Contact lenses
an update on extended wear

New extended wear contact lenses have the potential to change the lives of many of those people around the world who need vision correction. The lenses offer increased comfort and convenience at the same time as maintaining ocular health. A worldwide growth in contact lens use is expected as a direct result of these new lenses.

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In Australia, 3% of the population and 5% of those aged 15 or older wear contact lenses. Contact lens wear is undergoing a revolution with the appearance on the market of new, highly oxygen permeable, extended wear soft lenses which can be worn continuously for up to 30 days and nights. The convenience of such lenses means that we can expect more contact lens patients to change to this mode of wear. Further, spectacle wearers who have been discouraged by the inconvenience of contact lenses that have to be removed and cleaned or replaced, may now change to extended contact lens wear. The major concern of practitioners regarding extended wear – hypoxia – has also been eliminated, and they can now confidently prescribe such lenses. This article examines the development of the new lenses, discusses the ocular health issues including adverse responses, and provides information about appropriate care and management.

The 'Holy Grail'

In vision correction, patients have wanted immediate comfort, constant good vision, convenience and safety. Practitioners have wanted all that plus unaltered corneal physiology and trouble-free vision correction for their patients. Successful extended wear – that is, being able to wear lenses continuously night and day for substantial periods, has long been the 'Holy Grail' of researchers and industry, offering potentially the most convenient contact lens possible.

In surveys conducted by the Cornea and Contact Lens Research Unit of the University of New South Wales, patients have overwhelmingly indicated their desire for 'permanent' vision correction. In one survey, 97% of prospective patients said they wanted to be able to wear their lenses continuously for at least six nights per week.[1] In other recent surveys of patients attending the Unit's clinic, the most important features

IN SUMMARY

- **The most important features in a patient's choice of a contact lens are comfort and quality of vision. For most patients, extended wear is also an essential feature.**
- **'Hard' lenses can be worn successfully for extended periods, but most patients find them too uncomfortable. Disposable 'soft' lenses offer immediate comfort, but their low oxygen transmission can compromise ocular health during extended wear.**
- **New soft lenses have been developed that have high oxygen transmission, giving them potential to be worn continuously for up to 30 days and to overcome corneal hypoxia.**
- **Patient vigilance and compliance and expert fitting of lenses remain crucial to ocular health, especially in extended lens wear.**

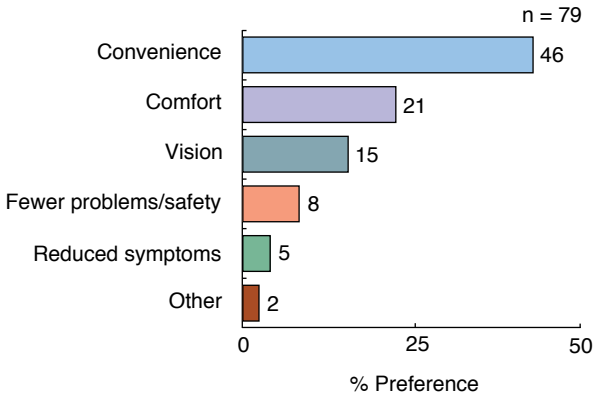


Figure 1. Why patients would prefer to wear lenses on a continuous basis.

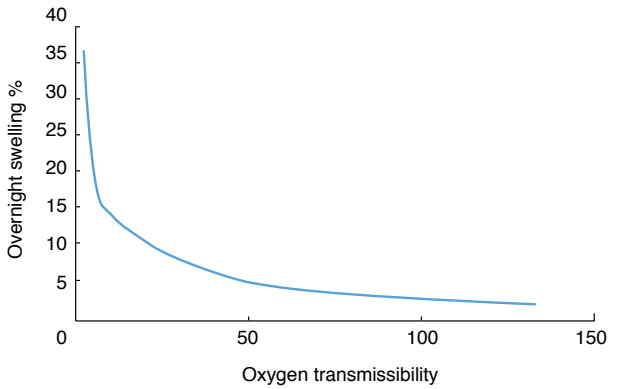


Figure 2. The relation between corneal swelling and oxygen trasmissibility.[3] To avoid corneal oedema with overnight contact lens wear a minimum lens oxygen transmissibility of 87 is required.

in determining patients' choice of a contact lens were initial comfort and quality of vision; however, 85% of patients believed that extended wear was also an essential feature in determining their choice of contact lens (see Figure 1).

'Hard' lenses made from rigid gas-permeable materials can be worn successfully on an extended wear basis, but most patients find them too uncomfortable. 'Soft' lenses offer immediate comfort; however, the low oxygen permeability of conventional hydrogel materials can compromise ocular health. Conventional hydrogel lenses have previously been used for extended wear but have led to relatively high rates of infection of about 1 per 1000 patients.[2] Contact lens and eye care practitioners in Australia and worldwide have, therefore, been rightly cautious about extended wear.

With the development of new, highly oxygen permeable silicone hydrogel materials, the contact lens industry has reopened the possibility of truly effective and safe extended wear. Multicentre trials have been conducted in North America and the United Kingdom. New extended wear lenses have recently been launched by both CIBA Vision (Focus Night & Day) and Bausch and Lomb (PureVision) and are now available in Australia. The lenses have been approved for 30 nights' wear in Australia and six nights' wear in the USA.

Key issues

Oxygen permeability

To date, the barrier to a successful extended wear lens has been limited oxygen permeability; contact lenses almost invariably reduce the oxygen levels available to the anterior corneal surface.

In the open eye state, the oxygen available to the anterior corneal surface is dependent primarily on the oxygen transmissibility (Dk/t) of the contact lens material – based on material permeability (Dk) related to material thickness (t) – and is supplemented from the oxygen in the tears behind the lens.

In the closed eye state, oxygen levels are reduced to those available from under the lid, and the barrier to oxygen presented by the contact lens is even greater. Any contribution from tears is further reduced, if not abolished. The level of oxygen available to the cornea under closed eye conditions can only be increased by either increasing the oxygen permeability of the contact lens material or by reducing the thickness of the lens.

Corneal hypoxia

The extended wear soft materials that first became available during the 1970s did not satisfy the needs of the patients or the practitioners. Rather, they posed a significant increase in risk to corneal health and integrity when used for extended wear. Chronic corneal hypoxia and acidosis induced changes in the corneal epithelium (i.e. epithelial microcysts, reduced epithelial adhesion), stroma (i.e. oedema) and endothelium (i.e. polymegethism – a variation in endothelial cell size) could be observed in all patients wearing, low oxygen-permeable hydrogel lenses over an extended period. Further, acute or chronic inflammatory adverse events affected a significant proportion of patients – up to 30% over a 12-month period. Serious infections, including sight-threatening microbial keratitis, were also reported.

In the 1980s, research by Holden and Mertz established that contact lenses must have an oxygen transmissibility of at least 87 to avoid overnight corneal swelling (see Figure 2).[3] Such swelling can lead to adverse effects on the corneal

structure and function, and susceptibility to ocular infection.

The contact lens industry has since tried to find an effective soft lens material that meets or exceeds this level of permeability. While high oxygen permeability can be achieved in a bulk material, it is extremely difficult to attain in a soft (comfortable) material of good optical quality from which lenses can be manufactured and which will move on the eye with each blink.

New extended wear

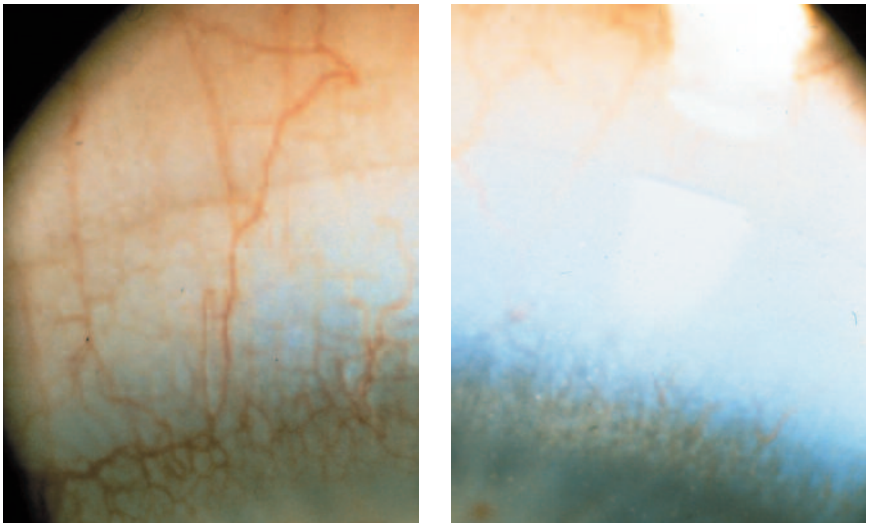
The industry is now seeing the development of entirely new materials, which is driving the production of successful extended wear lenses. The first generation of a new range of extended wear products has been launched by the major corporations – the silicone hydrogel and fluorosilicone hydrogel lenses that have the potential to be worn continuously for up to 30 days and to overcome hypoxia. These new lenses have oxygen transmissibilities in the range of 100 to 140, far exceeding the requirement set by Holden and Mertz, and up to six times the oxygen transmissibility of currently available soft lenses. The lenses will be suitable for successful use as 30-night extended wear lenses, as well as for occasional extended or daily wear in a range of patients.

How do the new lenses perform?

Corneal oedema is an important marker of hypoxic stress. Several studies have been conducted to determine the overnight level of corneal oedema with these new generation materials compared with no lens wear and commercially available disposable, low oxygen permeable soft lenses. Such studies have confirmed that induced overnight corneal oedema levels are significantly reduced relative to those observed with conventional products and are indeed similar to no lens wear.[4]

A number of other markers of hypoxic stress have been monitored in long term, prospective clinical studies at the Corneal and Contact Lens Research Unit:

- corneal striae – evident infrequently in the high oxygen permeable silicone hydrogel lens-wearing group compared with the disposable lens-wearing group
- limbal hyperaemia – reduced with the new lenses (Figures 3a and b)
- limbal vascularisation – increased over time with disposable lenses but remained at a constant and low level with silicone hydrogel lenses
- epithelial microcysts (the classic marker of hypoxia) – significantly lower numbers seen in the silicone hydrogel lens-wearing group compared with the numbers observed in the disposable lens-wearing group.[5]



Figures 3a and b. Limbal redness. a (left). With a conventional soft contact lens. b (right). With a high oxygen permeability soft contact lens.

How have patients responded?

At the Unit, patients who had worn silicone hydrogel lenses on a 30-night extended wear basis for at least 12 months were surveyed.

Advantages

Overwhelming patient satisfaction with the concept of extended wear was recorded in the survey. Ninety-three per cent of patients rated their extended wear lens system as excellent. The main reason for satisfaction was convenience. Factors such as no care and maintenance or lens handling (88%), being able to see in the morning (7%) and excellent comfort (5%) were also reported. Ten per cent of patients reported that they forgot that they were wearing lenses at all.

Prior to having tried 30-night extended wear lenses, 66% of those surveyed had considered refractive or laser surgery to permanently correct their vision. Following their experience with extended wear, only a third of these patients were still considering refractive surgery with the remaining 68% now preferring the use of extended wear contact lenses to provide their vision correction.

Disadvantages

Problems with discomfort (8%) and dryness (38%) were the most frequent complaints reported, although mild. Furthermore, 18% of those surveyed wanted to be able to wear their lenses for even longer than one month. Approximately 10% of the group surveyed

listed deposits as a disadvantage of both their current lenses and the 30-night schedule. Deposits are broadly defined as substances, such as proteins or lipids, which are deposited on the lens surface and not removed by normal blinking; they can interfere with the quality of vision and require the lenses to be removed and cleaned.

How will practitioners respond?

While the lens performance is excellent and patient response enthusiastic, an essential part of the growth in contact lens use brought about by the new extended wear lenses will be the knowledge and experience of contact lens and eyecare practitioners. For safe extended wear to be successful, practitioners must be knowledgeable about the product, to enable them to best fit, manage and educate their patients.

The ocular problems caused by unsuitable soft lenses used as extended wear lenses have taught practitioners about the importance of proper use of this mode of wear and there is widespread knowledge of contact lens-related infection. Unfortunately such experiences have also made many practitioners wary of extended wear as a whole.

The new lenses have been designed as far as possible to prevent such problems and therefore extended wear should not be dismissed out of hand. However, caution is still advised with regard to eye-care. The main forms of ocular inflammation are all caused by bacteria (usually) colonising the lens surface, and these responses continue to occur with silicone hydrogels. Hygiene, therefore, remains of paramount importance in safe lens wear, and should still be emphasised by the practitioner. Most importantly, patients need to be made aware of possible problems, and to recognise when to remove lenses and consult a practitioner. The box on this page summarises advice for patients.

Fitting performance is also crucial to successful extended wear, and contact lens practitioners need to ensure that the lens performs well on-eye prior to dispensing in terms of tightness, movement, vision and comfort.

What adverse events may occur?

There are a number of possible adverse responses associated with contact lens wear. With all such responses, lens wear should be discontinued until resolution. Similar types and rates of adverse res-ponses are seen in both low and high oxygen permeable lenses; however, indications to date are that the incidence of microbial keratitis is significantly reduced with the new lenses. The most significant adverse events are discussed below.

As referred to earlier in 'Key issues', it is generally accepted that corneal hypoxia during sleep with contact lenses brings about corneal changes that pre-dispose the cornea to infection. Chronic hypoxic stress reduces corneal sensitivity, increases epithelial fragility, and compromises epithelial adhesion. Solomon and co-workers have shown in their work with animals that the greater the degree of cornea hypoxia, the greater the likelihood of microbial keratitis.[6] The elimination of hypoxia with the new lenses, therefore, may reduce infection rates. Nevertheless, it will not be until large-scale clinical trials are performed and silicone hydrogel lenses are used in large numbers on the market that the effects of the elimination of hypoxia on corneal infection rates will be truly known.

Extended wear contact lenses – what the patient needs to know

Vigilance and compliance

Patient vigilance and compliance are perhaps the most important factors in maintaining ocular health. Patients must be carefully instructed about compliance with the wear and replacement schedule and appropriate solution use. Patients should also be told to check their eyes prior to sleep and upon awakening, and to consult their eye care practitioner if the answer to any of the following questions is 'No':

- Do my eyes LOOK as they normally do?
- Do my eyes FEEL as they normally do?
- Do my eyes SEE as they normally do?

Flexibility and discretion

Secondly, patients should have a flexible approach to their wear schedule. Patients using extended wear lenses should be advised to avoid overnight lens wear if they are unwell or in poor general health, or if they detect any potential problems with their eyes. Patients should therefore be told that they can't expect to 'throw away' their lens case, solutions and glasses, since these will be needed if removal of the lens becomes necessary.

Early contact and lens removal

Finally, patients must be encouraged to contact their eyecare practitioner if they have any problems. Serious conditions, including microbial keratitis, can be treated very successfully if identified early. For this to happen, all contact lens wearers need to be aware of the warning signs of infection and inflammation – increased redness, irritation or pain, discharge and possibly light sensitivity. If wearers experience any of these signs and symptoms they should contact their eyecare provider immediately. Importantly, the lenses should be removed as soon as any such signs occur.

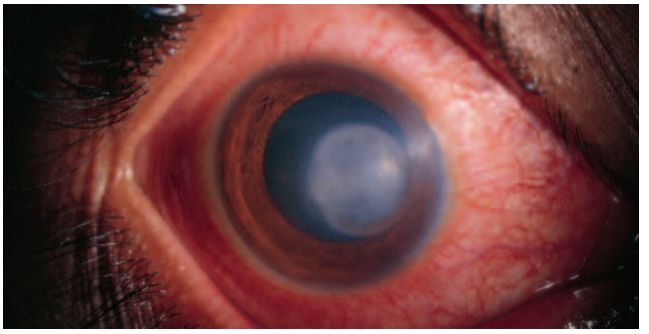


Figure 4. Microbial keratitis.

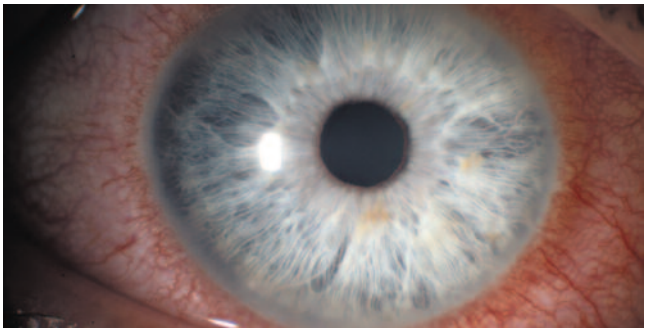


Figure 5 . Contact lens-induced acute red eye.

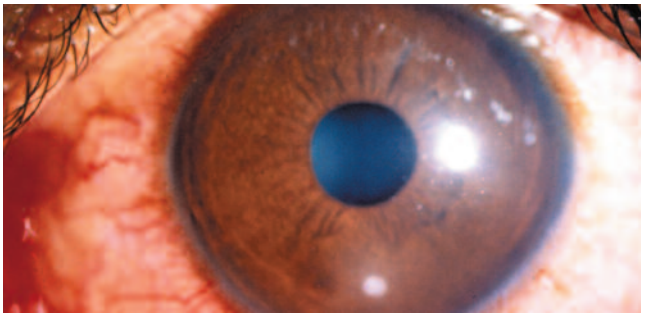


Figure 6. Contact lens-induced peripheral ulcer.

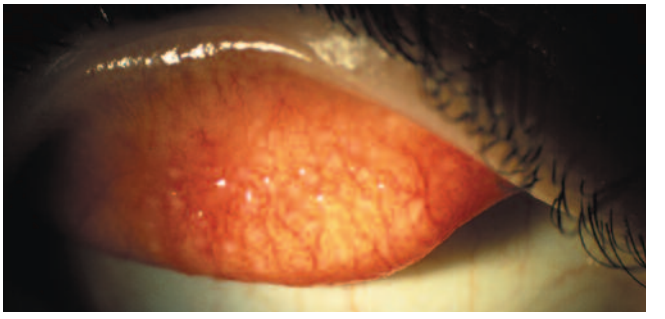


Figure 7. Contact lens-induced papillary conjunctivitis.

Microbial keratitis

Microbial keratitis (MK) is the most serious potential complication of contact lens wear. Fortunately, it is very rare; the latest study indicates a rate of 2.6 per 10,000 contact lens wearers, with a six times higher rate in those wearing conventional low oxygen permeable lenses for an extended period.[2] To date, no cases of microbial keratitis have been reported with extended wear of high oxygen-permeable lenses for extended period.[2]

Microbial keratitis is a microbial corneal infection, characterised by excavation of the corneal epithelium, Bowman's layer and stroma, with infiltration and necrosis of the tissue (Figure 4). Patients experience moderate to severe pain of rapid onset, and severe redness and tearing, and should be told to consult an eyecare practitioner or eye hospital as soon as any such symptoms appear. Although microbial keratitis is a sight-threatening condition, prompt treatment with antimicrobial therapy is generally very effective.[7] In the study cited above,[2] only five of the 92 patients found to have microbial keratitis had a visual outcome of less than 20/70.

Contact lens-induced acute red eye

A contact lens-induced acute red eye (CLARE) is an inflammatory reaction of the eye subsequent to a period of eye closure during wear of soft contact lenses, characterised by redness and/or irritation and pain on eye opening. It is accompanied by corneal infiltration with minimal or no epithelial involvement (Figure 5). Discontinuing lens wear during the active stage leads to rapid resolution.

Contact lens-induced peripheral ulcer

A contact lens-induced peripheral ulcer (CLPU) is characterised, in its active stage, by a focal excavation of the epithelium and infiltration and necrosis of the anterior stroma (Figure 6). Contact lens-induced peripheral ulcers normally heal rapidly without treatment, although close monitoring is required to ensure resolution without further complications.

Contact lens-induced papillary conjunctivitis

Contact lens-induced papillary conjunctivitis (CLPC) is characterised by itching or a sensation of a foreign body in the eye, mucous discharge and excessive lens movement that may lead to blurred vision (Figure 7). With high oxygen permeable lenses, there can be either a classic generalised inflammation or a more localised reaction, possibly caused by the lens edge. If caused by lens edge effects, a change in lens type may resolve the event.

Superior epithelial arcuate lesion

Caused by mechanical interaction, a superior epithelial arcuate lesion (SEAL) is characterised by an arc-like lesion in the periphery of the superior cornea (Figure 8). If sufficiently severe, it may be associated with corneal infiltration. No medica-

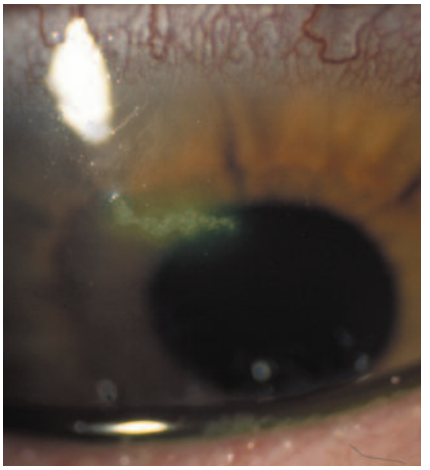


Figure 8. Superior epithelial arcuate lesion.

tion is required and the lesion normally heals rapidly; however, they usually recur and a change in lens type may be required.

Conclusion

Extended wear contact lenses have the potential to change the lives of many of those people around the world who need vision correction, offering increased comfort and convenience. Clinical studies have shown both excellent objective physiological results and patient enthusiasm for the lenses. However, the true rate of adverse responses and patient success will not be known until there is widespread market use. Practitioners still need to educate patients about appropriate eye care and ensure patients remain vigilant of their ocular health. While practitioners are coming to grips with new high oxygen permeable extended wear, researchers are already working on the next generation of products. They seek new levels of biocompatibility and comfort in an attempt to make contact lenses that are superior to and more convenient than spectacles.[8] Time will tell whether contact lenses can achieve the level of biocompatibility needed to realise their full potential. MT

Consultant's comment

Over a century after contact lenses were invented, we live in an era in which alternatives to spectacle correction are being promoted. In this setting, it is timely to review recent advances in contact lenses. Contact lenses have therapeutic, refractive as well as purely cosmetic applications. They have a particular advantage in providing a reversible correction for refractive error, unlike most of the surgical procedures currently in vogue.

Serious problems with early generation extended-wear contact lenses resulted in a moratorium on their use in the USA in 1989. The current generation of extended-wear lenses has been approved for up to six days of continuous use in the USA. Clearly, further work needs to be carried out to assess the long term safety of this new generation of lenses. This is also true of the new refractive procedures and undoubtedly comparisons will be undertaken.

A critical ingredient in successful contact lens wear is one of patient compliance and education of both patients and eyecare personnel. Compliance is a critical issue particularly in management of chronic ocular conditions such as glaucoma; lack of compliance can have devastating consequences. The importance of recognising the early onset of microbial keratitis both by the patient and health carers cannot be overstated.

Nevertheless, the development of these contact lenses represents a significant advance and will also have application in the areas of paediatric aphakia and pseudophakia where precise correction of refractive error can reduce the impact of the development of amblyopia. Furthermore, these lenses may play a role in those patients who have had unsuccessful refractive surgery. In the rush to achieve emmetropia by refractive surgery, the consequences of presbyopia are not always taken into consideration and this generation of contact lenses may well prove useful to this group of patients.

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The authors have been involved in the development and testing of new generation lenses and have a financial interest in the product.