

The rebirth of extended wear

— An introduction

BAUSCH & LOMB CIBA Vision

In an introduction to a forthcoming four-part series on extended wear, Professor Debbie Sweeney looks at the factors critical to success. The series is based on the BCLA's 1999 CET day on extended wear

THE FIRST BARRIER to achieving truly effective, safe extended-wear contact lenses has largely been overcome with the development of new silicone hydrogel materials which alleviate hypoxia and its side-effects.

These lenses are capable of supporting up to 30 nights of continuous wear for the vast majority of patients depending on the material type and power. The elimination of hypoxia means that we can expect practitioners to be willing to 'test' these new materials. The convenience of such lenses means that spectacle wearers who have been discouraged by lenses which have to be frequently removed and cleaned or replaced may now be attracted to contact lens wear. A worldwide growth in contact lens use as a direct result of these materials seems a real possibility.

INDUSTRY GROWTH

The eye care industry has seen enormous growth over the past 20 years in response to research developments and new lens designs. In 1970 there were 1-2 million contact lens wearers worldwide; in 1986 there were 25 million, and today there are 80 million.¹

Today, 40 per cent of contact lens wearers use soft lenses for daily wear, followed by rigid gas-permeables 21 per cent, soft lens extended wear 15 per cent, disposables 12 per cent, toric 8 per cent, PMMA 3 per cent, and bifocals 1 per cent.¹

Contact lens wearers are distributed worldwide, with 17 million wearers in Europe (3.1 per cent of the population), 17 million in Asia (0.5 per cent of the population), 32 million in the US (10 per cent of the population), and 0.5 million in Australia (1.7 per cent of the population).¹

Yet despite contact lens improvements, patients are still searching for the ultimate vision correction method. The key requirements for patient satisfaction have always been simplicity and convenience, ocular comfort, good vision and safety.

Daily disposable lenses were introduced earlier this decade and certainly provide the most convenient and safest means of wearing contact lenses on a daily wear basis. However, problems still exist, as up to 15 per cent of patients sleep in these lenses, which are designed only to meet the daily wear requirements for oxygen. The cost remains high, and patients still

complain of redness and dryness. Adverse responses with daily disposable lenses have also been reported in the literature.²

Practitioners are also looking to further developments to improve the performance of contact lenses, to reduce the rate of adverse responses and improve the satisfaction of patients.

In surveys by the Cornea and Contact Lens Research Unit (CCLRU), Sydney, Australia, patients have overwhelmingly indicated their desire for 'permanent' vision correction. In one survey, 97 per cent of prospective patients expressed the desire to be able to wear their lenses continuously for at least six nights per week.³ In recent surveys of patients attending the CCLRU clinic, the most important features in determining patients' choice of a lens were initial comfort and quality of vision. CCLRU researchers have found, however, that 85 per cent of patients believe that extended wear is also an essential feature in determining their choice of contact lens.⁴

OXYGEN REQUIREMENTS

To date the barrier to a successful extended-wear lens has been oxygen permeability. Contact lenses almost invariably reduce the oxygen levels available to the anterior corneal surface. In the open eye, the oxygen available is dependent primarily on the oxygen transmissibility of the contact lens material (Dk/t).

In the closed eye, with oxygen levels reduced to that available from under the lid, the barrier to oxygen presented by the contact lens is even greater. Therefore the Dk/t of the lens is of vital importance. The level of available oxygen to the cornea under closed-eye conditions can only be increased by either increasing the permeability of the contact lens material or by reducing its thickness.

Soft extended-wear materials that first became available during the 1970s did not satisfy patients or practitioners. In fact they posed a significant threat to corneal health and integrity. Changes in the corneal epithelium (epithelial microcysts, reduced epithelial adhesion), stroma (oedema) and endothelium (polymegethism) induced by chronic hypoxia and acidosis can be observed in all long-term hydrogel extended-wear patients.

Acute or chronic inflammatory adverse



Professor Debbie Sweeney: editor of OPTICIAN'S forthcoming CET series

events affect a significant proportion of patients (up to 30 per cent over a 12-month period). Serious infections, including sight-threatening microbial keratitis (MK), associated with hydrogel extended wear have also been reported.

In the 1980s, landmark research by Holden and Mertz established that contact lenses must have an oxygen permeability (Dk) of at least 87 to avoid overnight corneal swelling, which can lead to adverse effects on the cornea and susceptibility to ocular infection.

The contact lens industry has tried for the past 30 years to find an effective lens material that meets or exceeds this level of permeability. Silicone elastomer exceeds the specified oxygen requirements. However, problems with the lens adhering to the eye and causing subsequent adverse effects, as well as poor wettability and discomfort due to manufacturing difficulties, limited the success of this material.

High oxygen transmissibility has also been achieved in rigid gas-permeable (RGP) contact lens materials. These materials successfully meet the eye's needs for oxygen, and have been shown to induce no significant adverse responses when worn on a continuous-wear basis in a significant proportion of subjects in studies conducted at the CCLRU over the past 15 years.⁵ However, these materials have captured an insignificant proportion of the market, because of the inherent discomfort of RGPs plus the difficulty encountered by practitioners in fitting these lenses.

These developments showed that high

oxygen permeability could be achieved in a bulk material. However, they also showed that it is extremely difficult to attain such permeability in a soft material, of good optical quality, from which lenses can be moulded, which will move on the eye with each blink, and be immediately comfortable for the patient.

The first generation of a new range of extended-wear products is now being launched by the major corporations. They are silicone and fluorosilicone hydrogel lenses which have the potential to be worn continuously for up to 30 days and to overcome hypoxia. New silicone hydrogels have a Dk/t in excess of the criteria set by Holden and Mertz, and many times the oxygen transmissibility of currently available soft lenses.

EXTENDED-WEAR STUDIES

High-Dk soft contact lenses promise to meet the needs of both the practitioner and patient. Silicone hydrogel lenses provide immediate comfort and performance similar to current disposable soft contact lenses in terms of fitting and surface characteristics. They should also alleviate hypoxia and the associated changes of corneal function and structure associated with extended-wear hydrogels.

Several studies have been conducted to determine the overnight oedema level with these new-generation materials as compared with no lens wear and commercially available disposable soft lenses. These studies have confirmed that induced overnight oedema levels are significantly reduced relative to those observed with conventional products and are indeed similar to no lens wear.

A number of other markers of hypoxic stress have been monitored in CCLRU studies: corneal striae have been evident infrequently in the silicone hydrogel lens-wearing group compared with the disposable lens-wearing group; bulbar and limbal hyperemia have been reduced; limbal vascularisation increased over time with disposable lenses but remained at a constant and low level with silicone hydrogels; and significantly lower numbers of epithelial microcysts (the classic marker of hypoxia) were seen in the silicone hydrogel wearing group compared with those observed with disposable lenses.⁶

At CCLRU, patients who have worn silicone hydrogel lenses on an extended-wear basis for 12 months or longer were surveyed about their satisfaction.

Overwhelming patient satisfaction with the concept of extended wear was recorded. Ninety-three per cent of patients rated their lens system as excellent. The main reason for their satisfaction was convenience. They reported positive factors such as no care and maintenance or lens handling (88 per cent), being able to see in the morning (7 per cent) and

excellent comfort (5 per cent). Ten per cent of patients reported that they forgot that they were wearing lenses at all.⁶

Before having tried extended wear, 66 per cent of these patients had considered refractive or laser surgery to correct their vision permanently. Following their experience with extended wear only a third of these patients were still considering refractive surgery. Sixty-eight per cent now preferred the use of extended-wear lenses to provide their vision correction. This again indicates a strong preference for the modality once it has been tried and the patients' need for a convenient form of 'permanent' vision correction are met.

Fitting suitable patients should contribute positively to building and maintaining a contact lens practice as well as offering a safer vision alternative.⁶

PRACTITIONERS' ROLE

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

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

While extended wear should not be dismissed out of hand, caution is still advised. The main forms of ocular inflammation are all caused by bacteria, usually colonising the lens surface. Hygiene is therefore paramount, and should still be emphasised by the practitioner. Fitting performance is also crucial, and practitioners need to ensure that the lens performs well on the eye before dispensing.

Patients should be advised to avoid overnight wear if they are unwell or in poor general health. Patients should also be encouraged to check their eyes before sleep and on awakening, and to consult their 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?

Adverse responses still occur with the new highly oxygen permeable lenses. However, it is generally accepted that corneal hypoxia during sleep with contact lenses brings about corneal changes that predispose the cornea to infection.

Chronic hypoxic stress reduces corneal sensitivity, increases epithelial fragility, and compromises epithelial adhesion. Solomon *et al* (1994) have shown in their work with animals that the greater the degree of corneal hypoxia, the greater the likelihood of MK. The elimination of hypoxia with the new lenses, therefore, may reduce infection rates. However, it will not be until large-scale clinical trials are performed and silicone hydrogel lenses are used in large numbers that the effects of the elimination of hypoxia on corneal infection rates will be truly known.

THE FUTURE

While practitioners begin to come to grips with new extended wear, researchers are already working on the next generation of products.

In the survey of patient satisfaction at CCLRU, the disadvantages of the lenses were also rated by extended-wear patients. Problems with discomfort (8 per cent) and dryness (38 per cent) persisted even with the lower-water content materials, and 18 per cent of the patients wanted to be able to wear their lenses for even longer than one month. Approximately 10 per cent of the survey group listed deposits as a disadvantage of their current lenses and 30-night schedule. Problems with deposits which can interfere with the quality of vision and require the lenses to be removed and cleaned need to be overcome or reduced. Adverse responses need also to be avoided. These results indicate the need for further development in the area of true biocompatibility with the ocular environment.⁷

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◆ *Silicone hydrogels – the rebirth of extended wear contact lenses?* edited by Professor Sweeney, will be published by Butterworth-Heinemann and the BCLA early in 2000.

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