is no central touch as such (TLT = 0.01 mm), but the lens does touch at the junction of the tear reservoir and the peripheral curve. The final graph (*Figure 19.6c*) represents the proposed next lens in the series (8.30 mm BOZR). This shows extremely heavy central touch (TLT = 0 mm) and no peripheral contact. This lens would be very unstable and, due to the lack of peripheral bearing, would be overtly influenced by lid forces which would tend to make it decentre. The heavy central touch would then induce off-centre flattening and all future lenses would locate over this area. The obvious solution to this problem is to start again and have the patient return for a further trial wear using a lens with a different tear reservoir design.

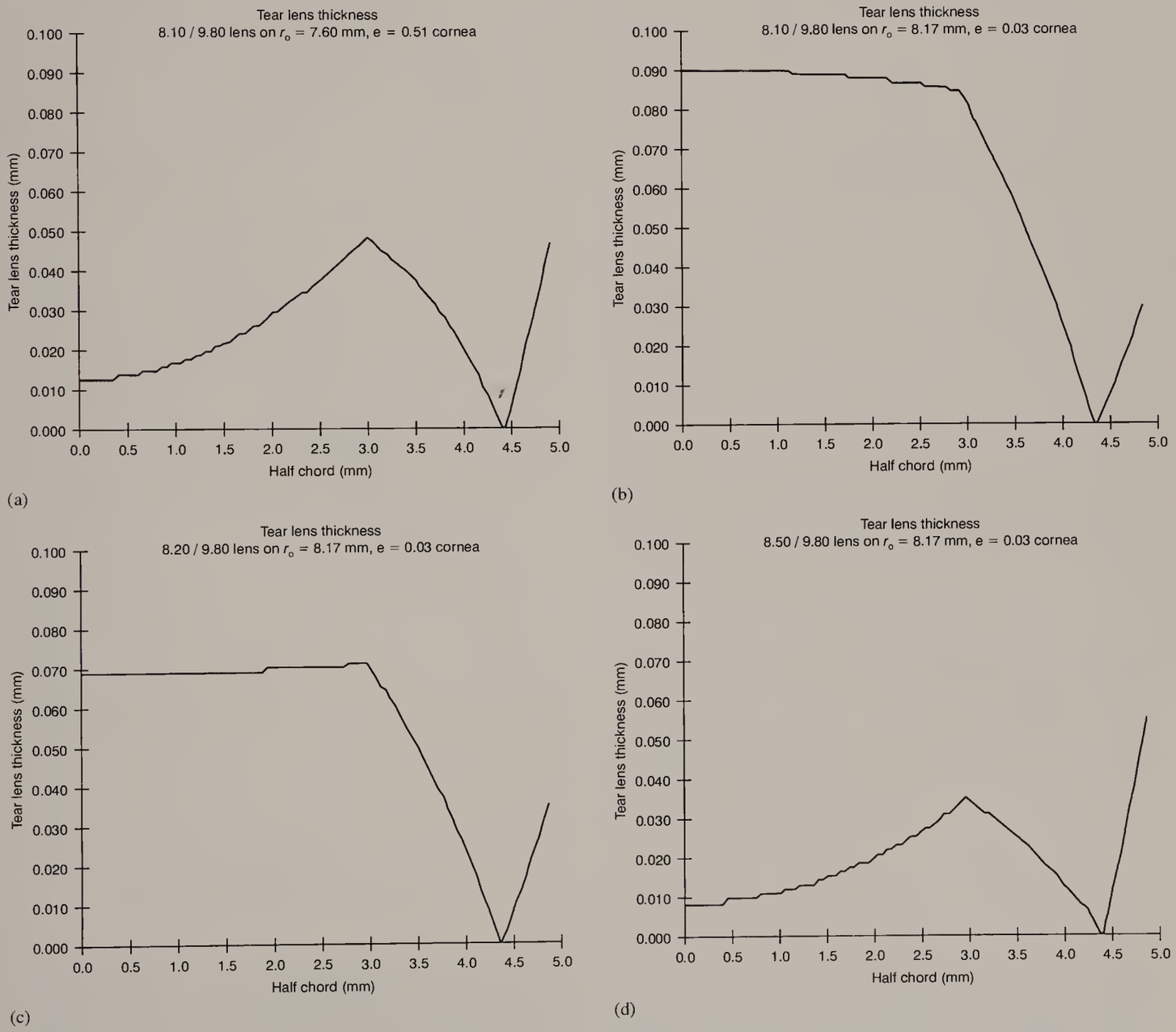


Figure 19.7 Patient 2: (a) Axial tear lens thickness of indicated lens (*b*) and after 6 hours wear (*c*). The fluorescein pattern would be similar to that shown in *Figure 19.1(b)*. The next lens in the series (*c*) is too steep with central clearance. The correct fit is shown in (*d*). Note that the TR is not as deep as in the original fit. An 8.6/OK604 would give a deeper TR

Patient 2

r_o (pre-fit) = 7.60 mm; e = 0.51; sag = 1.3643 mm (8.80 mm corneal chord); r_o (post-wear) = 8.17 mm; e = 0.03; sag = 1.2935 mm (8.80 mm corneal chord).

The indicated first lens at a chord of 8.80 mm is 8.10/9.80/OK603. The indicated lens for the altered corneal shape based on sag calculations is 8.50/9.80 and not an 8.20 as the rule of thumb would indicate. *Figure 19.7* represents the tear layer thickness under the conditions outlined above. The marked difference in sag is reflected in the depth of the TLT over the central and tear reservoir areas. The 8.20 lens on the altered cornea is far too steep, and would either 'lock on' or cause regression of the induced corneal shape

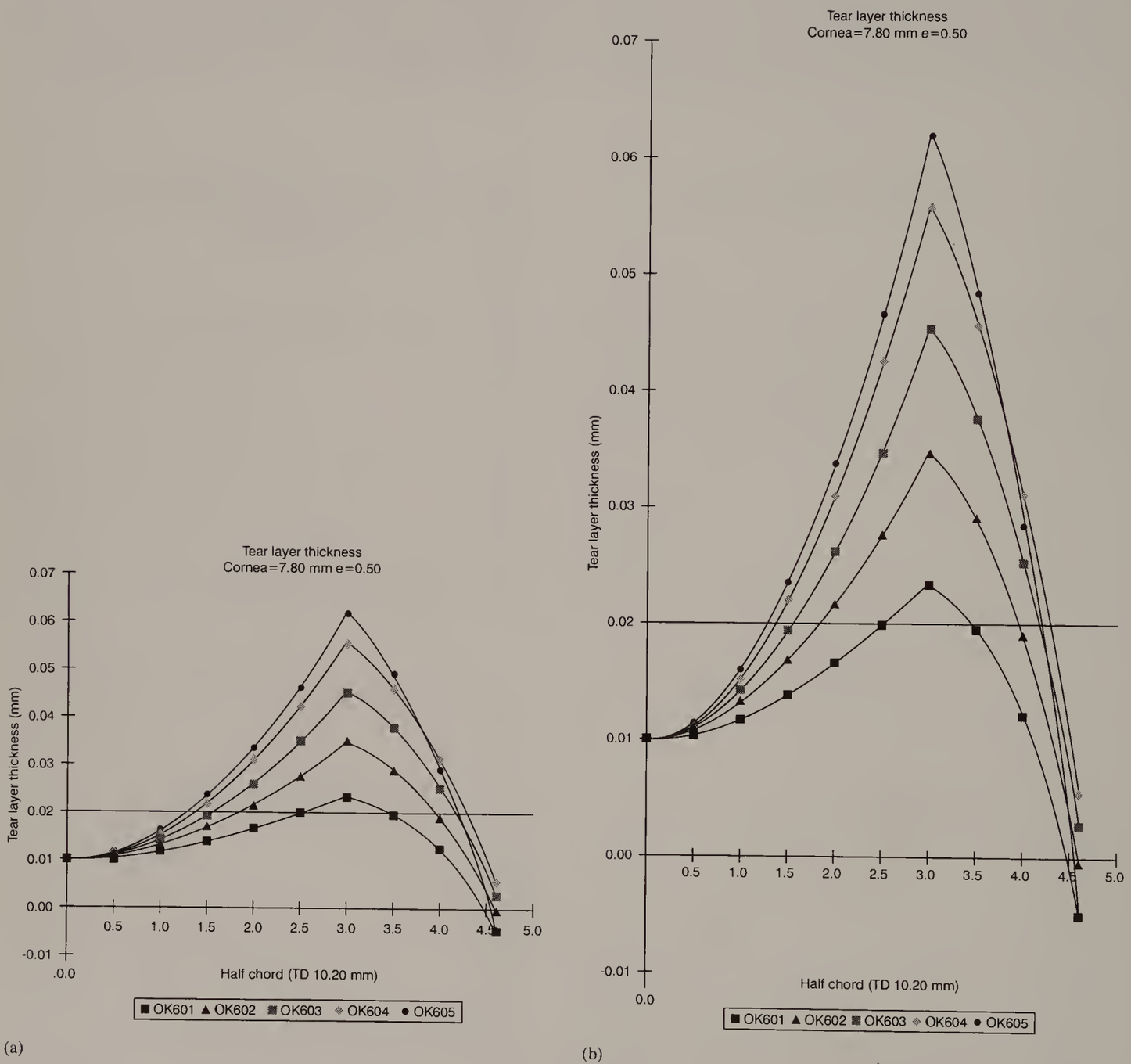
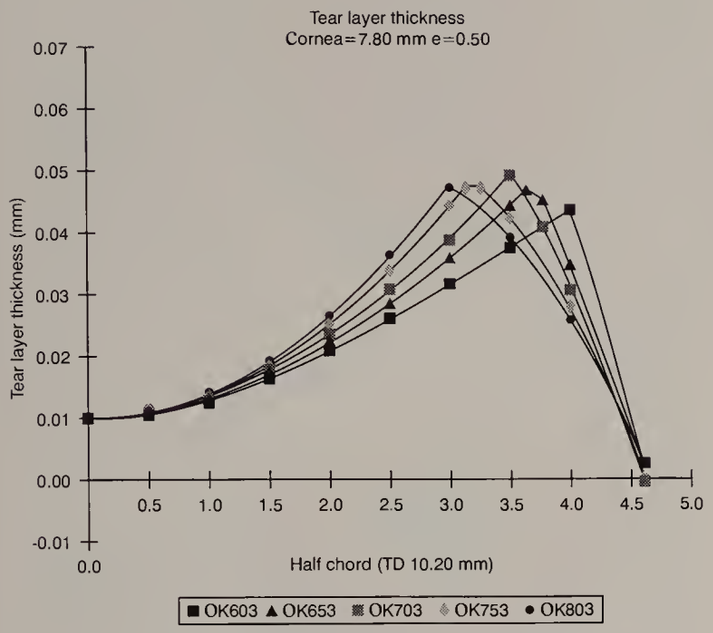
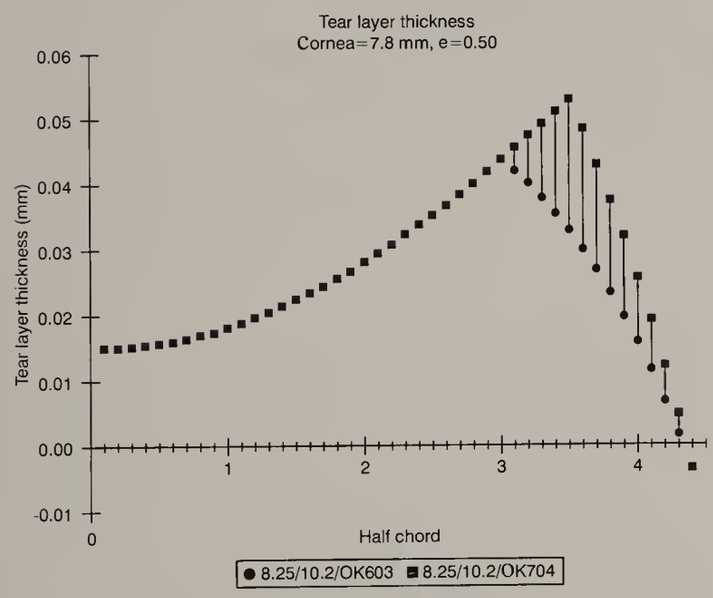


Figure 19.8 (*a*) Tear reservoir profiles of the 6.00 mm BOZD series of OK lenses. The x axis represents the corneal surface and the y axis the sagittal difference between the corneal surface and the back surface of the contact lens, plus the minimal tear layer thickness (0.010 mm) over the chord of the lens (BOZD plus BPD_1). The other BOZD/TR designs follow the same basic pattern in that the TR depth increases with the steeper BPR_1. (*b*) Same graph as (*a*) but with the y axis enlarged to show the area of central touch of each of the TR designs. If it is assumed that fluorescein becomes visible (in normal clinical concentrations) at 0.020 mm thickness, then the central touch area can be read by finding the x axis intersect at a TLT of 0.020 mm. The touch areas for the OK series are as follows: OK601–5.00 mm; OK602–3.5 mm; OK603–3.3 mm; OK604–3.00 mm; OK605–2.60 mm (*continued opposite*)

changes. The calculated lens demonstrates the correct tear profile. A comparison of the TR depths between the two cases indicates that in Patient 2 the TR is 10% deeper. A re-trial with a deeper TR (8.35/OK604) for Patient 1 would determine whether the response was due to a fitting problem or inherent corneal rigidity.



(c)



(d)

Figure 19.8 (*cont.*) (*c*) TR profiles of the equivalent OK series of lenses with the same TR depth. Altering the BOZD and keeping the TR constant results in an increase in width of the TR with minimal alteration in depth. (*d*) The similarities in TR between the OK603 and OK704. These lenses will show similar fitting characteristics except that the increased TR depth and width of the OK704 will enhance centration as compared to the OK603

In both cases, however, the corneal eccentricity had almost reached zero (corneal sphericalization) by the end of the trial wear period. The earlier controlled studies had found that further reduction in refractive error was unlikely once the cornea had become spherical. The importance in changes in corneal eccentricity after trial wear periods are discussed in greater detail below, but in general the ordering of 'future' lenses in cases where the eccentricity approaches zero after a trial wear period is unlikely to cause any further corneal flattening.

Fitting lenses to a predetermined schedule without taking the total corneal curvature changes (r_o and e) into account will lead to what appear to be uncontrollable and unpredictable results, and require more time and lenses to rectify. This is not to say that unpredictable changes do not occur. The fitting system outlined above is simply an effort to approach the subject on a more scientific basis, and to treat each cornea individually. The need for second and subsequent lenses cannot be predicted without first analysing the changes caused by the previous lenses. The phenomenon of the first set of lenses causing such a marked change in corneal shape that it binds due to relative tightness after a short wearing period of 1 to 2 days is invariably due to the initial lens being fitted too steeply in the first place if the traditional fitting of 0.30 mm flatter than K_f is used.

Fluorescein pattern evaluation is still essential as the validity of the eccentricity and r_o values provided by corneal topography instruments depend on variables such as the alignment, focusing and calibration accuracy of the instrument as well as the algorithms used in the programming. The ideal fitting OK lens must exhibit:

- Good centration
- 3.00 to 3.50 mm central 'touch'
- A wide, deep tear reservoir that tapers from the area of central touch to the peripheral contact band
- 1.00 to 2.00 mm movement depending on diameter
- Active tear exchange without the presence of bubbles in the tear reservoir, indicating a steep fit

The other factors that affect the behaviour of the lens are changes to lens diameter and mass, lid forces acting on those changes, and the individual corneal viscoelastic stress response. However, the single most important criterion when assessing the fit of an OK lens is centration without peripheral compression. It is the manipulation of TR depth and width, BOZR, TD and peripheral curve design that govern and optimize centration.

Strategies for centration control

Tear reservoir considerations

The role of the TR is thought to be two-fold: centration and positive and negative pressure distribution that induce changes in corneal shape. Steep fitting lenses have been traditionally linked with causing corneal steepening due to negative pressure effects under the lens, and flat lenses with corneal flattening due to positive pressure. The OK series

appears to involve a combination of the two. The central area is quite flat, inducing positive pressure to cause central corneal flattening, whereas the peripheral TR is steeper than the cornea, inducing negative pressure to cause peripheral steepening. Each appears to complement the other when the lens fit is correct. An incorrect fit invariably leads to marked corneal distortion. The OK series of lenses presently consists of 90 different combinations of TR and BOZD if the 'A' series is included (*see Table 19.1*).

Figure 19.8a represents the TRs of the 6.00 mm BOZD range of OK lenses on an 'average' cornea where r_o is 7.80 mm and *e* is 0.50. There are two main assumptions made when assessing a contact lens fit by referring to tear layer profiles: firstly, that the r_0 and *e* data obtained from the topographical instrument are clinically accurate and valid, and second that the tear film thickness necessary for fluorescein to be made visible at the concentrations usually used in contact lens practice is approximately 20 microns. In essence, if the TLT is less than 20 microns the lens will appear to 'touch' the cornea. As the TLT increases above this point, fluorescein becomes more visible. The line drawn across the tear layer profile shown in *Figure 19.8a,b* at the 20 micron level differentiates the areas of touch from the areas of clearance. *If the BOZD is kept constant, the TR depth increases with the steepening of* BPR_1. If the TR depth is one of the controlling factors in lens centration, then the deeper the TR, the better the centration. If a vertical line is drawn from the 20 micron line to the *x* axis, then the apparent area of central touch can be calculated. Similarly, those areas of tear layer profile above the line will show areas of clearance. The 'ideal' OK lens has a central touch diameter of 3.00 to 3.50 mm. The only lenses that meet the criterion are the 3.00 and 4.00 D TR lenses, the 5.00 D lens having a central touch diameter of approximately 2.50 mm and the 1.00 D and 2.00 D TR lenses showing greater than 4.00 mm of touch. The small area of central touch associated with the 5.00–9.00 D lenses invariably causes a correspondingly small area of corneal flattening, leading to a 'concentric bifocal' retinoscopy reflex. The topography plots similarly show an area of flattening less than the pupil diameter, which is unacceptable due to the negative visual effects of flare and ghosting (*Figure 19.9*). Therefore, (Figure 19.8b) as the TR depth increases, the area of central touch decreases and OK lenses with TRs of greater than 5.00 D become unsuitable for the procedure. However, these lenses become invaluable when fitting post surgical cases of photo-refractive keratectomy and radial keratotomy (6.00 mm BOZD) and penetrating keratoplasty (8.00 mm BOZD) due to the relatively steeper peripheral corneas that result from the procedures.

Figure 19.8c represents the change in TR as the BOZD is increased. In this case, the lenses all have a TR 0.60 mm (3.00 D) steeper than the BOZR and represent the equivalent sagittal fit with a TLT of 0.010 mm. Thus *as the BOZD is increased, the TR depth remains constant, but the width of the TR and the area of central touch is increased.* The above relationships remain constant over the entire range of OK designs (with some variations for the 'A' series) and eye shapes and these are the main factors involved in the choice of lens to control centration as well as provide adequate central touch and TR depth in order to elicit a change in corneal shape.

A computer program designed by the author and written by Michael Vincent was developed to calculate the corneal and lens sags and indicate the closest 'target' lens with a TLT of 0.010 mm over the entire OK design range. The inputs for a 'standard' cornea of $r_0 = 7.80$ mm and $e = 0.50$ over a chord of 9.00 mm (10.00 mm lens) are shown in *Table 19.7*. The inputs for the 'A' series are different, in that a TLT of 0.015 mm is used and a chord that is 1.20–2.00 mm less than the TD (*see above*). It would be tempting to assume that the lens with the closest matching sag would give the best fit, but this is not the case due to the limitations of the accuracy of the *e* calculations of corneal topography and the importance of the correct balance between central touch and TR depth and width. The interesting thing to note is that in some cases the same BOZR is indicated with different TR designs, i.e. the sagittal equivalent fit for the 'standard' cornea is either an 8.30/10.20/OK603 or 704. The TR profiles of these two lenses is shown in *Figure 19.8d*. The TR depth and width is increased without altering the BOZR or the area of central touch. If the OK603 was the initial trial lens of choice, but exhibited a narrow or shallow TR, then the alternative design would be the OK704. Increasing the depth and width of the TR will also lead to a greater control of centration. Clinical experience indicates that the OK704 consistently gives the best balance between TR depth, central touch and centration, and in most cases can be considered the most effective lens of the whole series, and the most obvious choice of trial lens.

If the TR of the OK704 appears too deep, the choice reverts to the OK603. As stated above, if the TR is steepened the area of central touch is reduced but the degree of pressure exerted centrally appears to be increased and can lead to a small central area of marked flattening surrounded by a steeper, more negative area which is usually smaller than the pupil. This causes marked ghosting and distortion.

Therefore the 'balance' between central touch and mid-peripheral clearance is critical in terms of both the degree of myopia reduction and the optical quality of the corneal topographical changes induced. The OK 704 combines the best attributes of corneal shape change, without central distortion, and centration at an optimal diameter of 10.2 mm. It must be stressed that the target lens indicated by the computer calculations is the *flattest* lens. If centration is poorly controlled, then alterations to either diameter or BOZR must be used to optimize centration.

The tear layer thickness (TLT) difference between a 9.80, 10.00 and 10.60 mm diameter OK603 lens is shown in *Figure 19.10*. In this case, changing the diameter of the lens will not improve the fit. The 10.00 mm diameter lens will be too steep (TLT 0.0134 mm) and the 10.60 mm lens too flat (TLT 0.0058 mm). A different result is shown in *Figure 19.11*, where increasing the diameter from 9.80 mm to

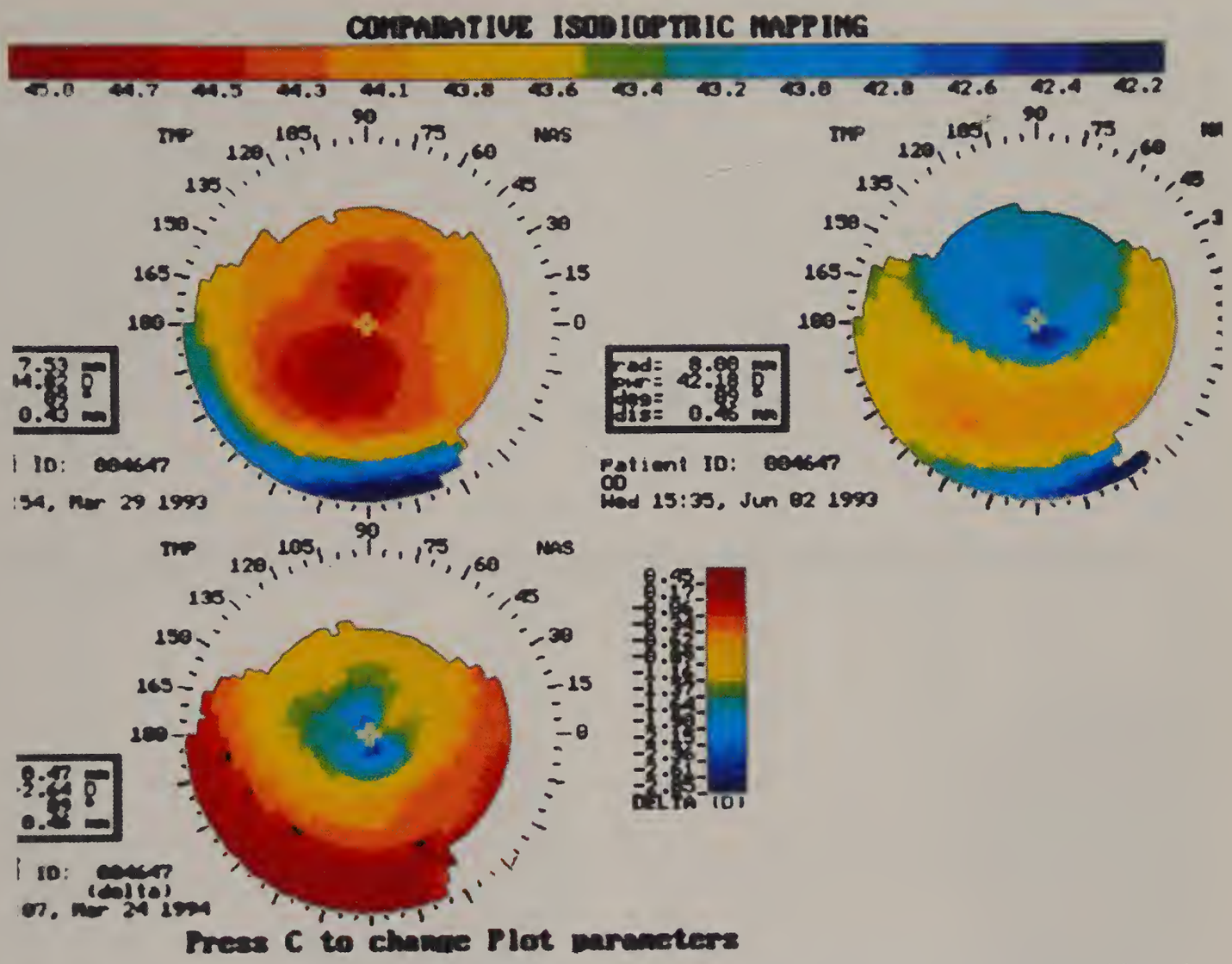


Figure 19.9 Topography plot showing the effect of using an OK605. Note the small area of central flattening which causes ghosting and flare and reduces unaided visual acuity. Compare the area of central flattening in this case to that shown in *Figure 19.2*.

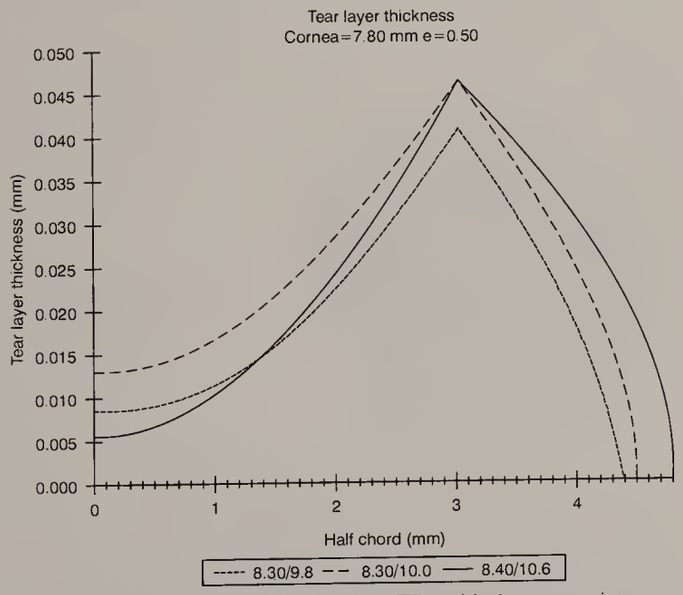


Figure 19.10 The effect of altering lens TD (with the appropriate alterations in BOZR) on the TR. In this case, changing the lens diameter does not improve the lens fit from the original diameter of 9.80 mm

10.40 mm (along with the required change to BOZR) gives an ideal fit. In this case the r_o is 8.00 mm and eccentricity 0.50. However, the ability to make such fine alterations to lens fit based on changes to lens diameter are limited in a practical sense due to the limitations outlined above and the restrictions of trial lens availability. The TLT is also sensitive to changes in BOZR. *Figure 19.12* represents the variations in TLT if the diameter is kept constant and the BOZR altered in an attempt to improve the fit for a cornea of r_o = 7.80 and e = 0.50. The indicated lens (8.30/10.20/OK603) still gives the best fit. Steepening the BOZR in 0.05 mm steps will cause a marked increase in central TLT (approximately 0.01 mm for each 0.05 mm) and associated peripheral compression. The BOZR and BPR_1 curve relationship is conserved when the BOZR is steepened and the corresponding change in the TR curve causes compression effects at the BPR_1/BPR_2 junction. The combination of central pressure and peripheral compression causes a premature change in corneal shape to that of an oblate ellipse and limits the refractive change possible (*see*

Table 19.7 Computer calculations of sag differences and indicated sag equivalent OK lens for the 'average' cornea*

Input variables		*Defaults*			Edit inputs
Apical radius	= 7.80	Display Window	2		Defaults
Eccentricity	= 0.50	Step in BC search	0.0500		Calculate!
Chord diameter	= 9.20	Sag gap	0.0100		Quit

Display Window 1 AR 7.80, *e* 0.50, TD 9.50,			CS 1.2307 TS 1.2407
	BOZR	SAG DIFF.†	LENS SAG†
OK601	8.000	0.0027	1.2433
OK602	8.150	0.0034	1.2373
OK603	8.250	0.0005	1.2412
OK604	8.400	0.0044	1.2362
OK605	8.500	0.0006	1.2413
OK651	8.000	0.0006	1.2401
OK652	8.100	0.0004	1.2402
OK653	8.200	0.0003	1.2410
OK654	8.300	0.0017	1.2424
OK655	8.400	0.0038	1.2445
OK701	8.000	0.0042	1.2365
OK702	8.050	0.0016	1.2423
OK703	8.150	0.0013	1.2393
OK704	8.250	0.0036	1.2371
OK705	8.300	0.0043	1.2450
OK751	7.950	0.0009	1.2416
OK752	8.000	0.0025	1.2432
OK753	8.050	0.0047	1.2454
OK754	8.150	0.0020	1.2387
OK755	8.200	0.0015	1.2422
OK801	7.950	0.0039	1.2368
OK802	7.950	0.0021	1.2427
OK803	8.000	0.0010	1.2397
OK804	8.050	0.0035	1.2371
OK805	8.050	0.0039	1.2446

Display window 2 AR 7.80, *e* 0.50, OD 10.20,			CS 1.4587 TS 1.4687
	BOZR	SAG DIFF.†	LENS SAG†
OK601	8.050	0.0043	1.4730
OK602	8.200	0.0006	1.4693
OK603	8.350	0.0026	1.4661
OK604	8.500	0.0051	1.4636
OK605	8.600	0.0046	1.4733
OK651	8.050	0.0011	1.4698
OK652	8.200	0.0057	1.4630
OK653	8.300	0.0004	1.4683
OK654	8.400	0.0057	1.4744
OK655	8.550	0.0009	1.4696
OK701	8.050	0.0025	1.4662
OK702	8.150	0.0014	1.4673
OK703	8.250	0.0004	1.4691
OK704	8.350	0.0031	1.4718
OK705	8.500	0.0051	1.4636
OK751	8.000	0.0048	1.4736
OK752	8.100	0.0018	1.4705
OK753	8.200	0.0004	1.4683
OK754	8.300	0.0018	1.4669
OK755	8.400	0.0023	1.4664
OK801	8.000	0.0001	1.4689
OK802	8.050	0.0039	1.4726
OK803	8.150	0.0031	1.4656
OK804	8.200	0.0023	1.4710
OK805	8.300	0.0030	1.4657

*r_0 is 7.80 mm and *e* is 0.50.
The chord is always 1.00 mm less than TD for the standard OK series. The 'A' series require a different set of inputs (*see text*). The practitioner simply enters the values for r_0 and *e* and the chord that is 1.00 mm less than the diameter of the trial lenses available. The range of OK lenses that are closest to the 'target' sag (ie. 0.010 mm greater than the corneal sag) are listed on the screen. The lens of first choice depends on the trial lens available. The lens closest to the target lens is inserted and the fit altered to achieve the best combination of centration and movement. The program indicates the *flattest* lens, so any alterations will require steepening of the BOZR in order to achieve the optimal fit. Alterations to TD can also be calculated by changing the inputs for Display Window 2, or the calculations for both eyes presented simultaneously.
CS = corneal sag. TS = target sag.
†The actual sag values do not appear in the new version of this program included with this book.

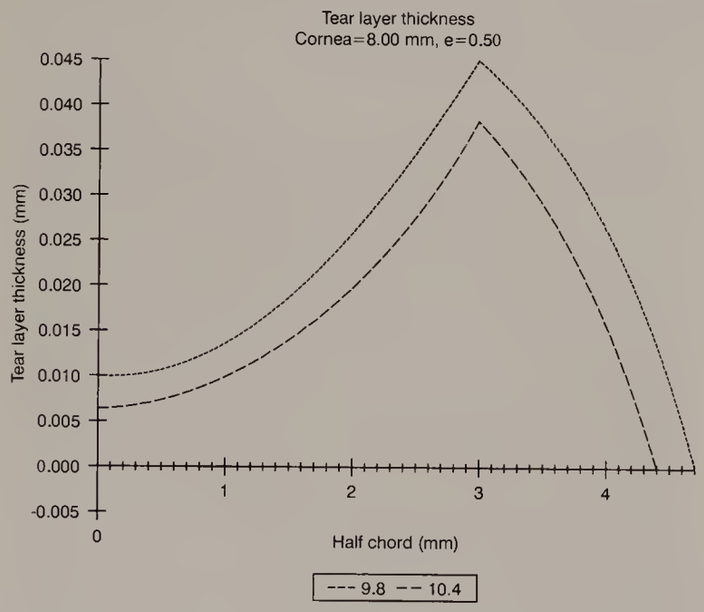


Figure 19.11 An example of improving the lens fit by altering the diameter of the lens. The cornea has r_o = 8.00 mm and *e* = 0.50. The 9.80 mm diameter (8.80 mm chord) has insufficient TLT centrally and a shallow TR. Increasing the diameter to 10.40 mm (9.40 chord) increases the central TLT and also the TR volume

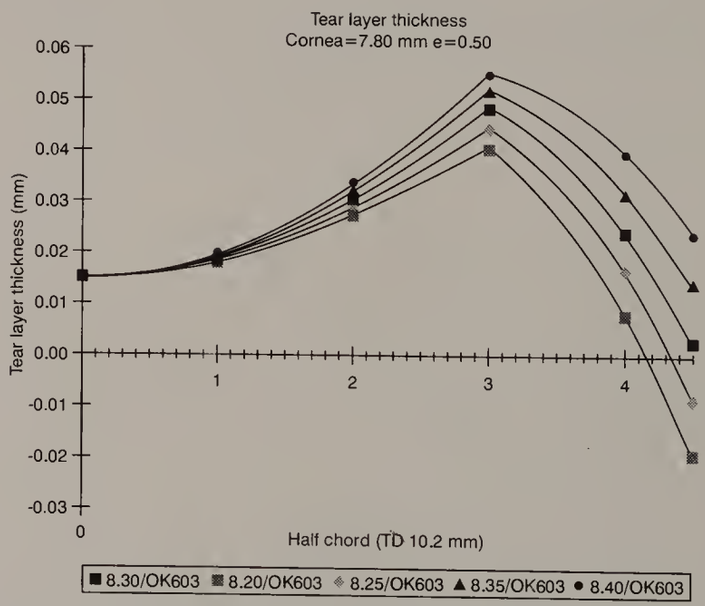


Figure 19.12 The effect on TLT and TR volume by altering the BOZR whilst keeping the TD constant. Both TLT and TR volume are far more sensitive to changes in BOZR than TD. Steepening or flattening the BOZR by even 0.05 mm causes marked changes in the optimal levels of central TLT and TR volumes

Figure 19.13). The steepening of the peripheral cornea associated with central flattening as noted by Wlodyga and Harris (1993) and others is therefore an induced change caused by a tight lens fit (compare *Figure 19.2* to *19.13*). Conversely, flattening the BOZR by 0.05 mm reduces the TLT to almost zero, resulting in heavy central touch and insufficient peripheral bearing to control centration. Lenses that are fitted too flat invariably decentre superiorly, causing inferior steepening of the cornea and superior flattening and associated induced astigmatism and ghosting (*see Figure 19.3*). All future lenses will tend to locate in the same area, so the only alternative for the practitioner is to redesign the lens to optimize centration. If the BOZR is kept constant and the TR steepened in order to centre the lens, the following occurs:

Example:

Current lens 8.00/10.2/OK704 sag = 1.559 mm
Altered lens 8.00/10.2/OK705 sag = 1.592 mm

However, the equivalent sag of the OK 705 in a 704 design indicates a BOZR of 7.90 mm. In other words, changing the lens design should always be accompanied by a change in BOZR unless sagittal equivalents are used. Steepening the BPR_1 has the same effect as steepening the BOZR, which in most cases leads to peripheral compression unless the lens was initially fitted too flat. As lens diameter increases, the sagittal differences between lenses with the same BOZR but steeper or flatter TR curves increases dramatically making the value of this means of centration control unadvisable.

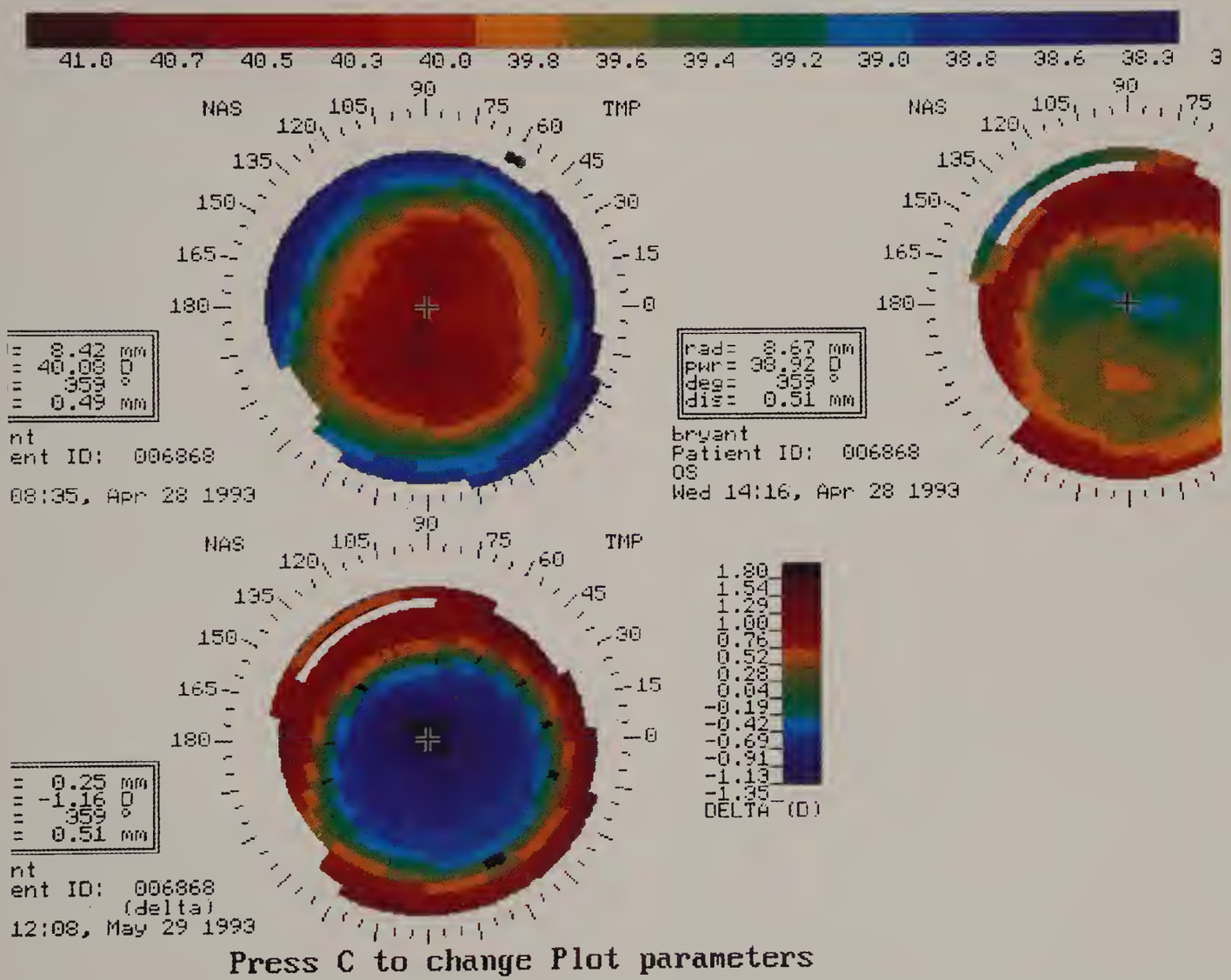


Figure 19.13 Topography plots showing the effect of fitting a lens with the BOZR too steep. Note how the central cornea has flattened but the peripheral cornea has steepened by a greater amount (refer to the colour scale). The reduction of myopia is 1.00 D, but the corneal eccentricity (0.62) indicates a much greater reduction is possible. Fitting lenses too steeply in order to control centration results in the premature induction of an oblate corneal shape (top left) and limits the refractive change possible

Calculations of the sag relationship between the corneal shape and lens design indicates that manipulation of lens diameter is a more accurate method of controlling TR parameters than altering the BOZR. Minimal or excessive movement is therefore best controlled by altering the diameter to decrease the TLT in the case of a tight lens, and increasing the TLT in the case of a loose lens. Alterations in the central TLT will cause a corresponding change in the level of peripheral contact and result in better control of lens movement. However, this becomes difficult to assess clinically as the cost involved in acquiring trial lenses in such small diameter variations would be prohibitive. In the majority of cases, simple manipulation of the TR, TD and BOZR does not result in a well centred lens, so the only other means of controlling centration rests with alterations to the design of the final peripheral curve (BPR_3).

Peripheral curve design

Both standard and 'A' series lenses have a BPR_2 that is aspheric and approximately 0.60 mm flatter than the BOZR with a width of 0.50 mm. The ideal lens has an assumed central clearance of 0.010 mm and rests on the cornea at the junction of BPR_1 and BPR_2. If the depth and width of the TLT in the TR area are insufficient to overcome the lid forces that cause lens decentration, then the interface between the peripheral curve and the corneal surface becomes the only stabilizing factor. The author redesigned the OK704 by adding a wide tangential curve to increase BPD_2 to 1.10 mm.The lens has a TD of 10.6 mm where BOZD is 7.00 mm, BPD_1 is 8.40 mm, and the balance of TD is being the tangent curve. Tangential curves meet the peripheral corneal curve at a tangent to the normal of the surface and theoretically apply a gradually increasing degree of pressure over the area of contact (Thomas, 1967). This in turn leads to a dramatic improvement in lens centration. Stoyan differentiated the lens with the letter C, i.e. OK704C. The design has two major uses, in that it can be used as either a lens of first choice or as a means of reducing the inferior corneal distortion caused by a superiorly decentred lens (*Figure 19.14*).

As stated previously, the fitting of the OK series of lenses is both difficult and time-consuming and requires a high degree of skill on the practitioner's part. The choice of the initial trial lens is more accurate when all of the factors that describe the corneal shape are taken into consideration. The 'rule of thumb' (i.e. 0.30 mm flatter than K_f), usually indicates a lens that is too steep, except when the cornea has a low asphericity. In the case outlined at the beginning of this section (r_o = 7.80 mm; e = 0.50), the indicated BOZR according to the fitting manual is an 8.10 mm BOZR whereas the sag calculation indicates a BOZR of 8.30 mm. The 0.20 mm difference is critical in that the cornea responds differently to 'steep' as compared to 'flat' fitting lenses, and this appears to be due to three main factors:

- Tear layer thickness.
- Compression at the junction of the BPD_1 and BPD_2.
- Lid forces on the lens.

Because centration is of prime importance, the tear layer thickness concepts outlined in Chapter 10, which state that the thicker the central TLT, the less effect lid forces play in lens centration, can be used to the practitioner's advantage in controlling lens behaviour. Standard lens designs, however, do not have the complicating influence of the deep peripheral tear reservoir of the OK lenses. If an OK lens shows excessive movement as a result of lid forces, steepening the BOZR in order to deepen the central TLT to control movement and centration will lead to peripheral compression and a tight lens. As shown previously, a change of 0.05 mm in BOZR will either increase or decrease the central TLT by approximately 0.01 mm, and since the optimal TLT is 0.01–0.015 mm, even small changes to the BOZR will adversely affect the central clearance. Changes to lens diameter effect far more subtle changes in sag and will give better control of movement and centration, but the costs and added chair time involved in trial lens variations make this an inadvisable option. The addition of a tangential BPR_2 in conjunction with the most effective lens (OK704), has, however, led to a simple resolution of the major problem associated with lens behaviour, namely centration.

When dealing with such small variations in lens sag, the question as to the accuracy of the data used in the calculations must also be taken into account. The accuracy of corneal topography is dependent on the factors mentioned previously, so the accuracy of the calculated lens fit will vary with the accuracy of the instrument. The accurate fitting of OK lenses is still therefore dependent on the practitioner's skill in interpreting fluorescein patterns, lens movement and centration and applying the results of the trial wear period as a diagnostic tool (*see later*). Practitioners must become conversant with the concept of fitting the OK series as a sagittal and not a BOZR relationship to the cornea.

Other considerations

Corneal staining

It would be logical to assume that lenses fitted so flat would cause a high degree of central epithelial staining. On the whole this has not been found to be the case unless the lenses are fitted incorrectly. Other factors that may induce punctate epithelial erosions are:

- A poorly cleaned lens or debris adhering to the back optic zone.
- A foreign body trapped under the lens during the trial wear period. It is essential to advise patients to return at the first sign of pain or marked discomfort.

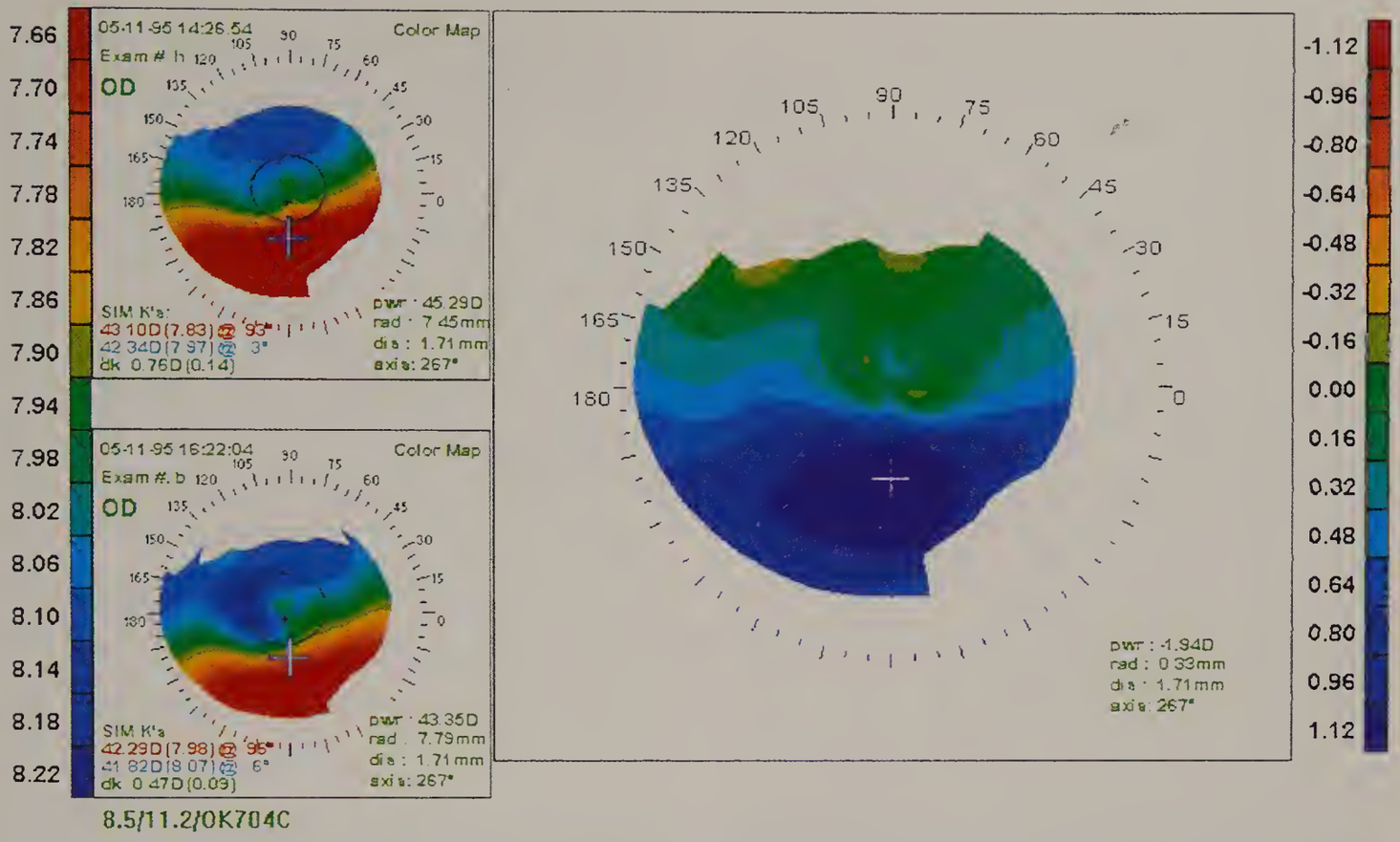


Figure 19.14 Reduction in inferior corneal distortion caused from a chronically high riding lens by the use of an OK704 with the tangential 'C' edge design, for 2 hours. The inferior cornea has been flattened by approximately 2 D in a very short period of time, indicating the relative plasticity of the cornea

- Scratches and deposits on the lens back surface. Due to the area of central 'touch', scratches or deposits on the lens back surface will cause marked centrally located corneal abrasions. If the lens cannot be successfully polished it must be replaced.
- Lens adherence from a tight fit or a lens fitted excessively flat. Also, incorrect removal of a bound lens will cause corneal staining.
- Poor quality tear film.
- 'Fragile epithelium' secondary to other causes such as underlying basement membrane problems not detected during the initial examination.

Is orthokeratology predictable?

The simple answer to the question is 'no'. In order to predict the final outcome of the procedure and the number of lenses required, the following variables would have to be known:

- Corneal rheology (*see* p. 683)
- Corneal topography and shape factor
- Initial refraction
- Intraocular pressure
- Lid force effects
- The effect each lens would have on corneal shape and refraction
- The relationships and interdependence of all of the above

However impossible it may currently be to predict success with orthokeratology, it may be possible to predict failure and whether proceeding with a course of treatment would be worth the time, effort and cost involved. Carkeet *et al.* (1995) performed a retrospective analysis of biometric and biomechanical data on three groups of patients consisting of an experimental group (orthokeratology) and two control groups (RGP wearers and non contact lens wearers). The control groups were age, gender and refractive error matched as closely as possible to the experimental group. Measurements included subjective refraction, corneal thickness and corneal thickness profile, intraocular pressure, ocular rigidity and epithelial fragility. The orthokeratology group were further subdivided into good responders, moderate responders and non-responders based on the results of a trial wear period of 6 hours.

Analysis of the results showed that there was no statistically significant difference between the experi-

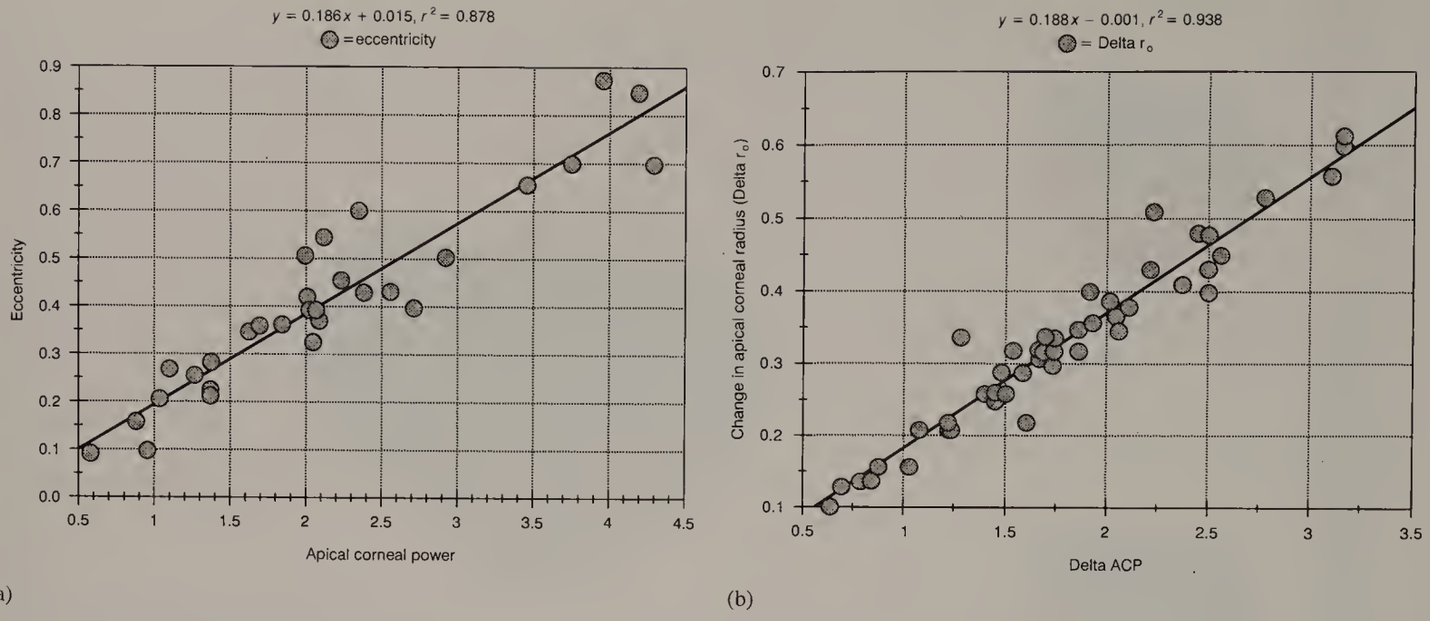


Figure 19.15 Regression analysis of the relationship between change in apical corneal power (dioptres) and corneal eccentricity

mental or control groups for any of the biometric or biomechanical data measured. The only significant finding was that the success of orthokeratology was dependent on the degree of the initial refractive error. The study commented on previous work that indicated that corneal shape could be of use in predicting success.

The practical limit of orthokeratology, according to Kerns (1976–78) and Binder *et al.* (1980) is reached when corneal asphericity is zero. Both researchers found that even with agressive therapy, the cornea changed little once a spherical corneal shape factor ($e = 0$) was reached. Further flattening of the contact lenses usually induced unwanted with-the-rule astigmatism and distortion. Joe *et al.* (1993) found a correlation between refractive change and initial corneal eccentricity in their orthokeratology group.

Therefore, if the initial shape factor of the cornea is the starting point and the end point of the procedure is reached when e is equal to zero, then knowing the relationship between refractive change and corneal shape change could form the basis of a predictable approach to the procedure. A retrospective study of 30 patients who had successfully undergone orthokeratology was performed by the author to assess the relationship between refractive change and corneal eccentricity change. The patients were chosen at random, and the choice of eye also randomized. Those eyes that exhibited oblate or distorted corneal surfaces that would give false eccentricity values were excluded from the study. The topographical plots of the patients at the beginning of the procedure and at the stable retainer stage were compared and the change in apical corneal power and corneal eccentricity noted. *Figure 19.15a* shows the correlation between the change in apical corneal power and eccentricity, with regression analysis yielding the following formula:

$$y = 0.186x + 0.015 \quad (r^2 = 0.878;\ p < 0.001)$$

where y = change in eccentricity and x = change in apical corneal power.

If the results of the relationship between change in apical corneal power and spectacle prescription (best sphere) described earlier are combined with the above equation, then the following relationship exists between eccentricity and spectacle refraction change:

$$y = 0.21x$$

where y = change in eccentricity and x = refractive change

Put simply, the above formula indicates that for every 1.00 D of myopia reduction change required, the eccentricity of the cornea will be reduced by approximately 0.21, or alternatively, for every 1.00 D of myopia reduction required, the cornea must have an eccentricity of 0.21. The limitations of the relationship are dependent on the accuracy of the e values generated by the corneal topographical device and other factors to be discussed later. Therefore, if a patient undergoing assessment for orthokeratology has a refractive error of 6.00 D, but a corneal eccentricity of 0.50, then the maximum reduction in myopia possible, assuming the cornea will be spherical ($e = 0$) at the completion of the procedure, will be approximately 2.50 D. Excluding this patient from treatment is the only option available to the practitioner. Also, since previous studies (Guillon *et al.*,

(1986) have shown the average corneal eccentricity to be approximately 0.50 then, in the majority of cases, the reduction of myopia with orthokeratology will be limited to approximately 2.50 D unless the individual corneal eccentricity is higher.

However, the initial assessment may not be so obvious in other cases, particularly since it is possible with the OK series to induce oblate corneal shapes without the accompanying distortions and astigmatism found in the earlier controlled studies. Soni and Horner (1993) showed that the refractive response increases with the duration of lens wear, and the previous section dealt with limiting the variables associated with incorrect fitting. Therefore, if the fit and the trial wear time are maximized, the corneal response to the lens will be optimized and the results used as a gauge to predict probable success or failure.

The protocol would therefore be:

- Optimal lens fit and the correct relationship between refractive error and corneal eccentricity.
- Adequate wearing time in which to elicit a worthwhile response *(6 hours)*.
- Accurate corneal topographical data (pre- and post-wear).
- Accurate refraction and unaided visual acuity (pre- and post-wear).

Rowsey *et al.* (1988), as part of the Prospective Evaluation of Radial Keratotomy study, found that for each 1.00 D refractive change the central cornea flattens by 0.166 mm radius of curvature. Retrospective analysis of 56 randomly chosen eyes showed the following results for orthokeratology using the EyeSys 2000 software (*Figure 19.15b*):

$$y = 0.188x + 0.001 \quad (r^2 = 0.938)$$

where y = change in apical radius and x = change in apical corneal power.

Therefore, a 3.00 D myope with an r_o of 7.50 mm would require a change of approximately 0.564 mm flattening of r_o in order to attain emmetropia, i.e. to an r_o of 8.06 mm. Thus there are now two factors that can be used as a predictor:

- For every 1.00 D of myopia reduction there must be an e value of 0.21.
- For every 1.00 D myopia reduction the apical corneal radius will flatten by 0.188 mm.

Therefore, by assessing the pre-and post-wear changes in the r_o and e values, the practitioner will be able to predict with a fair degree of accuracy whether the final outcome of the procedure will result in the desired degree of myopia reduction. Also, if the results of the trial wear period indicate that the cornea will become spherical before the total amount of myopia is reduced, then it is highly likely that either the patient will be undercorrected at the conclusion of the treatment or the cornea will need to be made oblate in order for a successful outcome to be reached.

The predictability of success for oblate corneas is poor, the results appearing to be dependent on the degree of central flattening compared to the peripheral changes, i.e. the degree of 'oblateness' required. Since there is currently no means of measuring the eccentricity of oblate surfaces except over small areas (3.00 mm TMS and approximately 4.50 mm EyeSys 2000), the relationship between changes of r_o and e in oblate surfaces is unknown. Also, the surfaces formed by orthokeratology past the spherical phase ($e < 0$) are best described as 'bi-aspheric', as they do not produce the same topographical plots as front surface oblate aspheric contact lenses.

The central cornea can be flattened further by the use of deep TR designs (5.00 D and greater), but the topography plots invariably show an area of central flattening less than the pupil zone, with the resultant induced haloes and flare. The *area* of central flattening is every bit as important as the *degree* of flattening; there is little to gain by increasing central flattening by 0.50 D if the quality of the ensuing unaided visual acuity is degraded.

However, it is possible to alter the cornea to an elliptical 'oblate' in some cases (Coon, 1984; *see Figures 19.2* and *19.16*). When this occurs, centration and lens movement once again become critical. Also, as stated above, the choice of TR can influence the degree of central distortion and corneal staining as the central cornea is flatter than the peripheral cornea, and the depth and width of the TR partly determine the rate of tear exchange. Once the eccentricity reaches zero, the cornea is effectively spherical and the sag calculations still apply. The lack of a clinically available technique to accurately measure oblate surfaces means that the fitting of future lenses in the treatment series is once again limited to the clinician's ability to interpret fluorescein patterns. Clinical experience indicates that oblate corneas do not retain the effect for as long as spherical corneas, and the proportion of retainer wear to non-wear is greater. Oblate elliptical back surface contact lenses are used in near-centre progressive aspheric designs for the correction of presbyopia (Benjamin and Rosenblum, 1992). Future developments in this area may also lead to effective retainer designs for use with the 'oblate' corneal surfaces produced by orthokeratology. However, it simply may not be possible to design an oblate lens that fits an oblate eye and still retain adequate lens movement and tear exchange. Mildly oblate induced corneal shapes will retain the Ortho-k effect without distorting vision, so at this stage it is reasonable to say that the upper limit in reducing myopia past the stage where corneal sphericalisation is reached is approximately 0.50 D (*see below*).

It must be stressed that this is a purely hypothetical approach, and in no way predicts the exact level of myopia reduction, but should be used as a guide in conjunction with clinical experience when deciding whether to proceed with a course of treatment. In general, low asphericity corneas (< 0.30) associated with moderate levels of myopia (> 2.00 D) are not good candidates for orthokeratology, whereas highly aspheric corneas (0.80) associated with up to 4.00 D myopia have a good chance of success. Orthokeratol-

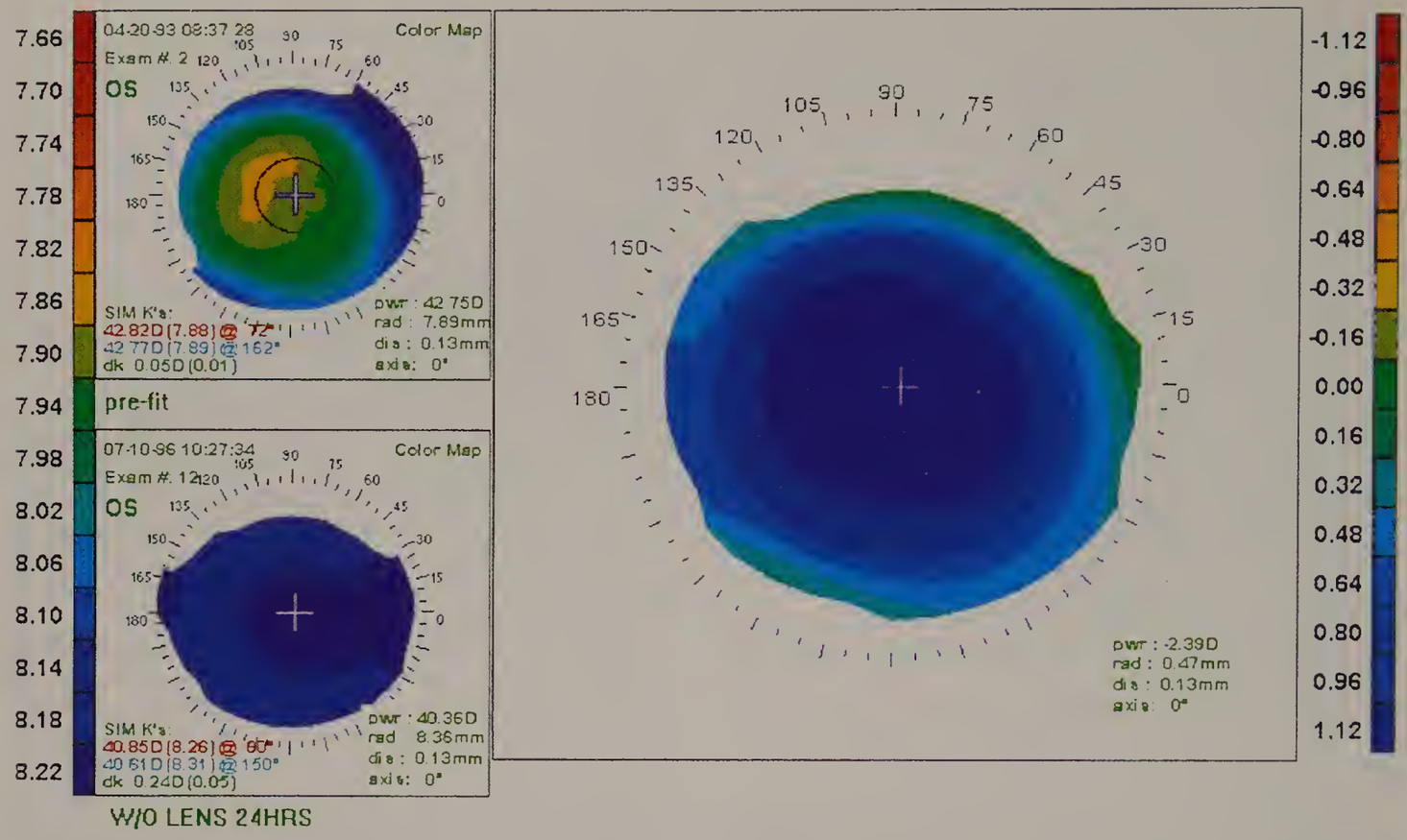


Figure 19.16 Subtractive plot of a long-term orthokeratology patient (3 years). The initial corneal shape is a prolate (Rx - 2.50 D sph.) and the final corneal shape following lens removal of 24 hours is mildly oblate (Rx plano). Note the centration of the flattening effect of the lens. The patient wears the lens every second night

ogy is easier to control, and the results more stable, if the final corneal shape is near spherical. Oblate corneas are quite successful if the level of induced change is small, brought about gradually and does not induce unwanted central corneal distortion.

The response of any given cornea is dependent on the intrinsic elasticity and stress/strain relationships of that cornea. The r_o and *e* combinations are responses to the forces induced by the lenses, and are, by their inherent complexity, totally unpredictable. Orthokeratology is as yet still unpredictable, but the process itself is self-selective in that only patients with low to moderate degrees of myopia are advised by their practitioner to begin treatment. As our understanding of the complex nature of corneal rheology (*see below*) improves, the ability to react more accurately to stress-induced changes in the cornea caused by contact lenses should lead to advances in lens design that make the procedure more controllable.

Interpretation of post-wear topography plots as a diagnostic tool

Trial wear periods (usually 6 hours) indicate that corneas typically respond in one of the following ways:

- Dramatic change in corneal shape and refraction (less myopia) (*Figure 19.17*).
- Little or no change in corneal shape and refraction (*Figure 19.18*).
- Slow but promising changes (0.75 to 1.25 D).

The second response is rare. The most common result is a slow but promising reduction in myopia of at least 0.75–1.25 D. Trial wear periods also have one other vital use: to verify that the initial choice of trial lens was correct, and if not, an indication of how to rectify the fit. An ideal response yields a topography map that shows an area of central flattening without peripheral steepening. Incorrectly fitting trial lenses will produce the following topography plots:

- Flat fit; superior flattening with an inferior crescent of corneal steepening (*Figures 19.3a,b*).
- Steep fit: para-central flattening with central steeper 'islands' and peripheral distortion zones from compression effects (*Figure 19.19*).
- Combination problems: central islands with off-centre flattening and inferior crescents (*Figure 19.20*).

The inherent limits of topography data leads to target lenses that are within +/– 0.10 mm of the ideal fit. In those cases where the lens appears to fit well but causes off-centre flattening with inferior steepening, the simple solution is to use the sagittal equivalent fit in a larger diameter. The

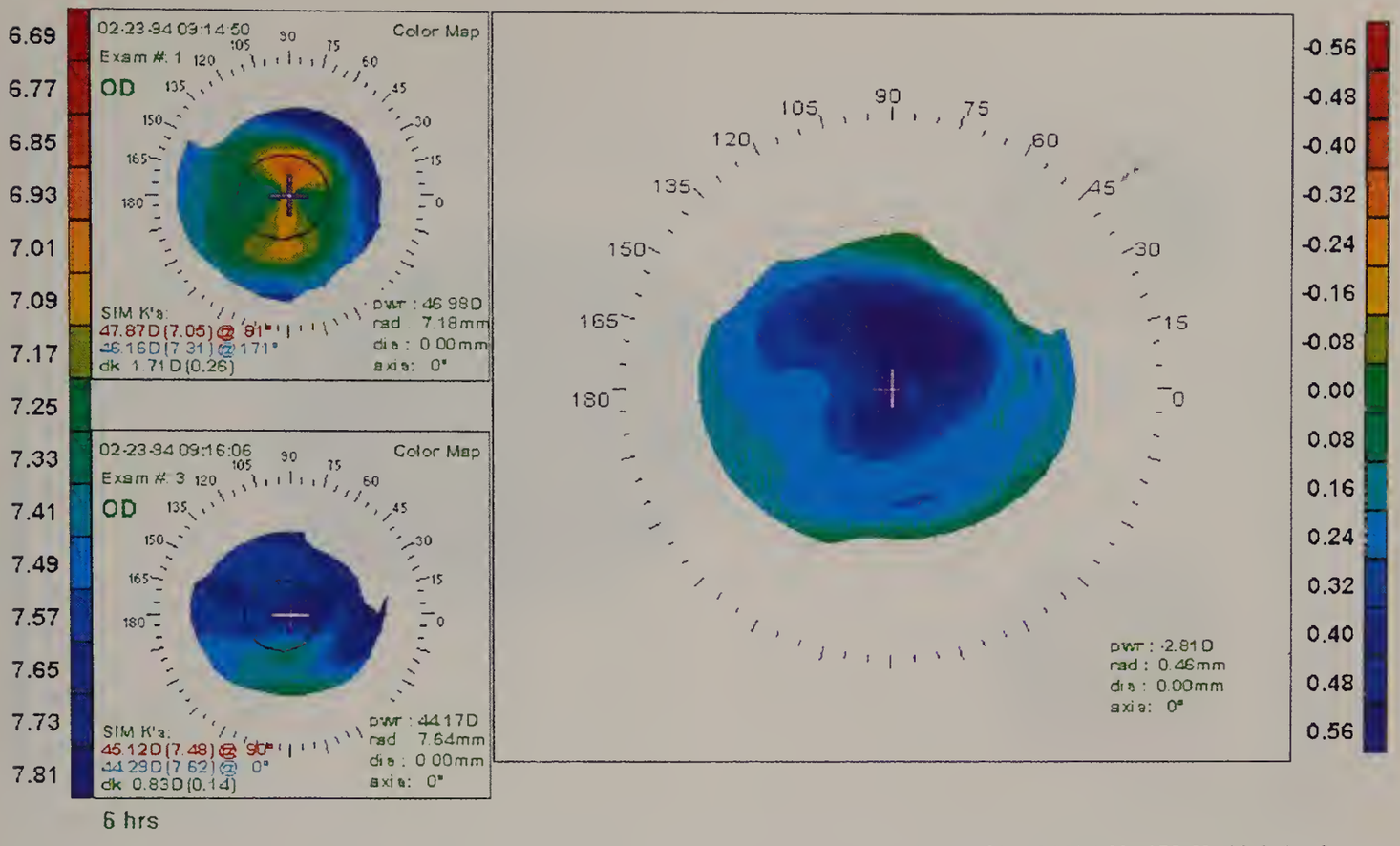


Figure 19.17 An example of a dramatic response to 6 hours of lens wear. Initial R_x: –5.50/–1.50×5; after 6 h: –2.00/–1.00×175. Unaided visual acuity: 6/12. Note the faster rate of flattening of the vertical meridian

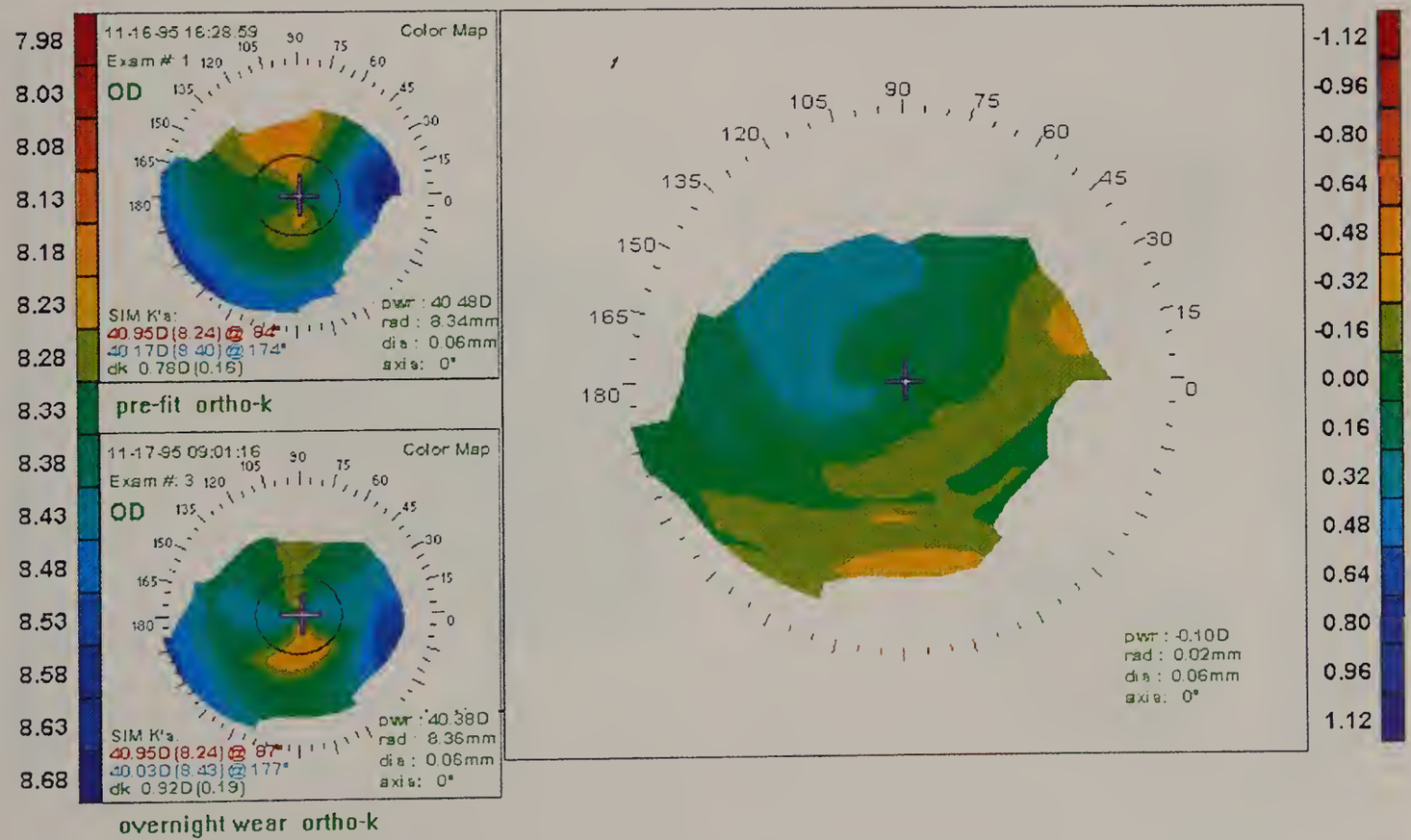


Figure 19.18 An example of a negative response to the trial wear period. There was little change in refraction despite three different trial wear periods. The patient was advised that the procedure would not be successful

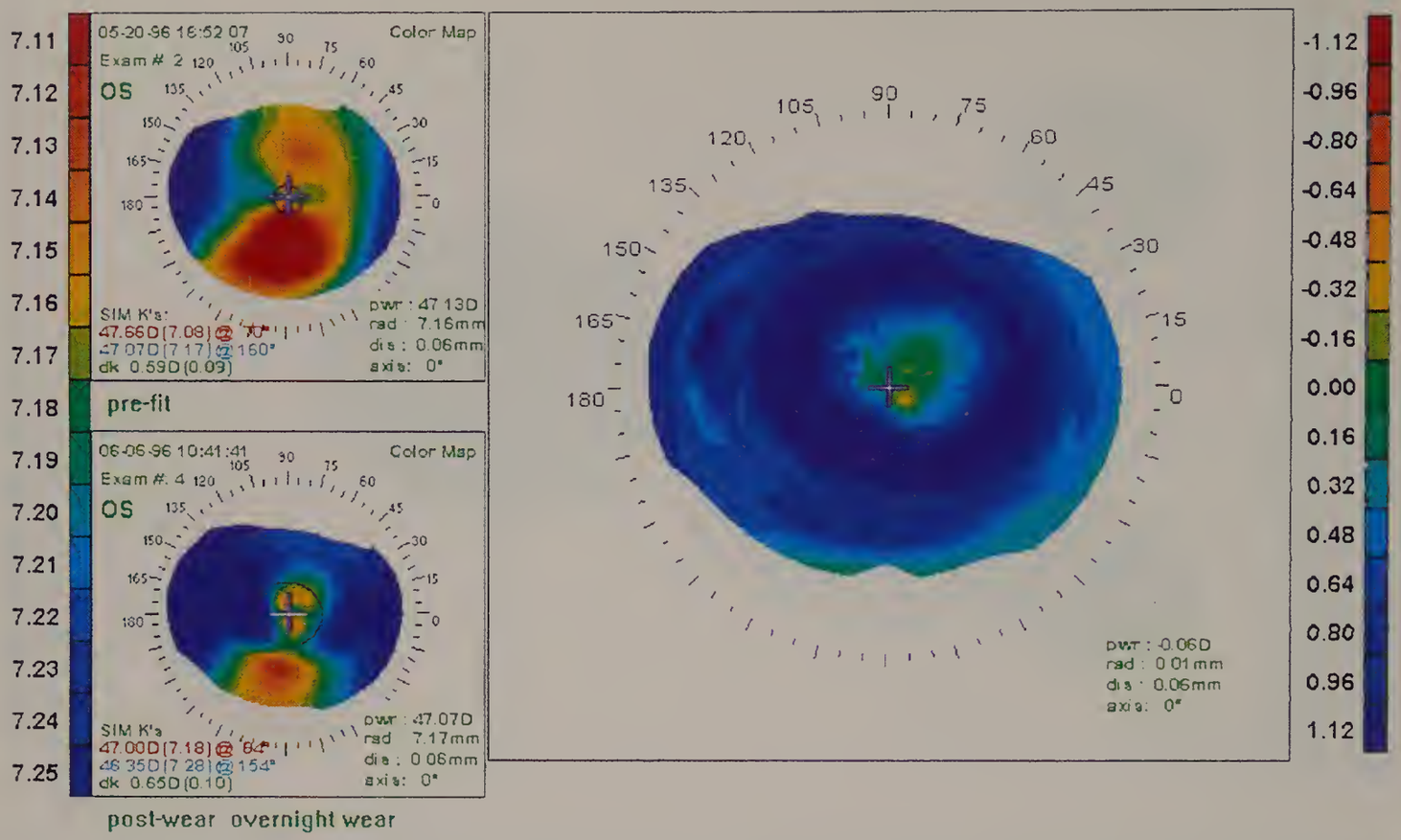


Figure 19.19 Central island of corneal steepening and paracentral flattening caused by a 704C being fitted too steeply. This problem can be resolved by performing a further trial wear session with a flatter BOZR

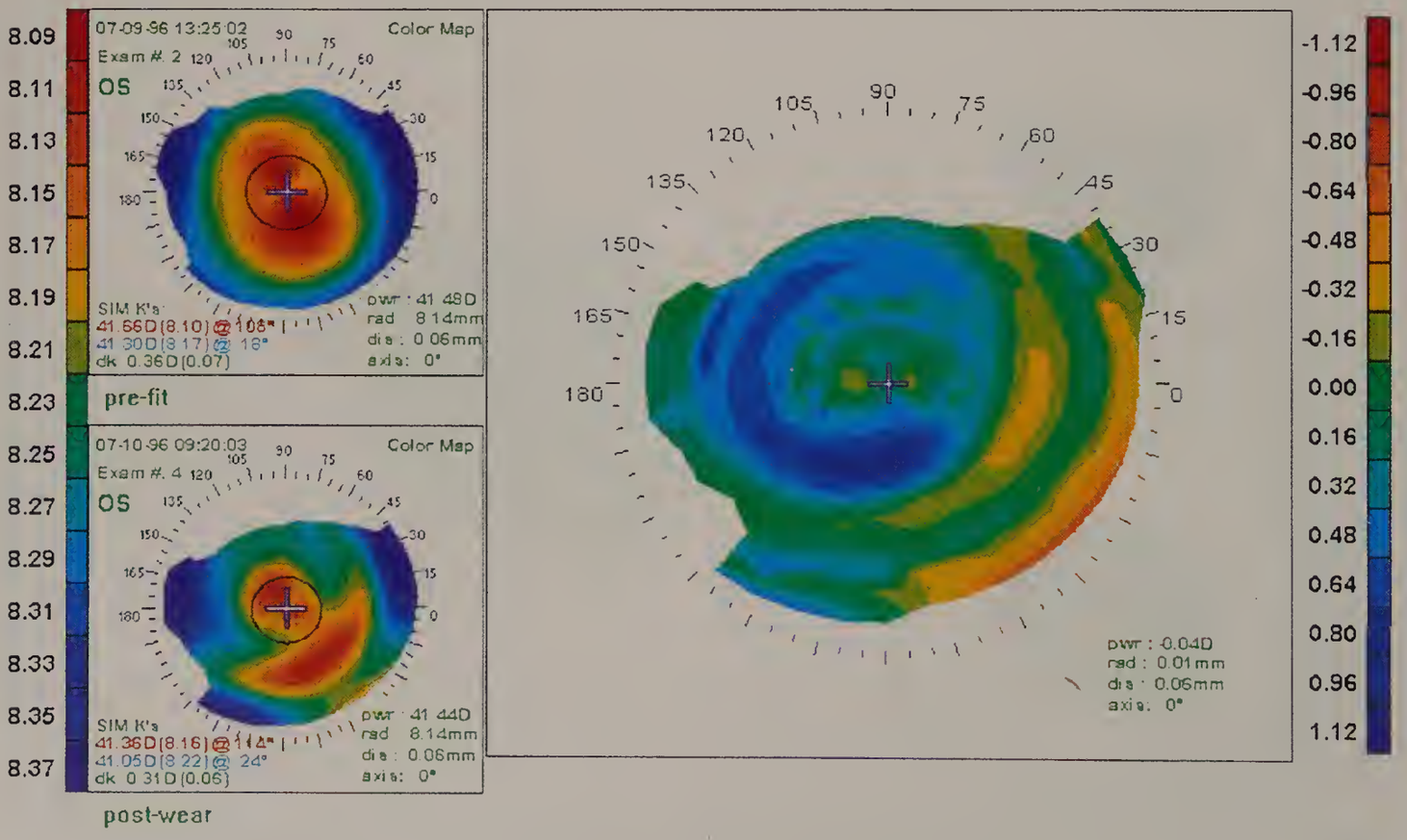


Figure 19.20 A combination of central island and inferior crescent

OK704C at a 10.6 mm diameter is the usual lens of first choice. Increasing the diameter to 11.2 mm with a corresponding change to the BOZR will usually solve centration problems. Central islands can be resolved by flattening the BOZR by 0.05 mm. Combination problems where central islands are present in conjunction with inferior crescents are resolved by increasing the diameter to 11.2 mm and flattening the BOZR by 0.05 mm more than that indicated by the sagittal equivalent. A retrospective analysis of 50 orthokeratology trial wear period responses gave the following results:

- Initial trial lens correct 42%.
- Initial lens too steep 46%.
- Initial lens too flat 10%.
- Nil response 2%.

The reason for the high percentage of tight initial fits is probably inherent practitioner conservatism in being reticent to induce central staining by fitting too flat. However, tight lenses also cause mild central punctate epithelial erosions, probably due to poor tear exchange or compression effects that cause the small steep central islands. The above example clearly shows the value in undertaking proper trial wear periods. The course of treatment is longer and the cost in replacing incorrect lenses higher if inadequate pre-fitting and post-wear information is obtained.

Night therapy

The advent of high Dk materials has made the overnight wear of RGP lenses a reality, and has led to the use of retainer lenses on this basis. Grant (1993) advocated the use of overnight wear as therapy for low myopes (up to 1.50 D) and children. The advantages, according to Grant are:

- Little or no adaptation required.
- Less risk of lens loss.
- Greater effectiveness due to lid pressure and the massaging effects of rapid eye movement (REM) sleep.
- Less problems with dust, wind and photophobia.

Patients put on a schedule of overnight wear with lens removal in the morning will usually take from 2 to 3 weeks to report clear vision for the majority of waking hours, depending on the initial degree of myopia. O'Callaghan (1995) reported on the successful use of the OK602 for night therapy for up to 2.00 D myopia. Herron (Henry, 1995, personal communication) advocated the use of overnight wear as the trial wear period in order to properly assess the corneal response to the lens if night therapy was the preferred treatment mode. Clinical experience has shown that if corneal eccentricity and refractive error correlation are used for patient selection, in conjunction with the OK704C (fenestrated), and time (creep and relaxation effects; *see* Corneal rheology *below*) used as the main impetus for corneal change, then up to 3.00 D of myopia can be reduced using night therapy alone.

The patient is advised to insert the lens prior to retiring and remove it in the morning. If the lens has bound, then instructions for the correct 'freeing up' of the lens are followed and the lens left *in situ* for a further 30–60 minutes in order to reduce any distortion effects induced. Low myopes (1.50 D or less) will often report all day clear vision within one week. Higher degrees of myopia will take longer to treat, and disposable lenses can be used as an interim form of correction until the Ortho-k effect lasts all day. After-care visits are scheduled in the morning, with the lenses left in place so the fit can be assessed. The morning reviews are repeated on a weekly basis until emmetropia or mild hypermetropia is reached. The following after-care visits are then performed in the late afternoon in order to monitor the regression effects. It is important for the sake of consistency that the post-wear assessments are performed at the same interval of time following lens removal (usually 8–10 hours).

Once the unaided vision and refraction remain stable, then the patient is advised to continue wearing the lenses on a nightly basis, but to leave them out one night per week and note the duration and quality of the uncorrected vision on the second day without lenses. After-care visits are then scheduled for the morning following lens removal and the afternoon of the next day in order to once again determine the rate of regression. The patient remains on a nightly wear schedule with one night per week without lenses until review shows that the effect of the lens is lasting long enough to give good clear vision for the second day.

Studies by Stone (1976) and Grosvenor *et al.* (1991) showed a positive retardation effect on the progression of myopia in children wearing rigid contact lenses. Also, Roth (1980) reported the reduction of up to 8.00 D of myopia in highly myopic children under the age of ten using orthokeratology. Could the progression of myopia also be retarded by the use of orthokeratology, particularly with the night therapy technique?

Unfortunately the technique lacks supportive studies to date, but anecdotal reports indicate that the treatment has merit in that it can allow children to engage in normal school and sports activities without depending on visual aids. Night therapy should therefore be considered as an experimental technique until the results of controlled research in the area are available.

Corneal rheology

Rheology is that branch of science that deals with the flow and deformation of matter as a result of stress. The alteration in the shape of the material is termed strain. When a contact lens is placed on a cornea it induces stresses that alter the shape of the cornea. The alteration in shape is the strain response of the cornea to the stress applied by the lens. Within the bounds of physiological limits, the stress/strain relationship of the cornea is linear (Nyquist, 1968). This means that for any given stress within the physiological range, the strain response (deformation) of the

cornea follows a predictable path. Corneal topographical instruments can therefore be said to measure the strain response, but to date there is no clinical method of measuring the stress induced by the fitting of contact lenses.

The cornea is a viscoelastic solid and as such has a strain response that is both time-dependent on the stress applied (i.e. the longer the stress is applied, the greater the degree of deformation) and quantity-dependent (i.e. the strain response varies according to the level of induced stress). A sudden increase in stress causes an initial increase in strain, followed by a further time-dependent increase in strain and is a phenomenon known as 'creep' (Nash *et al.*, 1982). This describes the rapid changes in corneal shape seen in the first hours and days of lens wear. Orthokeratology, during the active phase, depends on this relationship in order to bring about a change in corneal shape. The stress/strain relationship of the cornea governs the degree and rate of creep, which in turn may be responsible for the variations in response of individuals with respect to the degree of myopia reduction as well as the time interval between lens changes.

Conversely, if strain is suddenly increased there is a corresponding increase in stress, followed by a time-dependent decrease in stress termed 'relaxation'. The intrinsic elastic properties of the cornea react to the shape changes induced by the contact lens and, after lens removal, return the cornea to nearly its original shape. Over time this effect is reduced, and longer periods of altered corneal shape occur (*Figure 19.21*). The reduction of retainer lens wear and the stability of the final corneal shape is a function of relaxation. The time for creep or relaxation in biological tissues can be extremely long (Sjontoft and Edmund, 1987), such as the reduction in corneal distortion following long-term PMMA wear and the time taken for the treatment groups in the orthokeratology studies of Polse *et al.* (1983a,b) and Coon (1984) to return to baseline status. Horner *et al.* (1992) found that the recovery rate of subjects was not related to the degree of myopia reduction (corneal strain), indicating that creep is an individual response.

However, relaxation must be taken into account during the first few months of orthokeratology, especially when changing the patient over to the next set of lenses. Soni and Horner (1993) showed that the corneal recovery rate is dependent, among other factors, on the amount of time the lenses have been worn. In the majority of cases, the first set of lenses causes a rapid alteration in corneal shape. The parameters of the second lens are determined by the shape changes induced in the cornea by the first, the third by the

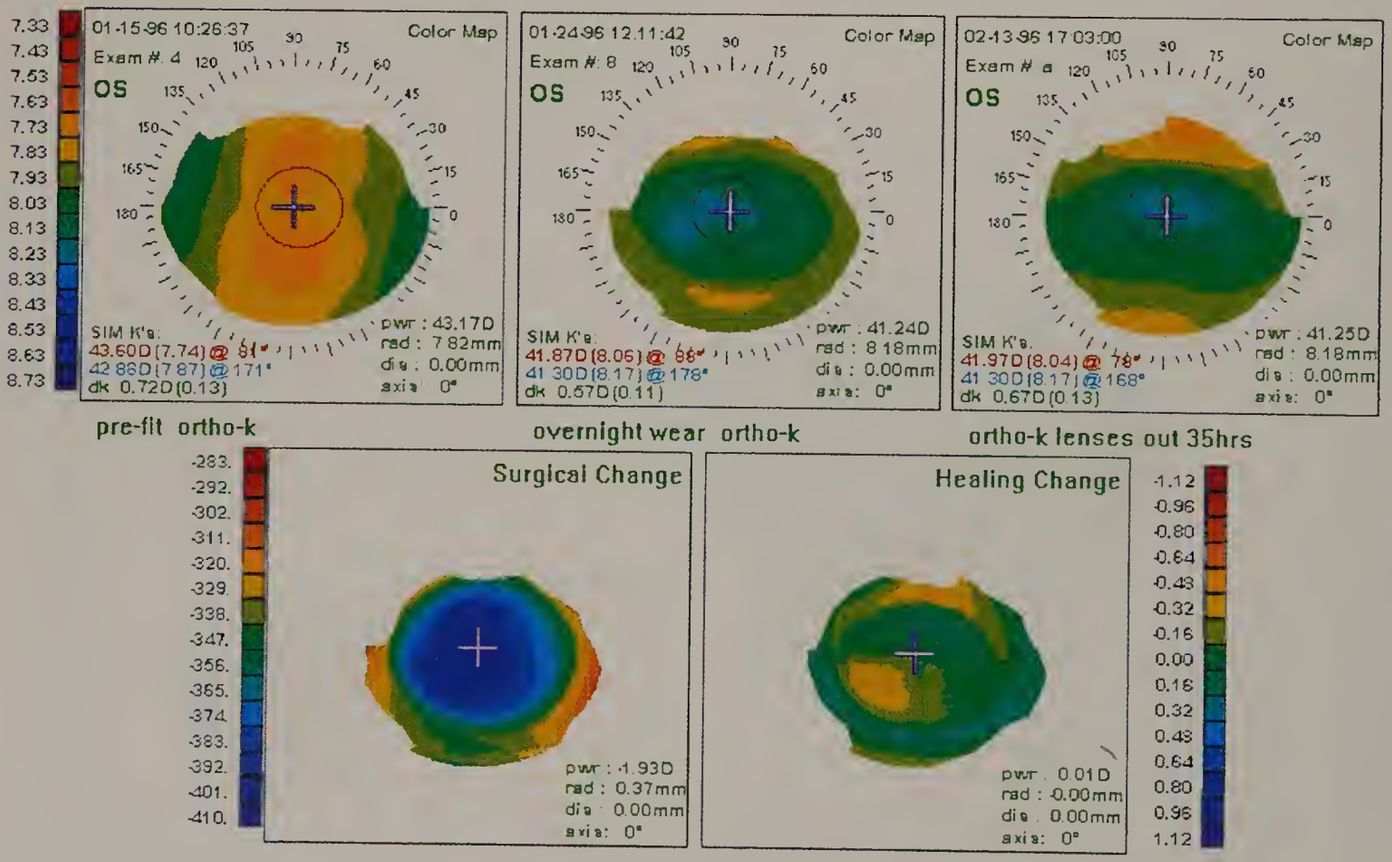


Figure 19.21 Sequential topography plots at the start of treatment (top left) following overnight wear (top centre) and 35 hours following lens removal (top right). The subtractive plots show the refractive change following the first night of overnight wear (lower left) and the degree of regression (lower right). Initial refraction –1.50 D sph.; Rx after 35 h of lens removal + 0.25 D sph. and 6/5 acuity

second and so on. If the cornea responds rapidly to the first pair, then the second will fit when the first are removed, *but not the next morning as the cornea will have relaxed back to near original shape by then.* The second pair will then be too flat and will almost certainly cause off-centre flattening.

When changing patients over to the next set of lenses, a few hours' wear of the preceding pair of lenses in the morning prior to the insertion of the next set will help maintain a central area of corneal flattening. As OK lenses become tighter due to the cornea changing shape, the level of discomfort increases, giving the patient a good indication of when to change over to the next pair of lenses.

However, the rapid tightening of OK lenses is usually due to the initial lens being fitted too steeply. The two groups of patients discussed above (p. 667) compared the average number of lenses required to reduce myopia by 2.25 D was 3.6 for Group 1 and 2.21 for Group 2. The use of the tangential edge design in combination with the time-dependent factors involved in corneal creep and relaxation has reduced the number of lenses required yet again. Retrospective analysis of 50 consecutive patients undergoing orthokeratology using the OK704C design concept and utilizing time as an indicator of corneal change factors shows the following:

- Average number of lenses to reduce myopia by 2.25 D: 1.10
- Number of patients requiring more than one set of lenses: 8 (16%)
- Reasons for the second set;
  incorrect choice of initial lens: 6 (12%);
  further reduction in myopia required: 2(4%)
- Average number of trial lens fittings: 1.8 (min.1; max 5)

Therefore, simply allowing enough time for the creep and relaxation effects to maximize the corneal response in conjunction with an ideal fitting lens will reduce the number of lenses required to achieve success. However, the savings in reduced lens costs are more than nullified by the extra consultation time needed to achieve the correct fit. In a further 11 patients who had reached a plateau of refractive change and corneal flattening, a second lens was *deliberately* fitted 0.10 mm flatter than the initial lens. The mean further reduction in myopia for the group was 0.21 +/- 0.11 D, and was invariably associated in induced corneal distortion. As stated previously, it is possible in some cases to induce an oblate shape to the cornea, but the extra gain in myopia reduction is limited.

The predictability of orthokeratology, or even the development of a predictive test, is dependent on understanding the complex interactions of the corneal stress/strain relationship and creep and relaxation.The stress induced by the lens is currently being investigated by Pye (David, 1994, personal communication) using the finite element method (FEM). This is an engineering technique used in structural analysis and approximates the effects of applied stress upon a continuous body by dividing the body into spatial

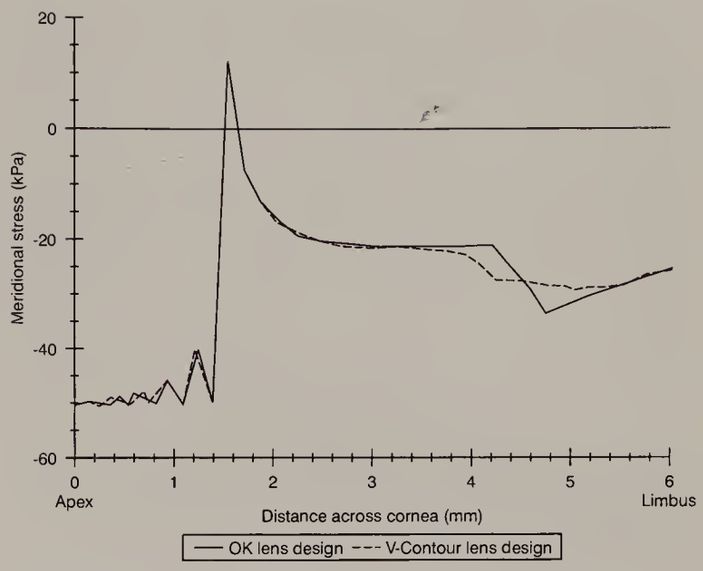


Figure 19.22 Linear static finite element method comparison between the stress effects induced on the cornea by a contour lens fitted on *K* and the calculated best fit OK603. Note that there is a negligible difference between the two, indicating that the effects caused by the OK lens are time-dependent

'elements' and calculating the displacement field within each element by utilizing a high speed computer. The complexity of the system is determined by the nature of the applied stress, the shape of the structure and the number of elements. The accuracy is dependent on the geometry used to describe the elements.

There are two main types of FEM: linear static analysis and dynamic analysis. Linear static analysis was used to compare the stress induced on the cornea by both a standard contour lens and an OK603 lens following a blink (*Figure 19.22*). The difference between the stress effects of the two different lens designs is negligible in the central area, indicating that the degree of central pressure exerted on the cornea by an OK lens is similar to that of a normal contour lens. The main difference between the two is in the degree of relative negative pressure in the mid-peripheral and edge areas of the lens.

A more accurate clinical picture would require a dynamic analysis. This is extremely complex as the functions are non-linear, but in the future may be able to help explain the intricate network of inter-relationships involved in orthokeratology.

Anatomical considerations

The unique viscoelastic nature of the cornea is due to the anatomy of the tissue. The induced stress effects of orthokeratology should therefore be reflected by anatomical changes in the cornea itself. O'Leary (1996) has taken a theoretical approach to the issue and his findings are summarized here.

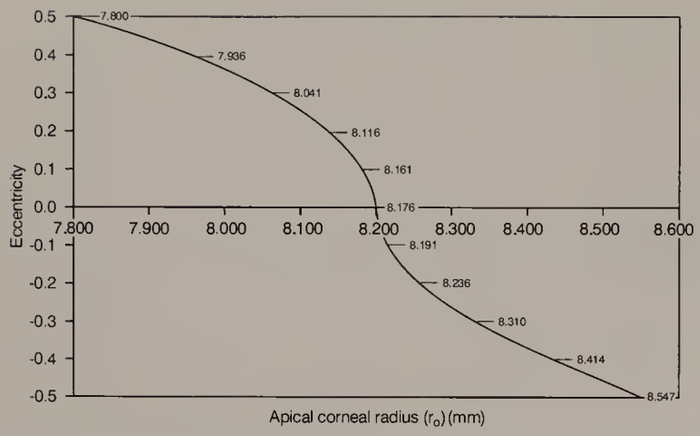


Figure 19.23a Mathematical relationship between eccentricity and apical corneal radius assuming a constant chord and surface length. Note that as corneal eccentricity approaches zero, the rate of change of apical corneal radius changes

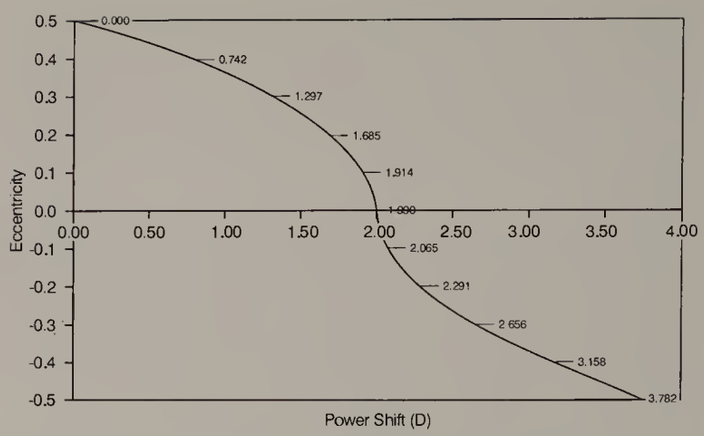


Figure 19.23b The same relationship as *Figure 19.23a* converted to refractive change. Once again, as corneal eccentricity approaches zero, the rate of change in refraction slows. Increasing refractive change by inducing an oblate shape requires a non-proportional change in eccentricity

Stroma

The stroma is composed mainly of collagen fibrils that are relatively inextensible. They are usually over 12 mm long and evenly spaced. An average cornea having an apical radius of 7.80 mm and an eccentricity of 0.50 will have a collagen fibril length of 13.474 mm over a chord of 12 mm. Assuming no alteration in the length of the fibril due to the forces induced by an OK lens, the same length of collagen altered to a spherical shape (e = 0) will have a radius of curvature of 8.175 mm. The same cornea would theoretically be able to be altered to reduce myopia by 2.00 D (*see* p. 679) with a corresponding change of 0.188 mm flattening of r_o for each 1.00 D refractive change. The calculated r_o would therefore be:

$$7.80\,\text{mm} + (2.00 \times 0.188) = 8.176\,\text{mm}$$

which is in close agreement to that predicted by O'Leary's model, which would also predict an eccentricity value of 0.25 for each dioptre of refractive change. The relationship between refractive change and eccentricity as measured with the EyeSys (version 2.208) mentioned previously yields 0.213 for each dioptre of change. Douthwaite (1995) compared the apical radius and eccentricity values of the same instrument to form talysurf calibrated aspheric surfaces and found that the EyeSys tends to underestimate both r_o and e. The underestimation of eccentricity in the mid-range is approximately 14%. If the value of 0.213 is corrected for this, then the calculated 'correct' e value would be 0.242.

Noack, D., (1996 personal communication) devised an iterative computer program that calculates the relationship between r_o and e assuming that the chord and the surface length of the ellipse are kept constant for a cornea of r_o 7.80 mm and an eccentricity of 0.50 from the prolate through to the oblate (*see Figure 19.23a*). The relationship is non-linear, indicating that the rate of change in apical radius slows as an eccentricity of zero is approached. *Figure 19.23b* shows the same relationship with apical radius converted to apical power change using the standard keratometer formula. Previous studies (Kerns, 1976–78; Coon, 1984; Wlodyga and Harris, 1993) all commented on the fact that the initial reduction in refractive error occurred rapidly and slowed as the cornea approached sphericalization. This is clearly reflected in Noack's curve; the initial rate of change in refraction as eccentricity falls is rapid, but slows dramatically as an eccentricity of zero is approached. The theoretical model also shows why any further gains in myopia reduction are small as the cornea changes from a prolate to an oblate shape. For example, a change in eccentricity from 0.50 to 0.20 is associated with a refractive change of approximately 1.70 D, whereas the change in eccentricity from 0.20 to zero is associated with a further reduction of approximately 0.30 D. Similarly, a further change in eccentricity from zero to 0.20 oblate results in a gain in myopia reduction of only 0.30 D. In order to achieve a reduction of 1.00 D once eccentricity is zero, the cornea would need to become oblate to the order of 0.35. This is purely a mathematical model, yet the results so closely reflect the effects seen clinically that the need for further research is obvious.

Corneal thickness

Comparisons of the shape differences between the corneal ellipse and sphere above with the chord fixed yields the following:

- The apex of the sphere would be displaced backwards by 22 microns.
- The sphere 'bulges out' by about 20 microns in the periphery.

This alteration in corneal shape would be sufficient to account for the refractive changes observed. However, a

change in the shape of the cornea by the above amounts could also be explained by a decrease in central corneal thickness of 22 microns and an increase in peripheral thickness of a similar amount. The retention of the effect of orthokeratology can also be accounted for by assuming a central corneal epithelial hypoplasia of 20 microns and a peripheral hyperplasia of the same order. Coon (1984) found that the orthokeratology group showed a statistically significant decrease in central corneal thickness of approximately 20 microns when compared to baseline levels, whereas the control group showed an increase in central corneal thickness. Both groups showed an increase in peripheral corneal thickness compared to baseline measurements. Further research in order to define whether the changes are due to alteration in shape or thickness is required.

Stromal remodelling: glycoaminoglycosides (GAGS)

Short and medium changes to stromal stresses may induce reorganization of collagen spacing but not length, but the keratocytes may induce changes in the GAGS distribution sufficient to cause some form of 'moulding'. O'Leary concluded that changes to the physical dimensions of the stroma induced by orthokeratology seem too small to induce long-term changes in the properties of the collagen fibrils and that the induced changes may be due to either epithelial remodelling or pressure-induced corneal moulding due to changes in GAGS distribution. The corneal shape changes induced by orthokeratology may therefore be based on the interactions of the corneal viscoelastic response and the predetermined limits set by the anatomical structure of the cornea. O'Leary's theoretical approach, which has been partly confirmed by two separate studies, therefore begs the following question: If the shape of the cornea is initially determined by anatomical factors, rheology governs the time dependent creep and relaxation effects that are induced by alterations to the stresses applied to the cornea by the lens, and the limit of those effects is once again determined by underlying anatomical factors, then are there inherent predictable constraints placed on the efficacy of the procedure? Once the interactions of these factors are understood, then it may be said that orthokeratology is predictable.

Clinical experience with accelerated orthokeratology

The development of a predictable and systematic fitting philosophy for accelerated orthokeratology has followed an evolutionary path, driven mainly by attempts to overcome the shortcomings of the traditional fitting techniques and the limitations of the lens design. The following information is the result of four years of clinical research on orthokeratology using reverse geometry lenses.

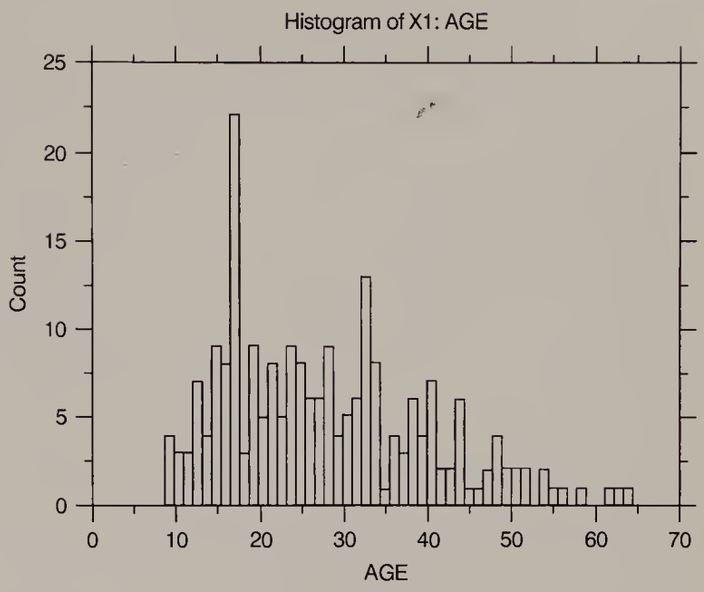


Figure 19.24 Age distribution of 220 patients undergoing orthokeratology. The mean age is 27.49 years

Patient data

A total of 583 patients were informed of the possibility of orthokeratology as an alternative to either spectacles or contact lenses. Of this group, 112 patients were not interested in proceeding further due mainly to either an unwillingness to wear contact lenses or the cost involved. A further 89 patients were advised not to proceed further following a trial wear period for the following reasons:

- Predictive factors (prescription and corneal shape) did not correlate: 63
- Poor response to the trial wear (little or no change in Rx): 13
- Adverse corneal response to trial wear: 9
- Previously undiagnosed keratoconus: 4

Fourteen patients who exhibited a positive result following a trial wear period decided not to proceed further due to cost (4) or discomfort with the lenses in place (10). A total of 368 patients proceeded on to a course of treatment. The distribution of the sexes was even (males 43%; females 57%). The age distribution (*Figure 19.24*) showed a mean of 27.49 s.d. +/– 12.11 years (min. 8; max. 64).

The distribution of corneal shape (eccentricity) for 220 randomly selected patients is shown in *Figure 19.25*. The mean eccentricity was 0.48 s.d.+/– 0.096. Of the 368 patients, 25 were fitted according to the manufacturer's fitting guide (0.30 mm flatter than K_f.), a further 97 with the sag philosophy and a range of various OK designs, and 244 with sag philosophy and the tangential peripheral curve design on a Contex OK704. There was a total of 46 failures in this group due to the following factors:

- Unacceptable unaided VA due to initial myopia being too high: 29.

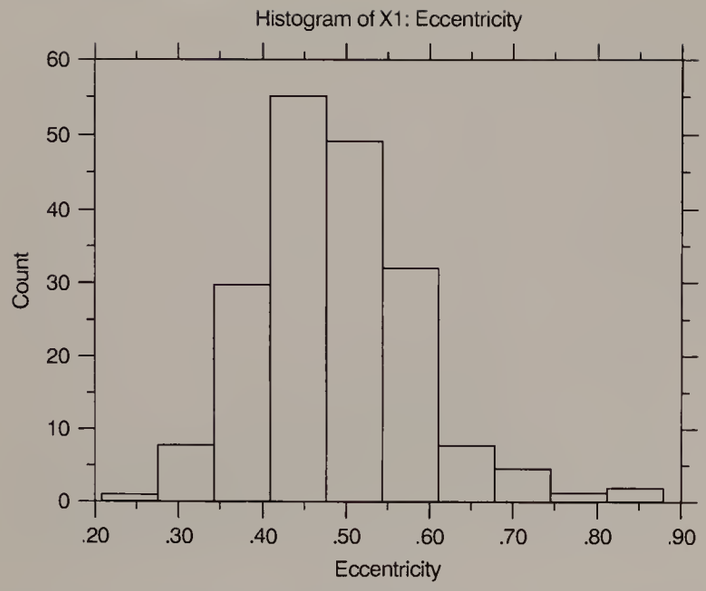


Figure 19.25 Distribution of corneal eccentricity in 220 randomly chosen patients prior to lens fitting. The mean value of 0.48+/- 0.09 is consistent with previous studies

- Chronic lens binding and associated corneal staining: 11
- Successful patients who lost interest: 2
- Could not adapt to lenses: 4

A further 15 patients were lost to follow-up. Of the 11 cases of unacceptable corneal staining, four presented with deep confluent staining, four with recurrent and consistent diffuse central staining and three with adverse corneal responses to chronic lens binding. There have been no cases of loss of best corrected vision, and no cases of corneal scarring. One patient presented with an acute red eye reaction following overnight wear.

Due to the evolutionary nature of the fitting philosophy and predictive tests, only the final 244 patients will be used for statistical analysis of the effectiveness of the procedure for the reduction of myopia, as they were only advised to proceed with the course of treatment if the corneal shape and refractive error correlation was met and the results of the trial wear period positive. Fifty-six patients were chosen at random and the choice of eye also randomized for the following statistical analyses.

1. Relationship between predicted versus actual refractive change

The relationship between refractive change and initial corneal eccentricity was given earlier and used as a predictive test to determine a patient's suitability for orthokeratology. The relationship between the predicted refractive change based on an *e* value of 0.21 for each dioptre of myopia was compared to the actual reduction in myopia achieved following a course of treatment and the result shown in *Figure 19.26*. The size of the circles

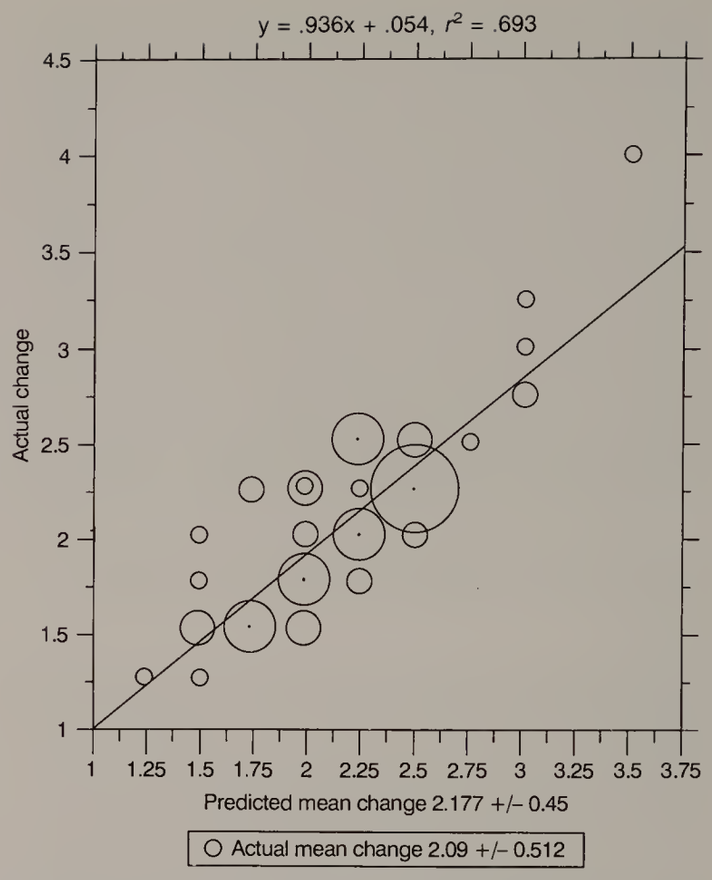


Figure 19.26 Comparison of the refractive change predicted by the initial corneal eccentricity and the actual refractive change achieved following a course of treatment. The regression line is of the form $y = 0.936x + 0.054$ ($r^2 = 0.693$; n = 56)

designates the number of data points. Regression analysis yields the following form;

$$y = 0.936x + 0.054 \quad (r^2 = 0.693)$$

The mean predicted change was 2.177 s.d.+/– 0.45 D and the actual change 2.09 s.d.+/– 0.51 D. This indicates that, even though the topographer underestimates eccentricity, when comparisons are made on the same instrument, the relationship between corneal shape and refractive change gives an accurate predictive test of the degree of myopia reduction possible with the procedure.

2. Relationship between original refraction and refractive change

Figure 19.27 shows the actual refractive change induced by orthokeratology compared to the original refraction. The size of the circles designates the number of data points. The line of equality (dashed) is the real area of interest in that it shows that for the lower degrees of myopia overcorrection is the norm, and for the higher degrees of myopia, a slight undercorrection is evident. The statement by Soni and Horner (1993) that 'most corneas change roughly the same amount' appears to be supported by the analysis, and that the procedure has a relatively high degree of accuracy for

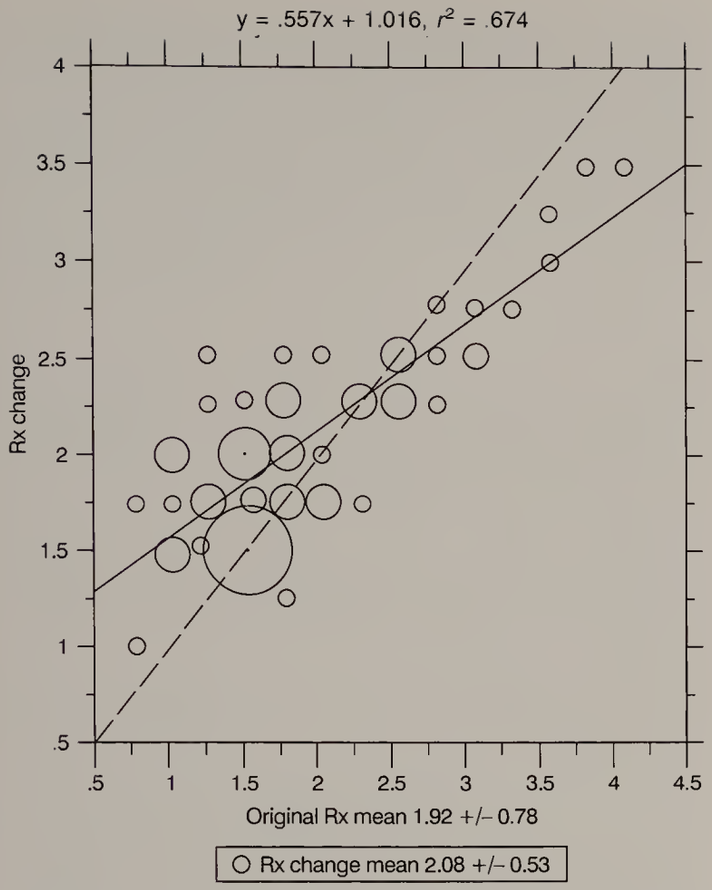


Figure 19.27 Comparison between the original refraction and the actual induced refractive change. The regression is of the form $y = 0.557x + 1.016$ ($r^2 = 0.674$; $n = 56$). The line of equality indicates that there is an overcorrection for the lower degrees of myopia and a slight undercorrection for the higher degrees. Overcorrection is controlled by the reduction in wearing time of the lens
——— regression line - - - - line of equality

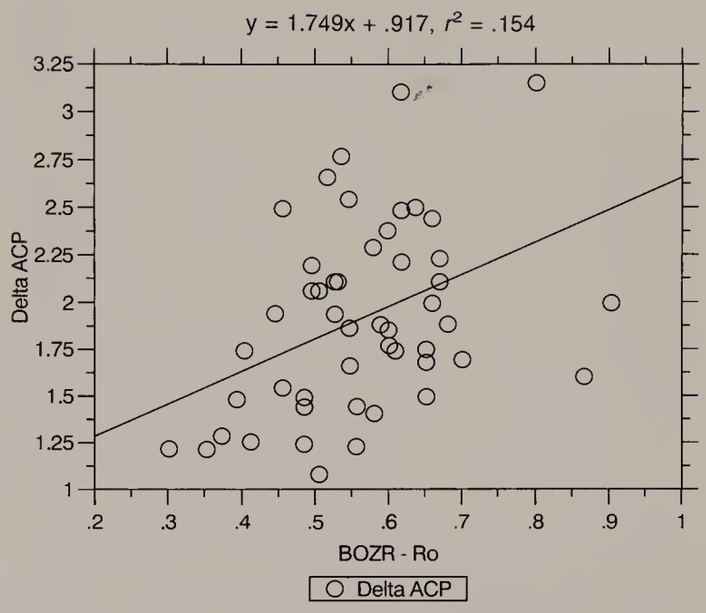


Figure 19.28 A poor correlation exists for the change in apical corneal power induced by lens wear to the fit of the lens (BOZR – r_o). The cause/effect relationship between lens fit and corneal shape change is not a function of the 'flatness' of the fit, and other, more complex interactions are involved

myopia of up to 2.50 D. Overcorrection (induced hypermetropia) is 'controlled' by a reduction in wearing time. Patients of 1.75 D myopia or less usually achieve all-day clear vision within one to two weeks and can be reduced to a wearing time of every second night within the first one to two months. The higher degrees of myopia usually take a longer period of time to reach the same standard of uncorrected vision and reduced wearing time. At the six-month stage, approximately 17% of patients wear their lenses nightly in order to maintain clear vision for the following day, 71% wear lenses every second-night and 12% wear lenses every third night or less. The ability to wear lenses on a less than every second night basis appears to be more due to a higher tolerance to blur than a slower regression rate. Data is still being collected in order to shed more light on the nature of the creep and relaxation effects in orthokeratology.

3. Relationship between lens fit and refractive change

The traditional view is that the degree of shape change induced in the cornea is in some way controlled by the fit of the lens, in such a way that in order to induce change, a proactive approach must be taken by deliberately fitting the lens flat. *Figure 19.28* shows the relationship between the degree of 'flatness' of the lens fit determined by subtracting the apical radius from the BOZR of the lens and the change induced by the lens on the apical corneal power. There is no correlation between the two. However, the consistency in the fitting philosophy is that all lenses are fitted with the same relationship to corneal shape, and it therefore assumes that the changes in corneal shape induced by the lens are far more complex than simply fitting 'flat' lenses to the cornea. There are large variations in corneal response to lenses of differing BOZR in individual cases, and these responses are used as a means of determining the ideal fit for any given individual. It would therefore appear that the corneal response is an individual one to an ideal fitting lens. The lens itself may simply be the platform that produces a tear layer profile that is responsible for the fluid dynamics which, in conjunction with lid forces, instigate the stress effect on the cornea.

4. Visual acuity

Analysis of unaided vision was performed immediately following lens removal and at intervals of eight to ten hours (end of day 1), thirty-four hours (end of day 2) and approximately sixty hours (end of day 3) for a total of 216 patients at a period of at least 3 months from the beginning of treatment. The results are as follows:

Unaided vision on lens removal	6/6 or better	97.2%
end of day 1	6/6 or better	94.0%

end of day 2	6/6 or better	89.0%
	6/9 or less	11.0%
end of day 3	6/9 or better	43.0%

Summary of results

The above results of prospective and retrospective studies indicate that orthokeratology is effective in reducing myopia and giving good clear vision for up to 36 hours in *suitably chosen patients*. Most of the failures in the orthokeratology group were those whose initial refractive error, in hindsight, precluded them from ever attaining acceptable uncorrected vision due to a lack of a suitable predictive test. The initial results show a high degree of success in the early phases. However, the long-term results over a period of years will give a much better indication of the absolute success or otherwise of orthokeratology. Further analysis of the creep and relaxation effects may give more information about the likely wearing time required to maintain clear vision for the maximum time with the minimum of lens wear.

Refractive surgery and orthokeratology compared

The two main surgical procedures currently available for the correction of myopia are radial keratotomy (RK) and photorefractive keratectomy (PRK) and there is a large volume of literature covering both. The long-term effects of RK (Waring *et al.*, 1991) include over- and under-correction as well as pathological complications such as infection, corneal perforation, vascularization and endophthalmitis (Binder, 1986).

Dazzle and flare affecting night vision, and decreased contrast sensitivity function (Tomlinson and Caroline, 1988) have also been reported. PRK has largely superseded RK as the preferred means of myopia reduction in most countries. The reports to date indicate a lower incidence of adverse response than RK (Lakkis and Brennan, 1993), but variability of results and a tendency towards regression over the long term have been reported (Brancato *et al.*, 1992; Gartry *et al.*, 1992). Both procedures have the potential to correct far higher degrees of refractive error than orthokeratology but at a greater risk to the patient and with unknown long-term effects.

The same variable responses seen in orthokeratology also occur in both surgical procedures. The 'accuracy' decreases as the level of refractive error increases and most patients will, at some time, require the use of a visual aid. Manni *et al.* (1991) found in a one-year post-surgery follow-up of PRK patients that 77% were using spectacles or contact lenses for an average of 68% of the time. The dependence of retainer lens therapy in orthokeratology should not, therefore be seen as a drawback when compared to the surgical alternatives. Orthokeratology can only be compared to PRK and RK if the higher refractive errors are excluded. High myopia is rarely corrected to emmetropia by orthokeratology; the aim is simply to improve unaided visual acuity to a functional level when the lenses are not being worn. Nevertheless for many patients this is a major advantage.

The development of the OK series of lenses has, however, made the correction of up to 3.00 D of myopia feasible, and it is on the correction of this level of myopia that the different techniques should be compared:

- Orthokeratology is reversible if unsuccessful, whereas both PRK and RK cause permanent changes in corneal structure.
- The 'treatment' time for all therapies is similar.
- Only one eye at a time is treated with RK and PRK, whereas orthokeratology is binocular, i.e. full binocular vision is retained throughout the course of treatment as both eyes are treated simultaneously.
- Visual acuity remains fully corrected during orthokeratology.
- PRK and RK cause pain following surgery, whereas adaptation to contact lenses causes mild discomfort only.
- Orthokeratology does not require adjunctive drug therapy in order to control the side-effects of the procedure.
- PRK and RK are usually performed on patients who are over 21 years of age with a stable refractive error for at least 12 months prior to surgery. Orthokeratology is not age-dependent and, indeed, one of its great advantages is in the treatment of young, active myopes.
- The cost of orthokeratology is lower to the patient.
- All successful orthokeratology patients must continue to wear retainer lenses, whereas successful PRK and RK patients may be independent of optical aids.
- The long-term effects of orthokeratology are better understood.
- Prescription changes can be induced by alterations to the retainer design or wearing schedule and do not require further surgery.
- Some myopia can be reintroduced as the patient becomes presbyopic to provide a monovision effect.
- Orthokeratology requires tolerance of RGP wear, whereas many RK and PRK patients undertake these procedures because they were proven contact lens failures.

There is insufficient data at this stage to be able to compare other faetors such as patient satisfaction, visual quality and the long-term effects on corneal integrity and function. Soni and Horner (1993) found that, compared to RK patients, orthokeratology patients consistently reported better post-treatment unaided and aided visual acuities.

The apparent lack of a correlation between unaided visual acuity and refractive error in RK has been explained by studies of corneal topography that show small islands of greater corneal flattening within the pupil area, which induce positive spherical aberration (Rowsey *et al.*, 1988; Holladay *et al.*, 1991; Moriera *et al.*, 1992). The results of work to date indicate the same factors may be responsible for the similar results seen in orthokeratology. The flattened

area over the pupil zone in orthokeratology does not appear to cause the same problems experienced in low illumination or dazzle reported by RK patients (Soni and Horner, 1993). Polse *et al.* (1983a,b), Coon (1984) and Binder *et al.* (1980) found orthokeratology to be a safe procedure with respect to corneal health and integrity even before the introduction of high Dk materials. The effects of RK and PRK will take much longer to assess.

Summary and conclusions

The introduction of the OK series of lenses has resulted in an upsurge of interest in the practical applications of orthokeratology. Results to date show a twofold greater effect over previous methods that is achieved in a much shorter time, but questions still remain as to the long-term retention rate. The development of a suitable lens for oblate corneas is another critical design factor still awaited. The results of clinical trials outlined in this chapter indicate that, if *the correct lens* is chosen and the predictive relationship between refractive change and corneal eccentricity applied, then a successful outcome with orthokeratology is possible with one set of lenses and not the series of lenses required by the traditional techniques. However, the choice as to what constitutes the 'correct lens' is still largely dependent on clinical expertise due to the lack of controlled research into the interdependence of lens design and tear layer fluid dynamics, corneal rheology and the underlying anatomical factors. The limitations of corneal topography are also a factor, especially with respect to lens fit and design. The long-term effects of the forces induced on the cornea by the procedure also need to be assessed.

The anatomical factors outlined earlier are an important step in the process of developing predictive algorithms for the procedure. It may well be that the degree of change that can be induced in the cornea is predetermined by anatomical factors, and that the design of the lens and the rheological response of the cornea simply determine the treatment time. Soni and Horner (1993) note that 'all corneas tended to change by the same amount', and clinical experience shows that a 1.50 D myope with an *e* value of 0.50 will tend towards 1.00 D hypermetropia at the cessation of treatment. The regression effect in orthokeratology is controlled by manipulation of the wearing time of the lens; fast regression requiring longer wear periods of the lens and increasing hypermetropia by reducing wearing time. The interactions of tear layer fluid dynamics, corneal rheology and anatomical factors hold the key to a full understanding of the procedure.

The true test of a procedure is the level of patient satisfaction with it. The fact that orthokeratology has been practised for 30 years with modest results seems to indicate a certain level of underlying demand for a non-surgical method of myopia reduction. Practitioners should appreciate the difficulties inherent in the fitting of the OK series of lenses as the complexities are similar to those encountered in fitting keratoconus and keratoplasty patients. The cost of trial lenses, a corneal topographical device and the extra time involved must also be taken into account when devising fee schedules.

Finally, there is the question of the validity of the keratometer compared to the corneal topography instruments currently available. It is the author's firm opinion that corneal topographical analysis is the only accurate means of assessing the effects of orthokeratology and should therefore be considered as clinically essential as the slit lamp. The OK series of lenses represents a major advance in contact lens manipulation of corneal shape. Further research is needed in orthokeratology in order to advance both the design of the lenses and the efficacy of the procedure. (For instructions to patients, *see* p. 310.)

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Chapter 20

Contact lenses in abnormal ocular conditions

Chapter 20.1 Keratoconus

E. G. Woodward

Incidence of keratoconus p. 693
Symptoms and signs p. 695
Management p. 696
Contact lens options p. 698
Fitting procedures p. 703
Patient management p. 704

Although keratoconus has been recognized as clinical entity for more than two millennia, the first monograph which adequately described the condition and fully differentiated it from other abnormalities of the cornea did not appear until 1854 (Nottingham). Nottingham was the first to appreciate that keratoconus is essentially a disease producing corneal thinning and subsequently ectasia, the initial corneal thinning rarely having been previously observed, or if observed not associated with the disease process. This is not so surprising when it is remembered that the first measurement of corneal thickness in the living eye was not carried out until 1880 by Blix. Nottingham described fully the degradation of vision produced by the irregular keratoconic cornea. The management of the condition as described by Nottingham was mainly surgical, all the techniques being designed to produce, in a controlled manner, scarring to strengthen the cornea. Cauterization, using silver nitrate and mercury, is described and the passing of a seton (a fine thread or bristle) vertically through the cornea to produce scarring, but he concluded the most simple and least dangerous technique was a straightforward puncturing of the cornea. Nottingham also mentioned using glass shells filled with gelatine to improve vision, but the first report of a powered contact lens used in connection with keratoconus was by Fick (1888).

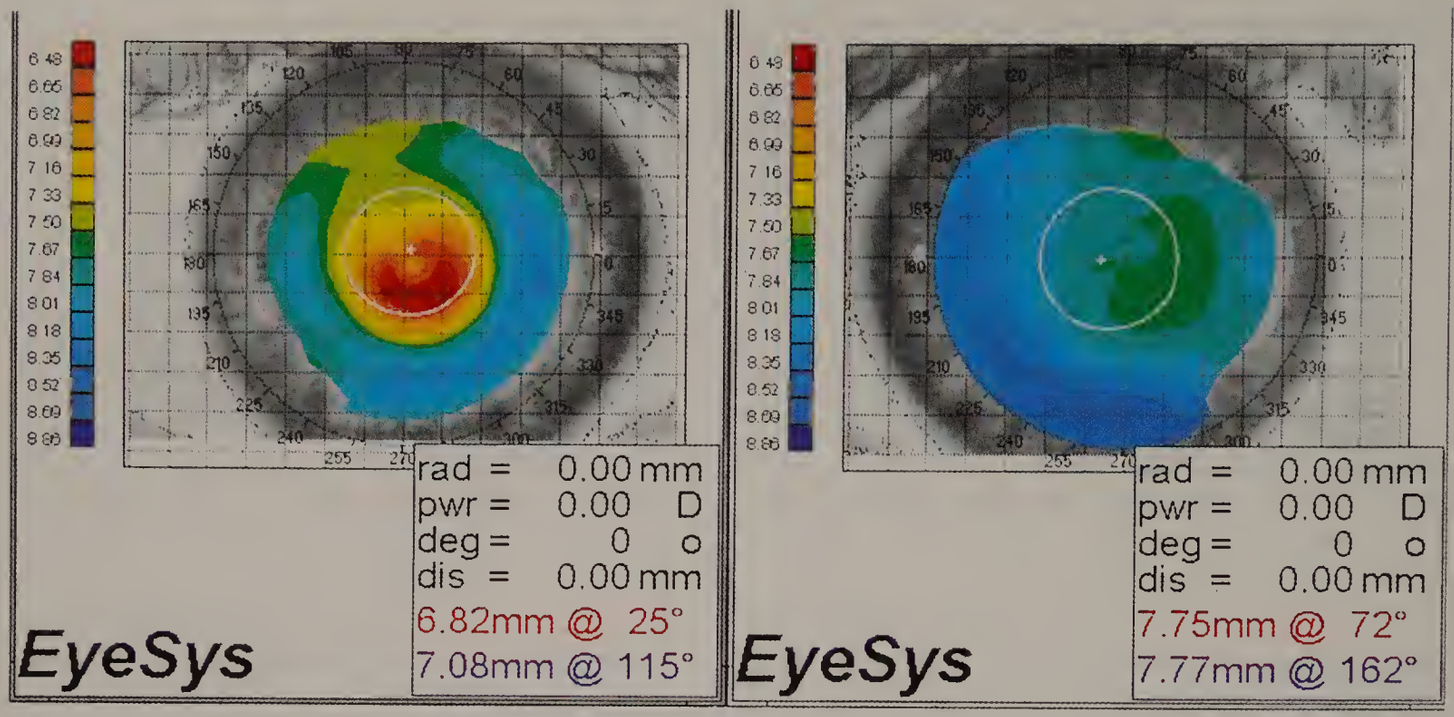
Until recent time it was possible to write that contact lenses were the management of choice in the majority of patients with keratoconus. However the advent of computerized photokeratoscopy has revealed many patients with a very mild form of the disease who have obtained a satisfactory level of vision with a spectacle correction (*Figure 20.1.1*). Where patients retain a reasonable level of visual acuity in one or both eyes, either with spectacles or unaided, there is no indication for the fitting of contact lenses. Such patients usually lack motivation and are notoriously unsuccessful with contact lenses; this is particularly the case where vision is affected in one eye but the contralateral eye retains normal vision. A high proportion of keratoconus patients have a personal or family history of atopic disease (Cox, 1984) and if they are able to achieve reasonable vision with spectacles this is a further contraindication for contact lens wear. In early keratoconus it is usually desirable to delay fitting until there is a significant difference between the best acuity achieved with spectacles and that achieved with contact lenses, thus increasing motivation.

Incidence of keratoconus

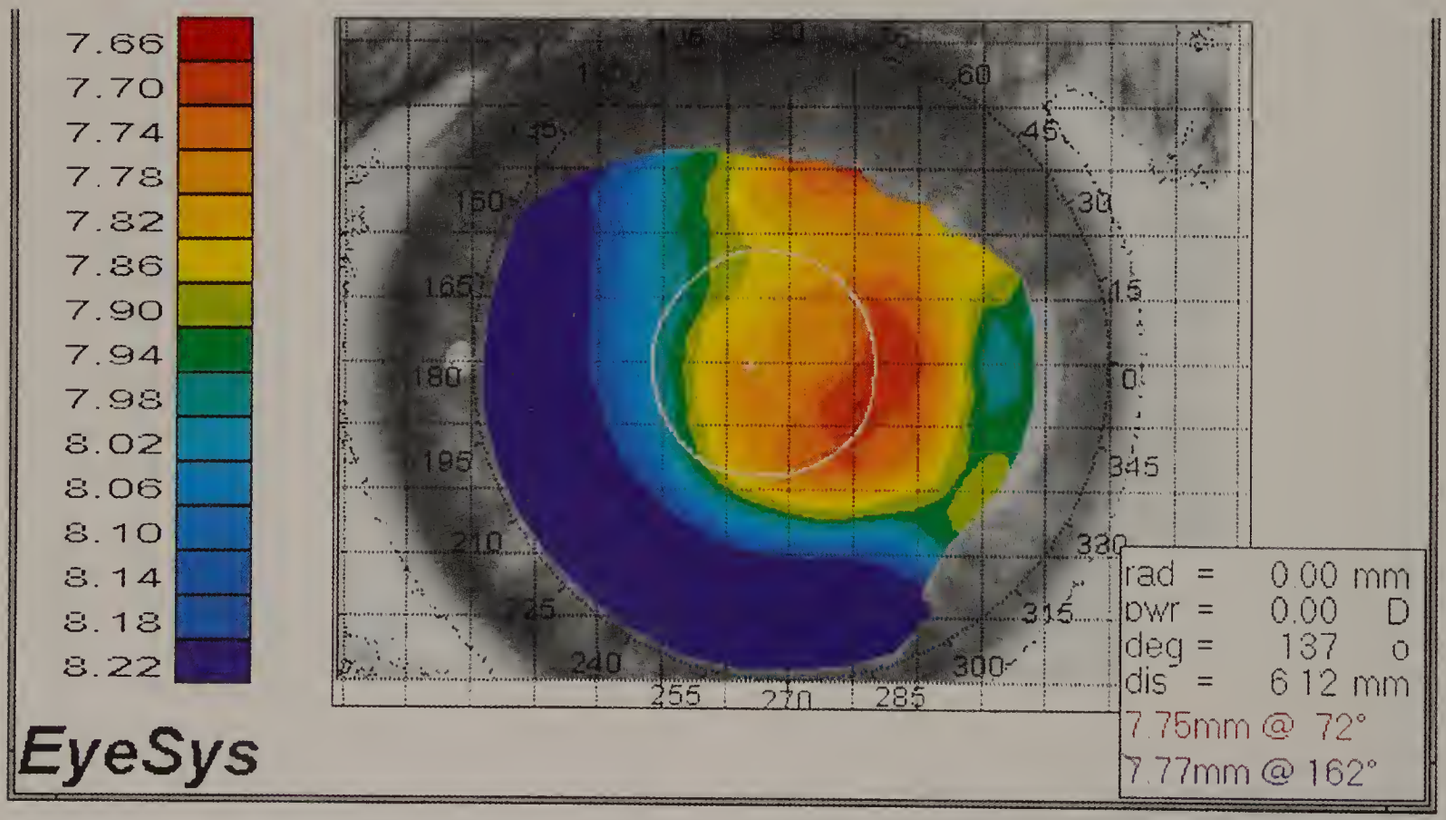
Although keratoconus is usually described as a rare disease, it is difficult to obtain consistent figures as to its prevalence. Jonkers (1950) found the incidence in Holland to be 1 in 40 000 of the general population, whereas other authors had given figures as high as 1 in 286 in Germany (Catsch, 1938) and 1 in 703 in Italy (Cambiaggi, 1955); Franceschetti and Carones (1960) in Italy and Jaensch (1929) approximately 1 in 3000 in Switzerland and Forrest (1929) in England, 1 in 7000.

Ruben (1978a) in England, basing his figures upon the number of keratoconus patients treated at Moorfields Eye Hospital for a catchment area of approximately 5.5 million, arrived at a figure of 1 in 10 000 who must be affected by this condition.

This large variation in the quoted prevalence of the disease may be explained in two ways: first owing to the possibly genetic nature of the condition there are pockets of the disease, i.e. areas where it is considerably more common (Nottingham, 1854; Woodward, 1980a; Ihalainen, 1986). Secondly, there is substantial variation in the diagnosis of the abortive forms of the condition. For example, Kornerup and Lodin (1959) showed that there is a significantly higher incidence of 'bi-oblique corneal astigmatism' amongst atopic dermatitis patients and some authors would classify these cases as keratoconus. Amsler (1961), using a classification based upon mire distortion, found that of 600 cases, 52% were of the rudimentary type and might often not be diagnosed.



(a)



(b)

Figure 20.1.1 (*a*) A corneal topographical plot showing a monocular keratoconus. The right eye shows an obvious central cone requiring rigid lens correction. The left eye shows an apparently normal plot with 6/6 acuity wearing a spectacle correction only. (*b*) If the scale is now reduced from 1.0 D steps to 0.25 D steps the left eye can now be seen to show a mild early or '*forme fruste*' keratoconus. (Courtesy of A. J. Phillips)

The advent of computer-assisted photokeratoscopy over the last few years is increasing the number of reports of subclinical keratoconus (McDonnell, 1991). The ability of such instruments to detect mild forms of the disease without any overt clinical signs may cause revision of our present views on the prevalence of the disease. The presence of corneal topographical abnormalities, shown by such instrumentation in family members of keratoconus patients, is adding additional weight to the view that some keratoconus is inherited in an autosomal dominant manner.

The question is also raised – at what point can a diagnosis of keratoconus be made? Kerr-Muir *et al.*, (1987) showed that atopic patients with normal vision had an abnormal distribution of corneal thickness skewed to the thinner end of the range. It is thus possible that there is a continuum of corneal variation in thickness and topography whose extreme presentation is keratoconus.

There is an interesting variation in the reported sex ratio in the incidence of the disease, all writers prior to 1955 reporting a preponderance of women sufferers – Thomas (1955), Barth (1948), Fox (1910), Nuel (1900), Hansell and Sweet (1903) and Wood and Woodruff (1907), who wrote 'Particularly females of a feeble or debilitated constitution', which may represent the prevailing view of the condition at the time of writing.

Since 1958 all writers have reported a preponderance of male sufferers with an average ratio of 60:40 (Obrig and Salvatori, 1958; Amsler, 1961; Arias, 1962; Karseras and Ruben, 1976; Woodward, 1981; Ihalainen, 1986).

A high prevalence of keratoconus in patients with Down's syndrome has been reported by many authors including Hofmann (1956), Zajacz (1963), and Stucchi and Erpelding (1966). Cullen and Butler (1963), who examined 143 patients suffering from Down's syndrome, found an incidence of keratoconus of 5.5%.

Keratoconus as a localized dysfunction in collagen metabolism

In recent years there have been an increasing number of reports supporting the theory that keratoconus is a localized manifestation of a mild connective tissue disorder causing corneal thinning and ectasia following a weakening of the corneal collagen. There have been several reports linking keratoconus and connective tissue disorders such as Ehlers –Danlos syndrome, osteogenesis imperfecta (Maumenee, 1975) and mitral valve prolapse (Beardsley and Foulks, 1982; Sharif and Casey, 1992). An increased hypermobility in the metacarpophalangeal and wrist joints has also been shown (Woodward and Morris, 1990).

It has also been suggested that patients with keratoconus have a shorter life expectancy due to underlying connective tissue related disease, however the largest cohort of patients investigated for this possibility at Moorfields Eye Hospital, London, England did not show a shorter life expectation than the general population (Moodaley *et al.*, 1992). The association of floppy eyelid syndrome with keratoconus has also been suggested as evidence of an underlying connective tissue disorder (Negris, 1992).

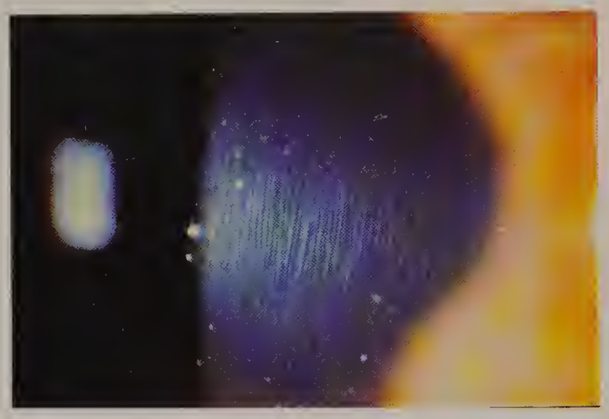


Figure 20.1.2 Striae form one of the diagnostic signs in keratoconus. They are almost invariably orientated vertically at the apex of the cone. They occur in the posterior stroma. (Courtesy of A. J. Phillips)

Symptoms and signs

The primary symptom of keratoconus is usually deteriorating vision more marked in one eye than the other. Occasionally patients first notice monocular diplopia in the form of a superior ghost image whilst retaining visual acuity as good as 6/5. Refraction reveals an against-the-rule astigmatism becoming increasingly irregular, but in the early stages, keratometry is not necessarily steep, but may appear irregular. Sometimes the mean keratometry readings are at the flatter end of the normal range, corneal thinning preceding ectasia by some considerable time (Woodward, 1980a). Also, if the ectasia is not central, the K readings can remain flat even with advanced cones, as the readings are taken of only the central 3 mm of the cornea.

In patients who have already been wearing contact lenses the differential diagnosis from contact lens-induced corneal warping can sometimes be difficult, even with the aid of computer-assisted photokeratoscopes. In such cases early keratoconus can best be diagnosed by topographical pachometry. A central or paracentral corneal thickness of less than 0.48 mm is almost certainly keratoconus, or where the thinnest part of the cornea can be shown to be off its visual axis.

As the condition progresses the characteristic swirling retinoscopy reflex appears and the near visual acuity is found to be better than would be anticipated from the distance visual acuity. Pin-hole acuity also shows a definite improvement.

One of the most early signs of keratoconus is enhanced visibility of the corneal nerves. The next finding is usually that of vertical striae (*Figure 20.1.2*), first described by Elschnig (1894). In 1906 Fleischer first described the iron pigment ring which bears his name. This ring (*Figure 20.1.3*), often only partial, is thought to be caused by some



Figure 20.1.3 Fleischer's ring is the faint brown ring, probably of ferrous deposits, sometimes found around the base of the cone in keratoconus. The deposits probably arise from stagnation of tear liquid in a zone not fully wiped by normal lid action since similar lines are seen in other conditions of corneal irregularity, e.g. Hudson Stahle lines. (Courtesy of A. J. Phillips)



Figure 20.1.5 Corneal hydrops

modification of the normal epithelial slide process. In its early stages it may be more easily detected by the use of blue light. The majority of keratoconus patients eventually show some corneal scarring, quite unrelated to, but possibility exacerbated by, contact lens wear. These scars may be small focal opacities, sub-Bowman's or pre-Descemet's membrane or Bowman's reticular scarring (*Figure 20.1.4*).

A certain percentage of patients will develop corneal hydrops sometimes incorrectly called 'acute keratoconus'. Here (*Figures 20.1.5, 20.1.6*) a sudden gross corneal oedema follows a rupture of Descemet's membrane, usually in a vertical or vertically oblique direction. Most of these cases resolve spontaneously by Descemet's membrane resurfacing over the split. There is often some reduction in vision due to the increased scarring but at the same time corneal curvature may flatten, rendering corneal lens fitting simpler. No relationship between contact lens wear or type of lens worn, with the incidence of corneal hydrops, has ever been demonstrated although it has been suggested that it occurs more frequently in patients with Down's syndrome.

Management

Many patients, when first diagnosed as having keratoconus, become extremely apprehensive about their long-term prognosis so it is important to be as reassuring as possible. For example, a long-term study of keratoconus patients presenting at Moorfields Eye Hospital (Cox, 1984) showed that over 70% retained a visual acuity of 6/9 or better over a 5-year period with contact lens wear and 88.6% were able to see well enough to drive. It also must not be forgotten that many patients retain adequate spectacle-corrected vision in at least one eye.

The management of the condition varies considerably with location, depending on the availability of a contact lens service capable of dealing with the more advanced cases and alternative strategies such as keratoplasty and epiker-



Figure 20.1.4 Central scarring – here showing staining with sodium fluorescein. The dense, but diffuse, nature of the staining indicates that Bowman's layer has been eroded and that the fluorescein is diffusing into the surrounding stroma. (Courtesy of A. J. Phillips)



Figure 20.1.6 Corneal hydrops (optic section)

Table 20.1.1 Published studies on long-term keratoconus follow-up, 1981–1990

Year	*Authors*	*Country*	*Eyes*	*Follow up*
1984	Cox	England	176	5 yr
1986	Ihalainen	Finland	424	4 yr
1986	Kennedy *et al.*	USA	122	48 yr
1988	Smiddy *et al.*	USA	230	5 yr
1990	Lass *et al.*	USA	746	4 yr

atoplasty. Since 1954, there have been five major studies relating to the management of keratoconus (*Table 20.1.1*).

In the initial management of keratoconic patients, the use of contact lenses varied between 72% and 82%, and the use of spectacles only, varied between 5.5% and 28%. At one centre, the Wilmer Eye Institute (Smiddy *et al.*, 1988) the initial management was penetrating keratoplasty in 7.5% of cases. However, the authors reported that many patients had been referred to the centre specifically for keratoplasty. Of those patients requiring transplants, 60% wore rigid corneal lenses after surgery.

At the end of the study periods the rate of surgical intervention of any description varied between 9.8% and 38.25%. In the United Kingdom the rate is probably between 10 and 12% varying with centre. Criteria for a transplant or explant will vary but typical indications would be:

- Visual acuity 6/18 or less.
- Contact lens intolerance.
- Contact lens management problems (e.g. Down's syndrome).
- Unresolved corneal hydrops.

In terms of a clear graft, success rates are very high (Marechal-Courtois and Prijat, 1972; Pouliquen *et al.*, 1972; Davies *et al.*, 1977). In the Moorfields series of patients with grafts 70% achieved a best acuity of 6/6 or better and 95% achieved 6/12 or better (Cox, 1984). However, Tuft *et al.* (1994) found that corneas transplanted after an episode of hydrops stand a significantly greater risk of rejection.

It was suggested in the past that scleral lens wear had a direct therapeutic effect on the keratoconic eye (Voss and Liberatore, 1962; Clifford-Hall, 1963), in that progressive deterioration may be halted. However Ruben and Trodd (1976) showed no difference in the rate of progression between lens wearing and non-lens wearing groups. Kemmetmuller (1962) had no doubt that large corneal lenses had a direct therapeutic effect on keratoconus, but again Woodward (1980a) showed no difference in the rate of progression between lens wearing and non-lens wearing groups.

Claims for retardation, remission or reversal being produced by contact lens wear have all been based on keratometry. This is inevitably misleading because contact lens wear can produce a temporary flattening of the cornea. As keratoconus is essentially a disease of corneal thinning it can only properly be monitored by serial topographical pachometry. Where this has been done, contact lens wear has been shown to have no effect on the progression of the condition. In some cases corneal thinning progresses very little, but in the majority of cases corneal thickness stabilizes at approximately 60% of normal (Woodward, 1980b).

Some patients arrive for fitting with the impression that contact lens fitting will control the disease and that this is an indication for fitting as early as possible. It should be explained to them that the only purpose of fitting is visual rehabilitation. In patients where the condition in one eye has not progressed sufficiently to affect vision the success rate for contact lens tolerance is significantly less good and many patients do not benefit from lens wear until or unless vision is reduced in the second eye. It is not particularly easy to tolerate a lens worn in one eye only, unless there is strong motivation, such as cases where binocular vision is required for a particular occupation.

Most keratoconic patients fitted with contact lenses are of above average intelligence (Woodward, 1981; Ihalainen, 1986) and demand a clear explanation of the rationale of their treatment.

It has also been suggested that contact lens wear may precipitate keratoconus. Gasset *et al.* (1978) compared the number of patients in their clinics who developed keratoconus after having worn hard and soft contact lenses and went on to claim an association between hard contact lens wear and the risk of developing keratoconus. However the soft lens wearers were analysed prospectively whilst they were compared with a group of patients already wearing rigid corneal lenses for some time. Although the refractive errors of the two groups were said to be similar in terms of spherical equivalents, it seems unlikely that the proportion of cases with irregular or high astigmatism were equal since these conditions would suggest the use of rigid lenses. In the early stages of keratoconus, before diagnosis many cases will show high regular astigmatism. A population of rigid lens wearers is thus much more likely to contain undiagnosed keratoconic patients than a population of soft lens wearers.

The possibility of rigid lens wear precipitating keratoconus was raised again by Macsai *et al.* (1990). This again was a retrospective study, where 53 patients from a total of 199 had previously worn contact lenses when they developed keratoconus. The authors stated that, 'The absence of keratoconus at the time of contact lens fitting was confirmed by slit lamp examination, keratometry readings and manifest refraction.' However, patients had not been evaluated by computerized photokeratoscopy, nor was corneal thickness measured prior to fitting. Thus the possibility of undiagnosed keratoconus still exists, as thinning of the cornea precedes ectasia, refractive change or clinical signs (Woodward, 1980b). Nevertheless, the authors consider that in some cases long-term rigid lens wear is a risk factor for keratoconus. This possibility cannot be completely ruled

out. It is known that contact lens wear over a period of years can produce stromal thinning. It has also been shown that atopic patients with normal vision have an abnormal distribution of corneal thickness skewed to the thinner end of the range (Kerr-Muir *et al.*, 1987). In view of those two findings it is perhaps possible that prolonged contact lens wear in atopic patients could precipitate latent keratoconus.

Contact lens options

Soft hydrogel lenses

Although keratoconic patients may present wearing hydrogel lenses, their usual complaint is of poor vision. They are thus never the lens type of first choice as the optical results are always inferior. Occasionally they are the only lenses tolerated and give better vision when used in conjunction with a spectacle overcorrection than spectacles alone. Keratoconus patients with abnormal lids and palpebral conjunctivae associated with atopic eczema and vernal conjunctivitis are in this group. Corneal sensitivity is reduced in keratoconus (Bleshoy, 1986), but the sensitivity of the upper lid margins is not affected and in these patients their stiffened and thickened lids render rigid lens wear difficult.

In the early stages of the disease it may be possible to use a low water content lens (38% or less) without overcorrection but these patients will probably still have reasonable vision with spectacles. The more usual arrangement is a medium water content lens of positive power to give a significant centre thickness (at least 0.35 mm) with a negative astigmatic spectacle overcorrection. However this cannot be regarded as anything more than a short-term expedient in view of the possible long-term deleterious effects of wearing thick hydrogel lenses for long periods.

Hydrogel lenses manufactured from HEMA material with a trapezoidal cross-section were first described by Ruben (1978b). These lenses have multiple fenestrations and fit rather in the fashion of the optic zone of a fenestrated scleral lens. *Figure 20.1.7* shows a trapezoidal lens in section and how it sits on an eye.

With a centre thickness of 0.60 mm good vision is often obtained without the use of an astigmatic overcorrection. A difficulty with these lenses is that of reproducibility in manufacture, small variations in the midperipheral thickness of the lens producing large changes in the lens flexure effect on the eye. As this design is the only hydrogel lens trapping an optically effective liquid lens, discrepancies in the refractive power may occur when a lens is replaced. In view of this, stock fittings are recommended, the three basic lenses being:

C3/12.00:8.50/8.00:14.00/9.00:15.00 BVP +5.00, t_c 0.60
C3/12.00:8.50/8.50:14.00/9.50:15.00 BVP +5.00, t_c 0.60
C3/12.00:8.50/9.00:14.50/9.50:15.00 BVP +5.00, t_c 0.60

Front optic zone diameter: 8.00 mm

A correctly fitting trapezoid lens should have a small peripheral circulating bubble, very much akin to the appearance of an FLOM (fenestrated lens for optic measurement) (*see* Chapter 17).

It might be thought that there was a role for toric soft lenses in the fitting of keratoconus. Except occasionally in *forme fruste* (where corneal thinning and irregular astigmatism do not proceed to complete keratoconus and can be managed with spectacle correction), this is not the case. First, in keratoconus there is asymmetry along a single meridian so it is very difficult to obtain a satisfactory fit. Secondly, in order to obtain a satisfactory visual result with materials of a low refractive index, large meridional differences in curvature are required. The consequential large differences in lens thickness are prone to cause localized corneal oedema. Thus although the lens may be tolerated, areas of corneal neovascularization are often produced to the detriment of any future keratoplasty. Blood vessels in the cornea provide easy access between donor antigen and host lymphocytes thus removing most of the immunological privilege normally enjoyed by the cornea.

The rarity of hydrogel lens fitting in keratoconus is demonstrated by the fact that at 5-year follow-up less than 1% of patients were using hydrogel lenses (Cox, 1984). Furthermore, patients initially fitted with soft lenses often find it difficult to convert to rigid lens wear if the condition progresses.

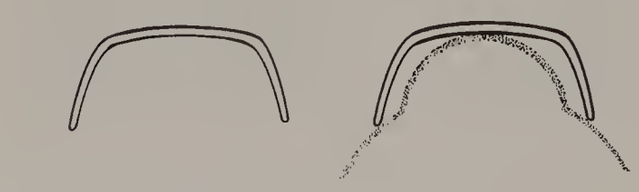


Figure 20.1.7 Trapezoid hydrogel lens (after Ruben)

Combination lenses and systems

In contemplating the fitting of a keratoconic eye, the concept of a lens option combining the visual result of a rigid lens with the comfort of a soft lens is very attractive. This may be achieved with two separate lenses or a single lens fabricated from two different materials.

The two lens system usually consists of an extra-limbal negative or plano powered lens of medium or high water content in conjunction with a rigid corneal lens of between 9.0 and 10.0 mm total diameter (Westerhout, 1973, 1985; Baldone 1985). In keratoconus this combination may be well tolerated but the problem is that the rigid lens usually rides low on the soft lens with little or no movement. Various expedients have been used to overcome this; Phillips (A. J., 1987, personal communication) reported the use of a centrally lenticulated low positive soft lens on to which the corneal lens is fitted, the lenticulation aiding centration of the corneal lens. Corneal lenses have also been fitted into a recessed portion on the front surface of a soft lens (*Figure 20.1.8*). Despite such strategies, and even if the



Figure 20.1.8 Sunken piggy-back lens. In cases of gross corneal irregularity and high sensitivity, such as advanced keratoconus, an RGP lens may have to be fitted over a soft carrier lens. In order to prevent lens decentration the RGP lens has been inset into a recess cut into the soft lens (lenses by Hydron (Australia) Ltd). (Courtesy of A. J. Phillips)

corneal lens is manufactured from a highly gas permeable material, the majority of patients have areas of localized corneal hypoxia (Fatt, 1977) which eventually results in corneal neovascularization. Patients are usually tolerant of the combination lenses and loath to abandon the system despite extensive new vessels. The other common reason for the discontinuation of wear is patient inability to handle and maintain two different types of lenses.

The first commercially available hybrid lens manufactured from two different materials was the Saturn lens initially designed by Precision Cosmet, Inc. in 1977. This lens was composed of a rigid central segment made of PMMA and a silicone skirt. In 1985 this was replaced by the Saturn II lens. This had a 6.5 mm diameter tertiary butyl styrene/silicone methacrylate optic zone with a hydrogel skirt. Although thought to be suitable for fitting keratoconus, results were disappointing and the lens found to be inadequate for fitting advanced keratoconus (Maguen *et al.*, 1991).

Currently available is the Softperm lens (Wesley Jessen). This lens has an 8 mm centre fabricated from Pentasilcon P, a rigid gas permeable material, with a modified HEMA skirt of 25% water content giving a total diameter of 14.3 mm. At the time of writing the central BOZRs available are 7.1 mm to 8.1 mm, in 0.1 mm steps and steeper curves of 6.50, 6.70 and 6.90 mm for moderate keratoconus. Success in fitting mild to moderate cases has been reported with this lens (Hewett and Hewett, 1991). However, the problem still remains that the chord width of the rigid portion is fixed as is the relationship between the radii of curvature of the rigid and flexible portions. Hence except in very early keratoconus, if the corneal portion fits well the peripheral flange is too tight and patients exhibit corneal oedema after a few hours' wear. This tendency is exacerbated by the relatively low Dk values of the lens, being 17 centrally and 7 at the mid-periphery (Morgan, 1992). For this type of lens to fit established keratoconus, the availability of differing chord widths and radii combinations would be essential, preferably with materials of greater gas permeability (*see also* Chapter 11).

The flexible gas-permeable lenses (e.g. the Epicon, described in Chapter 10, p. 327) can provide a useful alternative in order to achieve a reasonable fit.

Scleral lenses

Although the use of scleral lenses in keratoconus is not high, it is of significance because for many patients the fitting of such a lens is the only alternative to keratoplasty. The main candidates for scleral lens fitting are those whose corneas have steepened such that a corneal lens of back optic zone radius 5.5 mm is still too flat, yet with minimal corneal scarring and hence the possibility of a reasonable level of acuity. If the apex of the cone is decentred down more than usual, a corneal lens may not centre sufficiently near the visual axis for good acuity, and similarly penetrating keratoplasty would require a larger graft with the consequential increased risk of graft rejection. Down's syndrome patients usually find scleral lenses easier to cope with.

Until recently scleral lenses for keratoconus were invariably fitted by the impression technique. This was because with lenses fabricated from PMMA the clearance of the optic portion of the lens was crucial in determining success and hours of painstaking modification were usually required to achieve this. If a preformed fitting technique was used, the eccentricity of the cone in relation to the corneal axis and its asymmetry made the modifications required even more numerous. The advent of rigid gas permeable scleral lenses has changed this situation. These lenses are much more forgiving in terms of corneal clearance and it is becoming possible to fit preformed scleral lenses in either a sealed or fenestrated form. Sealed preformed RGP lenses in particular may offer a relatively straightforward option. A full description of this type of lens can be found in Chapter 17.

There are still a significant number of patients who have been wearing PMMA scleral lenses for many years, sometimes fitted prior to the availability of dedicated corneal lens fitting sets for keratoconus. These patients can present considerable management problems. Usually they wear their lenses most of their waking hours and the inevitable consequence is a low grade but chronic hypoxia and ensuing neovascularization. Furthermore these patients may have good contact lens tolerance and be asymptomatic, only complaining of a reduced level of vision when vessels and infiltrates reach the central corneal area. Generally scleral lenses give a higher quality of vision than the equivalent corneal lens because of their flatter back optic zone radii and larger back optic zone diameters. It can therefore be difficult to wean such scleral lens wearers from their lenses when they are beginning to exhibit undesirable contact lens-induced changes but have relatively minor



Figure 20.1.9 A flat-fitting corneal lens, shown from left to right, gradually making a keratoconic cornea more spherical

symptoms. A clear explanation that they are putting in jeopardy any future keratoplasty by increasing the possibility of rejection must be given.

Corneal lenses

Because the majority of keratoconic patients are fitted with corneal lenses it is not surprising that the question of the most appropriate fitting philosophy has been debated for many years.

In the early days of corneal lens fitting, large relatively flat fitting lenses were advocated and in a modified form this approach still has its proponents, mainly in in the Scandinavian and German speaking countries. There was a specific intention to reshape the cornea using a flat lens, the curvature of which bore no relationship to the corneal contour, depending entirely on the plasticity of the cornea (Clifford-Hall, 1963). The lenses had total diameters between 9.50 mm and 11.50 mm and had a single back curve apart from a well-blended edge bevel 0.50–1.00 mm wide. On initial insertion these lenses rode high, with the lower edge often standing away from the cornea. The weight of the lens then tended to compress the cone and 'sphericize' the cornea, as shown in *Figure 20.1.9*. Once this occurred, subsequent lenses were fitted even flatter. The fit was also evaluated by repeated refractions, the flattening of the cone reducing both the refractive power of the cornea and the axial length of the eye. The definitive lens was then described as the one requiring the least minus power.

Although not taken to these extremes, flat fitting lenses are still currently used and this philosophy does have some advantages, the Ciba Persecon E Keratoconus design being an example of this approach (Achatz *et al.*, 1985). The advantages of this type of fitting are mainly optical, flatter fitting lenses usually giving a superior visual performance. In addition, the patient's vision may be enhanced for some time after lens removal due to the cornea remaining relatively flattened. Reservations concerning the use of this fitting philosophy relate to its possible effect on the natural history of the disease. The majority of patients with

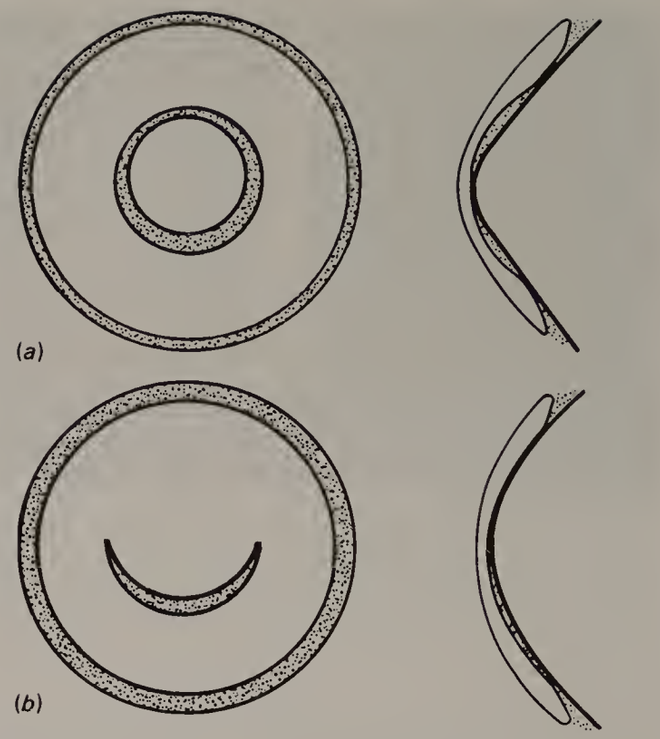


Figure 20.1.10 Fitting with the weight of the lens distributed (*a*) in developed keratoconus; (*b*) in early keratoconus. The left-hand diagrams show a representation of the fit where the dotted areas indicate corneal clearance. The right-hand diagrams show the same fit (exaggerated) in cross-section

keratoconus exhibit corneal scarring whether or not they have worn contact lenses (Bron *et al.*, 1978), but several writers have suggested that the wearing of a flat fitting corneal lens hastens the rate of scarring in sub-Bowman's stroma, as shown in *Figure 20.1.4* (Ruben, 1975; Korb *et al.*, 1982). The design of a controlled clinical trial to test the hypothesis that flat fitting corneal lenses exacerbate corneal scarring in keratoconus would be logistically difficult and ethically dubious. Nevertheless, many practitioners working in the field have the clinical impression that the relationship does exist.

Whilst the large flat fitting philosophy was being propagated in Europe, in South America and the USA an alternative approach was favoured. This was to fit small, thin lenses from 6.00 mm to 8.00 mm in total diameter, with BOZR values between 5.00 mm and 7.50 mm, combined with two flatter curves at the periphery (Arias, 1963). The disadvantages with this philosophy are mainly optical. The lenses had an effective optic zone of only 4 mm, they centred on the cone itself, which is rarely on or even near the visual axis, and monocular diplopia was a common complaint. Furthermore in all but the earliest cases such lenses need to be of high negative power with attendant edge thickness problems. This causes especial difficulty if the patient also suffers from atopic eye disease, as is often the case in keratoconus. Generally this group of keratoconic patients is more tolerant to larger corneal lenses.

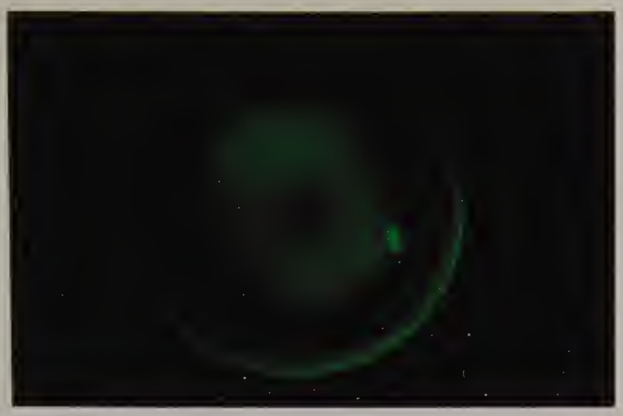


Figure 20.1.11 A classic 'three-point touch' alignment fit in keratoconus, i.e. alignment of the majority of the peripheral curve and capillary contact with the cone apex by the central back optic zone. (Courtesy of A. J. Phillips)

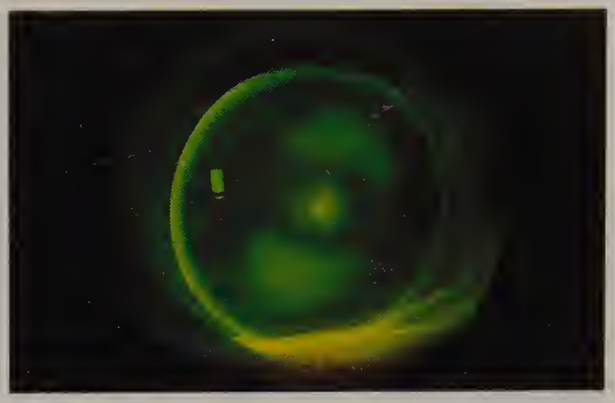


Figure 20.1.13 As keratoconus progresses the lens increasingly presses against the cone. If regular monitoring and re-fitting (where necessary) is not undertaken, either central scarring or epithelial erosion may result. Even with a lens that fits well, central scarring often occurs. (Courtesy of A. J. Phillips)

Since the 1970s the most widely accepted corneal lens fitting philosophy has been one in which the intention is to distribute the weight of the lens between the cone and the more peripheral cornea (*Figure 20.1.10a*). The peripheral cornea does thin in keratoconus but only at half the rate of the centre (Woodward, 1980b). In cases where the cone is well established this philosophy would result in a lens showing an apical contact area of 2–3 mm, an intermediate clearance zone and a mid-peripheral contact annulus with conventional edge clearance at the periphery (*Figure 20.1.11*). In the earlier stages of the condition, owing to the vertical asymmetry of the cone, the intermediate zone forms a crescent rather than an annulus, as shown in *Figure 20.1.10b*. With the exception of very early cases it is necessary to use specifically designed lenses to achieve this type of fit. If lenses of a conventional design are used, the lens with the desired central fit usually has insufficient edge clearance.

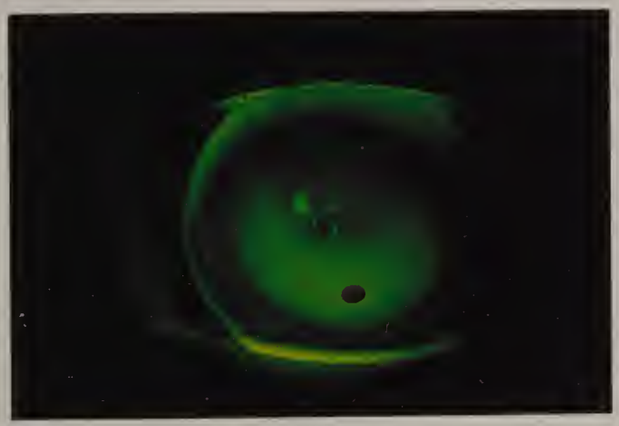


Figure 20.1.12 As keratoconus advances the cornea becomes so steep centrally that the sharp change in curvature between the back optic zone and aligning periphery produces bubbles under the optic zone area that cannot escape. These break up to form froth centrally. Dimple 'staining' is shown under the lens here and dimple veiling usually results. Fenestrating the lens may help but often worsens the situation. Utilizing a flatter BOZR may reduce the frothing but at the risk of causing increased cone pressure and possible subsequent central scarring. Just above the cone apex can be seen vertical epithelial wrinkling due to pressure on the cone apex. Fluorescein collects in the channels with the lens *in situ* but runs out on lens removal. The wrinkles can then only be seen by indirect illumination. Epithelial wrinkling can also occur after wearing thin hydrogel lenses. (Courtesy of A. J. Phillips)

Lens designs which may be used with this fitting philosophy include lenses with contralateral offset peripheral curves which simulate a true conicoid surface (Bennett, 1968), and have obvious advantages for fitting keratoconus (Ruben, 1966, 1975). The Ruben Offset design is of this type and is widely used in fitting keratoconus; three differing combinations being available (*Table 20.1.2*). The numbering of these lenses is rather anomalous in that in the earlier cases Offset 2 lenses would be used, then as the condition progressed Offset 1 and finally Offset 3. A special lathe is required for the production of these lenses (Ruben, 1975). An offset lathe differs from a conventional lathe in that the central axis (the lathe spindle) can be moved laterally, or offset, up to 8 mm on either side of the central position.

If the trial fitting lens does not give the desired fluorescein picture, the only variations from the trial lens which can be ordered by the practitioner are additional offset or spherical curves. Astin (1987), however, reported good results with bi-elliptical lenses which have a flatter elliptical periphery than the elliptical back optic zone. Alternatively, lenses can be used that have a greater

Table 20.1.2 Dimensions of offset lenses (Ruben)

Offset lens	*BOZD (mm)*	*TD (mm)*	*BOZR (range) (mm)*
1	6.00	9.00	6.60–8.50
2	7.00	10.00	7.00–8.50
3	5.50	8.50	5.50–7.00

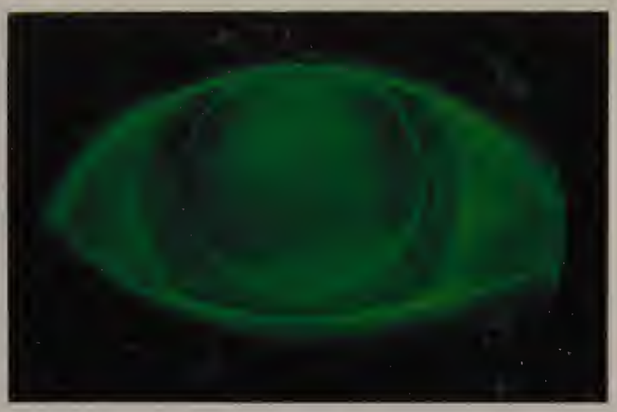


Figure 20.1.14 Keratoconic corneas frequently show marked with-the-rule toricity. This fluorescein fit shows minimal cone contact just below the lens centre with peripheral curves aligning (to borderline tight) in the horizontal meridian but with marked edge standoff vertically. The use of a toroidal periphery increases the area of alignment and may avoid the optical complications of a fully toric lens. (Courtesy of A. J. Phillips)



Figure 20.1.15 Keratoconic cornea fitted with (*a*) a spherical 'offset' corneal lens, showing bubbles under the lower edge, the dotted areas indicating corneal clearance; (*b*) a corneal lens with a toroidal periphery showing much more uniform clearance at the edge

eccentricity of the elliptical curve, for example the Zeiss Wöhlk A90.

Fully toroidal back surface corneal lenses are rarely used in fitting keratoconus. Although the cornea is highly astigmatic, the irregularity of the astigmatism is such that it has asymmetry in any one meridian, and centrally a toroidal back surface fits no better than a spherical one. However, toroidal back peripheral curves can often be used to enhance lens centration. A common problem is where the lens shows reasonable edge clearance except in the inferior quadrant where it is excessive (*Figure 20.1.14*), sometimes to the degree of allowing air under the lens edge (*Figure 20.1.15a*). Such lenses are unstable and often blinked out by the patient. Here a lens with a toroidal periphery may improve the situation, although the inferior clearance always exceeds the superior because of the meridional asymmetry. As this is less peripherally than centrally, a compromise fit can often be arrived at, as seen in *Figure 20.1.15b*.

A toric periphery fitting set designed by Phillips is shown in *Table 20.1.3*.

An alternative approach is to estimate the degree of peripheral toricity required from a spherical tri-curve set. A tri-curve set specifically designed for keratoconus is shown in *Table 20.1.4*.

In this fitting set the steeper lenses have greater edge clearance than the flatter ones, thus to a certain extent mimicking an increasingly keratoconic cornea. A 12.25 mm radius, 0.20 mm wide, may usefully be added as a final peripheral curve if there is any tendency for the lens periphery to fit too tightly in the upper quadrant. The higher negative power on the steeper lenses also represents the actual situation and reduces the power of any supplementary lenses over the trial lens when the lens power is determined.

Modifications of this original design by Woodward have been suggested by Phillips with the objective of increasing

Table 20.1.3 Toric periphery keratoconus fitting set (Phillips)

BOZR (*mm*)	*BOZD* (*mm*)	BPR_1 (*mm*)	BPD_1 (*mm*)	BPR_2 (*mm*)	BPD_2 (*mm*)	BPR_3 (*mm*)	*TD* (*mm*)	BVP (D)
5.80	6.50	7.80×7.40	8.50	10.50×10.10	9.10	12.25×11.85	9.50	−13.00
5.90	6.50	7.90×7.50	8.50	10.50×10.10	9.10	12.25×11.85	9.50	−12.50
6.00	6.50	8.00×7.60	8.50	10.50×10.10	9.10	12.25×11.85	9.50	−12.00
6.10	6.50	8.10×7.70	8.50	10.50×10.10	9.10	12.25×11.85	9.50	−11.50
6.20	6.50	8.20×7.80	8.50	10.50×10.10	9.10	12.25×11.85	9.50	−11.00
6.30	6.50	8.30×7.90	8.50	10.50×10.10	9.10	12.25×11.85	9.50	−10.50
6.40	6.80	7.90×7.50	8.80	10.50×10.10	9.40	12.25×11.85	9.80	−10.00
6.50	6.80	8.00×7.60	8.80	10.50×10.10	9.40	12.25×11.85	9.80	−9.50
6.60	6.80	8.10×7.70	8.80	10.50×10.10	9.40	12.25×11.85	9.80	−9.00
6.70	6.80	8.20×7.80	8.80	10.50×10.10	9.40	12.25×11.85	9.80	−8.50
6.80	6.80	8.30×7.90	8.80	10.50×10.10	9.40	12.25×11.85	9.80	−8.00
6.90	6.80	8.40×8.00	8.80	10.50×10.10	9.40	12.25×11.85	9.80	−7.50
7.00	6.80	8.50×8.10	8.80	10.50×10.10	9.40	12.25×11.85	9.80	−7.00
7.10	6.80	8.10×7.70	8.80	10.50×10.10	9.40	12.25×11.85	9.80	−6.50
7.20	6.80	8.20×7.80	8.80	10.50×10.10	9.40	12.25×11.85	9.80	−6.00
7.30	6.80	8.30×7.90	8.80	10.50×10.10	9.40	12.25×11.85	9.80	−5.50
7.40	6.80	8.40×8.00	8.80	10.50×10.10	9.40	12.25×11.85	9.80	−5.50

Table 20.1.4 Tri-curve keratoconus fitting set (Woodward)

BOZR (mm)	*BOZD (mm)*	*BPR_1 (mm)*	*BPD_1 (mm)*	*BPR_2 (mm)*	*TD (mm)*	*BVP (D)*
5.50	5.60	6.50	7.60	8.50	8.60	–11.00
5.60	5.60	6.60	7.60	8.60	8.60	–10.00
5.70	5.70	6.70	7.80	8.70	8.80	–9.50
5.80	5.70	6.80	7.80	8.80	8.80	–9.00
5.90	5.80	6.90	7.80	8.90	8.80	–8.50
6.00	5.80	7.00	8.00	9.00	9.00	–8.00
6.10	5.90	7.10	8.00	9.10	9.00	–7.50
6.20	5.90	7.20	8.00	9.20	9.00	–7.00
6.30	6.00	7.30	8.00	9.30	9.00	–6.50
6.40	6.00	7.40	8.00	9.40	9.00	–6.00
6.50	6.00	7.50	8.00	9.50	9.00	–5.50
6.60	6.00	7.60	8.00	9.60	9.00	–5.00
6.70	6.00	7.70	8.00	9.70	9.00	–4.50
6.80	6.00	7.80	8.20	9.80	9.20	–4.00
6.90	6.00	7.90	8.20	9.90	9.20	–3.50
7.00	6.00	8.00	8.20	10.00	9.20	–3.00

the zone of mid-peripheral alignment. The specifications for these fitting sets are as shown in *Table 20.1.5.*

Table 20.1.5a Keratoconus tetra-curve fitting set I (Phillips)

BOZR (mm)	*BOZD (mm)*	*BPR_1 (mm)*	*BPD_1 (mm)*	*BPR_2 (mm)*	*BPD_2 (mm)*	*BPR_3 (mm)*	*TD (mm)*	*BVP (D)*
5.00	6.00	7.20	8.00	10.50	8.60	12.25	9.00	–17.00
5.10	6.00	7.30	8.00	10.50	8.60	12.25	9.00	–16.50
5.20	6.00	7.40	8.50	10.50	8.60	12.25	9.00	–16.00
5.30	6.00	7.50	8.00	10.50	8.60	12.25	9.00	–15.50
5.40	6.00	7.60	8.00	10.50	8.60	12.25	9.00	–15.00
5.50	6.00	7.70	8.00	10.50	8.60	12.25	9.00	–14.50
5.60	6.00	7.70	8.00	10.50	8.60	12.25	9.00	–14.00
5.70	6.00	7.70	8.00	10.50	8.60	12.25	9.00	–13.50
5.80	6.00	7.80	8.00	10.50	8.60	12.25	9.00	–13.00
5.90	6.00	7.90	8.00	10.50	8.60	12.25	9.00	–12.50
6.00	6.50	8.00	8.50	10.50	9.10	12.25	9.50	–12.00
6.10	6.50	8.10	8.50	10.50	9.10	12.25	9.50	–11.50
6.20	6.50	8.20	8.50	10.50	9.10	12.25	9.50	–11.00
6.30	6.50	8.30	8.50	10.50	9.10	12.25	9.50	–10.50
6.40	6.50	8.40	8.50	10.50	9.10	12.25	9.50	–10.00
6.50	6.50	8.00	8.50	10.50	9.10	12.25	9.50	–9.50
6.60	6.50	8.10	8.50	10.50	9.10	12.25	9.50	–9.00
6.70	6.50	8.20	8.50	10.50	9.10	12.25	9.50	–8.50
6.80	6.50	8.30	8.50	10.50	9.10	12.25	9.50	–8.00
6.90	6.50	8.40	8.50	10.50	9.10	12.25	9.50	–7.50
7.00	6.50	8.50	8.50	10.50	9.10	12.25	9.50	–7.00

Fitting procedures

It has been suggested over the years that keratoconic corneas may be classified by shape and cone apex position into distinct groups and furthermore that such a classification is of value in deciding the design of corneal lens to fit such a cornea. However, advances in computerized photokeratoscopy (Rabinowitz and McDonnell, 1989; Wilson *et al.*, 1991; Young *et al.*, 1991), have shown that keratoconus produces a spectrum of change with no clearly defined taxonomy. In addition, consideration of the shape changes produced by eccentric thinning of the cornea does not support the concept of classifiable changes (Edmund, 1987).

Thus the procedure for trial lens fitting in keratoconus is essentially pragmatic. Keratometry gives only minimal help in deciding on the first trial lens to insert. In the earlier stages of the condition the lens closest to the flatter corneal radius is the first trial lens of choice but as the condition progresses keratometry readings become increasingly meaningless as the irregularity of the cornea increases. Keratometers are calibrated on the assumption that the areas from which the mire images reflect lie on a spherical surface. If the curvature differs in each area or if the areas do not have a common centre of curvature the measurement will be incorrect and this is invariably the case in keratoconus. Although keratometry is a useful indicator of corneal topographic change in keratoconus, results must be considered as qualitative rather than quantitative. As a means of selecting the first trial fitting set lens in more advanced cases, where *K* readings are possible, the BOZR of the optimum fitting lens is often found in the range corresponding to a value midway between the *K* readings of the two 'principal meridians' and slightly steeper than the flattest *K* reading.

Table 20.1.5b Keratoconus tetra-curve fitting set II (Phillips)

BOZR (mm)	*BOZD (mm)*	*BPR_1 (mm)*	*BPD_1 (mm)*	*BPR_1 (mm)*	*BPD_2 (mm)*	*BPR_3 (mm)*	*TD (mm)*	*BVP (D)*
6.00	6.80	7.50	8.80	10.50	9.40	12.25	9.80	–12.00
6.10	6.80	7.60	8.80	10.50	9.40	12.25	9.80	–11.50
6.20	6.80	7.70	8.80	10.50	9.40	12.25	9.80	–11.00
6.30	6.80	7.80	8.80	10.50	9.40	12.25	9.80	–10.50
6.40	6.80	7.90	8.80	10.50	9.40	12.25	9.80	–10.00
6.50	6.80	8.00	8.80	10.50	9.40	12.25	9.80	–9.50
6.60	6.80	8.10	8.80	10.50	9.40	12.25	9.80	–9.00
6.70	6.80	8.20	8.80	10.50	9.40	12.25	9.80	–8.50
6.80	6.80	8.30	8.80	10.50	9.40	12.25	9.80	–8.00
6.90	6.80	8.40	8.80	10.50	9.40	12.25	9.80	–7.50
7.00	6.80	8.30	8.80	10.50	9.40	12.25	9.80	–7.00
7.10	6.80	8.40	8.80	10.50	9.40	12.25	9.80	–6.50
7.20	6.80	8.50	8.80	10.50	9.40	12.25	9.80	–6.00
7.30	6.80	8.60	8.80	10.50	9.40	12.25	9.80	–5.50
7.40	6.80	8.70	8.80	10.50	9.40	12.25	9.80	–5.00

More information may be gained from fluorescein pictures with trial lenses and here the use of specifically designed fitting sets is essential. Offset lenses as described earlier may be used, or tri-curve or tetra-curve sets, but the classic three-point touch, keratoconic fit as shown in *Figure 20.1.10* and *Figures 20.1.11* and *20.1.13* may not always be achievable. Bubble formation and retention below the apex



Figure 20.1.16 A PMMA corneal lens fitted to a keratoconic cornea. Four fenestration holes have been used in an attempt to relieve the central oedema – visible as the haze in the pupil region. Bubbles have collected below the cone apex. (Courtesy of J. Mountford)

of the cone is not uncommon (*Figure 20.1.16* and *see Figure 20.1.12*); it may be necessary to use fenestrations if static bubbles produce dimple veiling. Gas permeable materials are now routinely used in a group of patients who will probably be wearing lenses for most of their lives. When considering lens materials, however, a low wetting angle and dimensional stability are of greater importance than the maximum permeability to oxygen. The steep high minus lens, usually necessary in keratoconus, is very prone to distortion if made from materials with a high siloxane content.

The concept of ordering contact lenses by computer analysis of photokeratograms or more recently videokeratographs is a very attractive one. This was first suggested using the Wesley–Jessen PEK System 2000 which made use of an ellipsoidal configuration of the illuminated rings. Despite this configuration, all the rings can only be perfectly in focus for one given corneal radius, the radius usually chosen being 7.90 mm. Within the normal range of corneal radii the fact that any other radius produces a slightly out-of-focus image is of little significance. As keratoconus progresses the reflected image becomes increasingly blurred, significantly reducing the accuracy. Although contemporary computer-assisted videokeratoscopes such as the EyeSys or TMS Corneal Topography systems use many more rings and have a highly sophisticated system of analysis, the illuminated targets are still in a fixed configuration. Because of this, as astigmatism increases it has been shown that that the precision of the output values is beyond the capability of the instrument (McCarey *et al.*, 1992). The accurate analysis of corneal topography in keratoconus is only possible using projection rather than reflecting techniques, such as rasterstereography (de Cunha and Woodward, 1993). Because of these constraints, the prescribing of contact lenses for keratoconus using such systems is only of use in very early cases. It has been suggested that they could be used for evaluating the front surface of the soft lens when fitting piggy-back systems (Soni *et al.*, 1991).

Patient management

If contact lens fitting is initiated at an appropriate time, i.e. when there is a significant visual gain, patients are usually enthusiastic wearers. It is, however, often counterproductive to attempt to fit patients if their spectacle vision is reasonable or they obtain good unaided vision in one eye.

During an active phase of the condition re-fitting as frequently as every 3 months may be necessary, the patient usually complaining of fluctuating vision and an unstable lens which easily decentres and sometimes falls out of the eye. The use of fluorescein will demonstrate heavy pressure on the cone with no peripheral bearing surface. If corneal hydrops occurs, lens wear must be discontinued until all the stromal oedema has resolved. Re-fitting is not always necessary following an episode of hydrops but the visual acuity is often reduced due to scarring of Descemet's membrane. If re-fitting is necessary the resultant lens may be flatter than the pre-hydrops lens, harking back to the treatment suggested by Nottingham of inducing scarring to strengthen the cornea.

Where contact lens-induced disease occurs, such as contact lens-related papillary conjunctivitis, it is often impossible to persuade patients to cease lens wear. This is understandable in view of the large visual loss. All that can be done is to initiate the appropriate management and try to persuade the patient to reduce their wear as much as possible. Where corneal vascularization is occurring it must be explained to patients that they are placing future surgical options in jeopardy, by imperilling the immunological privilege of the cornea. Seasonal allergic conjunctivitis and less commonly vernal conjunctivitis are often found in conjunction with keratoconus. Such patients may require treatment with mast cell stabilizers and mild topical steroids during the summer months.

Another complication of contact lens wear in keratoconics is the development of proud nebulae at or near the apex of the cone. Where these nebulae do not flatten when contact lens wear is discontinued treatment is required. This may be a superficial keratectomy followed by the fitting of a hydrogel therapeutic lens (Moodaley *et al.*, 1991) or more recently an excimer laser superficial keratectomy (Moodaley *et al.*, 1994).

Keratoconic patients have gained the reputation with many eye care professionals of being awkward and difficult. This has been shown not to be due to any psychoneurotic traits (Karseras and Ruben, 1976; Mannis *et al.*, 1987), but that compared with the typical ophthalmic patient they are more likely to have received higher education and to be more articulate, younger and more willing to voice their doubts and fears concerning the management of their condition. These characteristics must not be forgotten by the contact lens practitioner. It should also be remembered that keratoconus patients have to cope continually with reduced contrast sensitivity and some lens discomfort, as well as flare and glare problems, even with well-fitting lenses and good Snellen acuity. Even though their problems may not be resolvable, a certain amount of sympathy and explanation will help.

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Chapter 20.2 Aphakia

M. J. A. Port

General procedure p.707
Corneal lens fitting (daily wear) p.709
Soft lenses (daily wear) p.709
Extended wear lenses p.710
Refraction p.710
UV protection and tinted lenses p.711
Fitting babies and infants p.711
After-care p.711

The number of contact lenses routinely fitted for the correction of aphakia has declined since the advent of intraocular lenses, but contact lenses are still fitted at times (Stark *et al.*, 1979).

The aphakic eye has several physiological features of note. These are as follows:

- The patient is usually 60 years of age, or more. When comparison is made with a younger person the implications here are:
  - the basal metabolic rate (BMR) is lower;
  - there is less tear production;
  - the lids may be more flaccid;
  - more of the cornea may be covered by the upper lid;
  - there may be incomplete blinking.
- The absence of the crystalline lens means that the partial pressure of oxygen at the corneal endothelium is higher than that of a phakic eye, which is advantageous for contact lens fitting.
- If the cataract extraction has been performed by a scleral or corneal section, then up to half of the corneal nerves will have been severed and corneal sensitivity will be poorer than normal (Guillon, 1985).
- The surgery involved may also cause a change in the degree of corneal astigmatism (Kersley and Kerr, 1983) and a tendency towards 'against-the-rule' astigmatism (Reading, 1984; van Rij and Waring, 1984), a change in the position of the corneal apex (Port, 1983, unpublished data), and some corneal endothelial loss. There may be changes in the posterior segment, e.g. macular oedema, retinal detachment. These sequelae, together with any pupil changes, affect the standard of vision obtained with an optical correction (Koetting and von Gunten, 1969).

It is also important to realize that an eye without its crystalline lens is without the retina's ultraviolet protective filter. The effects of ultraviolet light on the retinal tissues are now beginning to be understood and it would therefore seem appropriate that contact lenses incorporate some ultraviolet filter in order to protect the retina from higher levels of this radiation (Port, 1986).

A contact lens for a unilateral aphake can provide binocular vision where the fellow eye has useful acuity. Even so Guillon and Warland (1980) found that most unilateral aphakes achieved only 140 seconds of arc on the Titmus stereopsis test and 80% had intermittent suppression. This may be because the retinal image size difference is still outside normal fusion limits because of the relative position of the contact lens to the natural lens (*see* Chapter 5 and *Figure 5.13*). The quality of vision with contact lenses is very good for aphakes. In comparison, spectacles tend to give distortion of vision and this can be upsetting to the wearer. Most aphakes will gladly sacrifice a line or two of Snellen acuity in exchange for the better field of vision that contact lenses provide. Astigmatism is often around 2D in an aphakic eye. The simplest solution is to correct this with a rigid lens but if such a lens cannot be tolerated then a soft lens may have to be used. In this case, if the astigmatic correction is still necessary it may have to be provided in the form of a spectacle correction as the basic power required is often outside the range of available toric soft lenses. In any case the aphakic patient requires a near addition so that bifocal spectacles can be used to correct the astigmatism at the same time. This has the virtue of keeping the contact lens part of the correction as simple as possible.

General procedure

(1) Where a corneal section has been performed a post-surgical period of 6–10 weeks is usually allowed to elapse in order to permit healing and settling to occur. If inflammation has not subsided by then, fittings should be delayed.
(2) Ensure that it is safe to fit contact lenses. For example, it is important to check that there is no aqueous leakage from wounds and that sutures are not causing problems.
(3) Refract the eye.
(4) Perform keratometry.
(5) Assess pupil size, shape and position.
(6) Examine eyelids.
(7) Contact lens fitting is then undertaken.
(8) Over-refraction, to include correction of any remaining astigmatism and near addition, as well as oculomotor balance tests are carried out.
(9) After-care is arranged.

Points (3) to (9) above are now discussed in greater detail.

Spectacle refraction

With sphere powers commonly in the order of +12.00 to +18.00 D it is essential that the back vertex distance is noted accurately. The ocular refraction can then be calculated later.

When a cataractous crystalline lens has been removed it is often assumed that the refraction is going to be straightforward. However, pupil size and position, vitreous movement and lens capsule presence may all conspire to make refraction difficult. Inconsistency of results should be anticipated – the prescription and visual acuity may well vary on a day-to-day, or week-to-week basis. It is important to establish if the eyes are straight. If an eye has had a cataract for a long time or even subjected to a blur of the order of 15 D for as little as 2 months, a squint may have resulted. If this has been the case, fitting a contact lens as soon as it is practical will help re-establish binocular vision and if it is likely to take a long time to obtain a special rigid lens for an eye, it may be useful to fit a soft lens on a short-term basis.

Keratometry

Keratometry permits measurement of the corneal astigmatism which should correspond to the total ocular astigmatism provided the pupil is reasonably central. The degree of astigmatism depends on the preoperative astigmatism and the changes induced during the surgical procedure. The keratometer mire images may show some distortion and the principal meridians may not be perpendicular, indicating some corneal irregularity.

Pupil size, shape and position

If the eye has been subjected to trauma an abnormal pupil may be present. There may even be some degree of 'aniridia' (*see Figures 20.6.8 and 20.6.16*).

Modern surgical procedures tend to produce only small pupil changes but the practitioner should take particular account of this important optical aperture. The design of lens chosen must take account of pupil characteristics.

It is pertinent to mention iridectomy apertures. These are usually found in the 12 o'clock position (*Figure 20.2.1*) and the size varies. If they are are not well covered by the upper lid there may be monocular diplopia problems. If such a problem exists then some form of opaque cosmetic lens might be useful (*see* Chapter 20.6).

Lid position

Low flaccid upper lids may cover much of the cornea and even without a contact lens a large percentage of the cornea may be relatively hypoxic. There may be some degree of incomplete blinking but the use of vital stains and a slit lamp should identify this problem if it causes epithelial drying. If there is some degree of lagophthalmos then rigid lenses may not centre well and hydrogel lenses may dry out.



Figure 20.2.1 Superior peripheral iridectomy created during surgery. Normally these are covered by the upper lid but can occasionally create visual problems. (Courtesy of A. P. Gasson)

Lens fitting

The majority of aphakes needing contact lenses are adequately served with either a rigid lens or a daily wear soft lens. The minority need either extended wear lenses, large diameter corneal lenses or scleral lenses. In choosing the best lens form many factors have to be taken into account, some of which are initially unknown. These fall into two categories – patient factors and ocular factors. As far as patient factors are concerned the following aspects must be assessed: Can they handle various types of lens? Can they understand and remember the hygiene regimen involved? Do they live alone? Are there any friends or relatives available to help out if a lens is lost or cannot be removed? These problems should be addressed as far as possible before fitting proceeds. If there are no indications for a particular type of lens it is worth trying a rigid lens first. Rigid lenses are more robust than hydrogels and are a little more tolerant to poorer hygiene compliance. They are also available in higher Dk materials which is advantageous in the aphakic prescriptions. If astigmatism is present then it may be corrected with a rigid lens. The second option of a daily wear soft lens should be considered if the rigid lens fails for some reason. If there are problems centring a rigid lens on an eye then a soft lens will usually centre better. The soft lens has a large optic zone which is useful when fitting slightly eccentric pupils.

If the handling of rigid and soft lenses proves to be poor then extended wear lenses should be considered. If patients live alone and perhaps have poor comprehension then extended wear may well be the best option (Kracher *et al.*, 1981).

In cases of corneal irregularity and astigmatism where centration is poor, the use of rigid lenses with a total diameter of 10.5–13 mm should be considered.

Scleral lenses have a place in aphakic fitting (Pullum and Trodd, 1984). The lenses are almost indestructible; they preserve a tear layer behind the lens and so are excellent for dry eyed patients; they are large and therefore can be handled more easily than corneal or soft lenses. Again, the

correction of high degrees of corneal astigmatism is straightforward with a scleral lens form (*see* Chapter 17).

Corneal lens fitting (daily wear)

The criteria used for fitting aphakic eyes are very little different from those used for normal eyes (*see* Chapter 10). High Dk materials do allow better oxygen transmission although much of the oxygen required by the epithelium is transported in the tear film and the practitioner should ensure that there is an adequate tear pump.

Lenses for aphakes often need to be made with larger diameters (up to 10.5 mm) in order to stabilize the lens and give better centration.

Fitting should be done with lenses from a high plus fitting set so that the effect of lens weight can be seen and also how the lids affect a relatively thick lens. With a well-fitting lens the habitual position should be noted especially in conjunction with the pupil characteristics. The BOZD and FOZD should cover the pupil area at all times, otherwise flare and diplopia will almost certainly occur. A decentred corneal apex may consistently cause lenses to decentre. The effect of the lids on a thick lens tends to accentuate this. Larger and/or steeper lenses may be tried to achieve better centration. If multi-curve lenses have been used, changing to an aspheric design, e.g. Persecon (Ciba Vision), may help. It may be possible to design a lens with a small front optic zone and a negative carrier in order that the lens may be hitched up by the top lid (*see* Chapter 10).

Large diameter corneal lenses

If a 9.0–9.8 mm corneal lens decentres badly and, there are pupil anomalies and corneal astigmatism, then a larger diameter lens may be useful; it is also simpler to prescribe than a scleral lens. Lens total diameters between 10.5 and 13 mm are used for this type of construction. The 'Apex' lens (aphakic experimental lens, *see* Chapter 1) (Bagshaw *et al.*, 1966) uses a bi-curve design. The author has found it preferable to use a tri-curve design for these diameters together with a BOZD of 8.5–9.5 mm. A small, four lens trial set powered at +17.00 D with BOZR of 7.5, 7.8, 8.1 and 8.4 mm should prove useful. Most of the lenses have to be individually designed due to the variation of corneal topography at these larger diameters, so a large trial set may be of limited value. It is better to make a prototype PMMA lens and modify the curves to achieve a good fit. The first lens should have enough thickness to enable such modifications to be carried out. A gas permeable lens may then be made to the modified specification.

Soft lenses (daily wear)

For aphakics, daily wear and extended wear lenses are both practical possibilities. If possible a daily wear lens should be tried in the first instance. The patient must be able to handle the lenses and be competent in lens cleaning, insertion and removal. The hygiene regimen should be understood.

As previously discussed, for a patient who does not tolerate a rigid lens or if the lens decentres badly, a soft lens can be useful. It also has the advantage of a large optic zone diameter so there is unlikely to be a flare problem. If there is significant residual astigmatism present with the lens *in situ* then a spectacle correction may be required to obtain the best acuity.

There are many aphakic lenses available in various designs and materials. The practitioner should therefore pay attention to several issues.

1. Transmissibility

If there is a level of corneal hypoxia which is unacceptable with an existing lens, then it is necessary to consider the material and the thickness profile across the lens covering the cornea. It may be necessary to contact the manufacturer directly to obtain this information if has not been published in their literature. There may be occasions when a lens which has been specially designed (in terms of the front optic zone diameter, centre thickness and the material) by the practitioner is the best solution. Knowing the oxygen permeability (Dk) and the thickness (t) of the lens at a given point, then the transmissibilty (Dk/t) can be calculated*. In an ideal world, the Holden and Mertz (1984) criteria should be satisfied (*see* Chapter 15).

2. Thickness

Consideration will have to be given to the strength of the lens (thicker lenses being generally more durable), lens handling (thicker lenses being easier to handle), comfort and gas transmissibility (see above) where thinner lenses have the advantage.

Regular hydrogel lenses for aphakia are thick, implying that their oxygen transmissibilities are low. Polse *et al.* (1978), in a provocative 5-hour test on aphakic eyes, found that corneal thickness increased by 7%. This was 3% better than phakic eyes (used for controls) but it is still a significant amount. The use of thinner designed lenses can reduce this corneal swelling. Bleshoy and Guillon (1984) found that the aspheric design used had a uniform thickness profile of about 0.21 mm. This was half the value of a conventional spherical lens design and ensured that oxygen transmissibility was even across the lens. However, the disadvantages of the design were that the lens did not always centre as well as expected and the visual performance (especially contrast sensitivity) was poorer as lens thickness decreased. Futhermore, because the lens was uniformly thin it tore more easily.

3. Total diameter

In common with rigid lenses, the total diameter of soft lenses tends to be 0.5 mm larger than for low-powered soft

*The CD-ROM accompanying this book allows the necessary Dk/t calculations to be made.

lenses on the same eye. This will keep the lens well centred and should not make the fit tight.

4. Material

In existing soft lens wearers any pre-disposition towards lens spoilation should be noted. In the elderly, a tendency towards dry eyes will lead inevitably to badly deposited lenses. If there has been a history of lipid desposition then the use of an ionic material, e.g. Permalens (Wesley Jessen) might be useful. If it has been one of protein deposition then ionic lenses should be avoided. If both lipids and proteins are being deposited then a biomimetic lens such as Proclear (Biocompatibles Ltd) may be indicated. Lens materials with strongly bound water are also advantageous. Maintaining a normal aqueous layer on the anterior surface of the soft lens ensures good comfort, reduces lens tightening due to dehydration and helps in minimizing surface deposition.

5. Lens fitting

As many soft lenses are relatively thick, the practitioner may need more control over the curvature of the back surface of the lens, especially if the corneal shape and scleral topography are outside normal limits. This may mean that more designs are tried in comparison to a low powered lens being fitted.

Extended wear lenses

The vast majority of extended wear (EW) soft lenses prescribed for aphakics are hydrogel lenses which can be costly. Management can be very different from the phakic patient using extended wear lenses (Janoff, 1983). The lenses tend to form deposits quickly and need more frequent replacement. The after-care is also time-consuming. For the person living alone who cannot handle contact lenses or look after them properly, the EW lens is a boon, but many elderly people are reluctant to seek help if they have a contact lens problem – they take the view that they are being enough trouble as it is without causing more. As a result serious infections can result (Carpel and Parker, 1985; Mondino *et al.*, 1986; Ormerod and Smith, 1986).

Hydrogels of 60–80% water content can be used for aphakic lenses. Again the total diameters are usually a little larger than for low power lenses. It is most important to give patients an adequate tolerance test as the older eye, being relatively dry, can cause severe lens tightening. In extreme cases all lenses tighten and this type of lens cannot be used. Some practitioners may consider using a silicone elastomer lens with dry eyes. Certainly the corneas stay exceptionally clear and oedema-free but deposits can still be a problem (*see Figure 20.5.6*)

Gas permeable rigid lenses can also be used for extended wear (Benjamin and Simons, 1984). The highest Dk materials available should be used. Elie (1986) reported good results with the Menicon EX material; Muir-Taylor and Levy (1985) reported success with the Paraperm EW material and Sigband (1986) claimed an 85% success rate using Boston IV material. For normal eyes, lens diameters of 9.3–9.8 mm suffice but in aphakia a larger total diameter may be required in order to prevent the lenses slipping off the cornea during sleep. The design of the lens should aim at minimum thickness and if a small front optic zone diameter is feasible this should be used. The main advantages of using rigid lenses are:

- Strength.
- Debris and excreta behind the lens are removed by blinking on waking.
- Higher gas transmissibilities are available compared to hydrogels.
- Better correction of corneal astigmatism.
- Easier to clean.
- Less corneal vascularization, microcysts, and infiltrates.
- Fewer red eyes.
- Fewer serious infections.

Refraction

If the pre-surgical ametropia was low then a trial contact lens powered at about +14.00 D is suitable for refraction. The contact lens prescription is found by taking the over-refraction and its vertex distance into account (*see* Appendix A). For example, if a +12.00 D trial lens on the eye required an over-refraction of +6.50 D with a vertex distance is 12 mm, then the effective over-refraction at the cornea is +7.00 D and the power of the contact lens required would be:

+12.00 and +7.00 = +19.00 D

With high powered soft lenses there are some bending effects on the eye (Chaston, 1979; Chaston and Fatt, 1980; Fatt and Chaston 1982; Weissman and Gardner, 1984). The over-refraction is carried out in the same manner but the final power of the contact lens may not correlate quite so closely to the spectacle prescription, as the power of a rigid contact lens.

The main characteristic of the aphakic patient wearing contact lenses compared to the patient with normal eyes is the variability of refraction and visual acuity. Even without a contact lens, factors such as pupil size, pupil position, vitreous variation and macular condition can all affect refraction and acuity. With a contact lens *in situ*, another high powered element is placed in the optical system. The contact lens is probably not static and lacrimation then affects lens position. It is the function of the practitioner to give as good a correction as possible. Having said that, the correction may well be a compromise and the patient should be advised about this. One of the advantages of fitting from an inventory of lenses is that power changes are easily made, but the power of the lens should not be changed at every after-care visit. Certainly over-refraction should be carried out and recorded, and perhaps some months later a

power change may be made in light of this information to provide a better spherical correction, once a consistent over-refraction is obtained.

If, for example, the spectacle Rx is as follows:

RE –4.00/–2.00 × 105 6/12

LE +14.50/–1.25 × 135 6/6

the practitioner should consider the spherical balance when the contact lens has been fitted. If the normal correction was applied to the contact lens for the left eye the spectacles would be:

RE –4.00/–2.00 × 105

LE Plano

The spherical imbalance might cause binocular problems. The practitioner has several options:

- If the second eye were due for a cataract extraction fairly soon then a normal full correction to the contact lens would be reasonable.
- If the patient can handle contact lenses, then a contact lens on the phakic eye might be accepted by the patient.
- Overcorrection of the aphakic eye's contact lens (using the above example) by about +4.00 D would result in a spectacle correction that would be:

  RE –4.00/–2.00 × 105, LE –4.00 DS.

  Cosmetically, the spectacle lenses would be balanced and there would be less likelihood of binocular problems.

In the case of soft lenses similar arguments apply. In addition, there is the likelihood that some correction of astigmatism will be required and this is best done with additional bifocal spectacles which correct both the residual astigmatism and the near vision.

The near correction

A near prescription for close work is usually needed for unilateral and always for bilateral aphakics. The practitioner should ensure that the near prescription is balanced. The patient should be told that the range of clear, near vision may be less in the aphakic eye compared with the normal eye. The choice of single vision or bifocal spectacles is determined by the individual's needs or preferences. In some cases varifocal lenses are appreciated (Koetting, 1969).

Multifocal and varifocal contact lenses

In the author's experience, the varifocal type of contact lens does not provide sufficient near power addition for satisfactory close vision. Some patients seem to manage the simultaneous vision types but it is dependent on the visual requirements, pupil characteristics, lens centration, optic diameters etc. (*see* Chapter 16).

UV protection and tinted lenses

All contact lenses prescribed for aphakia should provide some UV protection. It is now straightforward to incorporate UV blocking agents into rigid and soft materials. ISO/015 8321-2, dealing with soft lens specifications, describes two classes of UV absorbers. The more stringent would be suitable for contact lenses designed to correct aphakia.

Tinted lenses have two advantages to the aphakic patient. Firstly, the lens is more easily seen both on and off the eye and secondly, UV protection can be provided or increased if the tint is chosen carefully.

Fitting babies and infants

Although there are various reasons for contemplating the use of contact lenses for children (Kersley, 1978) the principal reason is for the correction of aphakia after congenital cataracts (*Figure 20.5.4*) have been removed (Holmstrom *et al.*, 1990). Fitting of contact lenses must always be considered in conjunction with an ophthalmologist (Morris *et al.*, 1979). Probably the most common lenses are either hydrogel or silicone rubber lenses fitted with the aim to use a daily wear modality from the beginning, if possible (Moore, 1985).

Silicone rubber lenses are very strong and fewer lenses are lost from the eye when compared with hydrogels (Nelson *et al.*, 1985; Hales, 1986; Matsumoto and Murphree, 1986). In some cases scleral lenses can be used (*see* Chapter 17).

With hydrogel lenses, the breakage and loss from the eye are more common than with silicone rubber or RGP lenses but deposition on the lens surfaces is rarely a problem when compared with elderly aphakic patients.

Paediatric contact lens fitting is covered in more detail below (Chapter 20.5).

After-care

After-care for aphakic patients is important and the general principles advised in Chapter 18 should be adhered to.

It is important that fundus and intra-ocular pressure checks are carried out at the same time as contact lens after-care and, where necessary, the patient should be seen by an ophthalmologist. The practitioner should also look for any changes in the lens capsule

The practitioner should carefully check hygiene regimens, enquiring about what solutions are used and when and how they are used.

Rigid lenses often need polishing due to poor handling. Surfactant cleaning by the patient may not have been very efficacious. Soft lenses may have significant deposits on them and nced replacing.

Geriatric population

Elderly patients may not be mobile and they may forget about appointments. Their eyes, being less sensitive than

normal, tolerate chipped and cracked lenses, lenses with significant deposits and early signs of infections. However, it should be remembered that the average life expectancy after a cataract extraction is relatively low compared to a young phakic population wearing contact lenses; therefore, long term problems are less relevant than in normal, younger eyes.

Soft lens wearers – especially those on extended wear – may develop corneal vascularization. Vessels may grow 3 mm or more in from the limbus but frequently stabilize at this level of invasion. The practitioner should consider carefully the patient as a whole. If life expectancy is short, it may be of little benefit to spend time and money trying to reduce the corneal vascularization. The patient may well be content, comfortable and seeing well; returning them to spectacles may lead to a poorer quality of life as a result of the visual distortion produced. This distortion may result in poor mobility and trauma. A discussion with the ophthalmologist is useful when considering the management of corneal vascularization in particular cases.

The younger aphakes

In these cases, corneal vascularization should not be tolerated and the same criteria applied as with the phakic population. Moving the patient from soft to rigid lenses is usually beneficial especially if the highest Dk material is used in conjunction with thin designs.

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Chapter 20.3 Postkeratoplasty

E. G. Woodward

Indications for keratoplasty p.713
Postkeratoplasty therapeutic lenses p.713
Postkeratoplasty optical lenses p.714
Fitting procedures p.718

In 1886 the first successful lamellar keratoplasty was performed by von Hippel. Two years later von Hippel (1888), reported that the patient's vision had improved from counting fingers to 6/60. In 1905 the first penetrating keratoplasty which remained clear and transparent was carried out by Edward Zirm on a patient who was blind as a result of lime burns.

Currently about 3500 transplantations are carried out each year in the United Kingdom (Easty, D. L., 1995, personal communication), 40 000 in the USA (Nenno and Abel, 1991) and 1000 in Australia (data from Australian Corneal Graft Registry, 1994). In contrast, only about 100 transplants a year are carried out in China, a country where it is estimated about 360 000 patients would potentially benefit from keratoplasty (Xiu and Feng, 1991). The number of procedures is steadily increasing all over the world but in many countries religious beliefs inhibit or prohibit donation of eyes.

Indications for keratoplasty

The indications for keratoplasty may be considered as optical, tectonic, therapeutic and cosmetic. Patients in all of these groups may have worn contact lenses prior to surgery and may, in fact, have failed with contact lens wear.

In the first group the most common indication, in the western world, is keratoconus and it also has the best prognosis. In a long-term study by Sharif and Casey (1991) it was reported that 93% of grafts performed for keratoconus remained clear over a follow-up period of six years and that 81% achieved a final visual acuity of 6/12 or better. Other frequent indications include stromal scarring following herpetic keratitis – 33% of patients with severe herpetic keratitis requiring keratoplasty (Menage and Claoue, 1988), corneal dystrophies, interstitial keratitis and trauma. In the Middle East, Africa and the Far East, trachoma, pterygium and measles keratitis are major indications for keratoplasty. The least successful outcome is usually considered to be with chemical burns in which, despite repeated transplantation, long-term results are poor (Casey and Mayer, 1984).

The term 'tectonic' is used in keratoplasty in its 'building' sense. For example if a cornea is very thin a large lamellar graft (tectonic) may be performed so that subsequently a smaller optical penetrating graft will have a host bed of reasonable thickness for suturing. In other words it is building up the cornea for later further surgery. A tectonic graft yields no immediate visual gain; in the short term it may render the cornea even more opaque.

Following keratoplasty for an optical indication, contact lenses may be used to maximize the visual outcome and for any indication they may have a role as a therapeutic device. Since chronologically, contact lenses are more likely to be used initially in a therapeutic mode, this application will be considered first.

Postkeratoplasty therapeutic lenses

Where an existing transplant (or graft) has perforated or is dehiscing a silicone rubber therapeutic lens may be used to reform the anterior chamber (Woodward, 1984). This can be a useful temporizing device, before regrafting, if theatre time or suitable donor material is not immediately available. A flat silicone rubber plano lens is inserted, usually having a back surface radius of at least 8.40 mm. As the perforation seals and the anterior chamber re-forms the lens becomes too flat and needs to be fitted more steeply. The relative rigidity of a silicone rubber lens is necessary for the successful sealing of a perforation. If such a lens is not available a low water content hydrogel lens may be tried but is rarely successful. An alternative approach to corneal perforations is sealing the hole with cyanoacrylate glue but here again a hydrogel therapeutic contact lens needs to be applied to protect the lids from the abrasive glue surface.

It is not usual to fit therapeutic lenses routinely following keratoplasty, but this management is advised in certain circumstances, for example after lamellar or penetrating keratoplasty for chemical burns where the donor epithelium has been retained (Casey and Mayer, 1974), or following corneoscleral grafting where failure to re-epithelialize is anticipated.

Other reasons include:

- Where there are protruding sutures which cannot or must not be removed. These cause discomfort to the patient and attract mucus. They may also act as a nidus for infection and stimulate vessel growth.
- If there is a leak due to faulty suturing demonstrated by a positive Seidel's sign (fluorescein instilled into the eye appears in the anterior chamber after a few minutes).

- Failure to re-epithelialize, or epithelial ulceration.
- Where a shallow anterior chamber follows grafting combined with drainage surgery for glaucoma.
- Where graft dehiscence has followed premature removal of sutures.

The choice of therapeutic lens is crucial and a number of differing lens designs and materials is necessary.

Therapeutic plano hydrogel lenses are manufactured as stock lenses by several companies and it has been suggested that disposable contact lenses may be used in the therapeutic mode (Gruber, 1991). These stock lenses usually have a total diameter of not more than 15 mm and a back optic radius of 8.70 mm or 9 mm. Unfortunately in the early stages after keratoplasty, when a therapeutic lens is most likely to be needed, the majority of these designs are too small or too steep. It is essential to obtain good cover with therapeutic lenses on corneal transplants. In addition most transplants at this stage, even when not leaking, are flatter than the surrounding host cornea. Because of this, in order to obtain good cover and good centration, larger, flatter, lenses are often necessary. At Moorfields Eye Hospital, London, England, the most frequently used lens forms for therapeutic use on corneal transplants are 9.00/15.00 and 9.50/16.50, although lenses of 18.00 or 20.00 mm total diameter are occasionally used, especially on corneoscleral transplants. Ruben (1978) suggested the use of a thin trapezoid lens on recently grafted eyes, this lens having a peripheral curve which is steeper than the central one.

As might be anticipated, materials with a high oxygen permeability are usually indicated, thus causing minimum metabolic stress to physiologically fragile new graft. An additional advantage of a high water content hydrogel is a commensurate high swell factor. With this, for a given blank size, a larger lens can be manufactured allowing greater scope in lens ordering. Lower water content materials are indicated where there are leaks or graft dehiscence as they form a firmer seal.

Lenses should be made as thin as possible compatible with reasonable handling. Insertion of lenses should be as aseptic and atraumatic as possible; very thin plano lenses can be extremely difficult to manipulate, particularly on a painful and tender eye (*see also* Chapter 20.7).

Postkeratoplasty optical lenses

It is usual to wait until most or all of the sutures have been removed before fitting optically powered contact lenses. If continuous suturing has been used, the final amount of refractive error and, in particular, corneal astigmatism is uncertain, thus the final refraction cannot be anticipated. If interrupted sutures have been used, these may gradually be removed over a period of time and the final refractive outcome predicted earlier. Occasionally there is an indication for the fitting of lenses to improve vision before suture removal. There may be pressing social reasons such as the retention of employment. The transplanted cornea may be in the only seeing eye and if spectacle corrected vision is unsatisfactory the patient may be unable to function in the workplace. Keratoconic patients may be at a crucial point in their career or training, or responsible for young children.

Fitting with sutures *in situ* is not considered likely to increase the risk of graft rejection but any contact lens-induced corneal oedema may cause vessel entry along the suture tracks (Steele, 1987, personal communication). In view of this, patients should be instructed to wear their lenses in 4–5 hour stretches only, with a break of at least 1 hour in between. When the sutures are eventually removed the lens invariably needs refitting and this should always be explained to the patient in advance.

A corneal transplant is an attempt to simulate a normal cornea in a normal eye, and in fitting contact lenses it is necessary to consider how successful that simulation has been (Woodward, 1981). Basic measurements demonstrate that both its physiology and topography are far from normal and that a grafted cornea lacks many of the inbuilt safety margins of the normal cornea and must be approached with particular caution.

The variations from normal will now be considered.

Keratoplasty thickness

Immediately following transplantation the donor button is extremely oedematous, its thickness then gradually returning to more normal levels. In the first year post-transplant, while steroids are still being used and sutures are *in situ*, the grafted cornea may be thinner than normal (Bourne, 1983). However, if corneal thickness is measured when all treatment has ceased and the sutures removed, the vast majority of transplants are thicker than normal. Ruben *et al.* (1979), in a study on 51 successful keratoplasties, showed a mean transplant thickness of 0.60 mm and found only 15% to be within normal limits. There was no correlation between the age of the transplant and thickness but there was correlation between visual acuity and transplant thickness, visual acuity falling significantly when the cornea was thicker than 0.62 mm. The implication of these findings is that, even with successful clear grafts, the majority are slightly oedematous even before the application of a contact lens.

Transplant endothelial morphology

Brown and Bron (1974) first showed that in many successful clear transplants individual endothelial cells are very much enlarged. It is now thought that most endothelial cell damage occurs at the time of keratoplasty, with more cells lost from the periphery of the transplant and recipient cornea nearer the host–donor junction than from the central area of the transplant. Cells are 'lost' from the central graft as they gradually move towards peripheral areas, enlarging as they do so. This slow process of cellular realignment lasts for approximately three years (Bourne, 1983). Ruben *et al.* (1979), on the same group of patients whose corneal thickness was measured, showed a mean endothelial cell

count of 1226.02 ± 393.84 mm cells for their grafted group as against 3233.62 ± 328.38 mm for a matched control group.

Although corneal thickness, near to normal limits, may be maintained with endothelial cell counts of less than a third of normal, clinical experience indicates that a cornea with a low endothelial cell density is more vulnerable to extraneous conditions that might induce corneal oedema. Thus the occlusive action of a contact lens to oxygen may prove too much for a cornea to cope with, resulting in neovascularization.

Transplant sensitivity

Resensitization of transplanted corneas occurs in a slow manner, and may be incomplete even after many years. There is some disagreement between studies where investigators evaluated transplants which had reached a different stage in their history and measured sensitivity at the same point in each. Skriver (1978) reported that sensitivity tended to be normal about 12 months after transplantation, whereas Ruben and Colebrook (1979b) could detect normal levels in only a third of their patients at the 3-year stage. They believed that the return of sensitivity was progressive. However, a later study by Rao *et al.* (1985) came to a different conclusion. These workers found that only a few eyes showed any recovery in sensitivity at the centre of the transplant, and this was not related to the length of postoperative period.

At the time of writing the only prospective longitudinal study of transplant sensitivity reported is by Macalister *et al.* (1993). This study showed that, in general, penetrating corneal transplants show slow but progressive recovery of epithelial sensation. However, individual transplants may show one of several differing patterns of resensitization. Recovery can be full, partial, or non-existent, and the rate of recovery can be rapid, slow or sporadic. At 4 years after transplantation, 68% of subjects had no central sensitivity, while only 9% had normal sensitivity. By 7 years 39% still had no sensitivity. Peripheral sensitivity did not show the variation between different quadrants that is seen in normal corneas. Peripheral sensitivity was higher than central sensitivity, which is in direct contrast to the situation in the normal cornea, and may indicate the expected centripetal progress of sensitization.

Most transplanted corneas are fitted with contact lenses soon after sutures are removed, which may be anything from 5 to 24 months after keratoplasty. This means that the majority of patients are fitted when their central corneal sensation is significantly reduced, if not absent.

This reduction in central sensitivity does not seem to make contact lens fitting any easier, possibly because there is no concurrent reduction in lid margin sensitivity. Indeed the presence of corneal sutures seems sometimes to have enhanced lid sensitivity, although this is not mentioned in the literature. Nevertheless, patients do not experience the usual discomfort produced by a corneal abrasion or corneal oedema. The symptoms relating to corneal oedema, about which transplanted patients complain, are nearly always visual ones.

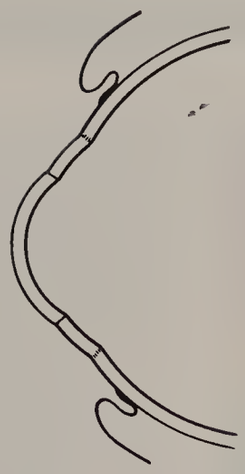


Figure 20.3.1 Corneal transplant in section: seen to be steeper than the host cornea, giving the effect of a nipple-like protusion

Transplant topography

When transplants are examined by photokeratoscopy it is found that there are no regular corneal transplants. Ruben and Colebrook (1979a) demonstrated that even the clearest corneal graft giving 6/5 unaided vision has only a small area (2–3 mm) of sphericity. Their results also suggested a decrease in post-graft astigmatism in patients wearing contact lenses compared with those who did not, possibly due to an advantageous moulding effect on the graft, particularly after the sutures had been removed. This was confirmed by Woodward *et al.*, in 1990. Two groups of patients who had transplants for keratoconus were analyzed. One group had been visually corrected with rigid corneal lenses and the other group had worn spectacles or no optical correction. The method of regression in groups was used to analyze the meridional differences in corneal curvature with time, for the two groups of patients. Both groups demonstrated a reduction in corneal astigmatism over the period analyzed and the percentage reduction was greater in the contact lens wearing group.

The irregularities of corneal grafts militate against successful contact lens fitting in several ways.

Nipple-like protrusion

Most graft margins are steeper than the host cornea and the transplant therefore protrudes slightly in a nipple-like manner (*Figure 20.3.1*). A tangential contour plot illustrates this (*Figure 20.3.2*). This protuberance has been attributed to the second anchor zone of collagen produced by scarring at the donor–host junction coupled with the lower rigidity of the transplant itself, due to its increased thickness, or high water content, or both. Many grafts are oversized by 0.2–0.3 mm in order to provide a better donor–host junction

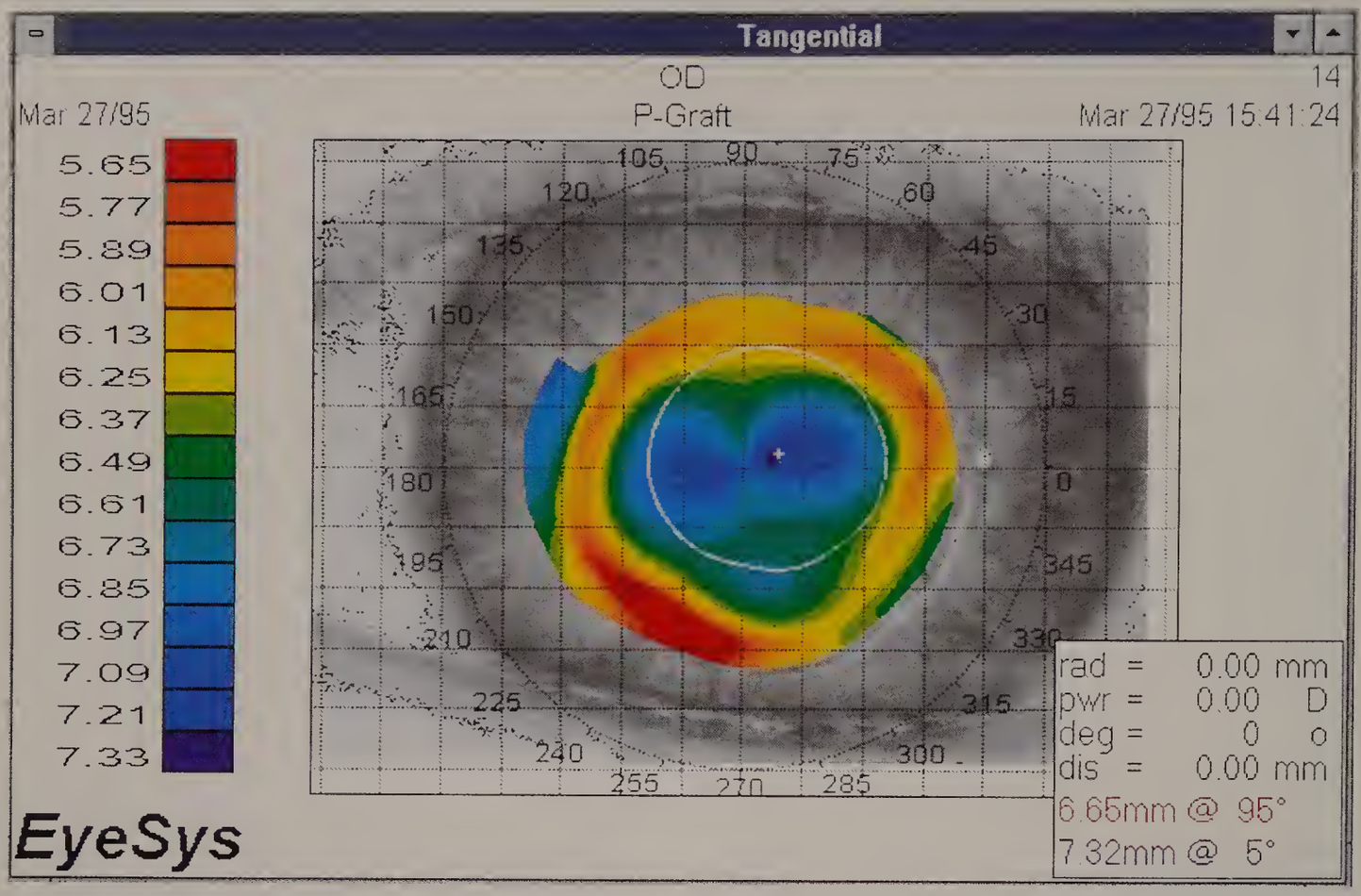


Figure 20.3.2 A tangential corneal topographical plot of a transplant showing with-the-rule astigmatism in the pupil area and a proud ridge at the transplant margin. The flat edge of the host cornea can just be seen beyond the graft. (Courtesy of A. J. Phillips)

seal (*Figures 20.3.3 and 20.3.4*). Whatever the cause, guttering formed by the abrupt change in curvature at the donor–host junction can cause problems to the contact lens practitioner. If the lens covers this area there is a likelihood of bubbles collecting. If the edge of the lens is near this sudden change of curvature, excessive stand-off occurs and the lens is unstable.

Transplant toricity

It has already been noted that there are no completely regular corneal transplants and all are toroidal to some

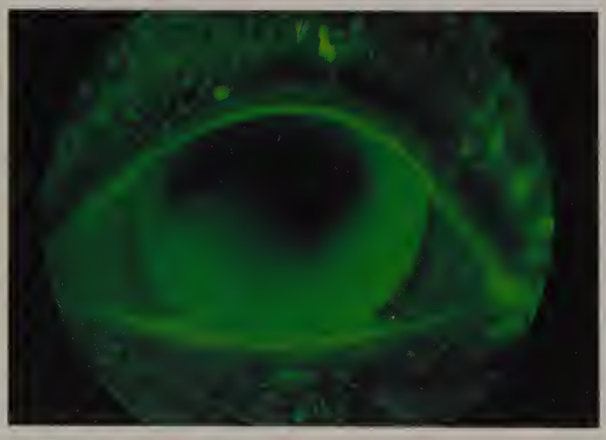


Figure 20.3.3 Corneal transplants commonly stand slightly proud of the host tissue. This is illustrated here by using a conventional tri-curve lens to align the graft. The clearance around the transplant area is easily visible. (Courtesy of A. J. Phillips)



Figure 20.3.4 'Optic section' viewing by slit-lamp microscopy of the graft-host junction in keratoplasty. The raised nature of the graft in this instance can be seen. (Courtesy of A. J. Phillips)

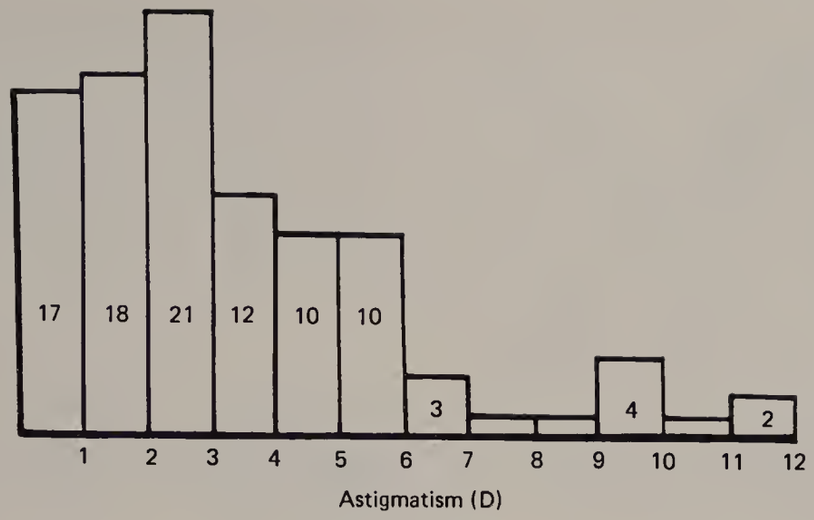


Figure 20.3.5 Distribution of postoperative astigmatism in keratoplasty following keratoconus (Davies *et al.*, 1977). The figures given in the histogram are percentages

extent. Ruben (1980, personal communication) reported that elliptical grafts with 1 mm difference between the major and minor axes produce less astigmatism, but these are technically difficult to perform.

The astigmatism produced by corneal transplantation, usually irregular, is the main reason why contact lens correction gives visual acuity superior to that obtained with spectacles in the majority of cases.

Davies *et al.* (1977) gave the method of optical correction following 100 grafts for keratoconus as shown in *Table 20.3.1*. As can be seen, 65% of patients needed some form of contact lens correction because of unacceptable visual distortion produced by significant degrees of corneal astigmatism. In this sample 65% of patients had more than 2 D of astigmatism, 23% between 4 D and 7 D and some were as high as 12 D (*Figure 20.3.5*). It might be thought that with improvements, both in suture materials and suturing techniques, there would have been a steady reduction in post-graft astigmatism over the years. However this does not seem to have been the case. Smiddy *et al.* (1988) reported on post-graft astigmatism following keratoplasty for keratoconus at the Johns Hopkins Hospital, Baltimore, USA. They found a mean corneal astigmatism of 4.5 D with a range of 0–12 D. Sixty per cent of the patients were corrected with contact lenses and 40% with spectacles; very similar figures to those at Moorfields Eye Hospital 11 years earlier.

Attempts are sometimes made to reduce post-graft astigmatism surgically by the use of relaxing incisions or wedge resections. However, despite the prior use of photokeratoscopy for guidance, the predictability of such surgery is still variable.

A toroidal transplant, caused by surgical technique or pre-existing in the donor cornea, in a spherical host cornea produces guttering in one meridian only. In *Figure 20.3.6* the vertical meridian shows this.

Table 20.3.1 Keratoconus: method of correction after keratoplasty

Method	*No. of cases*
Unaided	4
Spectacles	31
Corneal lenses	46
Scleral lenses	18
Hydrogel lenses	1
Hydrogel lenses plus spectacles	4
Total	104

Transplant tilting

A transplant may register only a low or moderate degree of astigmatism when measured with the keratometer, yet when

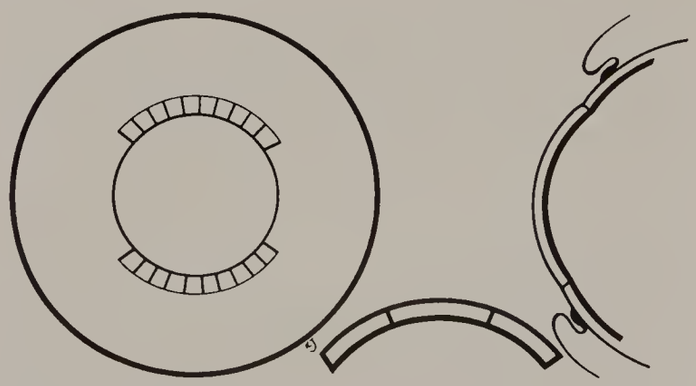


Figure 20.3.6 Guttering (shown hatched on the left-hand diagram) at the upper and lower graft–host junctions due to the host cornea being spherical whereas the graft is toroidal. The cross-sectional diagrams show the guttering in the vertical meridian (right-hand side) and the smooth graft–host junction in the horizontal meridian (lower diagram)

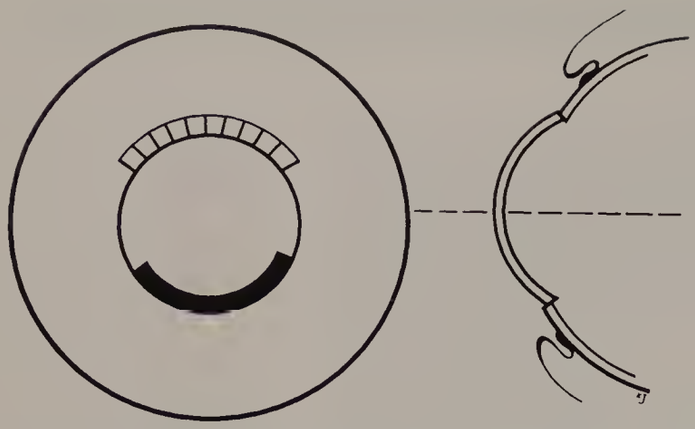


Figure 20.3.7 Tilted transplant. The hatched area on the left-hand diagram shows where the transplant tissue is proud whilst the black area shows where it is recessed. This can be seen more clearly in the right-hand cross-sectional diagram

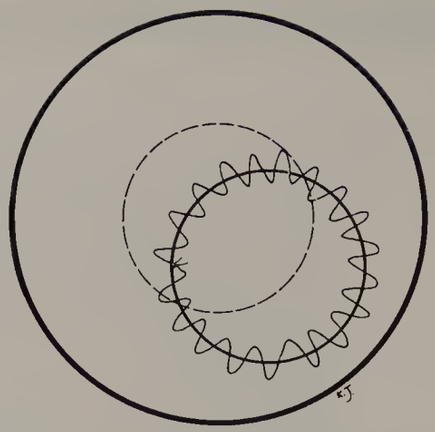


Figure 20.3.8 An eccentric transplant shown relative to pupil position, making contact lens centring relative to the visual axis extremely difficult to achieve

a corneal contact lens is fitted, it will not centre and shows excessive stand-off in one area. This is usually due to the graft being tilted in relation to the host cornea (*Figure 20.3.7*).

If the lens is large enough to bridge the graft there will be a localized guttering effect. In *Figure 20.3.7* this would be outside the graft superiorly, but inside the graft inferiorly. Tilted grafts present a severe problem to the contact lens practitioner and it is difficult to avoid persistent bubbles over a recessed area. However, a stationary bubble can soon induce localized corneal drying followed by neovascularization and must be avoided.

Transplant eccentricity

When transplanting a keratoconic cornea most surgeons centre their transplant on the thinnest part of the cornea, which is rarely on the visual axis of the eye. In the case of scarring produced by keratitis the graft is usually centred on what was the most densely scarred area. The implications of this are that a lens designed to centre on the graft may well be off the visual axis of the eye (*Figure 20.3.8*). Furthermore, although the postoperative complication of a dilated pupil, shallow anterior chamber and raised intraocular pressure (Uretts–Zavalia syndrome, 1963) is now considered rare, a partially dilated or sluggishly reacting pupil is not an uncommon sequel to keratoplasty.

Fitting procedures

The fitting of lenses to transplanted corneas generally follows conventional practice for irregular eyes. However, the physiological limitations of the transplant must never be forgotten and due awareness must be maintained for early signs of distress in the graft. Although high graft astigmatism is one of the main indications for fitting, the need to prescribe toroidal back surface lenses is no more than on normal eyes. Toroidal front surface lenses are sometimes necessary for visual reasons.

As stated earlier, the majority of transplants become less irregular with time after suture removal and it is usual for the eye to require re-fitting at least once in the first three years. It is also extremely difficult to design a suitable fitting set for corneal transplants. This is especially so for recent transplants, and most are fitted by a combination of accumulated old lenses from previous patients and experience.

Hydrogel lenses

As might be anticipated from the optical indications, hydrogel lenses are rarely fitted for visual reasons. In addition this type of lens may have a greater occlusive effect than a smaller diameter rigid gas permeable lens. As can be seen from *Table 20.3.1*, patients fitted with hydrogel lenses commonly require additional spectacles to obtain optimal visual acuity. A situation where they may perform satisfactorily on their own occurs where the patient is also aphakic. Here the greater central thickness of the lens reduces any residual astigmatism. However, this greater central thickness of the lens will also reduce its transmissibility, so wearing time may have to be limited. Extended wear, with the exception of thin plano therapeutic lenses, is definitely contraindicated with materials currently available.

Combination lenses and systems

It might be thought that with the high degrees of central corneal astigmatism found in transplanted corneas, there was a role for a two lens system as described in Chapter 20.1, p. 698. Unfortunately the combination of a soft hydrophilic lens beneath a rigid gas permeable lens invariably turns out to be a short-term expedient on a corneal transplant. The inevitable consequence after a variable period of time being neovascularization into the transplant.

The use of the Softperm combination lens, described in chapters 11 and 20.1, was proposed in transplanted corneas (Binder and Kopeckey, 1992). They were able to fit 14 of 22 transplants with this type of lens. This was a short-term study with a follow-up of only 3 months and there have been no further reports on the health of the transplants or eventual visual acuities. The low *Dk/t* of this lens also make it likely to produce neovascularization in the short to medium term.

Scleral lenses

Over the years the necessity for the use of scleral lenses has declined. Relieving incisions and wedge resections, despite dubious predictability, have reduced many of the gross cases of graft astigmatism. Nevertheless there are a few cases where a scleral lens is the only possible form of optical correction.

The advent of gas permeable materials has dramatically improved the performance of scleral lenses on transplanted corneas and the fitting of such lenses is fully dealt with in Chapter 17. On such eyes the best results seem to be obtained with minimum clearance over the transplant itself. A fluorescein picture which, on an ungrafted eye, would suggest the need for more central clearance is often satisfactory on a corneal graft. Adequate limbal clearance is most important as is the avoidance of bubbles impinging on the graft itself. Despite the use of gas permeable materials, long-term scleral lens wear on transplanted corneas must be monitored very carefully for signs of chronic hypoxia.

Corneal lenses

The majority of contact lenses currently fitted following corneal transplantation are corneal lenses manufactured from gas permeable materials. On grafts of long standing, where corneal topography begins to approximate to the normal, it may be possible to fit lenses of conventional design. But on more recent transplants, aggregation of the various corneal irregularities described earlier militate against conventional design lenses from centring on or near the visual axis. In order to obtain centration it is usually necessary to fit a larger lens.

When the only rigid lens material available was PMMA, fitting a larger lens usually produced graft oedema even where fenestrations were incorporated to improve tear exchange. The introduction of RGP materials suggested their use for the larger lenses on corneal transplants and these have been used since 1977 (Woodward, 1981).

The first material was one of the cellulose acetate butyrates, which by contemporary standards has a low permeability to oxygen. Notwithstanding this, lens designs which produced graft oedema, when manufactured from PMMA, usually did not do so when produced from CAB. It is unlikely that the relatively small increase in oxygen permeability was solely responsible for this, the lower wetting angle of CAB probably also had a beneficial effect. Possibly this lower wetting angle, combined with some gas transmissibility, alters the frictional forces between the posterior lens surface and tears in such a manner that there is an enhanced tear exchange beneath a lens manufactured from CAB as compared with same design in PMMA. In choosing a lens material from the highly permeable range available today, good wettability is therefore as clinically important as high permeability when fitting transplants.



Figure 20.3.9 Irregular graft–host junction being spanned by the back optic zone of a corneal lens

These larger lenses vary between 10.0 mm and 12.0 mm in total diameter and are of a simple bi-curve or tri-curve construction. Many transplants may also be successfully fitted using aspheric lenses of 10.30 mm TD or even occasionally 9.80 mm TD. As the intention is essentially to span both the graft and the irregular host–donor junction, it is essential that the back optic zone diameter be larger than the diameter of the graft itself (*Figure 20.3.9*).

Currently, the majority of transplants performed have diameters between 7.0 and 8.0 mm, hence the BOZDs of lenses prescribed vary between 8.0 mm and 10.0 mm. *Table 20.3.2* shows a suggested fitting set.

As suggested earlier, a dedicated fitting set for post-keratoplasty fitting has always to be considered as unlikely to contain the definitive lens. Most practitioners build one up from unsuccessful lenses! It should be explained to the patient that the definitive lens will probably not be achieved with the first fitting and this lens may have to serve as a subsequent fitting lens.

Keratometry represents curvature measurements taken near the centre of the graft so is not of great value in fitting. For these relatively large lenses, however, the flatter keratometry reading can be considered as an indication of an appropriate BOZR for a first trial lens. Fenestrations are occasionally employed, usually two or three 0.30 mm in diameter, 2 mm from the lens edge. Their function is not so much to enhance tear ingress, but to avoid the trapping of

Table 20.3.2 C2 Postkeratoplasty set

7.40:8.00/8.40:10.00	–2.00
7.60:8.00/8.60:10.00	–2.00
7.80:8.00/8.80:10.00	–2.00
8.00:8.00/9.00:10.00	–2.00
8.20:8.00/9.20:10.00	–2.00
8.40:8.00/9.40:10.00	–2.00
7.60:9.50/10.00:11.00	–1.00
7.80:9.50/10.20:11.00	–1.00
8.00:9.50/10.40:11.00	–1.00
8.20:9.50/10.60:11.00	–1.00
8.40:9.50/10.80:11.00	–1.00
8.60:9.50/11.00:11.00	–1.00
7.60:10.00/10.50:12.00	plano
7.80:10.00/10.70:12.00	plano
8.00:10.00/10.90:12.00	plano
8.20:10.00/11.10:12.00	plano
8.40:10.00/11.30:12.00	plano
8.60:10.00/11.50:12.00	plano

static bubbles (*Figure 20.3.10*). These frequently occur where the graft is slightly raised from the host cornea producing a gutter (*see Figure 20.3.4*). Conventional fluorescein patterns are very rarely obtained, criteria of satisfactory fitting being reasonable centration with the maximum bearing area and minimum hard touch.

Alternative lens types that can be used when fitting corneal transplants are lenses such as the OK80 range (Contex) which have a steep first peripheral curve (*see* Chapter 19) or flexible gas permeables such as the Ultracon (*see* Chapter 10).

Over a period of years, as the donor–host interface tends to become less irregular, it may become possible to fit lenses of a more conventional size. Even so, lenses with a total diameter of at least 10 mm are usually required. Where this is possible the Ruben Offset 2 design (described in Chapter 20.1, p. 701) or the Ciba Persecon 92E will usually centre more satisfactorily than axially symmetric multicurve designs. Even at this stage it is most unusual to obtain the same clearance all around the lens periphery.

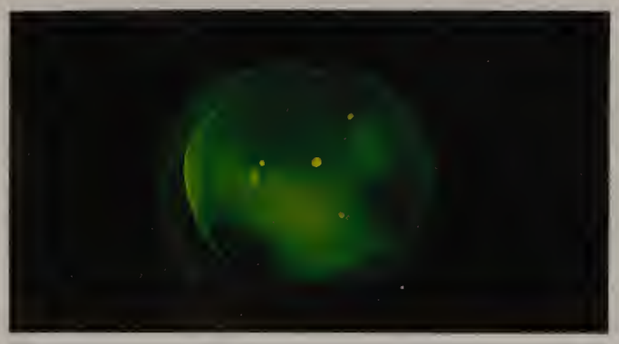


Figure 20.3.10 In some cases of corneal transplant a grossly irregular surface is produced, such that whilst a contact lens is the only means of producing reasonable vision, it is equally impossible to provide a normally fitting lens. The fluorescein fit shown is an example of the bizarre fitting sometimes necessary. Four fenestrations have been provided to prevent tear liquid stagnation in the gutter zones. (Courtesy of A. J. Phillips)

In summary, the fitting of transplanted corneas demands flexibility in lens designs and the thoughtful use of materials. Furthermore, whatever type of lens is fitted the intrinsic vulnerability of the transplanted cornea must not be forgotten.

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Chapter 20.4 Radial keratotomy and photorefractive keratectomy

Christine L. K. Astin

Radial keratotomy p.721
Problems with radial keratotomy p.721
Contact lens fitting and problems p.723
Photorefractive keratectomy p.726
Contact lens fitting p.727

Radial keratotomy

Radial (or incisional) keratotomy (RK) is a surgical procedure for reduction of myopia by incision into the anterior portion of the cornea, avoiding a central zone of 3–4 mm diameter (*Figure 20.4.1*). No sutures or supports are involved.

The procedure and effect of the number of incisions (usually 4, 8 or 16, equally spaced) have been described in several papers (Fyodorov and Durnev, 1979; Nirankani *et al.*, 1982; Waring *et al.*, 1991a,b). The incision depth is usually 90–95% of the previously measured central corneal thickness. Some surgeons cut to a depth equal to central thickness in order to further reduce myopia, but in so doing risk perforating Descemet's membrane.

The rigidity of the cornea is decreased such that intraocular forces act on the cornea, causing the mid-peripheral regions to 'bulge' forwards (*Figure 20.4.2*), effectively giving an apical cap of flatter curvature than that measured preoperatively. This flatter central curvature has less refractive power and results in a hypermetropic shift, hence reducing the original myopia. The extent of this and its relation to the curvature changes have been investigated by a number of researchers, including Akers and Binder (1981), Bores *et al.* (1981), Cowden and Cichocki (1981), Jester *et al.* (1981), Yamaguchi *et al.* (1981), Arrowsmith *et al.* (1983), Sanders *et al.* (1985), Astin (1991), Waring *et al.* (1991a,b) and Bates *et al.* (1992).

The corneal power change is usually greatest within the first few days postoperatively. During the following 6–12 months, the incisions heal with scar tissue or new collagen. The corneal rigidity increases and induces a change in the corneal shape returning towards the original shape and power, with variability of healing in each case.

Central keratometry readings taken at intervals show the radius of curvature gradually decreasing from the post-operative value, but still tending to remain greater than the preoperative value. Some studies (Sanders *et al.*, 1985; Schanzlin *et al.*, 1986) indicate stabilization by 1–2 years, but some patients still show changes at 5 years (Astin, 1991).

Example:

	Preop.	Postop.	1 year later
Keratometry	8.24 al 180	9.11 al 180	8.89 al 180
(mm)	8.10 al 90	8.93 al 90	8.77 al 90

The corneal contour becomes relatively flat centrally and steepens between the mid region and periphery of the cornea (Rowsey *et al.*, 1988; Fleming, 1992). The central plateau shape and mid-peripheral 'knee' shows a similar topography to that of the oblate portion of an ellipse. This can be monitored during the stabilization period using a videokeratoscope (Bogan *et al.*, 1991; Moreira *et al.*, 1992). In some cases the central plateau remains very flat (Damiano and Forstot, 1991).

Problems with radial keratotomy

Optical changes

Radial keratotomy may give a good result as measured by Snellen visual acuity, but there may also be residual visual impairment from the operation as follows.

Anisometropia

If both eyes are myopic and one eye is operated before the other, there may be up to 9 dioptres difference between the ocular refraction of the two eyes, possibly leading to diplopia and disturbed binocular fusion. If both eyes undergo the operation, they may stabilize differently from each other. Residual anisometropia can result in different retinal image sizes and possible intolerable prismatic effects of any corrective spectacles.

Diurnal fluctuation of vision

Cowden and Bores (1981) found visual fluctuations in two-thirds of their 20 study cases, with no relationship to incision or central zone size. Schanzlin *et al.* (1986) suggested a relationship to corneal curvature changes.

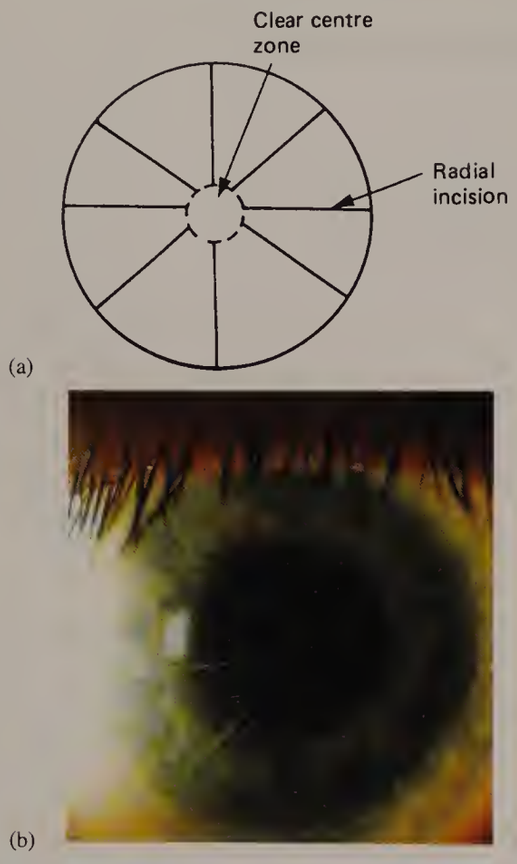


Figure 20.4.1 Incision pattern in radial keratotomy: (*a*) diagrammatically and (*b*) as seen with a slit lamp using sclerotic scatter

Kwitko *et al.* (1992) investigated diurnal variation in vision and corneal topography, finding increased myopia during the day.

Vision can vary throughout the day but spectacles are not an adequate correction during periods of poor or changing vision. Generally, a central steepening of anterior corneal curvature occurs as the day progresses, necessitating evening use of spectacles or contact lenses. Most stabilize at a point near to their evening refraction (Rowsey and Balyeat, 1982). Waring *et al.* (1991b) found some refractive instability as long as four years after RK and speculated that corneal hydration and lid squeezing play a part in this problem.

Astigmatism

A possible increase in astigmatism may result in unsatisfactory vision, even if the degree of myopia is diminished. The amount of astigmatism can also vary during the day, and so be difficult to correct with spectacles. Persistent irregular astigmatism may result from transverse crossing radial incision performed in an attempt to reduce astigmatism and from erroneous incisions near the visual axis.

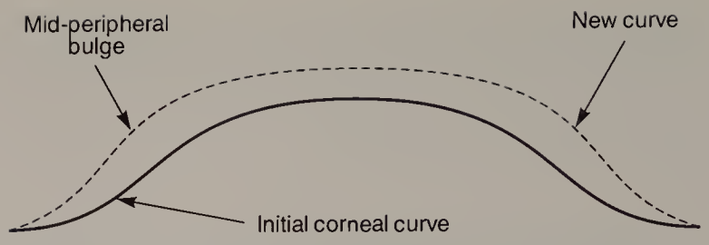


Figure 20.4.2 Mid-peripheral region 'bulges' forward after radial keratotomy

Example

	Preop.	Postop.
Refraction	–1.25/–4.00×15	–0.50/–5.00×20
Visual acuity	6/6	6/9
Keratometry	8.63 al 10	9.20 al 15
(mm)	7.99 al 100	8.45 al 105

One year postoperatively the patient was fitted with a HEMA soft toric lens 9.00:14.0×12.50 of BVP = –0.50/–4.00×15 which gave a visual acuity of 6/7.5 and daily wear of 10 hours per day without problems.

Increased sensitivity to glare

This and difficulty with detailed vision in low illumination seem to correlate with the size of the optical zone and the width of the incision scars. Clinical glare tests by Miller and Miller (1981) indicated that for pupil diameters greater than 5.0 mm, 40% of their 80 patients noticed disability glare above the 20% level. Glare gradually diminishes as scar density decreases up to 5 months, but persists in some patients. The increase of pupil diameter causing reduction in vision quality was investigated by Applegate and Gansel (1990) and Holladay *et al.* (1991).

Residual ametropia

This may be more than the patient expected, as shown in the previous example, and may persist for many years after the RK procedure (Anon., 1989; Waring *et al.*, 1991b). Repeating the operation may give even less predictable results (Kornmehl, 1991; Lindquist *et al.*, 1991) and increases the risk of permanent tissue damage. Regression of the corneal contour towards its preoperative shape and hence regression of the induced power change are more likely if the original myopia was of a high degree or the incisions were shallower than intended.

Physiological changes

Few papers on RK have revealed significant effects on the corneal physiology or evidence of endothelial cell loss although Waring (1984) enumerated the following serious

pathological risks of RK: cataract, endophthalmitis, bacterial keratitis and persistent corneal oedema.

Several laboratory studies on animals have shown that the globe may rupture more easily along the keratotomy wounds (Larsen *et al.*, 1983; Binder, 1988); although such problems are rare in human eyes (John and Schmitt, 1983; Simons and Linsalata, 1987).

Bates *et al.* (1992), reviewing a carefully monitored group of 300 cases, noted few problems. However, more needs to be known about the long-term effects of RK on resistance to infection and the risk of delayed wound healing following future surgery.

Bores *et al.* (1981) described small corneal changes and the problems presented when fitting contact lenses after RK. They described vessel ingrowth along incision scars 4–6 weeks postoperatively in eyes fitted with extended wear soft contact lenses. Within the incisions were noted the occasional appearance of: epithelial inclusion cysts, epithelial ferrous lines, degenerative blood products, foreign bodies, blood vessels, focal thickening of Descemet's membrane and small dense scars. Less myopia reduction was achieved when such features were present. Corneal perforation has become less common as more accurate pachometry and calibrated surgical knives have become available.

Delayed corneal wound healing with epithelial retention cysts remains the most common histopathological problem following RK, and could explain the lack of predictability and the long-term instability of refraction (Rashid and Waring, 1989; Jester *et al.*, 1992).

Why contact lens fitting may still be necessary

- Residual astigmatism.
- Residual ametropia.
- Anisometropia.
- To stabilize vision either by 'supporting' the cornea, or by providing a corrective tear liquid lens between a rigid contact lens and the fluctuating corneal shape.
- To make glare less noticeable.

Contact lens fitting and problems

Soft (hydrophilic) contact lenses

Astin (1986, 1994) and Hoffman *et al.* (1986) found that fitting soft lenses is very similar to fitting a normal cornea. The diameter of the first lens should be 1–2 mm greater than the horizontal visible iris diameter. For 38% water content soft lenses of centre thickness 0.06–0.12 mm, the back optic zone radius (BOZR) of the initial lens should be 0.50–0.80 mm flatter than the flattest keratometry (K) reading. In high water content lenses (60–75%) and ultrathin lenses (t_c = 0.04–0.12 mm) the BOZR should be 0.20–0.40 mm flatter than the flattest K reading. Close observation of the lens centration and movement after 20–30 minutes settling time should be made. The lens should centre correctly on the cornea but give 1–2 mm movement on full blinks. There should be neither conjunctival indentation nor vessel blanching. The advantages of soft lenses over corneal lenses are the same as those found in normal fitting. They 'wrap round' the irregularly shaped cornea and cause less edge sensation. They are also less likely to move or decentre. Easier adaptation and the larger BOZD are also advantages. Some patients prefer soft lenses having had previous problems with corneal lenses. Careful over-refraction should be carried out and the patient warned that vision may still vary.

Other recommended features required of the lens are good oxygen transmission, good edge quality and a deposit-resistant surface. Persistent lens deposits can give an increased risk of epithelial erosions, infection and allergy. It is not advisable to fit thick soft lenses in order to mask some residual astigmatism, as the reduction in oxygen transmissibility and increased pressure on the cornea can lead to greater corneal curvature changes and the increased risk of vessel ingrowth.

Problems with soft hydrophilic lenses

On unoperated eyes, the fitting of a soft lens can vary both with the hydration of the lens and also between individuals with differing peripheral corneal contours even with similar keratometry readings. On an RK patient there is an additional variable due to the diurnal variation in corneal contour and power. It is better to wait until the cornea has stabilized before attempting lens fitting and always to avoid a tight lens. Where possible, corneal thickness and topography should be measured at after-care visits to check for any adverse effects.

Shivitz *et al.* (1986) emphasize the increased incidence of corneal stromal vessel growth following soft contact lens wear. It is possible that the operation alters the oxygen requirements of the cornea or the mode of oxygen flow through the stroma. Endothelial cell loss could be a factor, although Steele (1984) did not reveal a significant loss after RK.

Even when a lens of high oxygen transmissibility is fitted, there may be pressure at the limbus (or negative fluid pressure between the lens and the eye) which could affect corneal curvature and epithelial physiology. Another possibility is that the flexing of imperfectly healed corneal segments acts as a stimulus to neovascularization, therefore extended or prolonged wear of contact lenses is not recommended. Evidence of vessel growth along the scar lines was reported by Bores *et al.* (1981). Soft lenses more easily retain deposits and so lead to an increased risk of epithelial erosions and infection, particularly where there is poor epithelial healing over the incisions (Karr *et al.*, 1985).

Soft lenses are more stable on the eye than rigid lenses and more adaptable if variable wearing times are required. Where possible the wearing time should be kept low to avoid vessel hyperaemia or ingrowth.

Example:

Two-year postoperative measurements:

Vision unaided	6/18
Refraction	–1.00/–1.00 × 170 VA 6/6
Keratometry	7.70 al 5 7.60 al 95
HEMA soft lens fitted	8.70:13.50 –1.00 D VA 6/5

At the 6-week follow-up, after 5 hours lens wear:

Vision unaided	6/5

After lens removal:

Refraction	–0.25 DS VA 6/5
Keratometry (mm)	7.97 al 180 7.84 al 90

Gradually this patient could manage most of the time without lens wear.

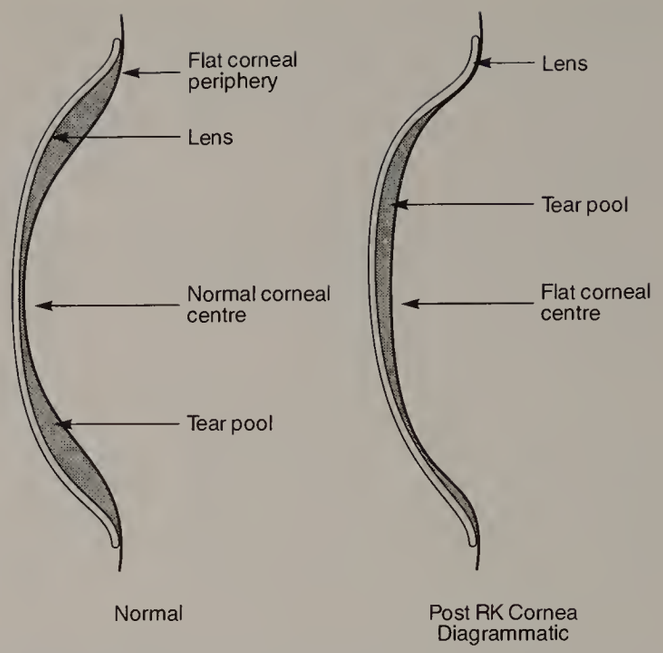


Figure 20.4.3 Standard design rigid contact lens on (*a*) a normal cornea and (*b*) post radial keratotomy

Rigid contact lenses

As with all RGP lens wear a material with good surface wettability and oxygen transmissibility is recommended as poor transmission of oxygen may lead to corneal oedema, resulting in reduced vision, and neovascularization. Changes in corneal curvature, including irregular astigmatism, may not recover as quickly in an RK patient, who is probably more susceptible to induced corneal warping.

After RK, the central corneal 'cap' is wider and needs a larger back optic zone diameter (BOZD) to cover it and give lens stability. Fitting sets are designed for the prolate elliptical contours of most unoperated eyes (*see* Chapter 10), and show excessive edge clearance and mobility on the RK eye. Rather than fit a steep lens, likely to produce excess central pooling with trapped bubbles and restricted tear flow, it is better to fit a minimum edge clearance aspheric lens, e.g. Quantum or Persecon, or to redesign a tri-curve lens to give less edge clearance. (*See below* for examples of trial fitting sets.)

Fluorescein assessment should reveal good tear flow beneath the lens and avoidance of undue pressure on the mid-peripheral region. The 11.50 mm TD lenses are fitted in a similar way to the Apex lenses fitted after penetrating keratoplasty (*see Table 20.3.2*). Slight central pooling gives a positive powered liquid lens, so extra negative power in the contact lens is necessary to counteract this. Some practitioners fit steep lenses then fenestrate to assist tear flow and the release of bubbles. Fenestrations may be unnecessary if excessive pooling is avoided.

There is no longer a central steep corneal region to assist contact lens centration and the negative aspheric corneal shape complicates lens fitting (*Figure 20.4.3*). The steep 'knee' in the peripheral region and any fluctuation of corneal topography may preclude satisfactory lens fitting. The RK contour encourages the lens to ride either very low or be held high by the upper lid (*Figure 20.4.4*) due to the reduced area of corneal alignment.

If the lens rides high, the lower edge projects forward, irritating the inferior lid margin on blinks. This gives rise to frothing, dimpling, increased mucus production and possible decentration. Care must be taken to ensure that the BOZD is large enough to avoid flare, especially in dim illumination.



Figure 20.4.4 Rigid gas permeable contact lens on a radial keratotomy eye

Examples of standard RGP lens fitting sets for radial keratotomy cases with aspherical back surface designs

1. **Quantum (Bausch & Lomb)**, Material: fluorosilicone copolymer, Dk 92, BOZR 7.20–8.40 mm in 0.1 mm steps; BOZD 8.00 mm; TD 9.00, 9.60, 10.20 mm.
2. **Persecon 92E Elliptical (Ciba Vision)**, Material: silicone-based copolymer of Dk 92, BOZR 7.30–8.50 mm in 0.1 mm steps; BOZD 8.00 mm; TD 9.30, 9.80, 10.30 mm.
3. **Aspheri P (Jack Allen, UK)** Material: wide variety of gas permeable types, BOZR 7.30–8.50 mm in 0.1 mm steps; BOZD 8.00 mm; TD 9.30, 9.80, 10.30 mm.

Examples of tri-curve lens designs

1. TD 11.50 mm
   BOZR 7.50–8.50 mm in 0.1 mm steps

   BPR_1 = BOZR + 2.00 mm; BPD_1 = 10.50 mm;
   BPR_2 = BOZR + 3.00 mm; (AEL 0.37–0.25 mm)

   Example: C3 8.00: 9.50/10.00:10.50/11.00:11.50

2. TD 10.00 mm
   BOZR 7.50–8.50 in 0.1 mm steps

   BPR_1 = BOZR + 1.00 mm; BPD_1 = 9.00 mm;
   BPR_2 = BOZR + 2.00 mm; (AEL 0.18–0.12 mm)

   Example: C3/7.50:8.00/8.50:9.00/9.50:10.00

If the lens is to be lenticulated, the front optic zone diameter (FOZD) should be at least 9.00 mm in Example 1 and 8.00 mm in Example 2.

Alternative methods of fitting

Shivitz *et al.* (1986) and Janes and Reichie (1986) described conventional procedures of fitting soft lenses based on postoperative keratometry and a fitting trial. Vickery (1986) suggested a large, 15.0 mm diameter, 55% water content soft lens aiming for a loose fit to allow the lens to drape over the flat RK contour with closer central corneal alignment, thereby avoiding limbal indentation and the variable vision given by a steep centrally vaulting fit. Anderson (1988), whilst agreeing with this method, also suggested the Softperm soft–rigid combination lens to stabilize the fit and correct astigmatism. However, the limitations of the Softperm design may lead to immobile lenses and pressure on the epithelium, which may aggravate the RK cornea more than a normal eye. Because it is so necessary to avoid a tight fit, it is recommended to allow extra time for the lens to settle and tighten on the eye before assessing the fit. Bearing in mind the environmental factors that affect soft lenses, it is safer to aim for a slightly loose fit than risk the lens tightening on the eye (*see* Chapter 11).

Rigid gas permeable lenses may be fitted in different ways. Goldberg (1993) utilized a special RK design lens with a toric or spherical base curve which produces light central corneal touch and clearance of the peripheral cornea. If an aspheric design is used it more closely aligns with the corneal contour. With information from keratoscopy, Anderson (1988) ignored central readings and recommended a trial lens of BOZR equal to the mid-peripheral corneal curvature.

Moore (1988) suggested a method of controlling the excess lens mobility by fitting a small, steep lens with the BOZR much stecper than the central corneal curvature. This was based on the preoperative keratometry readings and not necessarily related to postoperative measurements. Shivitz *et al.* (1986; Shivitz, 1988) recommended a large diameter lens with a BOZR of mean value 1.09 mm (5.9 D) steeper than the flattest postoperative *K* reading, making it similar to the preoperative values. The steep fitting lenses produced deep central pooling beneath the lens, adding positive power which had to be compensated for by extra negative power in the lens. Janes and Reichie (1986) aimed for a steep fit using a 9.50 mm diameter lens of BOZR 0.30 mm (1.50 D) flatter than the mean preoperative keratometry. Another technique was based on postoperative peripheral measurements from photokeratoscopy (Greco, 1986).

Steep fitting of rigid lenses restricts the tear flow beneath the lens and may lead to corneal oedema, epithelial disturbance, visual blur, refraction and curvature changes, and decreased tolerance to lens wear. In order to reduce these problems and to facilitate the escape of bubbles from under the lens, fenestration, BOZR flattening and increasing the oxygen permeability of the lens material have been tried. Even incorporating these adjustments, steep fitting lenses are still liable to cause corneal indentation by the lens edge and inhibit tear flow and the flushing of debris and waste products from beneath the lens.

El Hage and Baker (1986) and Karlin (1986) used rigid lenses to attempt orthokeratology on the RK cornea. The lens had a flat BOZR and the peripheral curve had a radius of curvature 0.75 mm steeper than the BOZR. Their aim was to apply controllable pressure on the corneal periphery to adjust the overall shape and thereby reduce any induced hypermetropia. Forced kerato-reformation by a tight lens increases the risk of corneal oedema and irregular astigmatism. Several years after RK, the cornea remains susceptible to curvature changes following rigid and soft lens wear (Edwards and Schaefer, 1987; Astin, 1991).

Summary of problems arising from contact lens wear

Numerous studies have investigated the physiological influence of lens wear on the RK cornea (Bores *et al.*, 1981; Katz *et al.*, 1982; Anderson, 1988; Ruben and Chu, 1989). As already mentioned, the risk of corneal compromise increases with tight fitting, over-wear, damaged and deposited lenses, and inadequate lens hygiene.

Binocular vision difficulties may arise, particularly if only one eye has had RK performed. Each eye may have

differing lens movements, anisometropia and accommodation demands. Some patients, rendered hypermetropic by RK, notice presbyopia earlier, or have to adapt to a new convergence–accommodation ratio. Without care in lens handling, the cornea may be abraded by the lens or finger leading to more serious infections and recurrent epithelial erosions in the RK eye. Distortion may be produced by eye manipulation on lens removal. These risks are influenced by the method of surgery and the healing response (Cotliar *et al.*, 1985).

Photorefractive keratectomy

Photorefractive keratectomy (PRK) is performed using argon fluoride excimer lasers which emit ultraviolet wavelengths (193 nm) of high proton energy capable of breaking intermolecular bonds within proteins and other large molecules without causing thermal damage to nearby tissues (Trokel *et al.*, 1983; Marshall *et al.*, 1988), Smooth, precise changes in the anterior corneal surface are produced by tissue ablation at 0.25 μm per pulse. The beam is adjusted according to the resultant tissue shape required. Usually the ablated zone perimeter has a graduated edge to discourage epithelial cells from filling in the area and so reducing the optical effect. Following the PRK treatment, the healing response results in the thickening of the zone due to subepithelial deposition of and growth of new layers of epithelial cells (Tuft *et al.*, 1989). Various grades of subepithelial haze have been noted. PRK for myopia results in a hypermetropic shift then a partial regression of the refractive effect over a variable period ranging from a few

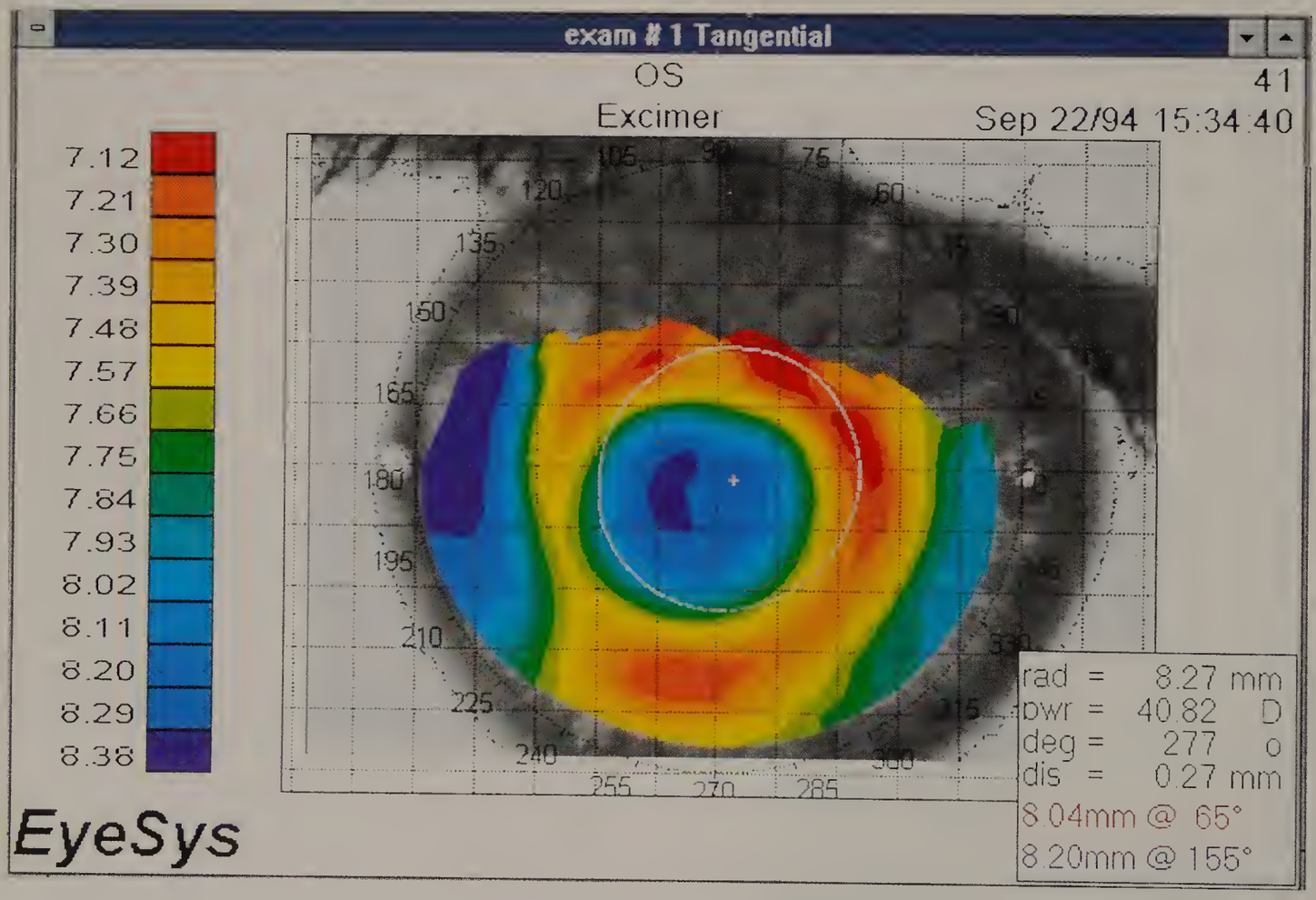


Figure 20.4.5 A tangential corneal topographical plot of an eye that has undergone photorefractive keratoplasty. It can be seen that the ablated area (blue) is decentred in relation to the pupil (white ring). The patient had her myopia reduced from –8.00 to –2.00 D. Although night-time flare is evident and a residual myopic error remains, the patient considers herself successful as she is not reliant on a contact lens for the eye when windsurfing. (Courtsey of G. J. O'Callaghan and A. J. Phillips)

weeks to several months (Ficker *et al.*, 1993; Stevens *et al.*, 1993).

As PRK becomes more widely available, there will be an increasing number of patients whose refractive problems are only partially solved by PRK. Post-PRK contact lens correction (PRKCL) of regression or irregular astigmatism will be required.

Information regarding the corneal response to PRK has increased following research at several centres in Europe and in the USA (Gartry *et al.*, 1992; Salz *et al.*, 1993; Sher *et al.*, 1992; Tengroth *et al.*, 1993) and in Australasia with Lakkis and Brennan (1993) describing the advantages and disadvantages of the procedure. Consideration of this information and the requirements for satisfactory contact lens wear are important when fitting lenses after PRK.

The main reasons for fitting are to correct residual ametropia. Gartry *et al.* (1992) showed that anisometropia and irregular astigmatism are probable following PRK treatment of high degrees of myopia. *Figure 20.4.5* shows a computerized corneal plot after PRK for –8.00 D of myopia. Contact lenses causing corneal moulding or undue pressure on the ablated cornea are not recommended.

Some patients have been fitted with soft therapeutic lenses for the week following PRK in order to protect the epithelium as it regrows over the ablated zone. This can relieve the ocular pain experienced in the first two days, but has not been proved to promote better epithelial healing.

As with RK patients the typical PRKCL patient is dissatisfied if PRK has not solved all their visual problems. Hence there is a disinclination to return to sensible lens wear and care and so further instruction and advice is needed in these matters.

Initially there were several concerns regarding the fitting of lenses to the post-PRK eye and the corneal response to contact lens wear. Del Pero *et al.* (1990) found apparently normal epithelial healing and adhesion over the ablated surface. Wilson *et al.* (1991) found that the corneal topographic and refractive status took between 6 and 12 months to stabilize. Therefore it is advisable to wait approximately 12 months before lens fitting.

Contact lens fitting

When the ablation zone is relatively small, e.g. 4.5 mm in diameter, and the curvature change at the zone margin is gradual, as described by Klyce *et al.* (1991) and Shovlin (1992), the problems of excess edge clearance and instability of movement of RGP lenses, which are found when fitting post-RK patients, are not encountered (Astin, 1994, 1995). In PRK, the peripheral region is not affected. Six months postoperatively the central corneal thickness returns to 90% of its preoperative value so that the central pooling beneath the lens is not excessive. The RGP lens bridges over the central ablated zone easily, allowing the corneal periphery to support the lens (*Figure 20.4.6*). An

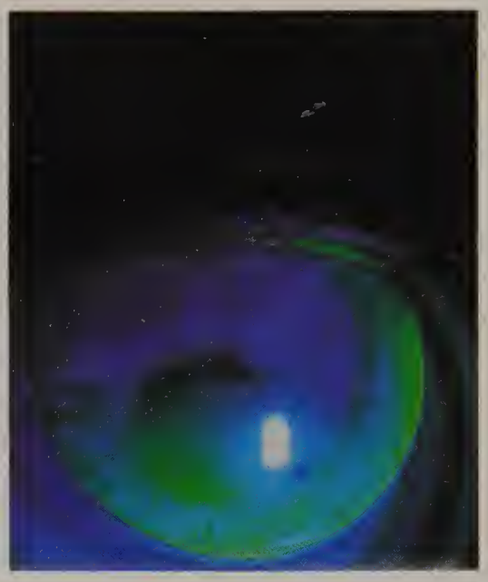


Figure 20.4.6 Rigid gas permeable contact lens on cornea after photorefractive keratectomy (PRK)

example of keratometry readings before and after PRK are as follows:

	Post-op. 1 week	Post-op. 6 months	Post-op. 12 months
7.60 al 180	8.49 al 175	8.13 al 180	8.10 al 180
7.44 al 90	8.23 al 85	7.82 al 90	7.83 al 90

When a large refractive power change is attempted, the ablated zone is likely to be wider (6–7 mm) and deeper; it is then more difficult to achieve satisfactory lens stability.

Aspheric back surface lens designs are recommended as these follow the peripheral corneal contour, spreading lens pressure, allowing smooth lens movement and encouraging good tear flow beneath the lens. The first trial lens has a BOZR of typically 0.25 mm (1.25 D) steeper than the flattest K reading. The total diameter of the RGP lens is 9.20–10.00 mm, depending on the lens design.

Good tear exchange and wettability are important to facilitate lens movement, thereby avoiding epithelial erosions, remove debris and supplement the corneal oxygen supply. As with any lens fitting, adequate oxygen transmissibility is required to reduce the risk of corneal hypoxia. Rigid lenses may need an extra –0.50 dioptres power to neutralize the positive power of the tear pooling underneath the lens. Before fitting, the PRK eye should be carefully assessed and measured.

Examples of RGP lens designs are the Persecon 92 E or Aquila Elliptical (Ciba Vision), Quantum (Bausch & Lomb) and Metro GP (Cantor & Silver, UK). For both RK and PRK patients the OK605A (*see* Chapter 19) may work well. This utilizes 'reverse geometry' (*see below*) and can be made with a 6.0 or 6.5 mm BOZD.

Edwards *et al.* (1995) developed a post-PRK lens which shows a fluorescein pattern similar to that of a standard lens

on a normal eye. The lens has a 'reverse geometry' design, such that the peripheral curves are steeper than the central curves (*see also* Chapter 19). The lens is available from Madden and Layman (UK) and is made to order. The practitioner needs to supply the company with either the pre- and post-PRK refraction or the pre- and post-PRK keratometry (and if possible topographical maps) and the post-PRK refraction.

Some patients, who complain of lid discomfort with RGP lenses before and after PRK, may be refitted with a daily wear soft lens. The lens diameter is selected as 2.0 mm larger than the visible iris diameter. Most types of soft lens can be used, but it is important to aim for maximum oxygen transmissibility. For a diameter of 14.00 mm, a radius of curvature 0.30 mm (1.50 D) flatter than flattest *K* reading is commonly chosen as the first trial lens. Soft lens fitting is judged on good centration, adequate movement and the lack of conjunctival and limbal vessel indentation after 20 minutes. If the corneal astigmatism is of a small degree, soft lenses can give good visual results.

Typical examples of soft lens designs suitable for fitting include CSI (Wesley-Jessen), ES70 (Lunelle) and Optima 60 (TD optics).

Visual blur during lens wear may be due to lens surface greasing or pre-existing reticular corneal haze resulting from the PRK. This effect shows up more in bright conditions (Lohmann *et al.*, 1993). Some patients show slightly irregular astigmatism with distorted keratometry mire reflections being observed, which were not present prior to PRK treatment. Contact lenses mask this irregularity but do not influence it significantly.

Original concern that the thicker central epithelial layer may be more prone to deformation by lens and lid pressure seems unfounded, although both RGP and soft lens patients show a slight curvature change after lens wear. Studies of the topographical change over the months following PRK have been carried out by Klyce *et al.* (1991) and Wilson *et al.* (1991). Astin (1994, 1995) noted only slight flattening of the central curvature (0.05–0.10 mm) and a myopia reduction in some patients after 8–10 hours of soft lens wear. These patients were susceptible to reticular stromal haze. The curvature changes were probably due to lid pressure on the lens, similar to that found in non-PRK cases. A few RGP lens patients showed central curvature steepening up to 0.15 mm. This was not associated with any corneal oedema signs but they were advised to reduce lens wearing time.

After 10 hours wear, some soft lens patients show a small but significant increase in central corneal thickness of 0.03–0.08 mm (5–15%). These tend to be the patients who show a large degree of myopic regression following PRK. Refitting them with higher oxygen-permeable soft lenses and reducing their wearing time can help. No significant conjunctival hyperaemia, epithelial staining or limbal vessel disturbance were noted on repeated slit lamp biomicroscopy, either in those corneas exibiting reticular haze, or in those demonstrating corneal thickness changes.

Contact lenses on PRK eyes usually give good visual acuity, especially in cases of mild irregular astigmatism, but



Figure 20.4.7 Example of significant reticular haze which can follow PRK

they cannot eradicate the blurring in some cases, which is due to the PRK-induced reticular corneal haze (*Figure 20.4.7*). A number of patients, either because of haze or because they still have to wear contact lenses, request repeat PRK (Seiler *et al.*, 1992; Derse and Seiler, 1992). As was their original intention, they continue to seek for a means to obtain clear unaided vision. However, these patients should be given further detailed counselling since repeat PRK can leave patients with focal disruptions of the basal lamina or 'pseudo-membrane' (Hanna *et al.*, 1992). Although PRKCL and repeat PRK can help those with residual vision problems following PRK, both procedures require close monitoring of the corneal parameters and integrity. These are particularly important because the long-term effects of PRKCL and repeat PRK are as yet unknown.

Patients demanding refractive surgery tend to be those who dislike having to wear contact lenses or who previously had poor tolerance of lenses (Bourque *et al.*, 1984). They are very disappointed by their residual ametropia and are therefore poorly motivated for future lens wear. They have to accept that there may be reduced quality of vision even if the best corrected visual acuity is good. These patients will require extra skill, time and patience from their practitioner in order to deal with the more complex lens fitting and to give advice and counselling.

Contact lens fitting of a patient following refractive surgery presents a challenge to the practitioner with respect to clinical skills, interpretation of fluorescein patterns, and designing lenses to minimize variations in visual acuity and in symptoms.

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Chapter 20.5 Contact lens fitting in infants and pre-school children

Lynne Speedwell

Indications for contact lenses p.731
Corneal topography and physiology p.731
Practicalities and types of lenses p.731
Cosmetic conditions p.737
Therapeutic lenses p.738
Handling of lenses p.739
Lens hygiene p.740
After-care problems p.740

Most of the infants and young children needing contact lenses are seen in hospital clinics. Older children requiring lenses mainly for refractive purposes are more likely to be seen in private practice. However, the need to cope with both the patient and the parents remains the same. Numerous short visits may be preferable to one long session and there is always a need to be adaptable whenever a child is fitted.

Indications for contact lenses

Contact lenses are only fitted in cases where spectacles would prove inadequate and visual or cosmetic improvements can be achieved in no other way.

Fitting falls into three categories:

- Refractive
- Cosmetic
- Therapeutic

Refractive

By far the largest group is the refractive group and of these the aphakes make up the greatest number. These are either congenital or traumatic, unilateral or bilateral.

Other refractive conditions include:

- High myopia
- Unilateral ametropia
- High hypermetropia
- Strabismus with a high refractive error
- Anisometropia
- Corneal irregularity as a result of trauma (without aphakia)

Cosmetic

The most common conditions which need cosmetic lenses are:

- Aniridia
- Iris coloboma
- Albinism
- Cone dystrophy
- Microphthalmos
- Unsightly scars and opacities

Therapeutic

Very occasionally therapeutic lenses are fitted in cases of corneal epithelial dystrophy and after a corneal transplant or trauma.

Corneal topography and physiology

The infant has a large eye/head ratio. The length of the eyeball is approximately 17 mm compared to 24 mm in the adult.

The average corneal diameter at birth is 10 mm; by the age of one year it has grown to 11.7 mm which is almost adult size. Many figures have been quoted for the refractive error in babies, ranging from slightly myopic in the premature infant to moderately hypermetropic and astigmatic in many normal neonates (Molnar, 1970; Marshall and Grindle, 1978; Weale, 1982). The corneal radius is around 7.1 mm which gradually flattens to an adult average of 7.86 mm (Asbell *et al.*, 1990), although other authors (Wood *et al.*, 1996) have suggested that the infant corneal radius may be somewhat flatter.

The corneal physiology differs little from that of the adult except that there are a greater number of endothelial cells per unit area (Speedwell *et al.*, 1988). This may account for the apparent ability of the infant cornea to recover rapidly from a hypoxic reaction. Topography of the infant aphake is only slightly altered by surgery. Lensectomy and aspiration are the most common procedures and the small scars which remain near the limbus induce a minimal degree of astigmatism.

Practicalities and types of lenses

Refractive conditions

Aphakia

Infants born with bilateral congenital cataracts (*Figures 20.5.1* and *20.5.2*) or posterior hyperplastic primary vitre-

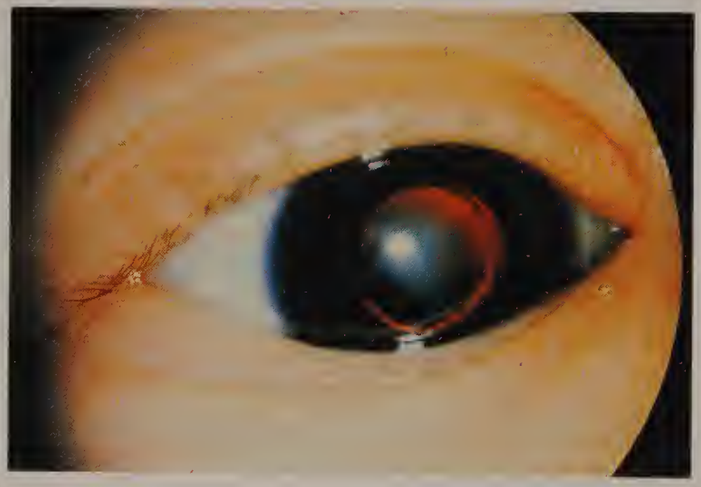


Figure 20.5.1 Congenital cataracts in an infant

ous (PHPV) should have surgery as early as possible, to prevent deep amblyopia, preferably before the age of three months, in order that optimum vision can develop (Taylor *et al.*, 1979). Infants who develop cataracts in the first few months of life need to be carefully monitored in order that surgery can be performed as soon as the cataracts start to interfere with vision.



(a)



(b)

Figure 20.5.2 Congenital cataracts do not always show as white pupils, as in (*a*). As with adults, it may be easier to recognize them with a retinoscope or ophthalmoscope held away from the eye as in (*b*)



Figure 20.5.3 Infant in aphakic spectacles

The small incisions from lensectomy heal very rapidly, so as soon as the inflammation has settled in the second eye, that is, not usually more than a week after the second operation, contact lenses are fitted.

Contact lenses provide a more normal visual environment for the aphake as well as overcoming the mechanical difficulties of wearing spectacles (*Figure 20.5.3*). However, a back-up pair of glasses should also be prescribed for periods when the contact lenses cannot be worn, thereby ensuring continuous visual stimulation.

The prescription is checked by retinoscopy: it is important that the visual pathway remains clear so that the prescription can be as accurate as possible while the acuity is developing. As there is no active accommodation, cycloplegia is not needed and a mydriatic is only necessary if the pupil is very small.

No trial frame is used as it is impractical on a baby's small features. The first trial lens to be held in front of the eye should be a +20.00 D which will usually show if there

is a with or against movement of the reflex. If a trial lens of a much lower power is used, the pupil area can be filled with light giving the appearance of a neutral reflex and hence the final contact lens will give a substantial undercorrection. Care must be taken not to produce a large back vertex distance (BVD) behind the lens being held, as a small increase in BVD induces a large increase in effective power; a +20.00 D lens held at a BVD of 16 mm requires a +29.41 D contact lens on the eye (*see* Chapter 5 and Appendix A).

The back vertex power (BVP) of the aphakic lens at the cornea is typically in the region of +30.00 D. Infants are motivated and attracted by objects that are close to them: faces, feeding bottle, toys etc. Being unable to accommodate themselves, they should be focused at a third to a half a metre; that is an overcorrection of +2.00 D – +3.00 D. The first prescription is of the order of +33.00 D (although microphthalmic, aphakic eyes can require lens powers of +50.00 D or more). These lenses are very thick; a centre thickness of 1 mm is not uncommon in soft lenses, and hence overnight wear can result in corneal hypoxia. This is less likely if RGP lenses are fitted.

Because of the potential danger to the retina caused by ultraviolet light in an aphakic eye, it is worthwhile to fit lenses with an ultraviolet inhibitor where possible. Most materials are now available with a UV inhibitor with the exception of silicone rubber.

Soft lenses

Manufacture of small high power hydrogel lenses is difficult. Once they are allowed to hydrate the parameters are likely to steepen more than the lower powers. The refractive index of the xerogel is 1.524 giving very high powers in the dry state which are difficult to measure, hence the BVP is likely to be less accurate and more difficult to check on the focimeter. The carrier lens and junction need to be thicker than in an adult's lens in order to make for reasonable handling.

High water content lenses are fitted both for comfort and convenience as it is impractical to expect that the lenses be removed every time the child has a day-time nap. It is, however, important to explain to the parents the risks of overnight wear and to encourage them from the beginning to remove and clean the lenses daily. If this is found to be impossible the lenses should be removed a minimum of once a week. If the parents cannot remove the lenses themselves, it could be considered as morally and legally irresponsible to fit a child with extended wear lenses knowing of the risks to the cornea. If the parents cannot remove soft lenses they may find that RGP lenses, either corneal or scleral, prove easier to handle.

When the infant is older and has stopped the daytime sleep, the water content of the soft lenses may be reduced, where necessary, in order to prevent epithelial damage due to lens dehydration and also to reduce lens turnover.

Astigmatism is not corrected until the child is older, except where RGP lenses are fitted, but it is usually only of a small degree induced by lensectomy or aspiration (note scars in *Figure 20.5.4*). It is not practical to fit these infants with anything other than spherical lenses, and many emmetropic adults start life with varying degrees of astigmatism (Atkinson *et al.*, 1980).



Figure 20.5.4 Bilateral aphake wearing contact lenses. The right lens did not centre perfectly but the pupil was covered by the lenticular part of the lens all the time. Note the scars from surgery

The total diameter (TD) of the lenses usually depends on the corneal diameter which, as previously mentioned, is around 10 mm at birth growing to 11.7 mm by age one year. Ideally, the lens should be 2 mm larger than horizontal visible iris diameter (HVID), so the first soft lens of choice is 12.00–12.50 mm TD depending on age and corneal appearance. In some cases this may not settle centrally over the cornea. Many congenital cataracts or PHPVs occur in microphthalmic eyes, having an HVID of 9 mm or less, whilst others are fitted when the infant is a few weeks or months old by which time the cornea has grown. A larger or smaller TD may be necessary (sometimes as small as 10.50 mm), depending on the peripheral corneal and scleral topography, in order to achieve adequate centration. This may be further complicated by the action of tight lids on the thick lens and the final lens can be as much as 3 mm or even 3.5 mm larger than corneal diameter. Where the lids are tight enough to displace the lenses superiorly, it helps to order lenses which are thinner and this can be achieved by making an aspheric lens or by reducing the front optic zone diameter (FOZD). Normally the FOZD is 8.00 mm on a 12.00 mm TD but can be reduced to 6.00 mm FOZD where appropriate.

Actual keratometry measurements are rarely done. Instead the BOZR of the first lenses are fitted according to age, that is on known average K, which for a neonate is 7.10 mm. Some of the infant aphakes have a marked nystagmus and it may be difficult to maintain reasonable lens centration on the eye; trial and error is then the only way to achieve good results (*Figure 20.5.4*). A compromise on centration may be necessary, but as long as the lenticular portion of the lens remains over the pupil and the lens does not knock the limbus, there are not likely to be any adverse effects.

Table 20.5.1 Back vertex powers (D) and appropriate BOZR and TD values for an infant aphakic soft lens fitting set

BOZR (mm)	*TD (mm)*				
	12.00	*12.50*	*13.00*	*13.50*	*14.00*
7.00	**+34.00**	**+32.00**	**+30.00**		
	+30.00	+28.00			
7.20	**+32.00**	**+30.00**	**+28.00**	+22.00	
		+26.00	+24.00		
7.40		**+28.00**	+26.00	**+24.00**	+22.00
			+22.00	+20.00	
7.60			+24.00	**+22.00**	+18.00
7.80				+20.00	+16.00

The ideal minimum number of trial lenses is 44 (*Table 20.5.1*), but if infant aphakes are only rarely seen the number can be reduced to 18 (figures in bold type). It is important to keep two of each set of parameters in stock so that lenses can be issued at the first visit. Where possible the parents should always have a spare pair of lenses to keep at home against loss or breakage.

The lenses frequently need changing after they have been allowed to settle. It is not possible to assess the fit conventionally; instead time must be spent watching the eye/lens movement whilst the baby is shown toys/lights etc.

Silicone rubber lenses

Silicone rubber can be used as an alternative to hydrogel, either as a first lens of choice or where problems are encountered with soft lenses (too many lenses lost/broken, low blink rate leading to lens dehydration, corneal hypoxia or lid irritation). These lenses have the advantage that they are not easily rubbed out or broken but they may be very difficult to remove if the eye is sore and also the lens surface degrades with time. They can be obtained from Zeiss (Wöhlk) in Europe and in more limited parameters from Bausch & Lomb in North America (*Table 20.5.2*).

The initial BOZR fitted is again age-dependent. If a hand-held keratometer (*see Figure 20.5.7*) is not available, the first lens of choice is 0.40 mm to 0.60 mm flatter than the known average corneal radius (Asbell *et al.*, 1990), i.e.

Table 20.5.2 Silicone rubber lenses currently available

	BOZR (mm)	*TD (mm)*	*BVP (D)*
Zeiss (Wöhlk)	7.30–9.00* (in 0.1 steps)	11.20–13.70 (in 0.5 steps)	–30.00–+30.00† (in 0.25 steps)
Bausch & Lomb	7.50 –7.90‡ (in 0.2 steps)	11.30‡ (only)	+23.00–+32.00 (in 3.00 steps)

*This range can be extended if necessary.
†Higher powers can be ordered.
‡There is a wider range of parameters in powers of less than +20.00 D.

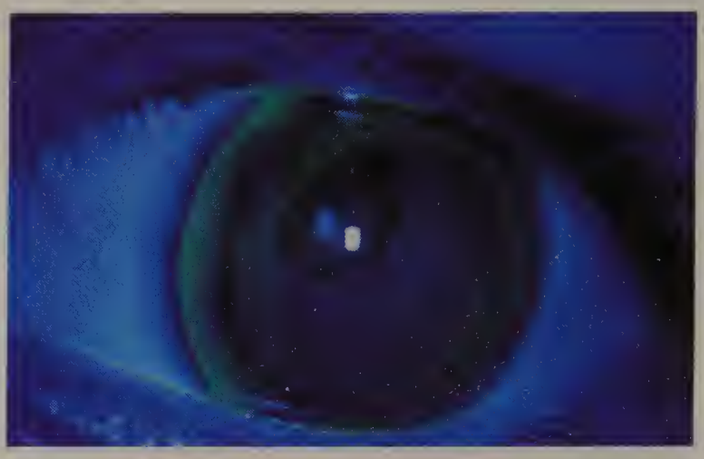


Figure 20.5.5 A well-fitting silicone rubber lens of parameters 7.80/11.70/+18.00. A lens with BOZR of 7.70 gave inadequate movement

BOZR of 7.40–7.60 mm. The TD should be 0.5 mm larger than horizontal visible iris diameter, that is 11.20 mm in a neonate. It is important to ensure that the lens is not too steep as a tight lens can be very difficult to remove. The fit of the lenses can be assessed using fluorescein and should be checked immediately after insertion. The picture should be one of minimal apical clearance and moderate peripheral clearance, and the lenses should move 0.5–1 mm on blinking (*Figure 20.5.5*). A further check needs to made after 10 minutes and the lenses then left to settle for a further 45 minutes as they can continue to tighten over that period. Even with the steepest BOZR the lenses may appear flat, giving central touch and peripheral stand-off. Although not ideal, such a lens is well tolerated and appears to cause no corneal damage (Cutler *et al.*, 1985) and it is better to err towards a flat fit than a tight one.

Very few trial lenses are needed: BOZR 7.60 mm, 7.80 mm and TD 11.20 mm, 11.70 mm and 12.20 mm in BVP of +30.00 D.

The cost of silicone rubber lenses is higher than both soft and RGP lenses. However, the number of lenses lost or broken is much less than is the case in soft lenses and hence the overall expenditure is similar. Silicone rubber lenses do have the drawback that the surface tends to break down (*Figure 20.5.6*) and therefore they do need replacing periodically.

Rigid gas permeable lenses

In spite of the advances in corneal measurement and lens material, RGP lenses may not be the first lens of choice. They can, however, be very successful and need not be fitted under general anaesthesia.

Keratometry readings are best taken with a hand-held keratometer (*Figure 20.5.7*) or, if the child is anaesthetized, a conventional keratometer can be used with the child on his or her side and then interchanging the horizontal and vertical measurements. A hand-held keratometer has the



Figure 20.5.6 (*a*) A silicone rubber lens with the surface degraded after 3 months of use. (*b*) The lens after cleaning in 5% sodium hypochlorite and (*c*) after further rinsing in distilled water. Although much of the surface degradation of silicone rubber lenses is due to the coating being damaged, some lenses are salvagable. (Courtesy of D. Westerhout)



Figure 20.5.7 An Alcon hand-held keratometer. (Courtesy of A. J. Phillips)

advantage that it can be used with the child either awake or asleep.

On the awake child, the lenses are best inserted using a local anaesthetic and the fit assessed conventionally with a UV lamp (but if the child is very upset at having lenses inserted then this method is not viable).

It is possible to fit a young baby empirically using known average *K*: with BOZR values of 6.70–7.50 mm and TDs of 9.00–9.50 mm increasing to BOZRs of 7.30–7.80 mm and TDs of 9.50–10.00 mm by 1 year of age. An aspheric design coupled with the relatively large total diameters with minimum edge lift, aids the comfort and reduces the risk of rubbing lenses from the eye. When the child is older the amount of edge lift may need to be increased to avoid indentation.

Amos *et al.* (1992) suggest that lenses should be inserted and assessed whilst under anaesthetic and the final lens can be ordered to be issued at the first after-care visit.

If corneal trauma is involved, several anaesthetic procedures may be necessary in order to check corneal healing, remove sutures etc., and RGP fitting can be performed at the same time.

It can be impossible to regain the confidence of a child of 18 months to 3 years old who has suffered a corneal trauma. The previous painful treatment may make it impossible to insert any lens without general anaesthesia. If an RGP lens is fitted while the child is under anaesthesia, it may be possible to remove the lens subsequently, whilst the child is asleep, using a suction holder. If this is still not a possibility, then some form of spectacle correction must be substituted. This often turns out to be a temporary measure as the child may not want to wear the glasses and is then prepared to try

contact lenses. If possible, it is better to start with a soft lens at that stage.

The main problem for the toddler wearing RGP lenses is in dusty environments such as sandpits or on the beach. Lenses are best removed in these environments.

Scleral lenses

Gas permeable scleral lenses can be fitted to infants using a standard preformed lens of +30.00 D. This can be done whilst the child is awake; the fit is then assessed and the power modified as necessary. Because of the high Dk of the materials used, the lens can safely be slept in during the day and removed at night. Although the initial cost may be high, these lenses are rarely lost and can be modified as the prescription alters (Ezekiel, 1995).



Figure 20.5.8 Dislocated lens cutting across the visual axis

Alterations with age

As the child gets older, the BVP reduces, the diameter increases and the corneal radius flattens. The lens that a 2-year-old aphake wears may be similar to that of an adult, the parameters being around 7.80/13.50/+20.00 in a high water content material. However, if the eyes are microphthalmic to begin with, they grow very little. The parameters that an adult patient may need, who was born with congenital cataracts in microphthalmic eyes, may be almost identical to those worn as a child except that the power is likely to have reduced.

When the child is ready to start school, the prescription is changed to a distance correction and bifocals are prescribed for reading. Any astigmatic error can be corrected at the same time. It is not practical to fit young children with the bifocal contact lenses currently available, as they rely too much on subjective responses and many do not provide the optimum focus for distance and/or reading. Soft lens wearers may be changed to RGP lenses before school age to improve the vision or if the eye is being compromised in any way; for example if the cornea is showing new peripheral vessels or if giant papillary conjunctivitis (GPC) is apparent. If the child will not tolerate RGP lenses and there are obvious lens-induced changes in the eye, then the amount of lens wear must be drastically reduced by giving them spectacles.

Unilateral and traumatic aphakes

Unilateral aphakes are treated in a similar way except that extensive patching of half the waking hours needs to be carried out to the good, phakic eye in conjunction with contact lens wear in the aphakic eye. This needs to be continued until the age of 7 years. Without effective patching the aphakic eye will always be densely amblyopic. Where patching is difficult, an occlusive black tinted contact lens or a high powered lens may be used in the good eye. Unfortunately these are not usually successful as the child soon learns to move the lens into the upper fornix or rub it out altogether. Another alternative in cases of mild amblyopia is to use a cycloplegic in the good eye. This is of no use if the eye is densely amblyopic, as the good eye is still the preferred eye.

The same applies to traumatic aphakes, where the injury occurs at less than three years of age. Dense amblyopia is common as a result of the injury but whilst visual results are usually poor, a contact lens may help in reducing the amplitude of a secondary strabismus. Extra care must be taken to watch for any corneal reaction, especially new vessels, which are more likely in the presence of scar tissue.

Dislocated lenses

Most eyes with dislocated lenses are very myopic and those in Marfan syndrome also have flat corneas. If the lens is mobile or if the edge of the lens cuts across the visual axis (*Figure 20.5.8*), then the lens is likely to be removed surgically as the vision is affected. Postoperatively the eyes have normal aphakic prescriptions and the corrected vision can start to slowly improve (Speedwell and Russell-Eggitt, 1995).

In those eyes with very flat corneas, care must be taken that the lenses centre adequately. Large soft lenses are often the only lenses that provide reasonable centration (Speedwell and Russell-Eggitt, 1994), but if RGP lenses are fitted it is usually necessary to incorporate a negative or parallel carrier (*see* Chapter 10), both for myopic and aphakic corrections. The same difficulties occur when fitting adults with dislocated lenses.

When surgical intervention is necessary, the two eyes are rarely operated on at the same time because the condition has usually progressed further in one eye than the other. The optimal way of treating the resultant anisometropia is with contact lenses, although children do not appear to have problems if contact lenses are not accepted and anisometropic spectacles are prescribed.



Figure 20.5.9 Child with clover-leaf skull and high myopia

High myopia

The low to moderately myopic child can develop vision unaided by holding objects close, provided there is no further disease or anomaly along the visual pathway. Minus lenses in hydrogel form are very thin in the centre which makes handling difficult. It is, therefore, not a particularly good idea to fit contact lenses with all their inherent problems to the very young myope unless the prescription is high or unless there is some other reason why they cannot wear spectacles, for example certain syndromes produce a misshapen skull which makes the wearing of glasses difficult (*Figure 20.5.9*).

In these children and also the slightly older child who will not wear spectacles, high water content soft or silicone rubber are the first lenses of choice as they are more comfortable initially, but RGP lenses should also be considered. Initial insertion may be helped by using a local anaesthetic.

The axially myopic eye is larger than normal and the cornea flatter. Infants may start with lenses of 8.00 mm BOZR in a high water content material and as large as 13.50 mm or even 14.00 mm diameter.

It has been suggested that PMMA lenses (Kelly and Butler, 1971; Stone 1976) and RGP lenses (Perrigin *et al.*, 1990) have a retarding effect on the progression of myopia, but this alone should not be a reason for fitting the very young unless there are other justifications for lenses. However, it may be worth considering in the older child or adolescent whose myopia is increasing. In teenagers, orthokeratology may also prove effective (*see* Chapter 19).

High hypermetropia, strabismus and anisometropia

High hypermetropes manage quite well with contact lenses, but they are rarely discovered until they reach school age unless a strabismus is also present. Unilateral ametropes who are discovered early, be they myopes or hypermetropes, are reluctant to wear spectacles with their resultant aniseikonia, as they derive no visual benefit from wearing them. Contact lenses are then the only solution. In these children, as in the unilateral aphakes, extensive patching needs to be done to the good eye to reduce the amblyopia in the ametropic eye. The most comfortable lens may prove to be the best to start with, therefore the initial choice of material is again high water content soft or silicone rubber.

The visual results obtained from the unilateral myopes have been found to be more successful than those from the unilateral hypermetropes (Morris, 1979). Myopia in children is thought to be only axial (Grosvenor and Scott, 1993) and since aniseikonia has been shown to be less for both axial and refractive anisometropia when contact lenses are employed (Winn *et al.*, 1986), better stereopsis should develop if lenses can be prescribed early.

Children with accommodative esotropias can benefit from contact lenses mainly for cosmetic reasons and in older children with a high AC/A ratio who would normally be fitted with bifocal spectacles, bifocal contact lenses may be an alternative (Rich and Glusman, 1992).

Cosmetic conditions

Conditions requiring cosmetic lenses are similar in both adults and children although the distribution of the pathology for which they are necessary is different. Soft lenses are most common, although occasionally other types are used. Cosmetic shells fall into a different category, which is dealt with in Chapter 20.6, p. 751.

Conditions inducing photophobia

Aniridia

Patients with congenital aniridia rarely benefit from tinted lens wear. If cataracts are removed, soft lenses are generally fitted at first but older children and adults do better with RGP corneal lenses as the cornea tends to opacify

and neovascularize, regardless of contact lens wear. RGP lenses provide better vision as well as being better physiologically.

In cases of traumatic aniridia, a tinted iris lens can be helpful (*see* Chapter 20.6 and *Figures 20.6.8* and *20.6.9*).

Iris coloboma

The cosmetic appearance of an iris coloboma in a small infant is rarely bad enough to warrant the fitting of tinted lenses. In the older child, if either the appearance or the photophobia require cosmetic lens fitting, the lens is fitted as for an adult (*see Figures 20.6.10* and *20.6.26*).

Albinism

Tinted lenses and even scleral lenses with an opaque sclera have been tried in an effort to improve the visual acuity, all to no avail (Ruben, 1967). The lack of pigment in the retina and foveal hypoplasia together with the abnormal percentage of fibres partially decussating at the optic chiasma precludes any recordable visual umprovement. Many albinos are hypermetropic and have a moderate to high degree of with-the-rule astigmatism, possibly induced by screwing up their eyes against the light. It is worth correcting their refractive error where possible, but many find that subjectively, correction of the cylinder provides little or no benefit, so the young albino is usually fitted with spherical soft tinted lenses (*see Figure 20.6.15*).

Albino babies can prove exceptionally difficult to fit. The lenses are thin, to avoid hypoxia during sleep, and the typical reaction to lens insertion is very tight lids and complete resistance. Once the lenses are in, the parents of a previously pink-eyed baby do not normally like the appearance of the dark irides and the result is that the lenses are abandoned until the child is much older.

Cone dystrophy

These children are not often diagnosed until they are 3 or 4 years old. The dark red or brown tinted glasses that they need to wear are unsightly but it is usually better to wait until they are older and keen to wear lenses themselves before fitting them.

Soft lenses with a dark brown tinted pupil work well in a high water content material as the irides are of a normal colour. The high water content is necessary in order to make the lenses dark enough (*see* Chapter 20.6). Good pupil coverage is important and so the tinted pupil diameter should be about 1–2 mm larger than the pupil measured in normal indoor illumination. For bright conditions outside, sunglasses are still required to wear over the tinted lenses.

Other conditions requiring cosmetic lenses

Microphthalmos and nanophthalmos

Microphthalmic and nanophthalmic eyes have a steep radius of curvature. The eyes are highly hypermetropic, possibly with a correction of up to +25.00 D. The eyes are treated, therefore, similarly to those of the infant aphakes, except that they are prescribed according to the distance correction as the child still has the ability to accommodate.

Like congenital cataracts with congenital microphthalmia, congenital micophthalmia and nanophthalmia occur in eyes which do not grow much from the size they are in infancy. It is worth remembering when fitting adults with these conditions, that they usually require lenses of similar parameters to those used for young children.

Unsightly scars and opacities

Scars and opacities can be caused by a variety of conditions, among them penetrating injuries, some keratopathies and dermoid cysts.

An eye that has been disfigured in such a way as to cause loss of vision is usually unsightly. In the first months and years of life, these eyes may be fitted more for the parents' sake than any other reason (*Figures 20.5.10a,b*). However, once the child starts playing with other children and going to school, he or she may develop worries and complexes about the disfigurement and a cosmetic lens will help overcome this. Many children will refuse to go to school on days when they are unable to wear their cosmetic lens.

Initially an iris tint lens is prescribed even if it does not exactly match the good eye. These lenses can be made in a high water content material and can therefore be worn during sleep. There is an extensive range of colours available and usually an acceptable match can be obtained. It is impractical to try to achieve perfection at this age as the lenses are frequently lost or broken. When the child is older, a hand-painted lens may be ordered.

In cases where some vision has been retained, great care must be taken to ensure that the cosmetic lens does not compromise the cornea. Initially a clear soft lens is fitted to watch for any corneal reaction, and only when that has been established is a cosmetic lens ordered.

If the eye is blind, the lens can be ordered with a prescription, possibly even as high as +14 D, in order to make the lens easier to handle. The parents are unlikely to be able to insert a thin plano lens into an infant's eye (and the practitioner, also, may have problems!).

Therapeutic lenses

Cases of corneal epithelial dystrophy and of corneal transplants or perforation are occasionally fitted with therapeutic lenses. Because of the difficulties of inserting a thin soft lens on an often painful eye, they may initially be inserted under general anaesthesia but subsequent handling is when the child is awake. These lenses do not always prove successful as they are frequently rubbed out and are very difficult to reinsert. However silicone rubber lenses can prove worthwhile in certain cases where a bandage lens is needed (*see* Chapter 20.7).



Figure 20.5.10 (*a*) Child with an anterior segment dysgenesis. (*b*) Same child wearing a cosmetic lens

Handling of lenses

At the first visit the lenses are inserted by the practitioner whilst the parent holds the child supine on a couch. The upper lid is held up, making sure that enough pressure is applied, and the lens is slotted underneath (*Figure 20.5.11*). Removal of a soft lens is as for a corneal lens (*Figure 20.5.12*) because an adult's fingers are too large to remove the lens by the conventional method of pinching it. Occasionally the lenses (of any material) may need to be removed using a hollow rubber suction holder, especially in cases where the eyes are deep-set or microphthalmic. Care must be taken in such cases to make sure that the lens is in place before attempting to remove the lens, and also to disinfect the suction holder.

Most parents, once they have been told of the potential dangers of extended wear, are willing to have a go at removing their children's lenses. Time spent in explaining and demonstrating lens insertion and removal at the beginning, can save many emergency visits later on, and it is important to stress that the lenses do not cause any pain to the child. However the regime must not become too big an event in the family's life. The parents need to be fairly relaxed when the lenses are to be handled; if the parent is tense, the child senses it and also tenses up, making lens insertion or removal much more difficult.



Figure 20.5.11 Inserting lenses in a baby's eyes



Figure 20.5.12 Removing lenses from a baby's eyes

The actual handling of the lenses is not automatically done by one parent; it is better if they can share the task, one holding the child while the other deals with the lenses. The infant can be wrapped in a blanket to make lens handling easier or if the parents are still having difficulty, the lenses may be inserted and removed whilst the child is asleep. If difficulties are encountered, they can be advised to start removing and cleaning the lenses weekly and gradually build up to daily removal.

For the non-cooperative toddler, insertion is best attempted by two adults together. The child can be laid supine on the floor whilst one adult restrains the arms and legs. The other adult kneels behind the child holding the head steady with their knees. This leaves both hands free to insert the lens. This method is usually only necessary for a short time before the child becomes used to having the lenses inserted without struggling. If this method is too traumatic for the parent or the child, spectacles should always be substituted. It is better to have a child wearing an anisometropic spectacle correction together with a patch, than to have the child continuously distressed. Contact lenses can always be tried at a later date when the child is older and more keen to try for themselves.

Many children who have had contact lenses since infancy are able to remove their own soft lenses by the age of 3 or 4, and by the age of 5 some are able to insert them. Of those who are not as adept, most are cooperative when their parents deal with their lenses. However, some toddlers become very uncooperative at around 18 months old and for those who are bilaterally aphakic, the best course is a change to spectacles. Although the parents are often reluctant to give up contact lenses, they usually appreciate the wisdom of the decision after a short time.

Children aged 2–5 years who have not worn lenses previously are not usually cooperative and, where spectacle wear is adequate at this stage, it may be advisable for them to remain thus corrected.

Lens hygiene

The cleaning regime of choice must be relatively easy and must avoid any potential danger to the child's eyes. Chemical disinfection can lead to an allergic reaction which might be confused with an infection when brought back to the clinic. Treatment may then be with drops containing the very preservative that caused the reaction in the first place. Hydrogen peroxide and chlorine based systems may lead to discomfort or corneal damage if not used correctly.

Soft lenses (all except the cosmetic lenses) should be cleaned with a preservative-free surfactant and can then be heat disinfected using unpreserved saline, although it is important to ensure that the type of lenses being used can withstand boiling. Young children tend to require changes to their lenses or lose/damage them before many of the deposits associated with this method of cleaning become troublesome or lead to the development of GPC. Once the parents have become adept at handling the lenses and the prescription has stopped changing, peroxide or new generation preservative systems may be used together with surfactant cleaning, and protein tablets where necessary. Silicone rubber lenses and rigid lenses are cleaned using the practitioner's preferred method (*see* Chapter 4).

After-care problems

Thick lenses worn continuously or even on a daily basis can lead to changes in the ocular environment. Also many infants have a low blink-rate and thus a keratitis may develop. A baby cannot tell the parent of a mild discomfort and so it is not until the eye becomes red or sticky that the parent discovers the problem. By then the child probably needs to have the lens removed for a few days and to be given topical antibiotics. Most medical and nursing personnel have no training in contact lens removal in adults let alone children, therefore the parents are advised to remove the lenses themselves before taking the child to the local eye specialist for treatment.

In infant bilateral aphakes up to 18 months old, where one lens needs to be removed, it is a good idea to remove both; the eye without the contact lens can quickly become amblyopic even within a few days of lens removal. While the infection is being treated, back-up spectacles should be worn.

Many babies blink infrequently and this can cause soft lenses to dry and fall out. In these children, and also in most children with Down's syndrome where the tears are poor, it may be advisable to instil normal saline drops (without preservative) every few hours during the day while the lenses are being worn or change to silicone rubber.

Anoxia and vessel ingrowth can be a problem, especially with soft lenses. In cases where the parents cannot handle the lenses daily, or where the child is too uncooperative to be refitted with rigid lenses, it may be necessary to change to spectacle wear for a time. Another problem for the young lens wearer is giant or contact lens-induced papillary con-



Figure 20.5.13 Examination using a hand-held slit lamp



Figure 20.5.14 The 'flying baby' position used to examine young infants at a conventional slit lamp

junctivitis (GPC or CLIPC) (*see* Chapter 18). It is not always possible to refit a child with gas permeable lenses at the first sign of GPC or CLIPC and it may be another reason for changing to spectacles. Occasionally, at around 2 years old, a child who has been wearing daily wear lenses successfully starts to rebel against insertion and removal. Again, spectacle wear will solve the problem until such a time as they are themselves keen to revert to lenses. As previously mentioned the parents of a child who has been wearing lenses successfully (or even unsuccessfully) are usually reluctant to see them change to spectacle wear. It is therefore expedient to warn them of the possibility when they first bring the child for fitting. It must also be stressed that the visual acuity will develop just as well in glasses as in contact lenses in spite of the reduction in field. Indeed, many aphakic children prefer to wear spectacles if their visual acuity is poor, as they see better due to the magnifying effect induced by the back vertex distance of the glasses.

The number of soft lenses lost or broken especially in the first few months of wear can be very high. It is not uncommon to lose or break a pair of soft lenses each month until both child and parents become used to the routine. It is important to have lenses ready in stock against such events, and it is a good idea to give the parents spare lenses if there is likely to be any delay in replacing the losses. Contact lens loss from the eye is frequently a reason for fitting or refitting with silicone rubber or RGP lenses as they need to be replaced less often.

In the early months of life the contact lenses usually need to be changed (or are lost or broken) before there is any build-up of deposits or protein but, once the lens parameters have stabilized, it is worth initiating a planned replacement system so that new lenses are issued every 3–6 months to avoid the problems incurred by deposited lenses.

Infants and young children need to be reviewed much more frequently than adults. Their lenses need changing more often and objective checks are more important as subjective information is less available. It is not difficult to examine the eyes of an infant on the slit lamp. A hand-held slit lamp provides one method of examination (*Figure 20.5.13*), but a conventional slit lamp can be used by holding the infant in the 'flying baby' position (*Figure 20.5.14*). This provides the practitioner with a reasonable view of the eye until the child is old enough to develop neck muscle control.

During follow-up visits care must always be taken to exclude any developing eye disease. The prescription of the infant aphake is expected to reduce with time, but too much of a reduction in plus power may indicate the development of buphthalmos (infantile glaucoma). Likewise a red or watery eye may not be contact lens-induced but due to an increase in intraocular pressure or irritation from a loose suture. The young aphakic contact lens wearer should regularly have fundus and intraocular pressure checks in conjunction with contact lens assessment, especially as infant aphakes have a 25% risk of developing glaucoma (Simon *et al.*, 1991, Johnson and Keech, 1996) and patients

with dislocated lenses should have regular fundus checks, especially in Marfan syndrome, as retinal detachment occurs in between 10 and 25% of patients (Nelson and Maumenee, 1982).

It is always important to keep the patient's interest in mind. There are occasions when the parents bring pressure to bear on the practitioner either to fit lenses initially or to maintain the child in lenses when the practitioner advises otherwise. Always be prepared to discuss with the parents the reason for your decisions and where possible give another appointment. If lens handling is the problem they should be shown how to deal with the lenses and by the next visit the decision may be reviewed. It may help to give the parents some saline drops to instil several times before the subsequent appointment so that they and the child can be used to having something instilled in the eye before attempting to insert a lens. It is also important to bear in mind the psychological effects of having to wear a thick pair of glasses and, where a child is keen to wear contact lenses and there are no obvious contraindications, they should where possible be fitted (Barnard, 1991).

Two topics commonly asked about at after-care visits are regarding swimming and holidays. The same advice should be given for children as for adults. It is safer to remove lenses for swimming or to wear closely fitting goggles (though not for diving). On holiday it is prudent to remove lenses for the duration of any flight and on the beach.

Although most of the problems of contact lens fitting and wear can be overcome and parents' questions answered, the long-term visual outcome remains elusive. Results differ in every case. Many children with congenital visual handicaps improve beyond expectation whilst others, unfortunately, do not. Even with the sophisticated checking equipment now available, VERs, ERGs and preferential looking techniques, it is still not possible to answer with anything other than a calculated guess.

Implants and epikeratophakias are rarely performed on infant aphakes unless the visual prognosis is poor (Holmstrom *et al.*, 1990). The eye is still growing, up to 2 years of age, and the prescription of the intraocular lens or epikeratophakia button cannot easily be changed. Ideas are, however, changing and the age at which implants are used has dropped dramatically in recent years. Modern surgical techniques obviate the need for contact lens fitting in many cases but the contact lens practitioner will still be required in paediatric fitting, where surgery is either not indicated or else leaves the eyes uncorrected.

Acknowledgement

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Chapter 20.6 Cosmetic and prosthetic contact lenses

M. J. A. Port

Uses p.743
Types of lenses p.743
Scleral lenses and shells p.751
Corneal lenses p.751
Soft lenses p.752
Ordering cosmetic lenses p.755
General approach with cosmetic lenses p.757

Cosmetic contact lenses are sometimes termed 'prosthetic' contact lenses. International Standard ISO 8320–1986 refers to a **cosmetic lens** or **cosmetic shell** being specifically designed to change the appearance of the eye, the former having a refractive effect and the latter not having a refractive effect. In either case the function of the lens or shell is to alter the appearance of the eye such that a disfigurement is covered by an artefact in order to restore the appearance of normality. In some cases, e.g. albinism and iris trauma, the lens may be functioning to reduce the amount of light entering the eye. Such lenses may be used on seeing and non-seeing eyes. In the latter case a plano lens is conventionally employed.

It is also worth remembering that in cases where both eyes are blind and unsightly, it can provide the patient with an immense psychological uplift to know that they are able to wear cosmetic lenses which can normalize their appearance.

Uses

- Covering opaque hypermature and traumatic cataracts (*Figures 20.6.1, 20.6.2*).
- Covering corneal opacities and dystrophies (*Figures 20.6.3* and *20.6.4*).
- Covering a large squint angle where a surgical procedure is not indicated (*Figures 20.6.5* and *20.6.6*).
- Restoration of the iris and pupil to normal size, appearance and colour (*Figures 20.6.7–20.6.11*).
- Microphthalmos (*Figures 20.6.12* and *20.6.13*).
- Covering iris holes that give diplopia and polyopia (*Figure 20.6.14*).
- Albinism (*Figure 20.6.15*).
- Eliminating intractable diplopia.
- Colobomas (*Figure 20.6.10*).

Lenses are not always used for a single purpose, for example, someone may have been in a car accident where broken glass has damaged the eye. The ocular complications which then need correction may be aniridia, aphakia and corneal scars (*Figure 20.6.16*).

Types of lenses

Scleral lenses and shells, corneal lenses and soft lenses are all used and necessary if all types of work are to be undertaken. Due to the large variety of lens tints and tint patterns which are available, soft lenses are used in the majority of cosmetic cases (McMahon and Krefman, 1984).

Implications of cosmetic lenses

Perhaps the most important thing to remember with these lenses is that the lens is on the anterior surface of the globe. Thus any artificial pupil or iris is placed in this forward position, whereas in the normal eye it is in a relatively flat plane some 4 mm behind the cornea. The appearance is therefore always something of a compromise even if the colour match is good, unless a sufficiently translucent lens is used that allows at least partial visibility of the natural eye through the cosmetic lens. If the general appearance is good, the casual observer will not notice the lens. Where the patient is very critical or has fairly exophthalmic eyes, this factor can be apparent but if the eyes are enophthalmic the effect is not so obvious. One disadvantage of a scleral lens is that its thickness may give a proptosed look to an eye (*Figure 20.6.5*).

Patients who need these lenses may have had a disfigured eye for some time and may therefore be extremely aware of the abnormality. In fact they often magnify its appearance in their own minds and think that it is very noticeable because they have looked at themselves close up in a mirror, whereas to the casual observer at one metre it may not be noticeable at all (*Figure 20.6.17*). When considering the general appearance of these contact lenses the patient should be encouraged to look at the lens on the eye from a reasonable distance, not from really close up.

With either a cosmetic lens or shell, the artificial 'pupil' is of fixed size and the cosmetic iris may appear to move as the lens moves. The practitioner has to decide on the best compromise in fitting which will permit minimal lens movement.

Eustis *et al.* (1990) reported that the Durasoft 3 Colors lens could show 10–22Δ of exo-deviation due to the temporal displacement of the lenses.



(a) (b)

Figure 20.6.1 (*a*) Congenital monocular cataract; (*b*) covered effectively with a black pupil soft lens



(a) (b)

Figure 20.6.2 (*a*) An eye with a disorganized iris, corneal opacity and cataract following trauma. (*b*) A traumatic cataract made very obvious by the loss of iris tissue creating a large pupil area



(a) (b)

Figure 20.6.3 (*a*) An inferior corneal opacity; (*b*) covered by an opaque printed lens. If the eye had useful vision a clear pupil could be utilized. If the opacity covered the pupil area a black pupil would look better



Figure 20.6.4 Fuch's dystrophy. The loss of a normal black pupil draws attention to the condition. A black pupil soft lens is a simple and effective remedy



(a) (b)

Figure 20.6.5 (*a*) A large angle left convergent squint (*b*) greatly camouflaged by a scleral shell with opaque optic and scleral zones



(a) (b)

Figure 20.6.6 (*a*) A disfigured right eye with permanent divergent strabismus (the left eye is looking temporally to show the disfigured eye clearly). (*b*) A cosmetic shell made by an impression taken over a soft lens and incorporating an off-centre painted iris pattern to make the eye look straight. (Courtesy of D. Westerhout)



Figure 20.6.7 (*a*) A simple tinted soft lens used for (*b*) heterochromia iridis. (*c*) The lens is used to darken the lighter coloured iris. (Courtesy of A. J. Phillips)



Figure 20.6.8 In cases of severe iris trauma the patient experiences both loss of vision quality and marked photophobia. The lens illustrated is semi-opaque and incorporates an iris pattern. Too opaque a lens can produce an unreal 'painted' eye effect even though better in terms of reducing the photophobia. The 'trade-off' must be carefully discussed with each patient (lens by Capricornia Contact Lenses). (*a*) Traumatized eye; (*b*) normal eye; (*c*) cosmetic lens; (*d*) cosmetic lens on eye. (Courtesy of A. J. Phillips)

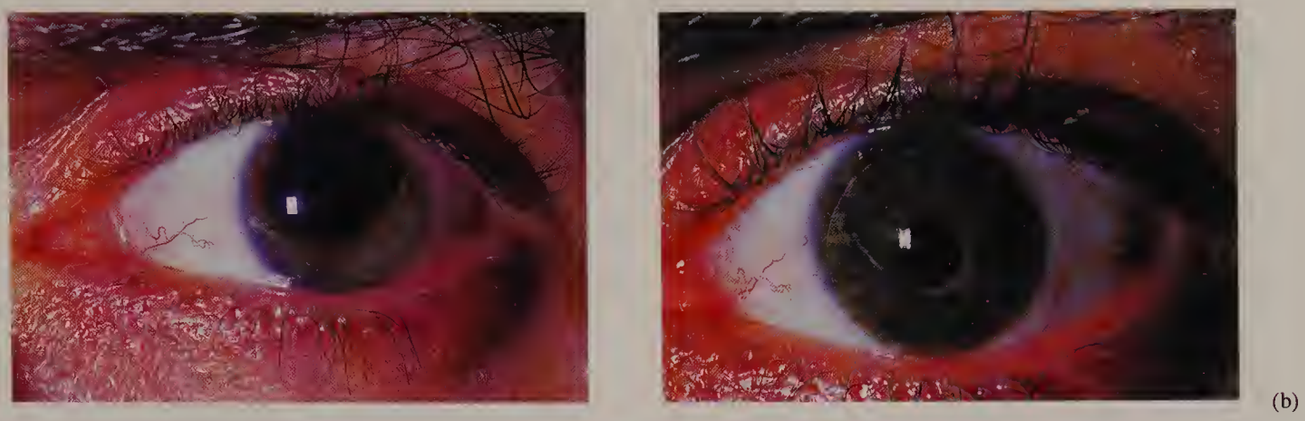


Figure 20.6.9 (*a*) Traumatic iridectomy. (*b*) The fully opaque cosmetic soft lens with clear pupil used to disguise it. The colour and the iris pattern are applied to the front lens surface and the back surface is opaque. The two tinting processes are clearly visible in the temporal pupil area where there has been slightly imperfect overlap of the clear pupil area (lens by Capricornia Contact Lenses). (Courtesy of A. J. Phillips)

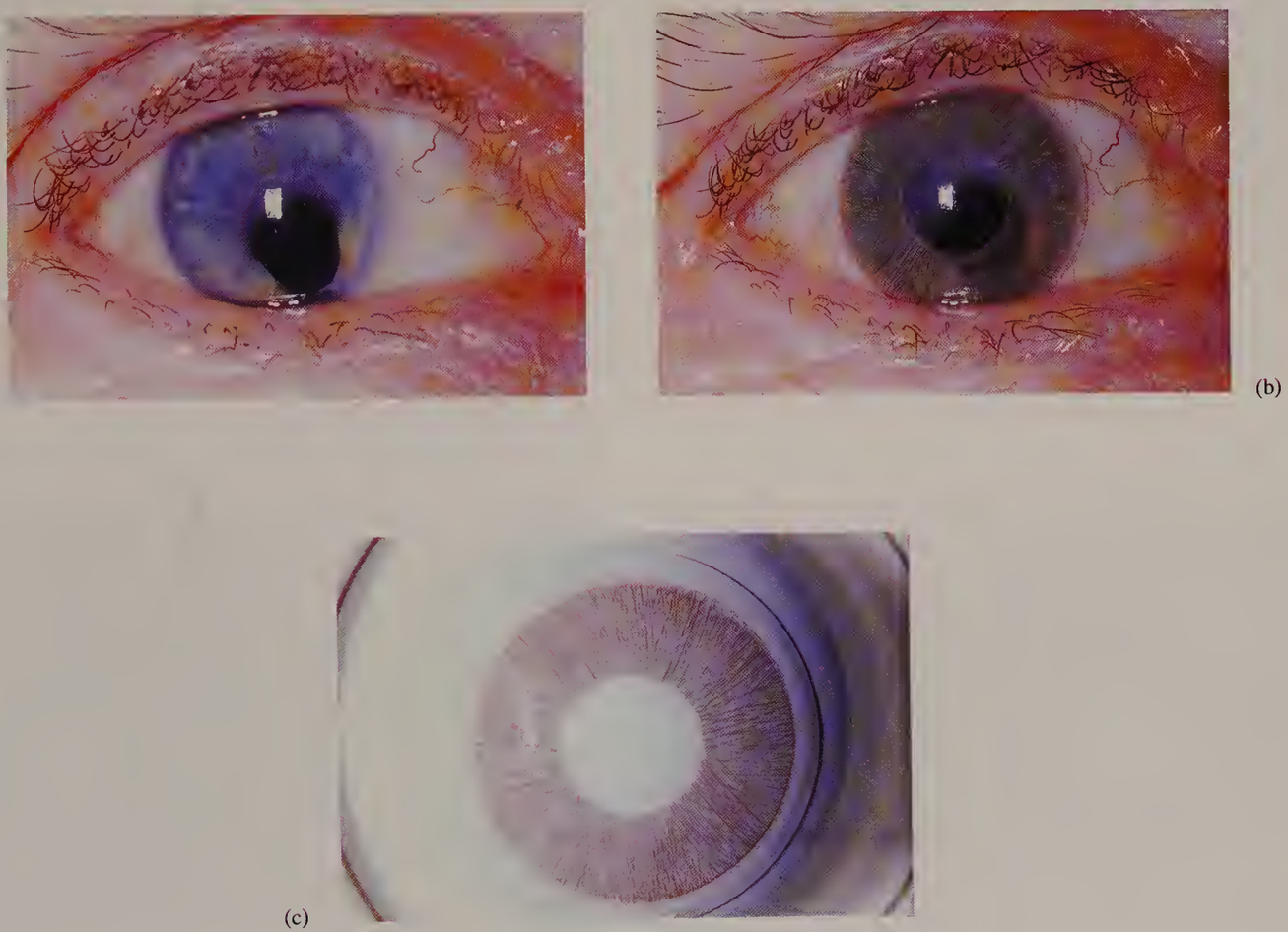


Figure 20.6.10 In iris coloboma (*a*) there are two subjective problems – cosmesis and photophobia. In (*b*) the patient has been fitted with a semi-opaque lens (*c*) incorporating an iris pattern similar to that in *Figure 20.6.8c*. A moderately large clear pupil area is necessary to allow overlap of the natural pupil area. From a metre or so the the coloboma is almost unnoticeable (lenses by Capricornia Contact Lenses). (Courtesy of A. J. Phillips)

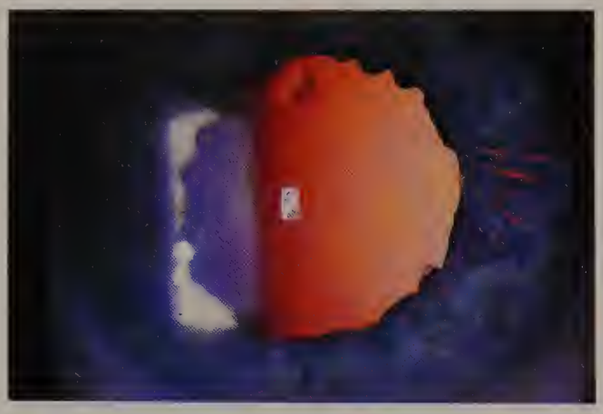


Figure 20.6.11 Iris atrophy shown by retro-illumination through the pupil. (Courtesy of A. J. Phillips)



(a)



(b)

Figure 20.6.12 Unilateral microphthalmos (*a*) disguised by (*b*) a simple brown tinted lens – the periphery of which lies over the sclera. The diameter of the tinted portion is the same as the visible iris diameter of the fellow eye



(a)



(b)

Figure 20.6.13 (*a*) A unilateral microphthalmic eye with a vertical iris split and an opaque lens capsule. The fellow eye had an unusual iris colour and pattern so the microphthalmic eye was best covered with a hand-painted opaque lens (*b*)

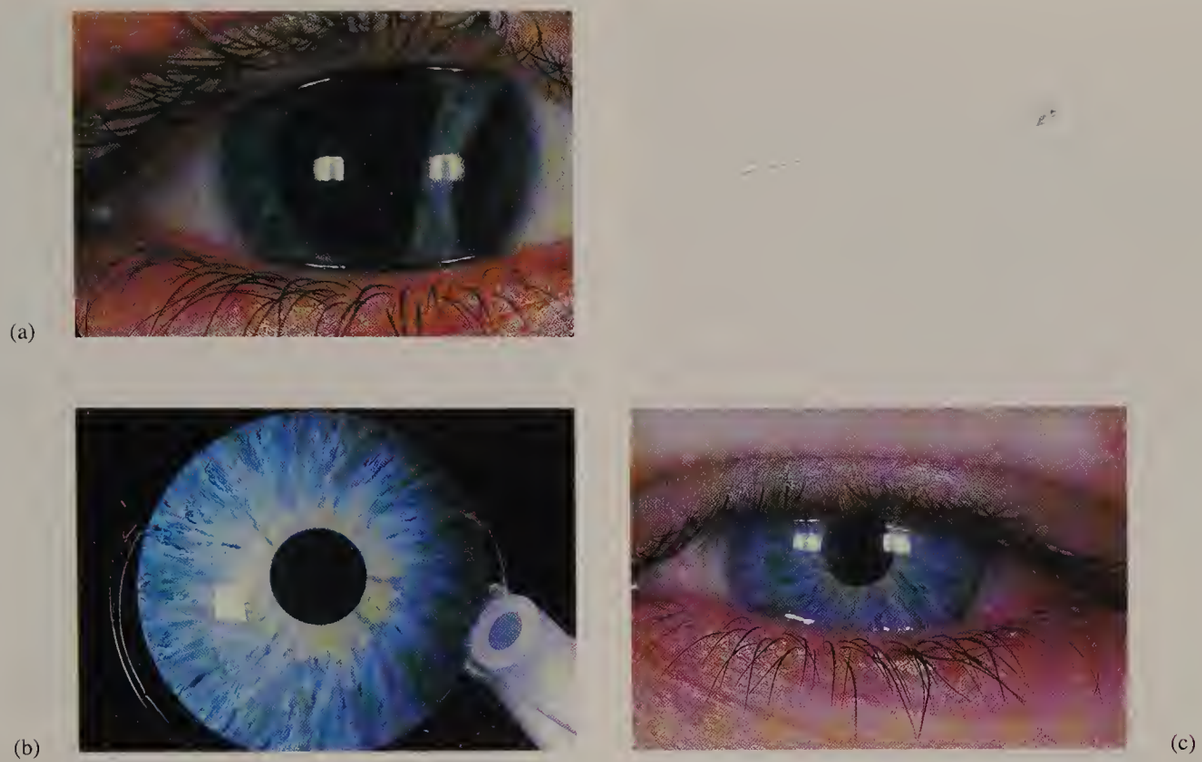


Figure 20.6.14 (*a*) Trauma due to an airgun pellet produced a damaged iris giving monocular diplopia and severe photophobia. (*b*) The hand-painted opaque lens. (*c*) The lens *in situ*. (Courtesy of G. Lowther)



Figure 20.6.15 Albinos suffer from photophobia, poor acuity and nystagmus. (*a*) The reduced aperture lens (a large black opaque pupil with a small central clear zone) may not change the acuity significantly but will reduce the photophobia. (*b*) A lens has been positioned on one eye for comparative purposes (lens by Capricornia Contact Lenses). (*c*) An albino wearing a now obsolete opaque lens (Irisprint by Ciba Vision) to reduce photophobia. As a pair of lenses is normally supplied, hand-painted lenses are not needed. Blue or grey irides are preferable to other colours. In cases of mild photophobia, opaque or semi-opaque lenses may not be needed. A simple homogeneous lens (pattern (*b*) in *Figure 20.6.21*) will suffice. (Photographs (*a*) and (*b*) courtesy of A. J. Phillips)



Figure 20.6.16 Trauma involving substantial loss of the iris, corneal opacity and aphakia. An opaque lens with a clear pupil incorporating the required correction will restore appearance and vision and reduce the photophobia



Figure 20.6.17 Slightly microphthalmic left eye. It would be noticeable to the patient, who would be concerned about the appearance. To most observers it would not attract attention. This is the same patient as shown in *Figure 20.6.12*. Once the eye was fitted with a cosmetic lens, she was a lot happier

If not warned about pupil size, the patient may comment that it is not large enough in low illumination, or perhaps that it is not small enough in very bright light.

An eye that has suffered trauma and/or surgery may well look a little red compared to the fellow eye (*Figure 20.6.18*). Even if the iris colour of a cosmetic lens is perfectly matched the contrast between the iris and sclera may still be different for both eyes. This may affect the decision on the choice of iris colour itself for the final cosmetic lens.

Friends and relatives usually have a certain attitude to the patient with a cosmetic lens. If someone has been used to seeing a person they know well with a 'disfigurement', then when it is corrected, the correction is obvious. The patient should be made aware of this. If a normal encounter does not produce a stare or a question such as 'Is there anything wrong with your eye?' then the cosmetic lens is having the desired effect.

With a seeing eye, refraction may be irregular. Due to poor lens centration, an artificial pupil or pathological changes, the visual acuity with the contact lens may be disappointing to the patient after having seen better with a spectacle correction. Of course, the reverse may be true and a contact lens correction may improve upon the spectacle acuity. Such possibilities should be discussed with the patient and, if applicable, it should be pointed out that different levels of vision can arise with different types of lens and a compromise between vision, appearance and comfort may be necessary.

A translucent tinted lens is often needed to reduce glare and photophobia (Garcia-Kramer and Weissman, 1992). It will reduce retinal illuminance with a corresponding



(a)



(b)

Figure 20.6.18 (*a*) A large superiorly displaced pupil but complicated by the conjunctival and scleral blood vessels being enlarged. (*b*) An opaque hand-painted soft lens (clear pupil) fitted to the same eye. If the vascular congestion did not subside then a scleral lens with an opaque scleral portion could be used (*see Figure 20.6.19*)



Figure 20.6.19 A scleral shell having an opaque scleral zone, opaque iris and opaque pupil. The optic zone is ventilated by the slot which is usually positioned under the upper lid

reduction in sensitivity. Lutzi *et al.* (1985) found that a 30–60% light transmission was required to reduce glare sensitivity. Various papers have reported constriction of visual fields with cosmetic lenses. For example, Insler *et al.* (1988) reported reductions of 5–20° but Trick and Egan (1990) thought that some of these findings were due to poor methodology. The degree of loss will depend on the light transmission through various parts of the lens. Bruce and Vingrys (1990) found a 0.7 dB reduction in both central and peripheral field sensitivity when testing a Durasoft 3 lens which had a 91% central transmission and a 60% peripheral transmission. Essentially, the smaller the size of the lens pupil zone and the more opaque the periphery of the lens the more the cosmetic lens will approach the effect of having a pin-hole aperture on the cornea.

Scleral lenses and shells

These are needed when an opaque scleral zone is required (*Figure 20.6.19*) to cover an eye with a large squint (*see Figures 20.6.5* and *20.6.6*). They may be needed when all other types of lens do not centre well on the eye. In cases of trauma the sclera and conjunctiva may be very irregular and chemosed and other lens types may be uncomfortable. A scleral lens is very durable and should last a considerable time. The fitting is tedious and the painting of iris and pupil is a very skilled process. As the lens is stable it is possible to incorporate cylinders and prisms. The lens or shell can easily be adjusted for thickness so that if an eye is enophthalmic compared to a fellow eye, thicker than average material can help to equalize the appearance. Often a lens thickness of 1.5 mm or 2 mm will suffice but if it is envisaged that a thicker lens or shell is required then PMMA sheet of 2–3 mm can be used. RGP scleral lenses cannot be used.

A scleral shell is made and fitted in the normal way (*see* Chapter 17). The necessary painting and construction is carried out for iris and pupil, and blood vessels on the scleral zone if it is opaque. Blood vessels are simulated by fine strands of cotton and/or painting.

The pigments for the iris are suspended in acrylic monomer and the colours are painted on with a fine brush in the same way as an artist would do an oil painting. The pupil area and iris are first painted to the correct size in black or white. If a clear pupil is required then an area of the correct diameter is left transparent. The iris colour is then applied over this opaque base. A further clear layer of monomer can be added subsequently to cover all the prosthetic components in order to give a smooth finish to the anterior surface of the shell. The monomer is polymerized by heat. It is at this stage that the thickness of the whole shell can be adjusted. If a powered contact lens is required this can be achieved by the correct power being added to the front surface. When the lens is on the eye an over-refraction may indicate that a change in lens power is indicated and this is achieved by re-working the front surface.

In order to render a scleral shell more life-like an actual photograph of the patient's unaffected eye can be used. This photograph must be reduced to actual size, i.e. 1:1, and taken in the most natural light possible. It can then be glued to the cosmetic/prosthetic shell and subsequently covered by a clear layer of PMMA. The photographic image must be stable to light or the colour of the artificial iris will change with time.

Corneal lenses

In common with scleral lenses, cosmetic corneal lenses are normally made from PMMA. With both types there is no problem with solution sensitivity or complicated hygiene regimens. Corneal types are sized between 11 and 13 mm in order to cover the cornea (*Figure 20.6.20*). The advantage of a rigid lens is in the correction of corneal astigmatism and distortion.

The lens is made in several stages:

- A clear PMMA lens is first made and adjusted to give good centration but maintaining good tear exchange. If good tear circulation is not achieved then corneal oedema is likely to lead to poor wearing times for many patients, although for others where the cornea is already vascularized the lack of oxygen available with these lenses does not give rise to problems. Careful monitoring of the results of any anoxia is necessary and it may be appropriate to advise only limited wearing of the final

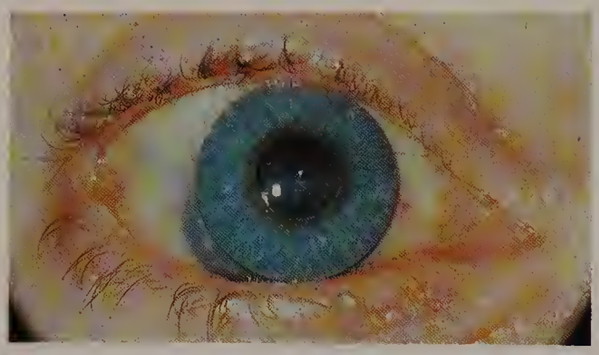


Figure 20.6.20 A poorly centring painted PMMA corneal lens. A scleral lens might be preferable if the lens centration is a problem with corneal or soft lenses. The scleral lens has the advantage of correcting any corneal astigmatism. If there is no astigmatism, then a well-centring opaque soft lens might be a better solution

lens to avoid long-term problems. If necessary, fenestrating the lens may help. The lens should centre well and ideally be as thick as the final lens (*see below*).

- Refraction should be carried out with a trial lens using a similar power and pupil size to that envisaged for the final lens.
- A cosmetic lens is ordered taking the above two aspects into account and remembering that with a painted iris it is not possible to check the fit of the lens with fluorescein and blue light.

The iris colours are painted on a black background as for scleral lenses, and then an additional layer of PMMA is polymerized over the pigments. The front surface is then cut to give the correct power. If a high power lens is to be produced then the front surface lenticulation can be reduced to approximately that of the pupil size. It is always worth considering the use of a lenticular form in order to reduce the thickness of the lens. The laminate construction implies that the lens thickness is likely to be greater than the clear lens used initially. A thick lens may be less comfortable and may not centre as well, hence the importance of considering this at the fitting stage (*see above*).

Soft lenses

As mentioned previously, soft lens types are used increasingly, especially as these types of lenses can now be manufactured in both spherical and toric forms. However, if the eye is dry, or irregular corneal astigmatism needs to be corrected, then some form of rigid lens is best. Soft cosmetic lenses can be either of two types:

- Homogeneous construction.
- Heterogeneous construction.

The first type can be considered as a normal soft lens which has been modified by one or more dyeing processes. The second type has a laminated construction.

Homogeneous types

Five possibilities are usually available, as shown in *Figure 20.6.21*.

The most widely used method of tinting soft lenses for both normal and cosmetic purposes is to introduce a form of water-soluble dye to masked off areas of the anterior surface of the lens. Demarcation of pupil and iris zones is accomplished by anterior clamping (*Figure 20.6.22*). This can be achieved with with various types of mask within the tinting apparatus. In this manner a variety of iris and pupil sizes (or no pupil at all) can be tinted. By utilizing specialized masks, life-like striations and iris patterns can be successfully produced (*Figure 20.6.23*). Using a range of

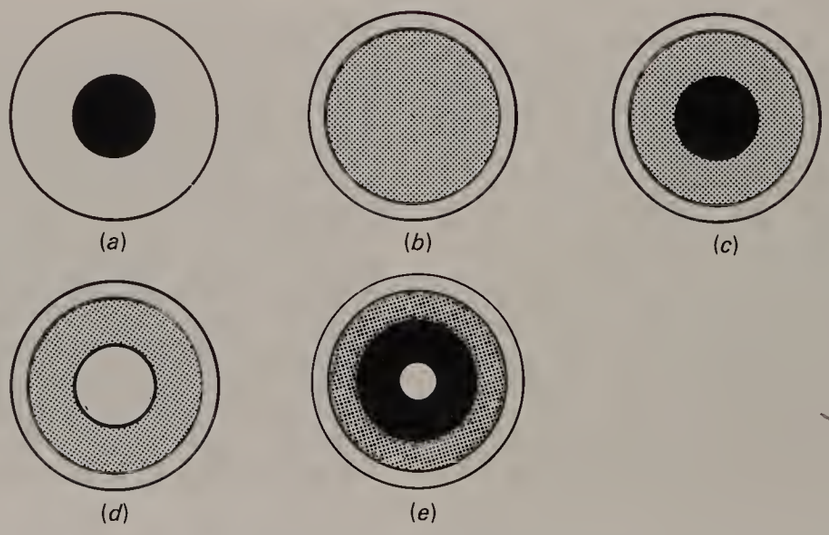


Figure 20.6.21 Different varieties of tinted or dyed cosmetic soft lenses. (*a*) A black pupil lens; (*b*) a lens with a tinted iris portion; (*c*) a lens with a tinted iris portion and black pupil; (*d*) a lens with a tinted iris portion and a clear pupil; (*e*) a black pupil with a small clear central zone, with or without a tinted periphery

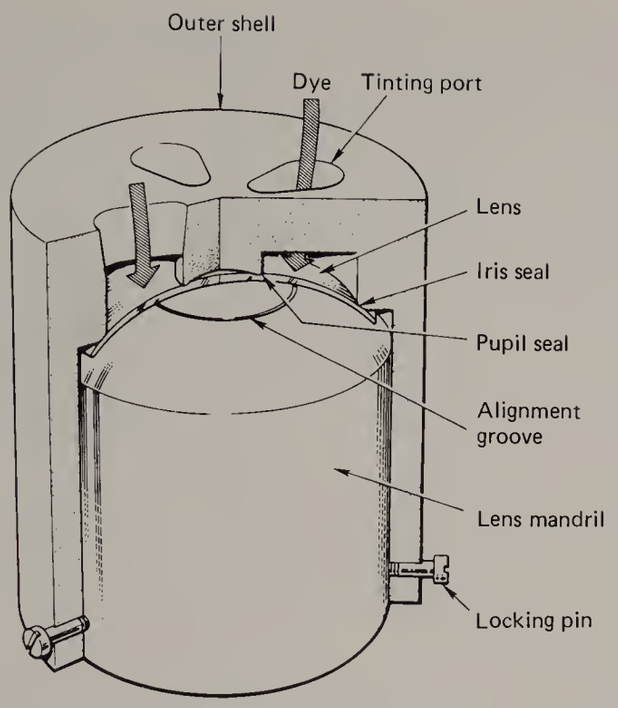


Figure 20.6.22 Clamp used to dye localized areas of a soft cosmetic contact lens

tint combinations allows the laboratory to match unusual eye colours. The lens can be pre-tinted with a neutral opaque emulsion by precipitating barium sulphate into the lens matrix and then applying the required colours and patterns to match the patient's sound eye.

An alternative method of tinting is to apply an opaque coloured dot matrix polymer which bonds to the front surface. These types of tint are fixed by various chemical methods in order to render the tint permanent. Methods of making the lens appear opaque include instilling various non-hydrophilic media into the liquid monomer before polymerization. This particulate matter is usually of a non-reactive nature, i.e. mica, titanium dioxide etc.

Occasionally the clamping process used can alter the shape (and hence fit) of the lens.

Over the past few years this part of the contact lens industry has developed considerably and the number of manufacturers producing these lens types for normal eyes has increased greatly (*see also Figure 23.43*). The number of different patterns and colours also varies according to each manufacturer. Thus the practitioner has an even bigger range of lenses to use for prosthetic purposes.



Figure 20.6.23 A 'homogeneous' soft cosmetic lens where a tint and pattern is dyed on top of an opaque base to change the colour of the right eye. (Courtesy of D. Westerhout)

Table 20.6.1 Some manufacturers of cosmetic (prosthetic) lenses

Aspect Vision Care Ltd. (UK)	Silver II tint (38%)
Bausch & Lomb	Optima 38 tint
Cantor & Silver Ltd. (UK)	Hydrofit 38
	Softwear 58 Pastel
	Softwear 58 Cosmetic
	Aquarius (74%)
Capricornia (Australia)	Hand painted (74%)
Ciba Vision	Focus Softcolors
David Thomas Contact Lenses Ltd. (UK)	Perfecta tints (38%)
Eyetech (CLM) Ltd (UK)	Eurosoft 38
	Eurosoft 77
Hydron Ltd	Z6 Softints (38%)
	Omniflex softints (70%)
	H67 Softints
	Mini Softints (38%)
Igel International Ltd	CD HI-TINTS (38%)
	58 Presto HI-TINTS
	58 Presto HI-Colour Select
	58 Presto HI-Colour Select X
	77 HI-Tints
	67 Prima HI-Tints
Lunelle Ltd	Couleur (70%)
	Solaire (70)
MJS Scientific Ltd (UK)	Seelite 73
	Seelite 38
Nova Contact Lenses	Soft 38
	Soft 60
	Soft cosmetic (58%)
Thompson Contact Lenses Ltd (UK)	Soft Colour (38%)
	Tintagel (38%)
Wesley–Jessen Ltd	Durasoft 2
	Durasoft 3 (55%)
	Durasoft Freshlook (55%)
	Elegance (38%)
	Permaflex 74
Zeiss (Wöhlk) Contact Lenses Ltd	Hydroflex Colour (38%)
	Hydroflex Mini Colour tinted (38%)
	Weflex Colour tinted (38%)

The availability of tinted lenses varies from country to country. The large multinational companies such as Bausch & Lomb, Ciba Vision, and Wesley Jessen all make tinted lenses. Many relatively small laboratories produce a range of tinted lenses and it is even possible to buy tinting kits to tint soft lenses in a practice (Broad, 1991).

The list of suppliers in *Table 20.6.1* is taken from a supplement (one of six) published by Optometry Today in 1994 and, although limited, may prove useful to those practitioners who cannot obtain tinted lenses locally.

Hickson (1994) reported the use of a pair of simple iris tinted lenses that were coloured black for a patient who had aniridia, aphakia and corneal scarring. The solution was inexpensive and proved to be satisfactory. However, some

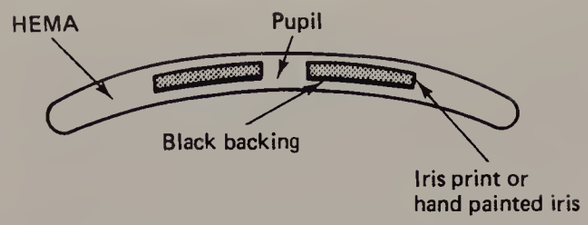


Figure 20.6.24 Cross-section of a laminated soft contact lens

patients with a light complexion may not accept the appearance of black irides.

Phillips (1994) showed that the dyed portion of certain tinted soft lenses can be more prone to surface cracking, crazing and deposition when compared to the untinted portion of the same lens. If this proves to be applicable to these types of lenses in general, then replacement may be warranted at shorter intervals than is usual.

Heterogeneous construction lenses

These soft lenses are of a laminate construction (*Figure 20.6.24*). The iris print version produced by Ciba Vision in Germany, are no longer available, but hand-painted iris pattern lenses can still be obtained. The iris pattern is painted on a black substratum and this is sandwiched between two HEMA sections (*see Figure 20.6.18*). Due to decreased demand, cost and production delays, availability is likely to be limited in most countries. Cantor & Silver in the UK produce hand-painted lenses of this type (*see Table 20.6.1*).

Due to the heterogeneous construction, the lenses are rarely spherical in form. The final shape of the lens is affected by its artificial iris size, pupil size, lens power and lens thickness. It is difficult to predict how some lenses will fit. Nothing is more frustrating than waiting 3 months for a lens, finding the colour matches well but the lens fit is poor. However, the lenses are very useful, particularly for unusual iris colours and textures, where complete occlusion is necessary and where there is a requirement for a new pupil aperture to be created.

When ordering a hand-painted lens there are several ways of specifying the colour. The numbered paper colour samples supplied by Ciba Vision can be used or a colour slide or artificial eye sample may be sent to the manufacturer. The problem with colour film is that the colour rendering is different for different films; the exposure can affect the colour (*Figure 20.6.25*) (*see* Chapter 7); the processing may affect the colour and the artist may not be illuminating the slide with a 'daylight' source. The author's experience has shown that it is better to use at least two of the three methods when trying to arrive at the correct colour and sending the results of both with the lens order. The lens order should also specify back optic zone radius (BOZR), total diameter (TD), BVP, iris diameter, pupil diameter, and state if a clear or black pupil is required.

The oxygen transmissibility of these lenses is very poor and the resulting hypoxia is expected to give rise to corneal oedema. There may well be limits on the wearing time because of this. The colours are generally stable provided that chemical disinfection is employed. Hydrogen peroxide has been tried but there may be some effect on lens shape and the chance of some pigment bleaching. Heat disinfection should be avoided as the lamination may break down and cause some bubbling of the lens surface with subsequent discomfort.

Calculating the lens power

When calculating the power of lenses with an opaque iris great care should be exercised. This is especially so in the case of high power lenses. It should be remembered that a new component has been added to the optical system, i.e. an aperture on the most powerful refracting surface. In some cases there may be a normal pupil plane as well, but in others there may be no pupil or a displaced pupil. For example, an eye requiring a lens power of +17.00 D with a transparent contact lens may actually need a power of +22.00 D with a cosmetic lens.

A comparison of the homogeneous and heterogeneous types is given in *Table 20.6.2*.

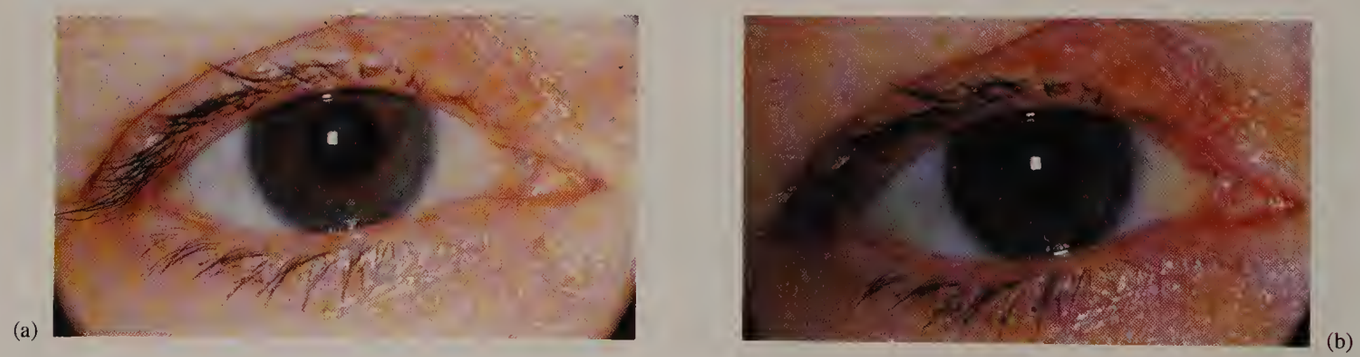


Figure 20.6.25 This illustrates the apparent difference in iris colour of the same eye at two different aperture stops: (*a*) f16 and (*b*) f22. For matching a hand-painted cosmetic lens, these are significantly different and such photographs should be backed up with another matching sample such as an ocular prosthesis or iris colour card

Table 20.6.2 A comparison of homogeneous and heterogeneous tinted cosmetic (prosthetic) lens types

Property	*Homogeneous*	*Heterogeneous*
Thickness	Normal	Thicker
Comfort	Normal	Can be poorer
Fitting	Normal	Not always predictable
Dk	Slightly reduced	Very significantly reduced
Cost	Reasonable	Expensive
Delivery	Good	Slow
Parameter range	Normal	Good
Colour range	Usually restricted	Unlimited
Darkening effect	Yes	Yes
Lightening effect	Yes	Yes
Iris texture/pattern	Restricted	Unlimited
Translucent iris colour	Possible	Not possible
Opaque iris colour	Possible	Yes
Clear or opaque pupil	Yes	Yes
Suitability for occlusion	Less satisfactory	Yes



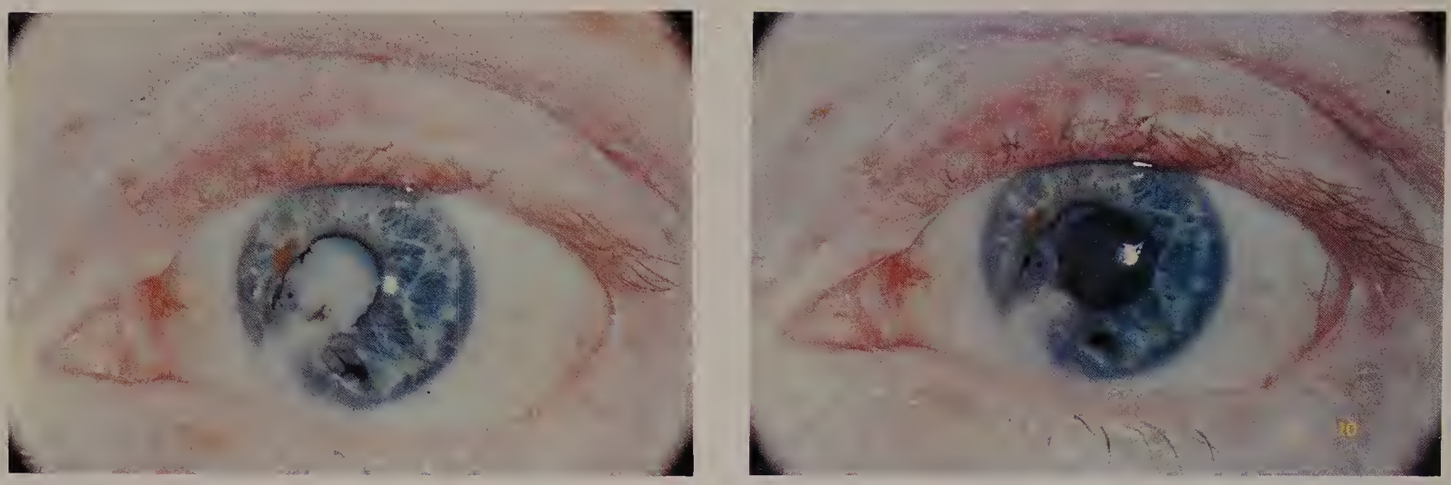
Figure 20.6.26 A cosmetic lens with a localized opaque area. Often more than one lens is required, as it is difficult to obtain the right colour, size, fit and location of the tinted portion at the first attempt. (Courtesy of A. J. Phillips)

Ordering cosmetic lenses

When ordering cosmetic lenses from a laboratory, the following guide can be useful:

- Lens parameters: ensure that the laboratory is supplied with a comprehensive list of the desired lens parameters. It is preferable to fit using trial lenses, as with some compromised eyes it is impossible to achieve accurate *K* readings. Calcified and phthisical eyes are typical of such a situation. If ordering lenses of higher water content make sure that any fitting differences due to lens shrinkage on the eye are allowed for.
- Let the laboratory know whether the eye is sighted or unsighted as the latter case will give the laboratory some latitude in manufacture. If the eye is sighted and the power is greater than +4.00 D the correct back vertex distance should be specified unless this has already been taken into account.
- Make sure that the correct material is used for the particular application. If the eye is severly compromised from injury, for example, vascularization may occur. In these situations the maximum oxygen transmissibility is desirable if vision is retained. It is therefore wise to check with the laboratory to see if the lens can be made in a high water content material.
- Specify whether a black, clear or tinted pupil is required. If the eye is blind and the cornea or lens opaque, then a black pupil can restore a normal appearance (*see Figures 20.6.1* and *20.6.3*). If the patient can tolerate a slight loss of light transmission a tinted pupil is usually more natural looking than an untinted pupil. It tends to break up the demarcation between the opaque iris and pupil areas. A small, clear pupil with a sharply defined, high contrast edge can often give a very artificial appearance.
- Iris colour and texture should be specified by colour, depth of pigment and whether the iris area should be patterned or plain.
- Note the total diameter of the tinted area. It is usually advisable to order the tint either the same as the natural iris size or just less than this (*see Figures 20.6.8* and *20.6.9*), then if the lens decentres slightly when blinking it will look more natural as the coloured area will not encroach onto the sclera.
- The opaque area can be ordered as either a complete iris or as an iris section in order to cover up, for example, a coloboma. Lens location techniques, as used for astigmatic lenses, will be necessary to locate correctly an iris section (*Figure 20.6.26*).
- As previously mentioned, a colour photograph and a paper sample should be sent to the laboratory if possible. The photograph should be taken in the most natural light and should be taken close enough to show up any iris striations, patterning etc. Due to various differences in photographic developing the finished colours may not be exactly true to life. In this case, indicate any discrepancies between the photography and the patient's eye colour to the laboratory. The technician can then modify the colour to get as close as possible to the practitioner's description.
- Darker tints can only be manufactured in the higher water content materials because the large pigment molecules are only able to penetrate into the matrix of these materials. Altering the water content will affect the tint obtained.
- Photograph the final lens on and off the eye to assist future duplication.

In some cases more than one lens is necessary before a satisfactory match is obtained. It is best to send the original lens back to the laboratory with a full description of any changes required. This helps the laboratory to produce a new lens to suit the patient's needs.



(a) (b)

Figure 20.6.27 (*a*) A white cataract with a corneal scar (*b*). Using a black pupil lens to hide the cataract leaves the natural colour and texture of the iris so attention should not be drawn to the corneal scar. This approach would not work as well if the iris was dark brown as the scar would contrast more with the iris



(a) (b) (c) (d)

Figure 20.6.28 Congenital displacement of the pupil (*a,b*) can result in a peculiar situation for the patient (similar to that occurring with subluxation of the crystalline lens). In the case illustrated the patient had two refractive results for the same eye. Wearing a –26.00 D lenticulated soft lens in her left eye, she achieved 6/24 through her own crystalline lens (*c*), whilst with +10.00 D she achieved 6/12 but with monocular diplopia. In order to gain the benefit of the higher acuity she was fitted with the lens shown in (*d*) which occludes the top of the pupil and gives better cosmesis. The clear sighted zone was located between superior and inferior thinned zones, similar to those used for stabilizing soft toric lenses (lens by Capricornia Contact Lenses). (Courtesy of A. J. Phillips)

General approach with cosmetic lenses

As in most spheres, the simplest solution is often the best as well as being easiest to reproduce when a replacement lens is needed. An example is the masking of a white cataract. A soft lens with a black pupil is the simplest, least expensive and least time-consuming option (*see Figures 20.6.1* and *20.6.4*). Even in the case of more than one problem, e.g. a white cataract and a relatively small corneal scar (*Figure 20.6.27*) just providing a black pupil will seem normal enough to the casual observer. On the other hand, on an eye where the corneal and scleral topography are extremely irregular only a scleral lens or shell would fit adequately. In *Figure 20.6.28* a simple design with a tinted iris and black pupil was used instead of a more expensive and complicated lens with an opaque sector.

Patience is required when fitting this type of lens. There are many failures. Disfigured eyes are very non-standard. Every eye poses a different problem and there are no set solutions. As experience is gained a collection of lenses is acquired and these become very useful. Flat and steep and, large and small lenses can be most valuable when fitting irregular eyes. Patients are frequently disappointed with the final appearance and this should be expected – they are looking for perfection and generally it is not forthcoming. The education of the patient is therefore all-important. He or she must realize the limitations of the lenses, and time explaining these is often well spent. If some compromises are expected, the resulting cosmetic lens is often better accepted. If a good enough match cannot be achieved by fitting the affected eye, it may be useful to fit both eyes with lenses of a colour similar to the patient's good eye.

Additional spectacles may be used if necessary to help mask the appearance of a cosmetic lens (Kumar and Krishna, 1981); a negative spectacle lens reduces the size of an enlarged palpebral aperture and a positive lens increases that of a shrunken eye. Where an increase or reduction in apparent size is required in one meridian only, a cylindrical spectacle lens may be used. The type of spectacle frame chosen can also help the general cosmetic appearance as can a slightly tinted pair of spectacle lenses. The practitioner who fits the cosmetic contact lens is in a good position and has a duty to point out the advantages of additional spectacles and to prescribe them with any suitable magnification and/or tint.

Although challenging and time-consuming, much can be achieved and patients are frequently delighted with their new appearance and resulting self-confidence.

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Chapter 20.7 Contact lenses in other abnormal ocular conditions

S. B. Hickson

Therapeutic mechanisms of contact lenses p.758
Selection of therapeutic lenses p.759
Conditions which can benefit from the use of therapeutic contact lenses p.762
Drug delivery p.772
Miscellaneous applications of therapeutic contact lenses p.773
Complications of therapeutic lens use p.773

Contact lenses are now well established in the field of ophthalmology as useful devices to assist in the treatment of many ocular conditions. When lenses are fitted primarily to protect or promote healing rather than to provide refractive correction they are known as therapeutic or bandage lenses. Hydrogel lenses, both conventional and disposable, provide the majority of therapeutic lens applications, but silicone rubber, scleral, collagen and, occasionally, rigid gas permeable lenses also have a role as therapeutic devices. Although the application of a contact lens to a diseased cornea seems to be a contraindication to some practitioners, the idea of introducing a foreign body to an eye in order to act as an ocular bandage is not new. In the first century AD, Celsus was purported to have applied honey soaked linen to the conjunctival fornices to prevent symblepharon formation following pterygium removal.

In modern times, scleral lenses were the first lens type to be used as a protective device in diseased or injured tissues (Ridley, 1962) and these lenses are still widely used for therapeutic purposes, particularly in patients for whom other lens types have failed (*see* Chapter 17). Gas permeable scleral lenses are a more recent development (Ezekiel, 1983) and their introduction has at least partially eliminated some of the hypoxic problems encountered with conventional scleral lenses, giving these lenses new applications in the therapeutic field (Schein *et al.*, 1989).

The development of hydrogel polymers by Wichterle and Lim (1960) in Czechoslovakia, was a major breakthrough and not long after these lenses became available worldwide, the first published report of hydrogel lens use as a therapeutic device was made (Gassett and Kaufman, 1970).

Therapeutic mechanisms of contact lenses

Contact lenses can act as a therapeutic device in a variety of different ways

Mechanical effects

Lenses can provide mechanical support to the cornea by acting as a protective barrier in conditions where eyelid loss or dysfunction could easily lead to exposure keratitis. In trichiasis, the presence of a contact lens protects the cornea from trauma caused by the lashes (*Figures 20.7.1, 20.7.2*), and in conditions where re-epithelialization is taking place a lens can protect the new tissue from the 'windshield wiper' effect of the eyelids. In cases such as corneal perforation or where a descemetocele has formed, a contact lens can act as a splint providing structural support to these weak areas.

Symptom relief

Another important function of therapeutic lenses is to alleviate symptoms. In conditions such as bullous keratopathy (*see Figure 20.7.3*), the presence of a lens greatly reduces the severe pain which patients would otherwise experience. Although visual improvement is not a primary function of therapeutic contact lenses, in certain eonditions the presence of a lens can aid vision by providing a more regular refractive surface than is provided by an irregular diseased cornea, or it can provide a powered correction together with its primary function of symptom relief.

Adjunct to healing

Contact lenses can assist the healing process of the cornea in many conditions such as recurrent epithelial erosions and persistent epithelial defects. The lens permits re-epithelialization to occur beneath it and also protects the vulnerable new epithelium from lid action.

Drug delivery

Hydrogel and collagen contact lenses may be used to deliver ophthalmic drugs to the eye. This method of drug delivery allows a variety of different drugs to remain in the ocular tissues for longer periods of time than generally occurs with topical application.

Maintaining corneal hydration

Therapeutic soft contact lenses can be used to maintain some level of hydration of the cornea in severe dry eye conditions, although ocular lubricants must be used on a



Figure 20.7.1 Severe entropion and trichiasis associated with blepharitis. The use of a bandage soft lens allowed regeneration of damaged corneal epithelium and prevented further disturbance prior to surgery. (Courtesy of D. Westerhout)

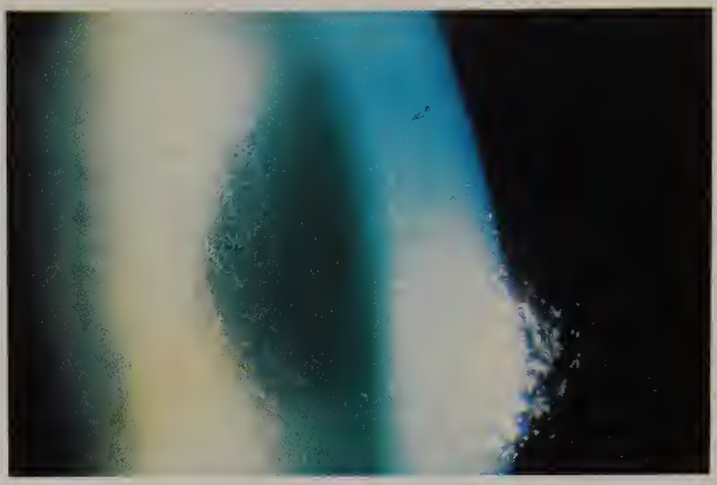


Figure 20.7.3 Bullous keratopathy (Courtesy of A. J. Phillips)

regular basis in conjunction with the contact lenses if this is to be a successful method of treatment. Sealed scleral lenses have the ability to hold a reservoir of fluid between the lens and the eye, and hence can also be of use in dry eye conditions.

Selection of therapeutic lenses

Selection of an appropriate therapeutic lens requires an understanding of the primary ocular disorder as well as a knowledge of the various therapeutic lenses available. An understanding of differing lens types and their effects on the cornea is also important to allow appropriate lens selection.

Lenses can affect corneal physiology in three ways. They induce variable degrees of hypoxia, alter the tear film distribution over the corneal surface, and induce low grade mechanical trauma to the corneal epithelium. An ideal lens fit minimizes all of these effects while aiding the recovery of the condition which is under treatment.



Figure 20.7.2 Trichiasis with RGP prescription lens. The lens sits superiorly on the cornea, thus protecting it from the misaligned lashes. (Courtesy of L. Speedwell)

Unless the eye is blind, it is even more important that therapeutic lenses should be chosen to allow the maximum amount of oxygen to reach the cornea than with contact lenses fitted for refractive purposes. Lenses should be fitted so that they move adequately but not excessively in order that the physiology of the diseased eye is not further compromised. Physiological considerations are of particular importance because in most cases therapeutic lenses are worn continuously. If, however, the eye is blind and has no future visual potential, the most important consideration becomes that of comfort. It is then less important to consider the oxygen permeability or fit of the lens.

Also to be considered is the desired mechanism of the therapeutic lens and the primary ocular condition which is under treatment. For example, silicone rubber lenses would provide a better result than soft lenses in conditions characterized by a very irregular ocular surface. This is because they provide a more regular anterior refracting surface than soft lenses which tend to drape the cornea and this is an important consideration if visual improvement is a possibility.

As well as lens type, other parameters, including total diameter, back optic zone radius and back surface geometry, must also be considered. The method of soft lens manufacture can play a part in the way in which a lens performs on the eye, for example spun-cast lenses move less than those that are lathe-cut. In conditions such as recurrent epithelial erosions this reduced movement is a desirable feature, as lenses which move excessively can damage the fragile newly formed epithelium which they were fitted to protect.

In summary, general fitting principles apply when choosing an appropriate lens for therapeutic purposes. However, the issue is somewhat complicated by the vast range of diseases and conditions which can benefit from contact lens therapy. Healthy eyes vary enormously in their anterior surface topography and diseased eyes vary even

more. Hence, each individual case should be considered separately and appropriate caution should be used so that the lens which is fitted actually does act in the intended manner.

As a condition heals, there may be changes in corneal topography which can in turn lead to a change in the lens fit. Practitioners should therefore be aware that refitting patients at differing stages of their recovery may be required.

Lens availability

Different therapeutic lenses are available in different countries and, in addition, large ophthalmic institutions may manufacture their own lenses for therapeutic purposes. Certain contact lens companies manufacture and market lenses specifically for therapeutic use but in theory any hydrogel contact lens could be used therapeutically if its parameters and material are known and if the lens is available in a suitably low power. Most therapeutic lenses are plano powered because refractive correction is not an issue, but in some cases refractive correction can be usefully incorporated into the therapeutic correction.

Soft lens materials and designs

Hydrogel contact lenses, whether used for therapeutic or refractive purposes, can be broadly classified into three major groups depending on their water content, in the same way as soft lenses, used to correct refractive error, are classified (*see* Chapter 11). (i) Low water content lenses contain 38–45% water and can be made in any thickness. When made extremely thin (0.035 mm) they allow good oxygen transmissibility. These very thin lenses are commonly known as **ultrathin** or **membrane** lenses. (ii) High water content lenses, containing 70–80% water, can be made in a variety of thicknesses. However, because very thin high water content lenses are extremely fragile, these lenses are made slightly thicker, usually in the range of 0.06–0.07 mm. (iii) Medium water content lenses containing 50–65% water are also available in a variety of thicknesses. Oxygen permeability of a hydrogel material increases with water content but oxygen transmissibility of a lens is dependent on both the water content of the lens material and the thickness of the lens (*see* Chapter 11).

Lenses with steeper back surface radii fit more tightly than lenses with flatter base curves made to the same overall diameter and design. Keratometry is a useful guide to BOZR selection and in cases where a distorted cornea does not allow keratometry readings to be taken, the contralateral eye may be of some use to obtain an approximate measure of corneal curvature. Of course this predictor is of little use when either or both eyes have undergone surgery which would change the corneal topography.

If a lens is fitted too flat, excessive lens movement on blinking may retard healing of the epithelial surface or cause pain, for example in bullous keratopathy. In addition, an excessively loose lens may displace from the cornea and even fall out of the eye, causing undue inconvenience to the patient who may then need to attend the clinic for cleaning and replacement of the lens. Conversely, steep lenses which move little on the eye can induce oedema and discomfort as well as trapping cellular debris behind the lens. This debris can break down to release toxic substances which, in turn, could lead to an inflammatory response (Zantos and Holden, 1978; Mertz and Holden, 1981).

The total diameter of the lens should be selected so that the limbus is completely covered during all version movements. In some conditions, however, particularly large lenses are required. Examples of this include treatment of a leaking filtration bleb or when aiding the healing process of a peripheral corneal lesion. The total diameter of a lens also has an effect on lens movement. Larger lenses fit more tightly and move less than smaller lenses of similar base curve.

Soft lenses for therapeutic use have several advantages. They can quickly make a painful eye comfortable, they are easy to fit, readily available in many types and parameters and are relatively cheap. They can also be fitted in tinted form to improve the cosmesis of an unsightly, painful eye. In such cases it is advisable to fit a clear lens initially to watch for any adverse effects before refitting with a tinted lens (Speedwell, 1991).

There are, however, several disadvantages. Soft lenses do not perform well on dry eyes, nor do they enhance the vision of irregular corneas. They can rapidly accumulate deposits because the tear film in an eye needing such a lens is likely to be abnormal. The lenses therefore require frequent replacement. It is always advisable to consider therapeutic soft lenses as bandage lenses and, when worn on an extended wear basis, they should be replaced rather than an attempt made to clean and reinsert them.

Disposable hydrogel contact lenses

Since the launch of disposable lenses in the late 1980s, numerous reports of their application as therapeutic devices have been made (Weinstock, 1990; Sulewski *et al.*, 1991; Gruber, 1991; Tanner and DePaolis, 1992). Most makes of disposable lenses have been used successfully to treat a wide variety of conditions such as recurrent corneal erosions, filamentary keratitis, bullous keratopathy and neuroparalytic keratitis.

Disposable lenses offer many advantages over conventional hydrogel lenses when used for therapeutic purposes. They are more convenient and cheaper than conventional alternatives and hence the costs are much lower when lenses need to be replaced because of deposit formation. Patients can be given extra lenses for replacement at home if they have an ongoing ocular surface problem which requires long-term therapy. The practitioner can tailor the lens replacement schedule to the needs of the patient and the condition under treatment, and weekly or even daily replacement of lenses is possible. However, it is important to realize that disposable lenses still carry the risks of conventional lenses such as hypoxia and infectious keratitis.

Silicone rubber lenses

Silicone rubber lenses have an important role to play in therapeutic lens work as the material is highly oxygen permeable and does not require hydration as a soft lens does. The high oxygen permeability is an obvious advantage for extended wear of lenses and, because fluid is not required to maintain lens shape, the fit of silicone rubber lenses is not affected by lack of tears (*see* Chapter 11). Hence, silicone rubber lenses may be the lens of choice in cases where chronic and severe dryness is a problem. Silicone rubber lenses are sturdier and less flexible than hydrogel lenses and can therefore improve acuity in an eye with an irregular corneal surface. They are, however, generally more expensive than other types of lens. Indications for silicone rubber lenses include keratinized mucous membranes, trichiasis and incomplete lid closure (Woodward, 1979).

Unfortunately, these lenses are not without their own disadvantages. The material is hydrophobic and must be surface treated to render it hydrophilic before it can be used as a contact lens. The surface is easily scratched, producing areas on the lens which do not wet properly (although this is not usually a problem in an eye that sees poorly) and a scratched lens is prone to deposits. In a seeing eye, the lens may need to be replaced frequently and this can become very costly.

It is important when fitting these lenses to allow plenty of time for them to settle. A lens which first appears to fit perfectly can tighten unpredictably (*see* Chapter 11) and adhere to the cornea, causing debris to become trapped under the lens, increasing the potential for inflammatory reactions.

Scleral lenses

Scleral lenses have been used for therapeutic purposes for over 100 years and in cases of dry eyes with cicatricial tissue, no other lens is as effective. Their main drawback is that of convenience. They are time-consuming to fit as well as requiring special equipment and expertise. However, with more recent availability of gas permeable materials for these lenses, they remain an important adjunct in maintaining useful vision in eyes that would otherwise become blind (*see* Chapter 17 on fitting techniques).

Collagen bandage lenses

The use of collagen to manufacture bandage lenses or 'shields' is a relatively recent innovation and has shown a small but useful place in the field of therapeutic lens work. Collagen accounts for approximately one-quarter of the total body protein and is the most abundant body protein in both humans and animals. It is actually made up of a number of different proteins which differ slightly in their amino acid sequence. Collagen degrades in a foreign biological environment and eventually disappears, leaving no permanent residue. This property lends itself well to many medical applications such as sutures which dissolve and therefore do not have to be removed, in dressings for burns, and in injections for facial augmentation. In ophthalmology, uses of collagen include scleral buckling devices, lacrimal drainage plugs and external eye patches.

Collagen lenses are usually manufactured from porcine or bovine tissue and are sterilized by irradiation. In most cases, collagen lenses are packaged and delivered dry and therefore require hydration prior to insertion in the eye. The effect of collagen shields on epithelial wound healing has been evaluated using animal studies. In rabbit eyes with central superficial keratectomies, the rate of epithelial healing was significantly faster in corneas treated with collagen shields than in those receiving no treatment (Frantz *et al.*, 1989). In cat corneas which had been mechanically de-epithelialized, collagen shields were found to accelerate corneal wound closure (Shaker *et al.*, 1989). The increased healing rate observed was thought to be due to epithelial lubrication and protection provided by the collagen shield. In a study in which radial keratotomies were carried out on rabbits, histopathological examination of corneas treated with collagen shields showed that these had more complete epithelial healing than untreated eyes (Aquavella *et al.*, 1987).

In human studies, collagen shields have been shown to have numerous applications as therapeutic devices, and have been used successfully to treat many corneal disorders and to promote wound healing after anterior segment surgery (DePaolis *et al.*, 1987; Aquavella *et al.*, 1988; Ruffini *et al.*, 1989).

Collagen lenses are thought to provide therapeutic functions via a number of mechanisms. Aquavella *et al.* (1988) suggested that when a collagen lens comes into contact with the tears, hydrolysis, proteolytic enzyme action and lid motion combine to produce a fine collagenous film which has a lubricating effect on the cornea. They also suggested that collagen fibres may provide a framework to guide cellular migration, and that the by-products of collagen degradation may be chemotactic. Both of these factors would contribute to the superior wound healing properties of collagen lenses. Shaker *et al.* (1989) suggested that collagen may act like mucin and facilitate the spreading of the aqueous layer of the tear film which would be beneficial in certain dry eye conditions. In addition to these properties, the hydrophilic nature and dissolution of collagen lenses allows enhanced drug delivery to the eye (*see below*). Studies into the oxygen transmissibility and corneal swelling response with collagen lenses have shown that they are comparable to high water content hydrogel lenses (Weissman and Lee, 1988; Ros *et al.*, 1991).

Advantages of collagen lenses over hydrogel lenses include the ability of the collagen lens to conform to the shape of the cornea, eliminating the need for multiple BOR. The collagen surface is particularly wettable and the material is not sensitive to pH changes which are normally encountered in the eye. Furthermore, the self-dissolution of the material eliminates the need for removal which can be advantageous.

Several disadvantages of collagen lenses compared to hydrogel lenses have, however, also been found. Greater discomfort and reduced visual acuity have been reported as has the increased difficulty of examining the cornea through the collagen lens due to lack of transparency. Dissolution rates of collagen lenses can be variable and the water content has been found to increase during wear, suggesting that the lenses are absorbing water from the ocular surface to maintain their own hydration (Ros *et al.*, 1991).

Although collagen lenses have wide-ranging applications in the therapeutic field their ability to dissolve in the eye is not a desirable feature in conditions where a lens of a more permanent nature is required, for example in long-term therapy for bullous keratopathy.

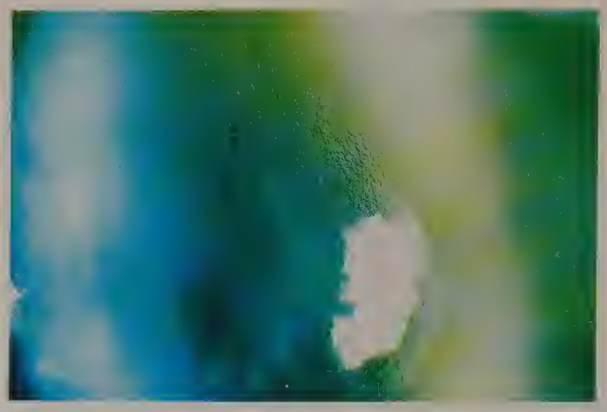


Figure 20.7.4 Bullous keratopathy. (Courtesy of C. McMonnies)

Patient follow-up

As with any contact lens patient, regular after-care appointments are a necessary part of therapeutic lens work. This continued patient care is of added importance because the risks of contact lens complications are greater in the compromised eye than in the healthy eye. After-care provides an opportunity to review the condition under treatment as well as to exchange or, if no other lens is available, to clean, disinfect and reinsert the bandage lens. Many gross corneal conditions can be examined through the lens and the use of fluorescein dye may not be necessary if its use does not provide added information regarding the status of the anterior eye.

In all cases, extreme care should be employed when carrying out an examination or when inserting or removing lenses to prevent further damage and disturbance. After-care frequency is dependent on the condition under treatment and the time course of the disorder. Astin (1989) suggests a pattern of after-care of one day, 3–7 days, one month, 2–3 months, or more frequently. Needless to say, each patient and condition should be assessed individually to ensure adequate monitoring.

Conditions which can benefit from the use of therapeutic contact lenses

Bullous keratopathy

The use of hydrophilic contact lenses in bullous keratopathy provides dramatic pain reduction and can also offer some visual improvement. Bullous keratopathy is a condition of chronic corneal oedema and is characterized by symptoms of pain, epiphora, blepharospasm and photophobia. The cornea is totally or partially involved and appears hazy or opaque due to the severe oedema. Small fluid-filled vesicles, known as bullae, form in the epithelium and rupture on the corneal surface (*Figure 20.7.3, 20.7.4*). The severe pain experienced by patients with this condition is thought to be due to exposure of nerve endings once the bullae rupture, or stretching of nerve endings due to acute swelling of the epithelium (Liebowitz and Rosenthal, 1971a). The visual reduction is due to the combined effects of the irregular anterior corneal surface and loss of corneal transparency.

There are many possible causes for bullous keratopathy but a common factor in all conditions is endothelial cell dysfunction. Dysfunction of the endothelium may occur due to diseases such as glaucoma or dystrophic conditions such as Fuchs' endothelial dystrophy. The most common cause of endothelial dysfunction is, however, intraocular surgery such as cataract extraction. The relationship between the preoperative endothelial cell condition and pseudophakic bullous keratopathy was investigated by Rao *et al.* (1984) who found that patients with more variation in cell size before surgery were more vulnerable to surgical trauma and were more likely to have endothelial decompensation following cataract extraction and intraocular lens implantation. Even with this knowledge and the availability of examination techniques which allow details of the endothelial status to be obtained prior to surgery, some patients must still undergo intraocular surgery and risk the possible side-effect of endothelial dysfunction.

Since the therapeutic applications of hydrogel contact lenses were first recognized by Gasset and Kaufman (1970), many authors have reported the beneficial effects of these lenses for patients with bullous keratopathy. In many cases the relief of pain which is provided by the contact lens is noted almost instantaneously by the patient (Liebowitz and Rosenthal, 1971a; Gassett and Kaufman, 1971a; Høvding, 1984; Rehim and Samy, 1989). This is thought to be due to the protection that the lens provides to exposed nerve endings from the atmosphere and from lid trauma during blinking.

Significant visual improvement may also be provided, particularly in less severe and recent onset cases which mainly affect the epithelium (Gasset and Kaufman, 1970, 1971a; Takahashi and Liebowitz, 1971; Høvding, 1984). In cases where gross stromal oedema and Descemet's folds are present, the visual improvement may be minimal (Liebowitz and Rosenthal, 1971a), although in other cases visual improvement may occur even with plano powered therapeutic lenses. This is because the lens provides a more regular anterior refracting surface than is provided by the

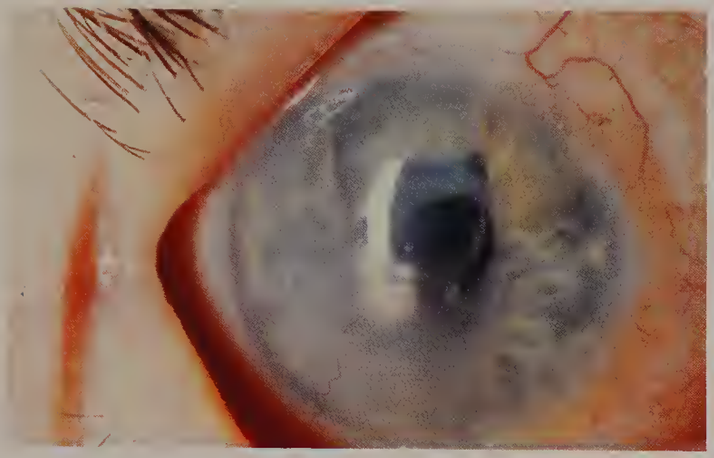


Figure 20.7.5 Aphakia with bullous keratopathy. This eye was fitted with an extended wear high water content aphakic soft contact lens which acted both as a bandage and gave the patient a visual acuity of 6/12. (Courtesy of L. Speedwell)

oedematous cornea. It is, of course, also possible to fit patients with appropriately powered lenses which would then have the dual effect of providing both refractive and therapeutic functions (*Figure 20.7.5*). A large number of patients with bullous keratopathy are aphakic and hence it may be tempting to fit them with aphakic soft contact lenses to correct their refractive error. Unfortunately, even high water content lenses made to the powers required have poor oxygen transmission due to the lens thicknesses involved. Hence these lenses may induce more oedema and actually exacerbate the condition they were fitted to assist. It is occasionally necessary, therefore, to fit high water content plano powered lenses and prescribe aphakic spectacles.

Mild cases of bullous keratopathy and corneal oedema may be treated initially with hypertonic eye drops and ointments in an attempt to draw water from the cornea. This is not usually successful in the long term and a hydrophilic contact lens is the next option, which may be worn in conjunction with the regular instillation of 5% sodium chloride drops. Repeated instillation of these drops throughout the day ensures that the water content of the lens will approach the ion concentration of the saline. This provides a hypertonic reservoir in equilibrium with the very thin tear film layer between the lens and the epithelium, and hence provides a greater osmotic dehydrating effect on the cornea than the contact lens alone (Takahashi and Liebowitz, 1971).

The use of hydrogel contact lenses in bullous keratopathy prevents neither formation nor rupture of the bullae (McDermott and Chandler, 1989). However, the concurrent use of a lens and 5% sodium chloride drops can cause a significant reduction in corneal oedema (Høvding, 1984), but does not usually prove successful in the long term.

Patients with bullous keratopathy generally wear lenses on a continuous wear schedule because pain recurs immediately the lenses are removed. The duration of lens wear is variable and is dependent on the severity of the condition. Some patients are able to cease the use of a bandage lens for intermittent periods or even completely; others may cease the use of a bandage lens and receive adequate relief from hypertonic drops and ointments. In numerous cases, however, bandage lenses are used for many years as the only alternative treatment is penetrating keratoplasty. Because surgery may be contraindicated due to underlying ocular pathology or patient age, bandage lens therapy is often used as a permanent method of pain relief.

The fitting of a soft bandage lens may be difficult and it is often helpful to take keratometric measurements from the non-affected eye to give guidance as to the required fitting. In general, larger lenses perform better than small ones, and lenses commonly used have diameters of 14.00–15.50 mm. Lenses should be fitted to avoid excessive movement which would cause pain, while at the same time avoiding a tight fit. When fitting eyes with bullous keratopathy the guiding parameter is patient comfort, keeping in mind that any neovascular complications of lens wear in an eye with visual potential may affect the success of a future penetrating keratoplasty. Hence, when choosing a lens, the oxygen transmissibility should be considered and a high water content lens of plano power is often the best choice.

Fuchs' endothelial dystrophy

Fuchs' endothelial dystrophy is a slowly progressive disorder which is more common in females than in males and is characterized by bilateral dysfunction of the corneal endothelium. This dysfunction eventually leads to corneal oedema and bullous keratopathy, at which time bandage lenses may be used to relieve pain, although penetrating keratoplasty is a more common alternative.

The condition usually presents during or after the sixth decade of life although clinical changes to the endothelium may be observed at a much earlier age. Early changes include the appearance of endothelial guttata (*see Figure 15.20*) and pigment dusting in the central cornea, which can be so subtle that there is often considerable overlap between early dystrophic changes and age-related changes seen in the normal population. The guttata gradually spread peripherally and increase in number, obscuring the endothelial mosaic which eventually becomes affected to such an extent that it can no longer maintain the balance of hydration of the cornea. Consequential stromal and epithelial oedema occur and patients start to report blurred vision, glare and haloes around lights, particularly in the mornings. During the day the symptoms often abate as the corneal swelling gradually reduces.

Initial treatment is employed in an attempt to draw fluid from the cornea to expedite de-swelling. Treatments include the use of hypertonic drops and ointment and the use of a hairdryer directed at the eyes for a few minutes each morning in an attempt to increase tear evaporation and draw fluid from the eye.

As the condition progresses, persistent epithelial oedema eventually leads to the formation of bullae which rupture leading to severe pain and further loss of vision. At this stage bandage contact lenses can help to relieve pain, and

can be used alone or in association with hypertonic drops. Bandage lenses are usually worn for 24 hours a day for long periods of time. These can also be tinted (*see Figure 20.6.4*). The only permanent cure for Fuchs' endothelial dystrophy is penetrating keratoplasty.

Recurrent corneal erosions

Recurrent corneal erosions can occur as a result of many different conditions, including anterior membrane dystrophies, certain stromal dystrophies and some viral or bacterial infections. The most common cause of recurrent erosions is mechanical trauma to the cornea (*see* Recurrent erosion syndrome below). Although the majority of corneas heal well after mild trauma, those that do not heal can result in chronic, intermittent attacks of painful epithelial cell loss lasting for weeks or even months due to incomplete reformation of the underlying basement membrane (*see below*). Treatment includes the use of ocular lubricants, hypertonic agents, topical antibiotics and mydriatics. Mechanical debridement and pressure patching or laser therapeutic keratectomy may also be helpful. However, the healing period may last for several days and is associated with continuing pain and further disability from the dressing. Alternatively, recurrent erosions may be treated successfully with soft bandage lenses, which allow healing to take place while maintaining visual function. The presence of the lens also prevents mechanical irritation of the eroded area by the lids, which further aids comfort.

Recurrent erosion syndrome

This syndrome manifests with characteristic symptoms of foreign body sensation or pain, accompanied by lacrimation, photophobia and blepharospasm. Typically patients awaken first thing in the morning with symptoms which may be accompanied by mild conjunctival injection. When the patient is questioned, a distant history of corneal injury is often reported. These injuries are often the result of trauma from a hairbrush, mascara applicator, fingernail or a tree branch, but may have any origin. If no such history can be elicited, careful examination of the cornea may reveal signs of an anterior membrane dystrophy (see below).

Symptoms occur when epithelial cells that are only loosely attached to the underlying basement membrane are detached due to the combined effects of reduced or absent tear flow during sleep and lid action on waking.

In normal healthy corneas the basal epithelial cells attach to the basement membrane by way of hemidesmosomes. Recurrent epithelial erosions occur when the basement membrane becomes damaged and does not permit secure hemidesmosomal adherence to occur. Clinically, this results in repeated epithelial breakdown with associated symptoms of pain, photophobia, lacrimation and blepharospasm.

In this situation, a hydrogel bandage lens can provide several benefits. Initially the lens acts to relieve pain caused by the repeated erosions. In addition the lens can promote re-epithelialization by protecting the delicate regenerating epithelium from the windshield wiper effect of the lids. Once epithelialization is complete, the hydrogel lens acts to stabilize the epithelial layer to allow optimum conditions for hemidesmosomal formation.

Hemidesmosomes can take many months to regenerate completely (Gipson *et al.*, 1989) and it is therefore necessary for lenses to be worn for long periods to ensure healing is complete. As epithelial detachment generally occurs during the night or immediately on waking, lenses should be worn on a continuous basis, and because removal can also result in detachment of a fragile epithelium, practitioners should take this into consideration when conducting after-care on these patients. Hence, minimal removal of lenses is advised, while still maintaining a relatively clean lens and a healthy eye. Practitioners must balance the advantages of continuous wear, which leaves the epithelium undisturbed, against the risks inherent in allowing a coated, contaminated lens to provide a source of irritation or infection.

Although the use of bandage lenses on a continuous wear schedule is generally advised with this condition, it should also be borne in mind that experimental work on cats has shown that extended wear can cause a loss of corneal epithelial adhesion to the basement membrane (Madigan *et al.*, 1987). While this may be so, epithelial healing does not appear to be adversely affected by extended wear of hydrogel lenses and the prognosis for the complete recovery of patients treated with bandage contact lenses is very good. Acheson *et al.* (1987) compared the healing effects of two methods of treatment on patients with traumatic corneal abrasions attending a hospital casualty department. One group was treated with occlusive pads and bandages while another group was fitted with high water content bandage lenses. The researchers concluded that abrasions over 4 mm in size may benefit from treatment with a bandage lens, and that those patients treated with lenses healed more quickly and experienced less discomfort than those treated with a pad and bandage.

Anterior membrane dystrophies

Anterior membrane dystrophies can frequently produce intermittent epithelial breakdown which, in more severe cases, may require bandage lens therapy for symptomatic relief.

Map-dot-fingerprint dystrophy

This is the most common anterior membrane dystrophy and is named after the biomicroscopic appearance of the epithelial basement membrane irregularities. The pathogenesis of these irregularities is thought to be the synthesis of abnormal and redundant basement membrane (Epstein and Donnenfeld, 1989). Maps, dots and fingerprints can occur separately or together in the same cornea. Maps appear as grey patches in a characteristic geographic pattern with

sharp, well demarcated edges, dots appear as grey or clear cystic spaces beneath the abnormal basement membrane, and fingerprints appear as fine grey lines arranged in a whirl-like pattern, giving the appearance of a thumb print. Patients with map-dot-fingerprint dystrophy may be completely asymptomatic or may complain of foreign body sensation, pain, photophobia and lacrimation which occur due to recurrent epithelial erosions. If symptoms persist, topical ocular lubricants and antibiotics with pressure patching are usually the initial treatments but in difficult patients who have not responded to this therapy, bandage contact lenses may be fitted. Siegel (1986) reported the successful use of hydrophilic contact lenses in cases of epithelial basement membrane dystrophy and emphasized the fact that therapeutic effects could be achieved while providing refractive correction. Williams and Buckley (1985), however, concluded that therapeutic contact lenses provide inferior treatment and have a higher complication rate than topical medications when treating this condition.

Reis–Buckler dystrophy

This condition is characterized by superficial, ring-shaped opacities at the level of Bowman's layer, which are most dense in the central cornea and give the cornea the appearance of a honeycomb. The condition is inherited in an autosomal dominant manner and usually first presents during early childhood. The typical course of the condition is characterized by recurrent attacks of painful epithelial erosions lasting for several weeks at a time. During exacerbations, bandage contact lenses may be used for symptomatic relief. Eventually, lamellar or penetrating keratoplasty may be necessary, particularly if visual acuity is significantly impaired, although recurrence of the dystrophy in the graft is common.

Meesman's epithelial dystrophy

This is a very rare dystrophy characterized by tiny intraepithelial cysts which are widespread over the cornea of both eyes. The cysts are best detected during biomicroscopic examination using marginal retro-illumination and are generally found to extend to the limbus. The dystrophy is inherited in an autosomal dominant manner and the epithelial changes are usually first detected in infants although they always increase with age. Some patients develop mild ocular discomfort, photophobia and lacrimation at which time a soft bandage lens may be of use. Other patients, however, do not experience any such symptoms or any visual impairment.

Stromal dystrophies

Recurrent epithelial erosions may occur secondary to certain dystrophies of the corneal stroma. Patients suffering from lattice or macular stromal dystrophies may require soft bandage lenses to alleviate symptoms associated with recurrent erosions.

Lattice dystrophy

This condition is inherited in an autosomal dominant manner and usually presents in the first or second decade of life with the appearance of fine dots and lines in the central corneal stroma. The condition is bilateral and symmetrical in its course, and progresses gradually with increasing opacities until the whole stroma becomes cloudy. Patients complain of blurred vision, accompanied by photophobia and pain due to recurrent epithelial erosions. Ultimately, the only cure is penetrating keratoplasty but soft bandage contact lenses can provide pain relief if other factors preclude surgery for any period of time.

Macular dystrophy

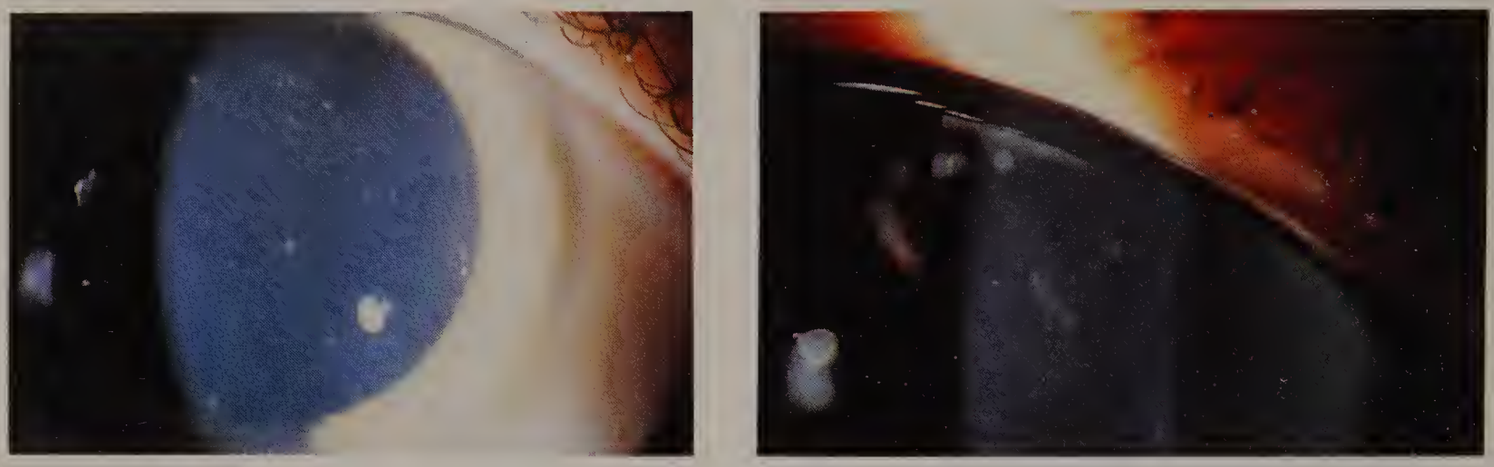
Macular dystrophy is also known as Groeouw's dystrophy type II, and is inherited in a autosomal recessive manner. The condition is bilaterally symmetrical and usually manifests in the first decade of life with the appearance of superficial central corneal cloudiness. Grey-white nodular lesions develop in the anterior stroma and the tissue between these lesions is hazy. The signs increase during the second decade of life and the condition spreads to include the corneal periphery. Epithelial irregularities may develop which are painful in some patients. The main aim of bandage lens therapy is the relief of pain until penetrating keratoplasty can be performed.

Thygeson's superficial punctate keratitis

Thygeson's superficial punctate keratitis (Thygeson's SPK) is a rare corneal condition characterized by the presence of distinctive central corneal lesions in the absence of conjunctival inflammation (*Figure 20.7.6a*). The condition is generally chronic and is typified by periods of exacerbation and remission lasting for weeks or even months at a time (Thygeson, 1950; Marshall and Holdman, 1992).

Thygeson's SPK is a bilateral condition which may be asymmetric, with each eye presenting a different clinical picture at any time (Thygeson, 1961). During the active phase of the condition, patients complain of photophobia, foreign body sensation, tearing and decreased vision, which may be disproportionately severe in relation to the clinical picture. Biomicroscopic examination reveals distinctive stellate or snowflake-like infiltrates in the corneal epithelium (*Figure 20.7.6b*). The epithelial surface is raised over the lesions, creating an irregular corneal area which stains incompletely with fluorescein dye. It is this irregularity which results in reduced visual acuity. During remission, patients are asymptomatic and the corneal lesions appear as flat, faint grey opacities or may be completely absent.

The aetiology of Thygeson's SPK is unknown and the search for an infectious agent using standard bacteriological and virological techniques has been unrewarding to date. Although never proven, there is evidence to suggest that the condition may be viral in origin (Nesburn *et al.*, 1984). Although there is no cure for the condition, it disappears



(a) (b)

Figure 20.7.6 (*a*) Thygeson's superficial punctate keratitis showing corneal infiltrates. The patient in (*b*) was fitted bilaterally with HEMA Bausch & Lomb U4 plano therapeutic lenses on an extended wear basis as the eyes were too painful to remove the lenses whilst the infiltrates were present. The patient had previously used steroid drops to no avail. The eyes immediately became more comfortable and the lenses could be removed a few weeks later. (Courtesy of (*a*) A. J. Phillips and (*b*) L. Speedwell)

spontaneously after several years without serious sequelae, and the main aim of treatment, therefore, is to relieve symptoms during periods of exacerbation. Various methods can be used, including ocular lubricants, topical corticosteroids or low water content bandage contact lenses. Forstot and Binder (1979) and Goldberg *et al.* (1980) found that patients with Thygeson's SPK could be treated successfully with bandage contact lenses. Lenses not only relieve symptoms but can also improve the optical characteristics of the irregular corneal surface and hence improve visual acuity. If the patient is ametropic, powered lenses may be used to correct refractive error while concurrently providing therapeutic benefits.

Low water content lenses usually provide the best symptom relief (Williams and Mackie, 1980) and are mostly worn on a daily wear schedule. In some cases, however, extended wear may be necessary, in which case the thinnest lenses should be chosen (e.g. Bausch and Lomb 04).

Filamentary keratitis

Filamentary keratitis is a condition in which fine, twisted threads of corneal epithelium form which are attached at their base to the surrounding epithelium (*Figure 20.7.7*). Symptoms usually consist of foreign body sensation and pain. Although the cause of the condition is unknown, it has been associated with keratoconjunctivitis sicca, superior limbic keratoconjunctivitis, and systemic disorders such as rheumatoid disease (Kowalik and Rakes, 1991).

The initial step in filament formation is damage to the basal epithelial cells, epithelial basement membrane or Bowman's layer with subsequent focal epithelial basement membrane detachment. This results in a slightly elevated area which acts as a receptor site for mucus produced by the eye, which in turn attracts loose epithelial cells and debris thus forming a filament (Zaidman *et al.*, 1985).

Treatments have included mechanical removal of filaments, the application of 0.5% silver nitrate solution, the use of hypertonic agents and, more recently, the use of hydrophilic bandage lenses.

The presence of a bandage lens on an eye with filamentary keratitis protects the epithelial surface from the shearing effect of the eyelids and also offers protection from further trauma to any damaged areas of epithelial basement membrane. This allows the basal epithelial cells to reattach smoothly to the epithelial basement membrane, preventing the formation of elevated receptor sites for further filament formation.

Bloomfield *et al.* (1973) used hydrophilic contact lenses to treat 20 eyes with filamentary keratitis and noted improvements in all eyes within seven days of continuous wear. More recently, hydrophilic disposable lenses have also been used in the treatment of filamentary keratitis. Ajamian and Winski (1990) reported the resolution of

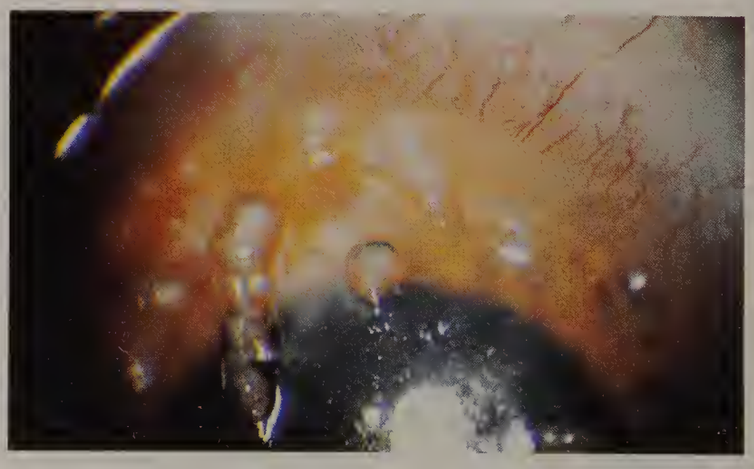


Figure 20.7.7 Severe filamentary keratitis. (Courtesy of A. J. Phillips)

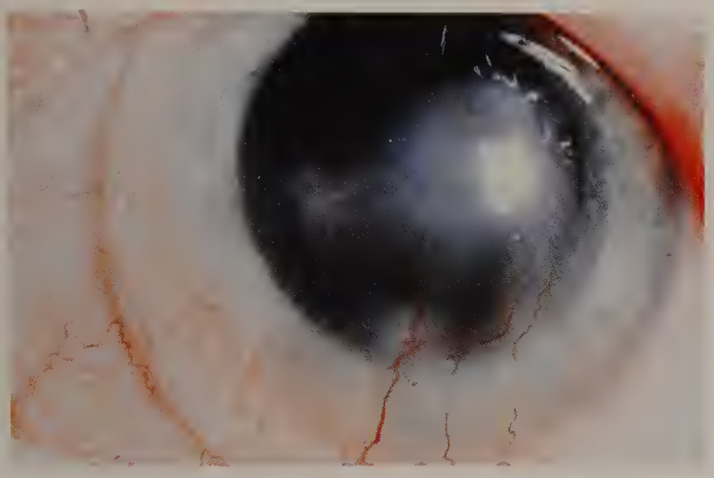


Figure 20.7.8 Healed herpes ulcer after treatment with a hydrogel bandage lens. (Courtesy of L. V. Prasad Eye Institute)

filaments within four days when Acuvue disposable lenses were used in conjunction with artificial tears for a patient with dry eye.

Short-term use of bandage contact lenses has therefore been shown to be of great use in the treatment of filamentary keratitis, although the filaments and their accompanying symptoms may return upon cessation of lens wear.

Persistent epithelial defects and stromal ulceration

Persistent epithelial defects (PED) can have numerous different aetiologies, including bacterial, viral or fungal corneal infections, following chemical or thermal burns, as a result of poor healing after surgery, or in association with neuroparalytic keratitis. One of the most common causes of PED is following infection with *herpes simplex* virus (HSV). An epithelial defect in such a patient may result from a geographic ulcer during active viral disease, or due to epithelial breakdown over an area previously damaged by HSV. In addition, an epithelial defect can occur due to the toxic effects of topical antiviral agents (McDermott and Chandler, 1989).

Indolent corneal ulcers

Corneal ulcers which are long standing and slow to heal often benefit from therapeutic lens treatment. In most cases, a therapeutic lens protects the corneal surface from lid trauma and splints the healing epithelium, as well as reducing pain (*Figure 20.7.8*).

Most corneal ulcers are treated medically for a long period of time before bandage contact lenses are fitted, as this is often considered as a final attempt at treatment. Before bandage lenses are used, smears, scrapings and cultures must be carried out to ensure that the ulcer is sterile, as active infection could easily be exacerbated by the presence of a contact lens.

There are a wide variety of clinical presentations of corneal ulceration but generally there is an area of chronic corneal erosion to the depth of the anterior stroma, which has not healed with previous medical treatment.

In some circumstances, treatment may be initiated by the total denudation of the corneal epithelium after topical anaesthesia (Liebowitz and Rosenthal, 1971b). A hydrogel lens can then be applied to the eye and is generally worn continuously with the concurrent use of topical antibiotics (Liebowitz and Rosenthal, 1971b). It is common for the lens to be left *in situ* for the first week while the healing cornea is observed with the biomicroscope through the lens, because premature removal of the bandage lens can disturb the vulnerable epithelial area and retard healing. The reducing size of the corneal lesion should be measured and monitored on a daily basis and the lens removed if any signs of deterioration or active infection are noted.

Høvding (1984) used hydrophilic contact lenses to treat corneal ulceration and observed that rapid epithelialization occurred in two-thirds of the patients, which is in agreement with an earlier report (Liebowitz and Rosenthal, 1971b). In the same study, Høvding also reported that ulcers recurred in 5 out of 21 patients within the first week after lenses were removed, indicating the advisability of continued lens use for a number of weeks after full epithelialization is achieved. Careful examination of the cornea is required during this period as the appearance of slight surface irregularities or dry spots between blinking is a suspicious sign that epithelial breakdown may recur, and should act as an indication that the bandage should be maintained for a longer period.

Despite the complications of this form of treatment, it is found to work well in the majority of patients (Leibowitz and Rosenthal, 1971b; Høvding, 1984; Mobilia and Kenyon, 1984). In most of the cases treated, there is no alternative to bandage lens therapy apart from drastic measures such as tarsorraphy or even enucleation, but after several months of well-monitored soft lens bandage treatment, the cornea has usually healed well and in some cases useful vision can be restored.

Neuroparalytic and neurotrophic conditions

Bandage lenses can be extremely useful when managing patients with Vth or VIIth cranial nerve damage which can lead to corneal disorders such as neurotrophic keratopathy or neuroparalytic keratitis.

Neurotrophic keratopathy (*Figure 20.7.9*) occurs in cases of an anaesthetic cornea, for example when the sensory branch of the Vth cranial nerve is damaged by herpes zoster, herpes simplex or other causes. In neurotrophic keratopathy, loss of neural influence affects epithelial mitosis which in turn leads to exfoliation and oedema of the corneal epithelium. This can occur even if the blink reflex and lacrimal secretions are normal.

In order to prevent keratopathy occurring prior to neurosurgery being carried out, drastic measures such as tarsorraphy are often taken, although an alternative therapy

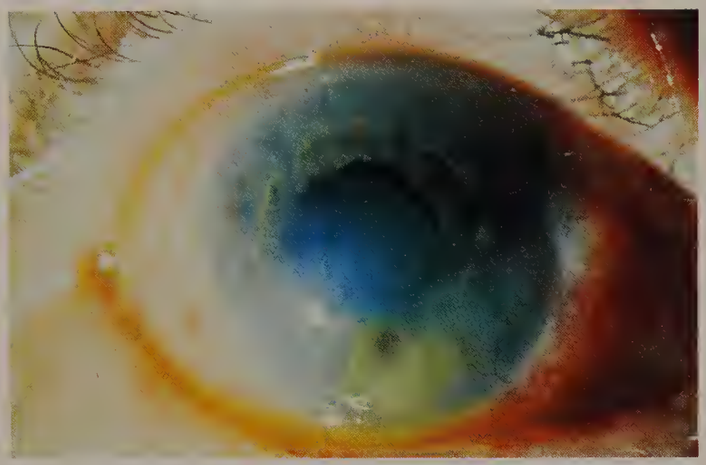


Figure 20.7.9 Neurotrophic keratitis. (Courtesy of A. J. Phillips)

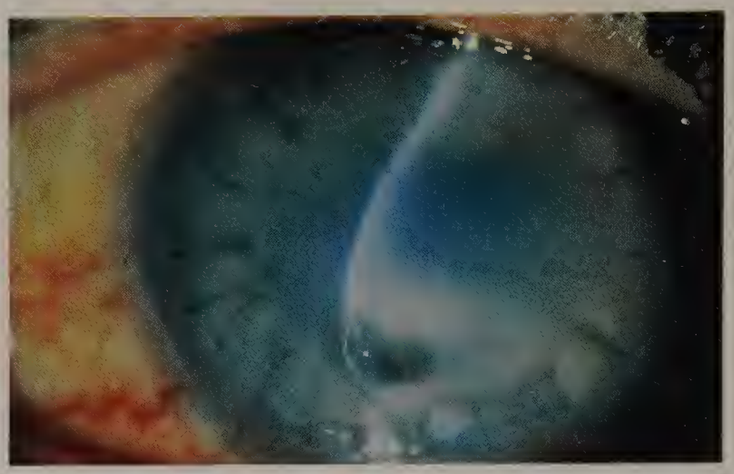


Figure 20.7.10 Descemetocele in a failed graft. (Courtesy of A. J. Phillips)

is the use of hydrophilic bandage lenses. Espy (1971) reported that patients with Vth nerve lesions and neurotrophic keratitis could be treated successfully with hydrogel bandage lenses. Complete clearing of epithelial irregularities was noted with associated visual improvement.

In cases of VIIth nerve paralysis, incomplete eyelid closure can lead to exposure keratitis. This can manifest initially as punctate epithelial erosions but can eventually lead to corneal ulceration if measures to protect the cornea are not initiated. In such cases, a silicone rubber or hydrogel bandage lens acts to protect the cornea from drying and is often used in conjunction with ocular lubricants. Silicone rubber lenses may be worn on an extended wear schedule if incomplete lid closure occurs during sleep or, alternatively, complete eye closure can be achieved by taping the lids together at night. Espy (1971) found that three patients with VIIth nerve paralysis who were treated initially with tarsorraphy achieved better results when they were fitted with hydrogel bandage lenses. All three patients wore the lenses for daily wear only and taped their eyelids together at night.

An alternative method of treatment for particularly difficult cases is the use of scleral lenses. Schein *et al.* (1989) found that gas permeable scleral lenses were more successful than hydrophilic bandage lenses when treating a patient who had bilateral Vth and VIIth nerve palsies. Previous treatments included ocular lubricants, hydrophilic bandage lenses and tarsorraphy, but the best results in terms of maintaining ocular health and visual function were achieved with gas permeable scleral lenses.

Corneal thinning and perforation

In patients with thinned corneas where perforation is imminent, a descemetocele often forms (*Figure 20.7.10*). In such cases a silicone rubber lens can often avert perforation by reinforcing the cornea and preventing distension of the descemetocele by intraocular pressure. Hydrogel lenses may be used but are not as effective, especially in a dry eye.

Corneal perforation can also occur due to accidental injury or surgical trauma of the cornea, or following a persistent epithelial defect. Soft bandage lenses are more useful in these cases to reinforce the cornea during healing.

Hydrogel or silicone rubber contact lenses can be used as a means of sealing small corneal perforations by offering protection to the wound while allowing it to repair itself. In carefully chosen cases, contact lenses can provide a more effective and easier method of repair then performing intricate suturing. Because a direct view of the wound can be obtained through the lens, if this method of therapy fails the lens can be removed and adhesives or direct suturing employed.

In corneal perforations, the main aim of therapy is to maintain or restore the corneal integrity, so that the anterior chamber either reforms or remains formed. Therapeutic lenses allow small perforations to heal themselves provided the wound edges are in good apposition and there is no incarceration or prolapse of the uvea or the crystalline lens. Rehim *et al.* (1990) reported a high success rate when non-infected perforations, less than 3 mm in size, were treated with thin, high water content lenses worn for one to two weeks. Larger perforations were not as successful and generally required surgical repair.

When silicone rubber lenses are used for this form of therapy, initially a flat lens should be tried, but must be observed closely as reformation of the anterior chamber can occur rapidly and this will cause the cornea to steepen. In this situation two or three lens refits may be required, with each subsequent lens being increasingly steeper. This form of treatment can take a whole day and is best carried out on an in-patient basis (Speedwell, 1991).

In certain cases, surgery is the favoured method of treatment, but a therapeutic contact lens may still be required to support the wound margins until an emergency operation can be performed.

Corneal perforations can also be treated using tissue adhesives (e.g. cryanoacrylate glue). In some cases a bandage contact lens is used over tissue adhesive both to

protect the 'seal' from being displaced by the lids and to decrease eyelid irritation from the rough surface of the dried adhesive. Weiss *et al.* (1983) studied 80 cases of corneal perforation or impending perforation which were treated with tissue adhesive. Almost half of these cases healed with the application of tissue adhesive alone or tissue adhesive and a bandage contact lens. The adhesive was in place for between one day and two-and-a-half years, with a mean length of time of 50 days. Eiferman and Snyder (1983) used cyanoacrylate glue and bandage contact lenses to treat infected corneal ulcers which had perforated. Intensive antibiotic therapy was also employed, and the incidental bacteriostatic effect of cyanoacrylate adhesive against Gram-positive organisms was thought to expedite healing in these patients.

In general, it is important not to apply a bandage contact lens to an eye until the tissue adhesive has polymerized completely, as the contact lens could become stuck to the adhesive. Subsequent lens movement could then cause the adhesive to dislodge causing additional trauma to the already compromised cornea. However, a method has been described where tissue adhesive is first applied to a collagen shield and then both are stuck to the cornea (Erdey *et al.*, 1991), and cases have been documented where a lens deliberately stuck to the eye has acted as a therapeutic device for treating severe ocular surface disorders (Ingraham *et al.*, 1992).

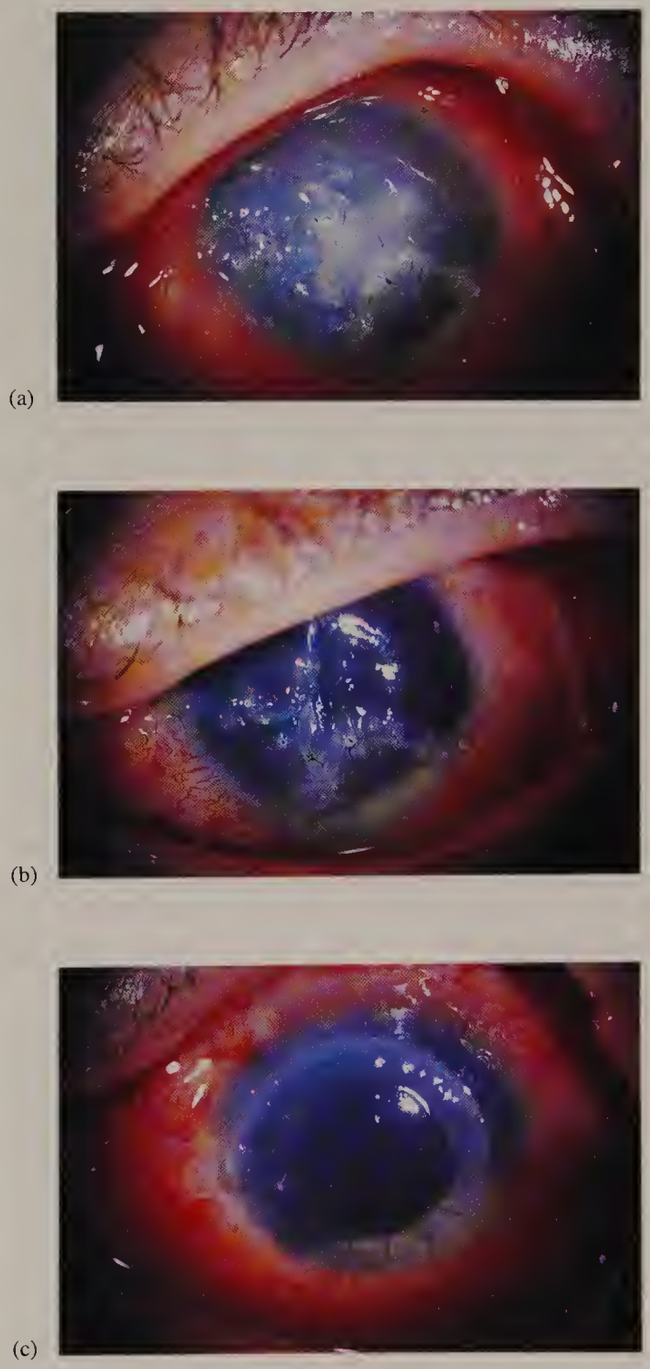


Figure 20.7.11 Primary care of this corneal wound was done at a remote hospital. The corneal surface was grossly irregular and the suture ends exposed (*a*). A bandage lens was used for comfort. When the cornea had healed and the inflammation settled (*b*) keratoplasty was performed with good results (*c*). (Courtesy of D. J. Coster)

Therapeutic contact lens use following ocular surgery

The therapeutic applications of contact lenses after ocular surgery are numerous and varied. Hydrogel lenses can be used to assist epithelial healing, to protect the eyelids from suture ends (*Figure 20.7.11*) and to reduce pain. In cases where post-surgical complications such as wound dehiscence or leaking filtration blebs have developed, bandage lenses can be of invaluable assistance during the healing process.

Following penetrating keratoplasty, punctate epithelial keratitis may develop which can be managed well with soft bandage contact lenses. Lenses act to protect the ocular surface and promote healing, and can also offer protection to the lids from exposed suture ends (Beekhuis *et al.*, 1991; Zadnik, 1990). In monocular patients where rapid visual rehabilitation is required, powered lenses can be fitted to give refractive correction as well as acting as a bandage, although corneal astigmatism often means that vision will be poor unless a rigid gas permeable lens is used. Fitting lenses in the early stages after penetrating keratoplasty can, however, lead to physiological stress on the vulnerable graft tissue and a higher risk of transplant rejection. In some cases, wound dehiscence after penetrating keratoplasty can occur, which can be successfully managed with medium water content, stiff, steep fitting soft lenses. These lenses have been used for a number of months to ensure complete wound re-apposition occurs without further surgical intervention (Mannis and Zadnik, 1988), but the risk of neovascularization and corneal oedema is high.

Pain relief and promotion of epithelial healing can be provided by bandage lenses after numerous different surgical procedures including excimer laser photorefractive keratectomy (Eiferman *et al.*, 1991; Sher *et al.*, 1992; Talley *et al.*, 1994), epikeratoplasty (Zadnik, 1990), and superficial keratectomy (Moodaley *et al.*, 1991).

Another application of therapeutic contact lenses after surgery is for complications arising following trabeculectomy. Trabeculectomy is one of the most common surgical procedures performed for the treatment of glaucoma, and a successful procedure is characterized by the formation of a filtering bleb, which is a sub-conjunctival accumulation of aqueous. The post operative course of this procedure can be complicated if the bleb leaks, leading to a shallow anterior chamber, peripheral anterior synechiae and the possibility of ciliary block glaucoma. Management of a leaking filtration bleb may include suturing, pressure patching, application of cyanoacrylate glue, drug therapy, or the use of a Simmons tamponade shell, a device similar to a scleral lens used to flatten thc bleb. Hydrogel contact lenses can also be used for this purpose, in very large TDs (up to 20.5 mm) (Blok *et al.*, 1990). Lenses with large TDs are also used after stem cell transplants for aniridia and epitheliopathies as the graft affects the peripheral cornea and conjunctiva and thick sutures are used (Tan *et al.*, 1996). An 18.00 or 20.00 mm TD covers the graft while new epithelium starts to grow. (These lenses are available from Madden and Layman in the UK.)

Cicatrizing conjunctival diseases

Many cicatrizing conjunctival diseases can be treated with therapeutic contact lenses which offer pain relief, provide protection to the cornea from exposure, entropion and trichiasis, and can help to maintain the conjunctival fornices by preventing symblepharon (adhesions between bulbar and palpebral conjunctiva).

Ocular pemphigoid

Ocular pemphigoid is a bilateral, chronically progressive disorder which occurs in approximately 70 per cent of people who suffer from cicatricial pemphigoid, a systemic, autoimmune disease which produces lesions of the skin and mucous membranes. Ocular involvement is characterized by progressive shrinkage of the conjunctiva due to the production of fibrous tissue at the level of the conjunctival basement membrane. Loss of goblet cells, cicatrization of lacrimal gland ducts and damage to the meibomian gland orifices results in an eye which is mucous-deficient and severely dry (*Figure 20.7.12*). The worst complications occur late in the disease and comprise symblepharon, keratoconjunctivitis sicca, entropion, trichiasis and eventually keratinization of the conjunctiva and cornea. Ankyloblepharon (fusion of the lid margins) may also occur.

Corneal complications are usually the result of dryness and aberrant lid trauma which leave the cornea vulnerable to infection. Therapy in the early stages of the disorder is centred around retarding the progression of surface pathology. Therapeutic contact lenses can assist in maintaining corneal hydration as well as protecting the cornea against the action of ingrowing lashes and malpositioned lids, and in some cases can prevent symblepharon formation.

Scleral, silicone rubber and hydrogel therapeutic contact lenses can be useful in this disorder. Hydrogel lenses used in association with ocular lubricants offer protection to the cornea from drying, and entropion and trichiasis. If hydrogel lenses are not frequently rewetted, however, evaporation of the lens water content can cause fluid to be drawn from the already deficient tear film, thus exacerbating the condition. Thin lenses should be avoided, and thicker, large diameter lenses are favoured which, if large enough, can also assist in lubrication and protection of the conjunctiva. Silicone rubber lenses provide a better choice as they do not need such frequent drop instillation. Scleral lenses maintain a good fluid reservoir between the lens and cornea when supplemented with ocular lubricants. They can be used for refractive correction of scarred and irregular eyes and, because they also cover most of the ocular surface, they can protect both the cornea and conjunctiva while assisting in the maintenance of the fornices. Scleral rings (the outer ring of a scleral lens cut off the lens and polished) (*Figure 20.7.13*) may also used for the latter purpose. In advanced cases of ocular pemphigoid, symblepharon may prevent the insertion of scleral lenses, and in

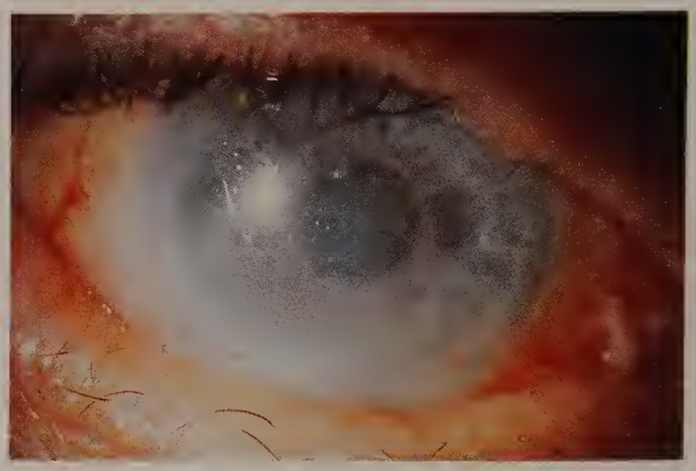


Figure 20.7.12 A silicone rubber therapeutic contact lens on ocular pemphigoid. (Courtesy of L. Speedwell)



Figure 20.7.13 Scleral rings: these are cut from different sized scleral lenses and are used in cases of symblepharon. (Courtesy of N. Sapp)



Figure 20.7.14 Chemical burn caused by paraquat. (Courtesy of A. J. Phillips)

such cases, silicone rubber or rigid gas permeable lenses can be successful in visual rehabilition of patients with ocular surface irregularities (Pesudovs and Phillips, 1992).

Stevens–Johnson syndrome (erythema multiforme)

This is an acute, inflammatory disease which is generally caused by a hypersensitivity reaction to a drug or infectious agent. The basic lesion is thought to be an acute vasculitis which affects the skin and conjunctiva.

Bilateral conjunctivitis occurs in the acute stage of the condition and usually leads to scarring of the conjunctiva. The ocular effects of the condition stabilize once the systemic disease has been resolved, but often severe, irreversible ocular surface damage has already occurred. Patients with this condition can have varying degrees of symblepharon, entropion, trichiasis, xerosis, as well as corneal scarring and vascularization. As in ocular pemphigoid, therapeutic lenses may be used to protect the cornea from drying, exposure and damage from lashes. Scleral and hydrogel lenses are most commonly prescribed for these purposes, although silicone rubber and rigid gas permeable lenses may also be used in selected cases.

Chemical burns

Chemical burns to the eye (*Figure 20.7.14*) form a complex aspect of ophthalmology due to the large variety of chemicals which can inflict ocular damage.

Chemical damage to the eye varies from as little as superficial punctate epithelial erosions to complete epithelial denudation, stromal opacification, lid deformities and injury to the trabecular meshwork, lens, iris and ciliary body. The severity of injury is dependent upon the toxicity, concentration, pH and volume of the chemical, as well as the duration of ocular contact. In most cases, even one drop of a potent chemical cannot be sufficiently diluted and buffered by the tears to prevent significant ocular damage. Strong alkalis inflict the worst damage due to their potential for penetration and continuing effect even after the eye has been irrigated. Acids can also cause significant injuries but tend to have less effect than alkalis as they precipitate tissue protein, producing coagulation which then limits further penetration.

Therapeutic soft contact lenses cannot be used in the early stages of chemical burns, but assist in later treatment, which must be carefully managed and continued until the epithelium has completely covered the area of the lesion. A therapeutic soft lens can aid this process by splinting the epithelium and also preventing damage from lids, trichiasis, exposure or insufficient tears. Provided no contra-indications are seen, continuous wear is a better alternative than daily wear until the epithelium has healed. Scleral or silicone rubber lenses may also be used in chemically damaged eyes, and can prevent the formation of symblepharon in some cases.

Thermal burns

Thermal burns rarely cause cicatrizing effects on the bulbar or palpebral conjunctiva because reflex lid closure generally protects the eye before significant damage can occur. If, however, eyelids are so badly damaged by burns that they are ineffective, a therapeutic lens used with concurrent frequent instillation of ocular lubricants may enable a relatively undamaged cornea to retain its integrity and thus prevent the loss of sight (*Figure 20.7.15*).

Trachoma

Trachoma is a chlamydial infection and a common cause of preventable blindness in underdeveloped countries. In its later stages, cicatrization and distortion of the lids, symblepharon and trichiasis are common. Corneal opacification and dryness of the conjunctiva and cornea are additional complications.

The condition is usually treated with oral antibiotics, but on occasions, therapeutic contact lenses can be used to protect the cornea and to prevent symblepharon.

Epidermolysis bullosa

This is an inherited dystrophic condition in which there may be pseudomembrane and vesicle formation, epithelial erosions and symblepharon. Therapeutic contact lenses may be used for certain cases when indicated.

The dry eye

The use of soft contact lenses in the management of keratoconjunctivitis sicca (*Figure 20.7.16*) and other dry eye conditions is a controversial aspect of therapeutic lens work. Some practitioners feel that therapeutic lenses should not be used, or only employed rarely in keratoconjunctivitis sicca (Dart, 1987; Mackie, 1985), whereas other practitioners advocate their controlled use (Gassett and Kaufman, 1971b; Gassett, 1978; Høvding, 1984).

(a)

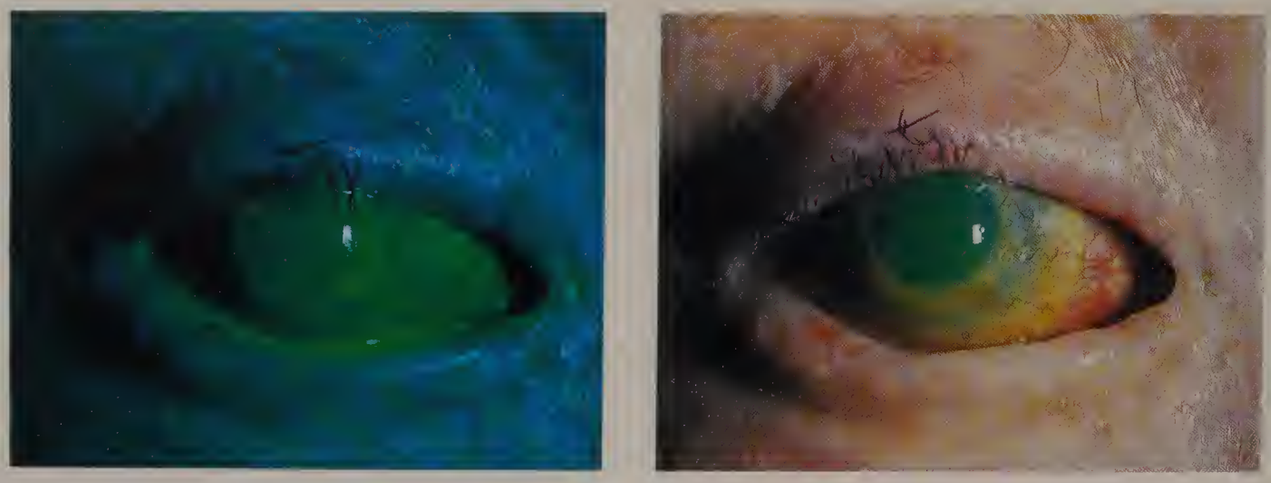


Figure 20.7.15 (*a*) The third keratoplasty of a severely burned eye and eyelids, showing gross staining with fluorescein due to the drying out of a standard sized hydrogel bandage lens because of incomplete lid closure leading to exposure keratitis. (*b*) A steeply fitted extended wear soft bandage lens custom-made in an extra large size provided the same eye as in (*a*) with protection against exposure keratitis. (Courtesy of D. Westerhout)

A therapeutic contact lens is generally only considered in the treatment of dry eye patients when other modes of therapy have failed. In most mild cases, artificial tear solutions are the first form of therapy to be prescribed. Numerous different artificial tear solutions are available and frequent instillation of these solutions throughout the day, used in conjunction with a sterile petroleum ointment at night, is often adequate to alleviate patient symptoms and prevent ocular surface drying. In patients with moderately dry eyes or those who are unwilling or unable to instil drops frequently, pellets of hydroxypropylmethylcellulose (Lacrisert) can be used. These are inserted into the cul-de-sac and dissolve slowly over a 6–12-hour period, releasing the lubricating agent.

If artificial tear solutions do not succeed in relieving dry eye symptoms, punctal occlusion can be performed. The mechanism of this method of treatment is blockage of the fluid outflow channel which helps to retain tears or tear substitutes in the eye for longer periods. Careful patient selection is important prior to punctal occlusion, however, because annoying epiphora can result if used on patients with only moderately reduced tear production. For this reason a trial of collagen plugs first is often useful, as these dissolve after 3–5 days.

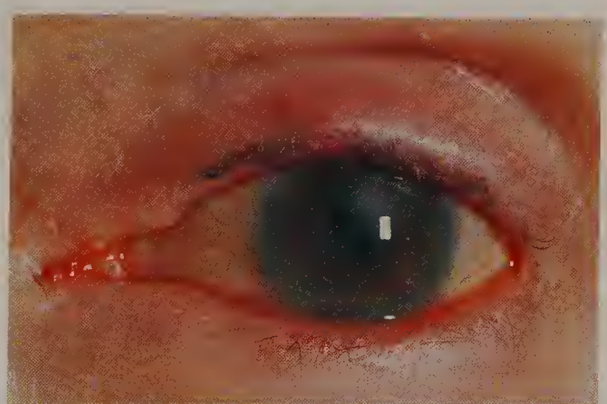


Figure 20.7.16 Keratoconjunctivitis sicca associated with chronic blepharitis. (Courtesy of D. Westerhout)

When these methods of managing the dry eye patient have failed or have proved to be inadequate, soft or silicone rubber contact lenses may be prescribed. All hydrophilic contact lenses partially dehydrate during wear (DeDonato, 1982; Fatt, 1983; Fatt and DiMartino, 1985), and this dehydration is more marked in high water content than low water content lenses (Andrasko, 1983). Mackie (1985) found that in eyes with inadequate tears, low water content lenses remain hydrated for a longer period than high water content lenses. In the same study, lens thickness was not found to affect dehydration rate, although another author found that thin lenses dehydrate more than thicker lenses of the same material (Andrasko, 1983).

From these facts it would appear that thick, low water content or silicone rubber lenses would be preferable to thin, high water content lenses. For dry eyed patients with associated ocular surface disease and corneal irregularity, a good wetting, rigid gas permeable material may also be considered (O'Callaghan and Phillips, 1994). For most patients, lenses alone do not alleviate dry eye symptoms and the frequent instillation of ocular lubricants is still required. However, sealed RGP lenses can be very beneficial.

In many dry eye patients, eye closure and, if necessary, taping the lids at night, relieves their symptoms, providing little justification for extended wear and the increased risks that this modality introduces. Because the risk of ocular infection secondary to contact lens wear in dry eye patients is high (Mackie, 1985), patient follow-up must be conducted very regularly.

Drug delivery

When a drug is instilled into the eye in drop or ointment form, there is an initial high concentration of the drug,

followed by a rapid decrease in concentration. The efficacy of any drug is therefore limited by the short contact time between the drug and the eye. If higher concentrations of a drug are used in an attempt to overcome this problem, adverse effects on the eye may occur if the maximum concentration of the drug exceeds the threshold for ocular toxicity.

Hydrophilic contact lenses have the potential to provide slow and prolonged delivery of low drug dosages to the eye, thereby increasing drug efficiency while reducing the risk of drug toxicity.

Drugs can be incorporated into hydrogel lenses in a number of ways. The most common method utilized is to soak the lens in a water-soluble form of the drug, saturating the aqueous component of the lens. A second method is to employ a water-soluble pro-drug, which biodegrades into its active form upon diffusion from the hydrogel and exposure to the ocular environment. A third technique attaches the drug to the lens polymer molecules. Upon contact with the tears and ocular tissues the bonds between the drug molecules and the lens polymer break down, thereby releasing the drug.

Waltman and Kaufman (1970) investigated the use of hydrophilic lenses for drug delivery using sodium fluorescein dye, and concluded that hydrophilic lenses were a useful method of maintaining a high drug concentration in the anterior segment of the eye. Since this report, many investigators have used hydrogel lenses to deliver a variety of different drugs to the eye, including the glaucoma drug pilocarpine (Ramer and Gasset, 1974; Ruben and Watkins, 1975), the antibiotic gentamicin (Busin and Spitznas, 1988) and the antiviral agent, 5-iodo-2-desoxyuridine (IDU) (Praus *et al.*, 1976).

A number of factors affect the rate of delivery of a drug using a hydrogel contact lens. The molecular size of a drug affects its ability to be taken up by a lens because large molecules penetrate a lens less well than smaller molecules. Also to be considered is the lens material, as lenses with a high water content hold more drug than low water content hydrogels and may deliver drugs more rapidly.

Although in most cases it is safe to use topical drugs in the presence of hydrogel lenses, in some instances drugs can interact with the lens material causing degradation or discoloration of the lens (Sugar, 1974). In general, however, therapeutic contact lenses can be safely used concurrently with topical ocular medications, although it is preferable to use unpreserved drops where possible.

Collagen shields are also useful devices for delivering drugs to the eye. Most collagen shields are packaged in a dehydrated form and require rehydration before use. When used for drug delivery, the shield can be soaked in a water-soluble form of the drug prior to insertion in the eye. As the shield dissolves the drug is slowly released, producing corneal and aqueous concentrations comparable to frequent drop therapy (Hwang *et al.*, 1989). In cases where water-insoluble drugs are to be delivered, the drug can be incorporated into the collagen shield during manufacture. Reidy *et al.* (1990) found that cyclosporin A concentrations in the cornea and aqueous humour were much greater when delivered using a collagen shield than when topical drops of the drug were used. Collagen shields have been used successfully to deliver a wide variety of drugs including dexamethasone (Hwang *et al.*, 1989), gentamicin (Liang *et al.*, 1992) and amphotericin B (Schwartz *et al.*, 1990). Friedberg *et al.* (1991) reported that collagen shields were a better method of ocular drug delivery than other devices such as iontophoresis or pumps, and also suggested that collagen shields could be used to deliver a combination of drugs, such as an antibiotic and a corticosteroid, to the eye. If this method is to be utilized, however, the drugs used must be compatible with each other.

Another method of drug instillation is the Ocusert, a small hydrophilic oval disc which can be placed in the lower fornix and left for several days (*see* Chapter 23).

Miscellaneous applications of therapeutic contact lenses

Hydrogel contact lenses can be used to provide corneal protection during ocular procedures such as specular microscopy and tonometry which require direct contact of an instrument with the cornea.

Many patients wearing therapeutic soft lenses need to have their intraocular pressure (IOP) monitored regularly, and although lenses can be removed for such a procedure, removal may have a detrimental affect on the condition under treatment, such as in patients who are being treated for recurrent erosions. In these cases, applanation tonometry is carried out through the bandage lens using white light. Measurements taken through ultrathin lenses have been found to be very close to those taken without a lens (Meyer *et al.*, 1978; Rubenstein and Deutsch, 1985; McMonnies, 1986; Mark *et al.*, 1992), although other authors have not reported such a good correlation, particularly when powered lenses are worn (Insler and Robbins, 1987).

Bandage contact lenses also provide protection of the epithelium in diabetic patients while photocoagulation is carried out (Arentsen and Tasman, 1981), protection of the cornea while an impression is taken during scleral lens fitting (Westerhout, 1975), the provision of increased patient comfort when a hydrogel lens is worn under a rigid lens in 'piggy-back' fitting of keratoconics and other unusually shaped corneas (*see* Chapter 20.1), and prevention of lens loss in a keratoconic patient when a hydrogel lens is worn over a rigid lens for contact sports (McKinnon, 1989).

Complications of therapeutic lens use

There is always a risk of minor or major complications secondary to the use of any contact lenses and this is even more likely when lenses are used for therapeutic purposes in diseased eyes.

Minor complications, include ocular redness and irritation, which may be associated with a minor anterior chamber reaction and early vascularization (Dohlman *et al.*, 1973). Corneal vascularization induced by therapeutic contact lenses is often superficial and will usually regress once lenses are removed. In certain cases, such as a thermal burn or stromal ulceration, vascularization can have a positive effect on surface healing (Conn *et al.*, 1980). In such cases the prognosis for vision is often poor and corneal vascularization is therefore not detrimental.

Corneal oedema can occur in any patient wearing bandage lenses and particularly in those wearing lenses on an extended wear schedule. This complication can easily be overlooked, particularly if oedema is a prominent feature of the condition under treatment (Thoft and Mobilia, 1981). Lens deposition occurs with all lenses worn for therapeutic purposes (Høvding and Seland, 1984) and lens discoloration may also occur, particularly when certain drugs are used in conjunction with soft contact lens wear (Sugar, 1974) (*see also* Chapter 4). Lenses should be replaced regularly to avoid the occurrence of additional complications such as papillary conjunctivitis resulting from old and deposited lenses.

Sterile corneal infiltrates are commonly observed in both cosmetic and therapeutic contact lens wear. In most cases, infiltrates will resolve after lens removal without sequelae, although they should all be viewed initially as an early sign of microbial keratitis. Similarly, the aetiology of a hypopyon must be determined to rule out an infectious cause, and in both instances lenses should be removed and cultured for infectious agents such as bacteria and fungi (Thoft and Mobilia, 1981).

Microbial keratitis is a sight-threatening condition and is considered a very serious complication of both cosmetic and therapeutic contact lens wear. Kent *et al.* (1990) conducted a retrospective study on patients who had presented with corneal ulcers secondary to bandage lens use. The majority of ulcers occurred in patients treated for bullous keratopathy, with neurotrophic and exposure keratitis the second most common indication. More than two-thirds of the ulcers in this study were culture-positive. Sani *et al.* (1988) reported a 9% incidence of corneal ulcers with bandage lens use following keratoplasty.

These complications emphasize the necessity to perform frequent after-care examinations on all patients who use therapeutic contact lenses, and also suggest that these lenses should only be prescribed when patients are able to attend for such visits. In all cases, the risks of therapeutic contact lens wear should be weighed against the likely benefits to the patient, prior to fitting, and these benefits should be ongoing if therapeutic lens treatment is to be continued.

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Chapter 21

Contact lens manufacturing

E. J. D. Proctor

Moulding p. 777
Generating/lathing p. 778
Additional procedures for RGP lenses p. 785
Bifocals p. 795
Practitioners' orders p. 797
Conclusion p. 797
Addendum: European Manufacturing Regulations p. 797
British and US approved names for contact lens materials p. 798

The aim of this chapter is to give the experienced clinician, the new practitioner and the undergraduate equally, an understanding of some of the contact lens manufacturing procedures. It cannot be totally comprehensive and will never be completely up to date. However the author feels it is important that some of the historical aspects of corneal lens production are explained because many of these techniques are still used by laboratories in emerging countries and similar techniques are still used by prescription laboratories when lenses have to be modified.

The emphasis in the chapter is on corneal lens production, with less emphasis on soft lens production since, apart from the various moulding techniques, this largely follows a similar pattern. However, where appropriate, the differences in fabrication techniques are discussed. Scleral lenses are not discussed at all. The impression technique of making scleral lenses is dealt with fully in Chapter 17, and preformed sclerals are made in a similar way to corneal lenses.

Contact lenses are produced by either moulding or lathe-cutting.

Moulding

Moulding can be by casting, compression or injection and these are techniques which lend themselves to mass production of contact lenses.

Soft lens moulding

Bausch & Lomb in the USA refined the original Czechoslovakian spin-casting technique to produce soft lenses. This procedure involves spinning a mould, at a computer-controlled speed, into which the mixture of monomers is injected. The centripetal force causes the mixture to climb the wall of the mould to form into the required shape. Thus the curvature of the mould determines the front surface of the lens and the back surface is determined by the speed of the spin and the volume of monomers. The polymerization and spinning occur simultaneously. This method is described in Chapter 11, p. 391 and Chapter 13, and *Figures 11.27 and 11.29* show diagrammatically the form of the mould and the resultant shapes of some lens back surfaces.

The formed dehydrated lens has to be edged before being hydrated and released from its mould.

The main disadvantage of this method of manufacture is the extreme expense in setting up the laboratory, making large scale production essential for viability. This may mean that initially the available lens parameters are restricted.

Injection moulding is used to produce soft (hydrogel) lenses by injecting liquid monomers between two dies and polymerizing prior to lens hydration. The advantage of moulding for soft contact lenses is evident, with thin, one-fit, disposable systems where cost is of major importance.

Rigid lens moulding: historical note

The moulding of rigid lenses is mainly of historical interest because the bulk of rigid gas permeable lenses are now produced by lathe cutting. In a compression moulding technique developed by Kelvin in the UK for production of PMMA corneal lenses, separate steel tools for front and back surface were made. Under controlled conditions of heat and pressure, both front and back curves were produced simultaneously on a disc of PMMA inserted between the tools.

On removal from the pressing jig, the surface finished lens was cut to the required total diameter and edged. This procedure required a very large number of tools to obtain all the various possible combinations of parameters. It had the advantage that lenses could be made both quickly and reasonably cheaply because it required relatively less skilled labour compared to lathe-cut lenses. However, it had the disadvantage that the cost of tooling limited the available range of parameters and, because of difficulties in controlling the production conditions, stress was readily introduced into the lens, resulting in post-manufacture changes to the finished lens.

Another hard lens moulding technique, developed by Wöhlk (Zeiss) of Germany, involved placing powdered

PMMA in the concavity of a Pyrosil mould to which was clamped a quartz-glass convex die. This was slowly moved through an oven at 200°C for 45 minutes after which the surface-finished lens was removed from the separated mould. The lens was then cut to the required size and edged. A similar technique using stainless steel moulds and dies was used by Silor in France. This procedure had one big advantage over the compression technique in that it did not introduce any strain. However, there were disadvantages in that, as with compressed lenses, the cost of tooling reduced the available range of parameters and there were difficulties whereby impurities, such as dust particles, could enter the powdered PMMA and thus the matrix of the finished lens.

Generating/lathing

Generating or lathing is the technique favoured by most laboratories throughout the world for the production of RGP lenses. For this reason it is the technique on which the author has concentrated in this chapter. Historically, this procedure has not lent itself to mass production as readily as moulding techniques, the emphasis having been on individual prescription work. However with CNC (computer numerical control) lathes there has been a greater potential for mass production. The method of manufacture by lathing is the virtually the same for PMMA, RGP and soft contact lenses, although swell factors (the effects of hydration) have to be taken into account when calculating the curves to be generated on a soft lens blank. The main difference in production occurs at the polishing stage of soft lenses when slightly different techniques may be employed as well as utilizing moisture-free oil-based polishes.

CNC lathe production

The two most important areas of quality control which have occupied manufacturers' attention in recent years are **surface finish** and **stress** in the finished RGP lens. Great care is taken in the manufacturing process to minimize these problems.

Annealing

RGP blanks are either individually cast or cast in rods, whereas PMMA blanks are made from cast sheet, cast block or rod turned from cast block. All casting introduces strain which needs to be released from the material to ensure consistent results in rigid lens fabrication. This is done by annealing which involves heating the material to a temperature between 140 and 150°C for a short period and slowly returning it to room temperature. This does not cause any difficulty when done with sheet material. However, with thick material the temperature has to be low enough to prevent depolymerization of the surface but heated long enough to ensure the centre of the block reaches at least 130°C. Annealing is usually carried out by the supplier of the blank.

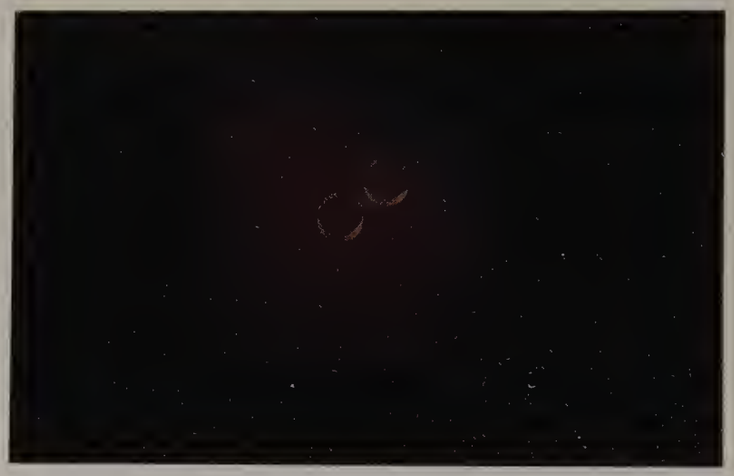


Figure 21.1 Stress assessment using a polariscope; the lower blank shows a stress pattern

Stress testing

Stress may already be a component in the blank prior to lathing, however, good material manufacture has helped to minimize this problem. Even so the lens laboratory still has to ensure that the blank reaches the quality claimed by the material manufacturer and so material stress analysis is an essential part of the initial manufacturing process – any stress present in the blank will later cause distortion to the finished lens. Blanks are assessed for stress by viewing with a polarized light strain tester (*Figure 21.1*).

Most modern laboratories utilize CNC lathes to generate both the front and back surfaces of RGP lenses. While there are differences in design between various types of lathe, the basic principles are the same. In the machine described and shown here there is an automatic feed into the collet to enable a stacking system to be used (*Figure 21.2*). A fully automated production of the back surface geometry is



Figure 21.2 Microturn CNC back surface lathe showing stacking of automatic feed system

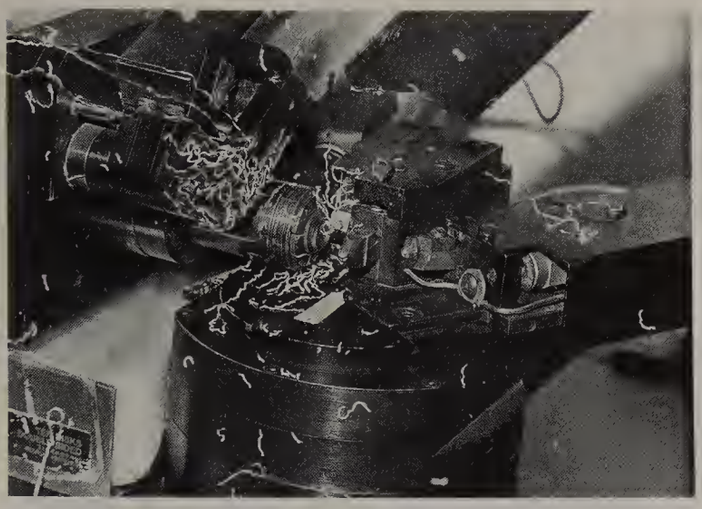


Figure 21.3 'CNC' diametering of blank

possible once the blanks have been fed into the stack and the computer details entered for each lens type. This enables each lens back surface to have completely different geometry and machining characteristics, and allows the technician to proceed with other work or to supervise several machines simultaneously.

Back surface lathing

The blank is fed from the stack, via the feed lever (*Figure 21.2*) into the collet which tightens to a predetermined tension. The consistency of the overall size of the blanks and the tightness of the collet will determine whether any stress is introduced as the collet tightens on to the blank. Too tight a collet, which causes the blank to be crimped during cutting, will result in a toroidal surface once the cut blank is released from the collet. Too loose a collet, which allows the blank to slip during machining, will produce a poor quality surface.



Figure 21.4 'CNC' back surface roughing cut

Once the blank is held by the collet the spindle starts to rotate and feeds in towards the cutting tools. The diamond diameter tool then feeds in from the side (*Figure 21.3*) reducing the blank, in a stepped form, to the required diameter. The speed at which this feed takes place, the spindle speed and the quality and design of the diamond tool will affect the surface material and, if incorrectly set, may introduce stress, in the form of burning, to the edge of the lens.

A diamond roughing tool then feeds in (*Figure 21.4*) and cuts the initial back surface geometry using a number of passes of pre-programmed moderately deep cuts. Lastly the diamond finishing tool feeds in to produce the final cut surface by removing much smaller thicknesses of material than the roughing tool. The last few cuts remove a thickness of 0.005–0.02 mm. The speed at which the diamond traverses the surface during these final cuts is much slower in order to produce the best surface finish. It is at this stage that some lathes form an edge shape by generating a curve continuous with the back periphery and terminating a short way on to the front surface.

The feed rate, depth of cuts and spindle speeds are all pre-programmed according to the particular characteristics of the material being machined. Machining can also introduce stress if too great an amount of material is removed with each cut or the speed of cutting is too fast – the surface may overheat causing changes to the surface polymer with a higher risk of back surface parameter changes on hydration and poorer back surface wetting.

The movement and speeds of both the spindle and the diamond cutting tools are controlled from the computer via the drive system. The tools and lens blank are cooled by a constant stream of cool air blown across the cutting surface via narrow metal pipes and the swarf is extracted by a vacuum system positioned immediately above the tip of the diamond tool.

When the generation of the back surface is complete the blank is ejected from the collet and collected in a tray beneath the spindle – the back of each blank having been numbered, prior to stacking, to assist in differentiating between each order.

Back surface polishing

The back surface of the blank will usually need to be polished and this is carried out in the conventional manner by mounting the blank in a plastic 'clippy' (*Figure 21.5, left*). The polishing tool may be formed from a spherical convexed tool covered with foam, and a velveteen outer cover held on to the tool by an O-ring (*Figure 21.5, centre*).

During polishing great care has to be taken to prevent the material from over-heating. This is done by ensuring that the blank is not polished for too long and that there is sufficient polish between the blank and the polishing tool – the better the surface finish after lathe cutting, the shorter the polishing cycle.

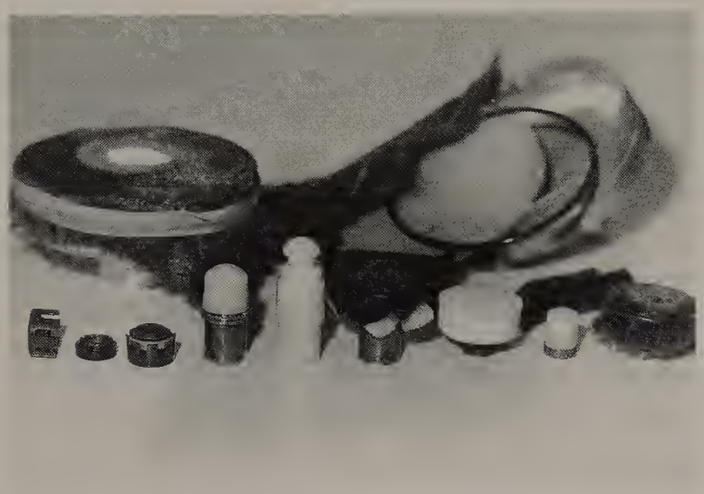


Figure 21.5 *Left to right*: plastic back surface polishing-clip; back surface polishers – wax, Delrin tool, foam and velveteen-covered tool; front surface polishers – small drum with sponge, wax and velveteen-covered tool with O-ring retainer

Front surface blocking

After polishing the back surface, the centre thickness of the semi-finished blank is measured as for measurement of centre thickness of an RGP contact lens (*see Figure 12.17*) and the blank is then mounted on to a front surface tool (*Figure 21.6*) using low melting point wax – excessive heat from the wax may cause damage to the back surface of the blank.

The blank is centred on a vertical spindle or special rotating centring device as shown in *Figure 21.6* by watching the reflected image of a strip of light seen in the rotating back surface edge adjacent to the chuck, and not the flat top which may not be parallel to the tangent of the centre of the BOZR. Various tools for front surface blocking have been used by different laboratories, of which one

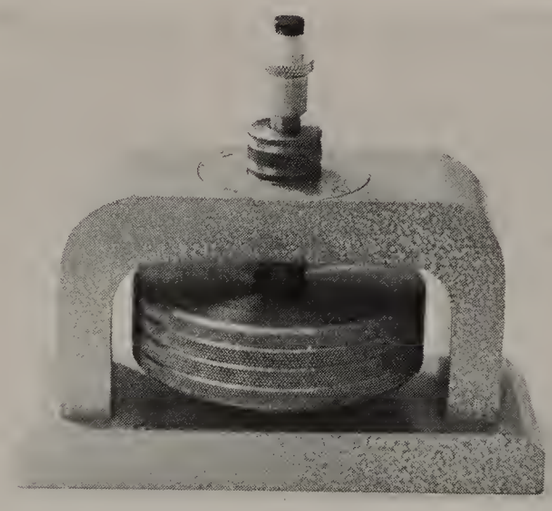


Figure 21.6 Blank mounted on front surface chuck on a hand centring device

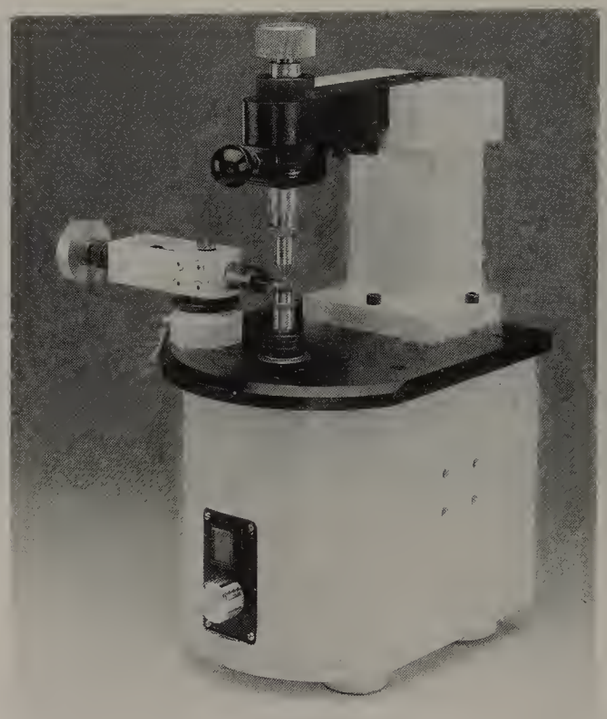


Figure 21.7 Nissel blocker

design is shown in *Figure 21.7*. They all have their devotees, but none is foolproof, and this area of contact lens manufacture has still to be perfected. If the blank has not been precisely blocked up when it is placed in the front surface lathe the back surface will not be at right-angles to the axis of the spindle with the result that a prism will be introduced when cutting the front.

Polytech blocking

The insert blocking system used by Polytech of the UK is based on disposable, low cost injection moulded inserts which are very accurately produced. These inserts are machined for either back or front surface blank blocking and are designed to take the skill out of blocking but still retain the accuracy. The insert has an internal taper which matches the lathe spindle taper. The uncut blank which has been accurately machined to 12.70 mm is fitted into the back surface insert and sits firmly on an internal stop. This is then fixed into a carousel to hold the assembly in position, inverted and loaded into the wax dispenser. Hot wax, at a controlled temperature, is then injected into the back of the insert/blank assembly. After cooling, the insert is removed from the carousel and placed on the taper of a back surface lathe. The back surface is then machined (*Figure 21.8*) and an 'insert fit' diameter cut on the blank to enable correct location in the front surface insert. The blank, still in the back insert, is then polished and afterwards transferred to a front surface insert (*Figure 21.9*). This front surface insert has an accurately controlled bore diameter into which the lathed 'insert fit' diameter just fits – there should be no

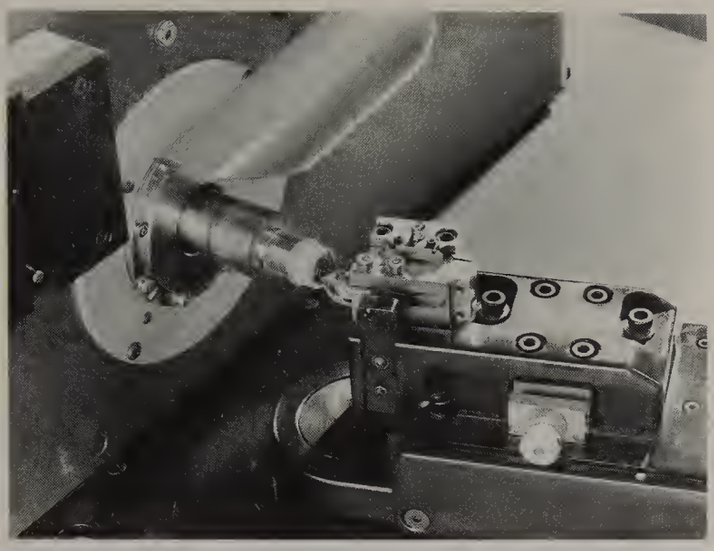


Figure 21.8 Polytech back surface insert blocker being machined on a Polytech air-bearing spindle lathe

more than 10–20 μm diameter difference between the bore diameter and the lathed blank 'insert fit' diameter, therefore producing no more than 5–10 μm decentration. This assembly is then loaded into the carousel, inverted and blocked with wax as before. The machined diameter and the shoulder on the blank ensure that the semi-finished blank is located squarely into the insert thus virtually eliminating unwanted prism and decentration. Once cool the assembly is placed on a front surface lathe taper and cut to the required radius and thickness (*Figure 21.9*). The front surface can then be polished with the lens still fixed in the insert. This blocking system, while originally designed for Polytech lathes only, can now be used on any lathing system.

Front surface lathing

The tool carrying the semi-finished blank is fixed into the collet or taper of the front surface lathe. With CNC lathes a sensor probe makes contact with the centre of the flat front surface to establish the datum reference point. This reference point enables the computer to calculate the amount the cutting tool has to feed in to arrive at the required centre thickness of the finished lens. The spindle is moved forward by predetermined small increments after each sweep of the cutting tool with the depth of the final cut being much less than the previous deeper cuts. Thus the front surface radius is generated to the required centre thickness and at the same time any lenticulation is cut.

Any required lenticulation is all too often left to the laboratory to calculate because practitioners frequently seem to have little idea of what is required. With negative lenses the lenticulation may be introduced to reduce the peripheral and edge thickness. Conversely lenticulation of a positive lens is done to improve the fitting dynamics of the lens, by reducing the centre thickness – achieved by reducing the FOZD – as well as providing some lid attachment, by increasing the peripheral/edge thickness. The dynamics of the lens on the eye, the required centration of the lens, as well as the lid awareness will be factors deciding whether lenticulation is needed and how much. (*See* Chapter 10.)

A periphery which is thicker than the central zone of the lens will have its centre of gravity further back and will be more likely to be held by the upper lid and so ride higher. The width of the lenticulation will be related to the FOZD which, in turn, is influenced by the BOZD. If the FOZD is the same or smaller than the BOZD the patient is likely to experience flare due to the lenticular junction being in the line of vision. Thus as a general guide the FOZD should be at least 0.4 mm larger than the BOZD. The lenticular radii will be influenced by both the edge and junction thickness. Depending on the total diameter many laboratories will automatically lenticulate negative lenses, whereas with positive lenses, unless of a medium or high power, it may be necessary for the practitioner to request this to be done.

The FOZD of a positive lens may have a significant effect on the patient's near vision because of the positive spherical aberration found in plus lenses, which may be as high as +2.00 D towards the optic periphery of a +12.00 D lens. Thus if the FOZD is increased the centre thickness will increase, assuming the same junction thickness, and if the total diameter remains the same the lenticulation band width will be reduced, all of which will contribute to the lens sitting lower on the eye. With the lens sitting lower, the patient will no longer be looking through periphery when reading and this may cause the aphake or early presbyope difficulty when reading. Conversely the required BVP may be lower than its theoretical value if the plus lenticular lens sits high on the eye.

The centre thickness of a plus lens is influenced by either its TD and edge thickness if non-lenticulated, or its FOZD and junction thickness if lenticulated. Another consideration with plus lens lenticulation is the relationship of junction thickness and the width of the lenticulation. Wider lenticulated peripheries (carriers) are more susceptible to breakage due to the sudden change in lens thickness and the greater leaverage involved; therefore careful handling is important.

As a general guide, on positive lenticular lenses it may be useful to put on a 'negative' front surface carrier curve such as –10.00 D or –15.00 D curve, that is to give the peripheral zone this power, which will facilitate lid attachment and thus assist in stabilizing the lens. Alternatively, a front surface carrier curve which is parallel with the back peripheral surface can be made (*see* Chapter 10). The determination of these curves is made easier if during computer design a cross-section of the lens is observed (*see* Chapter 5).

As with the back surface the feed rate, sweep speed of the cutting tool and spindle speed are entered into the computer program and stored for each type of material used by the laboratory.

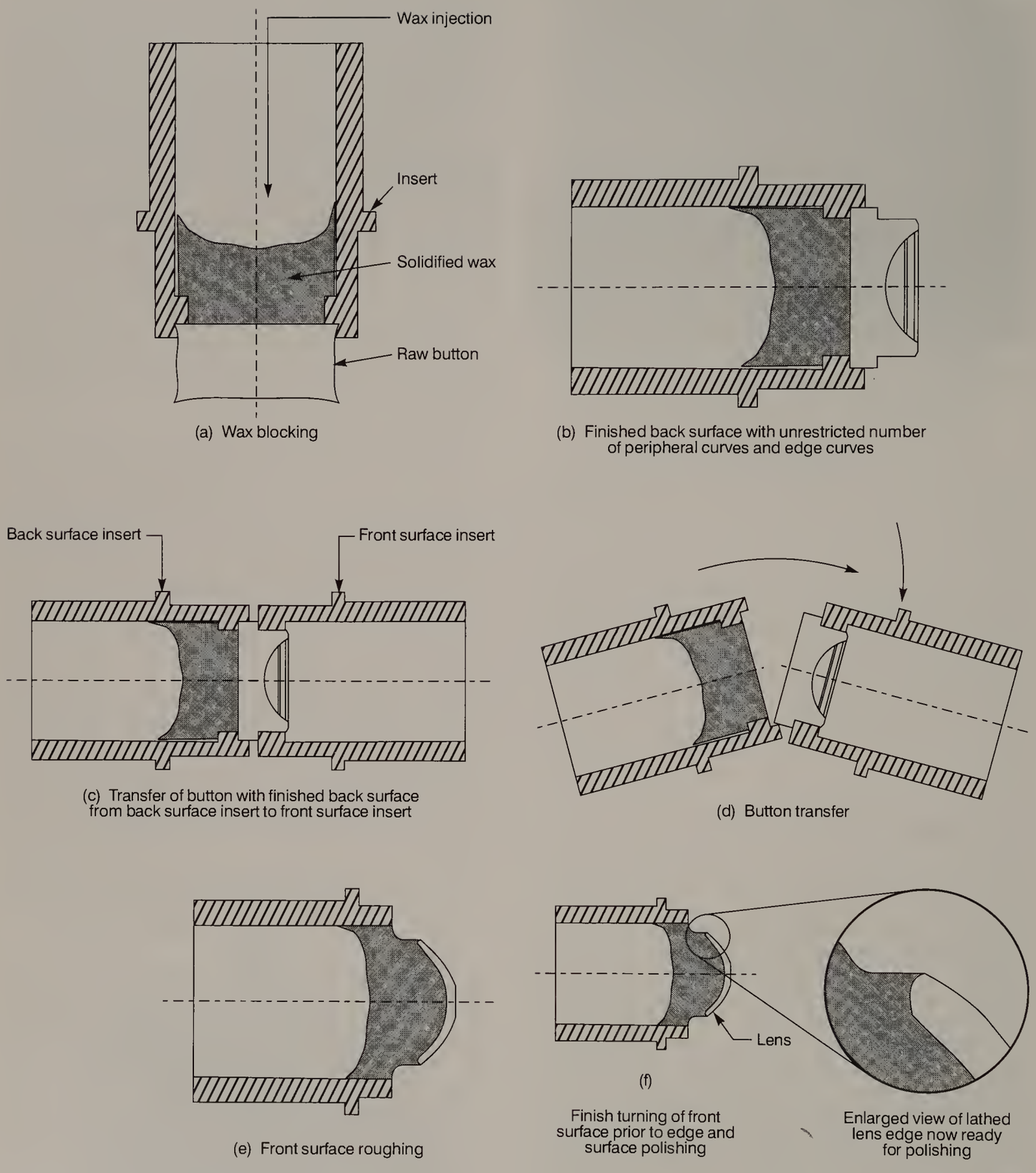


Figure 21.9 Diagram of the stages of the Polytech button blocking system

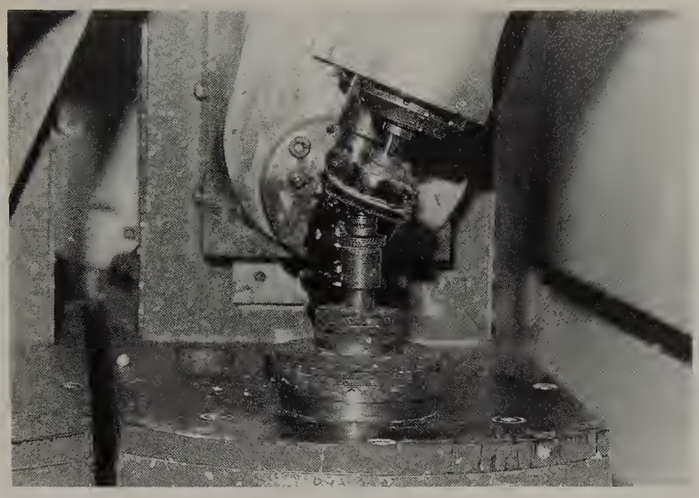


Figure 21.10 Front surface polishing

The surface is again cooled by having a stream of air blown across its face and the swarf is extracted by vacuum. Removing material at too great a rate will produce surface burning and so damage the finished surface characteristics and affect the lens wettability.

Front surface polishing

Once the front surface has been machined to the required radius and thickness, the front surface is polished (*Figure 21.10*). This process, as with the back surface, should be for the shortest time possible as excessive polishing and/or insufficient polish will damage the surface structure and again may lead to poor lens-wetting characteristics. The front surface polisher may be formed from a small drum tool filled in with foam and covered with velveteen which is held on to the tool by an O-ring (*see Figure 21.5.*) However, with a plus lenticulated lens, it may be necessary to use small wax polishers.

After any engraving (*Figure 21.11*) has taken place the lens is removed from the chuck. To remove the lens the mount is gently heated until the wax just melts and so loosens the lens. Once the wax is soft enough the lens is removed and all residual wax adhering to the lens is dissolved using a suitable solvent. During this process great care has to be taken to ensure that a minimum amount of heat is transferred from the chuck to the lens and also to ensure compatibility of the solvent with the lens material.

Edge polishing

The final stage of manufacture requires the lens edge to be polished. There are various machines designed to do this, each having claims of superiority of design by the respective manufacturers. However, most systems work on the basis that the lens, which is usually held in a vacuum-pump suction holder, is rotating and sometimes also oscillating, with its edge in contact with a sponge drum or wheel (*Figure 21.12*). The sponge drum or wheel is saturated with polishing fluid and either spins or rotates respectively at right-angles to the lens edge.

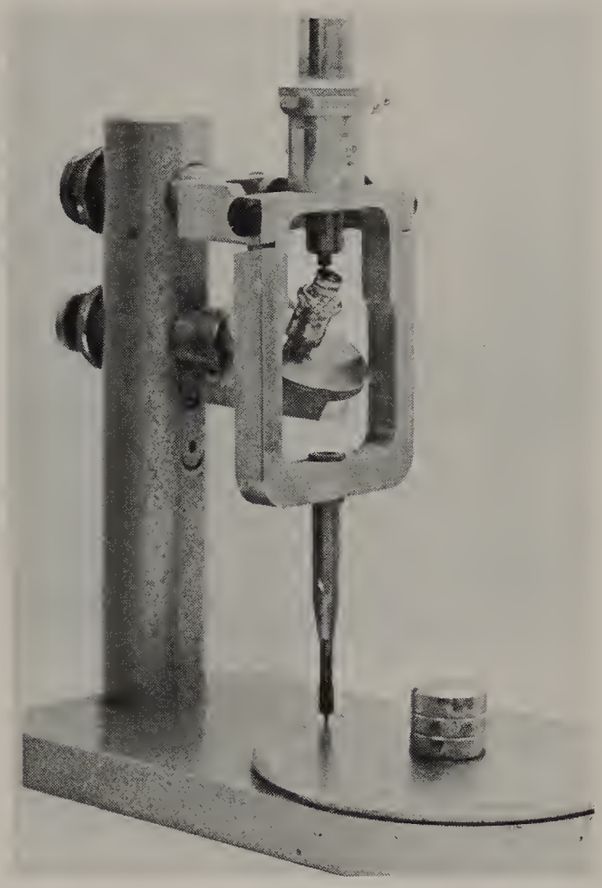


Figure 21.11 Unedged finished lens engraving using pantograph

Final checking

The checking of the final lens will encompass thickness, diameter, radius and back vertex power measurements as well as surface and edge quality inspection. It is at this stage that minor modification to a prescription lens may be made – total diameter, edge shape and polish, blending of peripheral curves and power adjustment.

Submicron CNC lathes

Some manufacturers of the latest CNC lathes claim that their lathes are capable of generating surfaces which *may* not need polishing, claiming a surface finish quality (roughness) of <0.03 μm and shape (radii) accuracy of <1 μm. These submicron lathes, which are adapted from other uses such as producing lenses for compact discs, are probably going to have a dramatic effect on the production of lathe-cut contact lenses in the future.

The Optomatic (Euro Precision Technology) and the Optoform 50 (Rank Pneumo) range of submicron CNC lathes use a T-shaped slide configuration and utilize precision air-bearing slides or hydrostatic bearings with air-

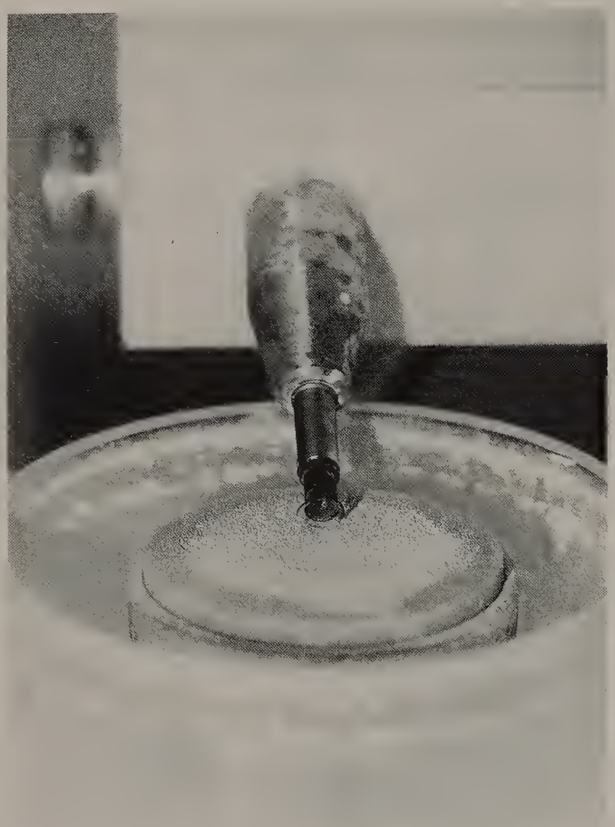


Figure 21.12 Edge polishing

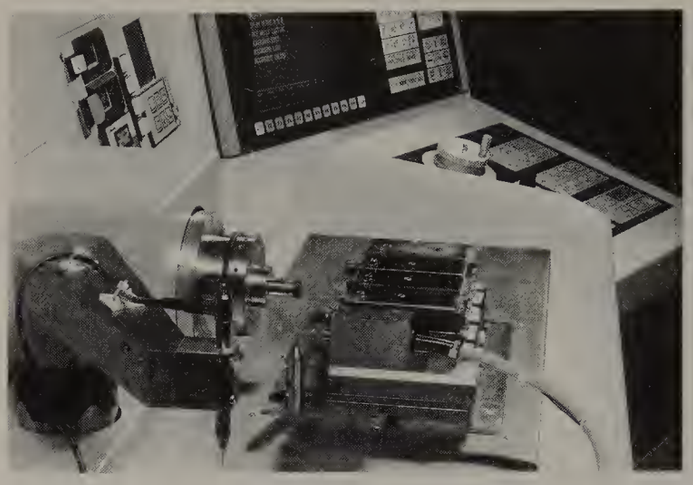


Figure 21.13 Optomatic (EPT) showing slide assembly

bearing spindles. The slides are mounted on an epoxy-granite or natural granite base which, it is claimed, provides thermal stability and good vibration dampening characteristics.

These machines generate the curves by moving the spindle, with the blank rotating, along its z axis, that is backwards and forwards, while the cutting tools move at right angles to the axis of the spindle, along the x axis or laterally (*Figure 21.13*). This is a departure from the conventional contact lens lathe, where the quadrant holding the cutting tool describes an arc of a given radius. On both axes a linear grating measuring system is used with resolution of 0.04–0.05 μm. Movements of both axes are performed by linear friction drive systems which are powered by fast and accurate DC-servo motors. This allows for accurate positioning and smooth operation, without hysteresis or backlash, down to nanometres.

The lower supporting frame is of rigid construction and the upper granite base and machining components are supported on a vibration isolation system.

The air feeding into the air bearings is dried with a freeze dryer and filtered to ensure error-free running. The tool holder assembly can hold up to five or six different tools for roughing, finishing and edging. The same machine can generate any type of symmetrical curve – spherical, aspherical, concave and convex for single vision or bifocal contact lenses. After defining the lens geometry, the software calculates the x and z data points in 10 μm points along the specified surface. This information is then used to execute the machine movements by continuous path linear interpolation, after modifying the data points with tool radius compensation values.

Additionally the lathe manufacturers claim that with their tool replacemcnt system it is possible to replace the diamond tools within 5 minutes and, using the optical probe, to calibrate the tool setting within an accuracy of 0.2 μm in all three axes.

EPT (Euro Precision Technology) have produced a blocking system with claims of accuracy within 3 μm, thus ensuring accurate edge thickness with no unwanted prisms. The system works by placing the back surface mount (chuck/arbor) with the intact blank (concave surface worked) in the upper part of a precision press with the heated and waxed front surface mount in the lower part of the press. The two are then presented to one another and the blank adheres to the lower front surface mount. The upper mount is released from the press and once the lower mount has cooled sufficiently the whole sandwich combination of front surface mount/blank/back surface mount is removed from the press. The back surface mount is then removed from the combination leaving the blank mounted and ready for front surface cutting.

Independent laboratory reports suggest that the surface quality produced with the latest CNC lathes does not quite reach all of the manufacturer's claims. However, even if the surface still requires polishing, it is evident that this finish is significantly superior to previous lathing systems and at the very least will further reduce the polishing times. Reduced polishing leads to greater accuracy and consistency of the lens parameters. Unfortunately lens polishing is under far poorer control than lathing and as such the longer the lens has to be polished the greater the chance of a shift from the original parameters as well as an increase in lens heating.

It is likely that we are approaching the absolute limitations to the finished surface quality that can be obtained by conventional lathing and perhaps the future lies

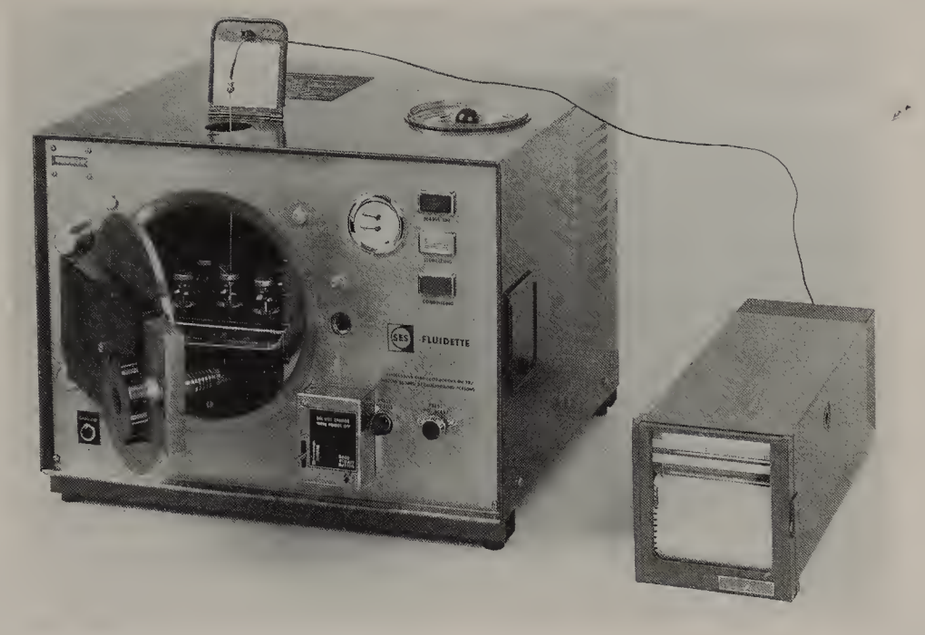


Figure 21.14 A small bottle autoclave with temperature recorder

in finishing processes that use low energy lasers as final cutting tools.

Soft lens fabrication

Lathe-cut soft lenses are produced in a similar manner to rigid lenses with a few important variations.

Because the lens is formed in the dehydrated state any error in tolerance will be increased by a factor of the linear expansion ratio, i.e. the amount the dehydrated lens expands when hydrated. Thus an environment which encourages lens hydration during its fabrication is to be avoided. This does not necessarily mean excessive environmental humidity control. However, extremes of humidity and temperature will have an adverse effect on all lens manufacture especially with high water content materials. It also means that all materials that come into direct contact with the lens must be completely free from moisture, and this can be achieved by storing such articles as polish, polishing tape, chamois leathers, cotton wool and so on in an incubator, and only removing small quantities as and when they are needed. Polishing compounds, which are free of water and utilize oil-based media, have been developed. Ideally there should be no pause or interruption to the manufacturing process, but if this occurs the lens blank should be sealed in an air-tight tube which has previously been stored in the incubator. The technicians must take great care not to breathe over the lens nor to touch the surface with their skin. If partial surface hydration occurs during manufacture not only will it affect the finished parameters but surface finish will be poor with areas which may be relatively hydrophobic. Equally dust has to be kept to an absolute minimum to avoid scratching the surface during polishing.

The dehydrated lens has to be cleaned in an ultrasonic bath of solvent and then hydrated in sterile physiological (0.9%) saline. The hydration time varies with the type of polymer. Following hydration the lens will be checked for surface blemishes, back optic zone radius, total diameter, thickness, edge shape and BVP. A temperature controlled wet cell analyser can be used to check lens geometry (*see Figure 13.15*). Other items used for checking are described in Chapter 13.

Sterilization

Soft lens sterilization will be carried out by autoclaving (*Figure 21.14*) in the laboratory and is also an essential process for the practice. The following tips may be helpful for practitioners:

- Isotonic saline should always be used, never solutions containing preservatives.
- The lens vials should be three-quarters full, thereby avoiding a build-up of excess pressure during autoclaving which might force off the caps.
- The caps should be metal crimp type.
- The material should be of a type not damaged by the repeated high temperatures of autoclaving.

Additional procedures for RGP lenses

Modification to rigid lenses may be required after lens production by the practitioner (*see* Chapter 22) or lenses may be returned to the laboratory for small adjustment. The next section covers some of the more frequently performed laboratory procedures.



Figure 21.15 Tools for edging and checking. *Left to right*: band measuring magnifier, razor blade, micrometer gauge, conical carborundum tool, ×10 loupe

Edge shaping

Edging, polishing and blending are among the most difficult procedures in making and modifying rigid lenses, and the success of the lens is frequently decided at this point.

Traditionally, the dry lens is mounted with wax on a hot edging chuck, the concave surface being uppermost. The hot chuck is then transferred to a rotating vertical spindle, and centred by steadying the rotating lens between the thumb and index finger of both hands (*see Figure 22.9*). If the reflection of an overhead spotlight or striplight from the rotating lens surface is seen to be steady, then the lens is correctly centred. Once the wax is cool and set the lens can be modified. Hot wax in contact with RGP materials may cause surface damage and it is therefore usual to mount the unedged lens using double-sided tape, which makes it difficult to centre the lens accurately. Alternatively a vacuum chuck may be used although the lens may distort if very thin or if the suction is too strong.

Reduction of the total diameter and edge shaping may be done by either arching a razor blade, emery board or 'stone' around the rotating lens, starting on the back surface and working round to the lower front surface as in edge shaping (*see Figure 22.10*). Care has to be taken not to cut into the peripheral curve on the back surface and to hold the razor blade so that it trails against the edge, i.e. with its edge facing in the direction of lens rotation to avoid nicking the edge. Because of the nature of RGP materials the reduction and shaping of the edge is usually done with an emery board or stone. The shape and thickness are checked by observing the edge with a loupe (×10) and the total diameter measured using a micrometer gauge (*Figure 21.15*). The surface is smoothed using a conical-shaped carborundum stone which is rolled around the rotating edge of the lens (*Figure 21.16*), and the edge is inspected before polishing.

The author feels the ideal edge shape for a rigid lens is as shown in *Figure 21.17*; this edge will not be so easily damaged from handling as one with its apex towards the back of the lens. However the final edge shape will be influenced to a certain extent by the peripheral curves and hence the thickness of the material available at the edge. A lens with very little edge lift will generally be more comfortable if it is quite thin, conversely this same edge shape may be uncomfortable on a lens with a large edge lift as this now has the effect of acting as a sharp knife. In general terms a lens with a large edge lift will need to have sufficient edge thickness to produce a well-rounded shape.

Polishing and blending peripheral curves

If the peripheral curves need further blending and polishing, either because of poor finishing or because modifications have been carried out to the finished lens, ideally the lens should be mounted on an edging chuck with either wax or double-sided tape. To blend the peripheral curves the apices of the transitions may first be removed with wax tools which are usually cut to either one-third or midway between the adjacent curves. The wax tool is mounted on a vertical spindle and the lens/edging-chuck combination is allowed to rotate and at the same time oscillated to and fro on top of the polishing tool (*Figure 21.18*). The lens is periodically inspected using a ×10 loupe and when all the transitions have been blended to the required degree, all the remaining peripheral curves are polished and blended using a progression of felt tools (*Figure 21.19*) so as to obtain a gradual and continuing flow of curves. Thus, as near as possible, a continuous curve is produced with the advantage that the original curves are known and can thus be altered at a later stage if necessary.

Wax polishers

To alter the radius of peripheral curves it is necessary to use solid polishers of known radii. Wax is the ideal medium for changing, polishing and blending these curves.

Back and front surface wax polishers are made with dental or paraffin wax and magnesium carbonate, the latter acting as a very fine abrasive. Some wax polishers, their chucks and the blocks in which they are made, are shown in

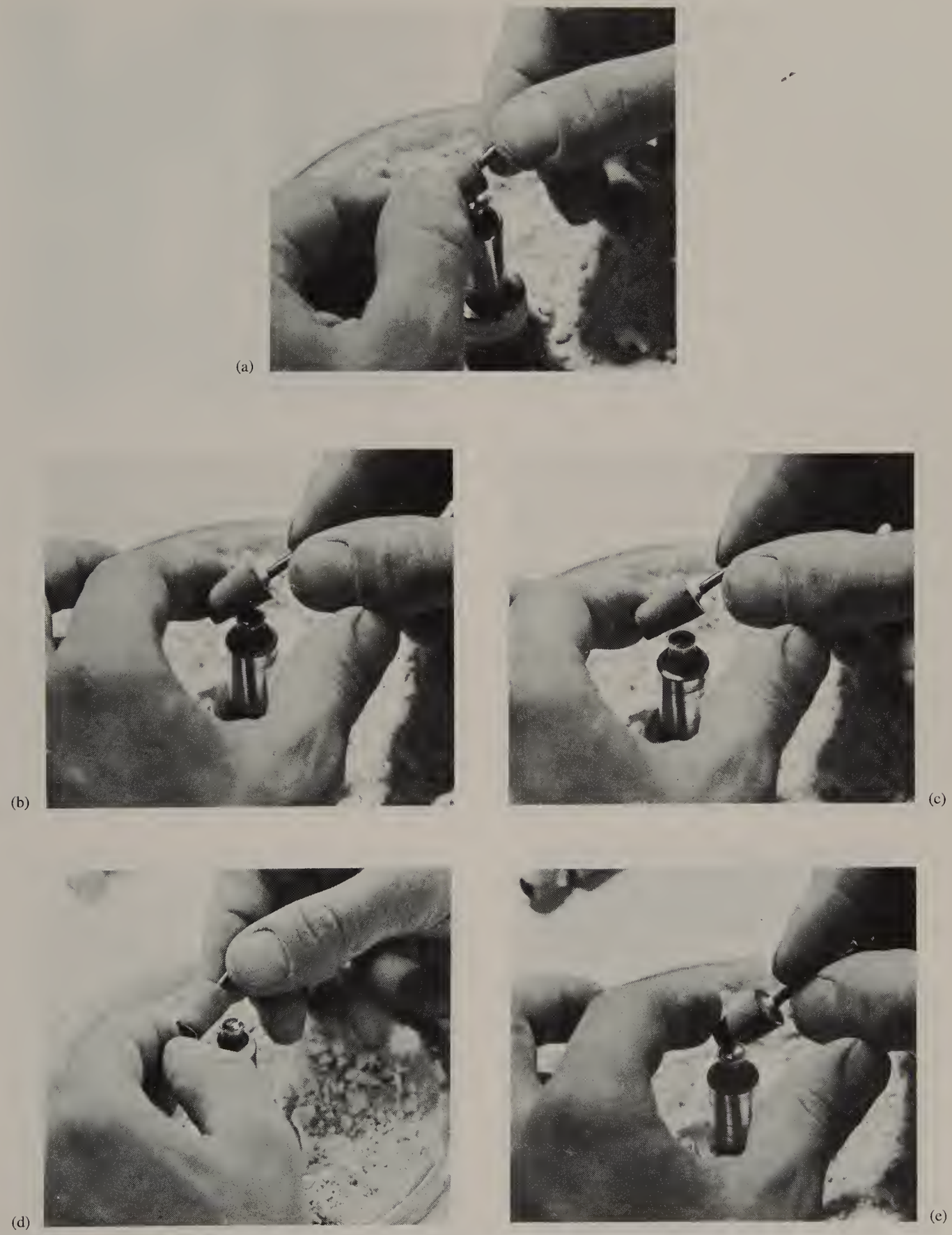


Figure 21.16 Shaping and smoothing the edge with a conical carborundum stone. The stone is carefully 'rolled' around the lens edge: (*a*) – (*e*) show successive positions of the conical tool

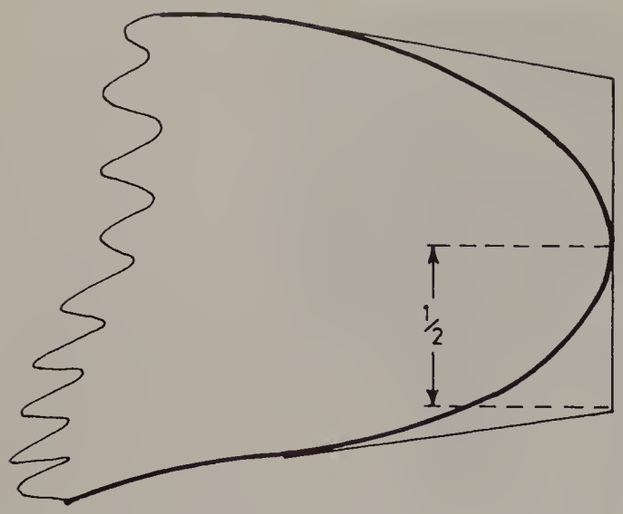


Figure 21.17 The author's ideal edge shape shown in cross-section



Figure 21.19 Blending of transitions and polishing of peripheral curves may be done with radius felt tools

Figures 21.20 and *21.21*. In hot climates larger quantities of magnesium carbonate are required to prevent the wax from softening.

After cleaning the chuck and casting blocks in paraffin, they are heated to approximately 85°C and the molten mixture of wax and magnesium carbonate, which is at approximately 125°C, is poured into the blocks. The casting blocks are then vigorously banged several times on a solid surface to release any air bubbles. After cooling slightly the wax contracts and needs to be topped up with additional molten wax.

When the wax is cold the chucks can be forced out of the casting blocks with the aid of a dowel. The back surface polishers are cut on the lathe or by using female steel gauges while the front surface polishers are cut using steel male gauges. These wax polishers can be re-cut many times before the need to re-cast.

Edge polishing

Finally, the edge has to be polished. There are several ways of doing this. If the lens is still mounted on the edging chuck it can be placed on the tapered vertical spindle with its concave side uppermost. With the spindle rotating, a chamois leather, soaked in polish, is wrapped around the index finger and a gentle forward and backward movement is made across the top of the lens edge. The ball of the



Figure 21.18 Blending transitions by removing their apices on a wax tool

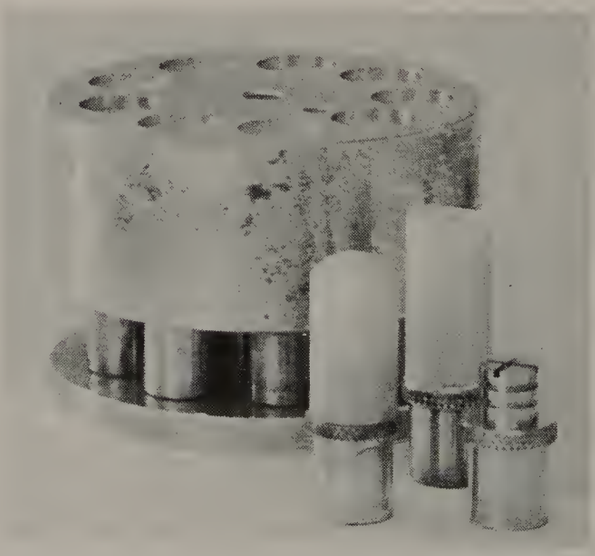


Figure 21.20 Block and chucks for casting back surface wax polishers. *Left to right*: the block for making nine wax tools, a radiused tool, an uncut wax tool and a basic chuck for taking a wax polisher

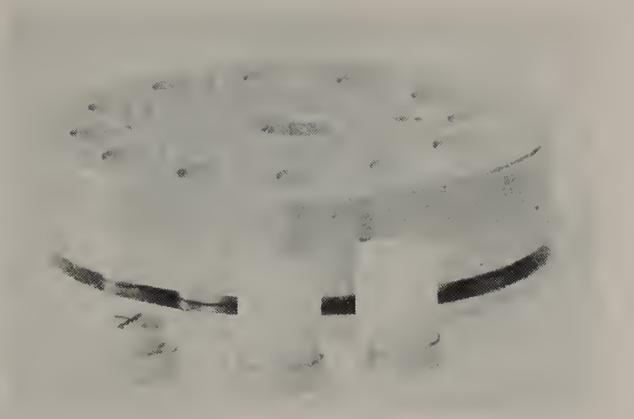


Figure 21.21 Blocks and chucks for casting front surface wax polishers: a basic chuck and a cut and uncut wax tool are shown in front of the block for making 12 wax tools

finger is then rolled around and under the edge of the edge of the lens as shown in *Figure 21.22*. When the inner or back edge of the lens is fully polished the lens is cleaned and remounted the other way round on a convex edging chuck. The outer or front edge of the lens is polished in a similar manner. The lens is removed from the edging chuck and cleaned in an aliphatic hydrocarbon solvent.

Some laboratories use a series of hollow-cone tools of varying angles to shape and polish the edge (*see* Chapter 22). These rotate on a vertical spindle and the edge shape and polish is produced by running the lens inside each tool for a specific time. This technique may give variable results.

Most laboratories use an automatic edge polisher (*Figures 21.12, 21.23*). The lens is usually held in a suction cup and rotated on a revolving sponge containing polish. This produces good results provided the edge has already been shaped. It is quite suitable for mass stock lens production. However, it may result in the edge being polished but poorly shaped, if this has not been correctly done prior to polishing; thus the lens may have a polished square edge.

The edge may also be polished by hand on a rotating velveteen-covered drum, the lens being held in a suction holder and rotated by hand with first the concave and then the convex surface facing the direction of rotation of the drum. This is followed by apical polishing of the edge with the lens rotated parallel to the edge of the drum. Although labour-intensive, shaping and polishing of the edge by a skilled technician can give very good results – there is constant observation of the lens and allowances are readily made for the different thicknesses of individual prescriptions.

Power adjustments

When the lens is being fabricated the power can be adjusted at the final checking stage, subject to certain requirements. On a lenticulated positive lens it is almost impossible successfully to add positive power without ending up with a double optic, whereas adding minus power is much easier. With the addition of positive power there is difficulty in removing the different amounts of material from across the whole of the optic. *Figure 21.24* shows a lenticulated positive lens in cross-section. When adding positive power, more material has to be removed from the periphery of the optic, and it can be seen from *Figure 21.24a* that the lenticulation prevents a continuous sweep across the lens surface. This means that the polishing cannot even out the 'bands' which are formed when removal of material from this area takes place. However, when adding negative power the majority of material is removed from the centre of the lens with hardly any from the periphery of the optic, as shown in *Figure 21.24b*. Thus the 'bands' resulting from polishing can be blended into one another to produce a single continuous optic curve. For this reason practitioners



Figure 21.22 Polishing the edge of a lens – concave surface uppermost. The chamois leather is rolled over the edge of the lens on the ball of the finger

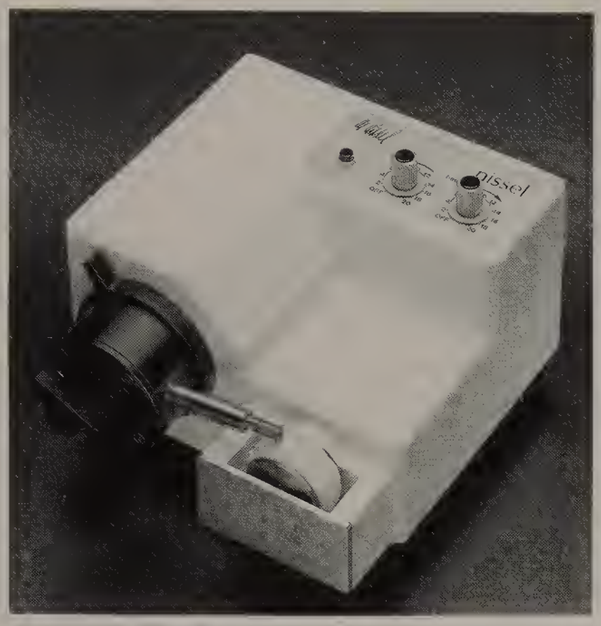


Figure 21.23 Automatic edge polisher

should err on the side of slightly over-plussing positive powered lenticulated lenses since the power can later be reduced if necessary but not vice versa.

With negative lenses the power can be altered by adding either negative or positive power although marked lenticulation may make this a more difficult procedure. *Figure 21.25* shows the areas where material has to be removed.

A polishing drum (*Figure 21.26*) (*see* Chapter 22) is the system most frequently used for power adjustments by laboratory and practitioner. Great care has to be taken when using this method for it has inherent problems and its use by the less skilled frequently results in poor power readings and disturbed wettability with RGP lenses. It is usually better to re-order the lens if a significant power change is required.

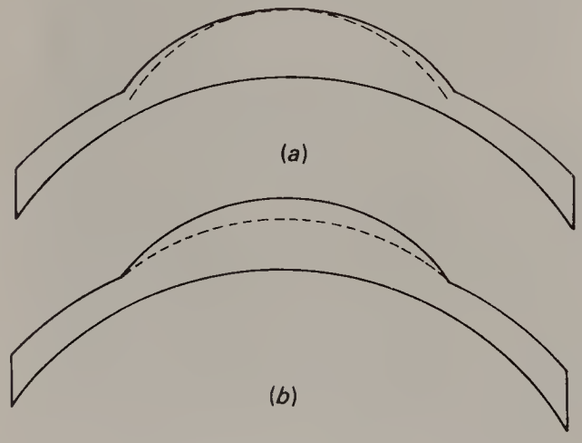


Figure 21.24 Power adjustments to positive lenticulated lenses. The broken lines represent areas where material is removed: (*a*) adding plus power; (*b*) adding minus power

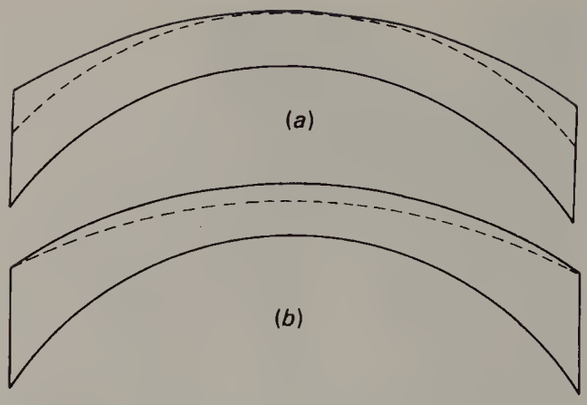


Figure 21.25 Power adjustments to negative lenses. The broken lines represent areas where material is removed: (*a*) adding plus power; (*b*) adding minus power

Fenestration

Fenestration involves forming a hole, typically 0.20–0.30 mm diameter, with a vertical drill (or laser) while the lens is mounted convex surface uppermost on a chuck containing a small depression (or hole) which receives the penetrating drill. Both sides of the fenestration must be countersunk and polished. This is best done with a sharpened boxwood stick which is rotated in a circular fashion in the opposite direction to the vertical spindle on which the chuck and lens is rotating. To polish and countersink the back surface of the fenestration, the lens is placed on a concave chuck with the fenestration hole at its centre. The lens may be held in place by wax or double-sided sticky tape, avoiding the central depression in the chuck. The central part of the fenestration may be polished by running the lens up and down a length of polish-soaked cotton, threaded through the fenestration hole.

Fenestration of corneal and scleral lenses is also dealt with in Chapters 10, 17 and 22.

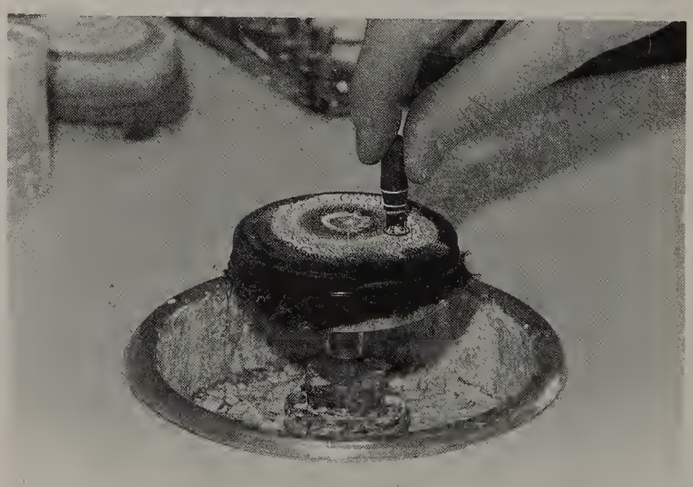


Figure 21.26 Adding minus power using a large polishing drum

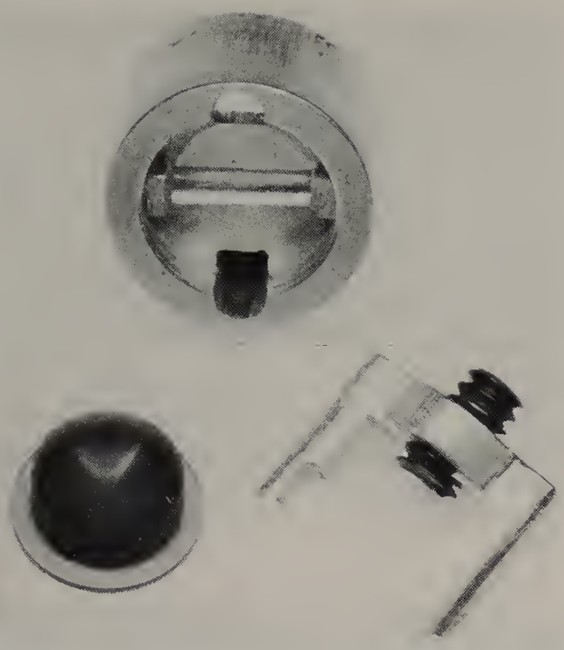


Figure 21.27 A simple crimping tool showing its three component parts, and a lens blank with an outer stepped rim for applying crimping pressure

Finally, the lens is cleaned, dried, inspected for surface blemishes and the blending and specifications checked – BOZR, BOZD, TD, centre thickness, edge thickness and BVP.

Toric lens production

Concave and convex toroidal surfaces can be produced by crimping, polishing, grinding or lathing.

Crimping

To produce a toroidal back surface, a concave spherical surface is first cut and polished with its radius midway between the required radii. The blank is cut with a central thickness of approximately 0.20 mm and a diameter of 0.20 mm more than the required total diameter. An outer stepped rim at the base of the blank is formed on which to apply the pressure during crimping. The blank is placed concave uppermost in the crimping tool (*Figure 21.27*) which applies pressure at four points on the stepped rim – two points along the one meridian to flatten the radius and the other two points at right-angles to steepen the radius. The amount of toricity is produced by altering the pressure until the required difference between the radii is achieved. The toroidal surface so produced is checked on the radiuscope. The blank, still held in the crimping tool, is re-cut on the lathe to produce a spherical curve midway between the required radii. After polishing, the blank is released from the crimping tool and forms into the required toroidal shape.

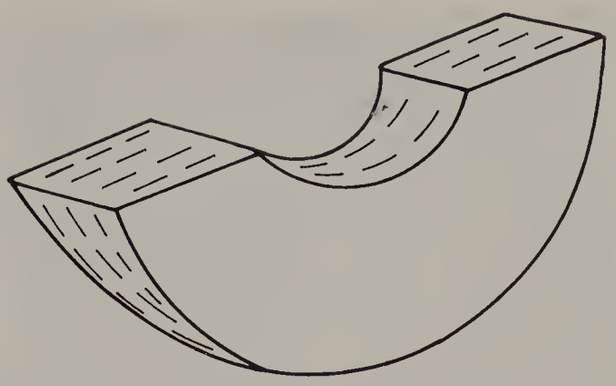


Figure 21.28 Half a felt wheel tool with central cut-out for hand polishing a toroidal front surface

A similar procedure can be used to produce a toroidal front surface. However, it is necessary to cut a curve on the back of the blank before crimping, although this does not require polishing. This back curve is necessary to reduce the amount of pressure required to flex the lens. Once the toroidal surface is completed the final back surface has to be produced. At the same time any prism necessary for stabilizing the lens has to be incorporated, as well as reducing the blank to the required thickness of the finished lens.

Polishing (historical)

This involved creating a toroidal surface by hand polishing and was usually confined to the front surface of a PMMA lens. It was only suitable for low cylindrical powers. The lens was finished on both surfaces and mounted on a hollow chuck. A positive cylinder was polished on the front surface using a felt wheel which had been cut across its diameter with a radius cut out of its centre, giving the appearance of a female cutting gauge as shown in *Figure 21.28*. An allowance was made initially when working the spherical power as some negative sphere would be added at the same time as the positive cylinder. This process required a skilled technician to obtain an acceptable result.

Grinding (historical)

To obtain a toroidal concave surface on a PMMA blank a spherical curve was first cut on the blank. The toroidal curve was then generated by attaching a toric wheel to the polishing machine by means of a spindle. A fork, which held the arms on which the blank was mounted, maintained the arms at right-angles to the spindle of the toric wheel. The whole unit then rotated together while the oscillating head of the polisher moved the blank across the axis of the toric wheel (*Figure 21.29*).

The toric wheels were usually cut from brass (*Figure 21.30*), and emery powder used as an abrasive. For the more popular toric radii, diamond-coated toric wheels were used. A wax toric wheel, which was cut in a similar manner to the brass wheel, was used for polishing.

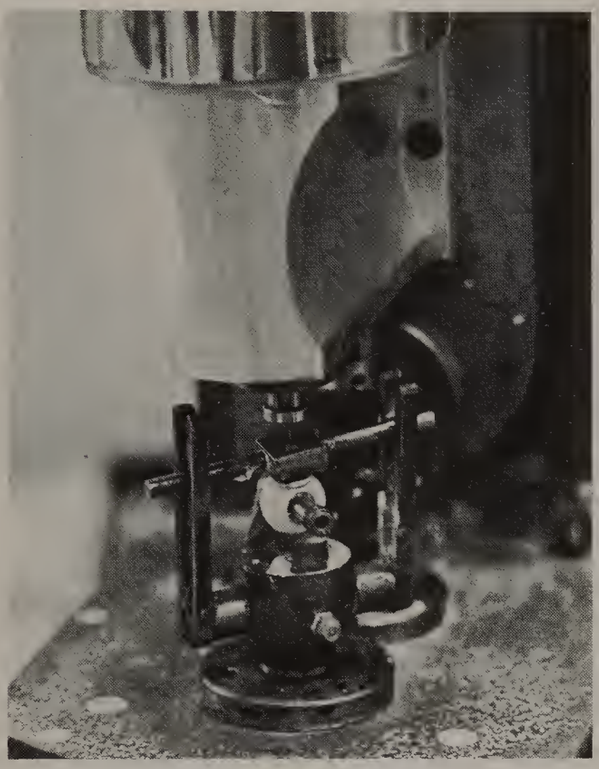


Figure 21.29 Close-up of a back surface toric polisher

The cutting of brass and wax toric wheels involved the use of a special toric lathe. The radius was cut at right-angles to the spindle axis which was displaced by the required difference between the two radii.

Once the central curves had been generated any number of toroidal peripheral curves were formed.

Lathing

Fly-cutter

Back surface toric lathes use a diamond fly-cutter – a diamond tool with its cutting tip at right-angles to the axis of its shank. The shank of the fly-cutter is held in the spindle collet while the lens blank is held in a collet in the radius cartridge (where the diamond would normally be in a conventional spherical lathe), thus the position of the blank and cutting tool are reversed (*Figure 21.31*). When the spindle rotates the fly-cutter tip describes, in the vertical plane and at right angles to the spindle axis, a circle whose radius is the distance from the centre of the spindle to the tip of the diamond. The radius of the vertical circle, which is the flatter radius (axis horizontal) of the toric surface, can be altered by:

- Changing the size of the cutting tool.
- Offsetting the axis of the fly-cutting tool centre-line in relation to the centre-line of the radius cartridge.

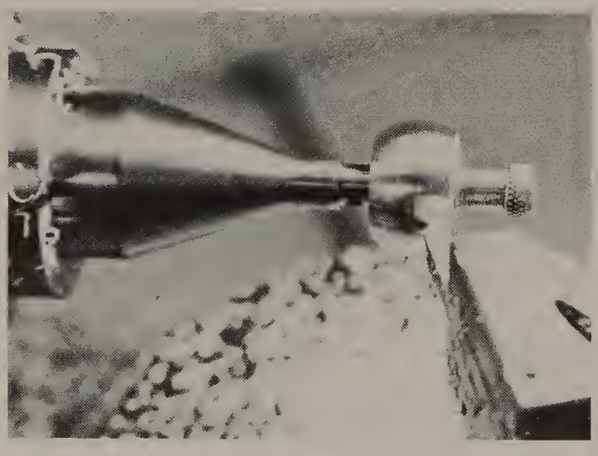


Figure 21.30 Cutting a back surface toric brass generator

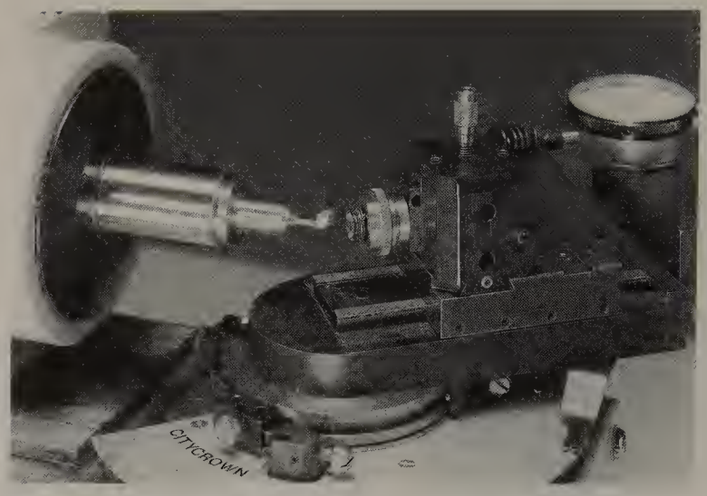
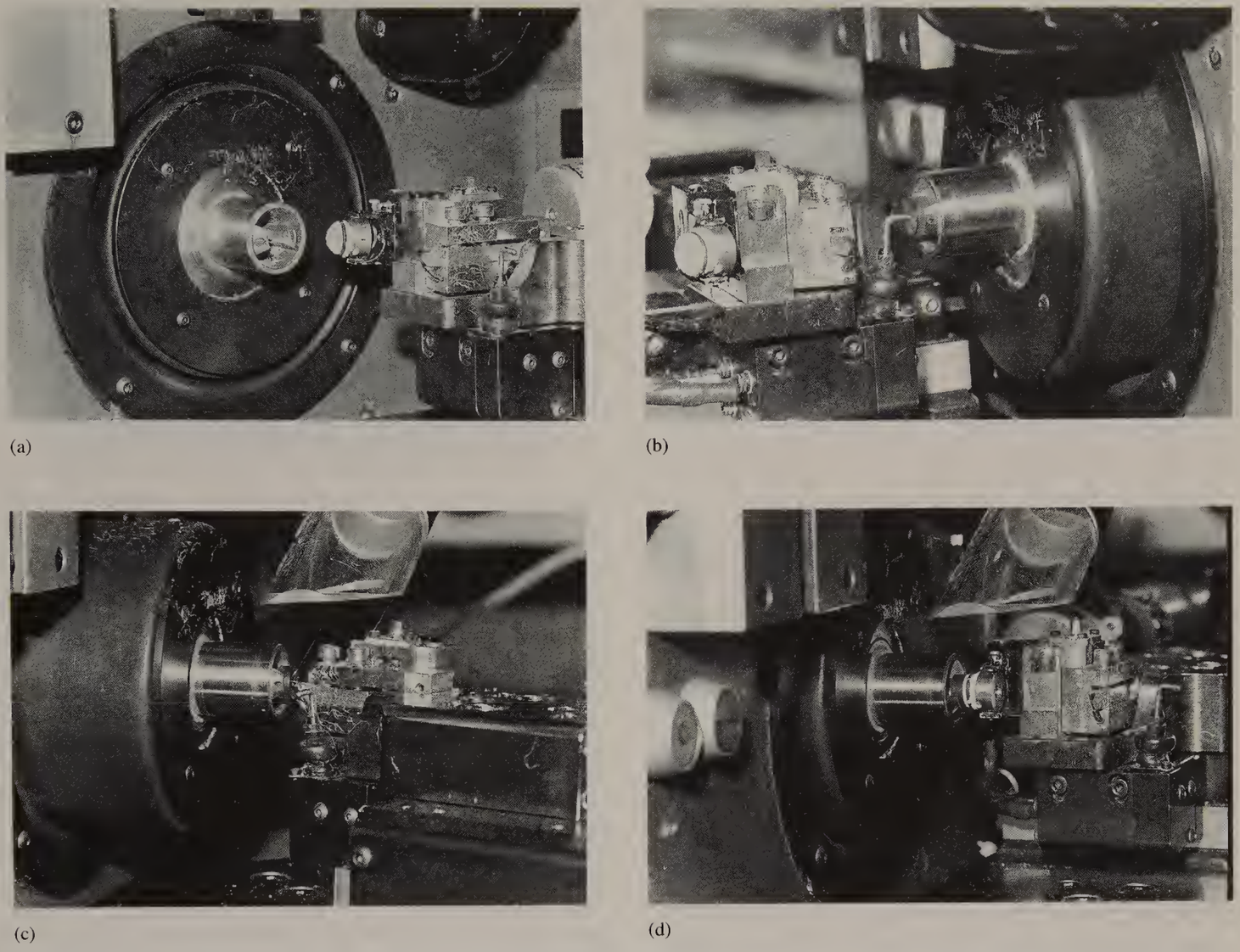


Figure 21.31 City Crown back surface toric lathe showing fly-cutter diamond tool and lens blank

In all back surface toric lathes the cutting tool remains constant for the flatter radii between 6.0 and 10.0 mm (Gfeller, Switzerland) and 6.0 and 12.0 mm (City Crown, UK). For radii (flatter curve) outside this range the fly-cutting tool has to be changed.

In the Gfeller back surface toric lathe, the offset of the centre-line is achieved by the special offset-collet fixed to the spindle. The fly-cutting tool is held in this offset-collet which effectively helps to extend the size (radius) of the cutting tool. The City Crown lathe achieves the offset of the centre-line by a facility on the radius cartridge. This offset facility enables the whole radius cartridge assembly to be displaced at right-angles to the spindle centre-line, thus effectively offsetting the spindle to the radius cartridge centre-line.

The toroidal surface is produced by presenting the non-rotating blank to the tip of the rotating fly-cutter tool. The non-rotating blank, held in the collet of the radius cartridge, describes an arc, along the horizontal plane, whose radius when it passes through the tip of the fly-cutter diamond is at right-angles to the spindle axis; this horizontal arc represents the steeper curve (axis vertical) of the toroidal surface. This radius can be varied by altering the distance by which the centre of radius of the cutting tool extends beyond the pivot point of the radius cartridge.



(a) (b) (c) (d)

Figure 21.32 (a-d) Polytech toric lathe: (a) Showing the two jaw collet and polishing tool; (b) the sensor probe making contact to find the reference datum; (c) cutting the crimped base curve; (d) polishing the cut surface while still crimped

These are the basic principles on which most back surface toric lathes work.

Front surface toric lathes, such as that produced by Gfeller, work on a similar principle to the back surface toric lathes just described, that is, by utilizing offsets of spindle axis in relation to cutting tool centre-line. However the diamond cutting tool is held in its conventional position and the work piece is mounted on the spindle but with its central axis at right-angles to the spindle axis – similar to the fly-cutter tool of the back surface lathe. This utilizes a special small front surface chuck on to which the lens blank is blocked. The blank rotates with the apex of its front surface describing a vertical circle at right-angles to the spindle axis. The process is very similar to the cutting of toric grinding and polishing wheels (*see above*, Grinding) at one time utilized by Nissel.

The method of polishing these toroidal surfaces will depend on the material and quality of the lathed surface finish. Generally a system similar to that described in the section on grinding toric surfaces may be used, this is especially so with PMMA. However if the surface finish is good enough then sponge-and velveteen-covered polishing tools may be used.

Polytech toric lathe

Polytech has introduced a combined back and front surface toric lathe (*Figure 21.32*) where the toricity is produced by double-toothed jaws of the collet crimping the blank *in situ*. The degree of crimp and hence toricity is controlled by computer which automatically adjusts the hydraulic pressure to the jaws of the collet by previously determined amounts. Once the requisite amount of crimp is formed the lens blank is machined using conventional spherical lathing. The machine, which has air bearings, produces a high quality surface finish which is then lightly polished using

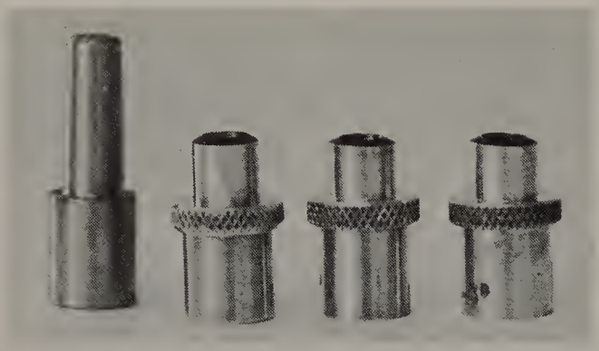


Figure 21.33 *Left to right:* 1.5Δ prism adaptor; standard hollow chuck; hollow chuck with 1.5Δ prism; hollow chuck with 3Δ prism

the integral polishing tool. Front surface toric lenses can be generated in a similar fashion with the back surface being finished last using the Polytech blocking system.



Figure 21.34 Truncating a lens with an emery board using the (stationary) vertical spindle as a base

Advantages and disadvantages of toric techniques

The traditional method of crimping has the advantage that a laboratory can produce a wide range of toroidal surfaces without the expense of a toric lathe. It is particularly useful for prescription toric soft lens production where, especially with high water content materials, very steep radii have to be generated in the dehydrated state. These are frequently too steep to cut on toric lathes. Its one disadvantage is in rigid lens production, where it introduces a degree of strain into the finished lens compared with soft lenses and where the stress is fully released on hydration. One of its advantages, however, is that the surface remains spherical during polishing thus making it possible to utilize conventional polishing techniques.

Until the introduction of the Polytech toric lathe, direct lathing of a toric surface was the most accurate system for producing toric lenses although the techniques available for polishing toroidal surfaces are still limited.

Prisms

A prism may be incorporated into the lens either to correct a vertical extraocular muscle imbalance or more frequently to stabilize the lens, i.e. to stop a front surface cylindrical lens from rotating on the eye.

The prism is introduced when the last surface, usually the front, is cut. Historically either a special prism chuck or a prism adaptor, on which a standard front surface chuck sat, was used for this purpose (*Figure 21.33*). The prism chuck had its face cut at an angle corresponding to the apical angle of the prism. The prism adaptor had an outer male taper which had a different axial centre line to that of its inner female taper. Thus, any standard chuck which sat on the adaptor was angled by the same amount as the apical angle of the required prism.

Use of the prism adaptor was preferable to the prism chuck because after polishing the front surface, which was done with the standard chuck still mounted on the adaptor, the chuck, without the adaptor, would be placed back on the lathe. The lens would then be re-cut and, because it contained a prism, only material from the highest spot (i.e. the thickest part of the prism base at the edge of the lens) was removed. Thus the thickness of the base of the prism could be reduced, producing a lens with a thin edge all around the periphery but still containing the necessary ballast to stabilize it. The reduced base was then polished either using a felt wheel in a flexible drive or by working the lower face of the lens against the rotating surface of a polishing drum.

A more modern method of generating a prism is with Gfeller's front surface toric lathe which incorporates a prism adjustable headstock used in place of a prism adaptor. Other lathe systems utilize a prism collet which works by an offset mechanism, a similar concept to a prism adaptor, whereby the collet, into which the conventional chuck is fixed, is offset by a amount calculated according to the degree of prism required. Incorporating a prism system into the lathe has the advantage of providing a more accurate orientation of the base–apex axis to the front cylindrical axis as the two processes, cylinder and prism, are cut on the same lathe without removing the blank from the collet.

Truncating

Lens truncation is usually carried out to help stabilize a toric or bifocal lens and is nearly always combined with a prism ballast. Most frequently it involves only the lower edge. The edge is removed using an emery board (*Figure 21.34*) or a diamond impregnated tool. It is polished with a felt wheel rotating in a flexible drive (*Figure 21.35*) or on a rotating



Figure 21.35 Polishing a truncation with a felt wheel driven by a flexible drive

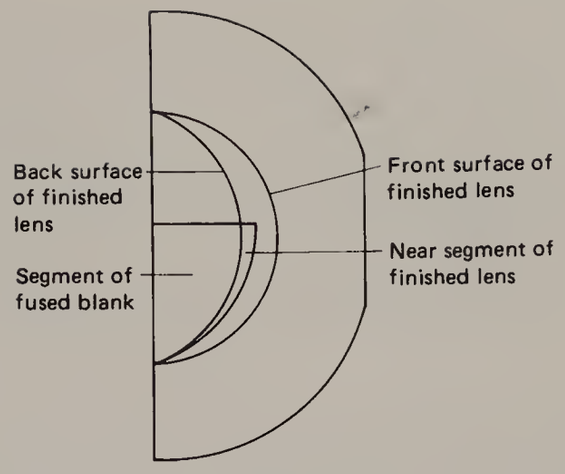


Figure 21.36 Crescent surface-fused bifocal blank in cross-section

velveteen drum-chuck, while the lens is mounted on an edging chuck. The corners of the truncation are rounded to minimize discomfort to the lower lid. With a bifocal, the edge is left fairly square to assist the lower lid in raising the lens when the gaze is depressed.

Bifocals

Bifocals may be fused or solid in the rigid lens form, but are only made in the solid form in soft lenses. They may also be simultaneous or alternating/translating – simultaneous being concentric, diffractive or aspheric types and alternating being conventional segmented types, similar to spectacle lenses (*see* Chapter 16).

Lathe-cut soft lens bifocals are constructed in the dehydrated state in exactly the same manner as rigid bifocals.

Fused bifocals

The fused bifocal blank (*Figure 21.36*) is made by fusing together two pieces of polymer with different refractive indices, in an oven at high temperature. This is a similar process to constructing a fused bifocal spectacle lens. The segment can be fused on the back surface of the blank or internally fused. With the former, the different powers of the near additions are obtained by varying the radius of the segment interface. Thus, for any given BOZR with any given near addition, an appropriate segment radius is cut into the blank and the matching segment inserted into the cavity. Therefore, for any given blank there is a fixed BOZR and near addition. Consequently, a comprehensive stock of blanks is required for surface fused bifocals to cover all possible combinations of BOZR and near additions (*see* Chapter 5), as well as the range of tints.

Internally fused bifocal blanks are more frequently used although they cannot be cut as thinly as surfaced fused blanks. They are constructed with an internal segment of higher refractive index than the outer material and the radii of the segments are adjusted to give the required near addition power. Internally fused bifocal blanks need only be stocked by their near addition power without any consideration for the front or back radii to be worked. Additionally there is no risk of the segment coming adrift from the main lens. However with thin lenses construction problems may occur as there is the likelihood of cutting into the segment. A small lip may then be formed on surface polishing due to the differing surface hardness of the two materials.

Fabrication of an internally fused bifocal is much the same as for a single vision lens. Greater care has to be taken in centring the lens on its mount, and in calibrating the cutting thickness in order to avoid the segment breaking through on to the front surface. Prism and truncation are usually needed to help stabilize the fit and quite often the optic is displaced upwards. Displacement of the optic requires the initial diameter of the blank to be cut oversize by an amount slightly above the required displacement. Once the back surface of the lens is finished the lens is displaced on its button by the required amount and the diameter re-cut to approximately 0.1–0.2 mm above the finally required total diameter as an allowance for final edging. The front surface is then cut in the normal manner.

Solid bifocals

Solid bifocals may be crescent, downcurve, straight-top, concentric or diffractive. Diffractive lenses are constructed using a laser hologram system on the back surface and are discussed in Chapters 12 and 16.

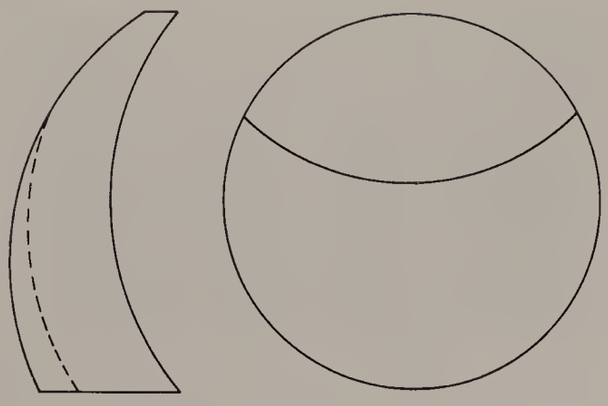


Figure 21.37 Crescent or upcurve solid bifocal lens. The broken lines represent the area where material has been removed to create the near segment on the front surface. Cross-section and front views are shown

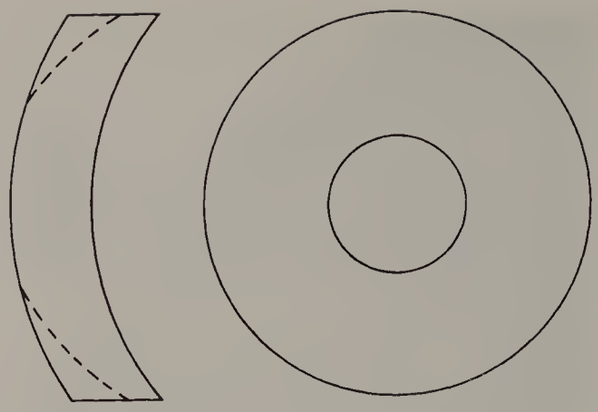


Figure 21.39 Concentric solid bifocal lens. The broken lines represent the area where material has been removed to create the near portion on the front surface. Cross-section and front views are shown

Crescent- or upcurve-shaped

This is constructed by cutting a lens incorporating a large prism (*Figure 21.37*). The base of the prism is then removed by cutting a steeper front surface curve corresponding to the near power of the lens. This produces a crescent-shaped segment. The whole of the front surface is then polished using a small velveteen-covered polishing drum.

Downcurve- or arc-shaped

This is constructed by the reverse approach to the crescent-shaped segment (*Figure 21.38*). Initially the front of the lens is cut with the near radius, to a thicker substance and with a small prism incorporated. The front surface is then re-cut with the flatter distance radius and a higher powered prism set with base–apex in the reverse direction to the original orientation. This produces an arc-shaped or down-curve segment, ballasted with prism. The whole of the front surface is then polished with a small polishing drum.

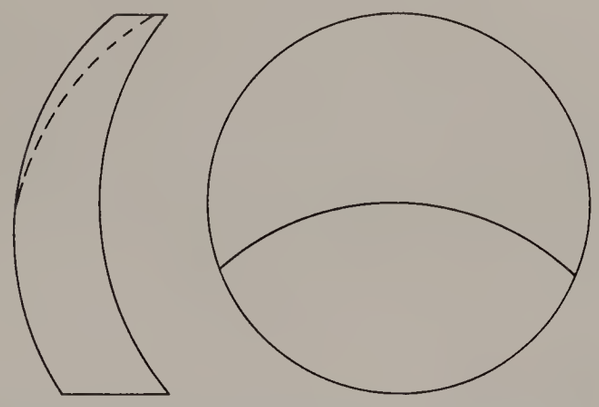


Figure 21.38 Downcurve or arc solid bifocal lens. The broken lines represent the area where material has been removed to create the distance portion on the front surface. Cross-section and front views are shown

Straight-top-shaped

A straight-top bifocal can be made by first cutting the distance curve across the whole of the front surface of the lens using a front surface toric lathe. To achieve this the lathe is set with no offset and at the required distance radius so the curve generated in both meridians is the same. The lower, near curve is then cut by re-setting to the near radius and again without any offset of the spindle so the radius generated is the same in both meridians. The cutting tool is then swept around from a line almost parallel with spindle axis to a predetermined point which is approximately where the perpendicular to the spindle axis, bisecting the lens blank, would meet the cutting tool. The cut is not taken beyond this predetermined line. The degree of sweep either beyond or before the perpendicular to spindle axis will determine the height of the segment above or below lens datum. Because the lens blank is describing a vertical circle at right-angles to the spindle axis (*see above*, Front surface torics) a vertical straight-line transition is produced. The lens is then polished with a drum polisher.

Concentric-shaped

These do not contain prism and are frequently used for simultaneous vision or 'bivision' or occasionally for alternating vision. Therefore any rotation on the eye is unimportant unless they contain a cylindrical element. These can be made as centre near (CN) or centre distance (CD) lenses. With CN the lens is constructed like a plus lenticular lens with a small optic portion. This is a difficult lens to make with a good transition. The CD lens has the flatter centre cut first and then the steeper periphery is cut much as in constructing a negative lenticular lens (*Figure 21.39*). The lens is then polished with a small drum polisher. It practice these lenses are now normally cut on CNC lathes with the radii being generated in one process.

The main difficulty in fabricating a solid bifocal lens is in obtaining a sharp transition between the distance and near

segments. During polishing there is inevitably some blending of the transitions and an area of visual confusion may occur although this blending may provide a zone of progressive power.

Practitioners' orders

Laboratories quite frequently have to refer back to a practitioner about an order which has been received with either insufficient or total lack of instructions. For example, a tint is omitted, there may be no instructions as to whether a lenticulation is required with a positive lens, no position given for a fenestration, no amount, angle or location (top or bottom) of a truncation given. Impossible or unnecessarily complex orders may be received. For example, an order may specify, with a positive lens, a centre thickness which is too thin for a given front optic zone diameter or total diameter.

Laboratories should soak RGP lenses for 24 hours before finally checking the parameters and practitioners should also check the lenses under the same conditions. However, there may still be changes occurring to the lens dimensions many days after hydration. There may also be variations in the BOZR recorded on different radiuscopes and between different personnel on the same instrument; these possible variations have to be kept in mind when ordering and checking lenses. In particular practitioners should be aware that the radical flattening found on hydration of high minus RGP lenses appears to be confined to the very central 2 or 3 mm and that this flattening may not affect the overall fit of the lens (Walker, 1988).

A little more thought by many practitioners when ordering lenses would save the practitioner and laboratory some time and inconvenience. Chapter 5 and the CD-ROM accompanying this book cover the calculations and/or drawing to scale necessary to determine adequate thicknesses to enable lenses to be made.

To help in the choice of lens materials, thickness calculations and lenticulations the practitioner is referred to Chapter 10 and the accompanying CD-ROM.

Conclusion

Good manufacturing practice is the key to consistently good quality lenses. The Food and Drug Administration (FDA) in the USA laid down a minimum of nine key-quality assurance activities (Ratkowski, 1984). They are as follows:

- Button inspection.
- Acceptance/rejection criteria at each manufacturing step.
- Identity and specifications for each processing compound, such as mounting waxes and polishing compounds.
- Cleaning instructions, and specifications for cleaning compounds.
- Final product acceptance criteria and test methods.
- Identity and specifications for packaging and labelling materials.
- Disinfection instructions (or sterilization instructions if labelled as sterile), process validation and product release procedures.
- Records maintenance, including but not limited to maintenance of batch records and complaint files.
- Continuing audit procedures to be employed by the laboratory's personnel.

Production of good quality lenses requires not only accuracy of parameters but also good surface finish. As equipment, in particular lathes, improves so the quality of lens production improves. Countering this improvement however is the change in materials which are continually introducing new challenges to the lens manufacturer along with the increased demand for more complex lens designs.

To achieve high quality surfaces with the minimum of polishing and ultimately no polishing, lathes must have minimum vibration and high mechanical stiffness (Dent, 1986), with variable spindle speeds, sweep speeds and depth of cuts in order to cope with the wide range of materials available. Modern lathes now frequently have roughing tools to remove the bulk of material and profile the lens to within 0.20 mm of its finished surface thickness, thus extending the life of the finishing diamond tool and minimizing heat-induced stress in the material. The rate at which the cutting tool is fed across the surface is extremely important as this decides the rate of removal of material for any given spindle speed. Changes in surface finish have been evident with feed rates as low as 2 degrees per second (Dent, 1986). CNC lathes have made controls in this direction much easier. Additionally, simplification and greater speed in changing the diamond cutting tools has encouraged more frequent replacement of tools and provided greater accuracy in setting up the lathe. The ultimate aim is to be able to lathe to such a high standard that polishing will be completely eliminated. To achieve this goal it may be that new technology in the form of low energy lasers may have to be utilized into the production process.

Addendum

European Manufacturing Regulations

In January 1995, the CE mark was introduced. The CE mark is the mark of regulation of supply of contact lenses as medical devices. There is a transition period, which will last until June 1998, for companies to register. After that date, all companies wishing to manufacture contact lenses will be required to affix a CE mark to them.

ISO 9000 is the international standard of procedures that a company has to follow in order to demonstrate that it uses

an approved Quality System (QS). Companies who wish to produce medical devices must put their name on a register in order to confirm that they use an approved QS. They must demonstrate that the procedures and processes that they use adhere to the Requirements and Regulations set out in the Medical Devices Directorate (MDD).

Competent Authorities (CAs) can issue licences to Notified Bodies who in turn register the companies. In the UK, the Department of Health acts as a CA.

British and US approved names for contact lens materials

British Standard BS 7208: Part 2: 1991, which has adopted the Association of Contact Lens Manufacturers (ACLM) classification (*Tables 21.1 and 21.2*), and the US Food and Drug Administration (FDA) (*Table 21.3, see also Table 3.2*), classify materials as given below, while rigid lens manufacturing tolerances are shown in Addenda 1 and 2 of Chapter 12.

Materials are divided into groups in both the ACLM and the FDA methods of classification. The ACLM classification has two groups:

Focon for rigid lens materials.
Filcon for soft lens materials.

In the ACLM system of classification a number, a letter and a parameter component appears after each group name. The number stands for the type in the group. The letter stands for the sub-type within the group (e.g. Filcon – (a) anionic; (b) ionic). The bracketed numbers stand for Dk in Focon and water content in Filcon.

Table 21.1 UK ACLM material classification: rigid lens materials – *Focon*

Group 1a Pure (99%) PMMA. Dk ≈ 0
Group 1b Copolymers of PMMA plus ≤ 10% of other monomer that may alter hardness, wettability and stability. Dk ≈ 0
Group 2a Pure (90%) CAB. Typically 2 ≤ Dk ≤ 8
Group 2b Copolymers or mixtures of CAB with ≤ 40% other monomers or polymers
Group 3 Copolymers of one or more alkyl methacrylates with one or more siloxanyl methacrylates, plus other water active monomers and cross-linking agents. Typically Dk > 6
Group 4 Hard lens materials formed from polysiloxanes
Group 5 Copolymers of one or more alkyl methacrylates and/or siloxanyl methacrylates, plus other water active monomers, cross-linking agents, and ≥ 5% by weight of fluoroalkyl methacrylate or other fluorine containing monomers. Typically Dk > 20

For example:

Focon 1a is PMMA which has zero Dk.
Focon 2a (4) is CAB which has a Dk of 4.
Filcon 1a (38) is polyHEMA with no significant ionizable chemicals and a water content of 38%.
Filcon 1b (60) is predominantly polyHEMA with an ionizable component (methacrylic acid) which increases the water content to 60%. (*See Tables 21.1* and *21.2*.)

The FDA classification has four groups: Group I is low water content (<50% H_2O) non-ionic polymers; Group II is high water content (>50% H_2O) non-ionic polymers; Group III is low water content ionic polymers; and Group IV is high water content ionic polymers. Within each of these groups are names allocated to the same types of material produced by different manufacturers. This classification is not very helpful when trying to match different lens materials and their possible fitting characteristics and in some instances can be very misleading.

For example:

Group I has within it **Tefilcon** which is a 38% water content polymer with a Dk = 8 and this includes CibaSoft, Softint, Bi-Soft and STD Illusions lenses. Also within this group is **Polymacon**, another 38% water content polymer but with a Dk = 9 and includes Allergan Mini, Newvue Optima and SeeQuence lenses.
Group 2 has within it **Surfilcon** which is a 74% water content polymer with a Dk = 35 under which only Permaflex is listed. Also within this group is

Table 21.2 UK ACLM material classification: soft lens materials – *Filcon*

Group 1a Essentially poly 2-HEMA, but ≤ 0.2% by weight of any ionizable chemical (e.g. methacrylic acid)
Group 1b Essentially poly 2-HEMA, but > 0.2% by weight of any ionizable chemical
Group 2a A copolymer of 2-HEMA and/or other hydroxyalkylmethacrylates, dihydroxyalkylmethacrylates and alkyl methacrylates, but ≤ 0.2% by weight of any ionizable chemicals
Group 2b As in group 2a, but > 0.2% by weight of ionizable chemicals
Group 3a A copolymer of 2-HEMA with an N-vinyl lactam and/or an alkyl acrylamide but ≤ 0.2% by weight of any ionizable chemicals
Group 3b As described in group 3a, but > 0.2% by weight of any ionizable chemicals
Group 4a A copolymer of alkyl methacrylate and N-vinyl lactam and/or an alkyl acrylamide, but ≤ 0.2% by weight of any ionizable chemicals
Group 4b As described in group 4a, but > 0.2% by weight of any ionizable chemicals
Group 5 Soft lens materials formed from polysiloxanes

Table 21.3 US FDA material classification: Soft Lens Materials

Group I *Low water (<50% H_2O)* *Non-ionic polymers*	*Group II* *High water (>50% H_2O)* *Non-ionic polymers*	*Group III* *Low water (<50% H_2O)* *Ionic polymers*	*Group IV* *High water (>50% H_2O)* *Ionic polymers*
Tefilcon (38%) (Dk = 8) ● CibaSoft ● Softint ● Ciba Thin ● Bi-Soft ● ToriSoft ● STD Illusions	**Lidofilcon B** (79%) (Dk = 38) ● CW 79 ● LL 79	**Bufilcon A** (45%) (Dk = 12) ● Hydrocurve II 45 ● Soft Mate	**Bufilcon A** (65%) (Dk = 16) ● Hydrocurve II ● Hydrocurve II 55 Bifocal
Tetrafilcon A (43%) (Dk = 9) ● AO Soft ● Aquaflex Standard ● Vantage ● Vantage Thin Preference	**Surfilcon** (74%) (Dk = 35) ● Permaflex	**Deltafilcon A** (43%) (Dk = 10) ● Amsoft ● Amsoft Thin ● Aquasight ● Aquasight Thin ● Comfort Flex ● Custom Flex ● Metrosoft ● Soft Form Toric	**Perfilcon** (71%) (Dk = 34) ● Permalens ● Permalens XL ● Permalens Therapeutic
Crofilcon (38%) (Dk = 12 ● CSI ● Aztech	**Lidofilcon A** (70%) (Dk = 31) ● B&L 70 ● LL 70 ● CV 70 ● Q&E 70 ● N&N 70		**Etafilcon A** (58%) (Dk = 20) ● Acuvue ● Surevue
Hefilcon A&B (45%) (Dk = 12) ● B&L Toric ● Unilens ● Flexlens ● Simulvue		**Droxifilcon A** (47%) (Dk = 17) ● Accugel	**Ocufilcon B** (53%) (Dk = 16) ● Ocu-Flex ● Continental
Phemfilcon A (30%) (Dk = 4) ● Durasoft ● Durasoft TT		**Phemfilcon A** (38%) (Dk = 8) ● DuraSoft 2 ● DuraSoft 2 Optifit	**Ocufilcon C** (55%) (Dk = 16) ● O.P.R.-55
Isofilcon (36%) (Dk = 5) ● AL-47		**Ocufilcon** (44%) (Dk = 16) ● Tresoft ● Tresoft Thin	**Phemfilcon A** (55%) (Dk = 16) ● DuraSoft 3 ● DuraSoft 3 Toric ● DuraSoft 3 Optifit
Mafilcon (33%) (Dk = 4) ● Menicon			**Methafilcon** (55%) (Dk = 18) ● Hydrasoft ● Kontur ● Metro 55 ● Hydrasoft Toric ● Eclipse ● LL 55 ● SunFlex ● Sunsoft Torin 15.0 ● Sof-form 55 ● Westcon
Polymacon (38%) (Dk = 9) ● CustomEyes 38 ● Sof-form II ● Softics ● Soflens ● Allvue ● EpconSOFT ● Cellusoft ● Nuview ● Allergan Mini ● SoftView ● Allergan Zero ● Metrosoft II ● Allergan Toric ● Edge II ● Allergen Zero T ● Optima ● LL 38 ● Ultra Flex ● Medalist ● SeeQuence			**Vifilcon A** (55%) (Dk = 16) ● Softcon ● Softcon EW ● Spectrum ● Spectrum Toric ● Spectrum Bifocal ● Focus

Lidofilcon A, a 70% water content polymer with a Dk = 31 which lists, amongst others, B&L 70.
Group 3 has within it **Bufilcon A** (45% H_2O Dk = 12), under which is listed Hydrocurve II 45 and Soft Mate, as well as **Ocufilcon** (44% H_2O Dk=16) under which is listed. **Tresoft**.
Group 4 also has a **Bufilcon A** (65% H_2O Dk = 16) under which is listed **Hydrocurve II** and **Hydrocurve II 55 Bifocal**. Also in this group is **Ocufilcon B** (53% H_2O Dk = 16) and **Ocufilcon C** (55% H_2O Dk = 16).

Perhaps the most misleading of all is **Phemfilcon A** which appears in both Group I (Non-ionic) as DuraSoft, a 30% H_2O polymer, and Group III (Ionic) as DuraSoft 2, a 38% H_2O polymer.

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Chapter 22

Modification procedures

A. J. Phillips

The importance of the practitioner being able to carry out modifications p.801
Modification equipment for corneal lenses p.801
Corneal lens modifications p.806
Points to note when modifying RGP lenses p.811
Scleral lens modifications p.812
Modification of soft contact lenses p.815
Conclusion p.816

The importance of the practitioner being able to carry out modifications

Nowadays, when modifications can be carried out relatively quickly and cheaply by laboratories, it is often difficult to impress on students, and even qualified practitioners, the following reasons why contact lens practitioners should be able to carry out their own modifications:

- There is no interruption to the patient's wearing schedule and no necessity for extra visits.
- Often only the practitioner knows exactly what is required and it may be difficult to describe this to the laboratory. (This is particularly so with scleral lenses.)
- Modifications can be done in increasing stages, with the effect on the fit of the lens noted at each stage. Laboratories either have to do the full modifications in one step, or the patient is required to make many unnecessary visits and to be without lenses for several days.
- Subsequent modifications may become apparent and can be done immediately.
- Practitioners who carry out modifications are better able to evaluate lenses which have been made or which have to be modified by a laboratory.

Against these advantages must be set the cost of the equipment involved. However, much of this cost can be redeemed, not only from tax relief but also on the savings of doing the modification oneself. It is important to remember also that patients are more satisfied because they do not have to be without their lenses. Further, most of the equipment, especially the more expensive items, will last a lifetime.

The advent of a whole range of new rigid gas permeable (RGP) materials has complicated practitioner modification of lenses but has not prevented it, except for the surface-treated and moulded groups which should not be modified, and the very highly permeable materials, such as the fluorosilicone acrylates, which warp and burn easily and should only be modified by a skilled technician.

The following section lists the equipment which can be used for contact lens modification. It should be emphasized that many of these are alternatives and are discussed as such.

Modification equipment for corneal lenses

Corneal lens holders

Glass tube and double-sided adhesive tape

This is one of the simplest and cheapest forms of corneal lens holder.

A glass tube of about 6 mm in diameter, with rounded ends, has a small strip of double-sided adhesive tape stretched over one end, on to which the lens is lightly pressed. An inverted glass tube from a dropper bottle is ideal.

This holder has the disadvantages that tape adhesive may stick to the lens when removed for checking and that the tape may need replacing if polishing liquid gets between the lens and the tape.

Modified scleral lens holder

Another simple form of corneal lens holder consists of an ordinary scleral lens suction holder which has been cut down and thinned on a rotating rough grinding stone to an internal diameter of about 7.5 mm and an edge thickness of about 0.5 mm (*Figures 22.1, 22.2*). A corneal lens holder may also be used with a hollow plastic tube in the stem to give support (Haynes, 1965). These holders are best used filled with water.

They have the disadvantage that they cannot be allowed to rotate between the fingers and may therefore occasionally cause oval optic zones – when polishing peripheral curves, for instance – or possibly occasional lens scratches. They can, however, be rotated manually.

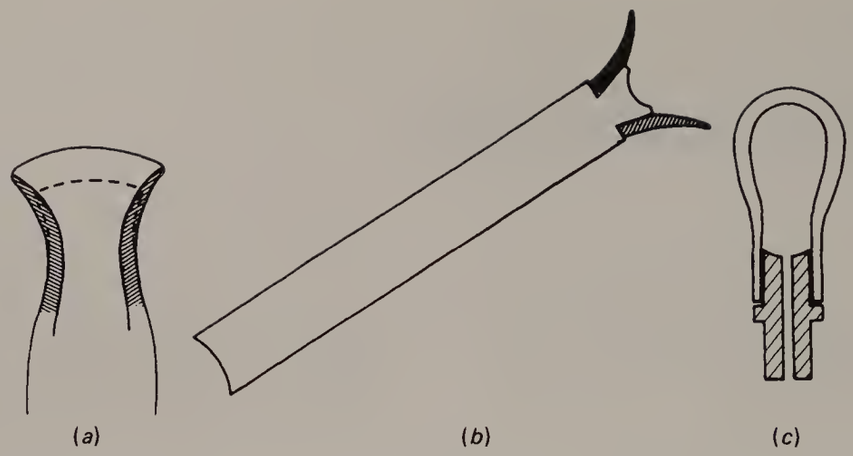


Figure 22.1 Cross-sections of corneal lens holders. (*a*) Scleral lens suction holder with the dotted line indicating the reduced size suitable for holding corneal lenses. (*b*) The end of a corneal lens suction holder mounted on a Perspex or nylon rod. (*c*) A double-ended suction holder. The lower shaded portion is removable and reversible having a flat end and a concave end for holding back and front surfaces of corneal lenses, respectively

Modified corneal suction holder

This design, as used by Shick in America and sometimes known by his name, is shown in *Figures 22.1b* and *22.2c*. The end of a corneal lens suction holder is placed over a short nylon or Perspex rod cut as shown. Again, best used with the open end full of water, this type gives good control and spins easily with one finger resting lightly on the upper end.

Spinner

A more efficient version of the previous holder, the spinner consists of a rotatable spindle with a corneal lens suction holder at the end, mounted in a handle (*Figure 22.2b,e*). The lens can rotate freely on the end of the spindle while the handle is held still.

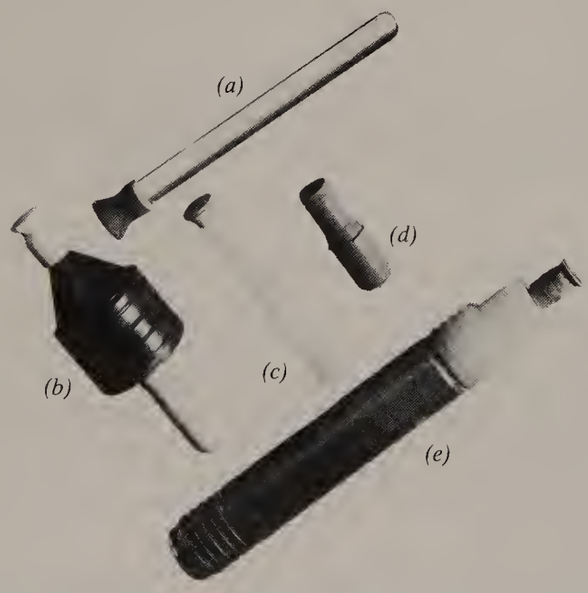


Figure 22.2 Corneal lens holders. (*a*) Corneal lens suction holder cup mounted on a Perspex handle; (*b*) spinner (Madden & Layman Ltd); (*c*) corneal lens suction holder cup mounted on a nylon handle; (*d*) modified scleral lens suction holder; (*e*) spinner

Double-ended suction holder

This type of suction holder has a reversible end, one end for attachment to convex surfaces and the other for concave surfaces. As this is the only type of lens holder, apart from those using adhesive tape, which will attach to the back surface of a corneal lens, it finds particular application in the alteration of lens power and removal of front surface abrasions (*see* p. 809). A cross-section is shown in *Figure 22.1c*. All suction holder ends have the disadvantage that the lens may flex, particularly with thinner lenses, so that the curves will be produced slightly steeper than desired, or slightly distorted. Also care must be taken when removing the lens from the holder.

Double-sided adhesive tape

Double-sided adhesive tape, of about 7 mm in width, is ideal for attaching corneal lenses to non-suction types of holder.

Vertical spindle or Office Modification Unit (*Figure 22.3*)

A speed of between 500 and 1500 rev./min is required – ideally, variable over this range, especially in the slower region. Models with clockwise or anti-clockwise rotation may be obtained, as preferred.

This is the most expensive single item of all modification equipment.

Ideally, the unit should be mounted in a bench or unit with the part shown situated above the level of the bench (*see Figure 22.3*). This enables the operator to rest with the elbows on the table top and thus steady the hands, and to roll the cutting blade and smoothing tools around the edge of the lens when shaping the edge or reducing the total diameter.



Figure 22.3 Vertical spindle or Office Modification Unit by PolyChem Inc. (Coburn Optical Industries Inc.)

Spindle lens chuck or edging chuck

This lens chuck (*see Figure 22.4*), used for edge and total diameter modifications, should be carefully chosen so that its taper fits the practitioner's own vertical spindle (for example, standard or 0-morse tapers). It is preferable to have a chuck, the stem of which is not too short or too thick; approximately 6 mm wide and 2 cm long enables easy holding by the stem.

The same chuck may also be used for holding lenses for peripheral curve modification of the back surface. The lens is stuck on to the chuck with wax or double-sided adhesive tape. As the lens is held rigid on the tool there should be no flexing of the lens during polishing, although if the stem is very narrow the periphery of a large corneal lens may still flex.

Adhesive wax and bunsen burner

Adhesive wax, obtainable in stick form, is one way of attaching the lens to the spindle lens chuck. A bunsen burner is used to melt the wax. Alternatively, a compressed butane burner may be used or even a spirit burner. More sophisticated electric heaters are also available to heat the metal chucks. Low melting point wax should be used for RGP materials.

Centring devices

Centring devices are used where double-sided adhesive tape is used on the spindle lens chuck instead of beeswax, and where the lens must be accurately centred when it is placed on the chuck.

The lens is placed in the well of the device. The centring part is carefully lowered on to the lens and slowly rotated to centre the lens within the well, and is then withdrawn.



Figure 22.4 *Left to right*: (*rear*) large wax tool and spindle lens holder (or edging chuck). (*centre*) small wax tools, cut and uncut, and large and small diamond impregnated brass tools, (*Front*) female gauges. (*See also Figure 17.35a,b*)

These devices do not, in general give such accurate lens centration as that carried out by hand, as described below.

Wax polishing tools

These tools are made up by the practitioner with molten wax poured into moulds and allowed to set hard. They are used for accurate polishing to a specific radius (*Figure 22.4*). Instructions for the manufacture of the tools are given by the laboratory supplying them. Alternatively, the tools may be made up by the laboratory. Further details are given in Chapter 21 on p. 786 and *Figures 21.20* and *21.21* show the blocks and chucks used for making back and front surface wax polishers, together with cut and uncut finished wax tools. Normally, only convex curves are cut on these tools by practitioners doing their own modifications. Front surface wax polishers (concave) are used almost exclusively by laboratories.

Female gauges

Female gauges are necessary to cut the wax tools to the required radius (*Figure 22.4*). Stainless steel gauges are the most accurate and long lasting. Ideally, a razor blade should be used to cut the wax cylinder to approximately the correct radius, and the female gauge should be used only for final 'truing-up' in order to prevent excessive wear on the gauge.

Metal or plastic tools and adhesive tape

Adhesive cloth tape 'sticking plaster' of the 'zinc oxide' type is stretched over a suitable tool, and this cloth surface is used for polishing lens peripheries – an allowance of approximately 0.2 mm (depending on the tape used) being made for the thickness of the tape. This can be used as an alternative to the wax polishing tools mentioned above. The practitioner using brass or plastic tools of this type must check with the manufacturing laboratory whether or not an allowance for an average tape thickness has been made when constructing the tool.

This method has the advantage that it is not normally necessary to put on a separate transitional curve as with the wax tools. For this reason, it is the one favoured by many laboratories for peripheral curves. 'Cloth polishing' has the one serious drawback that the accuracy of curves polished by this method cannot be guaranteed.

Wax tools may be used instead of the metal or plastic tools, the tape being stretched over the suitably cut wax curve.

Tools may also be covered in muslin, stretched taut and held in place with a rubber band.

Polishing liquids

The polishing liquid used most frequently for PMMA lenses is the metal polish Silvo. The container should be allowed to stand for 2 or 3 days, after which most of the excess clear fluid is poured off. This is in order to give a more suitable, slightly thicker polishing fluid.

For most rigid gas permeable lens materials the ammonia in Silvo acts as a solvent and this polish should not therefore be used.

As a general rule, solvents or polishing compounds containing alcohol, esters, chlorinated hydrocarbons, ammonia etc., should not be used. Suitable polishes* are X-Pal, Linde A, SPI, Hyprez, Boston, $Silo_2$ Care polish etc., but ideally individual material manufacturers should first be consulted.

For soft lenses a good standard polish which will give an excellent surface finish is CCPI* polishing compound mixed with silicone oil.

Paraffin oil

Ordinary paraffin oil (kerosene) is used to remove any wax that remains attached to a lens after removal from a chuck. It may also be used as a lubricant with diamond impregnated tools when putting on the major part of a corneal lens peripheral curve prior to final polishing, or grinding out the back optic surface of a scleral lens. Being slightly more viscous than water, it prevents such deep scratches (though grinding is slightly slower), enabling the final polishing to be done more quickly.

*X-Pal polish (Davison Chemicals, Tennessee, USA, available in the UK from Cerium Chemical Co., Tonbridge, Kent); Linde A polish (Union Carbide); SPI polish (Sauflon); CCPI polish (City Crown); Hyprez polish (Engis Ltd); Boston polish (Bausch & Lomb); $Silo_2$ Care polish (Chase Precision International Ltd).

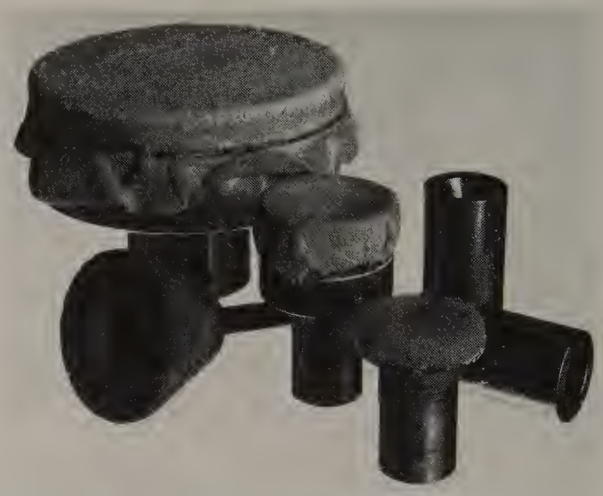


Figure 22.5 *Left to right: (rear)* large polishing drum. *(centre)* carborundum tool for reduction of total diameter, small polishing drum, and conlish tools; *(front)* flat plate sponge chuck

Paraffin oil, water, and polishing liquids are best used in 250 ml wash bottles with jet dispensers or 'sprays'. They may possibly be more economically applied with a large artist's paint brush from a bowl, especially where they are being used frequently and evaporation causes no problems – though, where applicable, the potential fire hazard must be considered.

Razor and scalpel blades

Single-edge ('safety') razor blades and scalpel blades, straight and curved, are useful for certain modifications (*see* p. 807). Alternatively, a thicker square-edged cutter may be used.

Carborundum tool for total diameter reduction

This consists of an internally tapering cone, which is held in a Jacob's chuck (*Figure 22.5*). It is used for reduction in lens size. It has the disadvantage that, if the lens is not placed centrally in the hollow, material will be removed unequally (Haynes, 1959). Also, with lenses incorporating prism, there is a tendency for more material to be removed from the thinner lens edge than the thicker edge.

Before use, the tool should be soaked well in water.

Assorted carborundum or diamond impregnated burrs

These (*Figure 22.6*) are used for final edge shaping. Very fine emery paper may also be used.

Polishing cloth

This very soft cloth (for example, 'Selvyt' cloth) is used for adding small amounts of power to lenses. Suitable cloth may be obtained from any contact lens laboratory at little cost, or ordinary velveteen material may be purchased.



Figure 22.6 Assorted grinding tools and polishing buffs. *Top centre*: large and small pin-vice holders for drills. *Lower centre*: corneal lens buttons with one surface cut for use as scleral lens runners. Left button shows guide hole on rear surface and right button has double-sided adhesive tape on concave surface

Flat plate and sponge or drum chucks

These chucks (*see Figure 22.5*) are used on a vertical spindle for adding positive and negative power to lenses, removing surface scratches, and for edge polishing. The drum chuck consists of a hollow chuck over which a piece of chamois leather or similar material has been stretched and held in place with a rubber band or wire. The flat plate chuck consists of a chuck with an upper flat portion to which is attached a thin piece of sponge rubber or moleskin.

Chamois leather

A large piece of chamois leather 15 × 15 cm often forms a useful backing to the polishing cloth mentioned above, and is sometimes used as an alternative.

A smaller piece of thinner chamois leather may be used for edge polishing while the lens is still mounted on the spindle lens chuck as shown in *Figure 21.22*. Alternatively, a small piece of sponge rubber may be used.

Conlish tools (from con*ical* and po*lish*)

These are a series of hollow cone tools of varying angles (*see Figure 22.5*) which are used on a vertical spindle.

Lined with adhesive cloth tape, they are used for shaping lens edges. The lens is mounted, for instance, on a glass tube and the edge is polished for a specific number of seconds on each tool. Generally, a slower speed vertical spindle appears preferable (100–500 rev./min). Although used successfully by certain laboratories, often as diamond impregnated tools, they are not very popular with practitioners in general practice. Further details can be found in most American textbooks on this subject and in the original paper on this method by Cepero (1959).

Drills

Drills of diameters from 0.10 to 0.30 mm mounted in hand drill (or pin-vice) holders are used to fenestrate corneal lenses. *Figure 22.6* shows pin-vice holders.

A dental counter-sink rose, as fine as possible (size 0 or 1), is necessary for counter-sinking fenestrations. Several finely sharpened boxwood sticks are also needed for hand polishing the countersink, or may be used for complete countersinking if the lens is mounted on a suitable chuck on a vertical spindle.

For scleral lenses the following additional tools are required.

Scleral lens runners

Scleral lens runners are attached to the front optic surface of lenses by means of broad (12 mm) double-sided sticky tape on the concave runner surface. They are used with a pencil

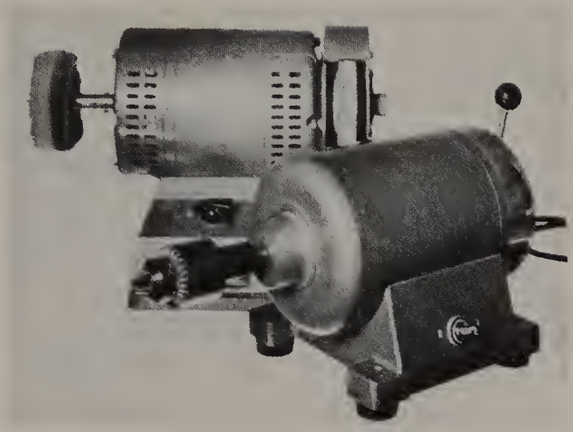


Figure 22.7 Grinding stone and buff (*rear*), and variable speed horizontal spindle with Jacob's chuck fitting (*front*). A flexible drive may be attached to the right-hand end of the grinding stone and buff motor

or ball-point pen tip in the guide hole on the upper flat surface (*see Figure 22.6*) to control the lens on wax or diamond tools.

Runners can be obtained from laboratories; or a corneal lens blank may be used, with the concave surface cut but not polished and a small central guide hole drilled a short way into the flat surface.

Rough grinding stone and buff

These (*Figure 22.7*) are used respectively for reducing lens total diameters and edge polishing. The grinding stone is not an essential since a file and emery paper serve the same function, though more slowly, or a 25 mm carborundum ball may be used (*see Figure 22.6, top left*).

Horizontal spindle with Jacob's chuck fitting or flexible drive (*Figure 22.7*)

This is necessary for holding many of the tools used for back scleral zone surface modifications and in fenestrating. A Jacob's chuck attachment may also be obtained for the vertical spindle. Alternatively, some practitioners prefer to use a small motor with flexible drive attachment, which should have a foot operated speed control to allow both hands freedom for lens and tool manipulation.

Grinding balls and polishing buffs

A selection of grinding balls and polishing buffs of various sizes and shapes are necessary (*see Figure 22.6*).

Tripoli or Buffite polishing compound

One or more polishing compounds are preferred by many practitioners for use with polishing buffs. The initial polishing after grinding is carried out more quickly with these compounds, but with some danger of burning the plastic. Final polishing is best carried out with Silvo or similar compounds suitable for RGP lenses as discussed above.

Diamond impregnated brass tools

Used with or without a runner, back optic zone and spherical transition grind-outs are performed by means of these tools (*see Figure 22.4*). Tools of radii commonly used by the practitioner for transitional curves are usefully obtained. A basic set includes the radii 7.80, 8.00, 8.20, 8.40, 8.60, 8.90, 10.00 and 11.00 mm but a more comprehensive range would include tools of radii from 5.00 mm to 15.00 mm.

Large wax tools

These (*see Figure 22.4*) are used for polishing spherical transitions.

Drills and dental burrs

Drills of 0.50 mm, 0.75 mm and 1.00 mm in diameter may be required for making fenestration holes in scleral lenses. Slightly larger round or flame-shaped dental burrs may be used for countersinking, or even a larger drill may be used.

Corneal lens modifications

Reducing the total diameter of a lens

Reduction of the total diameter of a lens may be carried out for any of the following reasons:

- To relieve corneal oedema by exposing more of the cornea to a normal atmosphere particularly with PMMA or low Dk materials, or in physiologically compromised corneas.
- To reduce any excessive edge clearance which may be causing discomfort, or causing visual interference due to bubbles getting under the edge during blinking. These bubbles frequently get under the lower edge of a high riding lens and can readily be seen with the slit lamp. They cause reflections and may result in dimpling of the corneal epithelium (*see Figures 18.7* and *20.1.12*). Excessive edge clearance (*see Figures 10.19, 10.20*) can also cause the lens to become misplaced easily or even ejected from the eye. It may also be partially responsible for drying of the 3 and 9 o'clock areas of the cornea which then stain with fluorescein when this is applied (*see Figure 18.29*)
- To reduce edge thickness of a high negative lens, which can cause discomfort, and if the upper lid is tight and grips the lens after a blink, the lens may ride too high. Alternatively, a thick edge may cause a loose lid to knock the lens down after each blink. Thick edges also encourage 3 and 9 o'clock staining as does excess edge

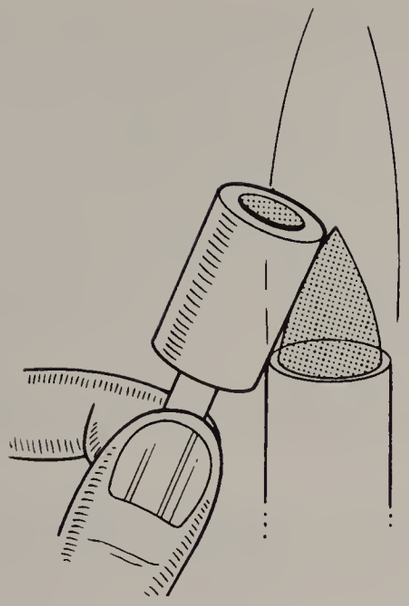


Figure 22.8 Heating the spindle lens chuck. The chuck is held by the stem and the base placed in the lower part of the bunsen burner flame

clearance by holding the eyelids away from these areas of the eye during blinking, thereby preventing proper wetting.

- To reduce the weight of a lens, thereby encouraging it not to ride so low on the cornea.
- To eliminate a small edge chip.

The lens total diameter is first checked on a magnifying gauge or V-gauge (*see Figures 12.9* and *12.10*), and the amount to be removed is noted. A spindle lens holder is now heated at its upper end with a bunsen burner for a few seconds, old wax polishing compound being removed with a tissue.

Directing the bunsen flame on to the top of the chuck, the end of the adhesive wax stick is touched on the upper end of

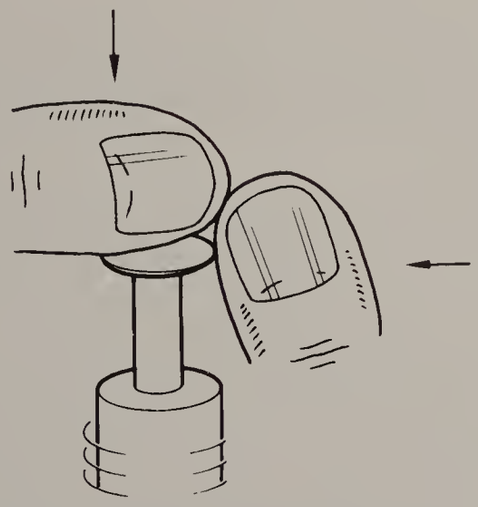


Figure 22.9 Centring the lens. While the adhesive wax is still soft, the lens is centred on the edging chuck by gently touching the top edge with one thumb and the side edge with the other

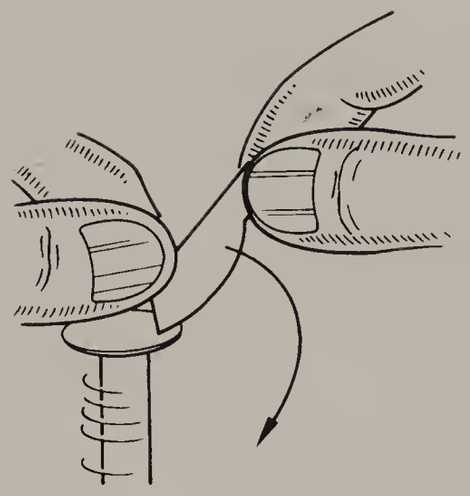


Figure 22.10 Shaping the edge. The blade or cutter is arching around the lens working from the back surface to just over the mid-edge, and then again from the front surface to slightly over the mid-edge position

the chuck stem so that one small drop of the wax is left in the concavity. Too much wax here causes it to spread over the underside of the lens when placed on the stem, often making the edge difficult to modify as well as making it difficult to check and clean.

While the wax is still soft (reheat for a second, if necessary), the lens with convex side down is placed on the chuck as near centrally as possible. Setting the spindle in motion will show that the lens is not yet exactly centred about the spindle axis of rotation. Cutting it now would give a non-circular lens. The next step, therefore, is to centre the lens.

For this, the wax on the chuck, if not still soft, must be softened without burning the lens. The safest way of doing this is shown in *Figure 22.8*. Holding the inverted chuck by the stem, the base of the chuck is held in the lower part of the bunsen burner flame until the stem begins to get too hot to hold. It is now placed firmly on the spindle, and the spindle is set in motion. One finger of each hand is immediately but very carefully touched on the lens – one on the side, and the other on the opposite top edge (*Figure 22.9*). This is done until an object (such as a strip light) mirrored by the concave surface of the lens appears perfectly stationary as the lens rotates. Two smooth round wooden rods may be used as an alternative to the fingers. The lens is now perfectly centred. (Centration will be difficult in those lenses incorporating a prism.)

Carefully holding the chuck as near vertically as possible, the base is held under running cold water to cool it. Care should be taken not to allow water to enter the spindle recess in the base and not to knock the lens off the chuck.

The lens is then replaced on the spindle, which is set in motion. A single-edge razor blade or hard, carborundum impregnated rubber tool is carefully brought into contact with the lens edge in line with the centre, with its cutting edge vertical and very slightly trailing to the direction of rotation of the lens edge. The total diameter is now reduced (*see Figure 22.10*).

Every few seconds, the total diameter of the lens is checked, and cutting is ceased about 0.20–0.30 mm above the final required total diameter to allow for the edging.

The lens is now edged as described below.

Edging and re-edging

When the total diameter is reduced a lens must be re-edged. Re-edging can also be useful if a small chip has accidentally been removed from a lens, in which case re-rounding that portion of the edge, although making the lens slightly 'truncated', may save having to order a new lens. This is an easy remedy for such slightly damaged lenses with thin edges that are easily damaged, for example, positive lenses (unless made lenticular) and the upper edge of prism ballasted lenses. In all these cases, re-edging may become necessary to restore a comfortable fit. Occasionally, a replacement lens has a different edge shape from the original and from the lens in the other eye, and it needs reshaping to make it comfortable to wear. Edges which indent the cornea or conjunctiva and cause epithelial damage should always be well rounded.

Unfortunately, many laboratories – even those using automated edging techniques – do not always produce ideal edge shapes. Edging and re-edging therefore becomes the most desirable modification to be able to carry out oneself.

The lens is mounted on a spindle lens chuck, as described above. The edge of the lens is then examined by the plasticine and binocular microscope (or slit lamp) method described in Chapter 12, and the points to be altered are noted.

A thick square-edged cutter or large curved scalpel blade with the tip removed (*Figure 22.10*) is used for cutting and shaping, though some practitioners prefer a single straight-edged razor blade. This is preferably held gently against the rotating lens by the first finger and thumb of both hands, as shown. A little practice and regular checking of the edge profile soon shows how much to remove from the lens, but the following points may be of assistance.

First, cutting should start either on the back or front surface of the lens, working round the outside of the edge and slightly over to the opposite surface.

Secondly, when cutting on the front surface, care should be taken not to cut more than 0.5–1.0 mm in from the lens edge as scratches caused by the blade can be difficult to remove. Similarly, when cutting on the back surface edge, care should be taken not to scratch any peripheral curve.

Thirdly, if the lens has yet to have a peripheral curve put on, the edge must be shaped as in *Figure 22.11a*, with a very rounded rear edge to allow for the material which will be removed when polishing the peripheral curve (*Figure 22.11b*).

Farnum (1959) stressed the importance of matching left and right lens edge thicknesses for optimum patient comfort.

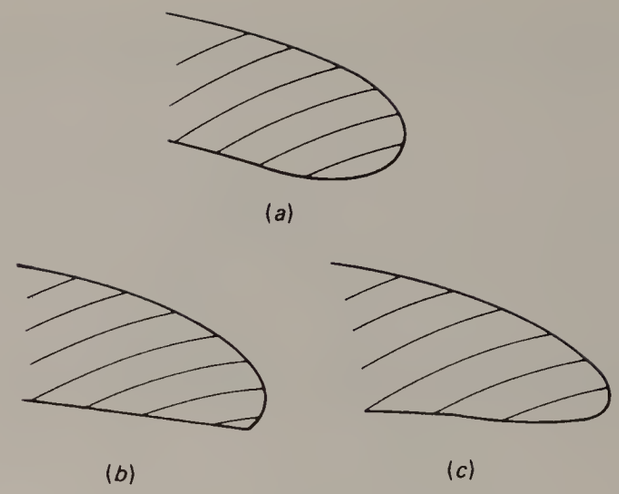


Figure 22.11 Corneal lens edge profiles. (*a*) Profile of initial mono-curve lens prior to the addition of peripheral curves. (*b*) The same lens after the addition of a small peripheral curve (no edge treatment). (*c*) The final edge profile (compare *Figure 21.17*)

These points having been carried out and the edge shaped to the practitioner's satisfaction, any sharp points, for example, those at the junction between the peripheral curve and edge curve, and scratches must be removed. This is carried out by means of a hard rubber burr, preferably cylindrical or conical in shape and impregnated with carborundum or diamond. The burr is carefully rolled around the edge a few times in the same manner as the cutting blade (*see Figure 21.16*).

Inspection should show the lens edge now ready for polishing and with a profile as in *Figure 22.11c*.

This is most easily done by means of a piece of thin chamois leather and polish, the leather either being wrapped around a finger or folded double and the folded edge used. Polishing should be done for several minutes until a high polish is obtained (*see* p. 788 in Chapter 21 and *see Figure 21.22*).

To remove the lens from the chuck, it is given a light flick with the finger on the front surface and it comes away easily. Any adhesive wax remaining on the front lens surface can be removed by wetting the surface with paraffin and rubbing gently with the finger, when the wax will slowly dissolve.

Some practitioners produce edge contours by means of a rag wheel buff particularly for polishing truncated edges. While this is not so easily variable for each lens, it does have the advantage of speed and can be usefully employed when razor-cutting the edge. For preference, a sewn rag wheel buff should be used, because this has plenty of body, and it should be only lightly applied with buffing compound. Ideally, the lens should be mounted on a spinner-type holder for regular polishing, as recommended by Haynes (1959), and held lightly against the edge of the rotating buff, hardly penetrating the fibres and, if not mounted on a spinner, slowly and evenly rotated, arching the holder and lens round the full edge curve. A final minute

or so is spent polishing, using a piece of chamois leather and the appropriate polishing compound. This gives a highly polished, well-shaped edge curve.

The edge may also be polished (or the total diameter reduced) on a drum tool or flat sponge pad. The lens, mounted by its front surface, is first pressed lightly into the drum surface perpendicular to the direction of rotation. It is then arched around the edge profile, parallel to the direction of drum travel, the lens being rotated all the while. This is then repeated with the lens mounted on its back surface.

Reduction of the BOZD, alteration of peripheral radii, addition of new curves and transition blending

All these modifications are normally carried out to improve tear flow under the lens, as a remedy for corneal oedema. Transition blending may be necessary to remove sharp transitions causing arcuate epithelial damage seen with fluorescein staining. Flattening of peripheral curves can remedy the epithelial damage caused by too steep a peripheral curve which digs into the cornea as the lens moves. All sharp transitions can cause breaking up of any bubbles which may get beneath a lens, thereby causing dimpling.

A wax tool, free from cracks and air bubbles, is first cut to the required radius by means of a razor blade and a female gauge of the correct radius (*see Figure 17.36*). This is held vertically and stationary on the centre of the wax tool rotating on a spindle. If stainless steel tools are used, it is best to incline them very slightly towards the operator initially and gradually approach the true vertical as the wax tool is cut to the correct radius. This avoids the gauge 'skidding' and damaging the wax tool.

Two or three small circular grooves are then cut in the surface of the wax with a pin point while the tool is rotating (*see Figure 22.4*). These grooves aid in retaining the polish on the tool surface and in preventing the lens adhering to the tool by suction. They also prevent surface waves forming, due to build-up of polish on the tool, during polishing. One small indentation cut in the very centre of the tool aids positioning of the female gauge during final cutting. The female gauge is then retouched on the wax tool to smooth off the surface of the grooves. Alternatively, tape or cloth-covered tools may be used.

The lens is then placed on one of the corneal holders or an edging chuck as described earlier. A few drops of polishing liquid are applied to the rotating wax tool and the lens is slowly oscillated either backwards and forwards from near the edge to near the centre of the tool or across one side of the tool, being slowly rotated at the same time. Too fast a movement results in the periphery being scratched. Polishing liquid should be applied to the tool every 5–10 seconds to prevent the surface drying and scratching the lens.

Depending on the adjustment being done, the lens should be taken off its holder every so often to see the effect of the polishing. Blending transitions and alteration of a peripheral curve by a small amount may only take 2 or 3 seconds; adding a small peripheral curve or reducing the back optic zone diameter takes a little longer; and putting on a complete peripheral curve may take several minutes.

Measurement of the back optic zone diameter is best carried out by means of a scale and magnifier. With a very narrow peripheral curve, however, the width may be impossible to measure. Such curves are best judged by means of a slit lamp or other high-powered magnifier, or by optical projection. The degree of blending may also be judged by inspecting the reflection of a strip light from the back of the lens surface using a ×8 loupe (*see* Chapters 12 and 17 and *Figures 18.50, 18.51*).

Approximate measurement of curves is facilitated by coating the lens back surface with a waterproof 'instant drying' ink. This is removed in the areas where the lens is being polished and makes the curve easily seen, though it is not necessarily sufficiently accurate for measurements to be made from it. When blending transitions, this becomes extremely useful. It may also be used as a gross test for checking the accuracy of a peripheral curve. The periphery is marked with ink and the lens is touched briefly on a wax tool of the correct radius. If the peripheral radius is accurate, ink will be removed over the whole width of the curve.

Alteration of power (and polishing)

Addition of negative power

Addition of negative power becomes necessary as the refractive error changes, particularly in children, keratoconic patients and those with senile nuclear sclerosis of the crystalline lens, although alterations of more than 1.00 D are not easily possible. Any other marked change in refraction should lead to further investigation in case of lens warpage, gross changes in the corneal curvature occasioned by the fit of the lens, gross changes in the crystalline lens due to pathological conditions, or changes in the retina also due to pathological conditions. It should be noted that lens warpage often occurs when patients accidentally squeeze their lenses in the screw cap of the soaking case. The power on a focimeter may then appear satisfactory, but this distortion of the surfaces can be seen with a radiuscope or keratometer. Usually, an irregular, hazy line where the lens has been bent is visible if it is held up to the light.

Negative power modifications are much easier than increasing positive power. For this reason, most practitioners tend to err on the positive side when ordering lenses.

The simplest method of carrying out this modification is by means of a 15 cm square of soft, clean, moistened polishing cloth spread over a similar-sized piece of chamois leather or moleskin laid on a smooth flat surface. A small amount of polishing fluid is spread in a circle on the cloth, using a finger. The dry back surface of the lens is then positioned, preferably, on a suitable lens holder, or on the tip of either the first or second finger. This is then placed on the polishing cloth in the circle of polish. Circular movements

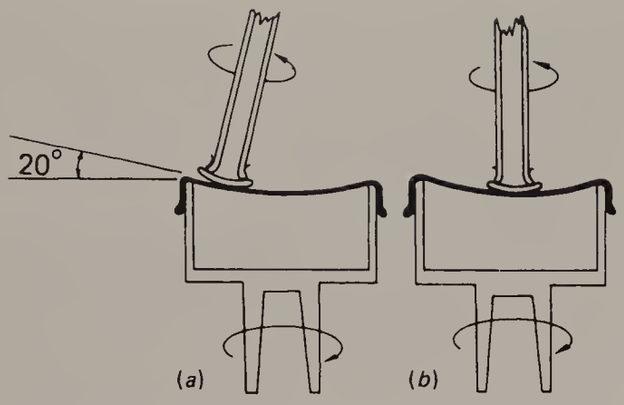


Figure 22.12 The use of a drum chuck for power alterations (cross-sections). (*a*) Addition of negative power. The lens is held near the drum edge at approximately 20° to the horizontal. The lens is slowly rotated in either the same or the opposite direction to drum movement. (*b*) Addition of positive power. The lens is held vertically close to the drum centre and again slowly rotated

of about 5–8 cm in diameter are then described by the hand, exerting only a light pressure on the lens and taking great care not to tilt the lens holder or finger. After every six complete circular movements, the direction of rotation should be reversed to counteract the effect of any slight tilting, which will either cause distortion or give cylindrical power. Depending on the pressure on the lens, approximately 12 rotations are needed for every –0.25 D increase, and when nearing the end of a power alteration, the pressure on the lens must be gradually lessened to almost zero. Even when adding more than –0.25 D, the power must be checked frequently, not only to check on the progress of the power alteration but also because this will ensure that the lens is rotated to a different position on the finger, again to counter any distortion effects.

A more accurate method of adding negative power is by the use of a 10 cm drum chuck as described by Isen (1959). The lens is mounted on a holder by its back surface and placed near the edge of the rotating chuck, normally being tilted to about 20° to the horizontal (*Figure 22.12a*). The drum 'skin' should be kept continually moist with polishing fluid with the one hand while the lens is kept slowly rotating. Pressure on the lens should be just sufficient to contour the drum material to the lens shape. Excessive pressure will cause vibration of the lens and holder. For RGP materials, which polish faster than PMMA, the lens should be held nearer the drum centre where the rotational speed is less (*see also Figure 21.26*). Morgan *et al.* (1992) recommended a spindle speed of less than 1000 rev/min in order to prevent surface degradation of the lens.

Addition of positive power

A drum chuck is also used for this modification, except that the lens is placed at or near the centre of the drum. Since the drum's speed of rotation is zero at its centre, more lens material is removed from the lens edge and, consequently, positive power is added. Provided the chamois surface is kept moist with a suitable polish, the addition of positive power is straightforward; and as long as the lens is gently rotated, no cylindrical effect should be introduced.

With conditions as for the addition of negative power, the lens is slowly moved in a small circle of about 3 or 4 mm or less around the drum centre, in either the same or opposite direction to that of drum rotation (*Figure 22.12b*). This avoids the small 'pip' sometimes obtained in the centre of the lens if it is held stationary at the drum centre, where there is no polishing action.

In adding positive power, occasionally a 'haze' may appear round the target image of the focimeter when checking the lens power. If this occurs, the diameter of the circle that the lens is being moved in should be increased to about 8 or 9 mm. This gives a more even polishing over the whole front surface and should add neither positive nor negative power. If this does not remove the 'haze', an alternative method is to add about +0.12 D too much positive power and then remove this by adding –0.12 D.

Either of these two latter methods may also be used for removing superficial front surface scratches.

Fenestration

Although rarely necessary with modern RGP materials, if corneal oedema should occur, central fenestration holes – up to five in number – may help to encourage tear flow, but only if the lens is fitted apically well clear of the cornea; otherwise each hole can provide an additional meniscus of tears between lens and cornea – discouraging tear flow but aiding lens centration and reducing movement.

A typical diameter is 0.20–0.30 mm (0.01 inch).

The lens is placed on the tip of the forefinger and, after marking the position of the holes with a waterproof fibre pen, it is drilled from the front by hand, using a pin-vice to hold the drill. This is easier from the front surface and keeps the drill at the correct angle, perpendicular to the convex surface. The pin-vice should be rotated slowly and without pressure as excessive pressure may break the fine drill or crack the lens. To minimize the risk of the drill slipping and scratching the front surface of the lens, it should protrude as little as possible from the pin-vice. Also, the hole can be drilled through sticky tape struck to the front surface of the lens.

The edges of the hole must now be counter-sunk on both sides. This is achieved by gently rotating a dental burr, size 0 or 1, anti-clockwise in the fenestration. Only a touch is needed, and it is quite easy to see the counter-sunk effect when using a suitable binocular magnifier.

Finally, the hole is carefully polished by hand using a finely sharpened boxwood stick and a trace of suitable polishing fluid with as rapid a rotation as possible. Several changes of sticks may be needed in order to maintain a sharpened point. For larger fenestrations, a fine-pointed felt buff in a spindle may be used for a few seconds. Final careful inspection is a necessity.

Alternatively (*see* Chapter 21), the lens may be mounted, using double-sided adhesive tape, on to first a convex

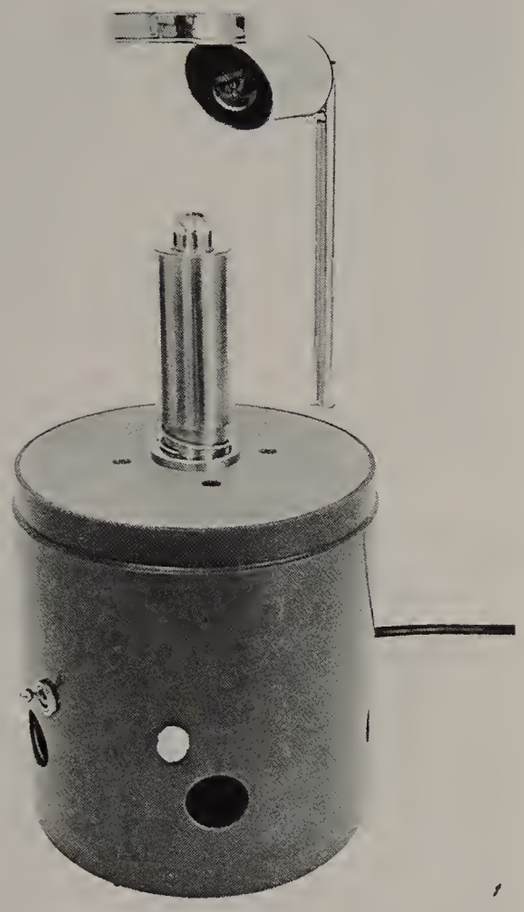


Figure 22.13 Fenestrating machine developed for the practitioner and suitable for both corneal and scleral lenses. (Photograph by courtesy of Focus Contact Lens Laboratory Ltd)

chuck, and then a concave chuck so that the fenestration hole is positioned over a small central depression in each chuck. As the chuck rotates on the vertical spindle, a drop of polish is applied in the hole, and a boxwood stick – sharpened to a suitably angled point – is gently held in the fenestration hole. The boxwood stick is slowly rotated in a small circle in the opposite direction to the spindle rotation. This both countersinks and gives a fine polish (Mackie, 1968). If necessary, the inner part of the fenestration may be polished by running the hole up and down a length of polish-covered cotton sewing thread.

A fenestrating machine formerly available to the practitioner is shown in *Figure 22.13*. It is still used by many laboratories.

Truncation

Truncation may bc necessary if an existing truncation does not line up correctly with the eyelid margin, or if the edge of a lens is slightly damaged in one place. Sometimes a round, prism ballast lens must be truncated to assist it to locate correctly if a front surface cylinder is present, or an already truncated bifocal lens must be truncated more to lower the segment height when the latter interferes with distance vision (*see* Chapter 16).

The most important factor to bear in mind before truncating a lens is the final edge thickness of the truncation (Haynes, 1959, 1965). For instance, it is useless to truncate a high-powered negative lens with minimal centre thickness as the edge thickness of the truncated portion may be too thin for easy modification and can be damaged.

The desired portion is first marked with a suitable marking agent, such as one of the 'instant drying' inks. Lens stock is then removed with either a pin-file, a hand manipulated abrasive stone or a rotating fine abrasive wheel, the lens being held between the fingers. The edge is then contoured, using a pin-file or fine emery paper. Polishing should be carried out using a rag-wheel buff, a drum chuck or a foam rubber pad. The part of the lens not being modified may be protected by adhesive tape. The lens may also be truncated by the edge being held firmly against the material of a rotating drum chuck and the edge shape rounded as previously described. It should also be stressed that in some instances the truncated edge may need to be kept relatively square in cross-section to prevent the lens moving under the lid margin. *Figures 21.34* and *21.35* also show lens truncation and polishing.

Truncating a lens can also be a way of rescuing a lens which might otherwise be scrapped because of a small edge defect. By grinding away the defective area and then repolishing the edge, the lens may be rendered wearable again. The fact that it is no longer round does not matter if it is comfortable. If successful the patient also gains a quick way of distinguishing right and left lenses!

Points to note when modifying RGP lenses

With many different RGP materials currently available it is important to remember the following points:

- Surface treated lenses should not be modified. Moulded lenses should also not be modified unless a spare lens has been worked on first in order to assess the effect.
- The higher Dk materials, e.g. fluorosilicone acrylates, warp and burn easily and are best done by a skilled laboratory technician.
- Ammonia-based polishes, such as Silvo, should not be used, and alcohols, esters, ketones and aromatic hydrocarbons will damage most materials. Suitable polishes have been discussed earlier.
- Over-heating RGP lenses induces material stress which causes subsequent lens flattening (Schwartz, 1986). All cutting and polishing should therefore be done as slowly and gently as possible and at a relatively slow lathe or spindle speed.

- RGP lenses should not be allowed to dry out during polishing. Surface 'burning' caused by drying out may show as poor wetting areas when the lens is dispensed and may also add to stress-induced flattening.
- Preheated blocks or high melting point waxes should be avoided. Suction holder attachments should be used where possible.
- Newman (S., 1987, personal communication) recommends the use of more than one type of polishing medium for modification to the optic zone in order to obtain a good surface finish, e.g. CCPI polishing compound in water followed by Boston finishing solution. Another method of maintaining good polishing medium viscosity is to add some dishwashing liquid to the medium. A mixture of dishwashing liquid and water also makes an excellent finishing solution.
- In order to prevent burning or 'orange peeling' of the lens surface, abrasive cloth type coverings of tools such as velveteen or pellan pads should be treated with respect. Velvet, cotton, chamois leather and vinyl are all preferable.
- Grind and polish lenses with the absolute minimum of pressure.
- Never wipe polish off a lens with a dry tissue. Keep a bowl of water and detergent mix next to the work station for washing the lens. Rubbing the lens between fingers while submerged in this solution will clean the lens adequately. The lens can then be gently blotted dry for inspection.
- Always store polishing cloths and polishing powders in clean, air-tight containers. This prevents dust and other contamination which may in turn cause lens scratching.

Scleral lens modifications

Indications for carrying out modifications to scleral lenses made from eye impressions are given in Chapter 17. A general reduction in total diameter is indicated when a lens remains stationary as the eye moves behind it, i.e. the lens appears a 'steep fit'. Localized reductions of diameter may be made if, for example, the lower scleral zone is too big for the lower fornix, or if the nasal scleral zone is pushed onto the nasal corneal limbus when the eye looks inwards. Sometimes the temporal scleral zone catches at the outer canthus but this is more often because that portion of the scleral zone is too small rather than too large.

A lens may be made horizontally oval if a horizontal oval fluorescein pool shows against-the-rule astigmatism with edge stand off at nasal and temporal edges and edge blanching at upper and lower edges. Making the vertical meridian smaller effectively flattens it in that meridian, allowing it to settle, but mid-temporal and mid-nasal back, scleral zone grinding out may also be necessary. A vertical oval lens for with-the-rule astigmatism is not normally satisfactory cosmetically unless the palpebral aperture is particularly small.

Reducing an equal amount from all round the lens edge, in the case of a regular preformed lens, is carried out by simply rubbing the lens against a piece of medium-grade sandpaper placed on a flat surface. Care must be taken to maintain an even pressure around the whole lens edge.

Localized or overall reductions in lens total diameter may be carried out by means of either a rotating grinding stone or an ordinary hand file.

The definition of back scleral size assumes sharp edges to the back lens surface. Thus, when reducing a lens to a specific back scleral size, provided that only minimal material is removed during the final edge shaping, little, if any, allowance need be made for plastic removed during this latter process.

As scleral lenses may be made from either PMMA or RGP materials, care should be taken in selecting the appropriate polish as mentioned earlier.

Edging

Edging is necessary when total diameter reductions have been carried out, if the edge has been damaged, or if scleral zone modifications have altered the edge shape.

A stone grinding ball of 1 inch (2.54 cm) in diameter, previously soaked in water and held in a horizontal spindle, may be used for the rounding of both front and back edge surfaces. Alternatively, an ordinary small hand file, followed by fine emery paper, may be used for the front surface. A large rounded rubber tool impregnated with diamond or carborundum may be used for the back surface.

Polishing is easily carried out, using a rag-wheel buff. The lens edge should be held vertically and approximately in line with the rotating buff to polish the back edge surface. The lens should be held lightly and continually rotated during polishing to prevent burning of the plastics. This also prevents a ridge of plastics building up on the back edge. Great care should be taken to check that this does not happen, and final examination must ascertain that there is no such ridge. The final edge should be of a blunt, rounded form.

Alternatively, the lens may be edged and polished by tools held in a flexible drive, as explained on p. 584, Chapter 17 and shown in *Figures 17.38d-l*).

Back optic zone grind-out

This is done to increase the clearance of the back optic zone from the cornea. A steeper radius may be required if heavy central touch exists with a large annular bubble at the limbus. A flatter back optic zone radius is indicated if central corneal touch and midperipheral corneal or limbal touch occur together. It must be borne in mind that changing the BOZR alters the power of the contact lens and liquid lens (*see* Chapters 5 and 17). Where possible the BOZR should therefore be kept the same.

The central optic zone thickness is measured and a waterproof mark is made on the front surface at this point. A 'runner' is attached to the centre of the front surface of the optic zone with double-sided adhesive tape. A diamond impregnated brass tool of the desired radius is placed on a vertical spindle, which is then set in motion. Using paraffin or water as the lubricating agent, the back optic zone of the lens is ground out, using a pencil point or similar object in the runner guide hole, the lens being moved slowly backwards and forwards across one side of the head of the diamond tool (*see Figures 17.37* and *17.39*). The lens should be allowed to rotate freely and lubricant should be used as necessary to prevent the tool surface drying out. The lens should be removed at frequent intervals to check the rate of reduction in central thickness. Final grinding is best performed with paraffin as the lubricating agent. Being slightly more viscous than water, it allows the tool less possibility of abrading the surface and thereby facilitates final polishing.

The increased viscosity slows the rate of grinding out, however. Paraffin is inconvenient with fenestrated lenses as it tends to leak through the fenestration, occasionally dissolving the adhesive, and causing the runner to become detached from the lens. About 0.02 mm thickness should be allowed for final polishing of the back optic zone. This is carried out in exactly the same way as for corneal lenses – retaining the lens on the runner and using either a wax, tape or cloth covered tool of the correct radius with suitable polish (*see* p. 809).

Transitional grind-out or extension

This is done if the transitions are sharp and cause frothing of the bubble, if limbal touch occurs or where there is insufficient clearance beyond the limbus, as indicated by the extent of the fluorescein pool.

This is carried out as described above (*see* Reduction of BOZD) but using the large-size diamond impregnated tool, the only other difference being that widths of transition are normally taken rather than thickness removed, and the final polishing is carried out using a large wax tool or felt ball.

A transitional grind-out is normally necessary after a back optic zone grind-out owing to the reduction in width of the transitional curve(s) caused by the central grind-out. (A fenestration will similarly need re-countersinking and polishing when such a transitional or optic zone grind-out has been performed.)

A transitional grind-out is best carried out after the back optic zone has been polished to facilitate measurement of the transition width. Alternatively, the area may be marked with ink to show the border between the transition and optic zones during grinding. (Paraffin cannot be used as a lubricant if it dissolves the inks used.)

Polishing the rough ground transition extends its width slightly. This becomes important when extending a transition well into the back optic zone, and especially when making a double curve back optic zone.

Localized scleral zone and transition grind-outs

This is done in regions where the scleral zone or transition touches the eye heavily, as evidenced by blanching of the conjunctival blood vessels. The latter may be seen more easily if a little digital pressure is applied to the lens. Also, if the optic zone gives too much clearance from the cornea the whole back scleral zone surface may be ground out to settle the lens. More substance should be removed from near the transition region to maintain the same curvature and give the most effective settling.

One of the most common modifications needed is a temporal scleral zone grind-out near the transition to permit the lens to settle and move slightly nasally. This is indicated when a large temporal static bubble occurs at the limbus accompanied by nasal corneal touch from the optic. A slight reduction in nasal scleral zone size may also be needed to permit the nasal shift of the lens.

The area to be ground is first marked on the back surface (or front, according to preference) with a suitable quick-drying ink or grease pencil. For the beginner, it is useful to measure the average thickness of the area to be ground out – at several noted points in the area if this is large. This can be checked during the grind-out to determine the amount of material removed and, in a large area, to check that the material is being removed evenly. If necessary, the back optic zone may be protected with a small piece of plasticine (Bier, 1957) or adhesive tape pressed firmly into it.

The grind-out is performed with a spherical, cigar-shaped or wheel-shaped stone, the size of which depends on the size of the area to be ground out. This is held in a Jacob's chuck on a horizontal spindle, and it should be kept moist throughout the operation. In order to prevent deep scratches in the scleral zone, the lens should be kept continually moving back and forth slightly, until the ink over the area (if on the back surface) is removed (*see Figure 17.51*). Surplus lens material and polish should be regularly removed with a tissue. The scleral zone thickness should be checked before continuing.

The rough area may now be smoothed, if necessary, with a rotating hard rubber burr. Polishing may be carried out with a felt buff and polishing compound or, more slowly, with a soft mop buff. Final polishing with a soft mop and polishing compound is always preferable as it gives a better finish. To save time, this may be omitted until the lens has been checked on the eye and has been found to fit satisfactorily.

Examination under magnification will show areas which have not been polished completely. Forknall (1953) showed that for equal scleral zone settling, relatively more plastics must be removed from near the transition than from the periphery.

Fenestration

Most PMMA scleral lenses are fenestrated to permit tear flow and oxygen exchange behind the lens. If a fenestration hole becomes covered by the upper lid regularly, or

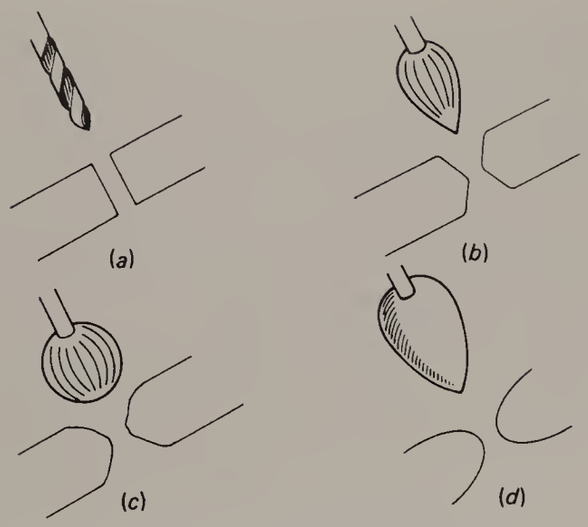


Figure 22.14 The four stages of fenestrating a scleral lens

otherwise blocked as by loose conjunctival tissue or mucus, then a further hole or holes may be required within the palpebral aperture.

The position having been determined, as explained in Chapter 17, the fenestration hole is made as follows.

With a 0.50 or 0.75 mm drill (typically), a hole is drilled normal to the surface to minimize its length. Care should be taken not to slip with the drill and scratch the optic zone surface. The drill should be held in a pin-vice so that a minimum length of drill protrudes. This gives greater control over exact positioning. Alternatively, the drill may be held in a Jacob's chuck on a horizontal spindle, which lessens the risk of the drill or lens slipping and scratching the optic zone surface, and the lens 'fed' on to the drill.

A flame-shaped dental burr is then turned anti-clockwise (to give a finer cut) in the hole to counter-sink (*Figure 22.14*) A few turns initially with a 1.50 or 2.00 mm drill can be used to speed up the process of counter-sinking. Counter-sinking should be continued equally on both sides of the lens until examination under ×50 magnification shows the two counter-sinks are almost meeting. Funnel shaping is essential to create an even tear flow and prevent turbulence likely to remove epithelium from the corneal surface.

A slightly larger spherical dental burr is then used, as before, to taper the outer edges of the counter-sinking.

The counter-sinks are then polished at low speed, to avoid burning, using a pointed soft felt burr soaked in polishing compound, until a high polish is obtained.

Inspection under ×50 magnification should show a fenestration polished all the way through and with tapered edges as shown in *Figure 22.14d*. Any remaining polishing residue may be removed with a tapered stick (for example, a toothpick), tissue, or bristle.

Channelling

Channelling is an alternative to fenestration, and may be indicated if the limbal region is very irregular and the introduction of a bubble would lead to frothing, or if the limbal conjunctiva is very loose and blocks the fenestrations. (A loose conjunctiva may also block a channel.)

Although sometimes not so successful as fenestration, it may become a necessity under certain conditions (*see* Chapter 17). Various uses and designs of channel were discussed by McKay Taylor (1969).

The channel is cut in exactly the same way as a local back surface scleral zone grind-out, along a specific line or curve, and, where possible, using a sharp-edged wheel-shaped grinding tool. This is usually cut from the upper temporal lens edge into the mid transition, though an inferior channel and/or other channels may also become necessary. The channel should occupy about half the lens thickness and have well blended edges to prevent conjunctival abuse.

Fluorescein examination should show a clear channel from the lens edge into the back optic zone.

An alternative method, using either the cast of an eye impression or of a preformed lens, is to glue a suitable piece of nylon film on to the cast along the desired line of the channel. A shell then made from the cast has a channel pressed into the plastic to the desired depth. The slightly raised area on the front of the finished lens is not noticed subjectively. The advantage of this method is that it enables the shell to be pressed from a thinner sheet initially than for a lens where a channel is to be ground into the scleral zone.

Power alterations

Power alterations must be made if the refraction changes or if a change in BOZR is carried out for fitting purposes. Other points to note are mentioned in connection with corneal lens power changes (*see* p. 809).

These are normally carried out by the laboratory as the front surface must be recut each time. Minor front surface alterations may be made on a drum, as for corneal lenses (*see* p. 810).

Practitioners should bear in mind that a back optic zone grind-out, by reducing the thickness of the optic zone, will effectively add a small amount of negative power to the lens. In order to prevent unnecessary modification, +0.25 to +0.50 D should be added to the power required if back optic zone grind-outs are likely to become necessary (*see* Chapters 5 and 17).

Spatulation

Spatulation should rarely be necessary but is indicated if an area of the scleral zone stands clear of the eye, and to settle the rest of the scleral zone by grinding it out would not be feasible due to too thin a lens – or lack of time to carry out the tedious grinding.

Such loose areas may be reshaped by means of spatulation (Obrig, 1942; Bier, 1957). A cast is made of the lens, and the loose area is marked on the back surface of the lens and on the cast. Material is then scraped off the cast in this area. A spatula is heated to approximately 70°C for lenses

cut from solid plastic and 60 °C for impression lenses (Bier, 1957) and pressed on the front lens surface over the loose area, the cast being held in position against the back surface of the lens.

Tight areas may also be removed in an opposite manner by taking a cast of the front lens surface. Spatulation is best performed on thin lenses, i.e. thinner than 0.75 mm. Too great a rise in temperature of the lens is not desirable as residual monomer may be released, which is toxic to the eye (Estevez, 1967).

Modification of soft contact lenses

While it has been traditional for rigid lenses to be modified for various reasons after the initial fitting, it is perhaps not as well known that soft lenses can be modified in a number of ways to achieve optimum fitting results. These range from simple dotting of lenses to aid identification to complicated cut-outs to circumnavigate pingueculae or fluid drainage blebs (*see* p. 831).

Most modifications are best done by skilled technicians at the laboratory from which the lens was obtained. This ensures that the modifications are performed by those with an intimate knowledge of both the lens material and design.

Lens dotting

Perhaps the simplest and often a very helpful modification the practitioner can do is to dot lenses either to identify left and right, or to enable orientation of a toric lens on the eye by the patient.

The lens should be blotted dry, preferably with lint-free tissue, and then mounted on the convex dome of a suitable soft lens container. A water-proof marking pen with a fine point, e.g. Sanford's Sharpie No. 3000 or Nikko Permanent Ink Marker No. 150, are then used to apply a single dot (right lens) or two dots (left lens) to the lens edge. The lens is allowed to dry for a further 1–2 minutes before thorough surfactant cleaning and rinsing. Dots applied by this method will gradually fade over several months, faster if the lenses are thermally disinfected, but are easily re-applied at after-care visits (Hallock, 1980).

Fenestration and truncation

Sellers (1979) described practitioner fenestration and truncation techniques for soft lenses. These are also mentioned below under laboratory modification procedures.

Laboratory modification procedures

While theoretically possible for a practitioner skilled at soft lens modification procedures, the following list shows those modifications possible to a soft contact lens best carried out by an expert laboratory technician:

- Adding peripheral curves in order to loosen, i.e. flatten, the lens fit.
- Diameter reduction; again to loosen the fit of the lens.
- Edge thinning and/or re-shaping to improve comfort or to reduce conjunctival indentation or blanching.
- Truncations: to loosen the lens and/or improve axis location in the case of a toric lens.
- Cut-outs can be positioned to circumnavigate pingueculae thus improving lens stability and comfort. This is usually performed on a reverse prism toric lens or on a spherical lens with prism ballast. Cut-outs will also have the effect of flattening the lens fit.
- Grinding ptosis prop-like shelves into a lens can help position a lens on the eye. This technique can be used to reposition a high riding lens downwards or conversely a low riding lens upwards.
- Fenestrations can be added to specific areas of the lens to reduce an oedematous response. Ang and Efron (1987) found increased subjective awareness if soft lenses were fenestrated with holes 0.39 mm in diameter. As the fenestration size increased the discomfort also increased. When the fenestrations were produced by laser, diameters as small as 45 μm could be produced (Efron, 1992). Ten wedge-shaped sectors, each containing 350 of these microfenestrations were found to be comfortable and increased oxygen transmissibility of HEMA lenses by over 200%.
- Re-shaping prism facets on a toric lens can be very effective in relocating the lens to its correct axis. Lens mislocations of up to approximately 20° can be corrected in this manner. This technique involves careful measuring of the geometrical thickness profiles of the lens, along and across prism faces. Careful assessment of the overall thickness of the lens gradients allow the laboratory to change these profiles in order to redirect the upper lids' blink action to other areas of the lens thereby effecting a location change. Due to the complications involved in re-ordering toric lenses with axis allowances incorporated, this method has proved very successful in improving practitioners' fitting success rate. However, it suffers from the disadvantage that lens duplication is difficult if not impossible.
- Minor power changes can be made to some types of soft lenses. This is an extremely delicate procedure and is best attempted by skilled technicians only. It requires very careful dehydration procedures and is not always successful. It can, however, be useful in the tailoring of bifocal contact lenses where one portion of the optic zone is changed only.
- The removal of small edge chips, gouges and some surface deposits can also be achieved by careful modification techniques.

Whilst it is possible to carry out these modifications to soft lenses, the increase in the prescribing of planned replacement and disposable lenses (both spherical and toric)

makes the need to modify existing lenses less common. Also the cost of laboratory modifications may be more expensive than simply replacing the lens.

The major factor controlling all of these soft lens modifications is the dehydration techniques used. The laboratory must be able to dehydrate the lens completely and still maintain the original surface geometry.

The most common problem encountered with soft lens dehydration is lens buckling. This is especially true of ultrathin lenses and high water content lenses. If the lens dries out to a buckled form it is almost impossible to modify it successfully.

Two of the more successful methods of lens dehydration are:

- Slow dehydration in silica gel filled chambers. This technique involves the use of special chambers which contain a small amount of used silica gel suspended in a permeable subchamber. This chamber is placed over the contact lens, which has been dabbed surface dry on lint-free tissue, and will dehydrate the lens over a period of hours. This technique is successful only when used silica gel is placed in the chamber. Fresh silica gel or a too short drying time will result in a buckled lens.
- Microwave ovens are very successful in dehydrating the lens back to a workable hardness. Again the lens is dabbed surface dry on a piece of lint-free tissue before being placed in the microwave oven. It must be accompanied by suitable energy absorbing material to prevent oven damage during the drying cycle. The drying time should be slow in order to maintain the lens shape. This technique will dehydrate the lens more completely than the current traditional methods.

It must be noted that soft lenses will dehydrate closer to their original form if they are soaked in distilled water for some time before drying out. This soaking (preferably in a magnetic stirrer) will remove the sodium chloride from the matrix and prevent crystallization.

The actual modifications to these lenses can be performed by a number of standard laboratory techniques.

Diamond wheels and domes are used for grinding material away. Padded flat wheels and domes can be covered with velvet, velveteen, chamois etc., for polishing the lens back to its original finish.

Different polishing compounds can be used for different requirements just as different polishing materials are used for various applications. A good standard polish which will give an excellent surface is CCPI polishing compound mixed with Silicone Oil.

One of the most important considerations that must be addressed when modifying soft lenses is to keep the material dry. A previously worn dehydrated lens will rehydrate far more quickly than an unworn lens and therefore must be kept dry at all times. It is often an advantage to modify the lens in stages, keeping it stored in silica gel periodically. If a lens starts hydrating while being modified, a good surface finish will be impossible to achieve.

Conclusion

Practitioners are advised to obtain a selection of reject lenses on which to practise modifications. The majority of modifications may be accurately carried out with only a little practice, but practitioners are urged to maintain their own standards to at least those that they would expect from their laboratory.

Acknowledgement

I am indebted to Stephen Newman of Capricornia Contact Lenses Ltd (Australia) for help with the laboratory section of soft lens modification and for additional help with the modification of rigid gas permeable lenses.

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Chapter 23

Special types of contact lenses and their uses

Janet Stone

Lenses to aid diagnosis and surgery p. 817
Protective lenses p. 829
Therapeutic lenses p. 831
Contact lenses used for research into visual function p. 833
Lenses for sports purposes p. 836
Lenses for the partially sighted p. 839
Animals' lenses p. 840
Miscellaneous lenses p. 841

Ocular surgical techniques continue to improve, and the use of special contact lenses adapted for viewing the interior of the eye during such procedures has played a significant role in refining the methods used and in the initial diagnosis. Along with other special types of contact lens not covered elsewhere in this book, these lenses are described in this final chapter.

Other contact lenses or aspects of contact lens work which were formerly considered as special are now commonplace; such features as tints, surface treatments, materials of different refractive index and oxygen permeability are now taken for granted as part of everyday fitting, and are only touched on in this chapter for the sake of completeness.

Yet other special lenses, mainly certain varieties of scleral and sports lenses are now of historic interest only and no longer included here, although interested readers may wish to consult the final chapter of the second edition. Their modern counterparts are mentioned on pp. 836–839.

Lenses to aid diagnosis and surgery

Various special contact lenses have been developed to assist observation of the eye in diagnosing eye disease.

Contact lenses for corneal observation

During examination of the corneal endothelium by specular reflection with the slit lamp biomicroscope, the bright reflection from the epithelial/tear layer surface is very intrusive. By employing a thick aplanatic planoconvex lens with the plane face towards the cornea but separated from it by a solution, such as 2% methyl cellulose or Celluvisc (Allergan), the annoying bright reflex is removed and transferred to the front of the contact lens where it is no longer within the field of view of the microscope. Haag–Streit's Eisner Contact Glass is manufactured for this purpose and is shown in *Figure 23.1a,b*. It has been fully described by Eisner *et al.* (1985), who demonstrated its usefulness in studying the corneal endothelium and epithelium as well as the stroma and Descemet's membrane, and for photographic documentation.

The lens includes an in-built orange filter to remove light scattered by the corneal stroma, and it provides ×2.2 magnification of the corneal endothelium with additional magnification supplied by the microscope itself. It is free from spherical aberration, coma and astigmatism, and any reflections from the plane back surface of the lens are easily removed by slightly tilting the lens. Light transmission is improved by anti-reflection coating of the lens surfaces. It permits observation of the epithelium and endothelium by both specular reflection and indirect illumination. Used with microscope magnification of ×25 a total of ×55 magnification is achieved, and with the McIntyre eyepiece grid (*Figure 23.1c*) it can be used for estimating endothelial cell density. Endothelial cell abnormalities (*see Figures 15.19* and *15.20*) as well as the state of the epithelial cells and other features of the cornea can be studied and photographically recorded to permit, for example, pre- and post-surgical comparison. There is no direct contact of the lens with the cornea, but a suitable solution should be chosen to fill the precorneal space and prevent oedema which would interfere with endothelial observation. A maximum area of specular reflection of about 10 mm^2 can be seen and recorded with this lens

A less elaborate system was developed by Tsubota (1988), who used a two-part specular-microscope-contact-lens consisting of a 6 mm diameter tube or 'tunnel' with an annular curved base which is held by surface tension to the front surface of a rigid contact lens, 0.2 mm thick, placed on the eye following local anaesthesia. The wide field specular microscope is applied to the base contact lens through the tube (or 'tunnel' lens) which serves to hold open the eyelids. Observation and photography can be carried out easily and speedily, and the system is said to avoid light scatter from the microscope objective lens and to prevent mucus getting between the objective lens and cornea. It also prevents epithelial damage from the objective lens and permits peripheral corneal photography, because as the eye moves the lids are kept apart by the tube.

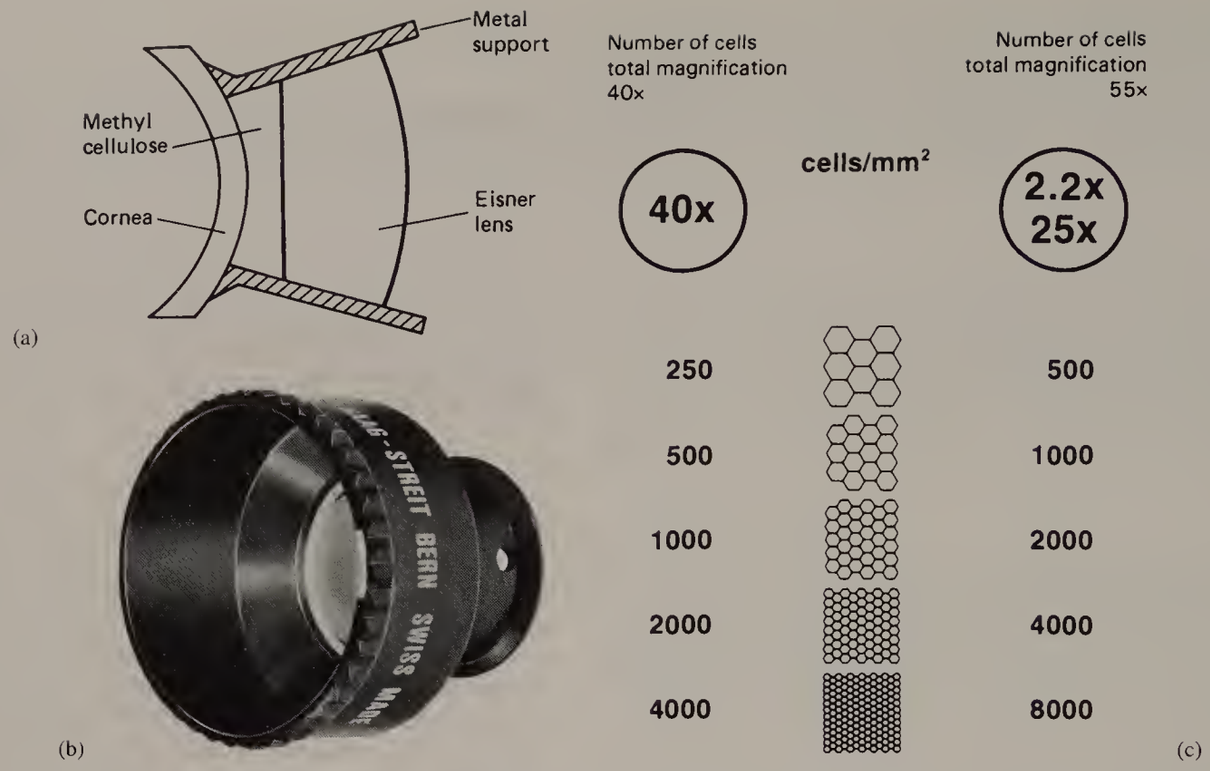


Figure 23.1 The Eisner Contact Glass: (*a*) cross-section on the cornea showing its planoconvex form which gives a ×2.2 magnification of the corneal endothelium. The bright anterior corneal reflex is removed by its presence and transferred to the front surface of the Eisner lens, out of the field of view of the slit lamp microscope. (After Eisner *et al.*, 1985.) (*b*) The supporting structure which holds the eyelids apart and permits easy handling of the lens so that it can be tilted *in situ* to get rid of any reflections from its plane back surface separated from the cornea by a solution such as methyl cellulose. (*c*) The McIntyre eyepiece comparison grid which allows the corneal endothelial cell density, seen by specular reflection, to be estimated. The illustration shows the number of cells per square millimetre for two different magnifications. On the right are the cell density values for a ×55 magnification achieved with ×2.2 from the Eisner lens, and ×25 from the slit lamp microscope. The McIntyre grid is incorporated in a ×12.5 eyepiece which is used with a ×2 objective lens. ((*b*) and (*c*) reproduced by kind permission of Haag–Streit Ag., Switzerland)

Diagnosis of corneal abnormalities

Any ordinary rigid contact lens may be used to assist in the diagnosis of suspected keratoconus. If visual acuity during refraction with a contact lens in place is markedly better than visual acuity with the best possible spectacle correction and keratoconus is suspected, its diagnosis may be confirmed. Suspected corneal dystrophies also show a similar improvement in visual acuity with contact lenses, as do many other conditions of corneal irregularity.

The presence of a contact lens also permits abnormal corneal conditions to be studied more easily with the slit lamp, for the contact lens gets rid of unwanted reflections from the irregular corneal surface.

By largely removing the corneal irregularities, a contact lens permits ophthalmoscopic or slit lamp examination of the media and fundus, thereby making easier the diagnosis of internal eye conditions in patients having an irregular cornea. The fundus of the high myope is also more easily observed if viewed through a high minus contact lens which reduces the excessively high magnification obtained in direct ophthalmoscopy of these patients.

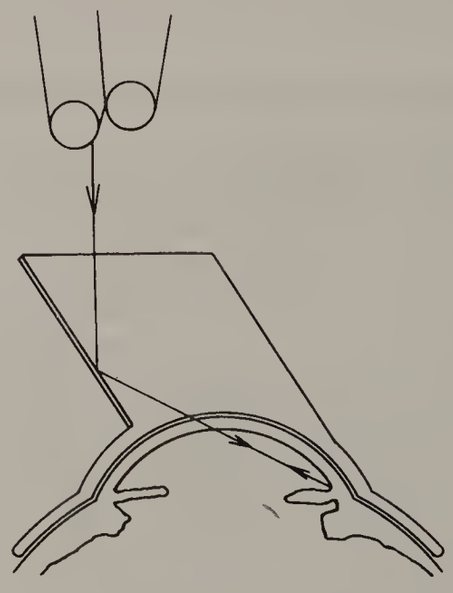


Figure 23.2 Cross-section of a Goldmann gonioscopy lens. Light from a slit lamp is reflected, as shown, into the anterior chamber angle, and returns along the same path to be viewed through the microscope



Figure 23.3 Lovac six-mirror goniolens giving a composite image of the entire anterior chamber angle. The central fundus can be viewed through the centre of the lens. (Reproduced by kind permission of Medical Workshop, Holland)

Slit lamp examination of the fundus using a Volk lens can be carried out with or without a contact lens in the eye.

Assessment of corneal thickness

Friedman (1967) developed a corneal lens having a stepped front surface to give a central portion 0.8 mm thick, an intermediate portion 0.6 mm thick and an outer portion 0.4 mm thick. Easily manufactured by contact lens laboratories, the lens is used with a narrow slit beam. Corneal thickness can be estimated by comparison with the different lens portions, prior to surgery (*see* Measurement of corneal thickness, Chapter 6, and Pachometry, Chapter 8).

Gonioscopy contact lenses

Observation of the angle of the anterior chamber has been made possible by the use of contact lenses which either partially or completely neutralize the power of the cornea, thus enabling observation of the anterior chamber angle directly or by means of mirror devices.

Most modern gonioscopy lenses are based on the designs introduced by Koeppe (1919), Uribe Troncoso (1921) and Goldmann (1938). The Goldmann lens incorporates a mirror and is used in conjunction with a slit lamp biomicroscope (*Figure 23.2*). The angle of the anterior chamber is seen by reflection.

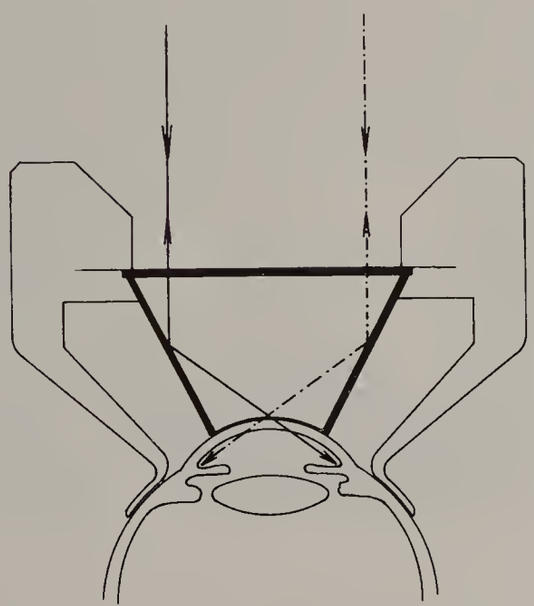


Figure 23.4 The pyramid gonioscope of van Beuningen. The pyramid goniolens is held in place by a support which rests on the sclera

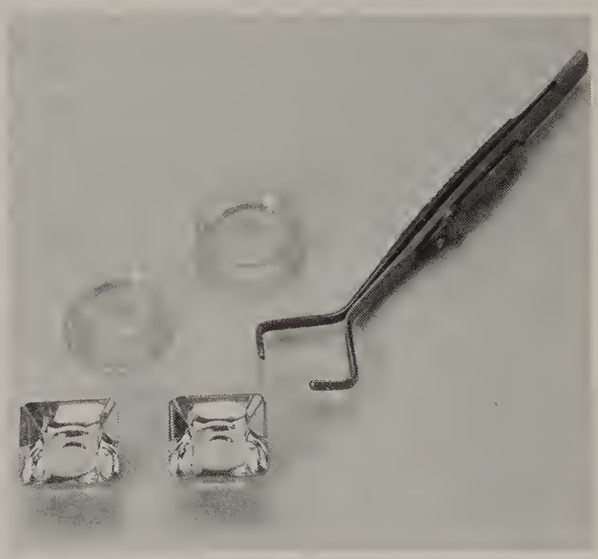


Figure 23.5 The Zeiss four-mirror gonioscope with special forceps, and scleral holders which keep the lids apart. (Reproduced by kind permission of Carl Zeiss, Oberkochen)

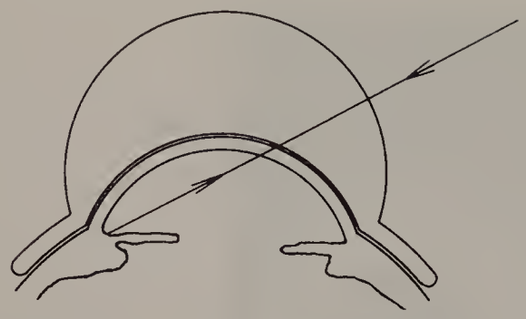


Figure 23.6 Cross-section of a spherical goniolens as used by Koeppe and Uribe Troncoso. Observation and illumination are from the same direction, perpendicular to the front surface. Alternatively, the limbus region may be illuminated by a slit beam from one side

To see the entire angle, the lens must be rotated on the eye and the slit beam rotated with it but perpendicular to it, a horizontal slit being used when the mirror is vertical and vice versa. Magnification is given by the biomicroscope. The need for all but small amounts of rotation of the lens has been overcome by the use of multiple mirrors, as in the Lovac six-mirror goniolens, the pyramid gonioscope of van Beunigen (1953) the Zeiss pyramid or four mirror gonioscope (*Figures 23.3–23.5*) and other similar lenses. The principle employed by Koeppe and Uribe Troncoso was to use a spherical contact lens and observe by looking perpendicular to the anterior lens surface (*Figure 23.6*). This allows observation of the entire angle of the anterior chamber without rotation of the lens. Although the narrow focal beam from a slit lamp is to be preferred, illumination without a slit lamp is possible and may be provided by an ophthalmoscope or pen torch. The magnification is about ×2 unaided and may be increased with the aid of a loupe. The disadvantage of this system is the aberration given by the steeply curved spherical front surface of the goniolens.

A more modern development of this is the Lovac Double Focus contact lens, which has a small section of convex radius of curvature of 6.00 mm incorporated in the major lens, which has a front surface radius of 8.00 mm (*Figure 23.7*). Magnification of ×15 may be obtained by direct ophthalmoscopy through the steeply curved sector. A stereoscopic appearance is obtained if an indirect binocular ophthalmoscope is used, as in *Figure 23.7*.

The Lovac series of lenses adhere readily to the eye by means of negative pressure afforded by a long cannula running from the back surface of the lens, which is filled with saline prior to insertion. As soon as the lens touches the eye, the end of this cannula is lowered, thereby creating a negative hydrostatic pressure. This prevents the lens dropping out and prevents the formation of bubbles behind the lens – problems common with other types of goniolens. However, if left in place for too long (more than about 15 minutes), corneal oedema sufficient to disrupt the observer's view may result (Sabell, 1970) but the cannula may also be used for irrigating the eye to avoid this.

A further type of goniolens is the Lovac Direct Goniolens as shown in *Figure 23.8*. The anterior chamber angle is viewed directly without reflection through the flat surface of the goniolens, which is angled at about 45° to the patient's visual axis. This allows about half the entire anterior chamber angle to be viewed at one time and readily permits goniophotography.

Lenses employing similar optical principles to the various gonioscopy lenses are also used in the surgical technique known as goniotomy. The Barkan lens, originally developed in 1936 (Barkan, 1936), is shown in *Figure 23.9* and the Medical Workshop prismatic goniotomy lens is shown in *Figure 23.10*.

The anterior chamber angle

Gonioscopy permits observation of the angle of the anterior chamber. The essential features of the angle are illustrated in *Figure 23.11a*. On the corneal side of the angle these are as follows.

Schwalbe's line is the termination of the corneal endothelium and Descemet's membrane. Sometimes this is visible using ordinary direct illumination and slit lamp biomicroscopy, because the endothelium may terminate in a small tag of tissue which projects into the aqueous. This is then known as posterior embryotoxon or embryotoxin and if it occurs all round the entire angle it adds to the risk of angle closure glaucoma. It delineates the anterior end of the

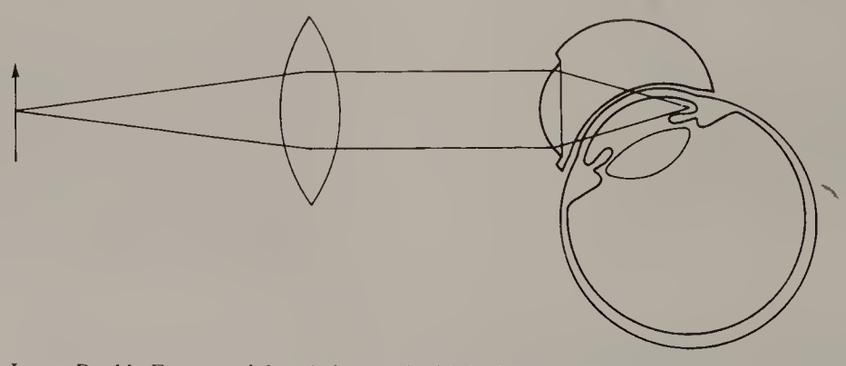


Figure 23.7 Cross-section of the Lovac Double Focus goniolens being used with indirect ophthalmoscopy

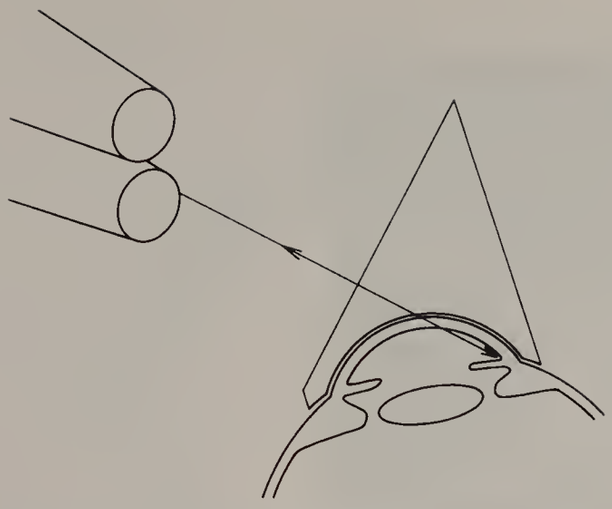


Figure 23.8 Cross-section of the Lovac Direct Goniolens being used with the biomicroscope. The direction of illumination and observation are the same

corneoscleral trabecular meshwork. This is the sponge-like tissue separating the aqueous from the canal of Schlemm. The latter becomes visible in gonioscopy if filled with blood. The rear of the corneoscleral trabecular tissue is demarcated by the scleral spur which is scleral tissue projecting forward as far as the angle at this point. It can be said to represent the midpoint of the angle as seen by gonioscopy.

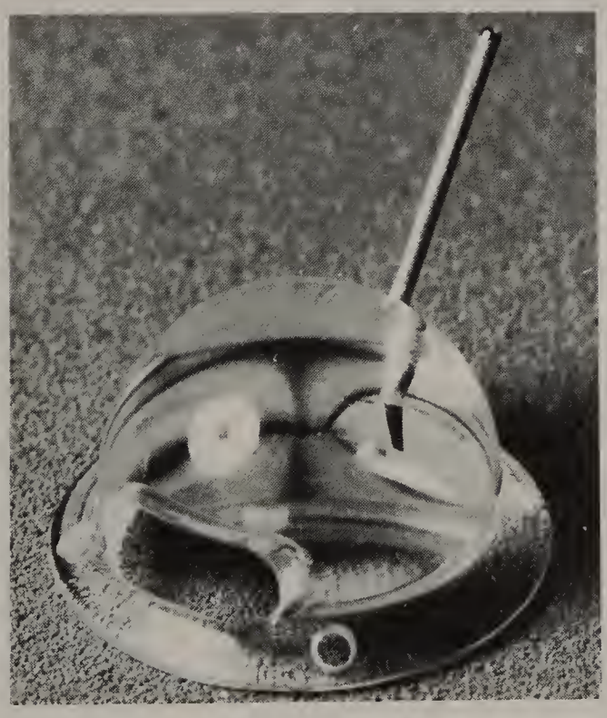


Figure 23.9 The Barkan goniotomy lens giving ×2 magnification. This has a small scleral zone with four perforations to allow the lens to be sewn into place during surgery. There is also a lateral window for scalpel access and a cannula. (Reproduced by kind permission of Medical Workshop, Holland)



Figure 23.10 The Medical Workshop prismatic goniotomy lens which is used in conjunction with an operating microscope. Other features are similar to the Barkan Lens shown in *Figure 23.9*. Reproduced by kind permission of Medical Workshop, Holland)

Beyond the scleral spur on the iris side of the angle is first the ciliary body and then the root of the iris at the apex of the angle and just beyond. Then the iris tissue itself takes over and the last roll of the iris is seen.

Becker (1972) devised a goniogram (*Figure 23.12*) to illustrate the state of the anterior chamber angle as seen by gonioscopy, which also relates to his classification of the angle. The goniogram consists of seven concentric circles, the central one denoting the scleral spur. The outer three circles are used to denote the apparent width of the trabecular tissue, i.e. the relative distance of Schwalbe's line from the scleral spur. If the trabecular tissue appears wide (classification 3) then Schwalbe's line is marked in on the outermost circle, if medium (2) on the next circle, and if narrow (1) on the innermost of these three outer circles. The apparent width of this trabecular tissue depends on the angle at which it is viewed. This in itself depends on the narrowness of the anterior chamber angle. If the latter is very narrow, the angle of view to see into it is so tangential to the trabecular meshwork that it appears foreshortened (1).

The three inner circles of the goniogram are used to denote the position of insertion of the iris root into the ciliary body relative to the scleral spur. The iris root is marked on the innermost circle if it is inserted posteriorly (classification C) allowing a good view of the ciliary portion of the angle; on the next circle if the iris is inserted in a midposition (B) and on the third circle in if the iris insertion is anteriorly placed (A) indicating a narrow angle, with hardly any of the ciliary body visible.

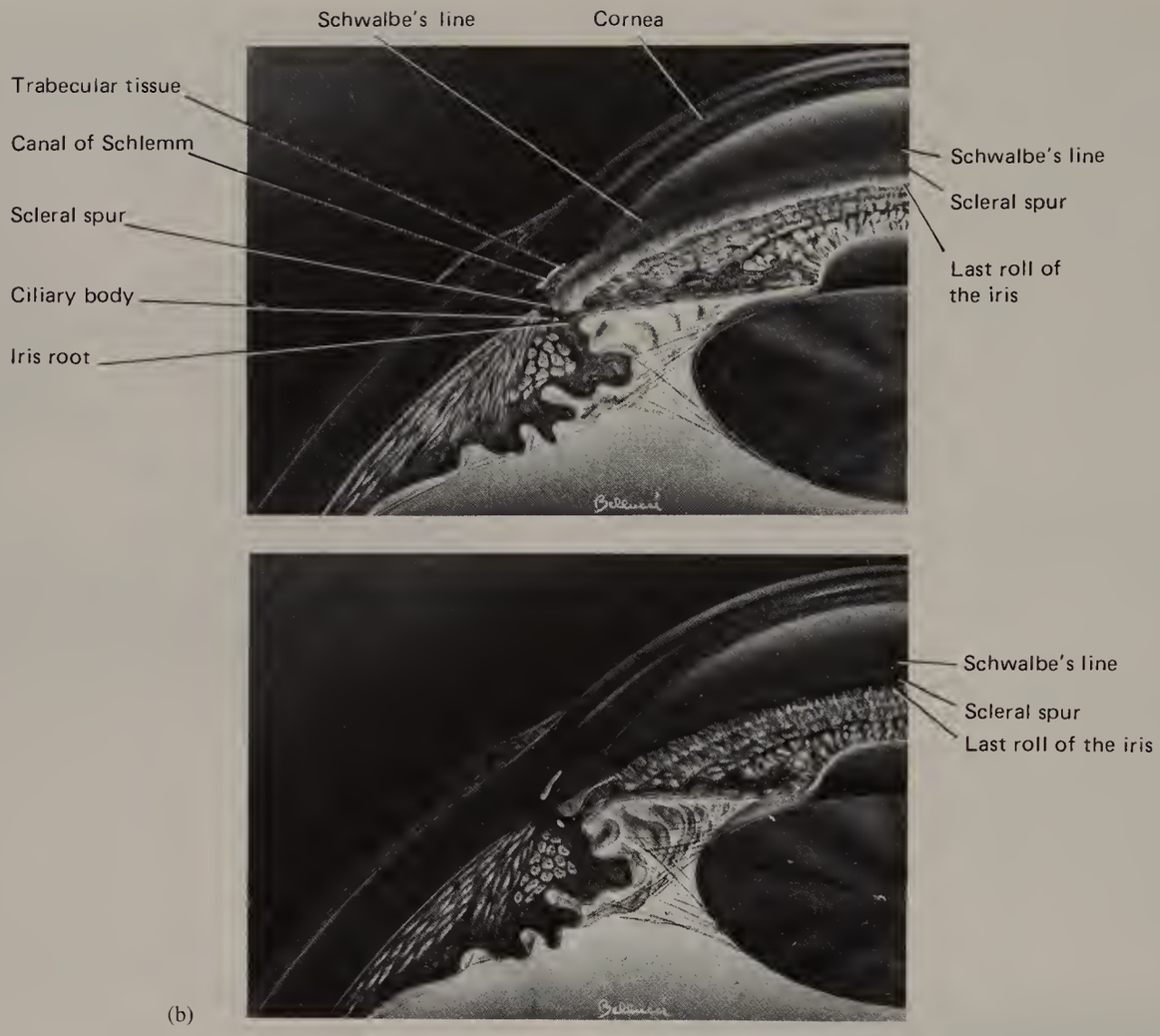


Figure 23.11 (*a*) Cross-section and gonioscopic appearance of an open angle. Both the trabecular meshwork (between Schwalbe's line and the scleral spur) and the ciliary body (between the scleral spur and iris) appear wide, with classification 3-C – *see* text. (*b*) Cross-section and gonioscopic appearance of an angle classified as 3–O. Such an angle might close completely during mydriasis as the last roll of the iris could move forward blocking the aqueous outlet via the trabecular tissue. This could occur with or without pupil block and its resultant iris bombé. (Reproduced from Becker (1972) by kind permission of the author and the publishers, Mosby, St Louis, Missouri)

Thus, the angle of the anterior chamber is denoted by first a number (0, 1, 2 or 3) and then a letter (O, A, B or C) enabling a description of both 'sides' of the angle. An O indicates that the structure is not visible and 0O indicates complete closure. All four quadrants of the angle can be drawn in on the goniogram as indicated, so that variations can be seen and pigmentation and other features such as iris processes can be marked in. The upper quadrant usually has the narrowest portion of the anterior chamber angle, and the angle is at its widest in the lower quadrant.

Other methods of classification include the Shaffer (1962) system which relates the grade to the angle made by the iris with the ciliary body and trabecular tissue. Grade 0 is a closed angle. Grade 1 is 10° or less – an extremely narrow angle. Grade 2 is 20° – a narrow angle. Grade 3 is 20–35° and grade 4 is 35–45° – both wide open angles. Angle closure is thought to be impossible in grades 3 and 4, possible in 2 and probable in 1.

Prior to this, Scheie (1957) used a grading system to denote angle width and pigmentation.

Considerable experience is required for correct interpretation of the anterior chamber angle. *Figure 23.11a* shows an open angle (classification 3-C), and *Figure 23.11b* shows a narrower angle (3-O) with potential for closure if pupil block should occur during mydriasis with resultant iris bombé pushing the last roll of the iris forward to close the angle.

Greater detail of gonioscopy and the appearances seen is available in Becker's work.

Contact lenses for examination of the fundus

As already mentioned, any high-negative-powered contact lens assists observation of the fundus of the high myope

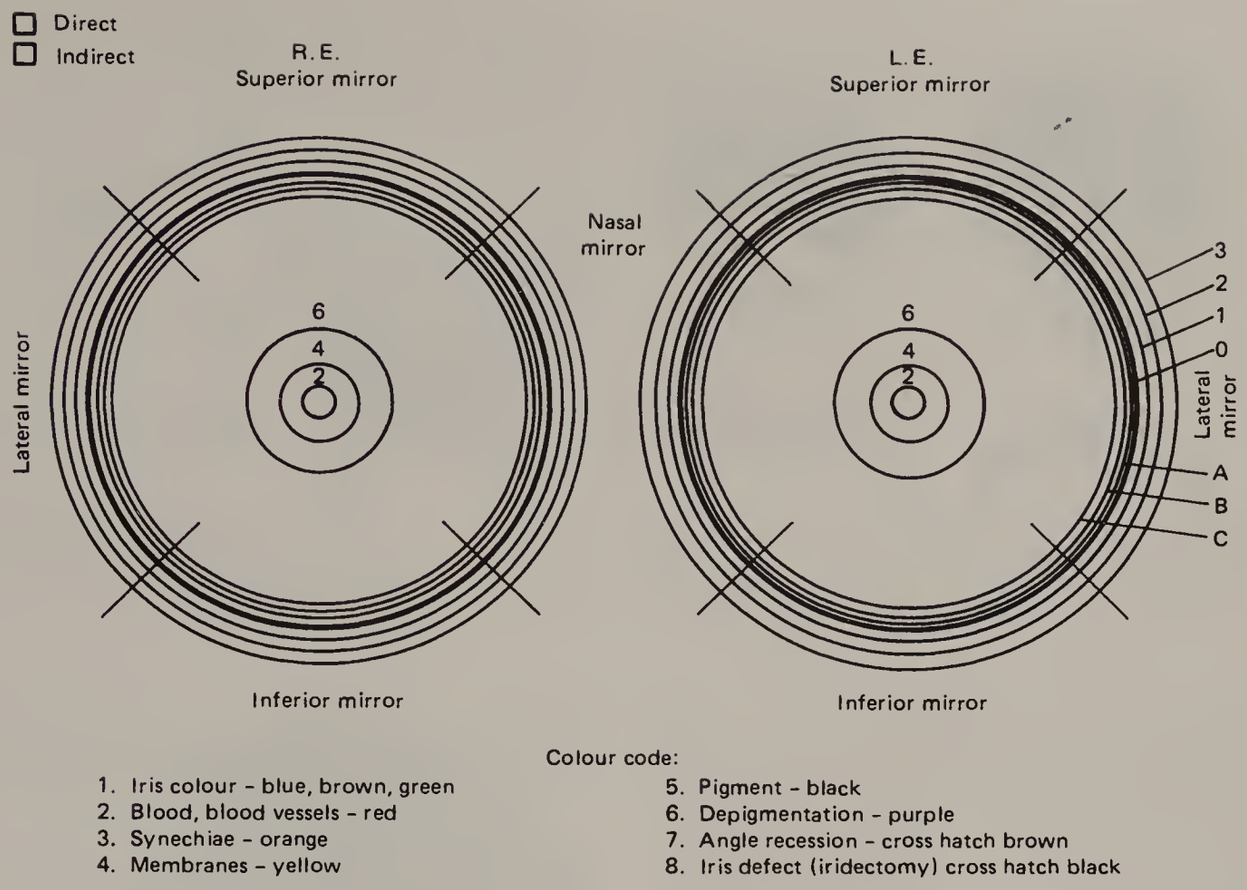


Figure 23.12 Becker's goniogram. The apparent width of the corneoscleral trabeculum is marked in on one of the outer three circles depending on the apparent separation of Schwalbe's line from the scleral spur. The latter is represented by the heavy central circle. Likewise, the width of the ciliary body seen between the scleral spur and iris is marked on the inner three circles. Other features may be drawn in as indicated. The pupil size and characteristics may also be recorded. (Reproduced from Becker[1](1972) by kind permission of the author and the publishers, Mosby, St Louis, Missouri)

during direct ophthalmoscopy by reducing the magnification and enlarging the field of view.

Observation of the ocular fundus employing the slit lamp is useful as it allows detection of changes in level of the fundus (by bending and alteration in focus of the slit) and permits a binocular view with magnification. Although Volk lenses are more commonly used nowadays, such observation is aided by the use of special contact lenses having flat front surfaces which eliminate refraction due to the cornea (*Figure 23.13*). The central (macula) region of the fundus may be observed directly with such a high negative lens, and mirrors may be employed to observe the midperiphery and extreme periphery of the fundus. A dilated pupil is necessary. The Zeiss three-mirror contact lens allows all these methods of observation as well as gonioscopy (*Figure 23.14*).

A lens with a flat front surface incorporating an internal fixation light in the form of a light emitting diode, angled at approximately 17° to the observation axis, was described by Richards *et al.* (1993). It is used in slit lamp observation of the optic nerve head in functionally monocular patients and those glaucomatous patients with fixed miotic pupils.

Haag–Streit make a lens with mirrors inclined at 73°, 66° and 59° to the plane front surface, the 59° mirror being used for gonioscopy, the 66° mirror for the region around the equator, the 73° mirror from there to within 30° of the posterior pole of the eye, and the posterior pole itself being viewed through the plane face of the lens. Slight tilting of the lens is sometimes needed to give complete fundus coverage. The same lens may be used with an ora serrata attachment for depression of the sclera to aid observation just behind the ciliary body (*Figure 23.15a–d*).

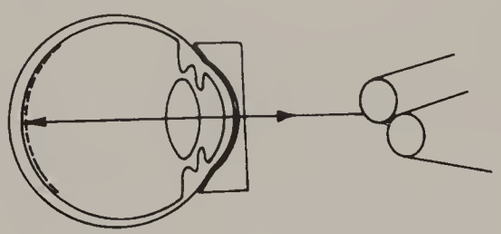


Figure 23.13 Fundus observation with the biomicroscope, by means of a contact lens with a flat front surface

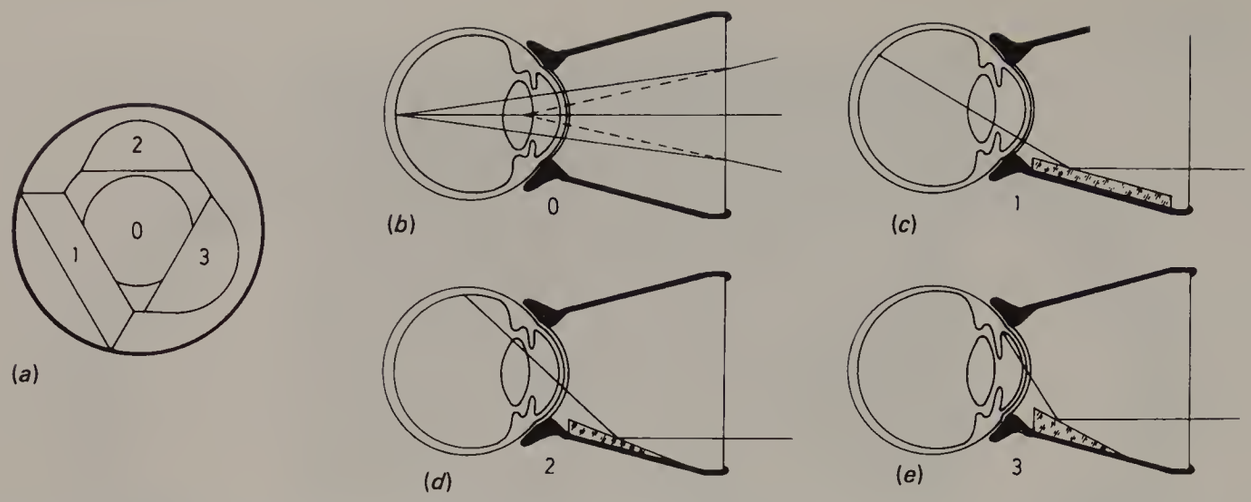


Figure 23.14 (*a*) Location of mirrors in the Zeiss three-mirror goniolens. 0 gives direct viewing as in (*b*). 1, 2 and 3 are mirrors inclined as in (c), (d) and (e). (*b*) The central fundus viewed directly through portion 0, without utilizing a mirror. (*c*) Observation of the midperipheral fundus using mirror 1. (*d*) Observation of the peripheral fundus using mirror 2. (*e*) Observation of the anterior chamber angle using mirror 3

Goldmann and Schmidt (1965) also described a contact lens which allows observation of the ciliary body and ora serrata with the assistance of scleral depression. It is similar to the three-mirror lens shown in *Figure 23.15*, but has one mirror inclined at 62° with the scleral depressor opposite it, as in *Figure 23.15*, allowing the depressed area to be seen in the centre of the mirror.

A paediatric three-mirror lens is also made by Haag–Streit in two sizes, one for the newborn and one for older children.

A lens similar to the Lovac Direct Goniolens (*see Figure 23.8*), known as the Lovac Peripheral Fundus contact lens, also allows direct observation of the peripheral fundus. The lens must be rotated to see the entire peripheral fundus and a scleral depressor is used to view the ora serrata. Schirmer (1965) described a modification of the Troncoso goniolens using either plane or concave facets. These may form part of the lens or may be additions adhering to the lens with methyl cellulose, and thus movable over its surface. The fundus may be inspected through these facets by means of a special gonio slit lamp suspended from above. These facets enable observation as far round as the ora serrata and pars plana of the ciliary body (*Figure 23.16*). Better viewing, with a bigger field of view, is obtained if the facet is cut with its surface as near to the pupil as possible (*Figure 23.17*).

An entirely different method of observation of the fundus is employed when using the Panfunduscope, a lens manufactured by Rodenstock (*Figure 23.18*). It allows the entire central fundus beyond the equator to be seen at one time, by means of a two-element optical system. A high positive lens contacts the cornea via a contact fluid such as methyl cellulose, and forms a real inverted image of the fundus, reduced in size by about 30%. To obtain field flatness and an image of adequate size, this real fundus image is formed within a completely spherical lens which then allows it to be viewed by the stereomicroscope of the slit lamp, the latter compensating via its magnification for the image size reduction.

Foreign body locator

Metallic intraocular foreign bodies show up on X-rays, but their relative position is difficult to decide on without adequate reference marks on the X-ray.

These reference marks may be provided by lead pellets incorporated in a scleral contact lens. Typically, four to six lead pellets are used (*Figure 23.19*), and X-rays taken in different planes allow the metallic intraocular foreign body to be located with respect to these. This method satisfactorily locates foreign bodies; their removal is then effected with a strong magnet from the nearest position to the foreign body. A similar lens has a metal ring for X-ray localization (*Figure 23.20*). However, in most countries these methods of localization have been superseded by the use of ultrasonic apparatus.

Vitrectomy

Where vitreous replacement is to be carried out lenses such as those made by Medical Workshop (Holland) aid observation. Any one of a number of high minus glass lenses may be placed on the eye in a silicone scleral ring support. They are held in contact with the cornea by methyl cellulose or similar viscous solution. They are illustrated in *Figure 23.21(a)–(i)*. When the cornea has opacities it may be necessary to use a temporary keratoprosthesis, as depicted in *Figure 23.22(a)–(c)*, in order to see to carry out pars plana vitrectomy.

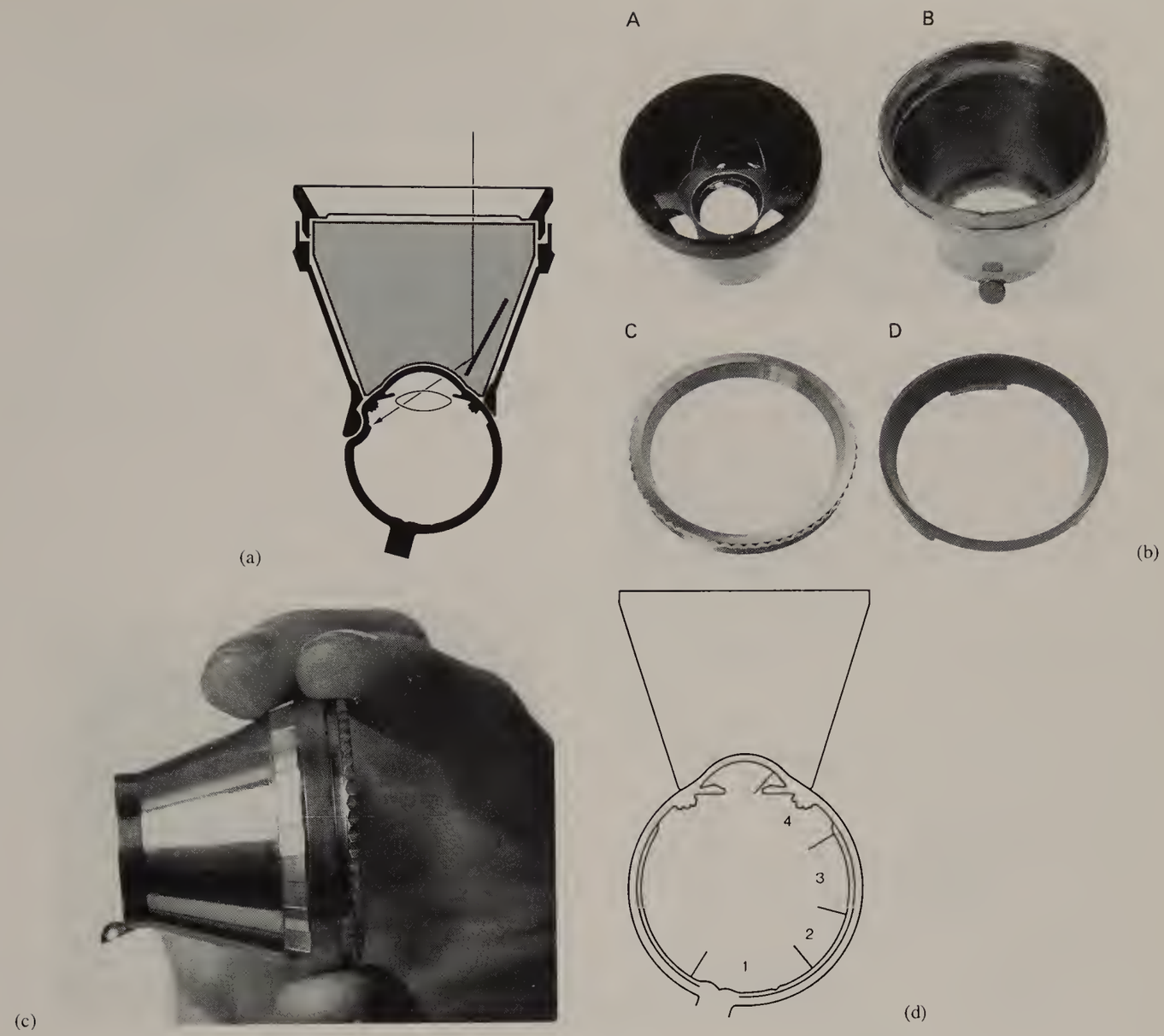


Figure 23.15 The Haag–Streit three-mirror diagnostic lens. (*a*) Diagram showing observation of the ora serrata using a 6 mm ball scleral depressor attached to the mount opposite the 59° mirror. (*b*) The three mirrors can be seen in A, the mount with scleral depressor in B, a locking ring C to hold the two together, and a plastic protection ring D, to prevent scratching of the front surface of the lens. (*c*) Side view showing scleral depressor which is rotated by the middle finger on the milled ring, the lens being held by thumb and forefinger on the notched locking ring or plastic protective ring if in place. (*d*) Diagram to show areas of the eye seen with the lens. Area 1 is seen through the plane face, 2 via the 73° mirror, 3 via the 66° mirror, and 4 via the 59° mirror. (Reproduced by kind permission of Haag–Streit Ag., Switzerland)

Exophthalmometry

Contact lenses incorporating a metallic insert at the central optic have been used with X-rays to make measurements for both relative and absolute exophthalmometry. Silva (1967) described these techniques.

Contact lenses for laser surgery

Photocoagulation employing argon, krypton or Nd:YAG (neodymium:yttrium–aluminium–garnet) lasers are used for:

- Iridectomy and trabeculotomy, as in the treatment of glaucoma.
- Capsulotomy and similar treatments to destroy opaque membranes in the pupillary region, often following insertion of intraocular lenses (pseudophakia).
- Vitrectomy to break up severe vitreous opacities and post-haemorrhagic conditions in the vitreous likely to result in retinal detachment.
- Certain types of retinal detachment, and for sealing new blood vessels in the retina particularly in diabetic patients.

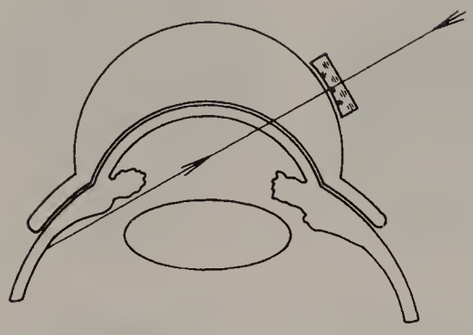


Figure 23.16 Observation of the ora serrata by means of a Troncoso goniolens with negative additional lens

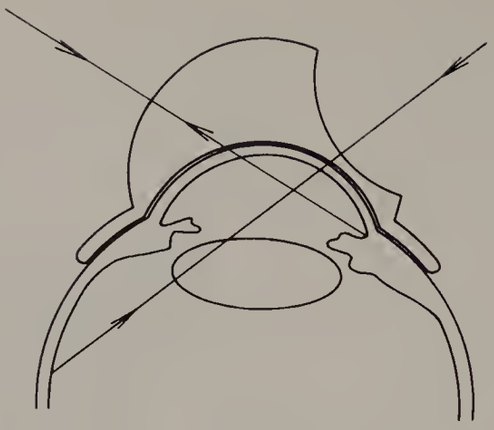
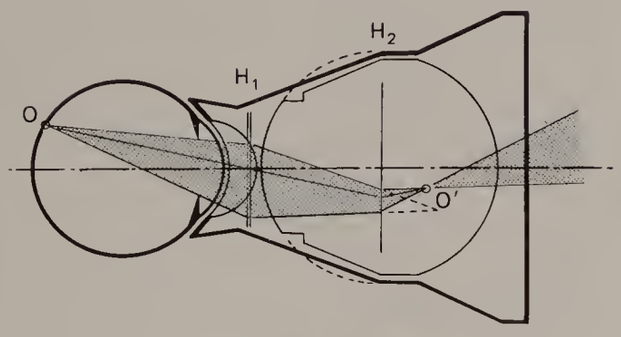


Figure 23.17 A negative facet cut into a Troncoso goniolens to allow observation of the peripheral fundus as well as the anterior chamber angle



(a)



(b)



(c)

Figure 23.18 The Rodenstock Panfunduscope. (*a*) Ray diagram showing the high positive lens in contact with the cornea, with its principal planes at H_1, and in front of it the spherical lens with the principal plane H_2 through its centre of curvature. For simplicity the rays showing the fundus point O imaged within the spherical lens at O′, are drawn as if refracted at the principal planes rather than at the lens surfaces. The entire fundus beyond the equator is imaged within the spherical lens and viewed by the slit lamp. (*b*) The lens in its mount which allows it to be supported by the observer's fingers and also acts to hold apart the patient's eyelids. (*c*) The supporting cone is removed for cleaning, revealing the spherical lens. (Reproduced by kind permission of Rodenstock)

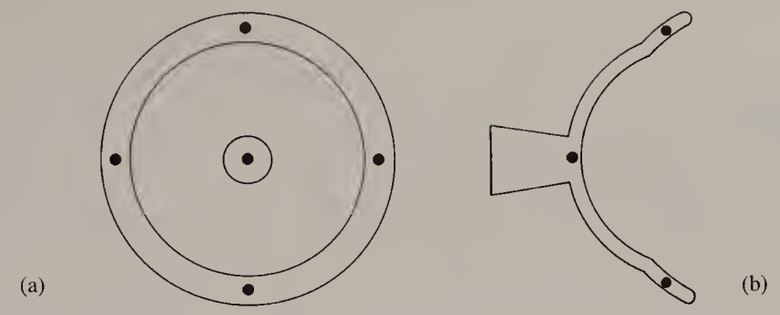


Figure 23.19 A foreign body locator with a handle attached to the front surface, showing lead reference pellets. (*a*) Direct view: (*b*) cross-section

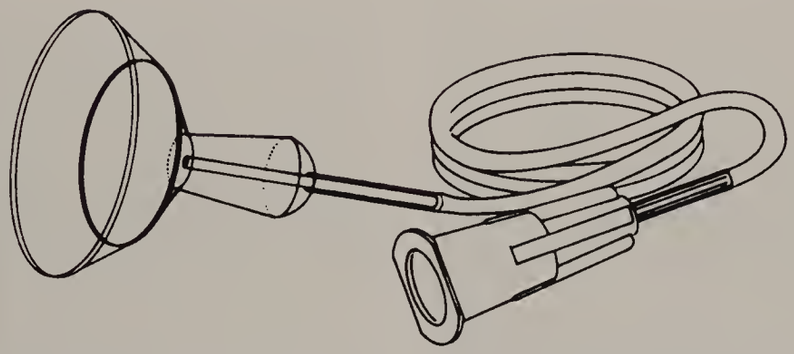


Figure 23.20 The Lovac Comberg contact lens for X-ray localization, containing a metal ring opposite the limbal region. (Reproduced by kind permission of Medical Workshop, Holland)

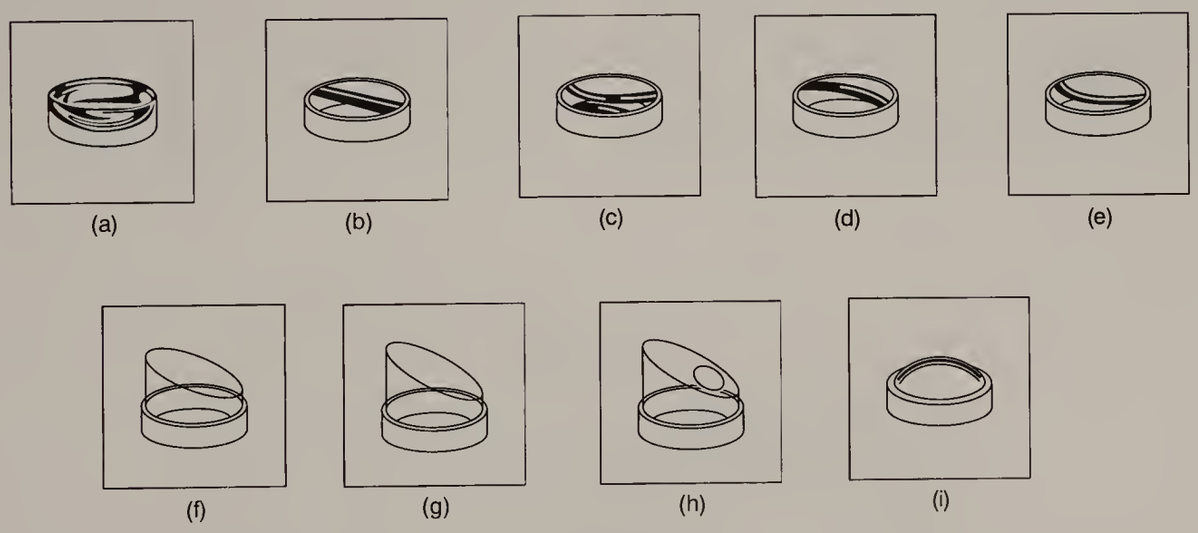


Figure 23.21 Vitrectomy lens system. The glass vitrectomy lenses are supplied with a special silicone scleral ring. Using methylcellulose the lens can be positioned on the eye. There is no need for manual holding or sutures. The lens can be easily rotated around its axis. (a) Kilp flat lens 60 D. Field of view 20°. Central posterior pole and central vitreous (b) Machemer flat lens. Field of view 20°. Central posterior pole and central vitreous (c) Landers biconcave lens 93 D. Clear view of the fundus in an air filled phakic eye (d) Machemer magnifying lens. Visualization of structures deep in the vitreous cavity or on the retinal surface (e) Peyman wide field lens. Field of view 30° central posterior fundus (f) Tolentino 20° prism lens. Posterior peripheral fundus and posterior peripheral vitreous (g) Tolentino 30° prism lens. Peripheral viewing beyond the equator (h) Woldoff prismatic biconcave lens. Allows clear view of retinal periphery in gas filled or pseudophakic eyes (i) Biom Eckhardt lens, for use with Oculus biom system (Reproduced by kind permission of Medical Workshop, Holland)

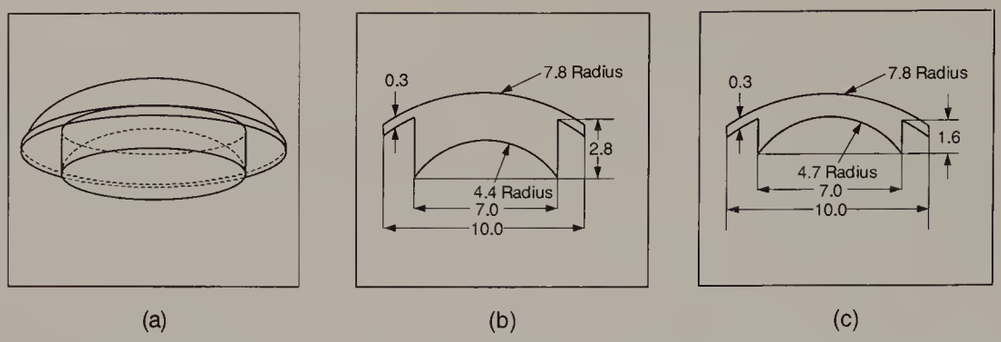


Figure 23.22 Keratoprosthesis lenses for pars plana vitrectomy. (*a*) General view of Eckhardt temporary silicone keratoprosthesis to enable viewing of the interior eye during pars plana vitrectomy. Shown in cross-section in (*b*) and (*c*) are constructions suitable for different types of corneal opacity. (Reproduced by kind permission of Medical Workshop, Holland)

To avoid risk of damage by the laser beam to areas of the eye which are not being treated, a minimal amount of laser energy should be used. To utilize this minimum amount of energy in as efficient a way as possible special contact lenses are often helpful. These are anti-reflection coated to give maximum transmission of the low energy beam. They can aid the surgeon by magnifying the image seen through the slit-lamp biomicroscope enabling accurate location of the laser beam focus; they can increase the cone angle of the beam (*Figure 23.23*), thereby dissipating the energy of the beam both in front of and beyond its focus, so avoiding damage to tissues in those areas; and they can, by suitable optical design, form a pinpoint focus rather than a comatic blur.

During laser surgery the eye must be kept wide open and eye movements avoided. This could lead to drying of the cornea disturbing the efficiency of the laser beam and risking corneal damage. The special contact lenses used have the added advantage of keeping the cornea moist, also of neutralizing any corneal irregularities which might otherwise distort the beam, and they keep the eyelids out of the way and steady the eye, as well.

However, there are certain instances where a smaller and therefore more efficient focal spot is formed without the use of a contact lens. For the midvitreous area, 12–15 mm behind the cornea, provided the eye is phakic, then the largest cone angle and smallest spot size is achieved without a contact lens in place (*Figure 23.24*). Beyond this area, and for retinal surgery, a lens with a plane front surface is optimal (*Figure 23.25*), whereas in front of the midvitreous lenses with convex front surfaces are desirable, as shown in *Figures 23.23*, *23.26* and *23.27*, illustrating pupil area surgery, iris surgery and trabeculotomy, respectively.

Alternatively laser gonioscopy lenses such as the Etienne lenses made by Haag–Streit may be used. These have three mirrors set at 57°, 59° and 61° inclination, the smallest being at 57°, as seen in *Figure 23.28*. The mirror which renders the laser beam as close to parallel to the iris as possible should be used, i.e. as close to perpendicular to the trabecular tissue to be treated as can be arranged. Greater magnification is afforded by aplanatic lenses on the front surface of the goniolens, as *Figure 23.29* shows. These give ×1.5 magnification and decrease the coagulated spot by two-thirds, as well as reducing the power density at the cornea.

For retinal laser surgery Rodenstock manufacture a spccial anti-reflection coated, mineral glass version of the Panfunduscope (*see Figure 23.18*).

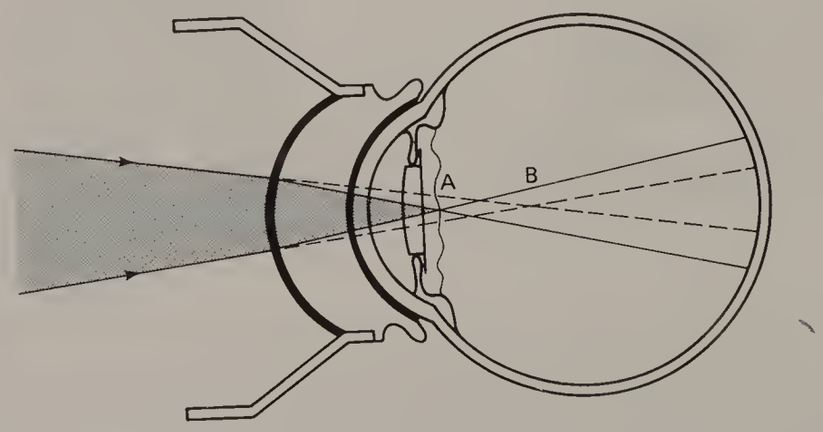


Figure 23.23 Lens used for laser capsulotomy. The spherical front surface refracts the beam to a larger angle at A, thereby diffusing the energy in the surrounding tissues. This gives less risk of damage than with a plane front surface which would give a smaller angle of beam, B, with less spread and more concentration of energy in the surrounding tissues

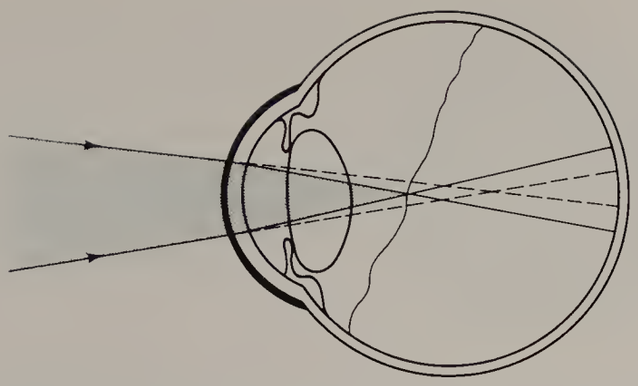


Figure 23.24 In the midvitreous region, provided the eye is phakic, then laser surgery is optimal without any contact lens

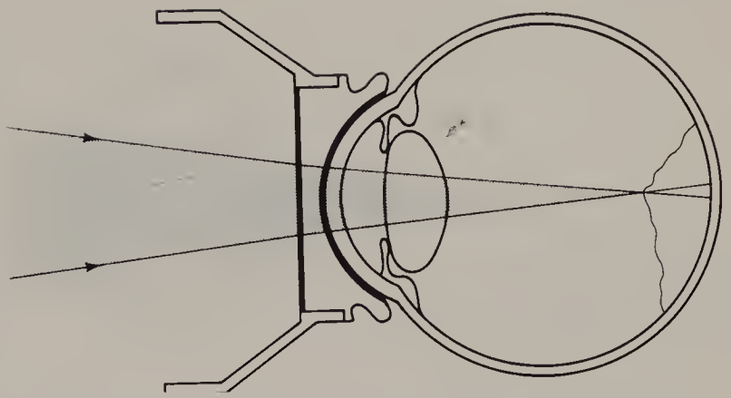


Figure 23.25 For the retina and rear vitreous region a Goldmann type of lens with flat front surface provides optimum conditions for laser surgery

Protective lenses

Radiation treatment

For malignant tumours of the orbital region, the eye itself may be protected by a plastic-covered lead scleral shell. Where the tumour is ocular, a partial lead shell may be specially constructed to cover all of the anterior eye except the part to be irradiated.

Laser surgery

Laser removal of port wine stains from the eyelid and cheek regions require protection of the eyeball from the laser light. A soft malleable hemispherical shaped eyeball protector has been developed for this purpose by Medasil (Surgical) Limited*. It is known as a Laserguard, and is a sterile single-use disposable item having a removal tag to ease removal from the eye. It has a matt pink surface preventing reflection of the laser beam affecting the operator and it is opaque to light and laser radiations.

*Medasil (Surgical) Ltd, Leeds LS10 1AU, England.

Visible light

During surgery of the anterior segment of the eye, particularly when an operating microscope is used, the intensity of the visible light beam is very high. With the dilated pupil and length of exposure of the eye to this beam, there is risk of damage to the ocular tissues from the visible, infrared and ultraviolet radiations (Kirkness, quoted by Hardy, 1986).

Brown and Parrish (personal communications, 1987) developed a black PMMA corneal contact lens of total diameter 11.00 mm and back optic radius of 10.00 mm, having a dimple in its front surface to enable it to be moved easily over the cornea with a probe or forceps. The flat curvature and large size also facilitate easy movement, permitting 90% of the pupil area to be covered during surgery. By blocking wavelengths below 500 nm they feel that there is less risk of damage to the macular area during, for example, cataract surgery and implantation of intra-ocular lenses. As a result of this simple expedient the number of patients suffering subsequent macular oedema has been reduced.

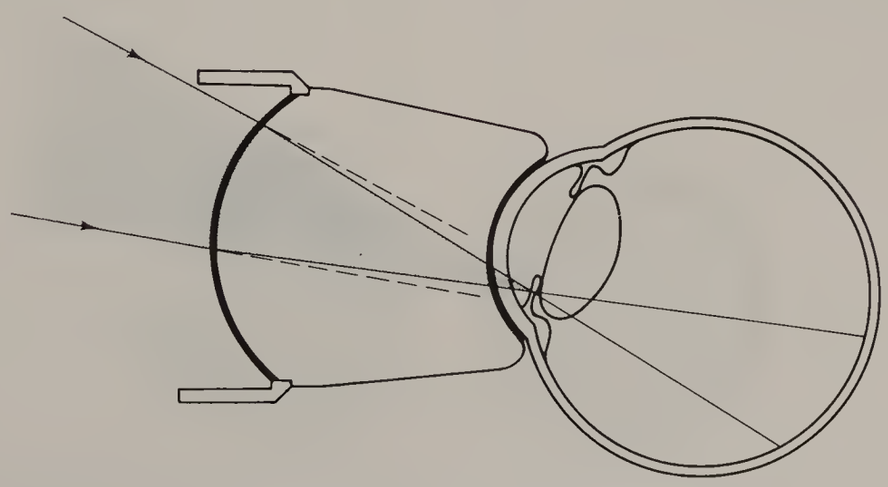


Figure 23.26 For iris surgery a thick convex front-surfaced contact lens provides best conditions for laser use

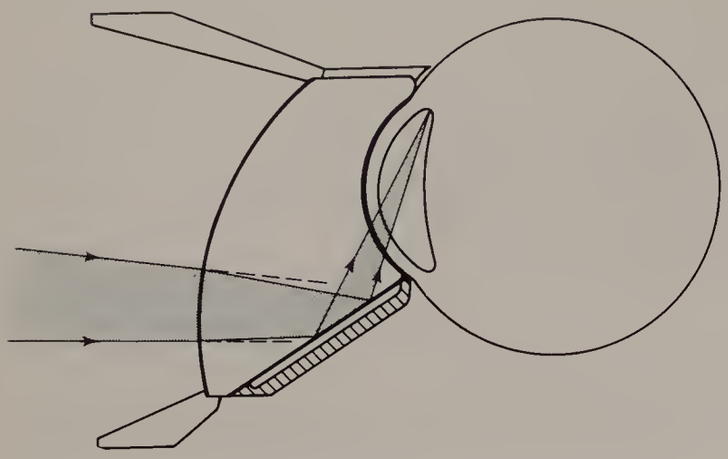


Figure 23.27 In the anterior chamber angle, for trabeculotomy, a goniolens with spherical front surface provides a small focal laser spot and a large angle beam

Protection from visible radiation in normal contact lens wear, for those individuals who are photophobic, is now an easy matter as most contact lens materials are available in a variety of tints. Further comments on tints are to be found on p. 841.

Ultraviolet radiation

As discussed in Chapter 8, ultraviolet radiation is damaging to ocular tissues. Not only may the epithelium, stroma and endothelium of the cornea itself be damaged, but also the crystalline lens may be affected, leading long term to early senile cataract formation. Ultraviolet exposure may also contribute to macular degeneration and loss of retinal sensitivity (Pitts, 1981; Bergmanson quoted by Benjamin, 1987).

As long ago as 1964, Ball postulated that some of the photophobia experienced by new contact lens wearers, transferring from spectacles to contact lenses, may be due to increased ultraviolet radiation reaching the cornea, which is most sensitive to a radiation of 288 nm. Most plastics, tinted or otherwise, have a cut-off at 290 nm.

Fortunately it is not just spectacle lenses which can be used to block ultraviolet radiation; contact lenses also are now available in all types of material – soft, RGP and PMMA – with varying amounts of ultraviolet absorption. Amongst others, soft lenses such as Permaflex UV and Precision UV (Wesley Jessen) block most wavelengths below 400 nm. The Lunelle aphakic ultraviolet lens and the Lunelle standard ES70 UV absorbing lenses have a light transmission cut-off at 350 nm. Other ultraviolet-absorbing soft lens materials are available from laboratories to be made up to prescription.

UV-absorbing RGP lenses are also available such as the Boston Equalens I and II, Optacryl UV, RXD and others (*see* Chapter 10).

A study of some of these materials by Chou *et al.* (1988) showed that the RGP materials are most effective in blocking UV-B (290–320 nm) and UV-C (200–290 nm) radiations, and all of the materials tested transmitted a significant amount of UV-A (320–400 nm). The soft lens materials, although less effective in blocking UV-B and UV-C, are made up in lens forms which cover the entire cornea, whereas RGP lenses, being smaller, do not give complete corneal protection. Of the materials they tested, Chou and co-workers showed that the material with the best protection factor (PF) was Vistakon UV-Bloc (Johnson & Johnson). PF is inversely proportional to the amount of ultraviolet radiation transmitted and therefore depends on lens thickness and power. They concluded that none of the contact lens materials is as effective in blocking ultraviolet light as proper sports and industrial eyewear, but that all these contact lenses probably afford ocular protection against normal lifelong exposure to environmental ultraviolet radiation.

Although rarely fitted now, there are still some PMMA materials in which the molecular structure is altered to improve the wettability of the surface. The method of cross-linking renders them opaque to wavelengths of less than 370 nm – thus cutting out all UV-B and UV-C radiation and a lot of UV-A. Some RGP materials which contain UV inhibitors also block the peak wavelength (365 nm) emitted by ultraviolet contact lens fitting lamps so that the fluorescein pattern cannot be satisfactorily seen, but must be viewed



Figure 23.28 Etienne three-mirror laser gonioscope lens with flat front surface. (Reproduced by kind permission of Haag–Streit Ag., Switzerland)

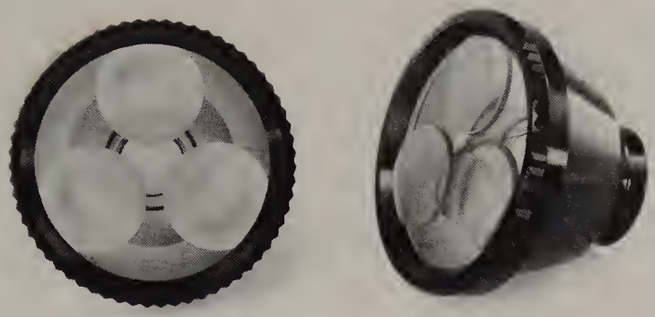


Figure 23.29 Etienne three-mirror laser gonioscope lens with three aplanatic lenses, each giving ×1.5 magnification, which assists observation thereby helping the surgeon, produces a smaller focal spot, and diffuses the energy more rapidly in the surrounding tissues. (Reproduced by kind permission of Haag–Streit Ag., Switzerland)

with slit-lamp biomicroscope and blue filter to obtain an accurate indication of the fit (*see* Chapter 10).

Therapeutic lenses

Contact lenses are often helpful in treating certain eye conditions. They fall into several categories.

Bandage and special soft lenses

Hydrophilic contact lenses, usually of high water content, have been successfully used as corneal bandage lenses for severe corneal ulceration, following keratoplasty and in the management of bullous keratopathy (Petropoulou, 1975; Aquavella, 1976). In the latter case they may be used in conjunction with hypertonic saline drops. In neuroparalytic keratitis and in the dry-eye syndrome silicone rubber lenses may be used as a corneal bandage, but it is still necessary for some of these patients to be supervised as hospital in-patients because of the high risk of infection. The presence of the bandage lens aids regular corneal healing and prevents the eyelid from rubbing the damaged cornea. Although less often fitted now because of the success of modern intraocular implants, aphakic continuous wear hydrophilic lenses have also been successfully applied at the time of operation for cataract extraction, acting as a splint and bandage, as well as permitting immediate good vision postoperatively (Kersley, 1975). Astin (1987) described fitting specially shaped soft lenses, cut with an upper crescent or upper truncation to avoid intraocular fluid draining blebs beyond the upper limbus, and proud upper scar tissue following cataract surgery. These types of lens are dealt with, in detail, in Chapter 20.7.

Medical applicators

The use of hydrophilic lenses as medical applicators is now well established (Hillman, 1976). As stated in Chapter 20.7, pp. 772–773, they have been used in the application to the eye of antibiotics, mydriatics, local anaesthetics and particularly the miotic pilocarpine in the treatment of glaucoma. The lens is soaked in the drug for about 2 hours so that it becomes saturated. When placed on the eye there is a slow release of the drug into the conjunctival sac over the following 2 hours. Hillman reported that high water content material is slightly more efficient than low water content material, and with pilocarpine treatment best results have been obtained using a solution of 1% strength rather than the higher strengths which are usually used in drop form. Hillman also described the Ocusert which is shaped to be placed in the lower or upper fornix and consists of a hydrophilic core, soaked in pilocarpine, 2% or 4%, surrounded by a hydrophobic membrane to delay drug release. This provides continuous delivery of the drug for 7 days, at which time it is replaced.

Backman (1983) reported on the use of a slow-release artificial tear (SRAT) insert known as Lacrisert similar to the Ocusert. Reaction to it varied considerably and in some patients it gave rise to blurred vision, but it is another option worth considering for dry-eyed patients.

Collagen lenses or shields, sufficiently transparent to permit hazy vision through them, can also be used for applying both water-soluble and non-water-soluble drugs to the eye, and to aid postoperative healing. They can be used with any preservative provided the patient is not allergic to it. The shield is placed on the eye by the practitioner, after using a topical anaesthetic if necessary, and does not require removal as it gradually dissolves away. They are based on an idea by Fyodorov of Moscow (Morris, 1988) of using collagen from pig sclera.

Other medical applicators are still sometimes used in intensive drug therapy when it is necessary to keep antibiotic or other drugs in constant contact with the eye. Two examples are the Klein applicator (Klein, 1949) and the Anderson medicator (Anderson, 1952), shown in *Figures 23.30* and *23.31*. Both basically consist of modified scleral contact lenses. The Anderson medicator has two holes – through one the drug is instilled and out of the other air escapes. The optic zone gives ample corneal clearance, and this acts as a reservoir for the drug. The Klein applicator

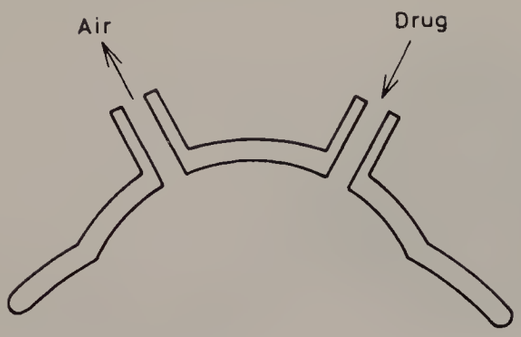


Figure 23.30 The Klein applicator

is similar but has two tubes extending from the optic in place of the holes. This is easier for nurses to handle but a little less comfortable to wear than the Anderson medicator as the lids cannot close over it.

Another, more elaborate lens is one containing a platinum electrode which almost touches the cornea. Another electrode is attached to the cheek, or elsewhere on the body, and a continuous low voltage electric current is passed. This serves to make the cornea more permeable. Drugs administered via the tube and holes around the electrode gain more rapid entry to the cornea and thence into the aqueous. The lens is illustrated in section in *Figure 23.32*.

Splints

In the emergency departments of hospitals, scleral shells or scleral rings (the outer annulus only of a scleral lens) are sometimes applied to the eye following facial burns. The shell prevents the lids sticking to the globe (symblepharon). Another type of shell can be used to prevent the lids sticking together (ankyloblepharon). The shells are left in place during the healing process so that the fornices remain formed, otherwise the conjunctival sac might become almost non-existent. As an alternative, large soft lenses may be used (*see* Chapters 17 and 20.7). Scleral or silicone rubber lenses may have to be worn during attacks of Stevens-Johnson syndrome, when all bodily mucous membranes become severely irritated: in the eye, the bulbar and palpebral conjunctivas may adhere unless a scleral or large silicone rubber lens is used to prevent it (*see also* Chapters 17 and 20.7).

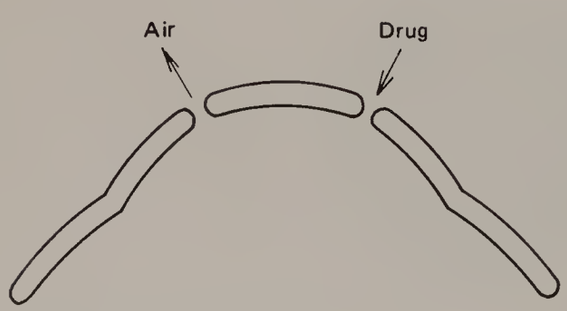


Figure 23.31 The Anderson medicator

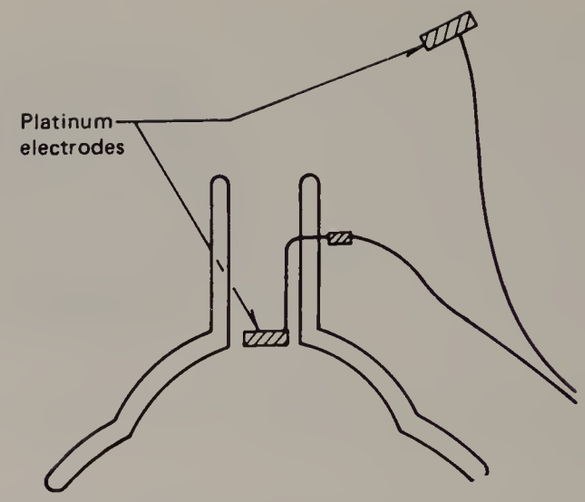


Figure 23.32 An iontophoresis contact lens used for application of drugs to the eye, seen in cross-section

Splints, in the form of large corneal lenses, have been used to hold corneal grafts in place following keratoplasty and to hold the cornea in position following cataract extraction. In both cases, the front surface of the cornea is not held by stitches, which tend to encourage irregular healing, but by the smooth spherical back surface of the contact lens. Good optical results have been achieved with this method of supporting the healing tissue. The splint itself is held by stitches to the bulbar conjunctiva. When these are cut, the splint is removed by special toothed forceps which fit into small slots on the front surface of the splint (*Figure 23.33*).

Orthoptic uses

A contact lens may be used as a cosmetic occluder in cases of intractable binocular diplopia. Any type of contact lens may be used. Usually, complete occlusion can only be

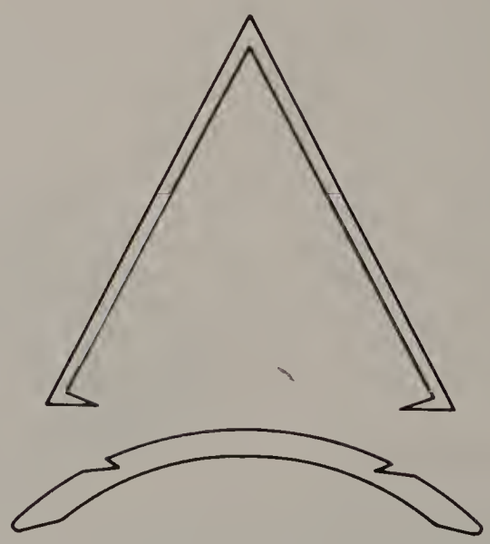


Figure 23.33 A contact lens splint and toothed forceps in cross-section

achieved by having an opaque iris pattern and opaque pupil (*see* Chapter 20.6), but an opaque pupil in an otherwise clear lens may be sufficient.

In squint treatment, contact lens occluders have been used on the better eye to assist in eliminating amblyopia. These are often unsuccessful as children soon learn to remove the lens! Rather than fitting an opaque lens, adequate occlusion may be achieved with a high negative lens or a very high positive lens (Catford and Mackie, 1968).

Partial occlusion with contact lenses has also been used in the treatment of suppression.

The fitting of anisometropic amblyopes with contact lenses can improve the visual acuity and assist in the orthoptic treatment of squints in such cases.

Control of refractive errors

It has been suggested that contact lenses prevent the progression of myopia. Most contact lens practitioners used to notice the apparent stabilization of myopia from the time when PMMA contact lenses were first worn, and there are many reports of such instances. Most, such as Dickinson (1957), Morrison (1958), Neill (1962) and Nolan (1964), attributed the stabilization directly to the contact lenses. Stabilization of myopia has been reported where no flattening of the cornea occurs, although the latter can obviously bring about reduction in myopia. On the other hand, Bailey (1966) showed that the apparent halt in the increase in myopia which occurred when PMMA contact lenses were worn could be explained by alterations in corneal curvature being neutralized by the liquid lens, by too much negative power being used at the start to minimize the blur due to residual astigmatism, and by other factors such as flattening of the contact lens itself.

Kelly and Butler (1964, 1971), Baldwin *et al.* (1969), and others, including the author, investigated this apparent stabilization of myopia. Controlled studies were undertaken in an attempt to produce positive proof of the therapeutic value of contact lenses on myopia. Results (Stone, 1976) showed that conventionally fitted PMMA corneal lenses, fitted with BOZR just steeper than the flattest keratometer reading, have brought about a slowing down of the rate of progress of myopia in a group of contact-lens-wearing children, as compared to a similar group of spectacle-wearing children. About half of the reduction in rate of progress could be attributed to corneal flattening by the contact lenses but the remainder can only be explained on the basis that wearing corneal lenses has some retarding effect on axial elongation. This aspect was monitored by Perrigin in a study of 9 to 12 year olds wearing silicone–acrylate RGP lenses which have also been found to retard myopic progression (Perrigin, reported by Morris, 1988).

The technique of orthokeratology developed many years ago (Jessen, 1964; Nolan, 1969; Grant and May, 1972) is a purposeful attempt to reduce the refractive error of an eye by changing the corneal curvature with rigid corneal contact lenses. The change in corneal curvature is normally brought about in gradual stages, by progressively changing the back surface radii of curvature of the lens fitted, utilizing special lens designs. The technique has certain uses in helping recruits achieve suitable standards of visual acuity to gain entry to the armed services or other occupations, and it has permitted many ametropes to obtain adequate visual acuity without any form of optical correction for at least part of the time. In some cases, myopia is reduced but contact lenses still have to be worn to permit maximum visual acuity; in other cases emmetropia is achieved and may last for a few hours, days, weeks or months but then retainer lenses must be resorted to for varying periods of time. To reduce myopia the aim is to fit lenses which slightly flatten the cornea, but do not cause distortion, oedema or tissue damage (*see* Chapter 19).

Kerns (1977) noted that the corneas of young people are more likely to be flattened than those of older patients, thus there remains the possibility that orthokeratology for young myopes wearing rigid gas permeable retainer lenses may reduce or reverse the progression of their myopia. Orthokeratology is discussed in greater detail in Chapter 19.

As an aid to defective colour vision

A red contact lens, of peak transmission 595 nm, worn in one eye only was recommended by La Bissoniere (1974) in an attempt to overcome certain red–green colour deficiencies, by allowing a comparison of the different contrasts then perceived by the two eyes. Known as the X-Chrom lens, during binocular viewing it gives rise to a different perception of hues, altering their saturation or brightness, or imparting a lustre, and the wearer learns to relate that appearance to a particular colour name. It takes some time to adapt to the situation but it is reported as being very successful. During the initial stages of wear, until adaptation has taken place, there may be some disorientation of depth judgement, which should be pointed out to patients for reasons of safety. Ciuffreda (1980) reported on the Pulfrich effect elicited when subjects first wore the lens in one eye, being equivalent to the effect of a 0.57 neutral density filter or of 27% light transmission.

Soft lenses with just the pupil area tinted red are cosmetically more acceptable than the smaller rigid lenses, are more comfortable and almost as effective in improving colour perception (Wood and Wood, 1991). Soft lenses with a larger area tinted red to cover the complete iris diameter are also manufactured by many contact lens companies and are proving effective, albeit they give rise to one iris looking darker than the other, but this can be balanced by a neutral grey lens on the other eye if necessary.

Contact lenses used for research into visual function

Contact lenses are a means of holding suitable objects in contact with the eye for research purposes. Such objects may be electrodes, thermistors, oxygen probes, mirrors or

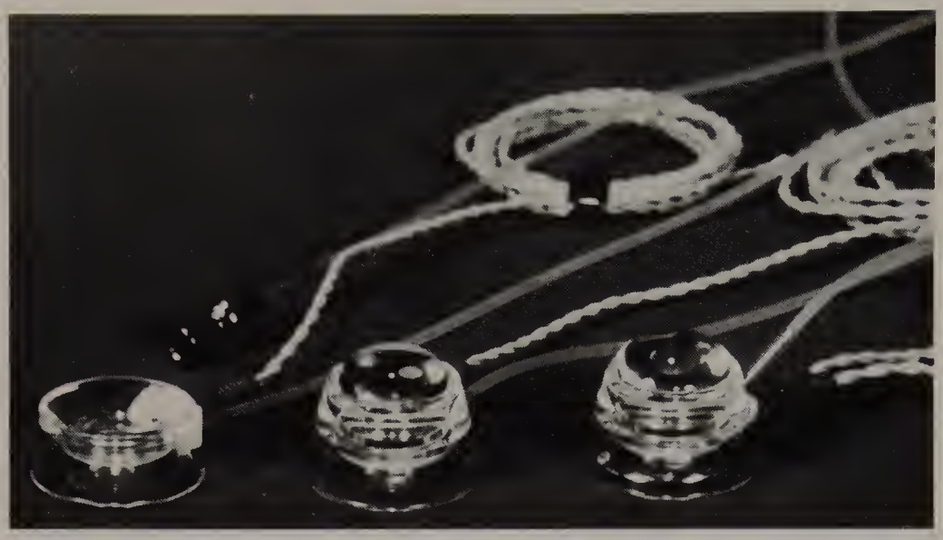


Figure 23.34 Lovac electroretinography lenses. These are lightweight electrode-bearing contact lenses used in ERG studies. Each has a small scleral zone and a blepharostatic cone which takes different colour filters and diaphragms. A circular silver electrode in the limbal region is connected to a tiny permanently attached electric flex leading to the electroretinograph. (Reproduced by kind permission of Medical Workshop, Holland)

telescopic devices, all of which have been incorporated in contact lenses at various times.

Electrodes

An electrode incorporated in a contact lens may be used in iontophoresis for therapeutic purposes, as already mentioned. For research and investigative purposes, the most frequent use of electrodes in contact lenses is in ERG (electroretinography). Most electrical activity in the eye region takes place in the retina, and the potential difference in the retina may be measured – as different light stimuli are applied – by means of one electrode attached to the nearby skin and one touching the eye, the two electrodes being connected to a suitable meter, amplifier and pen-recorder or computer analyser. Typical contact lenses for this purpose are illustrated in *Figure 23.34*. The conical front surface projection is to prevent eyelid closure and to prevent any discomfort from the eyelids contacting the electrode. Electrodes used to be of silver or platinum inserted into a small scleral lens. The method of manufacturing these lenses was described by Fletcher (1966) under the pseudonym Haptos.

A flexible glycol methacrylate corneal lens was described by Bornschein *et al.* (1966). This incorporated a silver spherical electrode in its front surface. The lens itself was electrically conducting. A corneal contact lens using a silver electrode was also described by Ruedmann and Noell (1961). ERG studies by Alvis (1966) predicted that this could form an additional diagnostic test in glaucoma.

It is more common, nowadays, to use gold electrodes inserted into a corneal-sited lens, for example the ERG-jet lens made by Universo SA of Switzerland.

Other more complicated types of electrode are used for measurement of temperature and gas exchange at the eye's surface and are described in the appropriate sections below.

Eye movements

Studies of voluntary and involuntary eye movements have been made by mounting a small mirror on a contact lens and reflecting light from a stationary source. The angular movement of the reflected image is then double the angular movement of the eye. However, the method has been largely superseded by video-photography of reflections from the anterior surface of the cornea, and by lenses incorporating a light emitting diode similar to the fundus observation lens described by Richards *et al.* (1993) (*see* p. 823).

Stabilized retinal images

A better understanding of the physiological and psychological aspects of seeing has been achieved by studying what happens when the retinal image of an object remains stationary on the retina, i.e. when small movements of the retinal image, due to saccadic movements of the eye, are prevented. This may be done by flash exposure of short duration or by means of contact lenses, which, because they move with the eye, may be used to overcome the effects of eye movements in the formation of the retinal image.

Two basic systems have been employed. One utilizes a tightly fitting contact lens with a protruding stalk on the end of which is a plane mirror. The mirror is used to reflect light from a target through a compensating optical system into the eye. Such a system was originally devised by Ditchburn and Ginsborg (1952). Another system (Millodot, 1965) is depicted in *Figure 23.35*.

Any movement of the eye causes a corresponding movement of the mirror, and the reflected image of the target is moved through twice this angle. To compensate for

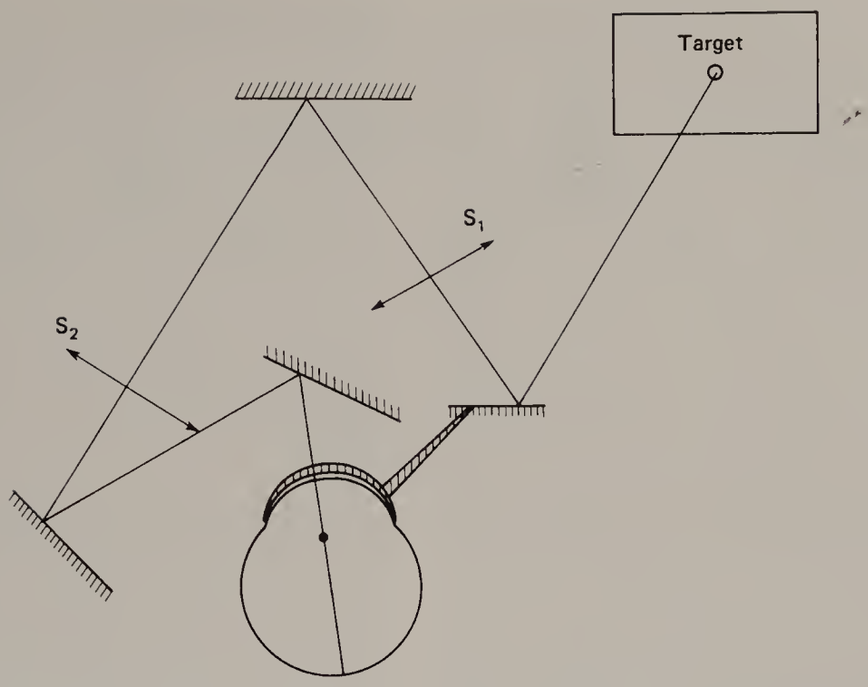


Figure 23.35 A contact lens with projecting stalk and mirror attached, used to produce a stabilized retinal image by means of a mirror and lens system (after Millodot, 1965)

this doubling of angular movement, lenses S_1 and S_2 give a reduction in magnification of a half. Thus, light passing through the optical system is always imaged on the same portion of the retina, regardless of eye movements.

The other system, used by Evans and Piggins (1963), is to incorporate a small telescopic device into the contact lens itself, as shown in *Figure 23.36* and as described by Evans (1965). A suitably illuminated target is placed approximately in the anterior focal plane of a high positive lens, which is itself separated from the contact lens by an afocal button. The whole optical system is contained in aluminium tubing, and the target and positive lens are movable relative to each other to facilitate accurate focusing on the retina.

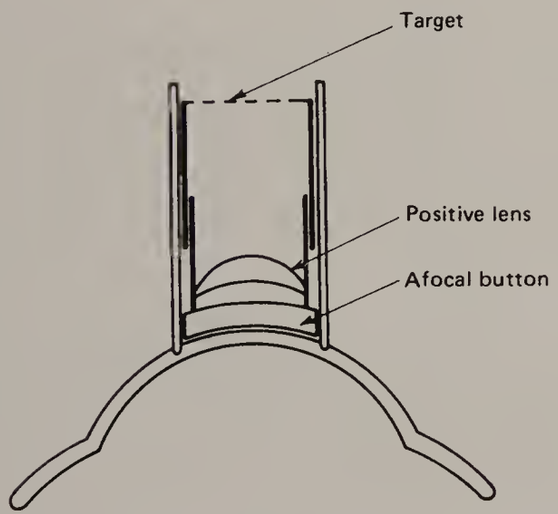


Figure 23.36 A contact lens incorporating a small telescopic device, used in the study of stabilized retinal images. The target is in the focal plane of a positive lens. Sliding supports allow some latitude in focusing. The positive lens is separated from the eye by an afocal button

In attempts to provide contact lenses which did not lag behind the eye during eye movements, rubber contact lenses with attached pressure bulbs to obtain suction were used in the past. These were liable to cause damage to the eye. Best results seem to have been achieved with small scleral lenses (17 mm back scleral diameter) for the telescopic type of device, and a 14 mm total diameter, single curve corneal lens, fitted tightly, for the type incorporating a mirror.

The results obtained with these devices suggest that perception comprises multiple pattern recognition.

Lid pressure

In the first part of a study of the effects of lid pressure on corneal shape, and on deformation or flexure of rigid lenses on the eye, Lydon and Tait (1988) used a scleral lens into which they incorporated a pressure transducer. They showed that the eye retracts 0.5 mm on blinking and 1 mm on forced blinking, and that upper lid tension is compensated for by orbital resistance and should not therefore affect corneal toricity. More research needs to be done on the effects of lid pressure on contact lens flexure.

Temperature measurement

In studying ocular changes due to contact lenses, the effects of lid aperture size, lid closure, eye position and the very presence of the contact lens itself cause temperature

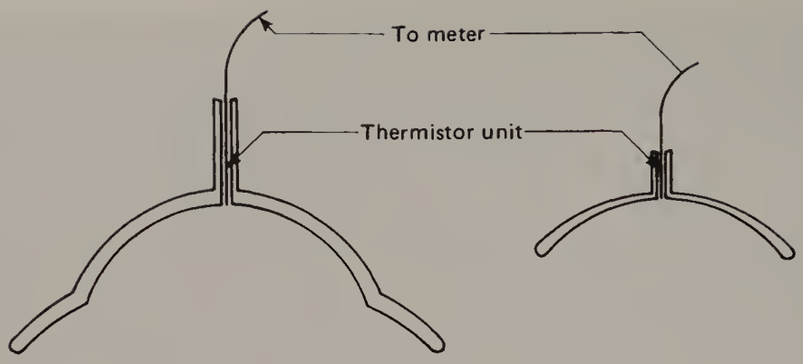


Figure 23.37 A scleral and a corneal lens, each incorporating a thermistor for temperature measurement

changes of the cornea, sometimes to an extent beyond which normal corneal metabolism can no longer continue.

These temperature changes can be monitored, using a thermistor – a tiny electrical device sensitive to temperature changes. Thermistors can be incorporated in both scleral and corneal lenses. Typical lenses are shown in *Figure 23.37*. Hill and Leighton (1965) described their findings on temperature changes of the eye when using a scleral contact lens containing one of these devices, and they have shown how the rise in temperature behind a lens affects the corneal metabolism.

Gas exchange of the cornea during contact lens wear

In order to hold an oxygen probe against the cornea, scleral lenses were used at first. Hill and Fatt (1966) described such a lens which is depicted in *Figure 23.38a*. The probe is a polarographic oxygen electrode covered by an oxygen-containing membrane. As the oxygen from this is lost to the corneal cells or surrounding liquid, the current in the electrode is lowered. A similar system was used in a corneal lens (Fatt and Hill, 1970) as pictured in *Figure 23.38b*, and lenses of this type continue to be used.

Similar systems allow the output of carbon dioxide by the corneal epithelium to be recorded.

Lenses for sports purposes

The criteria to be satisfied if contact lenses are to be worn for sports purposes are: the lens must not be capable of being misplaced on the eye due to accidental foreign pressure; the optic must remain centred; the tear lens must

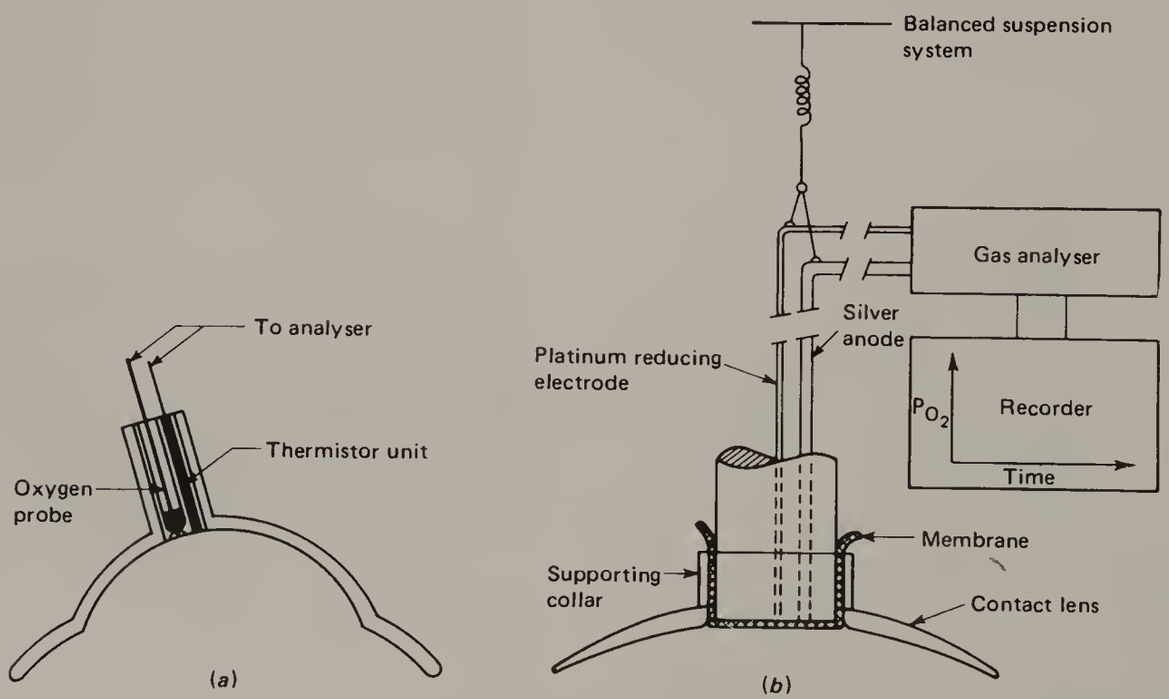


Figure 23.38 (*a*) A scleral contact lens incorporating a probe for recording oxygen tension (after Hill and Fatt, 1966). (*b*) A corneal lens used for measurement of oxygen uptake (after Fatt and Hill, 1970)

remain completely free of bubbles in front of the pupil area; and corneal metabolism should not be interfered with during the period required for the sport.

In the past (*see* earlier editions of this book), special large corneal lenses, as well as semi-scleral soft lenses and purposely designed scleral lenses have all been employed solely for sports use. With current materials and lens designs, in general a fairly tight fitting RGP corneal lens or a well-fitted soft lens satisfy the above criteria most of the time, although a slight risk of lens displacement remains. To minimize this risk a soft lens of total diameter 14.0 mm or more is desirable, fitted slightly steeper than normal. Special large soft lenses are manufactured specifically for sports purposes. A lens of 15.5 mm total diameter was described by Berman and Teig (1989), also by Legerton (1989), who recommended tinted lenses for water sports; and an even bigger lens of total diameter 18–24 mm – a scleral soft lens – described by Lichtman (1991). The same approach to lens stability is also advisable if fitting an RGP lens – as large a lens as possible should be used with a minimum of peripheral corneal clearance, and a large BOZD of 8.0 mm or more.

Softperm lenses (Wesley Jessen) (*see* Chapter 11), which replaced Saturn II lenses, and which have an RGP central zone and soft periphery overlapping onto the sclera, may prove useful for some people engaged in sports, particularly if corneal astigmatism requires correction and toric soft lenses are unsuccessful but the comfort of a soft lens is needed (Minarik, 1987).

Scleral lenses, although still ideal in that they are unlikely to be dislodged from the eye, are difficult to fit satisfactorily compared to other lenses, and they are now rarely an economic option. For all professional sports the contact lenses fitted must satisfy the standards laid down by the authorizing body of that particular sport in the country concerned (*see* Chapter 8).

Climbing and cold weather sports and activities

In a survey of contact lens wearers engaged in cold weather activities outdoors, Socks (1983) found that no significant problems were experienced and that contact lenses had a decided advantage over spectacles, as they do not mist up and do not become brittle and break as spectacles may do when cold. Contact lenses protect the eye from wind-driven ice and snow, and indeed have been successfully worn up to 26 000 feet on an assault on Mount Everest (Clarke, 1975).

Most difficulties occur with the cleaning fluids and procedures, as the liquids may freeze and contact lenses be difficult to handle with cold fingers if camping out in extremely low temperature conditions. In such cases extended wear lenses have a distinct advantage.

Swimming

There is some risk of loss of contact lenses from the eye while swimming, which is much less with soft lenses than with rigid lenses (Lovsund *et al.*, 1980), and with the latter it is less with RGP than PMMA lenses due to the mode of fitting. Other than this there is the possibility that contact lenses may to a certain extent protect the eye from chlorinated water and reduce the effects of exposing the cornea to swimming pool water which can lead to oedema (Hill, 1985; Solomon *et al.*, 1987), but this depends on methods of fitting and exposure time to pool water. If hypotonic saline or water is instilled or splashed into the eye prior to swimming, the osmotic effect is to make the lens cling to the cornea so reducing the initial risk of loss (Diefenbach *et al.*, 1988). The longer a soft lens comes into contact with pool water, the more hypotonic its own saline content becomes and the greater the risk of corneal oedema and difficulty of removing the lens from the eye, associated with the hypotonicity. (There may then be a need to bathe the lens and eye with hypertonic saline in order to effect lens removal, and incidentally to reduce oedema.) However, for short exposures, soft lenses have a definite protective function, but should be rinsed thoroughly in fresh sterile saline following any contact with chlorinated water and to minimize the risk of *Acanthamoeba* infection of the eye via the contact lens. *Acanthamoeba* is present to some degree in most types of water apart from water guaranteed to be sterile, so that swimming goggles provide the best protection and should be recommended for use over contact lenses.

Sealed scleral lenses are the ideal form of contact lens correction for swimming, with no risk of loss, and almost complete protection of the eye. However, the use of swimming goggles with normal contact lens wear is probably just as satisfactory. The optical aspects of swimming under water are covered in the following section on lenses for skin diving.

Lenses for skin diving

Under water, the power of the eye is reduced by approximately 42 D. This is due to water replacing air in front of the cornea. If the front surface of the cornea is assumed to have a radius of curvature of 8.0 mm, then the reduction in power is as follows.

$$\frac{\text{Power of front surface of cornea, in air}}{\frac{(1.376 - 1)1000\,\text{D}}{8.0}} - \frac{\text{Power of front surface of cornea, in water}}{\frac{(1.376 - 1.333)1000\,\text{D}}{8.0}}$$

$$= 41.5\,\text{D}$$

The emmetropic eye therefore becomes hypermetropic to this extent. This power loss may be replaced in two ways, as follows.

A contact lens may be worn which incorporates a steeply curved high refractive index glass button (*Figure 23.39a*). The additional power is achieved by the difference of refractive indices, these being 1.6 and 1.333 at the front

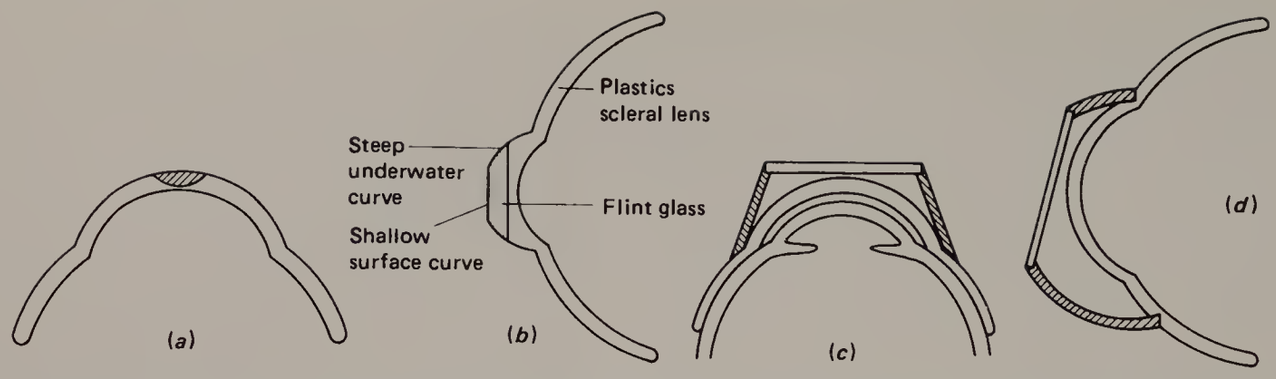


Figure 23.39 Underwater contact lenses. (*a*) Lens containing a high refractive index button to give added power. (*b*) Douthwaite's bifocal flint glass button lens (reproduced by kind permission of W. A. Douthwaite). (*c*) Lens containing an air space. The flat front surface has dark tinted supports to prevent distortion and glare. (*d*) An air space with tilted front surface, which gives added comfort and is supported by the lower lid during wear

surface as compared to 1.49 and 1.333 for the carrier portion, and 1.6 and 1.49 at the interface. It is necessary to incorporate the button in a fairly thick scleral lens.

The button may be made very small so that it only partially covers the pupil. This allows vision through the carrier portion of the lens when in air as the carrier portion can be correctly sighted to allow for the wearer's normal refractive error.

Such a lens was reported by Ward (B., 1961, personal communication and unpublished report). It suffered from two main disadvantages, namely, that it was extremely difficult to locate the button so that vision both above and below water was possible, and it was difficult to find a suitable cement which did not dissolve in sea water to attach the button to the carrier portion.

These problems appear to have been overcome by Douthwaite (1971) who described a similar type of lens in which a flint glass button was fused by the 'Uniseal' method to a plastics scleral lens, the interface between the two being flat (*Figure 23.39b*). The same concentric principle is employed but the outer steep curve on the front of the flint button permits vision under water where the illumination is low and pupil dilated, and the central flatter front surface curve caters for vision in air when the pupil is likely to be more constricted in daylight. The type of bifocal lens described is less noticeable than the air-cell type of lens described below, is more comfortable to wear, does not give rise to the magnification effect nor to the distortion encountered with the air-cell lens. It gives a full, unrestricted field of view. Its disadvantages are slight displacement on the eye which can cause a loss of vision above water, and also the out-of-focus image formed by the peripheral zone in air may give rise to a haze which reduces contrast and affects visual acuity.

Douthwaite also suggested a bifocal underwater lens similar to a solid spectacle bifocal lens, the lower part being used for vision above water when the wearer is likely to be looking in a relatively downwards direction while treading water, and the upper part being used for underwater vision when the gaze is usually relatively upwards as the diver swims along in a horizontal direction. He also admitted that direction of gaze can vary considerably which would then make this type of lens difficult to wear.

The air-cell type of lens is one which has a plane front surface enclosing an air space in front of a conventional scleral lens sighted to correct the wearer's normal refractive error. This type of lens is, as it were, a tiny 'face mask' worn in front of the eye only (*Figure 23.39c*). The optical effect is the same as looking through any plane surface into water.

Refraction of light from water to air causes objects to appear at three-quarters of their real distance, giving a magnification of $\times 1.333$. Due to total internal reflection at the plane face, the visual field is restricted to 97.2° in air and approximately 55–60° in water (Cockell, 1967). If the side supports are left transparent, there is considerable distortion of the peripheral visual field.

Mossé (1964) described a lens in which the front plane face is tilted, as in *Figure 23.39d*, and in which the supports are opaque, eliminating the distortion of the peripheral field. The tilt of the plane face makes upper lid movement more comfortable and prevents the lens from sagging as it is better supported by the lower lid.

The mode of attachment of the plane face to the lens is important so that the air chamber does not collapse in the pressures experienced under water. *Figure 23.39d* shows the system used in France, and *Figure 23.40* shows Cockell's construction in which all but the plane face is made from one solid piece of plastics material.

Attempts have been made to fill the space with air under pressure. The incorporation of a little silica gel in the air space prevents condensation. The plane face should be as close as possible to the front optic surface of the scleral lens, but not sufficiently close to cause interference fringes.

The advantage of such a lens is that it gives adequate vision both above and below water without allowing the diver to be seen from afar, which happens due to reflections when a plane face mask is worn. (This is an important function in times of war, when skin divers need to remain as invisible as possible – especially on surfacing.) This type of lens can be worn satisfactorily for periods of about 4 hours.

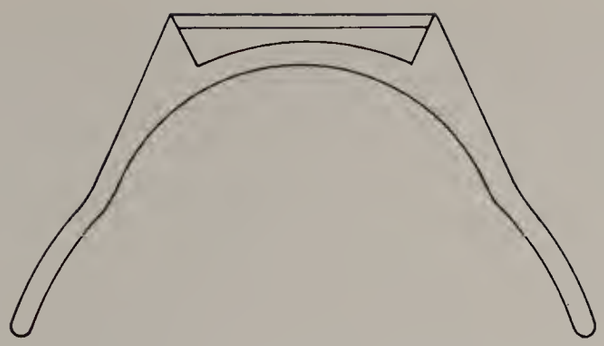


Figure 23.40 Cockell's underwater contact lens (developed at The City University, London)

Bennett (1985) stated that during normal diving procedures where a face mask is worn, soft lenses with their greater adhesion to the eye are preferable to rigid lenses particularly for highly ametropic wearers. In the unlikely event of the loss of the face mask the diver would then be able to surface and see his support vessel. This becomes important for police and military divers who might lose a face mask during a skirmish.

Where deep diving is undertaken PMMA lenses are contra-indicated (Simon and Bradley, 1980; Molinari and Socks, 1986) due to bubble formation under the lenses and oedema, and for commercial diving in a chamber or bell, contact lenses should not be worn at all (Bennett, 1985). This is due to the divers living for long periods under high pressure, as well as to the fact that *Pseudomonas aerugi-nosa*, which can rapidly destroy a damaged cornea, is known to thrive in diving chambers.

Lenses for the partially sighted

Partially sighted people need additional magnification in order to be able to see detail. Such magnification may be provided in the form of a Galilean telescope device, in which a contact lens forms the eyepiece and a conventional spectacle lens the objective. The optical system is depicted in *Figure 23.41*.

Since the eyepiece contacts the cornea, the magnification (for an emmetropic eye) is given directly by

$$\frac{w_2}{w_1} = \frac{f_1'}{f_2'} = \frac{f_1'}{f_1' - d} = \frac{1}{1 - dF_1'} \quad (d \text{ in metres})$$

With a typical power for F_1' of +25 D and a vertex distance, d, of 12 mm

$$\text{Magnification} = \frac{1}{1 - 3/10} = \frac{1}{0.7} = \times 1.4$$

The powers of the two lenses and their separation must be such as to correct the patient's refractive error, K, where

$$K = \frac{F_1'}{1 - dF_1'} + F_2' \quad (d \text{ in metres})$$

This system has been used with soft, scleral and corneal lenses forming the eyepiece, soft and scleral lenses being generally more satisfactory as they are more stable. The advantages over the telescopic type of spectacle aid are the reduction in weight and the psychological benefit of improved cosmetic appearance. The weight of the high positive spectacle lens can be further relieved by the use of a Fresnel press-on lens as utilized and recommended by Gerstman and Levene (1974). The disadvantage is that contact lenses cannot be removed as quickly and conveniently as spectacles. This is less of a disadvantage when the system is worn by one eye only, as is often the case. The patient then has a normal visual field with one eye, whilst the other eye receives the magnified image for detailed vision, in a reduced visual field (Moore, 1964). However, this does require the facility of alternate suppression by the patient, or else alternate occlusion of the eyes to avoid confusion. It is surprising how well patients with low visual acuity are able to adapt to such a system so long as it provides an obvious benefit to them.

The magnification reduces the visual field and can cause disorientation, but this may be minimized to some extent by magnifying only a small central portion of the visual field. This may be done by using a carefully fitted contact lens

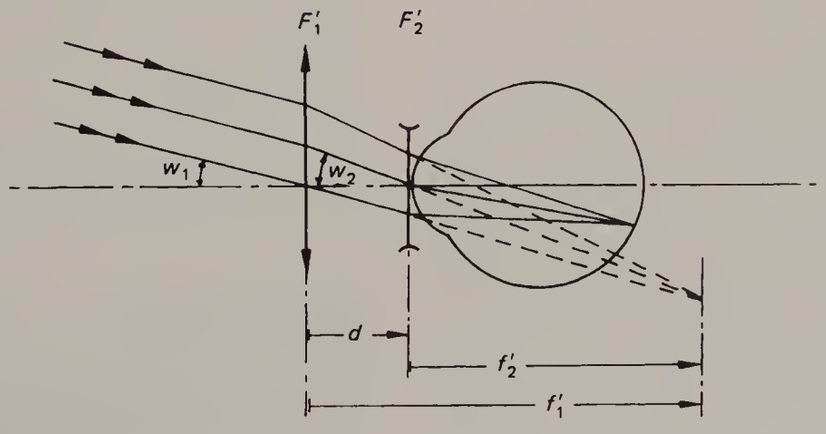


Figure 23.41 A Galilean telescope system incorporating a contact lens of power F_2' as eyepiece, and a spectacle lens of power F_1' as objective



Figure 23.42 A spectacle lens used as the objective for a Galilean telescope system, having separate portions for distance and near vision, cemented on to an afocal carrier lens

worked to correct the refractive error but with the front central portion made quite flat, giving a high negative power centrally. The diameter of this portion must be about two-thirds of the pupil diameter in normal illumination; and according to Filderman (1964), it is typically between 3.5 and 4.0 mm, and of about –50 D power. This is the high negative eyepiece of power F_2' which is used in conjunction with a positive segment of about 10 mm diameter and +25 D power, cemented on to the back surface of an afocal spectacle lens of 12 D base. Below this, a near addition may be cemented on to the carrier lens (*Figure 23.42*). Fresnel press-on segments may be used as an alternative to cemented segments.

F_2' depends on the thickness and back optic zone radius of the contact lens. Since

$$K = \frac{F_1'}{1 - dF_1'} + F_2'$$

and since d is known, or can be measured, F_1' may be determined. The magnification may then be computed from

$$\frac{1}{-dF_1'}$$

Filderman described a small corneal lens fitted to rest on the lower lid and ballasted to keep it down, with the optic zone displaced to put it in front of the pupil and the upper edge of the lens only just above the upper pupil margin. He also stated that best results were obtained with scleral lenses, but soft lenses may now supersede them (Stone and Breakspear, 1977), although a large lenticular rigid gas permeable lens fitted to give minimal movement provides superior optical quality and a higher power negative eyepiece due to its higher refractive index.

Such lenses cannot be fitted to old people. Not only do they have pupils which are too small but also the disorientation is usually too great to be tolerated by them. Young people can usually cope with these difficulties.

An attempt was made by Feinbloom (1961) to incorporate both positive objective and negative eyepiece in one scleral lens with an air space between the two. While being theoretically possible, the lenses were very thick and heavy, making them uncomfortable to wear and unsightly.

Drasdo (1970) developed a similar lens to be used in conjunction with a spectacle lens, which he described as a 'feedback corrected' lens system since it gives magnification without altering the angular amount of movement of the eye required to take up fixation of peripheral objects. It therefore overcomes one of the major disadvantages, i.e. disorientation.

A reversed telescope system was mentioned by Bier (1960) for people with loss of peripheral vision, and the author, with others, has also successfully fitted one for a person with homonymous hemianopia. A high positive stable contact lens used with a high negative spectacle lens, suitably designed to give minimum aberrations, gives a reduction in magnification (and, incidentally, a reduced visual acuity) but allows more to be seen in the existing visual field.

Animals' lenses

At various times, contact lenses have been used for animals. Most fall into three categories as follows.

Experimental lenses

Many experiments are carried out on animals prior to being carried out on humans, and special lenses have been constructed for monkeys, rabbits, cats, squirrels, octopi and other creatures to assess various aspects of visual function.

The contact lens has become a major tool in visual research, both from the physiological and psychological aspects. There is no doubt that it will find further uses in addition to those described above.

Utilitarian lenses

Chickens and turkeys have been provided with opaque and coloured contact lenses to reduce their acuity and so prevent featherpecking (Anon, 1967).

Therapeutic lenses

The use of a specially made 72% water content soft lens of 34 mm total diameter and 18 mm back optic radius for a horse with an injured cornea was reported by Tammeus *et al.* (1983). Worn continuously for 6 days in a therapeutic

capacity the lens permitted corneal healing to take place following corneal perforation. Soft lenses have been used in the same way for treatment of corneal conditions in dogs and cats (Schmidt *et al.*, 1977).

Miscellaneous lenses

Certain lenses or types of lens do not fall into any of the above categories, and yet some mention of them should be made.

Tinted lenses

The reasons for prescribing tinted lenses have already been dealt with. When PMMA hard lenses were the main type of contact lens fitted they were available in many different tints, but only in clear and two neutral grey tints (9042 and 9043) in the clinical quality material (known as CQ and guaranteed to be non-toxic). Most rigid gas permeable lenses are available in clear, and pale blue, green or grey materials; these are essentially handling tints. More recently dark tints have became available. Many soft lenses also incorporate a very pale blue handling tint to make them easier for the patient to see and handle when they are being cleaned. This tint may apply to the whole lens or just be confined to a central area of 10–11 mm diameter, and is usually virtually invisible in wear. Tinted soft lenses can, of course, be made to any tint or depth of tint by special order, and some tints are available in standard colours and light absorptions (*see* Chapter 11).

As suggested by Capelli (1966), the risk of possible toxicity from soluble dyes or surface dyeing of PMMA lenses (Estevez, 1967) has not posed any real danger in practice. Likewise there have been no reports of tinted contact lenses affecting colour perception (apart from the X-Chrom lens, *see* p. 433) or posing a risk during night driving (Fletcher and Nisted, 1963), although the possible risk remains that in monochromatic street lighting lenses of restricted spectral transmission could reduce visibility, for example blue lenses worn in sodium lighting; and green lenses might affect the visibility of red traffic lights or rear automobile lights, particularly if the wearer of the lenses already has defective colour vision. In some countries there is a legal limit to the density of any tint worn during night driving.

No toxicity problems have been reported due to the tints used in RGP materials. The stringent testing carried out to satisfy FDA requirements in the USA and similar authorities in other countries has ensured the safety of these lenses.

With tinted and coloured soft lenses, manufacturer's instructions must be followed carefully for cleaning and disinfection, as the dyes may be affected by some of the chlorine and hydrogen peroxide disinfection systems and by some of the more stringent professional cleaning processes (*see* Chapter 4).

Surface coating

Some contact lens wearers have problems because their rigid lenses do not wet properly. With PMMA lenses the contact angle may be reduced (i.e. surface wetting improved) by coating the surfaces of the lenses chemically (Erb, 1961; Blue, 1966) or by deposition of a thin metal compound by vacuum coating. In either case the surface of the lens is converted from a hydrophobic to a hydrophilic one.

Another vacuum method of converting PMMA surfaces to hydrophilic was described by Gesser *et al.* (1965). It was claimed that about half the surface molecular groups were changed in chemical composition by removal of hydrogen atoms. Lenses were placed in a vacuum discharge tube in the presence of ammonia but out of the path of the discharge glow. An electrical discharge caused a chemical action to take place on the surface of the plastics material. The altered molecules were hydrophilic instead of hydrophobic. Lenses treated in this way wetted well, and there was minimal build-up of grease and oil on their surfaces.

A similar technique, known as plasma modification, using an oxygen plasma glow discharge method has been successful in treating the surfaces of gas permeable rigid lenses (Hough and Patel, 1986). Acid treatment of certain RGP materials is also used to hydrophilize the surface. Many contact lens manufacturers now supply some RGP lenses with such a hydrophilic surface. These must be cleaned and disinfected using soft lens solutions (*see* Chapter 10).

Lenses of high and low refractive index

Chapters 3, 5 and 10 and Appendix B include details of refractive indices of various contact lens materials. It is sometimes useful to use a lower or higher refractive index to help solve an optical problem, as for example to reduce induced astigmatism with a back toroidal surface on a rigid lens (*see* Chapters 5 and 14).

Lenses of high refractive index have been tried, with varying degrees of success. The higher refractive index allows a thinner lens to be made, which is useful for lenses of high power.

High refractive index plastics can be used, with the addition of a fluorescent dye, for the segments of rigid bifocal contact lenses. The addition of the dye, though invisible in normal light, renders fitting easier when viewed by ultraviolet illumination (*see* Chapter 16).

The experimental use of synthetic sapphire material was reported by Nissel (G., 1969, unpublished report). This has a very high refractive index of about 2.

Lenses incorporating bactericides

Historically, the material for such contact lenses was developed in the USA (Torgerson, 1964). These lenses had



Figure 23.43 An example of soft lenses used for effect in dramatic productions

a significant effect in inhibiting bacterial growth as compared with normal lenses, the degree of inhibition depending on the contact time (Mote *et al.*, 1969; Mote and Hill, 1970). Conversely, Chalkley *et al* (1966) had previously found lenses of this material to be of no apparent value. It should not be forgotten that soft lenses stored in preserved saline effectively incorporate a bactericide, as the solution preservative is slowly released onto the eye during wear. The effect of this on the normal ocular flora has not been ascertained.

Lenses for stage and screen

Various designs of lens can be made in scleral, corneal or soft type (*Figure 23.43*), for use by actors as part of a costume for a stage play or more commonly television or film roles.

This concludes the details of special contact lenses; but no doubt many more types of special lenses will be developed as the need arises.

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Appendix A

Spectacle and ocular refraction, or effective power of spectacle lenses in air at various vertex distances

Body of table shows effective power at stated vertex distance (*see* formulae I and II, page 199, and the attached CD-ROM)

Spectacle refraction or spectacle lens power (BVP) (D)	*Ocular refraction (D) for vertex distances (mm) of:*														
	6	*7*	*8*	*9*	*10*	*11*	*12*	*13*	*14*	*15*	*16*	*17*	*18*	*19*	*20*
+0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25
.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.51
.75	0.75	0.75	0.75	0.76	0.76	0.76	0.76	0.76	0.76	0.76	0.76	0.76	0.76	0.76	0.76
+1.00	1.01	1.01	1.01	1.01	1.01	1.01	1.01	1.01	1.01	1.02	1.02	1.02	1.01	1.02	1.02
.25	1.26	1.26	1.26	1.26	1.27	1.27	1.27	1.27	1.27	1.27	1.28	1.28	1.28	1.28	1.28
.50	1.51	1.52	1.52	1.52	1.52	1.52	1.53	1.53	1.53	1.53	1.54	1.54	1.54	1.54	1.55
.75	1.77	1.77	1.78	1.78	1.78	1.79	1.79	1.79	1.80	1.80	1.80	1.81	1.81	1.81	1.81
+2.00	2.02	2.03	2.03	2.04	2.04	2.04	2.05	2.05	2.06	2.06	2.07	2.07	2.07	2.08	2.08
.25	2.28	2.29	2.29	2.30	2.30	2.31	2.31	2.32	2.33	2.33	2.34	2.34	2.35	2.35	2.36
.50	2.54	2.54	2.55	2.56	2.56	2.57	2.58	2.58	2.59	2.60	2.60	2.61	2.62	2.62	2.63
.75	2.79	2.80	2.81	2.82	2.82	2.83	2.84	2.85	2.86	2.87	2.87	2.88	2.89	2.90	2.91
+3.00	3.06	3.06	3.07	3.08	3.09	3.10	3.11	3.12	3.13	3.14	3.15	3.16	3.17	3.18	3.19
.25	3.31	3.33	3.34	3.35	3.36	3.37	3.38	3.39	3.40	3.42	3.43	3.44	3.45	3.46	3.48
.50	3.58	3.59	3.60	3.61	3.63	3.64	3.65	3.67	3.68	3.69	3.71	3.72	3.74	3.75	3.76
.75	3.84	3.85	3.87	3.88	3.90	3.91	3.93	3.94	3.96	3.97	3.99	4.00	4.02	4.04	4.05
+4.00	4.10	4.12	4.13	4.15	4.17	4.18	4.20	4.22	4.24	4.26	4.27	4.29	4.31	4.33	4.35
.25	4.36	4.38	4.40	4.42	4.44	4.46	4.48	4.50	4.52	4.54	4.56	4.58	4.60	4.62	4.64
.50	4.63	4.65	4.67	4.69	4.71	4.73	4.76	4.78	4.80	4.83	4.85	4.87	4.90	4.92	4.95
.75	4.89	4.91	4.94	4.96	4.99	5.01	5.04	5.06	5.09	5.12	5.14	5.17	5.19	5.22	5.25
+5.00	5.15	5.18	5.21	5.24	5.26	5.29	5.32	5.35	5.38	5.41	5.43	5.46	5.49	5.52	5.56
.25	5.42	5.45	5.48	5.51	5.54	5.57	5.60	5.63	5.67	5.70	5.73	5.76	5.80	5.83	5.87
.50	5.69	5.72	5.75	5.79	5.82	5.85	5.89	5.92	5.96	6.00	6.03	6.07	6.11	6.14	6.18
.75	5.96	5.99	6.03	6.06	6.10	6.14	6.18	6.22	6.25	6.29	6.33	6.37	6.41	6.46	6.50
+6.00	6.22	6.26	6.30	6.34	6.38	6.42	6.46	6.51	6.55	6.59	6.64	6.68	6.72	6.77	6.82
.25	6.49	6.54	6.58	6.62	6.67	6.71	6.76	6.80	6.85	6.90	6.94	6.99	7.04	7.09	7.14
.50	6.77	6.81	6.86	6.91	6.95	7.00	7.05	7.10	7.15	7.20	7.26	7.31	7.36	7.42	7.47
.75	7.04	7.09	7.14	7.19	7.24	7.29	7.35	7.40	7.46	7.51	7.57	7.63	7.69	7.75	7.82
+7.00	7.30	7.36	7.41	7.47	7.52	7.58	7.64	7.70	7.76	7.82	7.88	7.94	8.01	8.07	8.14
.25	7.58	7.64	7.70	7.76	7.82	7.88	7.94	8.01	8.07	8.14	8.20	8.27	8.34	8.41	8.48
.50	7.86	7.92	7.98	8.05	8.11	8.18	8.24	8.31	8.38	8.45	8.53	8.60	8.67	8.75	8.83
.75	8.13	8.20	8.26	8.33	8.40	8.47	8.55	8.62	8.70	8.77	8.85	8.93	9.01	9.09	9.17
+8.00	8.40	8.47	8.55	8.62	8.70	8.77	8.85	8.93	9.01	9.09	9.17	9.26	9.35	9.43	9.52
.25	8.68	8.76	8.83	8.91	8.99	9.07	9.16	9.24	9.33	9.42	9.51	9.60	9.69	9.78	9.88
.50	8.96	9.04	9.12	9.21	9.29	9.38	9.47	9.56	9.65	9.75	9.84	9.94	10.04	10.14	10.25
.75	9.23	9.32	9.41	9.50	9.59	9.68	9.78	9.87	9.97	10.07	10.17	10.28	10.38	10.49	10.60
+9.00	9.51	9.61	9.70	9.79	9.89	9.98	10.09	10.19	10.30	10.41	10.52	10.63	10.74	10.86	10.98
.25	9.79	9.89	9.99	10.09	10.19	10.30	10.41	10.52	10.63	10.74	10.86	10.98	11.10	11.22	11.35
.50	10.07	10.17	10.28	10.38	10.49	10.60	10.72	10.83	10.95	11.07	11.20	11.33	11.45	11.59	11.72
.75	10.35	10.46	10.57	10.68	10.80	10.92	11.04	11.16	11.29	11.42	11.55	11.68	11.82	11.96	12.11

Appendix A (*Continued*)

Spectacle refraction or spectacle lens power (BVP) (D)	*Ocular refraction (D) for vertex distances (mm) of:*														
	6	*7*	*8*	*9*	*10*	*11*	*12*	*13*	*14*	*15*	*16*	*17*	*18*	*19*	*20*
+10.00	10.64	10.75	10.87	10.99	11.11	11.24	11.36	11.49	11.63	11.76	11.90	12.05	12.20	12.35	12.50
.25	10.92	11.04	11.17	11.29	11.42	11.55	11.69	11.83	11.97	12.11	12.26	12.41	12.57	12.73	12.89
.50	11.21	11.33	11.46	11.60	11.73	11.87	12.01	12.16	12.31	12.46	12.62	12.78	12.95	13.12	13.29
.75	11.49	11.63	11.76	11.90	12.05	12.19	12.34	12.50	12.66	12.82	12.98	13.15	13.33	13.51	13.69
+11.00	11.78	11.92	12.06	12.21	12.36	12.51	12.67	12.84	13.00	13.17	13.35	13.53	13.72	13.91	14.10
.25	12.06	12.21	12.36	12.52	12.68	12.84	13.01	13.18	13.35	13.53	13.72	13.91	14.11	14.31	14.52
.50	12.35	12.51	12.66	12.83	12.99	13.16	13.34	13.52	13.71	13.90	14.09	14.29	14.50	14.71	14.93
.75	12.64	12.80	12.97	13.14	13.31	13.49	13.68	13.87	14.06	14.26	14.47	14.68	14.90	15.13	15.36
+12.00	12.93	13.10	13.27	13.45	13.64	13.82	14.02	14.22	14.42	14.63	14.85	15.08	15.31	15.54	15.79
.25	13.22	13.40	13.58	13.77	13.96	14.16	14.36	14.57	14.79	15.01	15.24	15.47	15.72	15.97	16.23
.50	13.51	13.70	13.89	14.08	14.29	14.49	14.71	14.93	15.15	15.38	15.62	15.87	16.13	16.39	16.67
.75	13.81	14.00	14.20	14.40	14.61	14.83	15.05	15.28	15.52	15.77	16.02	16.28	16.55	16.83	17.11
+13.00	14.10	14.30	14.51	14.72	14.94	15.17	15.40	15.64	15.89	16.15	16.41	16.69	16.97	17.27	17.57
.25	14.39	14.60	14.82	15.04	15.27	15.51	15.76	16.01	16.27	16.54	16.82	17.10	17.40	17.71	18.03
.50	14.69	14.91	15.14	15.37	15.61	15.86	16.11	16.37	16.65	16.93	17.22	17.52	17.83	18.16	18.49
.75	14.99	15.21	15.45	15.69	15.94	16.20	16.47	16.74	17.03	17.32	17.63	17.94	18.27	18.61	18.96
+14.00	15.28	15.52	15.77	16.02	16.28	16.55	16.83	17.11	17.41	17.72	18.04	18.37	18.72	19.07	19.44
.25	15.58	15.83	16.08	16.35	16.62	16.90	17.19	17.49	17.80	18.12	18.46	18.80	19.16	19.54	19.93
.50	15.88	16.14	16.40	16.68	16.96	17.25	17.55	17.87	18.19	18.53	18.88	19.24	19.62	20.01	20.42
.75	16.18	16.45	16.72	17.01	17.30	17.61	17.92	18.25	18.59	18.94	19.31	19.69	20.08	20.49	20.92
+15.00	16.48	16.76	17.04	17.34	17.65	17.96	18.29	18.63	18.99	19.35	19.74	20.13	20.55	20.98	21.43
.25	16.79	17.07	17.37	17.68	18.00	18.33	18.67	19.02	19.39	19.77	20.17	20.59	21.02	21.47	21.94
.50	17.09	17.39	17.69	18.01	18.34	18.68	19.04	19.41	19.79	20.19	20.61	21.04	21.50	21.97	22.46
.75	17.39	17.70	18.02	18.35	18.70	19.05	19.42	19.81	20.21	20.62	21.06	21.51	21.98	22.48	22.99
+16.00	17.70	18.02	18.35	18.69	19.05	19.42	19.80	20.20	20.62	21.05	21.51	21.98	22.47	22.99	23.53
.25	18.01	18.34	18.68	19.03	19.40	19.79	20.19	20.60	21.04	21.49	21.96	22.45	22.97	23.51	24.07
.50	18.31	18.65	19.01	19.38	19.76	20.16	20.57	21.01	21.46	21.93	22.42	22.93	23.47	24.03	24.63
.75	18.62	18.97	19.34	19.72	20.12	20.53	20.96	21.41	21.88	22.37	22.88	23.42	23.98	24.57	25.19
+17.00	18.93	19.30	19.68	20.07	20.48	20.91	21.36	21.82	22.31	22.82	23.35	23.91	24.50	25.11	25.76
.25	19.24	19.62	20.01	20.42	20.85	21.29	21.75	22.24	22.74	23.27	23.83	24.41	25.02	25.66	26.34
.50	19.55	19.94	20.35	20.77	21.21	21.67	22.15	22.65	23.18	23.73	24.31	24.91	25.55	26.22	26.92
.75	19.87	20.27	20.69	21.12	21.58	22.06	22.55	23.07	23.62	24.19	24.79	25.42	26.08	26.78	27.52
+18.00	20.18	20.59	21.03	21.48	21.95	22.44	22.96	23.50	24.06	24.66	25.28	25.94	26.63	27.36	28.12
.25	20.49	20.92	21.37	21.84	22.32	22.83	23.37	23.93	24.51	25.13	25.78	26.46	27.18	27.94	28.74
.50	20.81	21.25	21.71	22.20	22.70	23.23	23.78	24.36	24.97	25.61	26.28	26.99	27.74	28.53	29.37
.75	21.13	21.58	22.06	22.56	23.08	23.62	24.19	24.79	25.42	26.09	26.79	27.52	28.30	29.13	30.00
+19.00	21.44	21.91	22.41	22.92	23.46	24.02	24.61	25.23	25.89	26.57	27.30	28.06	28.88	29.73	30.65
.25	21.76	22.25	22.75	23.28	23.84	24.42	25.03	25.68	26.35	27.07	27.82	28.61	29.46	30.35	31.30
.50	22.08	22.58	23.10	23.65	24.22	24.82	25.46	26.12	26.82	27.56	28.34	29.17	30.05	30.98	31.97
.75	22.40	22.92	23.46	24.02	24.61	25.23	25.88	26.57	27.30	28.06	28.87	29.73	30.64	31.61	32.64
+20.00	22.73	23.26	23.81	24.39	25.00	25.64	26.32	27.03	27.78	28.57	29.41	30.30	31.25	32.26	33.33
–0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25	0.25
0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50
0.75	0.75	0.75	0.75	0.75	0.74	0.74	0.74	0.74	0.74	0.74	0.74	0.74	0.74	0.74	0.74
–1.00	0.99	0.99	0.99	0.99	0.99	0.99	0.99	0.99	0.99	0.99	0.98	0.98	0.98	0.98	0.98
.25	1.24	1.24	1.24	1.24	1.23	1.23	1.23	1.23	1.23	1.23	1.23	1.22	1.22	1.22	1.22
.50	1.49	1.48	1.48	1.48	1.48	1.48	1.47	1.47	1.47	1.47	1.46	1.46	1.46	1.46	1.46
.75	1.73	1.73	1.73	1.72	1.72	1.72	1.71	1.71	1.71	1.71	1.70	1.70	1.70	1.69	1.69
–2.00	1.98	1.97	1.97	1.96	1.96	1.96	1.95	1.95	1.95	1.94	1.94	1.93	1.93	1.93	1.92
.25	2.22	2.22	2.21	2.21	2.20	2.20	2.19	2.19	2.18	2.18	2.17	2.17	2.16	2.16	2.15
.50	2.46	2.46	2.45	2.44	2.44	2.43	2.43	2.42	2.42	2.41	2.40	2.40	2.39	2.39	2.38
.75	2.71	2.70	2.69	2.68	2.68	2.67	2.66	2.66	2.65	2.64	2.63	2.63	2.62	2.61	2.61

Appendix A (*Continued*)

Spectacle refraction or spectacle lens power (BVP) (D)	*Ocular refraction (D) for vertex distances (mm) of:*														
	6	*7*	*8*	*9*	*10*	*11*	*12*	*13*	*14*	*15*	*16*	*17*	*18*	*19*	*20*
–3.00	2.95	2.94	2.93	2.92	2.91	2.90	2.90	2.89	2.88	2.87	2.86	2.85	2.85	2.84	2.83
.25	3.19	3.18	3.17	3.16	3.15	3.14	3.13	3.12	3.11	3.10	3.09	3.08	3.07	3.06	3.05
.50	3.43	3.42	3.40	3.39	3.38	3.37	3.36	3.35	3.34	3.33	3.31	3.30	3.29	3.28	3.27
.75	3.67	3.65	3.64	3.63	3.61	3.60	3.59	3.58	3.56	3.55	3.54	3.52	3.51	3.50	3.49
–4.00	3.91	3.89	3.88	3.86	3.85	3.83	3.82	3.80	3.79	3.77	3.76	3.75	3.73	3.72	3.70
.25	4.14	4.13	4.11	4.09	4.08	4.06	4.04	4.03	4.01	4.00	3.98	3.96	3.95	3.93	3.92
.50	4.38	4.36	4.34	4.33	4.34	4.29	4.27	4.25	4.23	4.22	4.20	4.18	4.16	4.15	4.13
.75	4.62	4.60	4.58	4.56	4.54	4.51	4.49	4.47	4.45	4.43	4.42	4.40	4.38	4.36	4.34
–5.00	4.85	4.83	4.81	4.78	4.76	4.74	4.72	4.69	4.67	4.65	4.63	4.61	4.59	4.57	4.55
.25	5.09	5.06	5.04	5.01	4.99	4.96	4.94	4.91	4.89	4.87	4.84	4.82	4.80	4.77	4.75
.50	5.32	5.30	5.27	5.24	5.21	5.19	5.16	5.13	5.11	5.08	5.06	5.03	5.01	4.98	4.96
.75	5.56	5.53	5.50	5.47	5.44	5.41	5.38	5.35	5.32	5.29	5.27	5.24	5.21	5.18	5.16
–6.00	5.79	5.76	5.72	5.69	5.66	5.63	5.60	5.56	5.53	5.50	5.47	5.44	5.41	5.39	5.36
.25	6.02	5.99	5.95	5.92	5.88	5.85	5.81	5.78	5.75	5.71	5.68	5.65	5.62	5.59	5.56
.50	6.26	6.22	6.18	6.14	6.11	6.07	6.03	6.00	5.96	5.92	5.89	5.85	5.82	5.79	5.75
.75	6.49	6.45	6.41	6.37	6.33	6.29	6.25	6.21	6.17	6.13	6.09	6.06	6.02	5.98	5.95
–7.00	6.72	6.67	6.63	6.58	6.54	6.50	6.46	6.41	6.37	6.33	6.29	6.25	6.22	6.18	6.14
.25	6.94	6.90	6.85	6.81	6.76	6.72	6.67	6.63	6.58	6.54	6.50	6.46	6.41	6.37	6.33
.50	7.18	7.13	7.08	7.03	6.98	6.93	6.88	6.84	6.79	6.74	6.70	6.65	6.61	6.57	6.52
.75	7.41	7.35	7.30	7.25	7.19	7.14	7.09	7.04	6.99	6.94	6.90	6.85	6.80	6.76	6.71
–8.00	7.63	7.58	7.52	7.46	7.41	7.35	7.30	7.25	7.19	7.14	7.09	7.04	6.99	6.94	6.90
.25	7.86	7.80	7.74	7.68	7.62	7.56	7.51	7.45	7.40	7.34	7.29	7.24	7.18	7.13	7.08
.50	8.09	8.03	7.96	7.90	7.84	7.78	7.72	7.66	7.60	7.54	7.49	7.43	7.37	7.32	7.27
.75	8.31	8.24	8.18	8.11	8.05	7.98	7.92	7.86	7.79	7.73	7.67	7.62	7.56	7.50	7.45
–9.00	8.54	8.47	8.40	8.33	8.26	8.19	8.12	8.06	7.99	7.93	7.87	7.81	7.75	7.69	7.63
.25	8.76	8.69	8.61	8.54	8.47	8.40	8.33	8.26	8.19	8.12	8.06	7.99	7.93	7.87	7.81
.50	8.98	8.90	8.83	8.75	8.67	8.60	8.53	8.45	8.38	8.31	8.24	8.18	8.11	8.05	7.98
.75	9.21	9.12	9.04	8.96	8.88	8.80	8.73	8.65	8.58	8.50	8.43	8.36	8.29	8.22	8.16
–10.00	9.43	9.35	9.26	9.17	9.09	9.01	8.93	8.85	8.77	8.70	8.62	8.55	8.47	8.40	8.33
.25	9.66	9.56	9.47	9.38	9.29	9.21	9.12	9.04	8.96	8.88	8.80	8.73	8.65	8.58	8.50
.50	9.88	9.78	9.69	9.59	9.50	9.41	9.32	9.24	9.15	9.07	8.99	8.91	8.83	8.75	8.68
.75	10.10	10.00	9.90	9.80	9.71	9.61	9.52	9.43	9.34	9.26	9.17	9.09	9.01	8.93	8.85
–11.00	10.32	10.21	10.11	10.01	9.91	9.81	9.72	9.62	9.53	9.44	9.35	9.27	9.18	9.10	9.02
.25	10.54	10.43	10.32	10.22	10.11	10.01	9.91	9.81	9.72	9.63	9.53	9.44	9.36	9.27	9.18
.50	10.76	10.64	10.53	10.42	10.31	10.21	10.11	10.00	9.90	9.81	9.71	9.62	9.53	9.44	9.35
.75	10.98	10.86	10.74	10.63	10.51	10.40	10.30	10.19	10.09	9.99	9.89	9.79	9.70	9.61	9.51
–12.00	11.19	11.07	10.95	10.83	10.71	10.60	10.49	10.38	10.27	10.17	10.07	9.97	9.87	9.77	9.68
.25	11.41	11.28	11.16	11.03	10.91	10.80	10.68	10.57	10.46	10.35	10.24	10.14	10.04	9.94	9.84
.50	11.63	11.49	11.36	11.24	11.11	10.99	10.87	10.75	10.64	10.53	10.42	10.31	10.20	10.10	10.00
.75	11.84	11.71	11.57	11.44	11.31	11.18	11.06	10.94	10.82	10.70	10.59	10.48	10.37	10.26	10.16
–13.00	12.06	11.92	11.78	11.64	11.50	11.37	11.25	11.12	11.00	10.88	10.76	10.65	10.54	10.43	10.32
.25	12.27	12.13	11.98	11.84	11.70	11.56	11.43	11.30	11.18	11.05	10.93	10.81	10.70	10.59	10.47
.50	12.49	12.34	12.18	12.04	11.89	11.76	11.62	11.49	11.35	11.23	11.10	10.98	10.86	10.74	10.63
.75	12.70	12.54	12.39	12.24	12.09	11.94	11.80	11.66	11.53	11.40	11.27	11.14	11.02	10.90	10.78
–14.00	12.91	12.75	12.59	12.43	12.28	12.13	11.99	11.84	11.71	11.57	11.44	11.31	11.18	11.06	10.94
.25	13.13	12.96	12.79	12.63	12.47	12.32	12.17	12.02	11.88	11.74	11.60	11.47	11.34	11.21	11.09
.50	13.34	13.16	12.99	12.83	12.66	12.50	12.35	12.20	12.05	11.91	11.77	11.63	11.50	11.37	11.24
.75	13.55	13.37	13.19	13.02	12.85	12.69	12.53	12.38	12.22	12.08	11.93	11.79	11.66	11.52	11.39
–15.00	13.76	13.57	13.39	13.22	13.04	12.87	12.71	12.55	12.40	12.24	12.10	11.95	11.81	11.67	11.54
.25	13.97	13.78	13.59	13.41	13.23	13.06	12.89	12.73	12.57	12.41	12.26	12.11	11.97	11.82	11.69
.50	14.18	13.98	13.79	13.60	13.42	13.24	13.07	12.90	12.74	12.58	12.42	12.27	12.12	11.97	11.83
.75	14.39	14.19	13.99	13.80	13.61	13.42	13.25	13.07	12.90	12.74	12.58	12.42	12.27	12.12	11.98
–16.00	14.60	14.39	14.18	13.99	13.79	13.61	13.42	13.25	13.07	12.90	12.74	12.58	12.42	12.27	12.12
.25	14.81	14.59	14.38	14.18	13.98	13.79	13.60	13.42	13.24	13.07	12.90	12.73	12.57	12.42	12.26
.50	15.01	14.79	14.58	14.37	14.16	13.96	13.77	13.59	13.40	13.23	13.05	12.88	12.72	12.56	12.41
.75	15.22	14.99	14.77	14.56	14.35	14.14	13.95	13.76	13.57	13.39	13.21	13.04	12.87	12.71	12.55

Appendix A (*Continued*)

Spectacle refraction or spectacle lens power (BVP) (D)	*Ocular refraction (D) for vertex distances (mm) of:*														
	6	*7*	*8*	*9*	*10*	*11*	*12*	*13*	*14*	*15*	*16*	*17*	*18*	*19*	*20*
−17.00	15.43	15.19	14.97	14.74	14.53	14.32	14.12	13.92	13.73	13.55	13.37	13.19	13.02	12.85	12.69
.25	15.63	15.39	15.16	14.93	14.71	14.50	14.29	14.09	13.89	13.70	13.52	13.34	13.16	12.99	12.83
.50	15.84	15.59	15.35	15.12	14.89	14.68	14.46	14.26	14.06	13.86	13.67	13.49	13.31	13.13	12.96
.75	16.04	15.79	15.54	15.30	15.07	14.85	14.63	14.42	14.22	14.02	13.82	13.64	13.45	13.27	13.10
−18.00	16.24	15.98	15.73	15.49	15.25	15.02	14.80	14.59	14.38	14.17	13.97	13.78	13.59	13.41	13.23
.25	16.45	16.18	15.93	15.68	15.43	15.20	14.97	14.75	14.54	14.33	14.13	13.93	13.74	13.55	13.37
.50	16.65	16.38	16.12	15.86	15.61	15.37	15.14	14.91	14.70	14.48	14.28	14.07	13.88	13.69	13.50
.75	16.85	16.58	16.31	16.04	15.79	15.54	15.31	15.08	14.85	14.63	14.42	14.22	14.02	13.83	13.64
−19.00	17.06	16.77	16.49	16.23	15.97	15.72	15.47	15.24	15.01	14.79	14.57	14.36	14.16	13.96	13.77
.25	17.26	16.96	16.68	16.41	16.14	15.89	15.64	15.40	15.16	14.94	14.72	14.50	14.30	14.09	13.90
.50	17.46	17.16	16.87	16.59	16.32	16.06	15.80	15.56	15.32	15.09	14.86	14.65	14.43	14.23	14.03
.75	17.66	17.35	17.06	16.77	16.49	16.23	15.97	15.72	15.47	15.24	15.01	14.79	14.57	14.36	14.16
−20.00	17.86	17.54	17.24	16.95	16.67	16.39	16.13	15.87	15.62	15.38	15.15	14.93	14.71	14.49	14.29
.25	18.06	17.74	17.43	17.13	16.84	16.56	16.29	16.03	15.78	15.53	15.29	15.06	14.84	14.62	14.41
.50	18.25	17.93	17.61	17.31	17.01	16.73	16.45	16.19	15.93	15.68	15.44	15.20	14.97	14.75	14.54
.75	18.45	18.12	17.80	17.49	17.19	16.89	16.61	16.34	16.08	15.83	15.58	15.34	15.11	14.88	14.66
−21.00	18.65	18.31	17.98	17.66	17.36	17.06	16.77	16.50	16.23	15.97	15.72	15.48	15.24	15.01	14.79
.25	18.85	18.50	18.16	17.84	17.53	17.22	16.93	16.65	16.38	16.11	15.86	15.61	15.37	15.14	14.91
.50	19.04	18.69	18.34	18.01	17.70	17.39	17.09	16.80	16.53	16.26	16.00	15.75	15.50	15.26	15.04
.75	19.24	18.88	18.53	18.19	17.86	17.55	17.25	16.96	16.67	16.40	16.13	15.88	15.63	15.39	15.16
−22.00	19.43	19.06	18.71	18.36	18.03	17.71	17.40	17.11	16.82	16.54	16.27	16.01	15.76	15.51	15.28
.25	19.63	19.25	18.89	18.54	18.20	17.88	17.56	17.26	16.97	16.68	16.41	16.14	15.89	15.64	15.40
.50	19.82	19.44	19.07	18.71	18.37	18.04	17.72	17.41	17.11	16.82	16.54	16.30	16.01	15.76	15.52
.75	20.02	19.62	19.25	18.88	18.53	18.20	17.87	17.56	17.25	16.96	16.68	16.40	16.14	15.88	15.63
−23.00	20.21	19.81	19.43	19.06	18.70	18.36	18.02	17.71	17.40	17.10	16.81	16.53	16.27	16.01	15.75
.25	20.40	20.00	19.60	19.23	18.86	18.52	18.18	17.85	17.54	17.24	16.95	16.66	16.39	16.13	15.87
.50	20.60	20.18	19.78	19.40	19.03	18.67	18.33	18.00	17.68	17.38	17.08	16.79	16.52	16.25	15.99
.75	20.79	20.36	19.96	19.57	19.19	18.83	18.48	18.15	17.82	17.51	17.21	16.92	16.64	16.37	16.10
−24.00	20.98	20.55	20.13	19.74	19.35	18.99	18.63	18.29	17.96	17.65	17.34	17.04	16.76	16.48	16.22
.25	21.17	20.73	20.31	19.90	19.52	19.14	18.78	18.44	18.10	17.78	17.47	17.17	16.88	16.60	16.33
.50	21.36	20.91	20.48	20.07	19.68	19.30	18.93	18.58	18.24	17.91	17.60	17.30	17.00	16.72	16.44
.75	21.55	21.10	20.66	20.24	19.84	19.45	19.08	18.73	18.38	18.05	17.73	17.42	17.12	16.83	16.56
−25.00	21.74	21.28	20.83	20.41	20.00	19.61	19.23	18.87	18.52	18.18	17.86	17.54	17.24	16.95	16.67
.25	21.93	21.46	21.01	20.58	20.16	19.76	19.38	19.01	18.66	18.32	17.99	17.67	17.36	17.06	16.78
.50	22.12	21.64	21.18	20.74	20.32	19.91	19.52	19.15	18.79	18.44	18.11	17.79	17.48	17.18	16.89
.75	22.31	21.82	21.35	20.91	20.48	20.07	19.67	19.29	18.93	18.58	18.24	17.91	17.60	17.29	17.00
−26.00	22.49	22.00	21.52	21.07	20.64	20.22	19.82	19.43	19.06	18.71	18.36	18.03	17.71	17.40	17.11
.25	22.68	22.17	21.69	21.23	20.79	20.37	19.96	19.57	19.19	18.83	18.48	18.15	17.83	17.51	17.21
.50	22.86	22.35	21.86	21.39	20.95	20.52	20.10	19.71	19.33	18.96	18.61	18.27	17.94	17.62	17.32
.75	23.05	22.53	22.04	21.56	21.11	20.67	20.25	19.85	19.46	19.09	18.73	18.39	18.06	17.74	17.43
−27.00	23.23	22.71	22.20	21.72	21.26	20.82	20.39	19.98	19.59	19.22	18.85	18.50	18.17	17.84	17.53
.25	23.42	22.88	22.37	21.88	21.41	20.96	20.53	20.12	19.72	19.34	18.98	18.62	18.28	17.95	17.64
.50	23.61	23.06	22.54	22.04	21.57	21.11	20.68	20.26	19.86	19.47	19.10	18.74	18.40	18.06	17.74
.75	23.79	23.23	22.71	22.20	21.72	21.26	20.82	20.39	19.98	19.59	19.22	18.86	18.50	18.17	17.84
−28.00	23.97	23.41	22.88	22.36	21.87	21.41	20.96	20.53	20.11	19.72	19.34	18.97	18.62	18.28	17.95
.25	24.16	23.58	23.04	22.52	22.03	21.55	21.10	20.66	20.24	19.84	19.46	19.08	18.73	18.38	18.05
.50	24.34	23.76	23.21	22.68	22.18	21.70	21.24	20.79	20.37	19.96	19.57	19.20	18.84	18.49	18.15
.75	24.52	23.93	23.38	22.84	22.33	21.84	21.38	20.93	20.50	20.09	19.69	19.31	18.95	18.59	18.25
−29.00	24.70	24.11	23.54	23.00	22.48	21.99	21.51	21.06	20.63	20.21	19.81	19.43	19.05	18.70	18.36
.25	24.88	24.28	23.70	23.15	22.63	22.13	21.65	21.19	20.75	20.33	19.92	19.54	19.16	18.80	18.45
.50	25.06	24.45	23.87	23.31	22.78	22.27	21.79	21.32	20.88	20.45	20.04	19.65	19.27	18.90	18.55
.75	25.24	24.62	24.03	23.47	22.93	22.42	21.93	21.45	21.00	20.57	20.16	19.76	19.38	19.01	18.65
−30.00	25.42	24.79	24.19	23.62	23.08	22.56	22.06	21.58	21.13	20.69	20.27	19.87	19.48	19.11	18.75

Appendix B

List of oxygen permeabilities and refractive indices

General

Medium or instrument	*Refractive index*
Aqueous humor	1.336
Cornea	1.376
Keratometer (American Optical)	1.336
Keratometers (Most)	1.3375
Keratometer (Zeiss)	1.332
Tears	1.336

Lenses/material

Most manufacturers will produce solid bifocals (annular or segment), toric periphery and fully toric back and/or front surface (bi-toric) lenses in most materials to Rx.

In the following tables **Fo** in the second column is an abbreviation for Focon which is the ACLM classification for rigid lenses.

Non gas permeable hard

Brand name or material	*Group (ACLM)*	*Contact angle*	*Refractive index*
Modified PMMA, e.g. Paragon 18	Fo 1b	24	1.475
PMMA	Fo 1a	30	1.49
Seg for Fused PMMA (Hyfrax)	N/A	>30	1.568

Brand names and materials preceded by a plus sign '+' are considered by the manufacturer to be suitable for long periods of wear during the waking day and, exceptionally, for periods longer than the waking day.

Lenses are listed in alphabetical order.

Gas permeable rigid

Brand name or material	*Group (ACLM)*	*Dk; 35°C* $\times 10^{-11}$	*Contact angle (°)*	*Refractive index*
Alberta N	Fo 5	42	50	1.445
+Aqualine 50	Fo 5	50	N/A	1.467
Aqualine Soft GP	Fo 4b	50	N/A	1.463
Aqualite	Fo 5	71	N/A	1.463
+Aquaperm	Fo 5	50	N/A	1.463
Aquasil	Fo 4b	50	N/A	1.463
Aquasofone	Fo 5b	70	43	1.475

Gas permeable rigid (*Continued*)

Brand name or material	*Group (ACLM)*	*Dk; 35°C* $\times 10^{-11}$	*Contact angle (°)*	*Refractive index*
+Aquila	Fo 5	210	N/A	1.4308
+Boston 7	Fo 5	73	N/A	1.428
+Boston Equalens	Fo 5	71	N/A	1.439
+Boston Equalens 2	Fo 5	127	N/A	1.432
Boston II	Fo 3	14.6	N/A	1.471
Boston IV	Fo 3	26.3	N/A	1.468
Boston RXD	Fo 5	45	N/A	1.435
Conflex	Fo 2b	4	N/A	1.477
Conflex-Air	Fo 5	52	N/A	1.467
+Equalens	Fo 5	71	N/A	1.439
+Equalens 2	Fo 5	127	N/A	1.432
Excel 02	Fo 3	16	N/A	1.47
+FL 151	Fo 5	151	N/A	1.442
Fluorocarbon 20	Fo 5	20	23	1.48
Fluorocarbon 30	Fo 5	30	23	1.47
Fluorocarbon 40	Fo 5	40	23	1.475
Fluorocarbon 50	Fo 5	50	25.8	1.48
Fluorocarbon 60	Fo 5	60	23	1.473
+Fluorocarbon 70	Fo 5	70	24	1.473
+Fluorocarbon 80	Fo 5	80	24	1.473
+Fluorocarbon 90	Fo 5	90	23	1.473
Fluorolens 15	Fo 5	15	12	1.48
Fluorolens 25	Fo 5	26.5	12.8	1.475
Fluorolens 50	Fo 5	56	14	1.473
+Fluorolens 70	Fo 5	72	15	1.461
+Fluorolens 90	Fo 5	88	16	1.438
Fluoroperm 30	Fo 5	30	12.8	1.475
Fluoroperm 60	Fo 5	60	14.7	1.473
+Fluoroperm 90	Fo 5	92	16	1.453
+Fluoroperm 150	Fo 5	151	17	1.471
Fluoroperm ST (Fused)	Fo 5	50	14.7	1.452
Fused Seg for above	Styrene	23	N/A	1.6
GP 20	Fo 3	20	N/A	1.47
GP 50	Fo 3	50	N/A	1.475
Hanita ADE	Fo 2	8	N/A	1.487
+Hanita ADK	Fo 5	71	N/A	1.439
Hanita ASIV	Fo 3	26.3	N/A	1.469
Hanita RXE	Fo 5	45	N/A	1.435
Hartflex	Fo 2a	4	N/A	1.47
+Hoya Hard EX	Fo 5	125	N/A	1.44
Hoya Hard/OP	Fo 3	17.5	N/A	1.46
Hydroperm	Fo 4	50	N/A	1.463
Hyperm	Fo 3	16	24	1.48
KB 13	Fo 3	7	N/A	1.48
KB 14	Fo 3	13	N/A	1.47
KB 15	Fo 3	18	N/A	1.47
KB 16	Fo 5	36	N/A	1.47
KB 17	Fo 5	60	N/A	1.47
KB 18	Fo 3	15.6	N/A	1.48
KB 19	Fo 3	39	N/A	1.475
KB 20	Fo 5	56	N/A	1.475
Menicon 02	Fo 4	12	16	1.481
Menicon SP	Fo 5	32	20	1.48
Menicon Super 02	Fo 4	52	N/A	1.47

Gas permeable rigid *(Continued)*

Brand name or material	*Group (ACLM)*	*Dk; 35°C* $\times 10^{-11}$	*Contact angle (°)*	*Refractive index*
Metro 32	Fo 5	32	N/A	1.475
Metro 52	Fo 5	52	N/A	1.473
+ML 92	Fo 5	92	N/A	1.43
Nova Gas	Fo 5	7	N/A	1.47
Nova Gas 60	Fo 5	56	N/A	1.473
+Nova Gas 85	Fo 5	85	N/A	1.472
Nova Gas II	Fo 5	26.3	N/A	1.475
+Novalens	Fo 5	55	N/A	1.475
Optacryl	Fo 3	18	25	1.467
Oxyflex	Fo 3	13	N/A	1.48
Oxyflex 4F	Fo 3	30	N/A	1.475
+Paraperm EW	Fo 3	52	26	1.473
Paraperm 02	Fo 3	14	23.1	1.475
Paraperm 02+	Fo 3	37	25.6	1.475
+Persecon 92E	Fo 5	92	N/A	1.464
Persecon CE	Fo 3	54	N/A	1.465
Persecon E	Fo 2a	8	N/A	1.471
PGP I	Fo 3	18	25	1.467
PGP II	Fo 5	32	30	1.467
PGP III	Fo 5	59	30	1.464
+PGP IV	Fo 5	75	30	1.461
Polycon II	Fo 3	12	30	1.473
Polyfluor 50	Fo 5	56	N/A	1.473
Polyfluor 70	Fo 5	72	N/A	1.473
Polyfluor 90	Fo 5	85	N/A	1.473
Premi Air	Fo 5	45	17	1.475
+Quantum	Fo 5	92	N/A	1.43
+Quantum 2	Fo 5	210	N/A	1.422
Quasar	Fo 5	60	N/A	1.475
RXD	Fo 5	45	N/A	1.435
Tangent Streak (Bif)	Fo 5	70	N/A	1.457
TFL 30	Fo 5	32	N/A	1.467
+TFL 70	Fo 5	72	N/A	1.473
+TFL 100	Fo 5	102	N/A	1.472
+TFL 120	Fo 5	102	N/A	1.462
+TFL 160	Fo 5	160	N/A	1.457
TGP 24	Fo 3	24	N/A	1.475
Topflex	Fo 3	12.5	30	1.473
Uniperm I	Fo 3	18	N/A	1.475
Uniperm II	Fo 3	32	N/A	1.475
+UV 100	Fo 5	100	N/A	1.453
Vistasill II	Fo 4b	50	N/A	1.463
+Wöhlk A90	Fo 5	92	N/A	1.453
XL20	Fo 3	6.5	26	1.48
XL30	Fo 3	12	N/A	1.46
XL40	Fo 3	12	N/A	1.48

Soft Lenses

All soft lenses are considered by the manufacturers to be suitable for some period of daily wear. In general they consider thinner lenses of higher water content (preceded by a plus sign '+' in the following list) to be suitable for longer periods of daily wear and, exceptionally, for periods greater than the waking day. Thicker lenses of lower water content are usually more durable.

The term **Fi** in the second column is an abbreviation for Filcon which is the ACLM classification for soft lenses.

The refractive indices listed are for hydrogel lenses, fully hydrated at 35 °C, calculated using a formula derived by Fatt and Chaston (1980b), also published by Fatt and Ruben (1993): Hydrated refractive index

$$= 1.524 - 2.05 \times 10^{-3}\% \text{ Water content.}$$

Brand names or materials preceded by **C**: have a **C**osmetic feature, usually in addition to carrying Rx.

D: indicates '**D**isposable' lenses, marketed for scheduled replacement.

M: indicates **M**ultifocal. This group is divided into **B**ifocal (**MB**) and **P**rogressive (**MP**). The bifocal group is further sub-divided into **A**nnular (**MBA**), **D**iffractive (**MBD**) and **S**egment types (**MBS**).

Multifocal lenses whose description ends with **D** (e.g. **MBAD** or **MPD**) are disposable, i.e. marketed for planned replacement.

For annular and progressive multifocal lenses, **CD** indicates **C**entre **D**istance and **CN** = **C**entre **N**ear.

Diffractive lenses are of the simultaneous vision type.

T: indicates daily wear **T**oric; **+T**: = daily wear plus toric; **+TD** = disposable daily wear plus Toric.

Lenses are listed in alphabetical order within each group.

Single vision soft lenses

Brand name or material	*Group (ACLM)*	H_2O %	*Dk; 35°C* $\times 10^{-11}$	*Refractive index*
B-H Thin	Fi 1b	38	8.5	1.4461
B3/B4	Fi 1a	38	8	1.4461
Belgravia 38	Fi 1a	38	14	1.4461
+Belgravia 60	Fi 4a	61	23	1.3989
+Belgravia 72	Fi 4a	72	32	1.3764
+BL 70	Fi 4a	70	31.6	1.3805
+Ciba Soft S75 Bandage	Fi 4a	75	36	1.3702
Cibasoft Visitint	Fi 1a	38	8.5	1.4461
Classic	Fi 3a	42	13	1.4379
Clearflex	Fi 1a	38	8.5	1.4461
Cleargel	Fi 4a	60	22	1.401
+Cristelle	Fi 4a	78	61	1.3641
CSI	Fi 2a	38	12	1.4461
+CSI-T	Fi 2a	38	12	1.4461
+CW 79	Fi 4a	79	46.5	1.362
Durasoft	Fi 1a	38	9.03	1.4461
+Durasoft 3	Fi 4a	55	16.1	1.4112
+ES70	Fi 4a	70	45	1.3805
Eurolens	Fi 1a	38	7.5	1.4461
Eurosoft	Fi 1a	38	8.5	1.4461
Excelens	NoClass	64	27	1.3928
+Focus 60	Fi 4b	60	21	1.401
+Focus 80	Fi 4b	74	33	1.3723
+Focus Mirage	Fi 4b	60	21	1.401
+Formula 55 VHT	Fi 1b	55	23	1.4112
+G72D	Fi 4a	72	43	1.3764
+Geaflex 70	Fi 4a	70	43	1.3805
H3/H4	Fi 1a	38	8	1.4461
Hanita Ace	Fi 1a	38	13	1.4461
Hanita Age	Fi 4a	58	19.6	1.4051
HO 8	Fi 1a	38	9	1.4461

Single vision soft lenses (*Continued*)

Brand name or material	*Group (ACLM)*	*H_2O %*	*Dk; 35°C × 10^{-11}*	*Refractive index*
HO3/HO4	Fi 1a	38	8	1.4461
+Hydrocurve II 55	Fi 3b	55	16	1.4112
Hydrofit 38	Fi 1a	38	8.5	1.4461
+Hydrofit 74	Fi 4b	74	33	1.3723
+Hydrofit HP55	Fi 4b	55	20	1.4112
Hydroflex	Fi 1a	38	8	1.4461
Hydrolens	Fi 1a	38	8.5	1.4461
+Hydrolens E	Fi 4b	74	33	1.3723
Hydron	Fi 1a	38	10	1.4461
+Hydron H67	Fi 4a	67	30	1.3866
Hydrothin	Fi 1a	38	8.5	1.4461
Hypa 7	Fi 3a	60	26	1.401
Igel	Fi 1a	38	13	1.4461
Igel 58 Presto	Fi 4a	58	21	1.4051
+Igel 67 Prima	Fi 4a	67	30	1.3866
+Igel 77	Fi 4a	76	53	1.3682
+Incanto 78	Fi 3a	78	64	1.3641
+Lunelle Therapeutic	Fi 4a	70	45	1.3805
MCL 38	Fi 1a	38	10	1.4461
Media	Fi 1b	55	23	1.4112
Nissel 45	Fi 3a	45	9	1.4317
Nova Soft 38	Fi 1a	38	8.5	1.4461
Nova Soft 60	Fi 4a	60	18	1.401
+03/04	Fi 1a	38	8	1.4461
Omniflex Sofblue	Fi 4a	70	32	1.3805
Optima 38	Fi 1a	38	8	1.4461
Perfecta	Fi 1a	38	14.7	1.4461
+Permaflex 74	Fi 4a	74	43	1.3723
+Permaflex UV	Fi 4a	74	38	1.3723
+Permalens Bandage	Fi 4a	74	43	1.3723
Precision UV	Fi 4a	74	38	1.3723
RE 55	Fi 1b	58	22	1.4051
+RX 70	Fi 4a	71	38	1.3784
+Sauflon Bandage	Fi 4b	74	33	1.3723
+Sauflon PW	Fi 4b	74	33	1.3723
Scanlens 75	Fi 4a	71	36	1.3784
Scene DW	Fi 1a	38	8	1.4461
+Scotsoft 70% U/T	Fi 4a	70	32	1.3805
+Scotsoft 73% L/C	Fi 4a	73	45	1.3743
Seelite 38	Fi 1a	38	15.5	1.4461
+Seelite 73	Fi 4a	73	45	1.3743
+Silflex	Fi 5	Nil	200	1.435
Silver 07 VHT	Fi 1a	38	14.7	1.4461
Silver 38	Fi 1a	38	14.7	1.4461
Silver II	Fi 1a	38	14.7	1.4461
Simplon 'S'	Fi 1a	38	12.5	1.4461
Sofspin	Fi 1a	38	8	1.4461
Softmate B	Fi 3b	45	12	1.4317
+Softmate II	Fi 3b	55	16	1.4112
+Softwear 58	Fi 4b	58	24	1.4051
SP 40	Fi 1a	38	12.5	1.4461
SP 60	Fi 4a	58	21	1.4051
+SP 70	Fi 4a	71	38	1.3784
+SP 80	Fi 4a	75	43	1.3702
+Supergold 73	Fi 4a	73	43	1.3743
SV 38	Fi 1a	38	8.5	1.4461
+T.S.L 55	Fi 3a	55	24.5	1.4112
+T.S.L 70	Fi 4a	70	48	1.3805
U3/U4	Fi 1a	38	8	1.4461
Ultima	Fi 1a	38	14.7	1.4461
Ultra-2	Fi 1a	38	8.3	1.4461
Ultra-2A	Fi 4a	74	43	1.3723
Ultraflex	Fi 1a	38	8.5	1.4461
Ultralens	Fi 1a	38	8.3	1.4461

Single vision soft lenses (*Continued*)

Brand name or material	*Group (ACLM)*	*H_2O %*	*Dk; 35°C × 10^{-11}*	*Refractive index*
Ultrathin	Fi 1a	38	8.3	1.4461
W50D	Fi 4a	55	23	1.4112
Weflex 55	Fi 4a	55	23	1.4112
Weicon 38E	Fi 1a	38	8.5	1.4440
Weicon CE	Fi 4a	60	28	1.401
Z4 Sofblue	Fi 1a	38	10	1.4461

Cosmetic Single Vision Soft Lenses

Brand name or material	*Group (ACLM)*	*H_2O %*	*Dk; 35°C × 10^{-11}*	*Refractive index*
+C: Aquarius (Painted)	Fi 4a	74	33	1.3723
+C: Aquarius (Print)	Fi 4a	74	33	1.3723
+C: Couleur	Fi 4a	70	35	1.3805
C: Durasoft 2 Colors	Fi 1a	38	9.03	1.4461
+C: Durasoft 3 Colors	Fi 4a	55	16.1	1.4112
+C: Durasoft Complement	Fi 4a	55	16.1	1.4112
+C: Durasoft Freshlook	Fi 4a	55	16.1	1.4112
C: Elegance	Fi 1a	38	8.5	1.4461
+C: Enhanced Tints	Fi 4a	73	43	1.3743
C: Enhanced Tints	Fi 1a	38	10	1.4461
C: Eurosoft 38 (Tint)	Fi 1a	38	8.5	1.4461
C: Eurosoft 77 (Tint)	Fi 4a	77	50	1.3661
+C: Fashion Tints	Fi 4a	73	43	1.3743
C: Fashion Tints	Fi 1a	38	10	1.4461
C: Hydrofit 38 (Tint)	Fi 1a	38	8.5	1.4461
+C: Hydroflex Colour	Fi 1a	38	8.1	1.4461
+C: Hydroflex Mini Tint	Fi 1a	38	8.1	1.4461
C: Hydron H67 Softints	Fi 4a	67	30	1.3866
C: Hydron Mini Softints	Fi 1a	38	10	1.4461
C: Hydron Z6 Softints	Fi 1a	38	10	1.4461
C: Hydron Z6T Softints	Fi 1a	38	10	1.4461
C: Igel 58 Select	Fi 4a	58	21	1.4051
C: Igel 58 Select X	Fi 4a	58	21	1.4051
+C: Igel 67 Hi-Tints	Fi 4a	67	30	1.3866
+C: Igel 77 Hi-Tints	Fi 4a	76	53	1.3682
C: Igel CD HI-Tints	Fi 1a	38	13	1.4461
C: Igel Presto Hi-Tints	Fi 4a	58	21	1.4051
C: Nova Soft 38 Tinted	Fi 1a	38	8.5	1.4461
C: Nova Soft 60 Tinted	Fi 4a	60	18	1.401
C: Nova Soft Cosmetic	Fi 4a	58	21	1.4051
C: OmniFlex Softints	Fi 4a	70	32	1.3805
C: Optima 38 Tint	Fi 1a	38	8.5	1.4461
+C: Perfecta Tints	Fi 1a	38	9.5	1.4461
+C: Permaflex 74 Tint	Fi 4a	74	43	1.3723
C: Scene DW (tinted)	Fi 1a	38	8	1.4461
+C: Scene EW (Tinted)	Fi 4a	73	34	1.3743
C: Seelite 38 (Tint)	Fi 1a	38	15.5	1.4461
+C: Seelite 73 (Tint)	Fi 4a	73	45	1.3743
C: Silver II Tint	Fi 1a	38	14.7	1.4461
C: Soft Colour	Fi 1a	38	8.3	1.4461
+C: Softwear 58 Cosmet	Fi 4b	58	24	1.4051
C: Softwear 58 Pastel	Fi 4a	58	24	1.4051
+C: Solair (Brown)	Fi 4a	70	35	1.3805
C: Tintogel	Fi 1a	38	8.3	1.4461
+C: Weflex Colour	Fi 4a	55	23	1.4112

Disposable Single Vision Soft Lenses

Brand name or material	*Group (ACLM)*	*H_2O %*	*Dk; 35°C × 10^{-11}*	*Refractive index*
+D: Acuvue	Fi 1b	58	28	1.4051
D: B-H Thin	Fi 1a	38	15.5	1.4461
D: Cibasoft Visitint	Fi 1a	38	8.5	1.4461
D: Classic	Fi 3a	42	13	1.4379
D: Cristelle	Fi 4a	78	61	1.3641
D: CSI	Fi 2a	38	12	1.4461
D: CSI-Thin	Fi 2a	38	12	1.4461
+D: Exelens (Non Ionic)	Unclass	64	37	1.3928
D: Focus Plan (Lathe)	Fi 1a	38	13	1.4461
D: Focus Plan (Mould)	Fi 1a	38	13	1.4461
D: Focus Plan 55	Fi 4b	55	20	1.4112
D: Focus Plan 74	Fi 4b	74	33	1.3723
+D: Focus Visitint	Fi 3b	55	20	1.4112
D: Formula 55	Fi 1b	55	23	1.4112
D: Frequency 38	Fi 1a	38	14.7	1.4461
+D: Frequency 55	Fi 1b	55	23	1.4112
+D: FreshWear	Fi 4a	73	45	1.3743
+D: G72D	Fi 4a	72	43	1.3764
+D: Geaflex 70	Fi 4a	70	43	1.3805
D: HO 8	Fi 1a	38	9	1.4461
+D: Hospital Plan	Fi 4b	74	33	1.3723
+D: Hydrocurve II	Fi 3b	55	16	1.4112
D: Hydroflex	Fi 1a	38	8	1.4461
D: Hydroflex Mini	Fi 1a	38	8	1.4461
D: Hydroflex SD	Fi 1a	38	8	1.4461
D: Hydron Mini	Fi 1a	38	10	1.4461
D: Hydron Z6	Fi 1a	38	10	1.4461
D: HYPA 7	Fi 3a	60	26	1.401
D: Igel 58 Presto	Fi 4a	58	21	1.4051
D: Igel 67 Prima	Fi 4a	67	30	1.3866
D: Igel 77	Fi 4a	76	53	1.3682
D: Igel CD	Fi 1a	38	13	1.4461
D: Igel Omega	Fi 1a	38	13	1.4461
+D: Incanto 78	Fi 3a	78	64	1.3641
D: Medalist	Fi 1a	38	8	1.4461
D: Nova 38 CM	Fi 1a	38	15.5	1.4461
+D: Nova 55	Fi 1a	55	23	1.4112
+D: Nova 73 CM	Fi 4a	73	45	1.3743
+D: OmniFlex SofBlue	Fi 4a	70	32	1.3805
+D: Permaflex 74	Fi 4a	74	43	1.3723
+D: Permaflex UV	Fi 4a	74	38	1.3723
+D: Permalens 1L	Fi 3b	71	43	1.3784
+D: Permalens Aphakic	Fi 3b	71	43	1.3784
+D: Permalens Bandage	Fi 3b	71	43	1.3784
+D: Precision UV	Fi 4a	74	38	1.3723
+D: RE 55	Fi 1b	58	22	1.4051
D: ReView 38	Fi 1a	38	15.5	1.4461
+D: ReView 73	Fi 4a	73	45	1.3743
+D: Rx 70	Fi 4a	71	36	1.3784
D: Rythmic	Fi 4a	73	45	1.3743
+D: Scanlens 75	Fi 4a	71	36	1.3784
D: Seequence	Fi 1a	38	8	1.4461
D: Simplon 'S'	Fi 1a	38	12.5	1.4461
D: Softmate B	Fi 3b	45	12	1.4317
+D: Softmate II	Fi 3b	55	16	1.4112
D: SP 40	Fi 1a	38	12.5	1.4461
D: SP 60	Fi 4a	58	21	1.4051
+D: SP 70	Fi 4a	71	36	1.3784
+D: SP 80	Fi 4a	75	43	1.3702
+D: Spectrum Visitint	Fi 3b	55	20	1.4112
D: Surevue	Fi 1b	58	28	1.4051
D: SV 38	Fi 1a	38	8.5	1.4461
D: T.P.R 38	Fi 1a	38	10	1.4461
+D: T.P.R.73	Fi 4a	73	43	1.3743
D: W50D	Fi 4a	55	23	1.4112
D: Weflex 55	Fi 4a	55	23	1.4112
D: Weicon 38E	Fi 1a	38	8.5	1.4461
+D: Weicon CE	Fi 4a	60	28	1.401
D: Z4 SofBlue	Fi 1a	38	10	1.4461

Disposable Single Vision Soft Lenses *(Continued)*

Multifocal soft lenses

Brand name or material	*Group (ACLM)*	*H_2O %*	*Dk; 35°C × 10^{-11}*	*Refractive index*
MBA: Belgravia 38 CD	Fi 1a	38	14	1.4461
+MBA: Belgravia 72 CD	Fi 4a	72	32	1.3764
MBA: Concentric 38 CD	Fi 1a	38	10	1.4461
+MBA: Concentric 65 CD	Fi 3a	65	29	1.3907
+MBA: Concentric 75 CD	Fi 3a	75	32	1.3702
MBAD: Simulvue CN	Fi 3a	45	15.6	1.4317
MBD: Echelon Diffractive	Fi 1a	38	10	1.4461
MBS: R-Type 38 Cresc.	Fi 1a	38	10	1.4461
+MBS: R-Type 65 Cresc.	Fi 3a	65	29	1.3907
MP: Hydrocurve II CD	Fi 3b	45	12	1.4317
MP: Lifestyle CN	Fi 1a	38	8.5	1.4461
MP: N5 CN	Fi 1a	38	13	1.4461
MPD: PA1 CD	Fi 1a	38	8	1.4461
MPD: PS250 CN	Fi 1a	38	8.5	1.4461
MPD: PS45 CN	Fi 1a	38	8.5	1.4461
MPD: Softline CN	Fi 1a	38	12.5	1.4461
MPD: Unilens CD	Fi 3a	45	15.6	1.4317
+MP: Variations CN	Fi 4a	78	32	1.3641

Toric Soft Lenses

Brand name or material	*Group (ACLM)*	*H_2O %*	*Dk; 35°C $\times 10^{-11}$*	*Refractive index*
T: 38% Toric (M&L)	Fi 1a	38	10	1.4461
+T: 65% Toric (M&L)	Fi 3a	65	29	1.3907
+T: 75% Toric (M&L)	Fi 3a	75	32	1.3702
T: Belgravia 60T	Fi 4a	61	23	1.3989
T: CSI Clarity Toric	Fi 2a	38	12	1.4461
T: Durasoft 2 Toric	Fi 1a	38	9.03	1.4461
+T: Durasoft 3 Toric	Fi 4a	55	16.1	1.4112
TD: Focus Toric	Fi 4b	55	20	1.4112
T: Hanita ACTB	Fi 1a	38	8.5	1.4461
+TD: Hydrocurve 3 Toric	Fi 3b	55	16	1.4112
T: Hydrocyl BS.Cyl	Fi 1a	38	8.5	1.4461
T: Hydrocyl FS.Cyl	Fi 1a	38	8.5	1.4461
T: Hydroflex AT F.Cyl	Fi 1a	38	N/A	1.4461
T: Hydroflex MT B.Cyl	Fi 1a	38	N/A	1.4461
T: Hydroflex TS B.Cyl	Fi 1a	38	N/A	1.4461
+T: Hydrolens E Toric	Fi 4b	74	33	1.3723
TD: Igel 38 (UV Inhib)	Fi 1a	38	13	1.4461
TD: Igel 58 (UV Inhib)	Fi 4a	58	21	1.4051
+TD: Igel 67 (UV Inhib)	Fi 4a	67	30	1.3866
+T: Lunelle Toric	Fi 4a	70	35	1.3805
TD: Optima Toric	Fi 1a	43	12	1.4358
+T: Re 38T	Fi 1a	38	9	1.4461
+TD: Re 55T	Fi 4a	58	22	1.4051
T: Simplon 'Cert' 38	Fi 1a	38	12.5	1.4461
T: Simplon 'Cert' 60	Fi 4a	58	21	1.4051
+T: Simplon 'Cert' 70	Fi 4a	71	38	1.3784
+T: Simplon 'Cert' 75	Fi 4a	75	43	1.3702
+T: Softwear 58 Toric	Fi 4b	58	24	1.4051
T: Sunsoft Eclipse	Fi 4a	55	31.3	1.4112
T: Sunsoft Toric Rx	Fi 4a	55	31.3	1.4112
TD: Torisoft	Fi 1a	38	8.5	1.4461
+TD: Ultra T	Fi 3a	43	12	1.4358
+TD: WCE Toric	Fi 4a	60	28	1.401
T: Weflex 55 Toric	Fi 4a	55	23	1.4112
T: Z6 Toric	Fi 1a	38	10	1.4461

Appendix C

Appropriate drugs and solutions for use with contact lenses

Table C.I Solutions and drops for use with rigid lenses

Most soft lens solutions may also be used for rigid lenses (*see Table C.II*). However, for lens materials other than polymethyl methacrylate the manufacturer's instructions regarding solutions should be followed, as lenses containing silicone and cellulose acetate butyrate, for example, may not be compatible with all preservatives. Note that not all products or volume sizes are available in all countries, and the proprietary names may differ from one country to another.

Name of solutions and sizes available	*Manufacturer*	*Preservatives with percentage concentration*	*Remarks*
Soaking solutions (which may also be used for cleaning)			
Clean-N-Soak, 120 ml	Allergan	PMN 0.004	Dual purpose cleaner
Contactasoak, 7 ml, 120 ml	Ciba Vision	B CI 0.004; CHX 0.005; EDTA 0.1	
Duo-Flow Cleaning and Soaking, 120 ml	Ciba Vision	B CI 0.013; EDTA 0.25	Italy and USA only
Hoya Hard Daily Soaking/Cleaning, 120 ml	Hoya	EDTA 0.1; CHX 0.005	
Steri-Soak, 110 ml	Sauflon Pharmaceuticals	B CI 0.002; CHB 0.4; EDTA 0.1	
Transoak, 120 ml	Smith & Nephew	B CI 0.01; EDTA 0.2	
Wetting solutions (which may also be used for re-wetting on the eye)			
Liquifilm Wetting, 20 ml, 60 ml	Allergan	B CI 0.004; EDTA 0.1	
Contactasol, 10 ml, 60 ml	Ciba Vision	B CI 0.004; CHX 0.006; EDTA 0.1	
Hy-Flow, 60 ml	Ciba Vision	B CI 0.01; EDTA 0.025	Italy and USA only
Steri-Clens, 60 ml	Sauflon Pharmaceuticals	EDTA 0.1; THI 0.004	Suitable for cleaning
Transol, 50 ml	Smith & Nephew	B CI 0.004; EDTA 0.02	
Combined soaking and wetting solutions (some of which may also be used for cleaning)			
Soaclens, 120 ml	Alcon	EDTA 0.1; BCL 0.01	
Opti-Soak, 120 ml	Alcon	EDTA 0.1; Polyquad 0.005	
Comfort Care GP Wetting & Soaking Solution, 240 ml	Allergan	CHX 0.005; EDTA 0.02	Contains oxyethylene, PVA, providone, propylene glycol and hydroxyethyl cellulose
Duracare, 120 ml	Allergan	B CI 0.004	Dual purpose wetting. Alternative name Wet-N-Soak
Total Care, 60 ml, 120 ml	Allergan	Polyxetonium Cl 0.06 EDTA. 0.127	
Total, 60 ml, 120 ml	Allergan	B CI 0.004; EDTA. 0.127 PVA 2.5	
Wet-N-Soak, 120 ml	Allergan	B CI 0.004	Dual purpose wetting. Alternative name Duracare
Conditioning Solution (Wetting and Soaking Solution) 30 ml, 60 ml, 120 ml	Bausch & Lomb	CHX 0.06; EDTA 0.05	In UK, called Elite
Complete Care, 120 ml	Ciba Vision	B CI 0.01; EDTA 0.05	
O_2 Care, 100 ml	Menicon	EDTA 0.02 2-Bromo-2-Nitro-1 3-Propanediol 0.003	
Boston Simplicity	Polymer Technology		
Solo Care, 360 ml	Ciba Vision	Polyhexanide 0.0002 EDTA	Contains Poloxamer 407 1% which acts as a surfactant
Boston Advance Solution 120 ml	Polymer Technology	CHX 0.06; EDTA 0.05	
Delta DSW Solution 110 ml	Sauflon	BCL 0.005; EDTA 0.128	

B CI, benzalkonium chloride; CHB, chlorbutol; CHX, chlorhexidine gluconate; EDTA ethylenediamine tetraacetic acid; HAL; halazone; NAPH, naphazoline; PHE, phenylephrine hydrochloride; PVA, polyvinyl alcohol; PMN, phenylmercuric nitrate; PS, potassium sorbate; THI, thimerosal; SA, sorbic acid.

Table C.I (*Continued*)

Name of solutions and sizes available	*Manufacturer*	*Preservatives with percentage concentration*	*Remarks*
Cleaning solutions (see also Soft lens cleaning solutions, Table C.II)			
Pliagel	Alcon	SA 0.1; EDTA 0.25	Soft and rigid lens cleaner
Polyclens II (Opticlean II), 12 ml, 24 ml	Alcon	EDTA 0.1; Polyquad 0.001	Contains polymeric beads
Comfort Care GB Dual Action Daily Cleaner Tablets, 12	Allergan		Subtilisin poloxamer 338 tablet dissolved in Comfort GP wetting & soaking solution
Duraclean Daily Cleaner, 30 ml	Allergan	Self-preserving	
GP Daily Cleaner, 30 ml	Allergan	EDTA 2.0; PS 0.13	
LC 65, 15 ml, 30 ml, 60 ml	Allergan	Self-preserving	Rigid and soft lens cleaner
Total Care Daily Cleaner, 30 ml	Allergan	Self-preserving	
Concentrated Cleaner, 10 ml, 15 ml, 30 ml, 60 ml	Bausch & Lomb	Self-preserving	Contains sodium tridecylether sulphate 10%. In UK, called cleaner for rigid gas permeable lenses
Contactaclean, 35 ml	Ciba Vision	B CI 0.004; CHX 0.006; EDTA 0.1	
Hoya Hard Cleaner, 60 ml	Hoya	EDTA 0.1; CHX 0.005	
Boston Advance Cleaner, 15 ml	Polymer Technology	Self-preserving	
Boston cleaner, 15 ml	Polymer Technology	Self-preserving	Contains sodium tridecylether sulphate 10%
Delta Gas Permeable Cleaning Solution, 20 ml, 60 ml	Sauflon	Self-preserving	Imidazolinium amphoteric surfactants
Transclean, 10 ml	Smith & Nephew	B CI 0.01; EDTA 0.1	
Re-wetting solutions (see also Soft lens re-wetting solutions, Table C.II)			
Adapettes, 15 ml	Alcon	EDTA 0.1; THI 0.004	
Revive 20 × 0.4 ml	Allergan	Preservative free	Single use vials
Clerz, 15 ml	Ciba Vision	EDTA 0.1; SA 0.1	Polyvinyl alcohol 1.4, Providone 0.6
Comfort Drops, 15 ml		B CI 0.005; EDTA 0.02	
Lens Lubricant		EDTA 0.1; THI 0.004	For hard and soft
Boston Advance Conditioning Solution, 10 ml, 30 ml	Polymer Technology	Polyhexamide, Polyhexaride 0.0015, EDTA	
Boston Reconditioning Drops, 15 ml	Polymer Technology	CHX 0.006; EDTA 0.05	Alternative name Boston Rewetting Drops
Transdrop, 10 ml	Smith & Nephew	B CI 0.004; EDTA 0.02	
Artificial tears drops (which may be used for re-wetting rigid lenses) (some are Pharmacy Medicines)			
Tears Naturale, 15 ml	Alcon	B Cl 0.01; EDTA 0.05	
Isopto Plain (Isopto Tears), 15 ml	Alcon	B CI 0.01	
Isopto Alkaline, 15 ml	Alcon	B CI 0.01	
Liquifilm Tears, 15 ml	Allergan	CHB 0.5	
Lens Fresh	Allergan	Preservative-free	Single use vials. Polyethylene glycol 3.0%. Polyoxyl 40 stearate 0.5%
Refresh, 30×0.4 ml	Allergan	Preservative-free	Single use vials. Polyvinyl alcohol 1.4%. Providone 0.6%
Tears Plus, 15 ml	Allergan	CHB 0.5	Polyvinyl alcohol 1.4%, Providone 0.6%
Tears Naturale II (Poly-tears)	Alcon	Polyquad 0.001; Hypromellose 0.3; Dextran 700.1	
Tear Drops, 15 ml	Ciba Vision	CHB 0.5%	
Viscotears, 10 g	Ciba Vision	Cetrimide 0.1%	Lubricating gel
Snotears, 10 ml	Smith & Nephew	B CI 0.004; EDTA 0.02	
Viva Comfort Drops, 15 ml	Vision Pharmaceuticals	Preservative-free	Contains 500 IU vitamin A and Polysorbate 80

B CI, benzalkonium chloride; CHB, chlorbutol; CHX, chlorhexidine gluconate; EDTA ethylenediamine tetraacetic acid; HAL; halazone; NAPH, naphazoline; PHE, phenylephrine hydrochloride; PVA, polyvinyl alcohol; PMN, phenylmercuric nitrate; PS, potassium sorbate; THI, thimerosal; SA, sorbic acid.
Note that not all products or volume sizes are available in all countries, and the proprietary names may differ from one country to another.

Table C.I (*Continued*)

Name of solutions and sizes available	*Manufacturer*	*Preservatives with percentage concentration*	*Remarks*
Conjunctival decongestants (see also Table C.III) (these are all Pharmacy Medicines)			
Isoptofrin, 15 ml	Alcon	B Cl 0.01	Contains PHE 0.12%
Zincfrin, 15 ml	Alcon	B Cl 0.01	PHE 0.12%; Z S 0.25%
Naphcon, 15 ml	Alcon	B Cl 0.01;	NAPH 0.012
Naphcon A, 15 ml	Alcon	B Cl 0.01;	NAPH 0.025; pheniramine maleate 0.3
Prefrin, 15 ml	Allergan	B Cl 0.004; EDTA 0.001	PHE 0.12%, PVA 1.4%
Albalon, 15 ml	Allergan	EDTA 0.01; B Cl 0.004	NAPH-HCL 0.1%, PVA 1.4%
Albalon-A, 15 ml	Allergan	EDTA 0.01; B Cl 0.004	NAPH 0.05%, antazoline phosphate 0.5% PVA 1.4%
Oxylin, 15 ml	Allergan	EDTA 0.0127; B Cl 0.004;	Oxymetazoline HCl 0.025; Polyvinyl alcohol 1.4; Providone 0.5. Not available in Australia

B Cl, benzalkonium chloride; CHB, chlorbutol; CHX, chlorhexidine gluconate; EDTA ethylenediamine tetraacetic acid; HAL; halazone; NAPH, naphazoline; PHE, phenylephrine hydrochloride; PVA, polyvinyl alcohol; PMN, phenylmercuric nitrate; PS, potassium sorbate; THI, thimerosal; SA, sorbic acid.
Note that not all products or volume sizes are available in all countries, and the proprietary names may differ from one country to another.

Table C.II Solutions and drops for use with soft lenses

Most soft lens solutions may also be used for hard lenses (*see Table C.I*). However, for lens materials other than polymethyl methacrylate the manufacturer's instructions regarding solutions should be followed, as lenses containing silicone and cellulose acetate butyrate, for example, may not be compatible with all preservatives. The same caution should be observed with any soft lens made of a new material, as preservatives may bind to the material, and cleaning solutions and systems might alter the lens parameters. Note that not all products or volume sizes are available in all countries, and the proprietary names may differ from one country to another.

Name of solutions and sizes available	*Manufacturer*	*Preservatives with percentage concentration*	*Remarks*
Disinfecting and storage (soaking) solutions			
Hydrophilic lenses			
Flexcare, 355 ml	Alcon	CHX 0.005; THI 0.001; EDTA 0.1	Not available in Australia
Flexsol, 250 ml	Alcon	CHX 0.005; THI 0.001; EDTA 0.1	Not available in USA or Australia
Opti-Free (Opti-One), 120 ml, 240 ml	Alcon	EDTA 0.1; Polyquad 0.001	
Opti-Soft, 120 ml, 240 ml	Alcon	EDTA 0.1; Polyquad 0.001	Not to be used with lenses over 45% water content
Softab (Opti-tabs) 32 tabs	Alcon	Sodium dichloro-isocyanurate 0.065 mg	Chlorine release. To be used with unpreserved saline only
Complete, 240 ml, 360 ml, 2 × 360 ml	Allergan	Polyhexamethylene biguanide 0.0001, EDTA, trometamol 1.2	Combination rising, storage, and cleaning. Contains a surfactant
Hexidin (Soft Mate Disinfecting Solution), 120 ml, 240 ml	Allergan	CHX 0.005; EDTA 0.02; THI 0.001	
Hydrocare All-Purpose 360 ml	Allergan	Polyhexamethylene biguanide 0.0001, EDTA, trometamol 1.2	Combination rising, storage and cleaning. Contains a surfactant Only available in Australia
Hydrocare Soaking and Cleaning, 120 ml, 240 ml, 360 ml	Allergan	ATAC 0.03; THI 0.002	Contains surfactant for daily cleaning
Oxysept 1,235 ml, 360 ml	Allergan	H_2O_2 3.0	Used for a minimum of 20 minutes followed by neutralization in Oxysept 2 or Oxysept 2 tablets
Oxysept One-Step (Ultracare, USA) (Omnicare, Australia) 360 ml + 36 tablets	Allergan	H_2O_2 3.0	Use with catalase containing neutralizing tablet, 0.1 mg/tablet. Uses vitamin B_{12} colour indicator. One-step system using HPMC coated tablets (see text)
Soft Mate Consept 1 (Preform 1)	Allergan	H_2O_2 3.0	Contains a surfactant
Optimeyes Disinfecting Tablets 3 × 36 tablets	Bausch & Lomb	CHX 0.4 mg per tablet. Malic acid to buffer	Contraindicated for high water content, non-ionic lenses
Disinfecting Solution	Bausch & Lomb	THI 0.001; EDTA 0.1; CHX 0.005	Also called Sterile Disinfecting Solution
HP 1 (Quick Sept 1), 50 ml, 240 ml, 355 ml	Bausch & Lomb	H_2O_2 3.0	Not available in USA
Sensitive Eyes Soaking Solution, 50 ml, 60 ml, 120 ml, 240 ml, 335 ml, 480 ml, 500 ml	Bausch & Lomb	Dymed 0.00005	Alternative name Renu Multi-Purpose Solution
AOsept, 237 ml, 250 ml	Ciba Vision	Self-preserving	3% hydrogen peroxide. Sodium stannate + sodium nitrate as stabilizers. Isotonic, buffered
Insta Care Starting Solution (Quick Care), 15 ml	Ciba Vision	Self-preserving	Mildly hypertonic solution combined with 20% isopropylalcohol acts as rapid disinfectant and cleaner (not available in UK)
Insta Care Finishing Solution, 480 ml	Ciba Vision	0.006 H_2O_2 + borate buffer	Bacteriostatic storage solution for use following Insta Care Starting Solution (not available in UK)

ATAC, alkyl triethanol ammonium chloride; BA, benzoic acid; CHB, chlorbutol; CHX, chlorhexiding gluconate; EDTA, ethylenediamine tetra acetic acid; NIPA, Nipastat; PMN, phenylmercuric nitrate; PS, potassium sorbate; SA, sorbic acid; THI, thiomerosal.

Table C.II (*Continued*)

Name of solutions and sizes available	*Manufacturer*	*Preservatives with percentage concentration*	*Remarks*
Disinfecting and storage (soaking) solutions (*Continued*)			
Hydrophilic lenses (*continued*)			
10·10, 120 ml, 250 ml	Ciba Vision	H_2O_2 3.0	
Lensan A	Ciba Vision	H_2O_2 3.0	
In A Wink, 240 ml	Ciba Vision	H_2O_2 3.0	
Titmus H_2O_2 Solution 1	Ciba Vision	H_2O_2 0.6	
Lensept, 240 ml (Septicon system)	Ciba Vision		Hydrogen peroxide 3% solution used for 20 min followed by soak in Lensrins with platinum disc to neutralize residual hydrogen peroxide or Lensept Neutralizing Solution
used with			
Lensrins	Ciba Vision	THI 0.001; EDTA 0.1	
Lensrins NT	Ciba Vision	EDTA 0.1; SA 0.1	
Hydrosoak, 10 ml, 120 ml	Ciba Vision	CHX 0.0025; EDTA 0.128; THI 0.0025	
Medisoak, 35 ml, 120 ml	Ciba Vision	CHX 0.0025; EDTA 0.128; THI 0.0025	Belgium and Germany only
Mirasept 1, 120 ml, 250 ml	Ciba Vision	H_2O_2 3.0	
Solo-care	Ciba Vision	Polyhexamide 0.0001	Not available in UK
All in One	Sauflon Pharmaceuticals	Polyhexamide 0.0005; EDTA 0.3	
All in One (Light), 250 ml	Sauflon Pharmaceuticals		
Steri-Sal, 110 ml	Sauflon Pharmaceuticals	CHX 0.001; EDTA 0.1; THI 0.002	
Sauflon Disinfecting Solution	Sauflon Pharmaceuticals	H_2O_2 3.0	0.5% sodium thiosulphate neutralizer in aerosol
Aerotab (32/pack)	Sauflon Pharmaceuticals	HAL 0.16 mg	Effervescent tablets (8 ppm available chlorine)
Prymesoak, 120 ml	Smith & Nephew	CHX 0.002	
Preserved salines and hydrogen peroxide neutralizers (which may also be used for rinsing purposes)			
Alcon Preserved Saline	Alcon	SA 0.1; EDTA 0.1	
Normol, 250 ml	Alcon	CHX 0.005; THI 0.001; EDTA 0.1	Not available in USA or Australia
Consept 2, Aerosol, 240 ml	Allergan	†	Unpreserved
Hydrocare Preserved Saline 240 ml*	Allergan	EDTA 0.01; THI 0.001	
Lens Plus Purite, 360 ml	Allergan	ClO_2	Preservative breaks down to chloride and water on exposure to light. Not available in Australia
Oxysept 2, 235 ml, 360 ml	Allergan	EDTA 0.1; THI 0.001‡	
Oxysept 2 Unit Dose, 25 × 15 ml	Allergan	‡	Preservative-free neutralizer. Buffered. Not available in Australia or New Zealand
Soft Mate Consept 2, 360 ml	Allergan	EDTA 0.025; PS 0.13	Not available in UK
Soft Mate PS Saline, 240 ml	Allergan	CHX 0.001; †	
Sorbisal Saline Solution, 240 ml*	Allergan	SA 0.1	
HP 2 (Quik Sept 2), 120 ml, 240 ml†	Bausch & Lomb	Dymed 0.00004	Not available in USA
Sensitive Eyes Saline, 120 ml, 240 ml, 355 ml	Bausch & Lomb	EDTA 0.1; THI 0.001	
10.10 Rinsing and Neutralising Solution, 15 ml unit dose	Ciba Vision		Preservative-free neutralizer containing 0.5% sodium pyruvate
Insta Care Finishing Solution, 480 ml	Ciba Vision	Boric acid antimicrobial buffer + 0.006% H_2O_2	For use with Insta Care Starting Solution. Not available in UK
Lensept Neutraliser, 120 ml, 240 ml	Ciba Vision	EDTA, 0.2; SA 0.1‡	
Lensan B, 130 ml	Ciba Vision	THI 0.001‡	
In A Wink Neutralising Rinse, 240 ml	Ciba Vision	EDTA 0.2; SA 0.1‡	
Titmus H_2O_2 Solution 2, 10 ml unit dose	Ciba Vision	‡	Preservative-free neutralizer
Mirasol, 120 ml, 250 ml	Ciba Vision	EDTA 0.1; S A 0.1; THI 0.001	
Sterile Saline, 500 ml	Ciba Vision	Antimicrobial buffer system releasing trace H_2O_2	Known as Softwear Saline in Australia

* Contains sodium hexametaphosphate (chelating agent) for prevention and removal of calcium ions.
† Contains 0.5% sodium thiosulphate as neutralizer for hydrogen peroxide.
‡ Contains catalase as neutralizer for hydrogen peroxide.
ATAC, alkyl triethanol ammonium chloride; BA, benzoic acid; CHB, chlorbutol; CHX, chlorhexiding gluconate; EDTA, ethylenediamine tetra acetic acid; NIPA, Nipastat; PMN, phenylmercuric nitrate; PS, potassium sorbate; SA, sorbic acid; THI, thiomerosal.

Table C.II (*Continued*)

Name of solutions and sizes available	*Manufacturer*	*Preservatives with percentage concentration*	*Remarks*
Sterile saline solution (for rinsing and heat disinfection)			
Amidose, 30 ml	Abatron	–	Screw-capped tubes
Polyrinse, 15 ml	Alcon (France, Germany)	–	Unit dose
Alcon Aerosol Saline (Opti-pure), 240 ml	Alcon	–	Aerosol can also as Salette (buffered)
Lens Plus, 90 ml, 360 ml	Allergan	–	Aerosol (buffered)
B & L Aerosol Saline, 90 ml, 240 ml, 355ml	Bausch & Lomb	–	Suitable for boiling
Renu Saline, 120 ml, 240 ml, 355 ml, 480 ml	Bausch & Lomb	Dymed 0.00003; EDTA 0.025	
Saline Plus 240 ml, 500 ml	Bausch & Lomb	EDTA 0.11	Sold in Australia and New Zealand only. Suitable for boiling
Sensitive Eyes Plus, 500 ml	Bausch & Lomb	EDTA 0.025; Dymed 0.00003	Buffered. Suitable for boiling
Sensitive Eyes Saline 120 ml, 240 ml, 355 ml	Bausch & Lomb	EDTA 0.1; THI 0.001	
Sensitive Eyes Saline 50 ml, 120 ml, 240 ml, 355 ml, 480 ml, 500 ml	Bausch & Lomb	SA 0.1; EDTA 0.025	Suitable for boiling
Sensitive Eyes Saline/Clearing, 240 ml	Bausch & Lomb	SA 0.15; EDTA 0.1	
Solar Saline, 275 ml, 115 ml	Ciba Vision		Aerosol (buffered)
Sauflon Saline Solution, 300 ml	Sauflon Pharmaceuticals	–	Aerosol can (buffered)
Aerosolv	Sauflon Pharmaceuticals	–	Aerosol (buffered)
Sauflon Saline Solution, 10 ml	Sauflon Pharmaceuticals	–	Sachets
Daily cleaning solutions (for use on removal of the lenses from the eyes) (***These solutions may also be used with hard and RGP lenses, subject to the provisions stated in Table C.I***)			
Hydrophilic lenses			
Opti-Free Daily Cleaner, 12 ml, 24 ml	Alcon	EDTA 0.1; Polyquad 0.001	
Opti-Plus Active Cleaner, 3 ml	Alcon		Preservative free cleaning solutions containing pancreatin, to be used with Opti-Free
Pliagel, 25 ml	Alcon	EDTA 0.5; SA 0.1	Soft and rigid lens cleaner
Polyclens II (Opti-Clean II), 12 ml, 24 ml	Alcon	EDTA 0.1; Polyquad 0.001	Contains polymeric beads
Preflex, 25 ml	Alcon	THI 0.004; EDTA 0.2	Not available in Australia
LC 65, 15 ml, 30 ml, 60 ml	Allergan	Self preserving	Soft and rigid lens cleaner
Omnicare Daily Cleaner, 30 ml	Allergan	Self-preserving	Contains 4% ethanol to assist rinsing + surfactants
SorbiClean Daily Cleaner, 30 ml	Allergan	EDTA 0.2; SA 0.1	Not available in Australia
Cleaner No.4 (Softmate), 35 ml	Allergan	EDTA 0.2; THI 0.004	UK only
Soft Mate PS Daily Cleaner, 35 ml	Allergan	PS 0.13	
Daily Cleaner, 10 ml, 30 ml, 60 ml	Bausch & Lomb	EDTA 0.5; SA 0.15	
Sterile Daily Cleaner, 45 ml	Bausch & Lomb	THI 0.004; EDTA 0.2	
Hydroclean, 35 ml	Ciba Vision	CHX 0.0025; EDTA 0.1; THI 0.0025	
Insta Care Starting Solution, 15 ml	Ciba Vision	Isopropyl alcohol 20	Combination disinfection and cleaner. Hypertonic Plutonic and miranol surfactant for cleaning. Use in conjunction with Insta Care Finishing Solution. Not available in UK
Miraflow, 10 ml, 15 ml, 25 ml, 35 ml	Ciba Vision	Self-preserving	Contains 20% isopropyl alcohol
Mediclean, 20 ml, 35 ml	Ciba Vision	CHX 0.0025; EDTA 0.1; THI 0.0025	Belgium and Germany only
Hoya Soft Cleaner, 60 ml	Hoya	EDTA 0.1; SA 0.1	
ICN Uniclean, 5 ml, 60 ml	ICN Pharmaceuticals	EDTA ?; THI 0.0015	Universal cleanser of hard, soft and RGP lenses

ATAC, alkyl triethanol ammonium chloride; BA, benzoic acid; CHB, chlorbutol; CHX, chlorhexiding gluconate; EDTA, ethylenediamine tetra acetic acid; NIPA, Nipastat; PMN, phenylmercuric nitrate; PS, potassium sorbate; SA, sorbic acid; THI, thiomerosal.

Table C.II (*Continued*)

Name of solutions and sizes available	*Manufacturer*	*Preservatives with percentage concentration*	*Remarks*
Hydrophilic lenses (*continued*)			
Sterisoft Cleaning, 20/60 ml	Sauflon Pharmaceuticals	EDTA 0.1; NIPA 0.02	Not available in UK
Sauflon Soft Lens Daily Cleaner, 20 ml, 60 ml	Sauflon Pharmaceuticals	EDTA 0.1; THI 0.004	
Steri-Solv, 60 ml	Sauflon Pharmaceuticals	EDTA 0.1; THI 0.004	
Prymeclean, 10 ml	Smith & Nephew	CHX 0.002	Active ingredient poloxamer 0.5%
Occasional cleaners (those which do not involve heating are also suitable for rigid lenses)			
Amiclair tablets 10, 24	Abatron	EDTA 0.074	Contains the chelating agent EDTA, and three enzymes; a lipase, and two proteases, one being pronase for removal of lipids, mucin and protein
Polyzym (Opti-Zyme)	Alcon	Pancreatin	Triphasic, acts against protein, lipids, mucin
Liprofin, powder in sachets	Alcon		Oxidizing agent used hot or cold. Unsuitable for Menicon soft lenses. For practitioner use only
Optifree Enzyme	Alcon		Pancreatin. For use with Optifree
Complete Protein Remover Tablets, 24	Allergan		Subtilisin A for use with Complete All-in-one Solution. 0.06 mg/tab
Hydrocare Fizzy Protein (Enzyme) Remover Tablets, 12, 24, 48	Allergan		Contains papain, a proteolytic enzyme 10 mg/tab. Also marketed as Bausch & Lomb protein removal tablets
Total Care Protein Remover Tablets, 10	Allergan		Subtilisin A, 0.4 mg/tab
Ultrazyme Protein Remover Tablets, 5, 10	Allergan		Active ingredient subtilisin A 0.4 mg/tab. Suitable for dissolving in hydrogen peroxide
ComfortCare GP Dual Action Daily Cleaner	Allergan		Subtilisin, Poloxamer 338, Daily cleaning tablet dissolved in ComfortCare GP Wetting & Soaking Solution
Soft Mate Protein Remover, 8 × 8 ml, 12 × 8 ml	Allergan	–	Surfactant combination unpreserved
Sensitive Eyes Protein Removal Tablets, 4, 24	Bausch & Lomb		Subtilisin A 25 mg/tab
Effervescent Cleaning Tablets (Renu Effervescent) 4, 24	Bausch & Lomb		Subtilisin A, 25 mg/tab
Sensitive Eyes Thermal Cleaning Tablets (Renu Thermal) 4, 24	Bausch & Lomb		Subtilisin A, 25 mg/tab
Sauflon Protein Remover Tablets, 8, 24	Sauflon Pharmaceuticals		Papain
Prymecare Protein Remover Tablets, 8, 16	Smith & Nephew		Contain papain for protein removal
Rewetting solutions (these may be used for hard and RGP lenses)			
Adapettes, 2 ml, 15 ml	Alcon	EDTA 0.1; THI 0.004	
Opti-Tears, 15 ml	Alcon	Dextran; EDTA 0.1; Polyquad 0.001	Known as Opti-Free Comfort Drops in Australia
Refresh 30 × 0.4 ml	Allergan	Preservative free	Single use vials. Polyvinyl alcohol 1.4%; Povidone 0.6%.
Soft Mate PS Comfort Drops, 15 ml	Allergan	EDTA 0.1; PS 0.13	Not available in UK
Sterile Lens Lubricant, 15 ml	Bausch & Lomb	EDTA 0.1; THI 0.004	
Sensitive Eye Drops, 10 ml, 15 ml	Bausch & Lomb	SA 0.1; EDTA 0.25	Alternative names Sensitive Eye Lubricant or Lens Lubricant
Hydrosol, 20 ml	Ciba Vision	CHX 0.0025; EDTA 0.1; THI 0.0025	Intended to be rubbed into lens surfaces prior to wear

ATAC, alkyl triethanol ammonium chloride; BA, benzoic acid; CHB, chlorbutol; CHX, chlorhexiding gluconate; EDTA, ethylenediamine tetra acetic acid; NIPA, Nipastat; PMN, phenylmercuric nitrate; PS, potassium sorbate; SA, sorbic acid; THI, thiomerosal.

Table C.II (*Continued*)

Name of solutions and sizes available	*Manufacturer*	*Preservatives with percentage concentration*	*Remarks*
Rewetting solutions (*Continued*)			
Clerz, 15 ml,	Ciba Vision	EDTA 0.1; S A 0.1	Available as single dose units
Progent	Menicon		Intensive cleaner for use with RGP lenses
Multipurpose lens Drops (Renu Rewetting Drops), 15 ml	Bausch & Lomb	SA 0.15; EDTA 0.1	Liquid A : NaClO, Na_2CO_3; Liquid B : KBr, Na_2CO_3
Sterifresh, 10 ml	Sauflon Pharmaceuticals	CHX 0.001; EDTA 0.1; THI 0.002	Not available in U.K.
Viva Drops, 15 ml	Vision Pharmaceuticals	Preservative-free	Contains 5000 IU vitamin A and Polysorbate 80

ATAC, alkyl triethanol ammonium chloride; BA, benzoic acid; CHB, chlorbutol; CHX, chlorhexiding gluconate; EDTA, ethylenediamine tetra acetic acid; NIPA, Nipastat; PMN, phenylmercuric nitrate; PS, potassium sorbate; SA, sorbic acid; THI, thiomerosal.

Table C.III Drugs used in contact lens practice

Drug	*Conc. used (% W/V)*	*Legal category*	*Use by UK optometrist*	*Availability in single dose*
Topical anaesthetics				
Amethocaine Hydrochloride	0.5, 1.0	PoM	U	Yes
Proxymetacaine Hydrochloride	0.5	PoM	U	Yes
Oxybuprocaine Hydrochloride	0.4	PoM	U	Yes
Lignocaine Hydrochloride	4.0	PoM	U	Only with 0.25% fluorescein
Conjunctival decongestants				
Naphazoline	0.01	P	U/S	No
Xylometazoline with antazoline	0.5	P	U/S	No
Diagnostic staining agents				
Fluorescein Sodium	1.0, 2.0	P	U/S	Yes and paper strips
Rose Bengal	1.0	P	U/S	Yes (paper strips available in some countries)
Chemotherapeutic agents (*Antimicrobials*)				
Framycetin	0.5	PoM	U	No
Chloramphenicol	0.5	PoM	U/S	Yes
Propamidine Isethionate	0.1	P	U/S	No
Ointments				
Franycetin	0.8	PoM	U	No
Chloramphenicol	1.0	PoM	U/S	No
Dibromopropamidine Isethionate	0.15	P	U/S	No
Miscellaneous agents				
Hypertonic sodium chloride	2.0, 5.0	PoM	U	No
Normal Saline	0.9	P	U/S	Yes
Simple Eye Ointment		P	U/S	No
Sodium Chromoglycate	4	P	U/S	No

P, Pharmacy medicine; PoM, Prescription Only Medicine; U, use only; U/S, use and supply for prophylaxis only. More details of the following ophthalmic preparations mentioned in Chapter 4 are obtainable from *Mims*, pubished monthly by Haymarket Pubishing Limited, Medical Division, 76 Dean Street, London W1A 1BU, and the *Data Sheet Compendium* published yearly by the Association of the British Pharmaceutical Industry (Pharmind Publications). These publications give brand names and names of the various manufacturing drug houses, as well as strengths, dosages, legal categories, contra-indications, side effects etc.

Appendix D

CCLRU Grading scales

CCLRU GRADING SCALES

Cornea and Contact Lens Research Unit, School of Optometry, University of New South Wales

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APPLICATION OF GRADING SCALES

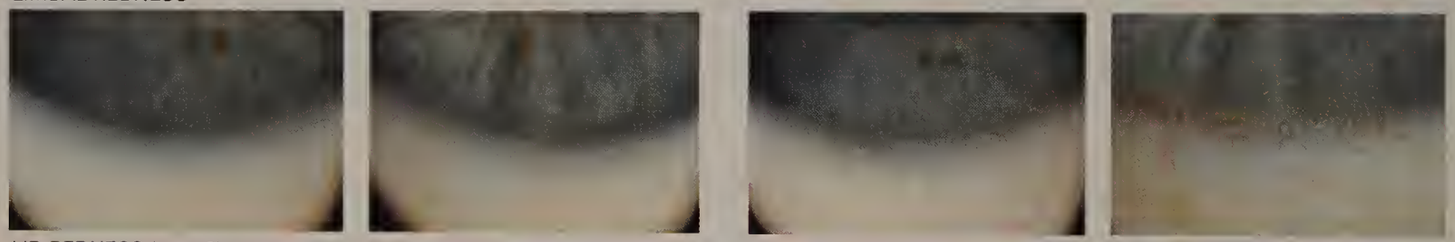
• Patient management is based on how much the normal ocular appearance has changed. • In general, a rating of slight (grade 2) or less is considered within normal limits for a population (except staining). • A change of one grade or more at follow up visits is considered clinically significant.

1. VERY SLIGHT	2. SLIGHT	3. MODERATE	4. SEVERE

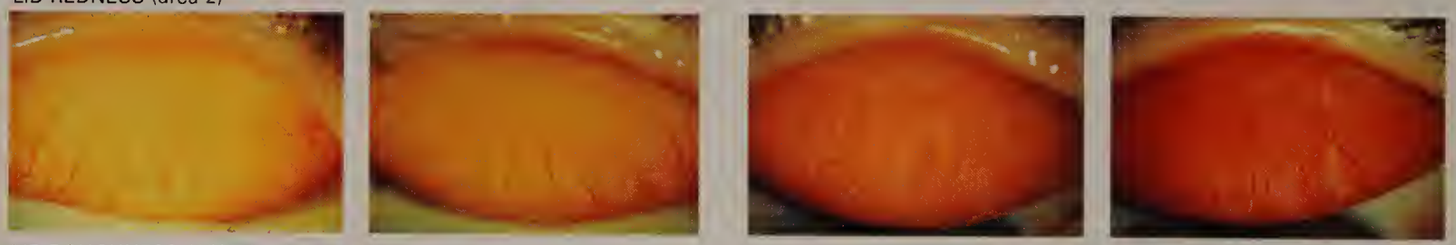
BULBAR REDNESS



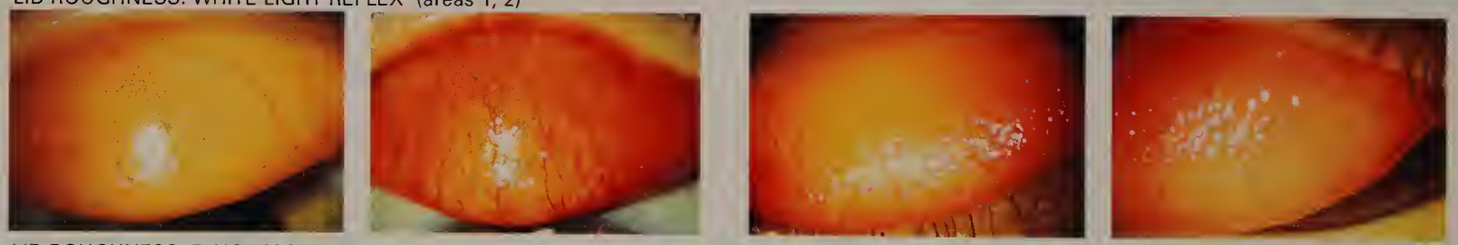
LIMBAL REDNESS



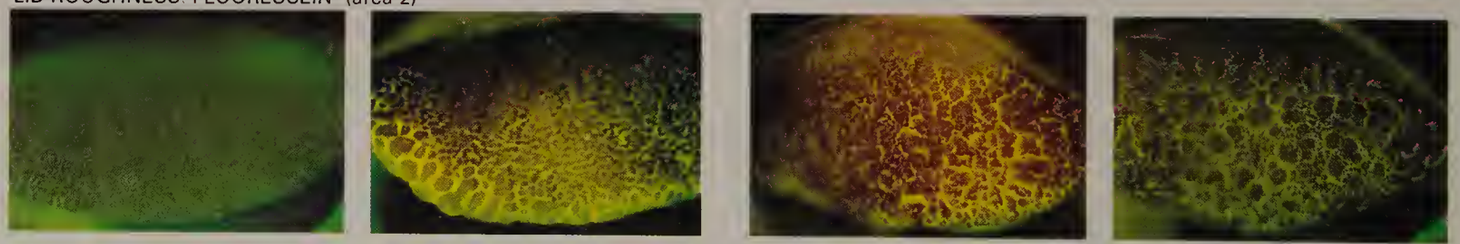
LID REDNESS (area 2)



LID ROUGHNESS: WHITE LIGHT REFLEX (areas 1, 2)



LID ROUGHNESS: FLUORESCEIN (area 2)



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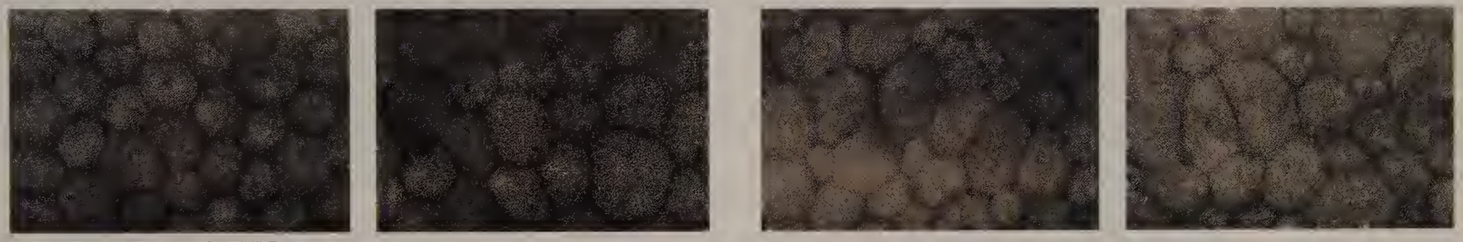
1. VERY SLIGHT

2. SLIGHT

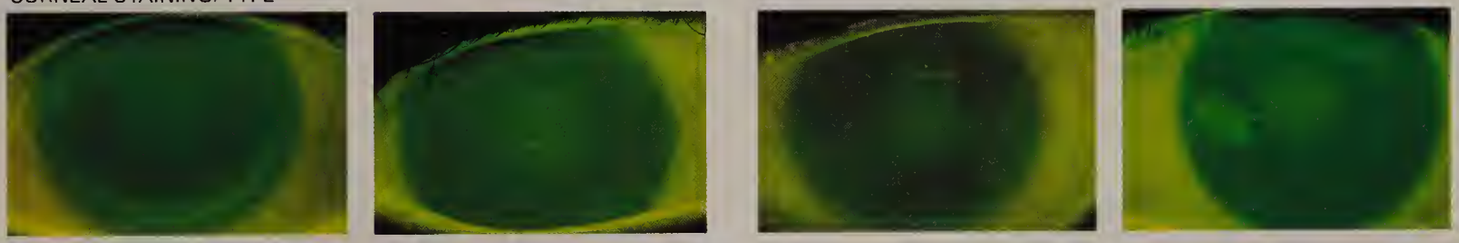
3. MODERATE

4. SEVERE

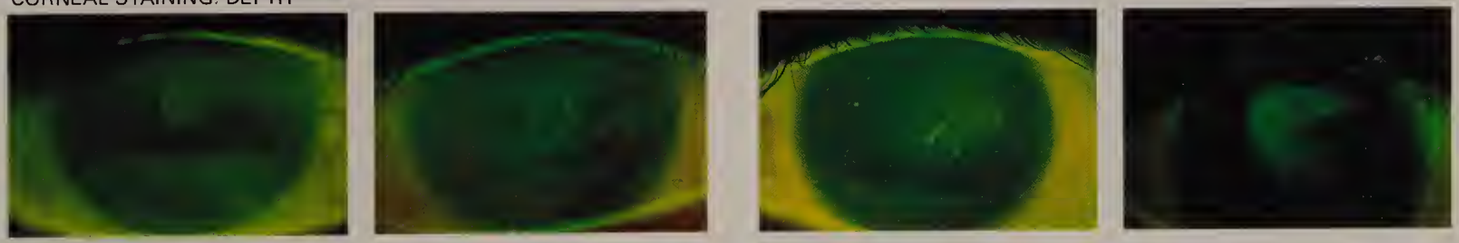
POLYMEGETHISM



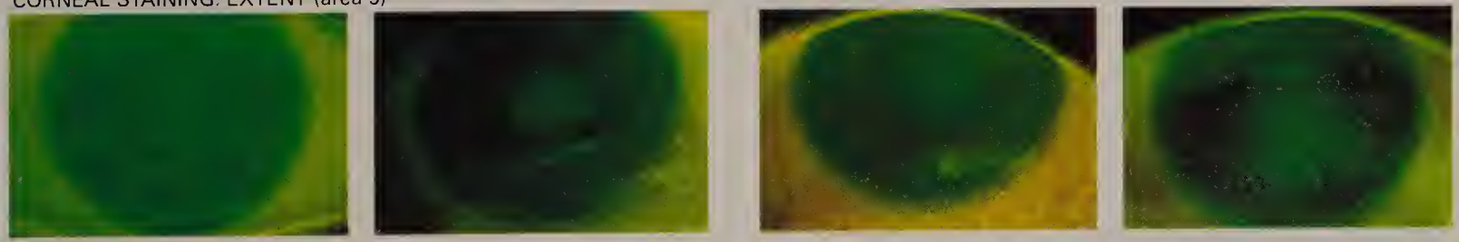
CORNEAL STAINING: TYPE



CORNEAL STAINING: DEPTH



CORNEAL STAINING: EXTENT (area 5)



CONJUNCTIVAL STAINING



CCLRU GRADING SCALES

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ADVERSE RESPONSES WITH CONTACT LENSES

INFILTRATES

Accumulation of inflammatory cells in corneal sub-epithelium or stroma



Signs:

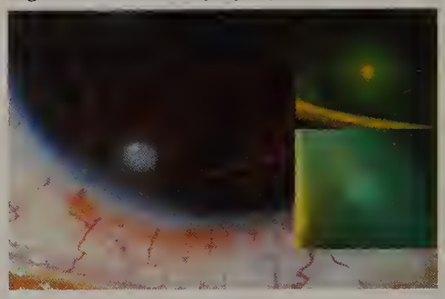
- Whitish opacity (local) or grey haze (diffuse)
- Mostly 2-3 mm from limbus
- Localised redness

Symptoms:

- Asymptomatic or scratchy, foreign body sensation
- Redness, tearing and photophobia possible

CNPU CULTURE NEGATIVE PERIPHERAL ULCER

Full thickness epithelial loss with stromal degeneration in corneal periphery. Inset: scar



Signs:

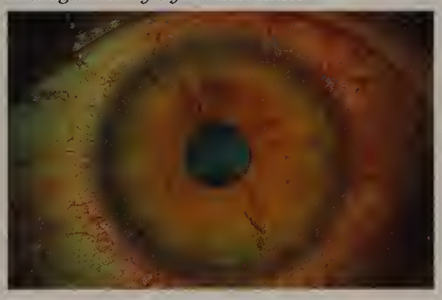
- Unilateral
- Localised redness
- Infiltrates
- Post healing scar

Symptoms:

- Varies from mild to foreign body sensation to pain
- Tearing and photophobia may occur

CLARE CONTACT LENS ACUTE RED EYE

Acute corneal inflammation associated with overnight wear of soft contact lenses



Signs:

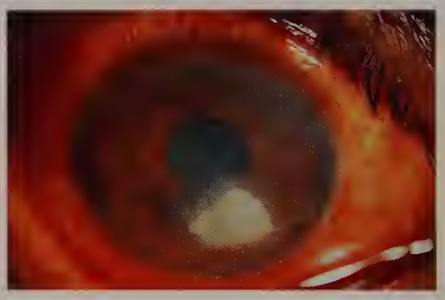
- Unilateral
- Intense redness
- Infiltrates
- No epithelial break

Symptoms:

- Wakes with pain
- Photophobia
- Tearing

INFECTED ULCER

Full thickness epithelial loss with stromal degeneration, typically central or paracentral



Signs:

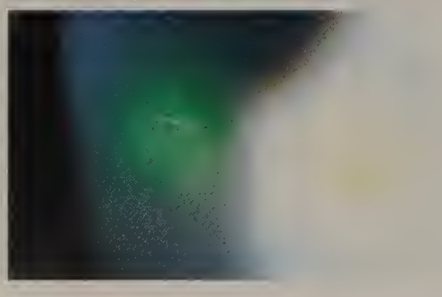
- Intense redness
- Large white patch
- Infiltrates
- Epithelial and stromal loss

Symptoms:

- Pain
- Red eye
- Mucoid discharge
- Photophobia
- ↓VA (if over pupil)

EROSION

Full thickness epithelial loss over a discrete area



Signs:

- No stromal involvement
- Immediate spread of fluorescein in stroma

Symptoms:

- Pain
- Photophobia
- Lacrimation

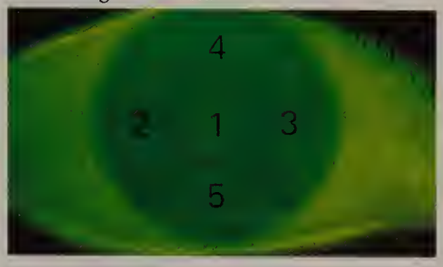
CCLRU GRADING SCALES

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CORNEAL STAINING GRADES (see p.865)

- Staining assessed and immediately after single installation of fluorescein using cobalt blue light and wratten 12 (yellow) filter over slit lamp objective.
- The cornea is divided into five equal areas to grade the type, extent and depth of staining in each area.



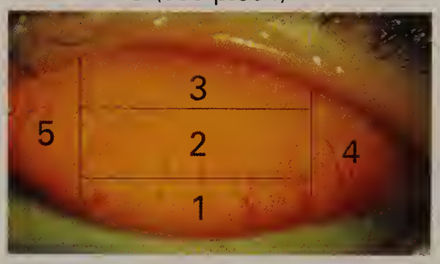
Type

- Micropunctate
- Macropunctate
- Coalescent macropunctate
- Patch

Extent: Surface area		*Depth**	
1	1 - 15%	1	Superficial epithelium
2	16 - 30%	2	Deep epithelium, delayed stromal glow
3	31 - 45%	3	Immediate localised stromal glow
4	> 45%	4	Immediate diffuse stromal glow

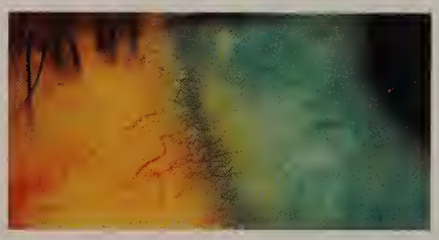
*Based on penetration of fluorescein and slit lamp optic section

LID AREAS (see p.864)



- The palpebral conjunctiva is divided into five areas to grade redness and roughness
- Areas 1,2 and 3 most relevant in contact lens wear

VASCULARISATION



- Vessel extension beyond translucent limbal zone (mm)

STROMAL STRIAE



Record number

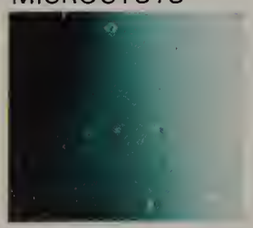
One striae = 5% edema
One fold = 8% edema

(each additional striae/fold is 1% more edema)

STROMAL FOLDS



MICROCYSTS



Identified by illumination

Microcysts = Reversed
Vacuoles = Unreversed

Recorded number

(>10 microcysts/vacuoles requires management)

VACUOLES



Appendix E

Instructions for the CD-ROM

System requirements

IBM PC or compatible, 386 SX or higher, running Windows 3.1 or Windows 95, with 4MB RAM, 4MB of hard disk free, 16 colour monitor and CD-ROM drive.

To install and use the CD-ROM

In Windows Program Manager, choose Run from the File menu (the Start menu in Windows 95), type in d:\setup.exe (where d is the CD-ROM drive) and press enter. Follow the on-screen instructions.

These programs have been designed with ease-of-use in mind so that you should find all the information you need to make them work on the screen. The procedures to which they relate are described in the book.

You will find that you can move between text entry boxes using the Tab key. To move backwards, use Shift+Tab. Otherwise, use the mouse to position the cursor in the correct box. Boxes which have up and down arrows beside them (the arrows are called 'spin buttons') can be controlled by either clicking on the arrows with the mouse or by holding down the Ctrl key and pressing the up and down arrow keys. You may find that you need to type in a figure instead of using the spin buttons; for instance if you want to set the displayed value to 0 (zero) in certain cases. Once all the necessary data have been entered, you can press Tab once more to highlight the calculate button. If you then press the Enter (return) key, the calculation will be performed.

If you receive an error message when you press calculate, check the values that you have set to make sure that they fall within the allowable range. If you are unsure about any of the values, refer to the relevant chapter in the book.

In the Lens Design program some options only become available when enough data have been entered – the buttons 'light up'. For example, this happens after you click on Lens Specifications. The View Lens Profile button doesn't become available until you have filled in values and calculated a back surface and then filled in a power and centre thickness.

In the case of toric lenses, you will find there is a 'Suggest' button, to give you some help with the back surface values. You will find that default values of corneal eccentricity (0.45; p-value = 0.7975), radii and spectacle Rx appear each time the Lens Design program is restarted.

Please note that for technical reasons it is not possible to display subscripts so that for example r0 on the screen is used to denote the BOZR.

For some calculations it is possible to generate a graphical representation; for instance, in the Lens Design program to show the tear layer profile. Here, it is necessary to click on the 'Draw' button (or tab to it and press Enter) in order to display the graphic.

There is no technical support available for this product. If you experience any problems, please make sure that your system meets the requirements detailed above and that you have followed the installation procedure correctly. If problems persist then in the first instance write to the publishers at:

Butterworth-Heinemann, Linacre House, Jordan Hill,
Oxford OX2 8DP, UK.

Index

Abrasions, 605
Acanthamoeba, 95, 96, 98, 119, 145, 277
  complicating hydrogel extended wear, 507
  lens contamination, 103
  saline contamination, 113
  storage case contamination, 103–4
  thermal disinfection, 112
Accelerated orthokeratology (Accelerated Ortho-k), 656
  clinical experience, 687–90
    visual acuity, 689–90
  refractive change
  lens fit relationship, 689
  original refraction relationship, 688–9
  predicted versus actual, 688
Acceptable quality level (AQL), 433
Accessory lacrimal glands, 41, 83
  tear components, 83
Accommodation: convergence (A/C) ratio, 169
Accommodation
  convergence changes, 158, 169
  spectacles versus contact lenses, 168–9
Accuracy of tests, 430
N-Acetylcysteine, 128
Acne rosacea, 264
Acne vulgaris, 264
Acrylamide hydrogels, 73
Acrylic contact lenses, historical aspects, 5–6, 11–13
Acuvue, 13, 50, 51, 360, 362, 394, 499, 501
  lens imperfections, 521
  manufacture, 429
  oxygen permeability, 520
Adaptation
  early difficulties, 299–300
  soft lenses, 362
    high water content, 370
Adenovirus conjunctivitis, 100
Adherence, RGP lens extended wear, 523, 524, 525–7
Adrenaline, 143
  lens discoloration, 86, 111, 135
Adrenochrome, 86
Aerotab, 118, 134, 138, 140, 304, 305
Aesthesiometry, 245, 275, 285
  soft lens fitting, 374
  see also Corneal sensitivity
Afocal lens approach, 10
After-care, 283, 299, 609–10
  advice for patients, 260, 612
  air bubbles, 614–15
  allergic reactions, 612–13
  aphakia, 711–12, 741
  bacterial conjunctivitis, 613
  bacterial corneal ulcers, 613
  biomicroscopy in, 613–14
  blinking efficiency, 614
  care of finger nails, 625
  case contamination, 616
  chronic hyperaemia, 616
  compliance with instructions, 617
  concretions, 617
  corneal exhaustion, 617–19
  corneal infiltration, 619
  corneal oedema, 619–20
  cosmetics, 620–1
  counselling, 621
  dermatological conditions, 621
  diabetics, 621–2
  diplopia, 622
  discolouration of lenses, 622
  discomfort, 622
  distortion of lenses, 622–3
  duplicate lenses, 623
  emergency consultation, 623–4
    out of hours, 634
  endothelial bedewing, 624
  endothelial response, 624
  epithelial splitting, 624–5
  examination structure, 609
  fenestration, 625
  fit evaluation, 625
  flare, 625–6
  flexure, 626
  fluorescein in, 626
  flying, 626
  foreign body sensation, 626–7
  ghost images, 627
  giant papillary conjunctivitis, 627–8
  glare, 628
  glaucoma treatment, 628–9
  guttata, 629
  hand washing, 629
  history taking, 610
  infants/children, 712, 740–2
  infection, 629–30
  inferior front surface deposits, 630
  informed patients, 630
  inside-out lenses, 630–1
  interviewing and history taking, 631
  irritation, 631
  itch symptoms, 631
  keratoconus, 704
  lens condition, 631
  lens insertion, 631–2
  lens parameters, 632
  lid twitch sensation, 632–3
  lost lenses, 633
  low vision, 633
  maintenance of lenses, 633
  medication, 633
  mixed lenses, 633
  modifications, 634
  no symptoms, 634
  ophthalmoscopy, 634
  oral contraceptives, 634
  over-refraction, 634
  over-wear syndrome, 635
  paper tissue, use of, 635
  patient interviewing, 610
  pingueculae, 637
  polishing, 635
  presbyopia, 636
  preservative reaction, 636–7
  pseudopterygia, 637
  pterygia, 637
  purging lenses, 638
  quality control, 638
  reactive eye, 638
  reconditioning of lenses, 638–9
  record keeping, 639
  recurrent corneal erosions, 727
  re-fitting lenses, 639
  re-instruction, 639–40
  reports, 640
  residual astigmatism, 640
  rigid gas permeable lenses, 640
  scratches, 640–1
  sequential stain, 641
  silicone rubber lenses, 641
  spectacles, 641
  stinging, 641
  suction holders, 641
  superficial punctate epitheliopathy, 641–2
  superior limbic keratitis, 642–3
  supplementary spectacles, 643
  surface deposits, 643–4
  swimming, 644–5
  symptom analysis, 610–12
    discomfort, 611
    vision problems, 610–11
  tear circulation, 645
  tear deficiency, 646–8
  three and nine o'clock peripheral stain, 648
  tonometry, 648
  toric lenses, 648
  toxic fumes, 648
  travelling, 733–4
  vasoconstrictors, 650
  visual field examination, 650
Agaricus, 95

Age
aphakia, 707
after-care, 711–12
corneal sensitivity changes, 31, 275
eyelid changes, 275
lens handling, 275
patient suitability for contact lens wear, 274–5
Ageing, soft lenses, 364
AIDS, 95
Albinism, 731
corneal sensitivity, 32
cosmetic lenses, 743, 749
infants/pre-school children, 738
Albumin, 83
lens polymer association, 88
protein film lens coatings, 85
tear film defences, 98
Alcian blue, 266
Alcohol intake, lens lipid deposits, 135
Alcon solutions, 854–62
Alges bifocal lens, 560
Alginate eye impressions, 580–1
casting, 582
Alkyl triethanol ammonium chloride
chemical disinfection, 117
misuse, 140
Allergan solutions, 109, 115, 117, 122, 124, 129, 140, 854–62
Allergic conjunctivitis, 262–3
mucoprotein-lipid lens deposits, 85
Allergic reactions
after-care, 612–13
care solutions
chemical disinfectants, 131, 401
hydrogel extended lens wear, 519
soft lenses, 131
indications for referral, 262–4
keratoconus patients, 704
soft lenses, 365
treatment, 143
Alternaria, 95
Alternating vision bifocal, 545, 557–9, 561
Amanita, 95
Amblyopia, 274
in aphakic infants, 736
Amethocaine, 142, 862
Amiclair, 127
Amidose, 859
Anaesthetic cornea, 266, 602
in impression taking, 602
Anaesthetics, epithelial repair inhibition, 21
Anaesthetics, topical, 142–3
Analgesic drugs, 137
Anderson medicator, 831, 832
Animals' lenses, 840–1
Aniridia, 731
infants/pre-school children, 737–8
Aniseikonia, 274
Anisometropia, 273–4, 731
axial, 165
infants/pre-school children, 737
post-radial keratotomy, 721
refractive, 165, 167
retinal image size, 165, 166, 167
spectacles versus contact lenses, 158–60
Annealing, 778
ANSI Z80.8, 432, 436, 446
Antazoline, 143
Anterior chamber
angle, 820–2
classification, 821–2
slit-lamp examination, 265
Anterior lens surface examination, 265
Anterior membrane dystrophies, 764–5
Anterior optic radius (*rao*), 191
optical formulae, 212–14
centre thickness (*tc*) not known, 214–16
Anti-adherence factors, 99
Anti-allergic agents, 143
Anti-bacterial agents, 145
Anticholinergic drugs, 136
Antihistamines, 143
tear flow reduction, 136, 633
Anti-Parkinson drugs, 137
AOSept system, 114, 140
information for patients, 303, 304
'Apex lens', 13, 709
Aphakia, 3, 9, 13, 273, 707–12
ability to handle lenses, 275
after-care, 711–12, 740, 741
age-associated influences, 707
astigmtism, 707
bullous keratopathy, 763
contact lens fitting procedure, 707, 708–9, 711, 732–3
corneal lenses, 709
extended wear lenses, 710
soft lenses, 709–10
hydrogel extended wear, 498
infants/pre-school children, 711–12, 731–6, 740, 741
alterations with age, 736
back-up spectacles, 732, 740
contact lens fitting, 711, 732–3
RGP lenses, 734–6
scleral lenses, 599–600, 736
silicone rubber lenses, 734
soft lenses, 733–4
surgical techniques, 742
traumatic aphakes, 736
unilateral aphakes, 736
iridectomy apertures, 708
keratometry, 708
lid position, 708
multifocal/varifocal contact lenses, 711
near correction, 711
ocular physiology, 707
pupil size/shape, 708
refraction, 710–11
spectacle, 708
retinal image size with spectacles/contact lenses, 165
scleral lenses, 599–600, 736
therapeutic/bandage soft lenses, 831
ultraviolet filter incorporation, 276, 284, 707, 711, 733
RGP lenses, 319
Apical radius of cornea (r_{OK}) from 'K' reading, 202
Appetite suppressants, 137
Aquasil, 328
Aqueous, corneal metabolite supply, 38, 39
Aquila Elliptical, 725, 727
Arc lights, 277
Arcus senilis, 264
Army personnel, 279
Arthroderma, 95
Artificial tears, 108, 140, 647, 648, 772
Ascomycetes, 95
Aspergillus, 95
keratitis, 96
Aspergillus fumigatus, 85, 111, 116
thermal disinfection, 112
Aspergillus niger, 85
Asperi P, 725
Aspheric designs
aspheric front surfaces, 174
bifocal contact lenses, 544, 545, 548, 549
concentric aspheric 'multifocal' lenses, 547
fitting, 551
hydrogel lens verification, 440
in keratoconus, 701–2
RGP lenses, 333–5, 340–1
rigid lens verification, 423
Aspirin, 135
Astigmatism, 171, 273
aphakia, 707
in aphakic infants, 733
approximate rule, 172
front surface of cornea, 171
induced, 473–5
keratometry, 171, 267
liquid lens effects, 171
orthokeratology, 664
postkeratoplasty, 717
post-radial keratotomy, 722
residual, 171–2, 640
RGP lenses
extended wear, 529
fitting, 339, 342, 344–5
soft lenses, 368
flexure/equilibrium change effects, 179–80
toric lenses
indications, 467
limitations, 490
optical considerations, 469
soft lenses, 482, 490
total ocular astigmatism, 171
Atalficon, 51, 88
Atopic dermatitis, 693
Atopic eczema, 263
Atopy, 262
Australia, drug regulations, 146
Autoclaving soft lenses, 113
Autofocal, 544
Automated keratometry systems, 236–7
Autostigmatic microscope, 439
Axial edge clearance, 195–8
peripheral radii calculation, 208–12
RGP lens design, 332, 333
Axial edge lift, 195–8
calculation, 198
modification of peripheral radii, 198
optical formulae, 222–3
conversion to radial edge lift, 223–4
peripheral radii calculation, 206–12
RGP lens design, 332, 333
rigid lens verification, 417
Axial edge thickness (t_{EA}), 190
optical formula, 214
rigid lens verification, 418–19
Axial junction thickness, 215, 217–19
Axial rotation of toric soft lenses, 487

B&L 70, 359
Babies *see* Infants/pre-school children
Bacillus, 507

Back optic zone diameter (BOZD), 340, 350, 444, 572, 724
bifocal lenses, 550, 558, 563
corneal lenses, 424, 809
in corneal lens fitting, 340
modification of, 809
poor light and, 276
tear lens thickness and, 332, 333
Back optic zone radius (BOZR)
alterations, 181–4
approximate rules, 182, 183–4
corneal lenses, 809
grind-out, 812–13
photorefractive keratectomy, 727
radial keratotomy, 725
rigid lenses, 339, 346–7, 350, 351
scleral lenses, 572, 588–9, 812–13
soft lenses, 436
soft lenses for infants, 734
therapeutic lenses, 759
toric lenses, 465
Back peripheral radius (BPR), 196–8, 340, 350, 465, 485
Back vertex distance (BVD), 351, 845–87
Back vertex power (BVP)
calculation, 170
corneal lens modification, 809–10
hydrogel lens verification, 450–1
lens thickness, 173–4
optical formulae, 204–6
ordering, 350
rigid lens verification, 419
scleral lens modification, 814
Bacteria, 93–5
adherence
structures, 94
to contact lenses, 103
to cornea, 104
cell wall, 94
cornea interactions, 104
disease processes, 95
Gram staining, 94
growth requirements, 94
lens interactions, 103–4
lens storage cases contamination, 103
morphology, 93
spoilation, 85–6
toxins, 95
typing methods, 94
Bacterial conjunctivitis, 96, 613
Bacterial corneal ulcers, 613
Bacterial glycocalyx, 104
Bacterial keratitis, 774
Bactericide-incorporating lens material, 841
Balantidium, 96
Band magnifier, 444
Bandage lenses *see* Therapeutic lenses
Barkan lens, 820, 821
Basidiomycetes, 95
Bausch & Lomb 04 lens, 766
Bausch & Lomb mires, 233–4
Bausch & Lomb Soflens, 391–4
Beclomethasone, 137
Bellows, photographic, 250
Bell's palsy, 29
Bell's phenomenon, 29
Benoxinate (oxybuprocaine), 142
Benoyl peroxide, 137
Benzalkonium chloride, 105, 108, 109
misuse/incompatibility, 140
Benzyl alcohol, 117
Berberine, 86, 111
Berkeley orthokeratology study, 655
Beta-blockers, 137
Betalysin, 98
Bifocal contact lens fitting
alternating/translating bifocals, 551–6
aspheric bifocals, 551
back surface concentric bifocals, 549–50
fitting sets, 562–3
front surface concentric bifocals, 550–1
lower lid position/tightness, 549
prism ballasted bifocals, 551–6
adjusting lenses, 556–7
central thickness, 553, 554
stabilization, 555–6
procedure, 549–59, 563–4
pupil diameter, 549, 564
Bifocal contact lenses, 186–8, 541–64
alternating/translating vision, 545, 557–9
aphakia, 711
aspheric, 545, 547
concentric solid, 186–7, 795–7
fused, 187–8, 795
historical development, 541–4
hydrophilic, 396, 560–4
manufacturing, 795–7
fused lenses, 795
solid lenses, 795–7
monovision, 545–6, 547–8
multizone, 546
non-refractive, 546–7
concentric aspheric 'multifocal', 547
diffractive, 547
pinhole lenses, 546
spherical aberration-correcting, 547
retinal image quality, 544–5
rigid lens verification, 423
scleral, 559–60
segment, 551–4
simultaneous vision/bivision, 545
surface power optical formulae
different segments, 200–1
various optic zone radii, 201
types, 545–8
selection, 548–9
Biguanide disinfection systems, 50
Dymed (polyhexanide), 117
Binocular vision, 274
Biomicroscopy *see* Slit lamp examination
Bionite, 359
Bi-toric lenses
compensated/spherical power, 185, 475
Stokes' construction, 185–6
Bivision, 542, 545
Blebs, 606
leaking, 769
Blending, 786
Blepharitis, 268
bacterial agents, 96
lid hygiene, 632
Blepharospasm, 29, 268
Blinking, 98
after-care examination, 614
infants/pre-school children, 740
lens movment, 29
lens wear effects, 29
microorganisms removal, 99
ocular defences, 111
spreading of tear film, 42
tears drainage, 43
Blinking rate, 29
Blown glass lenses (Muller), 4, 5, 11
Blurred image, 156
Boiling lenses, 112–13
Boundary effect, 68
Bowman's layer (lamina limitans anterior), 22
response to damage, 22
transparency, 36
BOZD *see* Back optic zone diameter
BOZR *see* Back optic zone radius
BPR *see* Back peripheral radius
Break-up time (BUT), 268, 271, 285–6, 375
age-associated variation, 275
gender-associated variation, 275
Breakage
RGP lenses, 276, 347
soft lenses, 364
high water content, 370
Brompheniramine, 136
Brown discoloration, 86
soft lenses, 132
BS 3521, 428, 434
BS 4778, 433, 434
BS 5562, 432
BS 7208, 407, 423–4, 433, 436, 444, 798
soft lens specification, 430
Bubbles of air under lens, 13, 614–16
keratoconus, 614
scleral lenses, 605
Buffering agents, 106
Bulbar conjunctiva, 25
blood vessels, 27
patient assessment, 285
pinguecula, 27
slit-lamp examination, 265, 268
Bullous keratopathy, 758
aphakia, 763
soft lenses, 363
therapeutic lenses, 762–3, 774
Bullseye bifocal lens, 560
Burns, 771
Burton lamp examination, 629
Butyl acrylate materials, 80

Calcium Deposit Preventer, 129, 134
Calcium deposits, 111, 132, 403
calcium phosphate coatings, 85
disinfection/cleaning solutions, 129, 134
lens calculi, 132, 134, 371
Calculi, lens, 132, 134, 371
CALS soft lens, 544
Camera, 248
Candida, 95
keratitis, 96
Candida albicans, 85
Candida tropicales, 85
Capillary attraction, 317
Capsulotomy, 825
Carbohydrate metabolism, cornea, 37–8
glycolysis, 37–8
hexose monophosphate shunt, 38
Carbon dioxide, 496
Carbonic anhydrase, 36–7
Carborundum tools, 804
Care solutions, 104–41, 854–61
combination lenses, 110
compliance with instructions, 617
formulation, 104–5
historical aspects, 5

Care solutions (*cont*)
hydrogel extended lens wear, 518
solution sensitivities, 519
information for patients, 300
misuse/incompatibility, 138–40
patient management, 297
pH, 104
prerequisites, 105
protein removing tablets, 109
rejuvenating systems, 129–30
rewetting agents/artificial tears, 108
rigid lenses, 105–7
buffering agents, 106
cleaning agents, 106–7, 109
colouring agents, 106
isotonic agents, 106
multifunctional solutions, 108
preservatives (storage solutions), 105–6
soaking solutions, 107
solution interactions, 108–9
viscosity-building agents, 106
water, 106
wetting agents, 106, 107–8
scleral lenses, 141, 597
silicone rubber lenses, 109–10
soft lenses *see* Soft lens solutions
statutes/government reulations, 145
sterility, 104
tonicity, 104
see also Cleaning agents
Carrier zone, 192, 329–330, 781
Caruncle, slit-lamp examination, 265
Case/container, 141
contamination, 103, 113
after-care examination, 616
microbial biofilms, 104
hygiene, 297
Casts, 582
Cataracts
congenital, 711, 731
cosmetic lenses, 743, 744
Catarrh, chronic, 262
CCLRU grading scales, 863–7
Cell-mediated immune response, 100
Cellulose, 52, 54
Cellulose acetate, 54
Cellulose acetate butyrate (CAB), 54, 55, 323, 325, 522
advantages, 323
disadvantages, 323, 325
hydration-dehydration changes, 346
lens solutions, 105, 108
Cellulose acetate propionate, 54
Centre thickness (*tc*), 191
aphakic lenses, 709
hydrogel lens verification, 445–8
optical formulae, 214–17
ordering rigid lenses, 351
rigid lens verification, 418–19
Cetylpyridinium chloride, 105
Chalazion (internal stye), 28
Channels, 590–2, 814
Checking lenses
CNC (computer numerical control) production, 783
RGP lenses, 354, 481
soft lenses, 365
focimetry, 451–4, 491
toric lens fitting, 481, 491
see also Verification
Chemical burns, 771
Chemical contamination of soft lenses, 365
Chemical disinfection, 114–22, 134
alkyl triethanol ammonium chloride, 117
allergic reactions, 131, 401
benzyl alcohol, 117
chlorhexidine, 115–17
Dymed (polyhexanide), 117
halazone, 118
hydrogen peroxide, 114–15
p-hydroxybenzoic acid (Nipastat), 119–20
infants/pre-school children, 740
information for patients, 302–3
hydrogen peroxide routines, 303–4
soft lens disinfection routines, 304–5
iodophors, 118
misuse/incompatibility, 138–9
Optimeyes, 118–19
Polyquad, 120
potassium sorbate/sorbic acid, 120
prescribing, 130, 131
sodium dichloroisocyanurate (Halane), 120
soft lenses, 364, 400–1
high water content lenses, 371
trial fitting, 374
thimerosal, 115–17
trimethoprim, 121
Chemotherapeutic agents, 144–5
Children
aphakia *see* Aphakia
fear of lenses, 261
fitting lenses, 259, 300
psychological aspects, 261
time for fitting, 259
see also Infants/pre-school children
Chloramphenicol, 144, 145
Chlorbutol, 105, 110, 140
Chlorhexidine, 105, 108, 109, 401
chemical disinfection, 115–17
lens discoloration, 86
misuse/incompatibility, 138, 139
see also Optimeyes
Cholesterol-rich food, lens deposits, 135
Cibatints, 138
Cicatrizing conjunctival diseases, therapeutic lenses, 770–1
Ciliata, 96
Civil pilots, 278
CL1 leaflet, 258
CLARE reaction *see* Contact lens-induced acute red eye (CLARE) reaction
Classification, 328
materials, 798–9
hydrogels, 73
polymers, 54–6
RGP lenses, 328
soft lenses, 369–70
Cleaning agents
information for patients, 260
prescribing, 130–5
rigid lenses, 106–7, 109
silicone rubber lenses, 110
soft lenses, 122–30
surfactants *see* Surfactant cleaning solutions
Cleaning lenses
daily wear lenses, 130
disposable lenses, 520
infants/pre-school children, 740
information for patients, 260, 298
daily cleaning, 302, 303
insertion of first lens, 294–5
on removal, 298
RGP lenses, 347
extended wear, 528, 530
soft lenses, 111, 112, 364
see also Disinfection
Clerz, 124, 140
Climate, 131
Clinical equivalents
scleral lenses, 572
soft lenses, 384
Clofazimine, 135
CNC lathes, 783–5
Coatings, lens, 85
Cockell's underwater contact lens, 838, 839
Cold alginate impression materials, 8–9
Cold weather activities, 837
Collagen bandage lenses, 758, 761–2, 831
drug delivery, 758, 773
Collagen dysfunction, 695
Collagen plugs, 772
see also Punctal occlusion
Coloboma, 731, 743, 747
corneal exposure, 602
infants/pre-school children, 738
Colour vision defects, 397, 833
Colouring agents in care solutions, 106
Combination lenses, 398
contact lens solutions, 110
keratoconus, 698–9
postkeratoplasty, 718–19
see also Softperm lenses
Comfort, soft lenses, 362
high water content lenses, 370
Comparators, 445
Complement activation, 99, 100
Complete storage solution/cleaner, 124
Computer screens, 365, 650
Concentric bifocal, 547, 548, 549–51, 561–3, 796–7
Concretions, 617
Conditioning solutions, 140
Cone dystrophy, 731
infants/pre-school children, 738
Congenital cataracts, 711, 731
Conjunctival biota, 96, 111
contact lens wear-associated changes, 102
fungal flora, 85
Conjunctival decongestants, 143
Conjunctival follicle enlargement, 27
Conjunctival goblet cells, 25–6
contribution to tears, 41, 42, 83, 84
mucin secretion, 26
Conjunctival indentation, 491
Conjunctival papillary enlargement, 27
Conjunctival radius of curvature, 9
Conjunctival sac
anatomy/physiology, 24–7
blood vessels, 27
epithelium, 26–7
migratory cells, 27
vesicle-bearing superficial cells, 26
innervation, 27
lymphatic vessels, 27
subdivisions, 24, 25
Conjunctival sensibility, 33–4
Conjunctival sensitivity, 30–4
Conjunctivitis, 96, 613
see also Contact lens-induced papillary conjunctivitis (CLPC); Giant papillary conjunctivitis (GPC)
Conlish tools, 805

Constant axial edge lift (CAEL), 322, 330
Contact angle measurement, 62, 64–5
  clinical significance, 66
  theoretical basis, 63
Contact lens solutions *see* Care solutions
Contact lens-induced acute red eye (CLARE) reaction, 85, 96, 497
  disposable lenses, 520
  hydrogel extended wear, 499, 503–5
RGP extended wear, 523, 524
Contact lens-induced papillary conjunctivitis (CLPC), 627–8
  infants/pre-school children, 740–1
  RGP extended wear, 523, 529
  soft lenses, 365
    extended wear, 505–6
  see also Giant papillary conjunctivitis
Contact lens-induced superior limbic keratoconjunctivitis, 491
Contact splint, 4
Contour lens, 12, 321
Contraceptive pill, 634
Contraindications to contact lenses, 258–79, 296
Controlled clearance RGP scleral lenses, 576–580
Convergence
  accommodation ratio (A/C ratio), 169
  prismatic effects, 157–8
  spectacles versus contact lenses, 157–8
Coon's orthokeratology study, 655–6
Copolymers, 52
  hydrogels, 71, 72
Cornea
  abnormality diagnosis, 818–19
  anatomy/physiology, 17–24
  astigmatism, *see* Astigmatism
  bacterial interactions, 104
  contact lens-associated changes, 188–9
  observation lens systems, 817
  patient assessment for contact lenses, 267, 285
    keratometry *see* Keratometry
    slit-lamp examination, 264–5
Cornea plana, 266
Corneal apical erosion, 12
Corneal burns, 363
Corneal calcification, 85
Corneal cap, 314, 315
Corneal clouding, 4, 9
Corneal contours, 12, 314
  irregularity, 1, 3
    infants/pre-school children, 731
  RGP lens fitting, 314–16
    mathematical models, 316–17
  scleral lens fitting, 566
Corneal dystrophies, 713, 731
  cosmetic lenses, 743, 745
  diagnosis, 818
  therapeutic lenses, 738
Corneal endothelium *see* Endothelium (endothelium camerae anterioris)
Corneal epithelium (epithelium anterius corneae), 17–20
  carbohydrate metabolism, 38
  cell production/renewal, 20
  contact lens-associated microtrauma, 102
  corneal surface, 18–19
  damage, 20–1
  desquamation, 98
  fragility, 21
  imprinting by corneal lenses, 21
  infection defences, 99
  innervation, 30
  Langerhans cells, 20
  reaction to damage, 20–2
  repair processes, 20–1
    anaesthetics inhibition, 21
Corneal evolute, 315
Corneal exposure, 268, 602
  scleral lenses, 605–6
  therapeutic lenses, 761
Corneal fatigue/exhaustion, 24, 617, 619
  hydrogel extended wear, 516
Corneal graft, *see* Keratoplasty
Corneal hydration
  corneal transparency, 36
  soft lenses, 401
Corneal hypoxia, 520–1, 606
Corneal infection, 629–30
  disposable lenses, 520–1
  hydrogel extended wear, 499, 506–9, 520–1
    causative organisms, 507
    clinical detection, 509
    long-term susceptibility, 514–15
    vmanagement, 509
    predisposing factors, 507–9
  RGP extended wear, 523
Corneal infiltrates, 619
  disposable lenses, 520
  soft lenses, 402
    extended wear, 511
  therapeutic lenses, 774
Corneal innervation, 29–30
  autonomic, 30
  corneal sensibility, 33–4
  corneal sensitivity, 30–3
  neuropeptides, 30
Corneal lens holders, 801–2
Corneal lenses
  aphakia, 709
    large diameter lenses, 709
  cosmetic lenses, 751–2
  dimensions, 317
  historical aspects, 11–13
    apical clearance fitted, 12
    fenestration, 13
  insertion, 289–90
  keratoconus, 700–3
  modification *see* Modification procedures
  postkeratoplasty, 719–20
Corneal metabolism, 37–41
  contact lens effects, 40–1
  endothelial pumping function, 36, 37
  glycolysis, 37–8
  hexose monophosphate shunt, 38
  oxygen requirements, 39–40, 494–6
  soft lens wear, 362
  sources of metabolites, 38–40
  waste elimination, 496, 497
Corneal moulding, RGP extended wear, 523, 525
Corneal oedema, 5, 619–20
  corneal oxygen deprivation, 40
  endothelial pump inhibition, 36, 37
  extended lens wear, 40–1, 501–3, 524–5
  menstrual factors, 629
  overnight
    with lens wear, 496
    with no lens, 40, 497
  refractive index, 189
  scleral lenses, 606
  soft lenses, 363, 401, 402
    toric, 491
  therapeutic lenses, 774
  transparency reduction, 36
  see also Stromal oedema
Corneal opacities, 738, 743, 744
Corneal oxygenation, 39
  extended wear lenses, 494–6
  oxygen probes, 836
Corneal perforation, 768–9
Corneal profile photography, 240
Corneal protection, 2, 3
Corneal radius of curvature, 315
Corneal reflecting power (*FK*R), 202
Corneal rheology, 683–5
Corneal scarring, 606, 696, 738
Corneal sensibility, 33–4
Corneal sensitivity, 30–3
  aesthesiometers, 245
  age-associated variation, 31, 275
  in corneal transplants, 715
  effects of contact lenses, 32–3
  with eye disease, 32
  eye/skin colouring-associated variation, 31, 275
  menstural cycle-associated variation, 31
  patient suitability for contact lens wear, 266, 285
  refitting former PMMA wearer with RGP lenses, 349
  soft lens wear, 363, 374
  touch threshold, 31
Corneal shape remoulding, 3
  see also Orthokeratology
Corneal staining, 265–6, 648
  RGP lenses, 345–6
    extended wear, 523, 524, 527–8
    lens adherence, 525, 527
  soft lenses, 363, 401, 402
    high water content, 371
Corneal stroma (substantia propria cornea), 22–3
  infiltrates, 402
  orthokeratology-associated changes, 686, 687
Corneal thickness
  assessment lens, 819
  orthokeratology-associated changes, 686–7
  pachometry (pachymetry), 244–5
Corneal thinning/perforation, 768–9
Corneal topography
  distortions, 597, 598
  infants/pre-school children, 731
  mapping/videokeratography
    patient assessment, 285
    soft lens fitting, 374
Corneal transparency, 34–7
  maintenance, 36–7
Corneal transplant *see* Keratoplasty
Corneal trophism, 20
Corneal ulcers, 100
  bacterial, 613
  RGP extended wear, 524
  see also Culture-negative peripheral ulceration (CNPU)
Corneal vascularization, 649–50
  in aphakia, 712
  in keratoconus, 606, 699
  scleral lenses, 606

Corneal vascularization (*cont*)
soft lenses, 365, 402
extended wear, 510–11
toric, 491
therapeutic lenses, 774
Corticosteroid therapy, 509
Corynebacterium, 96, 98, 99, 145
Cosmetic advantages, 261
spectacles comparison, 154
Cosmetic conditions, infants/pre-school children, 737–8
Cosmetic lenses, 9, 283, 743–57
corneal lenses, 751–2
definitions, 743
general appearances, 743
general approaches, 757
infants/pre-school children, 731
information for patients, 757
lens movement, 743
levels of vision, 750
ordering, 755
photophobia/glare reduction, 743, 750–1
psychological advantages, 261
pupil size, 743, 750
scleral lenses/shells, 605, 751
soft lenses, 517, 752–5
heterogeneous types, 754, 755
homogenous types, 752–4, 755
lens power calculation, 754
theatrical special effects, 842
types, 743
uses, 743
Cosmetics, 309, 620–1
Counselling, 621
Cranial nerve damage, 767, 768
Creep, 62
Crimping toric lenses, 791
Critical surface tension, 63
clinical significance, 65–6
Crofilcon, 88
Cross linkages
hydrogels, 71
RGP materials, 78
Crypts of Henle, 84
CSI soft lens, 728
Culture-negative peripheral ulceration (CNPU), 363, 510
disposable lenses, 520
hydrogel extended wear, 509–10
Cylinder effect, 160–1

Daily disposable lenses, 395
Daily lens cleaning, 130, 302, 303
Dallos, J., 5, 6–7, 8, 10, 11, 14
Danalens, 359, 394, 499
de Carle bifocal contact lens, 541
Decentration of optic, 571
Defence forces, 278–9
Dehydration
high water content soft lenses, 370, 371–2
lens material changes, 346
soft lenses modification procedures, 816
Demodex folliculorum, 268
Density of hydrogels, 77
Dental Zelex, 8
Deposits
after-care consultation, 631, 643–4
concretions, 617
corneal abrasion, 260
disposable lenses, 519
high water content lenses, 500
inferior front surface, 630
lipid, 86–7, 132, 134
protein, 85, 132, 134, 402
RGP lenses, 353
extended wear, 524
soft lenses, 111, 364, 402, 403, 460
extended wear, 519
Rudko classification, 461
visual performance, 367
systemic/ocular medication, 135–8
summary, 139, 140
see also Spoilation
Dermatological conditions, 621
Descemetocele, 768
Descemet's layer (lamina limitans posterior), 24
Design of contact lenses, 189–98, 321–2
anterior optic radius (*r*ao), 191
axial edge lift/clearance, 195–8
axial edge thickness (*t*EA), 190
central thickness (*t*c), 191
drawing to scale, 198
form of carrier zone, 192
front peripheral radius (*r*a1) calculation, 192
front surface sag (*S*ap; *S*ao), 190–1
historical aspects, 9
lenticular lenses, 191
negative lenses, 193
primary sag (*S*p), 190
sagitta of front and back surfaces, 189–90
tear layer thickness, 195
Deuteromycetes, 95
Diabetes, 262
aftercare, 621–2
corneal sensitivity, 32
retinal photocoagulation, 825
therapeutic lenses, 773
Diagnostic contact lenses
corneal irregularities, 817, 818–19
exophthalmometry, 825
foreign body locator, 824, 827
fundus examination, 818, 822–4
gonioscopy, 819–22
anterior chamber angle, 820–2
vitrectomy, 824
Diagnostic staining agents, 144
Diameters
corneal lens modification, 806–8
hydrogel lens verification, 444–5
rigid lens verification, 415–18
Dietary factors, 135, 276–7
Diethylpropion, 137
Diffractive bifocal contact lenses, 547, 561
rigid lens verification, 423
Digital camera, 248, 256
Dimple veil *see* Bubbles of air
Diplopia, 622
cosmetic lenses, 743, 749
therapeutic lenses, 832
Disciform (nummular) keratitis, 402
Discoloration, 86, 622
disinfection/cleaning solutions, 134
soft lenses, 402–3, 456
high water content lenses, 371
visual performance, 367
systemic/ocular medication, 135–8
summary, 139, 140
Discomfort symptoms. 295, 611, 622
Disfigured eyes, 738
Disinfection, 50
HIV guidelines, 115
soft lenses, 111, 112–22, 364, 400–1
chemical, 114–22
extended wear, 518
heating methods, 112–14
high water content, 371
trial fitting, 374
see also Cleaning lenses; Preservatives
Dislocated lens, infants/pre-school children, 736
Dispensing appointment, 297–9
example routine, 299
instructions on handing lenses, 298, 300–2
patient handouts, 299, 300–11
wearing schedules, 298–9, 301
Disposable lenses, 394–5, 622
acute corneal inflammation, 520
cast moulding, 429
cleaning, 520
corneal hypoxia, 520
corneal infection, 520–1
daily, 395
development, 51
extended wear, 499, 501, 519–21
historical development, 13, 50–1, 359
information for patient, 284
lens handling, 305
lens packaging, 305
lens deposits, 519
occasional wear, 363
oxygen permeability, 520
therapeutic lenses, 760
Distortion, 622–3
Disulfiram (Antabuse), 135
Diuretics, 137, 633
Diurnal fluctuation of vision, 721
Doubling systems, 233
Douthwaite's underwater contact lens, 838
Down's syndrome, 195, 699, 740
Drivers, 277–9
Drug delivery
collagen shields, 773
soft lenses, 363
therapeutic lenses, 758, 772–3, 831–2
Drugs, 862
lens deposits/discoloration, 135–8
ocular side effects, 633
ophthalmic, 2, 3, 104–5
patient suitability for contact lens wear, 276
tear secretion reduction, 136–7
Dry eyes
after-care, 623
disinfection/cleaning solutions, 131, 134–5
drug-induced, 276
high water content soft lenses, 371, 372
punctal occlusion, 772
RGP extended wear, 529
scleral lenses, 761
pre-corneal tear film maintenance, 602–3
tear solutions, 772
therapeutic lenses, 758–9, 761, 771–2, 831
Duplicate lenses, 623
Duragel, 359
Durasoft 3 Colors, 743, 751
Dust, 363
Dymed (polyhexanide), 117
Dynamic stabilization, 484–5

Ectropion, 268
corneal exposure, 602
Eczema, 621
atopic, 263
seborrhoeic, 263–4
Edge defects
moulded lenses, 429–30
soft lenses, 403
Edge shape
after-care problems, 623
foreign body sensation, 626
modifications
corneal lenses, 808–9
scleral lenses, 812
RGP lenses, 330–3, 354
rigid lens verification, 421–2
Eisner Contact Glass, 817, 818
Elastomers, 55–6
Electric circuit micrometry, 447
Electrodes, 834
Electron optics, 458–9
Electronic flash gun, 251–2
Elliptical lenses *see* Aspheric lenses
Emergency consultations, 623–4
out of hours, 634
EN/ISO 9339, 436, 446
Endothelial bedewing, 619, 624
Endothelial bleb response, 512–14, 624
Endothelial dystrophy, 286
Endothelial photography, 256
Endothelial polymegathism, 24
in corneal exhaustion syndrome, 619
extended lens wear, 41
hydrogel lenses, 515–16
RGP lenses, 528
Endothelium (endothelium camerae anterioris), 24
carbohydrate metabolism, 38
in corneal transplants, 714–15
photography, 256
pumping function, 36–7
Engravings, 351
Enophthalmos, 272
Entamoeba, 95
Entropion, 268
scleral lenses, 603
therapeutic lenses, 758–9
Environmental factors
patient suitability for contact lens wear, 275–6
soft lens wear, 365–6
high water content lenses, 370, 371–2
Enzymatic cleaning, 124–9, 134
hydrogel extended lens wear, 518
information for patients, 302, 303, 304, 306
lipases, 127–8
misuse/incompatibility, 139
pancreatin tablets (Alcon Polyzym), 128
papain tablets, 125–7
prescribing, 131
pronase (Amiclair), 127
RGP lenses, 306, 347
extended wear, 530
subtilisin, 128
EpiCon lens, 327
Epidermolysis bullosa, 261, 264
therapeutic lenses, 771
Epikeratoplasty, 769
Epithelial desquamation
extended lens wear, 497
ocular defence mechanisms, 98
contact lens wear effects, 102
Epithelial microcysts, 41
hydrogel extended lens wear, 511–12
RGP extended wear, 523, 528, 529
Epithelial splitting, 624–5
Epithelial wettability, 62–3
Epithelium *see* Corneal epithelium (epithelium anterius corneae)
Equalens, 530, 830
Equivalent oxygen performance, soft lenses, 361–2
Erythema multiforme *see* Stevens-Johnson syndrome
ES70, 728
Escherichia coli, 121, 145
Etafilcon-A, 51, 87
Ethylene propylene terpolymer (EPT), 55
Ethylenediamine tetraacetate (EDTA), 105
Etienne lenses, 828, 831
European Manufacturing Regulations, 797–8
Evaporation, soft lens power changes, 179
Examination questions and answers, 224–30
Excelens, 359, 388
Exophthalmometry, 825
Exophthalmos, 272
Exposure keratitis, 602–3
Extended wear lenses, 40, 283, 359, 394, 494–531
aphakia, 708, 710
infants/pre-school children, 733
complications, 494
corneal oedema, 40
corneal sensitivity effects, 33
corneal waste elimination, 496
carbon dioxide, 496
cellular debris, 497
disinfection/cleaning, 130, 131
high water content lenses, 370
instructions for patients, 394
materials, 494
oxygen permeability, 58, 361, 362, 494–6
measurements, 70
RGP lenses *see* RGP lenses extended wear
soft lenses *see* Hydrogel extended wear lenses
stromal thinning, 40–1
tear exchange, 362
Extension tubes, 250
External eye photography, 247–56, 286
bellows, 250
bifocal contact lens fitting, 553
camera, 248
fundus camera, 256
corneal endothelium, 256
exposure, 256
extension tubes, 250
film, 250
illumination, 251–2
instant films, 250–1
lens, 248–9
close-up (supplementary), 249
photokeratoscopy, 256
prints, 250
slit lamp photography, 254, 256
soft lens fitting, 373
technique, 252–3
transparencies, 251
ultraviolet photography, 253–4
Extraocular muscle pareses, 274
Eye drops, 141
associated discolouration, 111
Eye impressions
casting, 582
historical aspects, 4–5, 6–9
impression material application, 582
impression trays, 581
local anaesthesia, 581
materials, 580–1
post-impression examination, 582
removal of impression, 582
scleral lens fitting, 580–3
sources of error, 582–3
visual fixation, 581
Eye movements recording, 834
Eye ointments, 141
Eyelash follicles, 28
Eyelash parasites, 268
Eyelashes (cilia), 28
Eyelid closure, 29
reflex, 29
tears composition, 100–1
Eyelid margins, slit-lamp examination, 265
Eyelids
age-associated changes, 275
anatomy/physiology, 27–9
epithelium, 27
innervation, 29
levator palpebrae, 28
margin, 28–9, 265, 529
muscle fibres, 29
orbicularis oculi, 27–8
palpebral conjunctiva, 28
sebaceous glands of Zeis, 28
sweat glands of Moll, 28–9
tarsal muscles, 28
tarsal plate, 28
catching edge of lens, 29
control, 632
eversion, 28
hygiene, 632
microbiological flora, 96
movements, 29
patient suitability for contact lens wear, 268, 285
position with aphakia, 708
pressure, 835
RGP lens position, 319
twitch sensation, 632–3
EyeSys, 237–9, 256, 267, 704
in keratoconus, 693–4, 704
RGP lens fitting, 335–7

Familial hypercholesterolaemia, 264
Fatty acids in lens deposits, 86–7
FCOZD *see* Front central optic zone diameter
Fear of lenses, 261
Feincone lens, 11
Fenestration, 625
corneal lenses, 13
modification procedure, 810–11
manufacturing procedures, 790–1
RGP lenses, 353–4
scleral lenses, 589
scleral lens modification, 813–14
soft lens modification, 815
Fibronectin, 98, 99
Field of vision, 154–7
Fifth nerve lesions, 767, 768
Filamentary keratitis, 766–7
Film, photographic, 250

Filters, 244
Financial aspects
  information for patient, 261, 283
  soft lenses, 365
Fingernail damage, 625
Fire service, 278
First lens reactions, 294–5
Fischer-Schweitzer polygonal mosaic, 528
Fit assessment
  after-care examination, 625
  RGP lenses, 341–2
  soft lenses, 403
Fitting time, 259
Fixed doubling systems, 233
Flare/peripheral reflection, 156, 625–6
  soft lenses, 363, 365
Fleischer's ring, 696
Flexible contact lenses, historical aspects, 11
Flexible gas permeable (FGP) lenses, 327–8
Flexural resistance, 62
Flexure, 626
  RGP lenses, 353
    fitting, 343–4
    toric lenses, 481
  rigid lens power changes, 180–1
  soft lenses, 366–7
    effects on astigmatism, 179–80
    power changes, 174–8
FLOMS, 11
  scleral lens fitting, 571–3
  soft lens fitting, 382
Fluoflex, 376
Fluorescein, 144
  with blue light, 4–5
  high molecular weight, 144, 376
  ocular examination, 265–6
    after-care, 626
  patient assessment, 286
  sequential stain, 641
  soft lens absorption, 135, 376
Fluorescein break-up time *see* Break-up time (BUT)
Fluorescein patterns, 319, 320
  keratoconus, 703–4
  RGP lens fit assessment, 341
Fluoresoft, 144, 376
Fluorexon, 135, 143
Fluoroalkyl methacrylates, 80
Fluorocarbon-based materials, 79
Fluoromethacrylate monomers, 79
Fluoroperm ST, 189, 559
Fluoropolymers, 326–7
  patent literature, 90
Fluorosilicone-acrylate, 326–7, 522
Flying, 278, 626
Focimetry
  hydrogel lens verification, 451–4
    air checking, 453–4
    liquid cells, 451–3
  rigid lens verification, 419–20
    with trial lens, 413
  toric soft lens checking, 491
Follicular conjunctivitis, 85
Foreign bodies
  corneal abrasion, 260
  corneal epithelial reaction, 20
  protection afforded by spectacles, 260
  soft lenses, 363
  under eyelid, 28
Foreign body locator, 824, 827
Foreign body sensation, 626–7
Forniceal conjunctiva, 25
Fornix shrinkage prevention, 603
FOZD *see* Front optic zone diameter
Framycetin, 144, 145
Frequent replacement lenses, 51, 394–5
  cast moulding, 429
Freshlook, 429
Front central optic zone diameter (FCOZD), 550–1
Front optic zone diameter (FOZD),
  aphakic lens, 733
  corneal lens, 424
Front peripheral radius (*r*a1) calculation, 192
Front surface sag (*S*aP; *S*aO), 190–1
Front vertex powers
  optical formulae, 204–6
    rapid calculation, 206
  rigid lens verification, 420
Fuch's endothelial dystrophy, 745
  therapeutic lenses, 763–4
Full corneal clearance, 4, 5
Fundus camera, 256
Fundus examination, 818, 822–4
Fungal disease processes, 95
Fungal flora
  conjunctival sac, 85
  soft lens infiltration, 85, 111, 132
Fungal keratitis, 96
Fungi, 95
Fusarium keratitis, 96

Gas permeable materials, 79, 80
  historical aspects, 14
Gaylord patients, 79–80
  (*see also* Rigid gas permeable lenses)
Gaze, eyelid movements, 29
Geltact lenses, 358
Gender, 274–5
General anaesthetics, 137
General debility, 262
General Sales List, 145
Gentamicin, 773
Gentle Touch, 51
Ghost images, 627
Giant papillary conjunctivitis (GPC), 27, 359, 627–8
  infants/pre-school children, 740–1
  mucoprotein-lipid lens deposits, 85
  scleral lenses, 606
  soft lenses, 365
    extended wear, 505–6
  see also Contact lens-induced papillary conjunctivitis
Giardia, 95
Glands of Manz, 84
Glands of Moll, 84
Glands of Zeis, 84
Glare, 628
  cosmetic lenses reduction, 743, 750–1
  post-radial keratotomy, 722
Glass corneal lenses, historical aspects, 11–13
Glass transition temperature, 52–3
Glaucoma, 770
  treatment, 628–9
    laser surgery, 825
Glyceryl methyl methacrylate, 134
Glycocalyx, 26
Glycolysis
  contact lens effects, 41
  corneal metabolism, 37–8
Goblet cells, 25–6
Gold salts, 135
Goldmann gonioscopy lens, 819
Goniogram, 821–2, 823
Gonioscopy contact lenses, 819–22
  anterior chamber angle, 820–2
  laser surgery, 828
Goniotomy, 820
Grading scales, 243, 255, 618, 863–867
Gradual wearing procedure, 259
Gram-negative bacteria, 94
  contact lens-associated infection, 96
  lens contamination, 103
Gram-positive bacteria, 94
Graticules, 373
Gravity, 318
Ground glass (Zeiss) contact lenses, 4, 5
Guttata, 629

Haag-Streit keratometer, 233
Haag-Streit three-mirror diagnostic lens, 823, 824, 825
Haemophilus, 96, 145
Halane (sodium dichloroisocyanurate), 120
Halazone, 118
Hand UV lamp examination, 629
Hand-washing, 106, 629
Haptics, 7
Hardness tests, 61
Harmonic mean thickness (*t*HM), 219–22
Heat disinfection
  soft lenses, 112–14, 364, 400
  trial soft lens fitting, 374
HEMA lenses, 13
  silicone rubber materials, 79
  soft lenses, 369
    development, 358, 359
Herpes simplex virus (HSV)
  oral infection, 262
  persistent epithelial defects, 767
  therapeutic lenses, 767
Herpetic keratitis, 713
Heterochromia iridis, 746
Heterogeneous tints, 754
Heterophorias, 284
Heterotropias, 274
Hexose monophosphate shunt, 38
High altitude, 366
High heterophorias, 274
High hypermetropia, 731
  infants/pre-school children, 737
High myopia, 273, 731
  fundal examination, 818
  infants/pre-school children, 737
  scleral lenses, 601
High water content hydrogels, 14, 50, 75
  lysozyme diffusion, 87
  vinyl pyrrolidone (NVP), 72–3
High water content lenses, 359
  advantages, 370
  disadvantages, 370–2
  disposable lenses, 501
  hydrogel extended wear, 500
  ionic, 369
  non-ionic, 369
  spherical lathe-cut, 390
  spherical moulded, 389–90

therapeutic lenses, 760
thin lenses, 500–1
HIR/CAL grid, 375
Historical aspects, 1–15
acrylic contact lenses, 5–6
bifocal contact lenses, 541–4
contact lens solutions, 5
corneal lenses, 11–13, 321–2
disposable lenses, 13, 50–1
hydrogel extended wear, 498–9
lens design, 9
materials, 9, 50–1
moulded contact lenses, 4
multifocal contact lenses, 544
ocular topography/physiology, 5
ophthalmic impressions, 4–5, 6–9
optical principles, 1–2
orthokeratology, 653–4
practical trials, 2–4
preformed fitting sets, 4
RGP extended wear, 522–3
rigid gas permeable lenses, 14
rigid lens moulding, 777–8
scleral lenses, 9–13
soft lenses, 13–14, 358–61
History taking, 610
HIV, contact lens disinfection, 115
Hobbies, 277
Homogeneous tints, 752–4
Hormonal factors, 629
Hormone replacement therapy, 135
Horner's syndrome, 272
Hot climate, 131
Humphrey Auto Keratometer, 236
Hydration
high water content lenses, 370, 371–2
soft lens power changes, 366
Hydrocare, 117, 124, 125–7, 134
misuse/incompatibility, 140
Hydrocolloid materials development, 13, 14
Hydrocurve II, 174, 359, 386, 561
Hydrogel extended wear lenses, 41, 494, 495, 496, 498–522
acute complications, 499, 501–14
advantages/disadvantages, 499–500
care/maintenance regimens, 518
cellular debris elimination, 497
disposable lenses, 499, 519–21
follow-up visits, 521
high water content lenses, 500
historical development, 498–9
indications, 516–17
cosmetic, 517
lens handling difficulties, 516–17
therapeutic/'bandage' lenses, 516
lens ageing, 519–20
lens deposits, 519
lens fitting, 518
long-term effects, 514–16
low water content lenses, 500
oxygen permeability, 496
patient advice, 522
patient management, 521–2
replacement lenses, 499, 519
Hydrogel lenses in keratoconus, 698
Hydrogel lenses after keratoplasty, 718
Hydrogel lens verification, 365, 374, 426–61
back vertex power, 450–1
focimetry, 451–4
definitions, 430–2
diameters, 444–5
band magnifier, 444
comparators, 445
measurement in liquid, 444–5
travelling microscope, 445
V gauge, 445
measurement of parameters in air, 426–7, 443–4
measurement in saline solution, 426
liquid cells, 426, 427
oxygen transmissibility, 450
procedure, 436–61
radii, 436–43
aspheric surfaces, 440
autostigmatic microscope, 439
interferometry, 440
keratometers, 436–9
microspherometry, 440–1
optical gauging, 441–2
projection methods, 442–3
radioscope (optical microspherometer), 439
ultrasonography, 440
standards, 432–3
surface inspection, 454–9
electron optics, 458–9
light microscopy, 456–8, 460
thickness, 445–9
average, 448
electric circuit micrometry, 447
pachometry, 446–7
point-to-point, 448–9
projection, 447
radiuscope (optical microspherometer), 446
Rehder Electronic Thickness Gauge, 447–8
water content (WC), 449–50
Hydrogels, 56, 71–7
classification, 73
comercial lenses/materials, 73, 74
copolymers, 71, 72
cross-links, 71
deformational behaviour, 61
density, 77
dimensional stability, 73, 75
historical development, 72
lipid interactions, 87
manufacturing methods, 56, 57
mechanical properties, 58, 75
new materials, 51
optical transmittance, 76–7
oxygen permeability, 70, 76
patent literature, 71, 72–3, 89
properties, 53
refractive index, 77
rigidity modulus, 60
spoilation, 77, 84
proteinaceous debris adherence, 66
structural aspects, 71
surface properties, 77
wettability, 66–7
terminology, 358
vinyl pyrrolidone (NVP), 71, 72–3
water content (equilibrium water content), 73
see also Soft lenses
Hydrogen peroxide, 114–15, 130, 134, 135, 138, 140
information for patients, 303–4
soft lens disinfection, 401
trial lens fitting, 374
Hydron Echelon, 547, 561
Hydron soft lenses, 358, 359, 385–6
Hydron Z plus, 385
Hydron Zero 6, 385
Hydrophilic lenses *see* Soft lenses
Hydroxyapatite lens coatings, 85
p-Hydroxybenzoic acid (Nipastat), 119–20
Hygiene
care solutions, 300
chemical disinfection, 302–3
cleaning on removal, 298
daily lens cleaning, 302
eyelids, 632
hand-washing, 106, 629
hydrogen peroxide routines, 303–4
infants/pre-school children, 740
patient instruction, 260, 277, 297, 302–6, 308–9
rigid gas permeable (RGP) lenses, 306
soft lens disinfection routines, 304–5
Hyperaemia, chronic, 616–17, 618
Hypermetropia, 273
accommodation in, 168, 169
assessment, 273
effect of magnification when changing from spectacles, 162
in infants, 737
postradial keratotomy, 726
Hyperthyroidism, 262
Hypertonic saline dops, 763
Hypertonic surfactant cleaning solutions, 124
Hypokalaemia, 135–6
Hypopyon, 774
Hypoxia, 520

IgA, 99
IgE, 100
Igel tinted lenses, 753
IgG, 100
IgM, 100
Immunoglobulins in tears, 43, 83, 99, 100
Impression casting, 582
Impression lenses, 567–8, 594–5
Impression materials, 580–1
historical aspects, 4, 6, 7, 8, 9
Impression trays, 581
historical aspects, 7–8
Impressions *see* Eye impressions
Imprinting of corneal epithelium, 21
Incomplete lid closure, 268
therapeutic lenses, 761
Indications for contact lens wearing, 258–79
pathological conditions indicating referral, 262–4
pathological indications, 261–2
psychological factors, 258–61
Indolent corneal ulcers, 767
Infants/pre-school children, 731–42
after-care, 740–2
lens replacement system, 741
anisometropia, 737
aphakia, 731–6
contact lens fitting, 711
blinking, 740
corneal topography, 731
cosmetic conditions, 737–8
dislocated lenses, 736, 742
high hypermetropia, 737
high myopia, 737
indications for contact lenses, 731

Infants/pre-school children (*cont*)
keratometry, 734–5
lens handling, 739–40
lens hygiene, 740
refractive conditions, 731–7
response to corneal trauma, 735
spectacle wear, 740, 741
strabismus, 737
swimming, 742
therapeutic lenses, 738
travel, 742
Inferior tarsal muscle, 28
Inflammation, tear film cellular components, 100
Information for patients, 258, 259–60, 630
after-care, 260, 612
re-instruction, 639–40
AOSept system, 303, 304
care solutions, 300
chemical disinfection, 302–3
hydrogen peroxide routines, 303–4
soft lens disinfection routines, 304–5
cleaning agents, 260
cleaning lenses, 260
daily cleaning, 302, 303
on removal, 298
cosmetic lenses, 757
costs, 261, 283
dispensing appointment, 299, 300–11
disposable lenses, 284
lens handling, 305
lens packaging, 305
duration of contact lenses, 283
enzymatic cleaning, 302, 303, 304, 306
extended wear lenses, 394, 522
insurance, 260
lens contamination, 298
lens handling, 298, 300–2, 308–9
lens hygiene, 260, 297, 308–9
lens removal, 301–2, 307
make-up, 309
monovision lenses, 309–10
re-instruction, 639–40
rigid gas permeable (RGP) lenses, 306
Initial discomfort, 259, 294–5
Injection method of impression-taking, 8
Inorgainc film lens coatings, 85
Insertion fluid, 4
Insertion of lenses, 286–94, 296, 631–2
composite (Softperm) lenses, 293
first lens, 286, 341
infants/pre-school children, 739, 740
rigid gas permeable (RGP) lenses, 306–7
rigid lenses, 286–7
finger method, 286–7
lens on bulbar conjunctiva, 289–90
one-handed insertion, 287
suction holder method, 287
scleral lenses, 290, 566
soft lenses, 291–2, 300–1
Inside out lenses, 630–1
InstaCare, 124, 303, 374
InstaCare Starting Solution (ISS), 124
Insurance, 260
Interferometry
hydrogel lens verification, 440
rigid lens verification, 413, 415
Interferon, 98
Interstitial keratitus, 713
Intolerance of lenses, 28
Intraocular pressures, 284
Iodexemide, 143
5-Iodo-2-desoxyuridine, 773
Iodophor chemical disinfection, 118
Ionic/non-ionic lens materials, 369–70
Iontophoresis contact lens, 832
Iridectomy, 825
apertures, 708
Iris
absence/partial absence, 272
patient suitability for contact lens wear, 272, 284
slit-lamp examination, 265
Iris trauma, cosmetic lenses, 743, 746, 747, 748, 749, 750
Irregular astigmatism, 490
Irritation, 631
ISO 5725, 433, 435
ISO 8320, 434
ISO 10344, 449
ISO/DIS 8320, 428, 743
ISO/DIS 8321, 426, 433, 435, 444
soft lens specification, 430
ISO/DIS 9339, 436, 446
ISO/DIS 10338, 436
ISO/DIS 10339, 449
Isopropyl alcohol, 124
Isotonic lens solutions, 106
Isotretinoin, 137
Itch symptoms, 613, 631

Japan, drug regulations, 146
Javal-Schiötz mires, 234
Jelly-bump deposits, 500

Kelvin conic lenses, 11
Keratitis
bacterial, 723
contact lens-associated, 96
discrete punctate epithelial, 613
exposure, 602, 605–6
bandage lens for, 516
filamentary, 766
herpes simplex, 713
infiltrative, 511
measles, 713
neuroparalytic, therapeutic lenses for, 831
sicca, and phenazopyridine, 136
superior limbic, 642
Thygeson's, 765
storage case contamination, 103
Keratoconjunctivitis sicca (Sjögren's syndrome), 263
therapeutic lenses, 771
Keratoconus, 3, 4, 9, 266, 693–704
bubbles of air under lens, 614
combination lenses, 698–9
contact lens wear, 697, 698–703
fitting philosophy, 700–3
fitting procedures, 703–4
indications/contraindications, 693
corneal lenses, 700–3
corneal sensitivity, 32
corneal topography assessment, 239, 240
diagnosis, 818
historical background, 693
incidence, 693, 695
keratoplasty, 697, 713, 714
astigmatism, 717
management, 696–8
mild forms, 693, 694
patient assessment, 285
patient management, 704
scleral lenses, 597–9, 699–700
corneal neovascularization, 606
indications, 599
PMMA lens, 599
RGP lens, 599
soft hydrogel lenses, 698
spectacle correction, 693, 697
symptoms/signs, 695–6
underlying connective tissue disorder, 695
Keratocyte, 123
Keratoglobus, 597
Keratometer mire image diameter, 202
Keratometry, 171, 232–40
after-care examination, 611, 627
aphakia, 708
infants/pre-school children, 734–5
automated systems, 236–7
calculations, 202
contact lens-induced changes monitoring, 235
corneal contours, 314, 315
doubling systems, 233
fixed/variable, 233
extending range of measurement, 236
front surface, 627
keratoconus, 703
lens fitting, 235
mire type, 233–4
patient suitability for contact lens wear, 266–7, 285
preliminary assessment, 235
principles, 232–3
rigid lens verification, 235–6, 410–12, 413
scleral lens fitting, 588
scleral lens optic parameters selection, 580
soft lens fitting, 377
soft lens verification, 436–9
sources of error, 234–5
therapeutic lenses, 760
topographical keratometers, 236
see also Video keratometry systems
Keratoplasty
astigmatism, 717
eccentric transplant, 718
historical background, 713
indications, 713
infants/prc-school children, 731
therapeutic lenses, 738
keratoconus, 697
optical lenses
combination lenses/systems, 718–19
corneal lenses, 719–20
fitting procedure, 718–20
hydrogel, 718
scleral, 601, 719
scleral lens alternative, 599
splint support, 832
therapeutic/bandage soft lenses, 769, 774, 831
thickness, 714
tilted transplant, 717–18
transplant endothelial morphology, 714–15
transplant sensitivity, 715
transplant topography, 715–18
nipple-like protrusion, 715–16
toricity, 716–17
Keratoscopy, 236
Kern's orthokeratology study, 655

Kerr's hydrocolloid, 8
Kidney stones, 136
Klein applicator, 831, 832
Klein keratoscope, 267, 285
  soft lens fitting, 374
Kromogel, 580
Kromopan, 9

Labetalol (trandate), 138
Lacrimal canaliculi, 43
Lacrimal glands, 41
  patient suitability for contact lens wear, 269
  tear aqueous component secretion, 83
  tear protein components, 83
Lacrimal pump, 43
Lacrimal sac, 43
Lacrimation
  psychogenic, 41, 43
  reflex, 41, 43
  soft lens responses, 363, 364
Lacrisert, 831
Lactoferrin, 42, 83
  antibacterial activity, 98
  lens polymer association, 88
Lagophthalmos, 268
Laminates, 589
Laminin, 98
Langerhans cells
  conjunctival epithelium, 27
  corneal epithelium, 20
Laser surgery
  contact lenses, 828
  indications, 825
  protective lenses, 829
Laserguard, 829
Lashes *see* Eyelashes
Lathe-cut lenses, 56, 428, 778–85
  CNC (computer numerical control) production, 778–83
    annealing, 778
    back surface lathing, 779
    back surface polishing, 779
    edge polishing, 783
    final checking, 783
    front surface blocking, 780
    front surface lathing, 781, 783
    front surface polishing, 783
    Polytech blocking, 780–1, 782
    stress testing, 778–9
  high quality surface production, 797
  soft lens fabrication, 785
  submicron CNC (computer numerical control) lathes, 783–5
  toric lenses, 792–4
    fly-cutter, 792–3
    Polytech toric lathe, 793–4
Lattice dystrophy, 765
Lens adherence, 525–7
Lens flexure *see* Flexure
Lens handling
  patient instructions, 300–2, 308–9
  patient suitability for contact lens wear, 275
  RGP lenses, 347
  soft lenses, 300–2
Lens rotation, 487–8
Lens slip, optical aspects, 161
Lens spoilation, 84–7
Lens tilt, optical aspects, 161
Lens-related keratitis, 103
Lenses, photographic, 248–50
Lenticular lenses
  anterior surface specification, 216–17
  design, 191
    form of carrier zone, 192
    negative lenses, 193
  minimum junction thickness, 217–19
Levator palpebrae, 28
  eyelid closure, 29
Lidocaine (lignocaine), 142–3
Life span
  information for patient, 283
  soft lenses, 364, 403
Lifestyle bifocal lens, 562
Light microscopy, hydrogel lens verification, 456–8, 460
Lignocaine (lidocaine), 142–3
Limbal conjunctiva, 25, 27
  cell turnover, 26
  corneal epithelium repair processes, 20, 21
  slit-lamp examination, 264–5
  topography assessment for soft lens fitting, 376
Limbal injection, 402
Limbal pressure, 4
Limbal transection, 31–2
Lipases, 127–8, 134
Lipids, 127, 132
Lipid deposits, 86–7, 132, 369, 403
  disinfection/cleaning solutions, 134
Lipid keratopathy, 606
Lipid tear layer, 83, 84
Lipocalins, 98
Liprofin (sodium perborate), 130, 138, 140
Local anaesthetics *see* Topical anaesthetics
Lost lenses, 633
Lovac Direct Goniolens, 820, 824
Lovac Double Focus, 820
Lovac electroretinography lenses, 834
Lovac six-mirror goniolens, 820
Loveridge grid, 271, 375
Low vision, 633
Low water content lenses
  disposable lenses, 501
  hydrogel extended wear, 500
  lathe-cut lenses, 385–6
    fitting, 386
    lens geometry, 386
  therapeutic lenses, 760
Low water content materials, 14, 51, 70–1
  oxygen permeability, 76
Lunelle, 359
  aphakic ultraviolet lens, 830
Lunelle ES 70, 390, 830
Lymphocytes, 27
Lysozyme, 42, 83, 84
  antibacterial activity, 98, 99
  lens deposits, 85, 87, 88, 122–3, 132
  ocular defences, 111

McKellan, G., 11, 14
Macular dystrophy, 765
Madden, P., 14
Magnification, 161–7
  relative spectacle magnification, 165–7
  shape factor, 163–5
  spherical lenses, 161–2
  toric lenses, 162–3
Make-up, 620–1
  patient information, 309
Mandell 'No-Jump' bifocal contact lenses, 543, 544
Manufacturing processes, 56–7, 777–99
  bifocals, 795–7
  European Manufacturing Regulations, 797–8
  generating/lathing, 778–85
  materials classification, 798–9
  moulding, 777–8
  practitioners' orders, 797
  prisms, 794
  quality assurance, 797
  RGP lenses additional procedures, 785–91
  toric lenses, 791–4
  truncating, 794–5
Map-dot-fingerprint dystrophy, 764–5
Marfan's syndrome, 266, 736, 742
Marginal tear strip, 42, 43
Mastigophora, 95
Materials, 50–89
  classification, 54–6, 73, 798–9
  historical aspects, 9, 50–1
  hydrogels, 71–7
  oxygen permeability, 55–6, 58, 67–71
  polymer characteristics, 51–4
  properties, 57–71
    mechanical, 57, 58–62
    surface, 62–7
    test methods improvement, 82
  RGP lenses, 77–82
    identification, 354–5, 422
  UV blocking, 830
May-Grant ortho-k technique, 654
Measles keratitis, 713
Measuring magnifier, 415
Mechanical agitators, 124
Mechanical complications, soft lenses, 365
Mechanical properties, 57, 58–62
  creep, 62
  flexural resistance, 62
  hardness tests, 61
  hydrogels, 75
  rigidity modulus, 59–61
  tear strength, 62
  tensile strength, 59
  test methods improvement, 83
  test units, 59
Medalist, 427
Medical Workshop prismatic goniotomy lens, 820, 821
Medication, effects on lenses, 135–40, 633
Medicines Act, 145
Medium water content soft therapeutic lenses, 760
Medium water content spherical lathe-cut lenses, 386–7, 390–1
  spherical front surface, elipitcal back surface, 387–8
Meesman's epithelial dystrophy, 765
Megalocornea, 266
Meibomian (tarsal) glands, 28
  contribution to tears, 41, 42
  dysfunction, 647, 648
  infection (chalazion; internal stye), 28
  lid hygiene, 632
  tear lipids secretion, 28, 83, 84
Melanin, 86
Melanocytes, 27
Melt-pressed lenses, 57
Menicon O_2, 109
Menicon Super-EX, 328

Menopause, 275
Menstrual cycle changes, 275, 629
Merchant Navy personnel, 278–9
Mercurial deposits, 132
Methacrylic acid, 71, 113
Methyl methacrylate hydrogels, 73
Metro GP, 727
Microbial spoilation, 85–6, 459
Microlens, 12, 321
Micrometer measurements, 416–17
Microorganisms, 93–6
  bacteria, 93–5
  eye colonization, 96
  fungi, 95
  metabolic activity, 93
  nucelic acids, 93
  ocular disease, 96, 97
  protozoans, 95–6
  structure, 93
  viruses, 95
Microphthalmos, 731, 733, 738
  cosmetic lenses, 743, 748
Microspherometry
  electronic microspherometers, 441
  hydrogel lens verification, 440–1
Microwave disinfection, 118
Minims, 141, 341
Miraflow, 124, 134
Mirasept, 134
Mire keratometers, 233–4
Mixed lenses, 633
Modification equipment, 801–6
  carborundum tool for total diameter reduction, 804
  centring devices, 803
  conlish tools, 805
  corneal lens holders, 801–2
  drills, 805, 806
  drum chucks, 805
  female gauges, 803
  grinding stone and buff, 806
  horizontal spindle, 806
  lens chuck, 803
  polishing compounds, 804, 806
  scleral lens runners, 805–6
  vertical spindle/office modification unit, 802
  wax polishing tools, 803
Modification procedures, 634, 801–16
  corneal lenses, 806–11
    addition of new curves, 809
    blending curves, 786
    BOZD reduction, 809
    edge polishing, 788–9
    edging/re-edging, 808–9
    fenestration, 790–1, 810–11
    peripheral radii alteration, 809
    power alteration, 789–90, 809–10
    total diameter reduction, 806–8
    transition blending, 809
    truncation, 811
  practitioner competence, 801
  RGP materials, 811–12
  scleral lenses, 592–3, 812–15
    back optic zone grind-out, 812–13
    channelling, 814
    edging, 812
    fenestration, 813–14
    localized scleral zone/transition grind-outs, 813
    power alterations, 814
    spatulation, 814–15
    transitional grind-out or extension, 812–13
  soft lenses, 815–16
  dehydration procedures, 816
  fenestration, 815
  lens dotting, 815
  truncation, 815
Modified contour lenses, 321, 329
Modified surface materials, 328
Moll, glands of, 28–9
Monocentric bifocal contact lenses, 543
Monovision, 545–6, 547–8, 634
  after-care, 634
  patient instructions, 309–10
Moraxella, 96
Moulded lenses, 10, 362, 428–30, 777–8
  concentric moulding technique, 8
  historical aspects, 4
  rigid lenses, 777–8
  soft lenses, 777
  soft stabilized moulding, 429
Mountain climbing, 277, 837
Mucins
  epithelial surface wettability, 63
  lens deposits, 132
    soft lenses, 122–3
  ocular defences, 98
    contact lens wear effects, 102
  tear layer, 83, 84
Mucoprotein-lipid deposits, 84–5
Mucor, 95
Multifocal contact lenses
  aphakia, 711
  historical development, 544
Multifunctional lens solutions, 108
Multiple aperture lenses, 542
Multizone bifocal, 546
Munson's sign, 285
Myopia, 3, 273
  reading difficulties, 638
  stabilization, 833
  see also High myopia
Myopic retinal degeneration, 633

Naegleria, 95
Nanophthalmos, 738
Naphazoline, 143
Nasal decongestants, 136
Near vision correction, 284
  soft lenses, 369
Negative-carrier peripheral zone lenses, 329–30
Negocoll, 6, 7, 8, 9
Neisseria gonorrhoeae, 99
Neovascularization *see* Corneal vascularization
Netrafilcon, 51
Neuroparalytic/neurotrophic conditions, therapeutic lenses, 767–8, 831
Neuropeptides, 30
Neurotrophic keratopathy, 767, 774
  scleral lenses, 602
Neutrophils, 27
New Zealand, drug regulations, 146
NewVues, 499, 501
  oxygen permeability, 520
Nicotine lens discoloration, 86, 136
Night therapy, 683
Nipastat (*p*-hydroxybenzoic acid), 119–20
Nissel EV38, 174
Nissel, G., 11, 13, 14
Nissel PV200, 174, 547, 561
Nissel PV250, 174, 547, 561
Nitrofurantoin, 136
Non-invasive break-up time (NIBUT), 271, 272, 285
  keratometric assessment, 235
  soft lens fitting, 375
Non-lysozyme antibacterial factor (NLAF), 42
Non-tolerance of spectacles, 261–2
Norn's test, 267–8
Novalens, 328
Novel Ophthalmic Delivery System (NODS), 142
Nu Contacts bifocal lens, 558

Oblique aberrations, 157
Occasional wear, 363, 365, 370
Occupational factors
  bifocal contact lens selection, 548
  patient suitability for contact lens wear, 275–6, 277–9
  soft lens disinfection/cleaning solutions, 131
Ocular examination
  patient management/instruction, 284
  patient suitability for contact lens wear, 264–7
    classic keratometry, 266–7
    corneal analysis, 267
    corneal sensitivity, 266
    pachometry, 266
    slit lamp examination, 264–5, 268
    staining, 265–6
Ocular infection
  contact lens contraindications, 263
  defence mechanisms, 96, 98–101
    contact-lens wear effects, 101–4, 111
    immune, 99–100
    non-immune, 98–9
  microorganisms, 96, 97
  see also Corneal infection
Ocular pemphigoid, 268, 602
  therapeutic lenses, 770–1
Ocular refraction, 164, 171, 845–8
  optical formulae, 199
Ocusert, 831
Offset peripheral curve lenses, 330, 701
Offset scleral lens, 10
OK orthokeratology lenses, 656, 657, 658, 691, 727
  see also Orthokeratology
Omnicare, 303
Omnicare Daily Cleaner, 124
Omniflex, 359
Ophthalmic drugs
  application, 2, 3
  formulation, 104–5
  pH, 104, 105
Ophthalmic Moldite, 8
Ophthalmic preparations, 141–6
  statutes/government regulations, 145–6
Ophthalmic Zelex, 8
Ophthalmoscopy, 284
  after-care examination, 634
  patient suitability for contact lens wear, 272
Optacryl UV, 830
Optic-lens prescription, 419–20

Optical formulae, 198–224
anterior optic radius (*r*aO), 212–14
centre thickness (*t*c) not known, 214–16
anterior surface specification in lenticular form, 216–17
apical radius of cornea (*r*OK) from 'K' reading, 202
axial edge lift, 222–4
axial edge thickness (*t*EA), 214
back vertex powers, 204–6
central thickness (*t*c), 214–17
change in vergence due to thickness, 200
corneal reflecting power (*FK*R), 202
front vertex powers, 204–6
rapid calculation, 206
harmonic mean thickness (*t*HM), 219–22
keratometer mire image diameter, 202
minimum junction thickness of lenticular lenses, 217–19
peripheral radii
to create axial edge clearance, 208–12
to create axial edge lift, 206–8
radial edge lift, 222–4
radius, 199
sagitta calculations, 201–2
spectacle and ocular refraction, 199
surface power, 199
bifocal lens segment differences, 200–1
bifocal lenses of various optic zone radii, 201
change with radius change, 200
tear layer thickness (TLT), 202–20
new BOZR (*r*ON) for specified change, 203–4
Optical gauging, 441–2
Optical microspherometers *see* Radiuscope
Optical principles, historical aspects, 1–2
Optics, 154–230
contact lens effects
astigmatism, 171–2
back vertex power and thickness, 173–4
bi-toric lenses, 185–6
bifocal contact lenses, 186–8
liquid lens effects, 170, 171
refraction, 170, 171, 172–3
rigid lens flexure, 180–1
scleral lens back optic zone radius alterations, 181–4
soft lens power changes, 174–80
spherical aberration, 173, 174
toric contact lenses, 184–5
contact lens-associated changes to eye, 170–1, 188–9
differences between contact lenses and spectacles, 154–69
accommodation, 168–9
field of view/fixation, 154–7
magnification, 161–7
oblique aberrations, 157
prismatic effects, 157–60
examination questions and answers, 224–30
lens slip/tilt, 161
prism incorporation, 160
cylinder effect introduction, 160–1
Optic zone projection, 577, 578
Optifree Enzymatic Cleaner, 124, 304
Optima, 362, 427
Optima 60, 728
Optimec Soft Lens Analyser, 443, 444
Optimeyes, 118–19, 304, 305
Optoform 50, 783
Optomatic, 783
Oral contraceptive pill, 136, 275, 634
tear flow reduction, 137, 633
Orbicularis oculi, 27–8
eyelid closure, 29
tears drainage, 43
Orbit, recti muscle insertions, 566
Ordering lenses, 296, 797
cosmetic lenses, 755
RGP lenses, 350–4
scleral lenses, 594–5
Orthokeratology, 3, 653–91, 833
accelerated (Accelerated Ortho-k), 656
clinical experience, 687–90
astigmatism, 664
centration control, 664
peripheral curve design, 676
tear reservoir considerations, 671–6
controlled studies, 655–6
Berkeley study, 655
Coon's study, 655–6
Kern's study, 655
corneal anatomical changes, 685–6
corneal thickness, 686–7
glycoaminoglycoside distribution, 687
stroma, 686
corneal rheology, 683–5
corneal staining, 676–7
current research, 665
definition, 653
fitting philosophy, 658, 667–71
fitting routine, 659–62
after-care, 662
specific approach, 665–7
historical background, 653–4
May-Grant technique, 654
lens decentration, 664
night therapy, 683
OK series of lenses, 656, 657, 658
patient instructions, 310–11
patient selection, 658–9
post-wear topography plots interpretation, 680–3
prediction of outcome, 677–80
protocol, 679
projected myopia reduction, 658
refractive surgery comparison, 690–1
retainer lenses, 662–3
design, 663–4
Tabb technique, 654
trial lens set, 658
Otrivine Antistin, 143
Over-refractions, 634–5
soft lenses, 367–8
Over-wear, 635
soft lenses, 363
Overnight wear
orthokeratology, 683
RGP lens adhesion to cornea, 345
Oxidative cleaning, 130, 401
Oxybuprocaine (benoxinate), 142
Oxygen permeability/transmissibility, 495
aphakic lenses, 709
corneal oxygen supply, 495–6
definitions, 67–8
disposable lenses, 520
extended wear lenses, 394, 523
materials, 55–6, 58, 67–71, 76, 78, 79, 80
measurement
boundary effect, 68–71
techniques, 68
units/terms, 88–9
RGP lenses, 80, 352, 523
scleral lenses, 569
silicone elastomer lenses, 501
silicone rubber lenses, 78, 79, 398
soft lens verification, 450
soft lenses, 76, 361–2
high water content, 370
toric, 491
synthetic elastomers, 55–6
test methods improvement, 82
thermoplastics, 55
Oxygen requirement, corneal, 67, 494–6
corneal sensitivity, 33
Oxygen supply, corneal, 14, 39–40, 495–6
contact lens effects, 40
therapeutic lenses, 759, 760
Oxysept, 114, 134
information for patients, 303, 304
Oxysept One-Step, 115
information for patients, 303, 304
Oxywash, 137

Pachometry (pachymetry), 244–5
axial edge thickness measurement, 418
hydrogel lens verification, 446–7
patient suitability for contact lens wear, 266
soft lens fitting, 373
Pain sensibility of cornea, 33–4
Palpebral aperture, 268–9, 284
Palpebral conjunctiva, 28, 29
examination, 28
Panasil C, 581
Pancreatin tablets (Alcon Polyzym), 128
Papain tablets, 125–7
Paper strips, 141
Paper tissue cleaning, 635
Parallel-surfaced peripheral zone lenses, 329–30
Partial sight, telescopic magnification aid, 262, 839–40
Pasteurization, soft lenses, 113
Patent literature
hydrogel materials, 71–2, 89
RGP materials, 77–9, 90
Gaylord patents, 79–80
Japanese patents, 80, 90
silicone rubber, 79
vinyl pyrrolidone (NVP), 72–3, 89–90
Pathological indications for contact lens wear, 261–2
Patient Acknowledgement Form, 258
Patient management, 283–311
after-care, 299
care system selection, 297
case hygiene, 297
children, 300
collection of first lenses, 296–7
dispensing appointment, 297–9
early difficulties, 299–300
insertion of lenses, 286–94
ocular examination, 284
ordering lenses, 296
reactions to first lens, 294–5
refraction assessment, 295–6

Patient suitability for contact lens wear, 258–79, 284–5, 296
ability to handle lenses, 275
binocular vision, 274
bulbar conjunctiva, 285
corneal analysis, 267, 285
corneal sensitivity, 285
eyelids, 268, 285
tightness, 268–9
iris, 272, 284
lacrimal gland, 269
ocular examination, 264–7
slit-lamp, 264–5, 268–72, 284–5
ophthalmoscopy, 272
palpebral aperture, 268–9, 284
personal factors, 274–9
diet, 276–7
drugs, 276
environmental factors, 275–6
hobbies, 277
hygiene, 277
occupations, 277–9
smoking, 277
puncta, 272
pupil diameter, 272, 284–5
pupil reactions, 272
soft lenses, 365–6
staining, 286
tear analysis, 285–6
precorneal tear film tests, 269–72
tear output, 267–8
tonometry, 272
visual acuity/refraction, 272–4
visual fields, 272
Penicillium, 85, 95
Pentafluorostyrenes, 51, 80
Peptostreptococcus, 96
Peripheral halo, 156
Peripheral radii *see* Back peripheral radius and Front peripheral radius
Permaflex, 359, 362
Permaflex 74, 389
Permaflex UV, 830
Permalens, 14, 359, 394, 500, 710
historical development, 498
Persecon 92E, 725, 727
Persistent epithelial defects, 767–8
pH, 376
ophthalmic preparations, 104, 105
tears, 497–8
topical medication soft lens effects, 138
Phenazopyridine, 136
tear flow reduction, 137
Phenol-red thread (PRT) test, 268, 375
Phenolphthalein, 136
Phenylephrine, 105, 111, 136, 143
lens deposits/discoloration, 135
Phenylmercuric acetate/nitrate, 105
Phenylpropranolamine, 136
Phoma, 95
Phosphate buffered contact lens soutions, 85
Photo CD systems, 250
Photo-electric keratoscope (PEK), 237, 267
Photography *see* External eye photography
Photokeratograph computer analysis, 704
Photokeratoscopy, 256, 267
Photophobia
cornea oedema, 620
cosmetic lenses, 743, 750–1
infants/pre-school children, 737–8
soft lenses, 363
tinted lenses, 353
Photorefractive keratectomy (PRK), 726–8
application of videokeratographic images, 239
contact lens fitting, 727–8
indications, 727
residual visual problems, 728
therapeutic lenses, 769
Phycomycetes, 95
Pigment deposits, soft lenses, 132
Pigment in limbus area, 265
Pilocarpine, 773, 831
Pilots, 278
Pingueculae, 27, 265, 268, 637
Pinhole lenses, 3, 9, 540–1, 546
presbyopia management, 541–2
Placido disc, 267, 285
soft lens fitting, 374
Plasmodium, 95
Plica semilunaris, 265
Pneumatic gauging, 413
Polaroid camera, 251
Police, 278
Polishing, 635
lathe-cut lenses, back surface, 779
lathe-cut lenses, front surface, 783
lathe-cut lenses, edge, 783, 788–9
scleral lenses, 584
Polishing compounds, 804, 806
Poly(2-hydroxyethyl methacrylate) (PHEMA), 53, 58
deformational behaviour, 61
dimensional stability, 73
hydrogel properties, 53, 56
mechanical properties, 75
oxygen permeability, 76
spoilation, 87–8
water content (equilibrium water content), 73
Poly(4-methyl pent-1-ene) (TPX), 54, 55, 60
Polyclens (Opti-Clean), 124, 134
Poly(dimethylsiloxane) *see* Silicone rubber
Polyhexanide *see* Dymed
Polymegathism *see* Endothelial polymegathism
Polymeric beads, 124
Polymers
characteristics, 51–4
classification, 54–6
cross-linkage, 53–4
deformation/recovery properties, 53, 54
glass transition temperature, 52–3
Polymethylmethacrylate (PMMA), 12, 14, 53, 314
corneal oxygen supply, 40
corneal sensitivity effects, 32–3
cosmetic corneal lenses, 751–2
critical surface tension, 66
dimensional stability, 57
disadvantages, 322–3
historical aspects, 6
hydration-dehydration changes, 346
hydroxyl groups incorporation, 53
manufacturing methods, 56, 57
properties, 51, 52, 53, 57, 58
refitting former PMMA wearer, 348–9
RGP polymers, 77, 78
scleral lenses, 567–8
flush shell, 584–5
keratoconus, 699
sealed shell, 585, 588
shells production/fitting, 583–8
surface coating, 841
ultraviolet radiation protection, 830
Polyperfluoro-alkylene oxide copolymers, 51, 80
Polyquad, 120
Polysulphide rubber impression materials, 9
Polytech blocking, 780–1, 782
Polytech toric lathe, 793–4
Polyvinyl alcohol solutions misuse, 139, 140
Polyvinyl siloxane eye impressions, 581
Polyzym (pancreatin tablets), 128, 304
Posterior embryotoxon, 264–5
Posterior hyperplastic primary vitreous (PHPV), 731–2, 733
Postkeratoplasty, 713–20
optical lenses, 714
therapeutic lenses, 713–14
Potassium sorbate, 120
Power
alterations in, *see* Power changes
back vertex, *see* Back vertex power
scleral lenses, 595–6
Power changes, 596
addition of negative, 809–10
addition of positive, 810
astigmatism, effects on, 179–80
corneal lenses, 809–10
flexing and, 174–8, 179–80, 384, 485
hard lenses, 789–90
lens radii and, 178–80
radial keratotomy, 721
scleral lenses, 814
soft lenses, 174–80
Practical clinical development, 2–4
Precision UV, 830
Precorneal tear film, 42
clinical tests, 267, 268
patient suitability for contact lens wear, 269–72
lens material surface wettability, 62
scleral lenses in maintenance, 602–3
slit lamp biomicroscopy, 245
Preformed fitting methods, 569
Preformed fitting sets, 4, 567–9
Pregnancy, 275, 629
Preocular tearfilm (POTF), 269
Presbyopia
after-care consultation, 636, 638, 643
bifocal contact lenses, 541
management options, 541
monovision, 547–8
pinhole lenses, 541–2
soft lenses, 396–7
Prescription Only Medicines (PoM) List, 145
Preservatives
chemical disinfection, 115–17
lens discoloration/deposits, 136
rigid lens, 105–6
interactions, 108–9
sensitivity reactions, 636–7
see also Disinfection
Primary sag (*Sp*), 190
Prism ballast, 477–80
bifocal contact lenses, 543, 548, 553, 554–5, 556
adjusting lenses, 556–7
central thickness, 553, 554
fitting, 551–6
manufacture, 794
stabilization, 555–6
toric rigid lenses, 477–9
toric soft lenses, 483

Prism incorporation, 160
cylinder effect introduction, 160–1
manufacturing, 794
Prismatic effects, 157–60
anisometropia, 158–60
during convergence, 157–8
Prison officers, 278
Proclear, 710
Projection, hydrogel lens verification, 447
Pronase (Amiclair), 127
Propamidine isethionate, 145
Propionibacterium, 96, 98
Prosthetic lenses *see* Cosmetic lenses
Protective lenses, 829–31
laser surgery, 829
radiation treatment, 829
ultraviolet radiation, 830–1
visible light, 829–30
Protein deposits
film coatings, 85
soft lenses, 132, 402
disinfection/cleaning solutions, 134
Protein removing tablets, 109
Proteins migrating faster than albumin (PMFAs), 98
Proteolytic enzyme cleaners, 125–7, 134
Proteus, 96, 145
Protozoans, 95
classification, 95–6
Proxymetacaine, 142
Prymecare, 125–7
Pseudomonas aeruginosa, 96, 104, 105, 111, 116, 117, 145, 347, 839
corneal adherence, 514
hydrogel extended wear, 507
lens contamination, 103
disposable lenses, 520
Pseudopterygia, 637
Psoriasis, 264
Psychological factors, 283, 284
in cosmetic lens wear, 743
fear of lenses, 261
indications/contraindications, 258–61
restoration of normal appearances, 261
soft lens wear, 366
Psychotropic drugs, 137
Pterygium, 268, 637, 713
Ptosis, 268
RGP extended wear, 524, 529
scleral lenses, 603–4
Punctal occlusion, 272, 772
Puntum lacrimale, 43
patient assessment, 272
Pupil
in aphakia, 708
in bifocal measurements, 549
in cosmetic lenses, 750, 755
patient suitability for contact lens wear, 272, 284–5
in orthokeratology, 659
reactions, 272
slit-lamp examination, 265
Purging lenses, 638

Quality assurance, 638
manufacturing, 797
soft lenses, 433–5
instrument calibration, 435
precision of measurements, 435
ring testing, 435
sampling procedures, 434–5
standards, 433–4
Quality Assurance Standards (QAS), 434
Quality of conformity (QOC), 434
Quantum, 724, 725
Quantum 1, 530

Radial edge lift
optical formulae, 222–3
conversion to axial edge lift, 223–4
rigid lens verification, 417–18
Radial keratotomy, 721–6
contact lens fitting, 723–6
indications, 723
problems, 725–6
rigid lenses, 724–5
soft hydrophilic lenses, 723–4, 725
corneal physiological changes, 722–3
corneal power changes, 721
regression, 722
residual visual impairment, 721–3
anisometropia, 721
astigmatism, 722
diurnal fluctuations of vision, 721–2
glare sensitivity, 722
residual ametropia, 722
Radial thickness, rigid lens verification, 418–19
Radiation treatment, 829
Radii
checking device, 412
hydrogel lens verification, 436–43
aspheric surfaces, 440
autostigmatic microscope, 439
interferometry, 440
keratometers, 436–9
microspherometry, 439, 440–1
optical gauging, 441–2
projection methods, 442–3
ultrasonography, 440
optical formulae, 199
surface power change with alteration, 200
rigid lenses verification, 407–9
accuracy of methods, 413, 415
focimeter and trial lens, 413
interference patterns, 413
keratometers, 410–12, 413
microspherometry, 407–10, 413
pneumatic gauging, 413
templates, 413, 415
Radiuscope (optical microspherometer), 407–10
accuracy, 413
back peripheral radii, 409
centre thickness measurement, 418–19
concave surfaces, 408–9
convex surfaces, 410
hydrogel lens verification, 439, 446
rigid lenses verification, 407–9
Railway employees, 278
Reactive eye, 638
Reading difficulties, 638
Reconditioning, 638–9
Record keeping, 639
Recti muscles, 566
Recurrent corneal erosions, 764
therapeutic lenses, 764–5

Red eye reaction *see* Contact lens-induced acute red eye (CLARE) reaction
Re-fitting contact lenses, 639
Reflex tearing, 83, 98
Refraction, 170, 171
aphakia, 710–11
changes following contact lens wear, 403, 639
contact lens of incorrect back optic zone radius, 172–3
approximate rule, 173
optical formulae, 199
patient assessment, 284
RGP lens fitting, 343
rigid lenses, 295
soft lenses, 296, 403
spectacle/ocular, 845–8
toric lenses, 469–72
Refractive index, 841, 849–53
corneal transparency, 35–6
hydrogels, 77, 367
Refractive surgery, orthokeratology comparison, 690–1
Refractometer, 422
hydrogel lens water content (WC), 449
RGP lens material identification, 355
Rehder Electronic Thickness Gauge, 447–8
Re-instruction, 639–40
Reis-Buckler dystrophy, 765
Rejuvenating systems, 129–30
Relative spectacle magnification, 165–7
Removal of lenses
composite (Softperm) lenses, 293–4
infants/pre-school children, 739, 740
RGP lenses, 307
rigid lenses, 287–9
'scissor' method, 288–9
scleral lenses, 291, 566
soft lenses, 293
patient instructions, 301–2
suction holders, 289, 641
ReNu system, 50
Replacement lenses
hydrogel extended wear lenses, 499, 519
infants/pre-school children, 741
Reports, 640
Research into visual function, 833–6
corneal gas exchange, 836
electrodes, 834
eye movements, 834
lid pressure, 835
stabilized retinal images, 834–5
temperature measurement, 835–6
Resident ocular biota, 98–9
contact lens wear-associated changes, 102–3
Residual astigmatism, 171–2, 368, 469, 640
Respiratory drugs, 137
Retainer lens, 663
Retinal image
distortion, 163
magnification, 161–7
with anisometropia, 165, 166, 167
shape factor, 163–5
stabilization, 834–5
Retinal laser surgery, 825, 828
Retinoscopy, 284
after-care examination, 611
aphakia, 732
Reverse geometry lenses, 656, 728

Rewetting agents, 108
RGP lens extended wear, 494, 496, 522–31
acute complications, 523, 524–8
corneal moulding, 523
lens adherence, 523
advantages/disadvantages, 522–4
after-care, 530–1
care/maintenance, 530
cellular debris elimination, 497
discontinuation, 529
historical background, 522–3
indications, 529
lens fitting, 529–30
long-term effects, 528–9
oxygen transmission, 496, 523
patient management, 530–1
RGP lens fitting, 313, 328–55
basic requirements, 314
corneal contours, 314–16
mathematical models, 316–17
corneal lens dimensions, 317
with EyeSys, 335–7
fitting designs, 328–39
aspheric, 329
extrapalpebral, 328
former PMMA designs, 329
intrapalpebral, 328–9
lens-lid attachment, 329–30
modified contour technique, 329
sphere/asphere designs, 330
spherical, 329
fitting sets, 349–50
fluorescein patterns, 319, 320
forces affecting lens on eye, 317–19
capillary attraction, 317–18
frictional forces, 319
gravity, 318–19
lid force/position, 319
tear meniscus, 319
general principles, 321
historical developments, 321–2
lens tint, 353
ordering, 350–1
centre thickness, 351, 352
edge shape, 354
fenestration, 353–4
lens engraving, 351
materials selection, 351–3
transitions, 351
routine, 339–47
assessment of fit, 341–2
astigmatic corneas, 339, 342, 344–5
lens flexibility, 343–4
lens-cornea relationship, 343
refraction, 343
selection of first trial lens (aspherical designs), 340–1
selection of first trial lens (spherical designs), 339–40
scleral controlled clearance lenses *see* Scleral lens fitting
with Tomey TMS-1, 338–9
RGP lenses
adhesion phenomena, 345
advantages, 323
back optic zone diameter (BOZD), 340, 350
back optic zone radius (BOZR), 339, 346–7, 350, 351
back peripheral radius (BPR), 340, 350
back vertex power (BVP), 350, 419
back vertex distance (BVD), 351
care/maintenance, 109, 347, 530
checking final lens, 354
classification, 328
corneal oxygen supply, 40
designs, 330–5
aspheric, 333–5
tear lens thickness/axial edge clearance techniques, 330–3
flexure, 180–1
high myopia, 737
historical aspects, 14
hydration changes to BOZR, 346–7
indications, 313–14
infants/pre-school children
aniridia, 737–8
aphakia, 734–6
lathing, 778
materials, 314, 323–8
identification, 354–5
refractive indices, 355
modification procedures, 785–91, 811–12
edge polishing, 788–9
edge shaping, 786, 787
fenestration, 790–1
peripheral curve polishing/blending, 786
power adjustments, 789–90
wax polishers, 786, 788
patient instructions, 305–8
care of eyes, 307
hygiene, 306
lens handling, 306–7
lens storage, 306
wearing programme, 308
post-photorefractive keratectomy, 727
post-radial keratotomy, 724–5
tri-curve lens designs, 725
refitting former PMMA wearer, 348–9
initial transfer irritability, 349
scleral lenses, 568–9, 576–94
surface coating, 841
surface crazing/cracking, 276, 347
surface properties (wettability), 66
therapeutic lenses, 758
three and nine o'clock staining, 345–6
toric lenses *see* Toric lens fitting; Toric lenses
ultraviolet radiation disinfection, 121
ultraviolet radiation protection, 830
written prescription, 354
RGP materials
commercial materials, 80–2
cross linkages, 78
development, 77–9
dimensional stability, 57
hybrid, 56
manufacturing methods, 56, 57
oxygen permeability, 68, 70, 80
patent literature, 77–9, 90
Gaylord patents, 79–80
Japanese patents, 80
properties, 77–83
mechanical, 58
structural aspects, 77–8
Rheology, 683–5
Rhizopodia, 95
Rhizopus, 95
Rifampicin, 137
Rifampin, 137
Rigid gas permeable lenses *see* RGP lenses
Rigid lens verification, 407–24
diameters/linear parameters, 415–18
axial edge lift, 417
measurements on casts, 415–16
measuring magnifier, 415
micrometer and spheres, 416–17
radial edge lift, 417–18
thickness, 418–19
V gauge, 415
edge form, 421–2
material tint, 422
optic-lens prescription, 419–20
parameters to be checked, 407, 408
radii, 407–9
accuracy of methods, 413, 415
focimeter and trial lens, 413
interference patterns, 413, 415
keratometers, 410–12, 413
optical microspherometers (Radiuscopes), 407–10, 413
pneumatic gauging, 413
radius checking device, 412
templates, 413, 415
stress, 422
surface quality/polish, 420–1
toric lenses, 422–3
Rigid lenses
aphakia, 708, 709
contact lens solutions *see* Care solutions
corneal changes, 188–9
flexure, 180–1
historical aspects, 11–13
insertion *see* Insertion of lenses
materials classification, 798
moulding, 777–8
parameter changes, 632
refraction, 295
removal *see* Removal of lenses
transition quality, 648
Rigid-soft combination lenses, 398–400
fitting, 399–400
Rigidity modulus, 57, 58
testing materials, 59–61
Ring test monitor (RTM), 435
Rodenstock Panfunduscope, 824, 826
Rodotonita sp., 85
Rose Bengal, 144
hydrogel lens accumulation, 135
ocular examination, 266
patient assessment, 286
Rosifocin A, 328
Royal Air Force personnel, 278
Royal Navy personnel, 278
Ruben offset lenses *see* Offset lenses
Rust spots, 111
disinfection/cleaning solutions, 134
soft lenses, 132, 403
Saccharomyces, 95
Safety goggles, 261
Sagitta of front and back surfaces, 184
calculations, 201–2
design of contact lenses, 189–90
scleral lenses, 577
soft lenses, 382–3
Salazopyrin, 137
Salbutamol, 137
Saline solutions for thermal disinfection, 113
Sampling procedures, 434–5
Sattler's veil (Fick's phenomenon), 3, 5, 322
oxygen deprivation, 39
soft lenses, 14

Saturn lens, 398, 699, 837
see also Softperm lenses
Sauflon, 14, 359, 498, 500
Sauflon PW, 394
Scanlens, 498
Scars, 738
Schirmer test, 43, 267, 375
Sclera
anatomical aspects, 566
slit-lamp examination, 265, 268
Scleral indentation, 491
Scleral lens fitting
anterior ocular anatomy, 566
controlled clearance RGP lenses, 576–94
eye impressions, 580–3
hydrogel lens *in situ* for impression, 588–9
laminates, 589
lens optic zone projection (OZP), 578
lens scleral zone radius, 577–8
optic parameters selection, 580
optic zone projection method, 577
PMMA shells production/fitting, 583–8
sagittal depths, 577
special parameters, 579
manufacture of finished lens, 594–7
BOZR alterations, 596–7
cutting front optic, 595–6
modification, 592–4
optic zone fitting
FLOMs, 571–3
optic zone clearance, 572
ordering finished impression lenses, 594–5
preformed methods, 569
principles, 569–76
scleral zone fitting, 569–71
decentration of optic, 571
scleral zone radius (SZR), 570
total diameter, 570–1
scleral zone/optic zone integrated fitting, 573–6
lens verification, 576
transcurve lenses, 575–6
wide angle lenses, 573–4
ventilation, 589–92
channels, 590
fenestrations, 589
RGP lenses, 592
slotted lenses, 589–90, 591
truncations, 590, 592
Scleral lenses, 566–607
advantages, 566–7
aphakia, 599–600, 708, 736
back optic zone radius alterations, 181–4
approximate rules, 182, 183–4
back scleral radii, 9–10
bifocal lenses, 559–60
care solutions, 141, 597
chemically damaged eyes, 771
complications/problems, 605–6
cosmetic lenses, 743, 751
high myopia, 601
historical aspects, 5, 6, 9–13
indications in pathological conditions, 597–605
insertion, 290
keratoconus, 597–9, 699–700
materials, 567
modification *see* Modification procedures
oxygen transmissibility, 569
pathological indications, 597–601
outcome, 601–2
PMMA preformed/impression lenses, 567–8
postkeratoplasty, 601, 719
removal, 291
RGP lenses, 568–9
sports use, 837
therapeutic lenses, 758, 761
protective functions, 602–5
types, 567–9
Scleral ring splints, 770, 832
Scleral shells, 751
splint function, 832
Scleral zone fitting, 569–71
Scleral zone radius, 570, 577–8
Scratches, 640–1
Sealed shell, 585–8
Sebaceous glands of Zeiss, 28
Seborrhoeic eczema, 263–4
Secretory IgA (sIgA), 99, 100
SeeQuence, 499, 501
oxygen permeability, 520
Sensitive Eyes (subtilisin), 128, 304
Serratia, 96, 121, 507
Sessile drop measurements, 64, 65
Seventh nerve lesions, 268, 767, 768
Shape factor, 163–5, 317
Shells, 583–8
Silflex lenses, 398
Silicone elastomer lenses, 501
Silicone hydrogel materials, 73
Silicone rubber, 55, 56, 78–9
impression materials, 9
oxygen permeability, 78, 79, 501
patent literature, 79, 90
properties, 57, 58
surface properties, 79
Silicone rubber lenses, 327–8, 397–8, 641
advantages/disadvantages, 398
aphakia, 734
babies/infants, 711, 734, 737
care solutions, 109–10
wetting agents, 110
extended wear, 501
fitting, 398
high myopia, 737
manufacturing methods, 57, 362
therapeutic lenses, 758, 761, 768, 770, 772, 831
postkeratoplasty, 713
Silicone-acrylate materials, 325–6, 522
advantages/disadvantages, 325–6
hydration-dehydration changes, 346
modified surface materials, 328
surface cracking, 347
Siloxanyl-acrylate, 325–6
Siloxymethacrylate materials, 78, 79, 80
patent literature, 90
Silyl acetylene polymers, 51, 80
Simultaneous vision bifocal, 545, 560–1
Sinusitis, chronic, 262
Sjögren's syndrome (keratoconjunctivitis sicca), 263, 771
Skin creams, 137
Skin disorders, indications for referral, 262–4
Skin diving, 837–9
Sleep
corneal changes, 20
corneal oxygenation, 495
RGP lens adhesion to cornea, 345
wear during, 283
Slit-lamp examination, 232, 240–5
after-care, 611, 613–14
applications, 243–5
corneal sensitivity assessment, 245
filters, 244
fundus examination, 823
grading scales, 243, 863–7
illumination system, 241
observtion system, 241
pachometry (pachymetry), 244–5
patient suitability for contact lens wear, 264–5, 268, 284–5
anterior chamber, 265
anterior lens surface, 265
bulbar conjunctiva, 265, 268
caruncle, 265
cornea, 264–5
iris, 265
lid margins, 265
limbus, 264–5
plica semilunaris, 265
pupil, 265
sclera, 265, 268
photography, 254–6
pre-corneal tear film analysis, 245
soft lens fitting, 373–4, 377
techniques, 241–3
illumination methods, 242
Slotted scleral lens, 589–90
Slow-release artificial tear (SRAT), 831
Smoking, 277
Soaking solutions, 107
Sodium cromoglycate, 137
Sodium dichloroisocyanurate (Halane), 120
Sodium hypochlorite (Milton), 130
Soflens, 359, 362, 391, 427
Soft lens associated corneal hypoxia syndrome (SLACH), 642
Soft lens fitting, 358–404
after-care, 401–2
assessment techniques, 373–4
clinical routine, 377
assessment of fitting/vision, 378
insertion of lenses, 377
preliminary examination, 377
tolerance trials, 378–9
corneal diameter soft lenses, 383–5
extended wear lenses, 394
fitting characteristics, 379
flat fitting, 380
steep fitting, 379–80
fitting criteria, 381
flexibility, 385
fluorescein, 376
high water content lenses
aspherical cast-moulded, 388–9
spherical lathe-cut, 390
spherical moulded, 389–90
lens movement, 381
lens selection, 381
limbal topography assessment, 376
low water content lathe-cut, 385–6
medium water content lathe-cut
spherical, 386–7, 390–1
spherical front surface, elipitcal back surface, 387–8
radii, 385
'semi-scleral' lenses, 381–3
primary sagitta, 382–3
technique, 381–2
spun-cast lenses, 391–5

Soft lens fitting (*cont*)
tear flow assessment, 374–6
trial lens disinfection, 374
Soft lens materials classification, 798, 799
Soft lens polishes, 428
Soft lens solutions, 122–30
adverse reactions, 131
calcium preventing solutions, 129
enzymatic systems, 124–9
information for patients, 302
prescribing, 130–1
rejuvenating systems, 129–30
surfactant solutions, 123–4
Soft lens-associated corneal hypoxia syndrome (SLACH), 507
Soft lenses, 111, 112
acuity, 364, 366
advantages, 362–3
ageing, 402–3
aphakia, 708, 709–10, 733–4
astigmatism, 368
back surface designs, 13–14
bifocal, 396, 560–4
concentric 'multifocal', 561–3
fitting sets, 563–4
simultaneous vision bifocals, 560–1
translating/alternating vision, 561
central thickness, 372–3
checking, 365
classification, 369–70
cleaning, 111–12, 122–30
complications, 365
contact lens solutions *see* Soft lens solutions
corneal changes, 189
corneal oxygen supply, 40
corneal sensitivity effects, 33
cosmetic lenses, 397, 752–5
heterogeneous types, 754, 755
homogenous types, 752–4, 755
lens power calculation, 754
deposits, 111, 132–4, 367
disadvantages, 322–3, 364–5
discoloration, medication-associated, 135
disinfection, 112–22, 400–1
chemical, 114–22
microwaves, 118
prescribing, 130–5
procedure, 128–9
sonication, 120–1
ultraviolet radiation, 121–2
equivalent oxygen performance, 361–2
extended wear *see* Hydrogel extended wear lenses
historical development, 13–14, 358–61
infants/pre-school children, 711, 733–4
aniridia, 737
high myopia, 737
information for patient, 283, 400
lens handling, 300–2
insertion, 291–2, 300–1
inside out, 630–1
keratoconus, 698
lathe fabrication, 778, 785
hydration, 785
sterilization, 785
lens identification, 397
manufacture methods, 57, 362, 427–30
modification, 364–5, 815–16
moulding, 777
near vision, 369
over-refractions, 367–8
oxygen permeability, 361–2
parameter changes, 632
patient selection, 365–6
postkeratoplasty
optical lenses, 718
therapeutic lenses, 714
post-photorefractive keratectomy, 728
post-radial keratotomy, 723–4, 725
power changes, 174–80
due to lens environment, 366–7
effects on astigmatism, 179–80
evaporation effects, 179
flexure, 174–8
temperature effects, 178
presbyopia, 396–7
properties, 360–1
summary, 360
quality assurance *see* Quality assurance
re-fitting of rigid lens failures, 363
refraction, 296
refractive index, 367
removal, 293, 301–2
Sattler's veil, 14
specification, 430
terminology, 358
therapeutic lenses, 363, 758, 760, 768, 769, 770, 772, 831
advantages/disadvantages, 760
bullous keratopathy, 762
disposable lenses, 760
drug delivery, 758, 773
manufacturing methods, 759
tolerances, 432, 434
toric lenses *see* Toric lens fitting; Toric lenses
ultrathin, 372–3, 445, 446
ultraviolet radiation protection, 830
verification *see* Hydrogel lens verification
visual advantages, 369
visual performance, 366–9
water content, 369
Soft stabilized moulding, 429
Softab, 120, 134, 138, 304, 305
Softperm lenses, 398–400, 699
insertion, 293
postkeratoplasty, 719
removal, 293–4
sports use, 837
Söhnges control and projection system, 443, 444
Solutions *see* Care solutions
Sonification, 120–1
Sorbic acid, 120
lens discoloration, 86
misuse/incompatibility, 140
Special types of contact lenses, 817–42
Specific gravity
RGP lens material identification, 355
rigid lens verification, 422
Spectacle blur, 188, 189, 323, 334, 348–9, 363, 619–20
soft lenses, 363
Spectacle intolerance, 261
Spectacle refraction, 845–8
optical formulae, 199
Spectacles, 641
infants/pre-school children, 740, 741
aphakia, 732, 740
supplementary, 643
Spectroscopy, 354–5
Sphercon lens, 12
Spherical aberration, 173, 174
Spherical aberration-correcting bifocal contact lenses, 547
Spherical lenses magnification, 161–2
Spinner, 802
Splints, 832
Spofa lenses, 358
Spoilation, 83–8
hydrophilic lenses, 111
incidence, 84
lens coatings, 85
lens discoloration, 86
lipids, 86–7
manifestations, 84–6
microbial, 85–6
proteins, 87–8
white spots, 84–5, 86–7
see also Deposits
Sporozoa, 95
Sports, 283, 836–9
advantages of contact lens wear, 261
contact lens criteria, 836–7
contact lens wear regulations, 277
injury protection, 261
soft lenses, 363, 365
high water content, 370
Spun-cast lenses, 56, 359, 362, 391–5
fitting technique, 392–3
lens geometry, 391–2
material properties, 391
soft lens manufacture, 427
Squint
cosmetic lenses, 743, 745
therapeutic lenses, 833
see also Heterotropias
Stability
hydrogels, 73, 75
temperature changes, 73
RGP lenses, 353
soft lenses, 363
high water content, 370
Stabilization, 477, 483, 555–6
Standards
hydrogel lens verification, 432–3
soft lens acceptable quality level (AQL) policies, 433
see also Quality assurance
Staphylococcus, 96, 347
hydrogel extended wear, 507
lens contamination, 103
Staphylococcus aureus, 96, 99, 111, 116
Staphylococcus epidermidis, 96, 98, 99, 121
Static on lenses, 276
Static-cast polymerization lenses, 57
Sterile unpreserved saline, 113
Steroid drugs, 276
Stevens-Johnson syndrome (erythema multiforme), 268, 602, 832
therapeutic lenses, 771
Stinging, 641
Stokes' construction, 185–6
Strabismus, 734
cosmetic lenses, 745
infants/pre-school children, 737
Streptococcus, 145
Streptococcus faecalis, 113
Streptococcus pneumoniae, 96
Streptococcus pyogenes, 96
Stress testing, 778

Striae
RGP extended wear, 523
soft lenses, 401
see also Corneal oedema
Stroma (substantia propria cornea), 22–3
cellular elements, 23
lamellae, 22, 23
matrix, 23
transparency, 35–6
Stromal dystrophies, 765
Stromal oedema
extended lense wear, 40–1
hydrogel lenses, 501–3
RGP lenses, 524–5
Stromal ulceration, 767–8
Submicron CNC (computer numerical control) lathes, 783–5
Subtilisin, 128, 304
Suction holders, 641, 802
EpiCon lens, 327
lens insertion, 287
lens removal, 289, 641
infants/pre-school children, 739
silicone rubber lenses, 641
Sulphacetamide, 105
Sulphasalazine, 137
Sulphonamides, 144
Sunglasses, 649
Superficial epithelial arcuate lesion (SEAL), 624–5
Superficial keratectomy, 769
Superficial punctate epitheliopathy (SPE), 641–2
Superficial punctate keratitis, 402
Superior limbic keratitis (SLK), 642
Superior tarsal muscle of Muller, 28
Supplementary camera lenses, 250
Surevue, 51
manufacture, 429
Surface coating, 841
Surface deposits *see* Deposits
Surface fissures
RGP lenses, 276, 347
soft lenses, 403
Surface inspection
after-care examination, 631
hydrogel lens verification, 454–9
deposits, 460, 461
discoloration, 456
electron optics, 458–9
lesions, 455
light microscopy, 456–8
microbial contamination, 459
surface films, 455
rigid lens verification, 420–1
Surface power
optical formulae, 199
bifocal lens segment differences, 200–1
bifocal lenses of various optic zone radii, 201
Surface properties (wettability), 58, 62–7, 352
clinical significance, 65–7
contact angle measurement, 62
definitions, 63–4
hydrogels, 77
measurement techniques, 64–5
RGP lenses, 352
silicone rubber, 79
surface tension
critical, 65
dispersive component, 63–4, 65
polar component, 63–4, 65
test methods improvement, 82–3
Surface tension
critical surface tension, 63
dispersive component, 63–4, 65
polar component, 63–4, 65
wettability relationship, 63
Surfactant cleaning solutions, 123–4, 134
alcohol incorporation, 124
combined storage solution/cleaner, 124
hydrogel lenses extended wear, 518
hypertonic, 124
mechanical agitators, 124
polymeric beads incorporation, 124
RGP lenses extended wear, 530
Sweat glands of Moll, 28–9
Swimming, 138, 277, 644–5, 837
infants/pre-school children, 742
Symblepharon, 603
Sympathomimetic eye drops, 135

Tabb technique, 654
Tangent Streak bifocal contact lenses, 544, 557–8
Tarsal conjunctiva, 25
Tarsal glands *see* Meibomian glands
Tarsal plate, 28
Tear analysis in patient assessment, 267–8, 285–6, 374–6
Tear deficiency, 646–8
Tear film, 83
aqueous layer, 83
break-up time *see* Break-up time (BUT); Non-invasive break-up time (NIBUT)
inner mucoid layer, 26, 83
lipid layer, 83
stability with high water content soft lenses, 370, 372
see also Precorneal tear film
Tear layer thickness (TLT)/tear lens, 170, 171, 667
in blinking, 614
design of contact lenses, 195
optical formulae, 202–3
new BOZR (*r*ON) for specified change, 203–4
orthokeratology lenses, 665–6, 668–70, 672–6
RGP lens design, 330–3
toric lenses, 469
Tear osmolarity, 498
Tear output, 43
after-care evaluation, 645–8
contact lens wear effects, 101–2
drugs reducing, 136–7
Norn's test, 267–8
patient suitability for contact lens wear, 267–8, 285–6
phenol-red thread (PRT) test, 268, 375
Schirmer test, 267
Tear proteins
lens deposits, 132
ocular defence mechanisms, 42–3, 83, 98, 99, 100
contact lens wear effects, 102
Tear replacement solutions, 108, 140, 647, 648, 772
Tear reservoir, 658, 659, 660, 671–5
Tear strength, 57
hydrogels, 75
testing materials, 62
Tear Thinning Time (TTT), 271
Tear-specific prealbumin, 83, 98
Tears, 41–4
antibacterial properties, 42–3, 98
buffer systems, 105
circulation, 645
changes under closed lid, 100–1, 497–8
composition, 83
dietary influences, 276–7
lipid, 83, 84
mucous, 83, 84
protein, 83–4, 98, 100
corneal metabolite supply, 14, 38
corneal oxygen supply, 39, 495
drainage, 43
function, 42–3
immunoglobulins, 99, 100
lens material wettability measurement, 65–6
liquid lens optics, 170, 171
astigmatism correction, 171
meniscus, 319
microorganisms removal, 99
neural control, 43–4
in newborn, 43
ocular defence mechanisms, 100–1
pH, 376, 497–8
prism, 285
secretion, 41, 83, 98
surface tension, 63
Tearscope, 245, 269, 270, 375
Tectonic keratoplasty, 713
Temperature
measurement, 835–6
sensibility of cornea, 34
soft lens effects
high water content lenses, 370
power changes, 178, 366
tear changes under closed lid, 497
Templates, rigid lenses verification, 413, 415
Tensile strength, 57
hydrogels, 75
testing materials, 59
Terpolymers, 52
Terrien's marginal dystrophy, 598
Tetracyclines, 137–8
Tetrafilcon, 88
Tetrahydrozoline (Visine), 135, 143
Theatrical special effect lenses, 842
Therapeutic lenses, 758–74, 831–3
after-care, 774
in animals, 840–1
bandage lenses, 831
bullous keratopathy, 762–3
cicatrizing conjunctival diseases, 770–1
collagen lenses, 761–2
colour vision defects, 833
complications, 773–4
corneal hydration, 758–9
corneal thinning/perforation, 768–9
drug delivery, 758, 772–3, 831–2
dry eyes, 771–2
filamentary keratitis, 766–7
following ocular surgery, 769–70
Fuch's endothelial dystrophy, 763–4
healing promotion, 758
infants/pre-school children, 731, 738
after keratoplasty, 713–14, 769

Therapeutic lenses (*cont*)
lens availability, 760
mechanical support, 758
myopia stabilization, 833
orthoptic uses, 832–3
patient follow-up, 762
persistent epithelial defects, 767–8
recurrent corneal erosions, 764–5
scleral lenses, 761
selection, 759–60
silicone rubber lenses, 761
soft lenses, 363, 759, 760
splints, 832
stromal dystrophies, 765
stromal ulceration, 767–8
symptom relief, 758
Thygeson's superficial punctate keratitis, 765–6
Thermal burns
scleral shell splint functions, 832
soft lenses, 363
therapeutic lenses, 771
Thermal disinfection, 134
misuse, 139
soft lenses, 112–14
Thermistors, 836
Thermoplastics, 54–5
Thickness of lenses
axial edge, 190, 193
back and front vertex power, 173–4
bifocals, minimum central, 552
centre, 316–17
change in vergence formula, 200
corneals, 316–17, 418–19, 424
determination of
electric circuit micrometry, 447
pachometry, 446–7
radiuscope, 446
edge, 190, 193
extended wear, 372–3
optics, 173–4
oxygen permeability and, 68–71
sclerals, 424
soft, 372–3
verification, 418–19
soft lenses, 445–9
water content and, 500
Thimerosal, 105, 401
allergic reactions, 131
chemical disinfection, 115–17
misuse/incompatibility, 138, 139
'Thin' soft lenses, 372–3
Three and nine o'clock stain, 345–6, 648
Thrichotecium roseum, 111
Thygeson's superficial punctate keratitis, 765–6
Thyroxine treatment, 276
Time for fitting, 259
Tinted lenses, 276, 284, 841
infants/pre-school children, 738
RGP lenses, 353
rigid lens verification, 422
soft lenses, 397
solution incompatibility, 138
ultraviolet-absorbing, 284
aphakia, 711
see also Cosmetic lenses
Tissutex, 9
TMS (Topographic Modelling System), 267, 704
RGP lens fitting, 338–9
Tolerance, 3, 4
trials, 259
Tolerances, soft lenses, 432, 434
Tonicity
contact lens solutions, 104
soft lens power changes, 366
topical medication soft lens effects, 138
Tonometry, 648
patient suitability for contact lens wear, 272
through therapeutic lenses, 773
Topical anaesthetics, 142–3
Topical medication, 138
Topographical keratometers, 236
Toposcope, 413, 415
Tori-Check, 491–2
Toric lens fitting, 464–92
cylindrical power equivalent toric lenses, 475–7
alignment bitorics, 475
back surface torics, 475–6
front surface torics, 476–7
oblique bitorics, 477
prism ballast, 477–80
rigid gas permeable lenses, 464–81
checking lenses, 481
lens flexure, 481
soft lenses, 396, 481–92
back vertex power determination, 485
back vertex power measurement, 491–2
checking, 491
empirical prescribing, 488–9
lens rotation, 485–8
limitations, 490–1
methods, 488–9
principles, 485
spherical trial lenses, 489
stock versus custom-made lenses, 489–90
toric trial lenses, 489
spherical back optic zones and toroidal peripheral zones, 467–8
spherical power equivalent bitoric lenses (compensated bitorics), 475
toroidal back optic zones
induced astigmatism, 473–5
optical considerations, 468–77
refraction, 469–72
and spherical peripheral zones, 467
and toroidal peripheral zones, 465–7
toroidal front surfaces with spherical back optic zones, 477
Toric lenses, 184–5
after-care, 648
forms, 465–8
spherical back optic zones and toroidal peripheral zones, 467–8
toroidal back optic and peripheral zones, 465–7
toroidal back optic zones and spherical peripheral zones, 467
indications, 464–5, 466–7
magnification, 162–3
manufacture, 791–4
advantages/disadvantages, 794
crimping, 791
grinding, 791–2
lathing, 792–4
polishing, 791
rigid lens verification, 422–3
soft lenses, 395–6, 481–2
complications due to thickness differentials, 490–1
criteria for use, 482
design trends, 492
irregular astigmatism, 490
prism ballast, 483
stabilization techniques, 483–5
surface optics, 482–3
toroidal back surface, 395
toroidal front surface, 395–6
Toric periphery, 702
Total corneal power, 171
Total lens diameter (TD), 332, 340, 350, 409, 416, 432, 445, 709–10
radial keratotomy, 570–1
scleral lenses, 570–1
silicone rubber lenses for infants, 734
soft lenses for infants, 733
therapeutic lenses, 759
Total ocular astigmatism, 171
approximate rule, 172
Touch (irritation) sensibility of cornea, 33, 34
Toxic fumes, 648
Toxoplasma, 95
Trabeculectomy, 770, 825
Trachoma, 713, 771
Trandate (labetalol), 138
Transcurve lens, 11, 575–6
Translating bifocal, 545, 557–9, 561
Transferrin, 98
Transitions, 351, 648
Trapezoid lenses, 698
Traumatic aphakia, 736
Travel, 649
infants/pre-school children, 742
Travelling microscope, 445
Trichiasis, 268, 758–9
scleral lenses, 603
therapeutic lenses, 761
Trichlorethylene vapour, 138
Trichomonas, 95
Tricyclic antidepressants, 276
Trimethoprim, 121
Troncoso goniolens, 824, 826
Truncation
bifocal contact lenses, 552, 555–6
corneal lens modification procedure, 810–11
manufacturing procedure, 794–5
scleral lenses, 590
soft lens modification, 815
toric rigid lenses, 479–80
toric soft lenses, 483–4
Trypan blue, 266
Trypanosoma, 95
Tuohy lenses, 12
Type shells, 6, 8, 11

UltraCon lens, 327
Ultrasonography, hydrogel lens verification, 440
Ultrathin soft lens, 14, 445, 446
therapeutic lenses, 760
Ultraviolet photography, 253–4
Ultraviolet protection/tinted lenses, 276, 649, 830–1
aphakia, 707, 711, 733
fluorescein patterns, 319
infants, 733
RGP lenses, 319

Ultraviolet soft lens disinfection, 121–2
Ultrazyme, 128, 140, 304
Underwater contact lenses, 837–9
Unilateral ametropia, 731
Unilateral aphakia, 165, 708, 736
Unilens, 174
Uniocularity, 274
Urethane siloxanol acrylates, 51, 80
USA, drug regulations, 146

V gauge
  hydrogel lens verification, 445
  rigid lens verification, 415
Validity of tests, 431–2
Vantocil, 50
Variable doubling systems, 233
Variations lens, 562
Vasoconstrictors, 143, 650
Vascularization *see* Corneal vascularization
Vergence change due to thickness, 200
Verification
  hydrogel lenses *see* Hydrogel lens verification
  keratometry, 235–6
  rigid lenses *see* Rigid lenses verification
  scleral lens, 576
Vertex distance *see* Back vertex distance
Vertical total diameter of bifocal, 555
Video keratometry systems, 237
  applications, 239–40
  data analysis, 237–9
Videokeratography
  keratoconus, 704
  soft lens fitting, 374
Videokeratoscopy, 232, 267
  patient suitability for contact lens wear, 267
Vifilcon-A, 87
Vinyl pyrrolidone (NVP) hydrogels, 71, 72
  patent literature, 72–3, 89–90
  silicone rubber materials, 79
  water content (equilibrium water content), 73
Viral conjunctivitis, 96, 100
Viruses, 95
Viscosity-building agents, 106
Visual acuity
  patient suitability for contact lens wear, 272–4
  soft lenses, 364, 366
Visual display units (VDUs), 650
Visual fields
  after-care examination, 650
  ocular examination, 284
  patient suitability for contact lens wear, 272
Vitamin A deficiency (xerophthalmia), 263
Vitrectomy, 824, 825
  lens system, 824, 827, 828
Vitronectin, 98, 101

Water, contact lens solutions, 106
Water content, hydrogels, 73, 369
  copolymerizations increasing/reducing, 73
  density, 77
  hydrogel lens verification, 449–50
  mechanical properties, 75
  oxygen permeability, 76
  refractive index, 77
Wax polishers, 786–8, 803
Wearing schedules
  dispensing appointment, 298–9, 301
  rigid gas permeable (RGP) lenses, 308
  soft lenses, 362–3
    high water content lenses, 370
Weicon CE, 387
Welflex 55, 390
Wesley-Jessen bifocal contact lens, 541–2
Wesley-Jessen PEK System 2000, 704
Wettability *see* Surface properties
Wetting agents
  functions, 107–8
  rigid lenses, 106, 107–8
  silicone rubber lenses, 110
White spots, 84–5
  lipids in formation, 86–7
  soft lenses, 132, 403
    high water content, 371
Wide angle lens, 11, 573–5
Written prescription, 354

X-Chrom lens, 397, 833
Xerogel, 733
Xerophthalmia (vitamin A deficiency), 263
Xylometazoline, 143

Yeasts, 95
Yellow discoloration, 86
  soft lenses, 132
Ysoptic bifocal, 544

Zeiss mires, 234
Zeiss three-mirror contact lens, 823
Zygomycetes, 95

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