Silicone hydrogels –

What are they and how should they be used in everyday practice?

In part two of our series on extended wear, **Professor Brian Tighe** examines the structure of silicone hydrogel materials and explains how they work, while **Dr Noel Brennan** and **Dr Chantal Coles** advise on how the lenses fit in to clinical practice. This series is based on the BCLA's 1999 CET day on extended wear

THE STRUCTURE OF hydrogel materials can be described as 'washing-line' polymers. In this analogy the hydrogels are composed of a long backbone (ie the 'washing line') from which a variety of chemical groups may be suspended (the 'washing'). The function of these chemical groups, or monomers, is to attract and bind water. In conventional hydrogel materials, frequently used monomers include N-vinyl pyrrolidone (NVP), methacrylic acid, and HEMA. The washing lines may be fastened together at intervals by the use of cross-links to give greater physical stability. The same 'washing line' principle can also be applied to the silicone hydrogels but groups containing silicon-oxygen bonds (silicones) are attached to increase oxygen permeability.

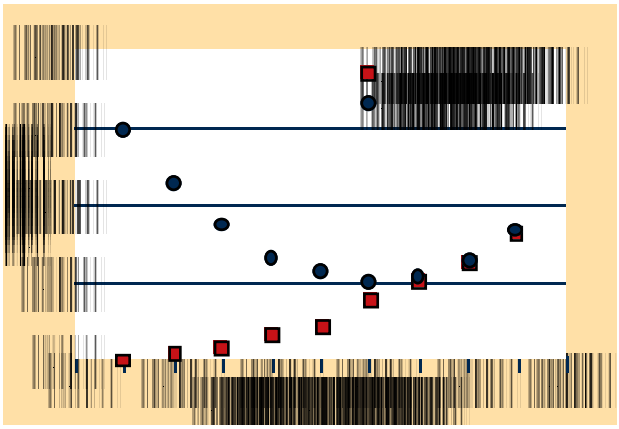

FIGURE 1 The variation of oxygen permeability (Dk) with equilibrium water content for conventional (Non-Sil) and silicone-containing (Sil) hydrogels.

ADVANTAGES OF SILICONE HYDROGELS

With contact lenses, oxygen permeability, wettability, material strength and stability must all be balanced to achieve a usable contact lens. In order to increase oxygen permeability of a conventional hydrogel material the water content must be increased. Incorporating the structural elements of silicone rubber into hydrogels produces a dramatic enhancement of oxygen transmission properties without increasing water content. This is illustrated in Figure 1 which compares the oxygen permeability (Dk) of conventional hydrogels with typical values for silicone-containing hydrogel materials.

This enhanced oxygen permeability is due to the fact that oxygen is more soluble in silicone rubber than it is in water, whereas, with a conventional hydrogel, oxygen is more soluble in water than it is in polymethyl methacrylate (PMMA).

THE DEVELOPMENT OF SILICONE HYDROGELS

The difficulty of combining silicone rubber with a typical hydrogel-forming monomer was the first major obstacle in the development of the silicone hydrogels. The first answer that springs to mind is to combine HEMA with TRIS, the monomer used in the preparation of RGP lens materials. However, combining hydrophobic TRIS with hydrophilic HEMA and then hydrating the product presents the same difficulty as trying to combine oil and water to form an optically clear product.

The earliest patents were granted to the Toyo Contact Lens Company in 1979 with Kyoichi Tanaka and four others as the named inventors. However, it was not until the mid-1990s that the patents explicitly addressed the question of lens movement.

The first commercially available silicone hydrogels adopted two different approaches. The first approach, by Bausch & Lomb,[1,2] is a logical extension of its development of silicone monomers with enhanced compatibility in hydrophilic hydrogel-forming monomers. The second, by Ciba Vision, was the development of siloxy macromers containing hydrophilic polyethylene oxide segments and oxygen permeable polysiloxane units. Polyethylene oxides, better known as polyethylene glycols or PEGs, are very hydrophilic materials and are widely used as components of surfactants, foodstuffs and various biomaterials.

Until the mid-1990s, three measurable properties of a contact lens material were based on wetting properties, mechanical properties, and oxygen permeability in order to predict the minimum acceptable baseline performance. The publication of the Ciba Vision patent in 1996, entitled 'Extended Wear Ophthalmic Lens',[3] proposed a fourth, of property measurement linked to lens movement on the eye – hydraulic and ionic permeability – and demonstrates that biphasic materials present a successful way of balancing these properties.

HYDRAULIC AND IONIC PERMEABILITY

Conventional hydrogels behave in some ways as though they consist of dynamically fluctuating water-filled pores, the size of which diminishes as the water content decreases. The permeability behaviour of oxygen and water has many similarities, as water and oxygen molecules are very similar in size. Therefore, the way in which the oxygen curve varies with water content may, to a first approximation, be taken to represent the behaviour of water transport.

In the case of silicone hydrogels with a homogeneous structure (ie not biphasic materials as described in the Ciba Vision patent) the hydraulic permeability will follow the oxygen curve of conventional hydrogels whereas the oxygen permeability increases with decreasing water content. This is because hydraulic permeability always takes place through

◆ This is the second in a series of continuing education articles on the rebirth of extended wear contact lenses, edited by **Professor Debbie Sweeney**. Successful participation in each module of this College-approved series counts as one credit towards the College of Optometrists' CET scheme and towards the Association of British Dispensing Opticians' scheme. There are six multiple-choice questions and the pass mark is 70 per cent

TABLE 1

Summary of the principal properties of two commercially available silicone hydrogel lenses

	PureVision	Focus Night and Day
Manufacturer	Bausch & Lomb	Ciba Vision
Material	balafilcon A	lotrafilcon A
Water content	35%	24%
Dk (barrers)	110	140
Modulus	110 (g/mm^2(ca 1.1 MPa)	1.2 MPa
Surface treatment	Plasma oxidation	25nm plasma coating
Water transport	10% above pHEMA	not quoted (ca 2x pHEMA)
Sodium transport	Not quoted (but cf pHEMA)	not quoted (ca 2x pHEMA)

the aqueous phase, whereas in silicone hydrogels the transport of oxygen takes place predominantly through the silicone polymer phase.

As the water content increases, the difference between ionic and hydraulic permeability becomes unimportant. As the water content falls, however, it is the ionic permeability that becomes critical since the tear layer on both sides of the lens behaves as a dilute salt solution. The critical minimum sodium ion permeation value claimed in the patent to be necessary for lens movement (0.2 x 10^{-6} cm^2 sec^{-1}) is very similar to the reported literature value for polyHEMA (0.18 x 10-6 cm^2 sec^{-1}). The patent claims that the same minimum value for hydraulic permeability is required for lens movement (0.2 x 10^{-6} cm^2 sec^{-1}) consistent with the analysis suggested here.

Hydraulic flow through the lens is capable of maintaining (not replacing) the hydrodynamic boundary layer between lens and eye at adequate thickness to avoid hydrophobic binding. If the flow falls below a critical level the co-efficient of friction between the lens and substrate rises rapidly, which promotes adhesion. Parallel phenomena are observed in the development of hydrogel skin adhesives and articular joint liners.

DISADVANTAGES OF SILICONE HYDROGELS

Increasing silicone may bring the benefit of increased oxygen permeability but the disadvantages of decreased wettability, increased lipid interaction, and accentuated lens binding, have to be overcome. To overcome the first two problems involves surface treatment, a notoriously difficult task with any silicone-based material.

COMMERCIALLY AVAILABLE SILICONE HYDROGELS

Two silicone hydrogel lenses have recently become commercially available, Bausch & Lomb's PureVision and Ciba Vision's Focus Night & Day. This has taken over 20 years, since the publications of Tanaka's patent, reflecting the difficulties of lens fabrication and subsequent surface treatment on a commercially viable scale, at economic cost, and with adequate quality assurance controls.

Also, bearing in mind the potential risks involved in unsupervised overnight wear, clinical and regulatory approval are required in order to provide adequate minimum information for an initial patent filing to bring a new extended wear lens to market. The timescale and costs of the necessary experimentation are extensive.

PureVision and Focus Night & Day, although apparently similar, have significant differences in their material properties. These are summarised in Table 1.

The PureVision material, balafilcon A, is based on a homogeneous co-polymer of a vinyl carbamate derivative of TRIS with a water content of 35 per cent and a Dk of 110 barrers. It is said to have a water transport slightly in excess of that of polyHEMA. This would put it above the critical minimum value of ionic and hydraulic permeability for lens movement on-eye.

The Focus Night & Day material, lotrafilcon A, is based on a fluoroether macromer co-polymerised with TRIS monomer and N,N-dimethyl acrylamide in the presence of a diluent. It is therefore a fluorether-based silicone hydrogel with a water content of 24 per cent and a Dk of 140 barrers. If this structure were homogeneous, the sodium ion and hydraulic permeability would not approach that of polyHEMA. However, because of the biphasic structure which allows oxygen and water permeability to be uncoupled, the hydraulic and ionic permeability of the material both exceed that of polyHEMA and consequently the lens is reported to have adequate on-eye movement.

Surface treatment

Both lenses are treated using gas plasma techniques but PureVision is treated by plasma oxidation producing glassy islands, whereas Focus Night & Day is plasma coated with a dense 25nm-thick high refractive index coating.

The imaging technique of Atomic Force Microscopy produces a 'relief map' that enables an area equivalent to a square with 50µm (0.05mm) sides to be visualised. If this very small square is imagined to be a chessboard, the glassy silicate islands of PureVision coating would have the size and distribution of the white squares but less regular in size and with a rounded appearance. The black squares would correspond with the balafilcon material indicating that the silicate islands do not completely occlude the surface. The wettability of the glassy silicate area 'bridges' over the hydrophobic balafilcon area because of the relatively small size of the regions.

In contrast, the Focus Night & Day lens surface is chemically uniform and there is no distinctive appearance of islands. However, the surface is gently undulating in the form of curved diffuse ridges from edge to edge of the square. The height of the undulations is only a few nanometres and seems to reflect the surface of tools used to produce the lens moulds.

Mechanical properties

A comparison of the mechanical properties of the lenses, available at the time of going to press, is shown in Table 1. The reported mechanical properties indicate the lenses are similar to each other and over twice as stiff as conventional polyHEMA.

Early clinical reports indicate that both lenses produce 'mucin balls'. This is most probably due to the shearing effect of the lens as it is deformed by the closing eyelid, causing the mucin in the tear film and ocular surface to be rolled up like a snowball.

CONCLUSIONS

PureVision and Focus Night & Day appear to provide an excellent basis for the 'rebirth' of extended wear. Developments in surface modification, with attention paid to improved ocular biocompatibility, biotribology, tear film interaction, and tear film stability, are expected in the near future. The new millennium offers the prospect of improved contact lens products.

References

1 Bambury RE and Seelye D. Vinyl carbonate and vinyl carbamate contact lens material monomers, US Patent 5070215, 1991.

2 Bambury RE and Seelye D. Vinyl carbonate and vinyl carbamate contact lens material monomers, US Patent 5610252, 1997.

3 Greisser HJ, Laycock BG, Papaspiliotopoulos E, Ho A *et al*. Extended wear ophthalmic lens, 1996.

◆ *Professor Brian Tighe is group leader of the Biomaterials Research Unit, Aston University, Birmingham*

Where do silicone hydrogels fit in to everyday practice?

Dr Noel Brennan and **Dr Chantal Coles** explain the procedure for the management of extended wear and highlight the planning required for both practitioner and patient success

THERE ARE TWO KEY QUESTIONS when considering the introduction of silicone hydrogels to a clinical practice:

◆ Is it clinically and ethically legitimate to offer silicone hydrogel materials for extended wear?
◆ Is the provision of silicone hydrogels for extended wear a worthy application of the clinical skills of contact lens practitioners?

The first question relates to issues of safety of extended wear balanced against the advantages to be gained from the wearing pattern, the popular demand for this modality, and the community assessment of the risk-benefit ratio. Current critical opinion suggests that silicone hydrogel lenses are appropriate for use in extended wear providing there is adequate devotion to patient care.

The second question relates to the scope of the optometric practice, practitioner competence, and profitability of extended wear. Practitioners aim to provide the highest quality of service to their patients. Some may choose not to prescribe extended wear lenses but, with consumer awareness at an all time high, this failure may be an unreasonable restriction on services provided. Competitive forces, including corrective options such as refractive surgery, and from fellow practitioners willing to fit extended wear lenses, should not be underestimated.

Demand for extended wear is strong with data suggesting that up to 73 per cent of patients would like to be able to sleep or nap in their lenses.[1] Patients interested in refractive surgery come largely from the same population that desires extended wear contact lenses.

The introduction of silicone hydrogel lenses is likely to increase the success and therefore the demand for extended wear, and should be seen as a bonus for eye care practice. Professional services will necessarily be more complex and it is therefore reasonable to charge accordingly for these services.

TABLE 1

Documentation kit

◆ **Information brochure:** Informative and accurate to generate awareness of new extended wear lenses. It should stress that a comprehensive examination is required.
◆ **Practitioner-patient extended wear agreement:** This agreement, to be signed by both the practitioner and the patient, briefly describes the lenses to be worn, the wearing schedule, and the importance of attendance at follow-up visits. It also confirms that the patient has been given a thorough eye examination, is suitable for extended wear, and has been given the opportunity to ask questions. The agreement should also contain the following caution; 'If you have any medical or ocular condition or know of any reason which may invalidate your consenting to this agreement, it is your duty to advise your practitioner'.
◆ **Instruction sheet:** This should cover the following:

- Complications
- Alternatives to extended wear
- Discontinuation
- Wearing and cleaning schedule
- Care and maintenance of lenses
- The lens case
- Follow-up visits
- What to do in the event of a problem
- Three-point guide to problem management (see Table 2)
- Warning
- Dos and don'ts
- 24-hour contact number (mobile telephone or pager number)

It is essential that the patient follows the instructions laid out in this sheet to minimise the risks of complications with extended wear.
◆ **Question and answer sheet:** A separate blank sheet of paper appended to the documentation kit providing a record of any questions the patient has and the answers provided.
◆ **Informed consent:** Patients must be at least 18 years of age and have full legal capacity to sign this document. It is common practice for this item to be separated from the agreement. It should state that the patient has been informed of possible complications as listed in the agreement, given appropriate instruction, afforded the opportunity to ask questions and had these questions answered to their satisfaction.
◆ **Emergency documentation:** It is recommended that the practitioner provide the patient with a credit-card sized emergency information card containing the following information:

- Three-point problem instruction
- Practitioner contact numbers
- Emergency clinic phone number and address
- Details of lenses being worn
- Details of removal and replacement schedules
- Details of care and maintenance system

PREPARING FOR EXTENDED WEAR

Updating practitioner knowledge

A well-prepared practitioner should be able to identify and enumerate relevant corneal signs such as striae, folds and microcysts, and changes in the regularity of the endothelial matrix. For many practitioners, simple revision may be all that is required. Practical training workshops and continuing education sessions, taught by professionals in the field, will help to update those with a deficiency in this area.

Additional understanding of the differential diagnosis of complications, general pathology, microbiology, immunology and pharmacology can be an asset in the prevention and handling of adverse events.

Documentation

The practice should establish clear practice guidelines for patient eligibility,

TABLE 2

Three-point guide to problem management

◆ **Pain, severe discomfort or aversion to bright lights**. Notify your eye care practitioner without delay on the contact number indicated. Failure to do so immediately may result in permanent partial loss of vision

◆ **Discomfort, eye redness, blurred vision or ocular discharge.** Remove your contact lenses and make an appointment for an examination at your earliest convenience. Do not recommence contact lens wear until you are advised that it is safe to do so by your practitioner. If the problem does not diminish within an hour after removal of the contact lens, you should notify your eye care practitioner immediately

◆ **Minor irritation or minor blurring of vision.** Remove the contact lens, clean it in the prescribed manner and re-insert it. If the symptoms persist, you should arrange for an appointment as soon as possible and cease lens wear until then. If the irritation or blur is eliminated by removal and cleaning, then you should make a note of the event so that you can report it to your practitioner at your next visit

aftercare procedures, and criteria for ongoing extended wear. An example of a documentation set is shown in Table 1. Clearly it is important that detailed clinical records are kept for extended wear patients.

Education of practice staff

Staff should be well informed on all aspects of extended wear in order to deal with enquiries both from potential new patients and existing wearers. As well as giving well-informed advice, they should be aware of the requirements for appointment scheduling. They should be familiar with the documents of informed consent, information sheet and three-point guide to problem management (Table 2).

Review of practice efficiency

The availability of extended wear lenses may create an increase in the number of patients interested in contact lens wear and a subsequent increase in appointments. Systems to keep track of patient recall, follow-up visits, trial lens stocks and upkeep of documentation should be in place and efficiently run. The aftercare programme for an extended wear patient is more intensive, requiring more chair time and staff time per patient. In addition, 'on-call' time for after-hours emergency contact adds to the burden.

Additional equipment

Most aspects of extended wear will be able to be dealt with in a well-equipped consulting room. The essentials are a visual acuity tester, keratometer, biomicroscope, and phoropter or trial lens set. A grading scale, such as those published by the Cornea and Contact Lens Research Unit (CCLRU) or Efron, should be kept at hand in the consulting room. Other items that would assist the practitioner in the assessment of lens fit, corneal response and corneal swelling would include video or photographic slit lamp, corneal topographer and pachometer.

Emergency care

Twenty-four hour access for patients is mandatory for undertaking extended wear practice in order to deal swiftly with infection or acute red eye. Options include a pager or mobile phone. Answering machines are not recommended, as any delay may be critical in the development of an adverse reaction. A co-operative arrangement could be set up with a neighbouring practice in order to maintain the necessary recreation time for the practitioner.

PATIENT EXPECTATIONS WITH EXTENDED WEAR

Caution should be exercised by the practitioner to guard against the patient considering extended wear as a cure-all. It is important to present extended wear to the patient in the context of other corrective devices such as spectacles, daily wear contact lenses – including daily disposables – and refractive surgery. Each of the refractive options has its advantages and disadvantages, which should be made clear to the patient.

FITTING SILICONE HYDROGELS

Patient selection

The successful selection of patients for extended wear relies on attention to ocular status and general health issues, lifestyle and demographic considerations, as well as motivational and personality factors. It is probably even more important with extended wear to fit the right patient to the lens rather than vice-versa. We have developed a table describing acceptable ocular appearance to fit a patient with extended wear. For these details, refer to *Silicone Hydrogels: The Rebirth of Extended Wear Contact Lenses?*, to be published by Butterworth-Heinemann.

Lens fitting

Trial lens fitting should always be performed prior to allowing a patient to undertake extended wear. Currently, the silicone hydrogel lenses are only available in a single base curve. The lens should centre well with complete corneal coverage. Edge lift or fluting of the edge is unacceptable. If the lens is uncomfortable it should not be dispensed.

Dispensing

A 30-day replacement of lenses is recommended by both of the current manufacturers of silicone hydrogels. It is not advisable for patients to extend the wearing period beyond 30 days because of the increased likelihood of deposit-related problems.

Patients should be given a spare pair of lenses to overcome the temptation of wearing an unsuitable lens. However, in order to secure the patient's compliance, it is recommended that his or her supply of lenses is geared around the next scheduled aftercare visit or limited to a six-month supply.

Lens care

A standard multi-purpose solution is adequate for lens care if the lenses are removed for any reason. Peroxide care systems and surfactant cleaners with abrasive compounds or alcohol bases may not be suitable for all types of silicone hydrogel lenses. It is advisable to check with suppliers regarding the suitability of specific lens care products. Lubricating drops are recommended especially before sleep and on eye opening.

Patients should be advised to look at their eyes every night before sleep and in the morning on awakening. The patient should confirm that their eyes 'look good, feel good and see well'. It should be stressed that if there is discomfort prior to sleep the lens must not be worn overnight. Also, if the patient is physically unwell they should not wear their lenses.

Aftercare

Clinical experience has shown that adverse effects are most likely to occur within the first six months. Therefore, follow-up visits should be frequent during this time and preferably after 24 hours, one week, one month, three months, and six months of extended wear.

For all visits, the patient should be seen early in the morning soon after waking to enable assessment of striae and post-lens tear debris. Reinforcement of all safety procedures is essential at all aftercare visits. The aftercare examination should involve a detailed slit-lamp assessment as well as a vision assessment,

Sponsored jointly *by*

BAUSCH & LOMB CIBA Vision

MULTIPLE-CHOICE QUESTIONS

There is one correct answer for each question

1 Which of the following has been a major difficulty that the manufacturers have had to overcome in the development of the new silicone hydrogel materials?
A Increased oxygen transmissibility
B Decreased surface wettability
C Low water content
D Disposability
E Lens flexure

2. Which of the following advice should NOT be given to an extended wear patient complaining of minor irritation?
A Continue wearing lenses and only remove them if the discomfort worsens
B Remove the lenses
C Clean the lenses and reinsert, removing only if symptoms persist
D Note the time of onset of the event
E Inform your practitioner of the event

3. Which is the most important reason for seeing a patient for an aftercare visit early in the morning?
A Subjective assessment of comfort
B Observation of corneal staining
C Observation of microcysts
D Observation of striae
E Measurement of visual acuity

4. You are advised to provide all of the following to your extended wear patients except:
A 24-hour contact number
B Answerphone number
C Information brochure
D Practitioner-patient extended wear agreement
E Emergency documentation

5. Silicone hydrogel lenses increase their oxygen permeability through:
A Water binding capabilities
B Long, polymer backbone molecules
C Incorporation of silicone groups
D Surface treatment
E Tear exchange and lens movement

6. The Dk (oxygen permeability) for silicone hydrogel lenses falls within which range?
A 40-60 barrer
B 70-90 barrer
C 100-140 barrer
D 150-170 barrer
E 170+ barrer

The deadline for response is December 3

Answers – Module EW1 Insert your answers to the multiple-choice questions on the answer sheet inserted in this week's issue and return it to OPTICIAN. Successful participation in each module of this College-approved series counts as one credit towards the College of Optometrists' CET scheme and towards the Association of British Dispensing Opticians' scheme. Participants will be sent an analysis of their response. The names of successful participants will be forwarded to the College and ABDO for entry onto their databases.

history, and ocular examination with and without the lens in place.

We have modified the CCLRU table for extended wear success as a guide to safe ocular appearance for continuing extended wear. Further details are available in the book from which this excerpt is drawn.

CONCLUSION

The silicone hydrogel lenses for extended wear represents an exciting new professional and business opportunity for eye care practitioners. This article has attempted to highlight the procedure for fitting and managing extended wear patients, and to emphasise the fact that considerable planning is required for both practitioner and patient success with extended wear.

References

1 Barr J. The 1997 annual report on contact lenses, *Contact Lens Spectrum*, 1998; 13: 23-33

◆ *Dr Noel Brennan is co-director of Melbourne Ocular Science and Technology Enterprise, of which Dr Chantal Coles is founding director*

◆ *Silicone Hydrogels– the Rebirth of Extended Wear Contact Lenses?* edited by Professor Debbie Sweeney, will be published by Butterworth-Heinemann and the BCLA early in 2000