

Silicone hydrogel contact lenses

Part 2 Therapeutic applications

After three years on the UK market, silicone hydrogels are enjoying increased interest from contact lens practitioners and in 2002 have gained a rapidly growing share of fits (Figure 1).

Both CIBA Vision Focus[®] NIGHT & DAY[™] and Bausch & Lomb PureVision[®] silicone hydrogel contact lenses are designed to permit up to 30 days' continuous wear through their unique properties. For PureVision contact lenses, it is claimed that they are specifically designed to provide a balance of properties (Table 1) which, together, help ensure maximised success with overnight wear.

In particular, the main obstacle to successful continuous wear has been the inability of conventional hydrogels to prevent significant overnight corneal swelling because of low oxygen transmission. While this has not been a problem with silicone elastomer lenses, the problems of lens adhesion (due to a high modulus of elasticity) and poor wetting (due to the hydrophobic nature of the silicone material) have made this a specialist lens only really indicated for aphakia and, in particular, paediatric aphakia.

Figure 2 shows the overnight corneal swelling response for no lens wear and a range of materials including conventional hydrogels, silicone hydrogels (PureVision) and a silicone elastomer lens (Silflex). As expected, the corneal swelling responses follow a normal distribution. If it is accepted that clinical signs of oedema are evident once 7% swelling is reached, this provides a useful cut-off for clinically obvious signs and is shown by the vertical dotted line.

It can be seen that approximately 77% of those who wear conventional hydrogel lenses overnight will experience clinical signs of corneal oedema. With no lens wear, this is closer to 2% (all subjects in these groups are adapted daily wear contact lens wearers).

The levels of oedema with silicone elastomer and silicone hydrogel wear are not significantly different from those with no lens wear. Interestingly, even silicone elastomers with a Dk in excess of 350, do not exactly match the no lens wear response, suggesting that a constant quest for higher Dk materials is pointless and will

not generate any material improvement to the physiological response. However successful overnight wear is also dependent on other factors such as the surface treatment which renders the surface hydrophilic while also helping to resist deposition. Fluid transport is also important to help prevent lens binding, particularly after a period of sleep, and to assist free movement of the lens on eye opening after sleep. This movement is also enhanced by the back surface design and edge contour, both of which contribute to the improved lens movement of silicone hydrogels compared with conventional hydrogels.

Given the increasing acceptance of silicone hydrogels in elective contact lens fitting, the inevitable question becomes whether the benefits of these materials can be applied to therapeutic uses. As such, it is interesting to note that both CIBA Focus NIGHT & DAY and Bausch & Lomb PureVision lenses have recently received CE mark approval for therapeutic indications.

Applications of therapeutic contact lenses

A wide variety of conditions can benefit from the application of contact lenses. These may vary from 'bandage' applications, where the therapeutic effect is either to improve comfort or protect the cornea during healing, to situations where the optical effects of the lens can improve vision (such as keratoconus).

Table 2 lists the types of benefit which may be derived from contact lens wear, while Table 3 shows a variety of conditions in which contact lens wear may be of value.

Mechanical protection may be appropriate where conditions such as trichiasis occur either with age-related entropion (when lens wear may be short-term prior to surgery) or trauma (where lens wear might be on a long-term basis). In bullous keratopathy, protection of the



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Overnight Corneal Swelling

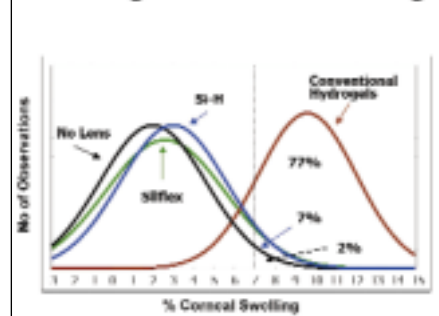


Figure 2 Overnight corneal swelling with no lens and a variety of lens materials

corneal nerve endings through a bandage lens may make a significant impact on comfort while the bullae resolve. Following corneal surgery, the bandage properties of the lens may assist in protecting the affected cornea as well as providing protection to prevent mechanical trauma from stitches in full thickness grafts. In LASIK, lenses may prevent trauma to the flap in

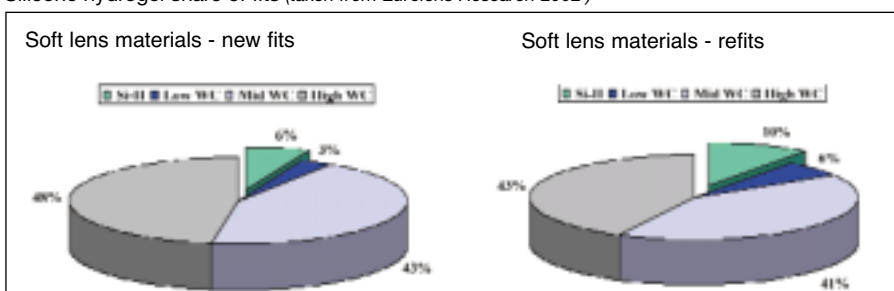
Table 1 Properties of PureVision silicone hydrogel lenses

- Oxygen permeability
- Fluid transport
- Material elasticity
- Wetting properties
- Lens movement
- Deposit resistance

Table 2 Benefits of therapeutic contact lens wear

- Mechanical protection
- Relief of symptoms
- Protection and promotion of healing
- Prevention of desiccation
- Optical correction
- Drug delivery

Figure 1 Silicone hydrogel share of fits (taken from Eurolens Research 2002')



Module 1 Part 2

the early days following the procedure or may decrease discomfort in LASEK.

In corneal epithelial dystrophies and recurrent erosions, a bandage contact lens may enhance comfort by protecting exposed nerve endings while the lens may also help prevent subsequent epithelial loss by stopping the lid from adhering to recently re-attached epithelial cells during sleep, when the tear film becomes less aqueous. Frequently on lid opening, poorly attached areas of epithelium are 'ripped off' by the lid causing a further episode of trauma and pain.

In other conditions, the lens will either work to improve comfort or to offer protection to an otherwise exposed corneal surface, while in cases of pathological dry eye, a contact lens may help prevent corneal desiccation. In the latter case, silicone elastomer lenses are often preferred due to their lack of water content which prevents dehydration, but silicone hydrogels may also be of value² given their low water content and relative thickness.

In cases of corneal irregularity from trauma or conditions such as keratoconus, a contact lens may restore a uniform optical surface, significantly improving visual performance.

Selection of therapeutic contact lenses

While the fundamental aim of the therapeutic lens is to assist the recovery of the cornea from the condition under treatment or to ameliorate symptoms, the lens should also have minimal impact on corneal physiology. High Dk lenses are to be preferred since they reduce hypoxic stress^{2,3} and are especially indicated in cases where healing is required⁴, since epithelial healing is promoted in the presence of normal levels of oxygen. A further requirement is that mechanical trauma to the cornea should be minimal and, as far as possible, the lens should act to create a stable, well-distributed tear film.

The design criteria for silicone hydrogel contact lenses almost exactly match these requirements. Limited hypoxic stress is guaranteed for the majority of patients based on the Holden-Mertz criterion for both daily and overnight wear⁵. The low water content of the lens and surface treatment both contribute to excellent wetting⁶ with a minimal opportunity for dehydration since dehydration is water content dependent^{7,8}.

The higher modulus (stiffness) of these materials should not be a direct cause for concern although any tendency to create epithelial splitting⁹ or the formation of mucin balls¹⁰ should be monitored carefully.

Other applications

Given the high Dk and high modulus of silicone hydrogel lenses, they may have a place for more extreme fitting requirements.

Westerhout^{11,12} reported on a combination system employing a medium or high water content soft lens with a rigid lens of 9.00-10.00mm diameter fitted over the top. However, the rigid lens often rode low and there

can be evidence of localised hypoxia even with high Dk RGP lenses¹³ in such lens combinations. Nevertheless, others have subsequently also used this approach¹⁴⁻¹⁷.

In similar fittings using silicone hydrogel lenses, the improved rigidity and enhanced oxygen transmission may improve the success and results have been recently reported¹⁸. In this particular case, a bilateral keratoconic patient was fitted with a PureVision lens with an aspheric RGP lens of 9.20mm diameter fitted over the top. Wearing times of 12 to 14 hours were achieved with acuities of 6/6 and 6/9 with 6/5 binocularly.

In other conditions, therapeutic contact lenses have been used to deliver drugs to the anterior ocular surface. Uptake and release of drugs is a function of water content¹⁹ and lens thickness²⁰ which together determine the reservoir available to take up the drug and then release it onto the eye. High water content lenses take up and release drugs much more quickly than low water content materials^{21,22}. While silicone hydrogels have been shown to be capable of taking up and releasing drugs in-vitro^{23,24}, there is little evidence of this being applied in a therapeutic setting.

Lim et al²⁵ have reported on the use of silicone hydrogel lenses on a group of 54 cases including post-keratoplasty, post-LASIK, bullous keratopathy, chemical burns, epithelial abrasions, recurrent erosions, corneal perforations, neurotrophic ulcers and lacerations. In this paper, they reported that for a group of 28 patients fitted with lenses to provide pain relief, 27 had considerable to complete pain relief. Where the lens was used to assist wound healing in 40 eyes, 33 (83%) showed complete healing, while a further five (13%) showed partial healing. These latter five were reported to have severe ocular surface disorders including Stevens-Johnson syndrome and ocular burns. Where ocular protection was required, the lens provided adequate protection in 100% of patients (21 out of 21). Equally, where wound sealing was required, the lens performed adequately in four out of five cases where the fifth case required penetrating keratoplasty to resolve the problem.

It was noted that where the lens fit was too loose over a graft, the lens had to be withdrawn and such poor fitting would be a contra-indication for therapeutic lens wear.

In a number of cases in the Lim study, concomitant topical medication was also given including antibiotic and anti-inflammatory treatment. While it was not suggested that the lens was used to increase the contact time of the medication or deliver higher doses of the drug, the use of eye drops in this study does support the view that medication can be given topically during silicone hydrogel lens wear without adverse effects.

Clinical follow-up in therapeutic cases

Due to the nature of the conditions managed with therapeutic contact lenses, frequent

- Trichiasis
- Bullous keratopathy
- Post corneal surgery post graft post refractive surgery
- Corneal dystrophies
- Recurrent erosions
- Filamentary keratitis
- Indolent ulcers
- Kerato-conjunctivitis sicca
- Neurotrophic and neuroparalytic disorders
- Trauma preventing lid closure
- Keratoconus
- Irregular astigmatism

Table 3

Conditions benefiting from therapeutic contact lenses

follow-up is advisable. As in all cases where the lenses are worn overnight, a follow-up on the day following first overnight wear is appropriate. Following that, the frequency of visits is often dictated by the condition being treated but will often be at weekly intervals to monitor the progress of the underlying condition as much as the performance of the lens. The lens replacement interval should be no less frequent than on a monthly basis, given that this is the approved period of continuous wear. In some cases, it may be necessary to replace the lens more frequently than this in order to maintain surface quality or fitting characteristics. This may be true where there is a grossly abnormal tear film resulting in lens deposition or where the lens is fitted over a grossly abnormal corneal topography and distorts over time.

In general, the risk-benefit ratio in therapeutic cases is considerably different to that for elective continuous wear fitting. For this reason, some side effects may be acceptable in the short term if there are no practicable clinical alternatives.

Case examples

The following case examples show situations in which silicone hydrogel lenses can contribute to the successful management of ocular disorders. The authors would like to acknowledge the generous help of the named practitioners in providing information.

Case 1 (courtesy of Dan Ehrlich)

The patient had a prior history of buphthalmos and enucleation of the contralateral eye due to end-stage glaucoma. The eye under treatment had undergone multiple glaucoma surgery and a repeat corneal transplant. Following transplant and the need to ensure adequate suturing of the graft to prevent wound leakage, the cornea had become irregular with a rubber-tyre profile. A silicone hydrogel lens was indicated to drape over the irregular cornea and was inserted,



Figure 3
Patient with buphthalmos wearing silicone hydrogel lens on distorted cornea following re-graft (see Case 1) (courtesy of Dan Ehrlich)

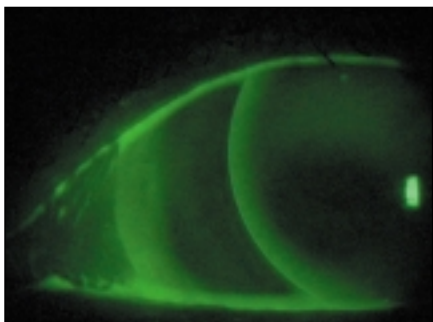


Figure 4
Piggy-back lens on keratoconic patient (see Case 2) (courtesy of Brian Tompkins)



Figure 5
Piggy-back lens on keratoconic patient to prevent desiccation and vortex staining (see Case 3) (courtesy of Lyndon Jones)

filled with saline to avoid trapped bubbles. **Figure 3** shows the lens in situ. The corneal defect resolved over time and the acuity improved from hand movements only to 1/60 with the lens.

Case 2 (courtesy of Brian Tompkins)

A 36-year old patient had worn PMMA lenses since the age of 14 years. Keratoconus was diagnosed at a later time. The patient was fitted with a PureVision lens (BVP -9.00) and an RGP lens with a power of -3.00. Vision was good, but not at night. **Figure 4** shows the piggy-back combination.

Case 3 (courtesy of Lyndon Jones)

This keratoconic patient presented with severe corneal desiccation staining (three and nine o'clock) and vortex staining of the cone apex. Ks were R: 7.65 x 7.40 (irregular) and L: 7.62 x 7.25 (irregular). Each eye was fitted with a -0.50

PureVision lens over which RGP lenses were worn as follows – R: 8.10:10.80 +2.00 L: 7.80:10.80 +2.00. **Figure 5** shows the fitting. Acuities were R & L: 6/5 on dispensing and wearing times of 16 hours had been achieved by the first follow-up at which acuities were R&L: 6/4 with no positive slit lamp findings.

Case 4

Patient NB had a history of limited tolerance to conventional hydrogel lenses due to marginal dry eye and poor tear film quality. Assessment of the pre-lens tear film showed significant disruption after approximately two hours of lens wear, at which time comfortable lens wear became impossible. After refitting with PureVision lenses, wearing times of up to eight hours could be achieved and pre-lens tear film quality was maintained at an acceptable level over this time. Lenses required replacement at between two and four weekly intervals.

Case 5

Patient LM was a long-term gas permeable contact lens wearer who had not attended for follow-up for several years. She presented with both lenses being immobile, riding low and bound to the cornea. Significant effort was needed to release the binding and create lens movement but after a short period, the lenses returned to their habitual position and lens movement was lost. Slit lamp examination showed an imprint of the bound lens, significant corneal distortion and peri-limbal hyperaemia with vessel encroachment into clear cornea nasally in each eye by approximately 1.5mm.

Given the high myopia (R&L: -6.50D) the vessel changes and the need to rehabilitate the distorted cornea, PureVision lenses were fitted and the patient elected to wear them on a continuous wear basis. Examination the morning after the first overnight wear was uneventful and after one month, the cornea looked normal and the nasal vessels had emptied.

Discussion

One of the advantages of the higher modulus of silicone hydrogel lenses is that they have a lesser tendency to wrap to irregular shapes. In the case of grossly irregular corneas, improved vision can be attained with such lenses. However, where the cornea is grossly distorted, steps must be taken to overcome the physical limitations of the fit. In the case presented, this required the silicone hydrogel lens to be inserted, filled with saline to prevent air bubbles being permanently trapped under the lens during wear. Failure to do this could lead to chronic desiccation of the graft and/or host cornea, which may have led to allograft rejection.

Piggy-back fitting can often extend the lens wearing life of a keratoconic patient, obviating the need for grafting. Depending on patient prescription, the vertex power of the silicone hydrogel lens can be varied to contribute to the required overall power of the system. Fitting of the rigid lens over the silicone hydrogel lens is very much a process of trial and error.

Keratometry taken over the soft lens is not generally a good predictor of final rigid lens BOZR and so diagnostic fitting lenses are virtually essential. To promote good centration (and therefore good vision) large total diameters are often required (10.00-11.50mm). Due to the low uptake of fluorescein into the low water content silicone hydrogel lens, fluorescein assessment of the piggy-back lens is possible. The base lens of the piggy-back system reduces the extreme variance in shape of the cornea facilitating an improved fit with the piggy-back rigid lens.

Patients with compromised tear quality or quantity may benefit from the use of silicone hydrogel lenses. While no significant trials have been conducted on dry eye patients, anecdotal evidence suggests that wearing times can be improved by the use of silicone hydrogel lenses. This is perhaps as a result of the low water content, relative thickness and excellent surface wetting properties engendered in these materials. Where tear production is an issue, it would be unwise to consider these lenses for overnight wear but rather as a means of extending periods of daily wear.

Where a soft lens is required to permit corneal distortion to regress, silicone hydrogel lenses also provide the benefit of high oxygen transmission. In this case, the vessel changes associated with a bound rigid lens together with the moderately high myopia suggested the need for a silicone hydrogel lens. The added convenience of continuous wear was not lost on the patient. Oxygen transmission with these lenses is sufficiently high to enable corneal rehabilitation even during continuous wear, Nilsson having shown regression of vessel changes on switching patients from conventional hydrogels to continuous or extended wear silicone hydrogels²⁶.

Summary

Silicone hydrogel lenses have been developed to address the major issues of overnight wear. High levels of oxygen transmission, along with excellent surface wetting, contribute to significant wearer benefits.

When considering therapeutic uses, the need for overnight wear without further compromise to an already unhealthy cornea, suggests that silicone hydrogel lenses could offer a significant step forward.

In addition to the routine uses of these lenses for bandage applications, there may be some indications for piggy-back/silicone hydrogel/RGP combinations in keratoconus and other corneal irregularities to limit the hypoxic complications evident when conventional hydrogels are used in this configuration. In addition, the unique characteristics of silicone hydrogel lenses may provide additional benefits for those patients who have marginal dry eye or poor tear film quality.

The high oxygen transmissibility of these lenses also permits the management of previous hypoxic stress, even during a continuous wear modality.

Module 1 Part 2

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Part 3

"Fitting silicone hydrogel contact lenses in everyday practice" will appear on November 15.

Multiple choice questions - Silicone hydrogel contact lenses

Part 2 - Therapeutic applications

Please note there is only one correct answer

- Which one of the following is not a key success factor for continuous wear with silicone hydrogel lenses?**
 - Oxygen permeability
 - High water content
 - Deposit resistant material
 - Material elasticity
- Which one of the following is not generally an indication for therapeutic lens fitting?**
 - Pain relief
 - Epithelial protection
 - Management of active microbial keratitis
 - Delivery of therapeutic drugs
- On which factors is lens dehydration dependent?**
 - Lens oxygen transmissibility
 - Lens thickness
 - lens water content
 - Lens water content and thickness
- Which one of the following is likely to have the fastest release of drugs from within the lens?**
 - Silicone elastomer
 - Silicone hydrogel
 - Low water content hydrogel
 - High water content hydrogel
- What is the best guide to selecting the BOZR of a piggy-back RGP lens over a silicone hydrogel lens?**
 - Diagnostic lens fitting
 - Keratometry of the cornea
 - Keratometry over the soft lens
 - 0.20mm steeper than the mean corneal keratometry
- Which feature of the silicone hydrogel lens may be of particular benefit in fitting irregular corneas?**
 - Low water content
 - High modulus
 - High oxygen transmission
 - Good surface wetting properties
- Which one of the following statements is false?**
 - Higher Dk/t will improve the corneal swelling response of the next generation of silicone hydrogel lenses
 - Lens adhesion is a problem with silicone elastomer lenses
 - Fluorescein can be used with a silicone hydrogel lens in situ
 - 7% of overnight silicone hydrogel wearers are likely to exhibit some of the clinical signs of hypoxia
- To which of the following are silicone elastomer lenses particularly suited?**
 - Bullous keratopathy
 - Post refractive surgery
 - Recurrent erosions
 - Paediatric aphakia
- What is the best advice for patients using therapeutic lenses and topical ophthalmic drops?**
 - Instil drops five minutes prior to lens insertion
 - Instil drops 30 minutes prior to lens insertion
 - Instil drops as instructed while lenses are being worn
 - Do not wear lenses on the days that drops are used
- Therapeutic lenses are worn on a continuous wear basis in recurrent erosion case particularly:**
 - to facilitate healing during sleep
 - to enhance epithelial reattachment during the day
 - to prevent detachment of poorly attached epithelium on waking
 - to prevent corneal desiccation
- Which one of the following is unlikely to be a problem with piggy-back fitting in keratoconus?**
 - Rigid lens centration
 - Comfort
 - Selection of RGP lens parameters
 - Poor vision with decentred lenses
- Corneal vascularisation caused by previous hydrogel lens wear is:**
 - likely to get worse with silicone hydrogel continuous wear
 - unlikely to improve with silicone hydrogel continuous wear
 - a contraindication to silicone hydrogel continuous wear
 - likely to improve with silicone hydrogel continuous wear

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