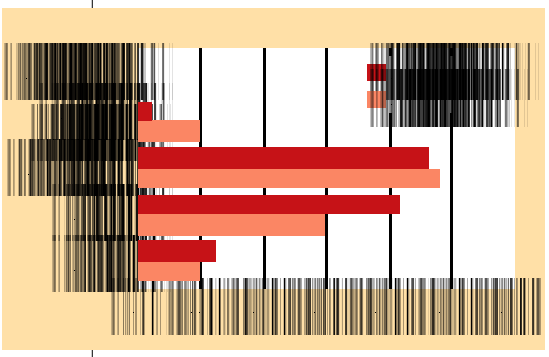
OCULAR IRRITATION AND DRYNESS

The descriptor 'chronic ocular irritation' encapsulates the symptoms of dryness and discomfort that are associated with contact lens wear. Patients use these terms interchangeably but it has been difficult to associate ocular signs with these symptoms. There is a strong correlation between the symptoms of discomfort and dryness but the aetiology of this chronic problem still remains a mystery and is probably multi-factorial.

The demands on extended wear lenses are much greater than daily wear because of the continued presence of a lens, which may be less than biocompatible, on the eye. Sustained comfort would enable patients to wear lenses (without symptoms) for a sufficient length of time and, for many patients, this would be a month of continuous wear.

Symptoms of dryness with hydrogel and rigid gas-permeable lenses are usually worse at the end of the day. In extended wear multicentre clinical trials comparing PureVision (balafilcon A) and Acuvue (etafilcon A) lenses, the high-Dk PureVision lenses were found to be significantly more comfortable and less dry. In similar studies conducted at the Centre for Contact Lens Research (CCLR) at the University of Waterloo, there was little difference in dryness between Focus Night & Day (lotrafilcon A) and etafilcon A lenses during the day (Figure 1) but there was a marked contrast between the two lenses for the 'end-of-day' dryness (Figure 2), where Focus Night & Day

FIGURE 1. The frequency of general dryness ratings at three months for lotrafilcon A and etafilcon A lenses



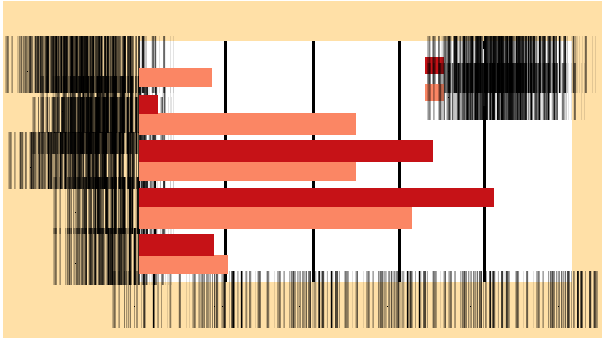


FIGURE 2. The frequency of 'end of day' dryness ratings at three months for lotrafilcon A and etafilcon A lenses

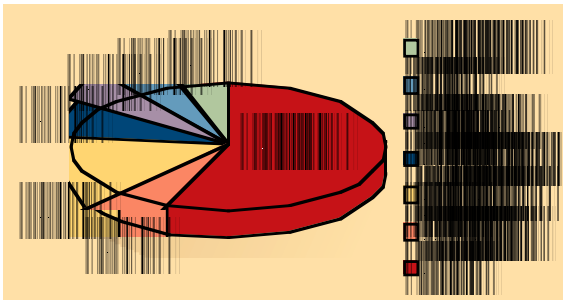


FIGURE 3. The percentages and reasons for lotrafilcon A lens removals at the end of a 9-month clinical trial. The wearing schedule for the lotrafilcon A lenses was 30 nights' continuous wear

appeared to produce less dryness. It is hoped that reduced levels of dryness symptoms with the silicone hydrogel lenses will translate into longer, sustained extended wear.

WEARING TIME

One of the attractions of 30-day continuous wear would be to sustain wear for the entire period. This would mean not having to remove the lenses at frequent intervals for re-wetting or cleaning because of irritation or visual decrement. In a nine-month study wearing Focus Night & Day on a 30-day continuous wear cycle, 62 per cent of subjects required no unscheduled lens removals by the end of the study (Figure 3). Discomfort and dryness were the predominant causes of unscheduled lens removals.

LENS DEPOSITS

All currently available soft contact lenses are prone to similar types of lens deposits regardless of whether the lenses are worn on a daily-wear or extended-wear basis. The difference in severity and rate of deposition depends on the type of material, cleaning regimen, wearing time, replacement frequency and patients' individual tear film characteristics.

In recent clinical trials, PureVision and Focus Night & Day worn continuously for 30 days and replaced monthly were compared with lenses manufactured from etafilcon A and replaced weekly. Both back and front surface deposition was generally low and similar for the silicone hydrogels and etafilcon materials even though the silicone hydrogel lenses were worn for up to 30 nights.

Biochemical analysis has shown that Focus Night & Day has significantly reduced levels of protein deposition compared to etafilcon A. However, traditional *in vivo* lens deposits such as calculi and small, white circular deposits have been observed on balafilcon A lenses. These deposits resemble jelly bump and calcium deposits observed on extended wear of traditional hydrogel lenses.

FRONT SURFACE WETTING

Front surface wetting is generally acknowledged to be an index of lens biocompatibility. Wettability will be poor if the lenses are either coated with deposits or if the pre-lens tear film is unstable. No difference in front surface wettability was found between the silicone hydrogel and etafilcon A lenses.

POST-LENS TEAR DEBRIS AND MUCIN BALLS

Post-lens tear debris is a common observation in patients who wear soft lenses on an extended-wear basis and is more readily observed soon after wakening.

Post-lens debris may also be an aetiological factor in adverse ocular responses such as inflammation and corneal ulcers associated with extended wear. This may be facilitated by the corneal epithelium, which is more susceptible to bacterial binding due to chronic hypoxia from low-Dk lenses.

Post-lens tear debris has traditionally been considered to have the appearance of amorphous cellular material and in at least one study the build-up of post-lens debris appeared to be greater under silicone hydrogel lenses. In addition to the cellular amorphous post-lens debris, researchers and clinicians have observed another type of post-lens collection predominantly under silicone hydrogel lenses that has been described as 'lipid plugs' and more recently as 'mucin balls'. The chemical composition of these 'mucin balls' has not been confirmed.

Mucin balls are round, vary in size (but usually less than 1mm in diameter) and clarity, and are generally observed in the superior quadrant of the cornea beneath the resting position of the upper eyelid. They tend not to move even if the lenses move. The reason is that lid pressure on the lens during eye closure causes the mucin to indent the corneal surface and, therefore, becomes immobile. When the lens is removed and fluorescein is instilled, a pattern similar to dimple veiling is

observed as the depression from the mucin balls fills with fluorescein. The proliferation of mucin balls can give rise to visual disturbance and discomfort.

Greater numbers of mucin balls have been observed with the silicone hydrogel lenses than with conventional hydrogel lenses. It has yet to be established whether this relates to the lens material, design or surface treatment and whether there are any clinical ramifications apart from a visual disturbance or reduction in comfort.

The early results from silicone hydrogel clinical trials are encouraging and a high proportion of subjects was able to sustain 30 nights of continuous wear. It remains to be seen whether silicone hydrogel lenses reduce symptoms of ocular irritation such as discomfort and dryness in large clinical populations and whether this has an impact on the number of patients who discontinue lens wear.

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Tear exchange – Does it matter?

Dr Michel Guillon and **Cecile Maissa** discuss the importance of the tear film in successful silicone hydrogel extended wear

THE ADVENT OF HIGH-DK SOFT hydrogel materials has made it possible to wear contact lenses on an extended-wear basis without hypoxic-related complications. However, this has been associated with the occurrence of inflammatory events and the need for accurate lens fitting. The structure of the tear film plays a critical part in the interaction between the contact lens and the anterior surface of the eye.

TEAR FILM STRUCTURE

Post-lens tear film – aqueous phase

The aqueous phase of the post-lens tear film of silicone hydrogel lenses has been studied extensively at the Corneal Biophysics Laboratory at the University of Melbourne. Their principal findings with implications for extended wear were:

◆ During closed-eye wear the aqueous layer becomes depleted within 180 minutes.
◆ Upon eye opening the aqueous phase replenishes quickly and a thick aqueous layer is present after 30 minutes.
◆ Lenses made of different conventional hydrogel materials produce different aqueous phase profiles. With low-modulus, mid-water content materials, the aqueous phase is of uniform thickness. In contrast, high-modulus, low water content materials have an uneven aqueous layer phase thickness that is discontinuous at the mid-periphery of the cornea.

The maintenance of an aqueous phase is essential in controlling the viscosity of the post-lens tear film and facilitating the elimination of back surface debris. The closed-eye wearing period, with its associated aqueous depletion and reduced lens movement, produces the most challenging wearing phase. The key recovery phase, when post-lens tear film aqueous replenishment takes place, occurs immediately upon eye opening. Both the environmental conditions and the mechanical characteristics of the contact lens influence this phase.

Follow-up visits should therefore take place in the morning and include an evaluation of the post-lens tear film and assessment of lens movement. In addition, patients should be instructed to carry out self-evaluation of lens binding upon waking. Non-viscous eye drops, such as saline, should be dispensed for use upon waking. To avoid contamination only single-dose saline should be used.

Post-lens tear film – mucin phase

The mucin phase is a visco-elastic meshwork, which acts as a pressure buffer from external mechanical pressure for the corneal and conjunctival epithelia. The maintenance of the integrity of the mucin layer is essential to safe contact lens wear.

INFLUENCE OF MECHANICAL CHARACTERISTICS OF THE LENS

Lens rigidity

The lens effective rigidity is influenced by both the material's modulus of rigidity and by the lens profile. The modulus of rigidity is a measurement of the material's resistance to deformation under compression. In the clinical situation, compression relates to the deformation exerted by the eyelid on the contact lens surface. Lens effective rigidity for a given modulus increases with increasing thickness. For minus-power lenses, the thickest and therefore most rigid part of the lens is the mid-periphery.

Silicone hydrogel materials have a higher modulus of rigidity than any conventional hydrogel material. In Part Two of this series, Tighe reported similar rigidity (110 to 120 g/mm^2 = 1.1 to 1.2 MPa) for the two silicone hydrogel materials currently available, even though their water content differs by 11 per cent (lotrafilcon 24 per cent, balafilcon 35 per cent).

High-rigidity lenses such as the silicone hydrogel lenses mould incompletely to the cornea/conjunctival front surface and produce a post-lens aqueous phase of variable thickness, minimal in the corneal periphery. These lenses are more efficient at converting the tangential component of the eyelid force applied during blink into lens movement and are therefore likely to produce good blink-induced lens movement. Their lens fit will be sensitive to changes in back optic radius; a choice of parameters may be necessary.

Lens elasticity

Currently, the coefficient of elasticity of silicone hydrogels has not been reported but, in view of the high elasticity of silicone, one can expect these contact lenses to be more elastomeric than conventional hydrogel materials.

Contact lenses are stretched both between and during blinking. Clinically, the lens effective elasticity influences performance as follows:

◆ Upon eye opening, following a blink, a contact lens with high elasticity returns rapidly to its original shape. This produces a rapid recentration associated with a strong repetitive squeeze pressure.
◆ During closed-eye wear the eyelid exerts a constant pressure that stretches the lens, particularly during lens decentration associated with the very large eye movements occurring during the rapid eye movement phase of sleep.

Combined effects of lens rigidity and elasticity

The clinical implications of using high-rigidity combined with high-elasticity contact lenses such as the new silicone hydrogel lenses are hypothesised to be as follows:

◆ High-rigidity and high-elasticity contact lenses produce repeated high

levels of localised pressure which deform and may ultimately locally erode the mucin gel that cushions the epithelium.

In those cases where the mucin gel is fully eroded, the contact lens is in direct contact with the epithelium producing mechanical damage and possibly lens binding.

Both phenomena are due to the very high friction present between the contact lens and the epithelium during lens movement in the absence of the lubrication normally provided by the mucin layer.

◆ The high squeeze pressure and possibly the high surface friction exerted by silicone hydrogel contact lenses disturb the mucin layer and create the 'mucin balls' observed with these lenses.

Summary of clinical investigations

The lens movement for Focus Night & Day has been reported to be between 0.2 and 0.3 mm; optimum to slightly loose fit.

Push-up test –The fitting characteristic to avoid with silicone hydrogel materials is a contact lens that is difficult to decentre and returns very rapidly to its initial position. A lens that is difficult to decentre is one that produces excessive negative pressure in the post-lens tear film. This fitting problem is resolved by flattening the lens fit. Currently, clinicians are left with the limited choice of trying the other lens types available and, if that fails to resolve the problem, to abandon silicone hydrogel contact lens fitting for that patient.

Corneal staining – Two signs indicating possible excessive mechanical pressure are arcuate corneal staining similar to superior epithelial arcuate lesion (SEAL), in the region of the upper and/or lower lid borders, and limbal conjunctival indentation by the lens edge. The presence of either is indicative of chronic mechanical damage and an unacceptable risk factor during extended wear.

Tear exchange – Tear flow within the post-lens tear film involves two mechanisms: tear aqueous mixing under the contact lens and tear exchange (outflow and inflow) at the lens periphery. Both mechanisms are produced by the lens deformation and lens movement during blink and play a key role during extended wear.

During sleep the tear film is greatly modified:

◆ Tear-film viscosity increases markedly
◆ Aqueous production stops
◆ Inflammatory proteins and cells increase in concentration.

The importance of tear exchange for successful extended wear which has been recognised with conventional hydrogel materials remains a requirement for successful wear with silicone hydrogels. Back surface debris that accumulates during sleep must be eliminated within two hours of waking.

Conclusions

The maintenance of a normal post-lens tear film is essential to ensuring long-term extended-wear success. For all materials the elimination of back surface debris is the key clinical parameter to monitor. Silicone hydrogels, because of their high rigidity and elasticity, must be accurately fitted to avoid mechanical corneal and/or conjunctival epithelial damage. Hence, a choice of lens parameters and a strict selection of potential wearers will be necessary for their success.

◆ *Dr Michel Guillon is director of London-based Contact Lens Research Consultants and associate professor at the University of Paris-Sud, Orsay.*
Cecile Maissa is bioanalysis manager at Contact Lens Research Consultants

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

MULTIPLE-CHOICE QUESTIONS

There is one correct answer for each question

1 The performance of silicone hydrogel lenses worn for 30 nights' extended wear has been compared to that of disposable hydrogel lenses worn for six nights' extended wear. Which of the following is NOT true?
A End of day dryness is reduced with silicone hydrogels
B There is no refractive change with silicone hydrogels whereas disposable hydrogel extended wear induces a myopic shift
C Lower numbers of microcysts occur with silicone hydrogels
D A higher amount of inferior quadrant corneal staining was seen with silicone hydrogels
E Limbal redness is lower with silicone hydrogels

2. The most common cause of unscheduled removals of silicone hydrogel lenses during 30 nights' extended wear was:
A Poor vision
B Lens deposition
C Preference for daily wear
D Discomfort and dryness
E Ocular redness

3. Mucin balls are more frequent under silicone hydrogel lenses than under conventional hydrogel lenses. Which of the following is FALSE?
A Mucin balls frequently occur in the superior cornea
B Mucin balls are round and vary in size
C Mucin balls leave an indentation in the cornea where fluorescein pools after lens removal
D Mucin balls move as the lens moves
E 8 per cent of people wearing silicone hydrogels have >35 mucin balls

4. What was one of the problems with silicone elastomer lenses which has been overcome with silicone hydrogels?
A Insufficient oxygen permeability
B Silicone elastomer lenses bound on-eye
C Poor visual acuity
D Overnight levels of corneal oedema
E All of the above

5. Which of the following is FALSE?
A Silicone hydrogel lenses move well with the blink
B The two currently available silicone hydrogel lenses have low rigidity compared to conventional hydrogels
C The water content of lotrafilcon A is 24 per cent and balafilcon A is 35 per cent
D The post-lens tear film of a silicone hydrogel lens has an aqueous phase of variable thickness
E Silicone hydrogels have higher elasticity than conventional hydrogels

6. Which of the following is FALSE?
A During sleep there is an increase in tear film viscosity.
B During sleep there is a decrease in inflammatory proteins and cells in the tears
C During sleep back surface debris accumulates
D During sleep aqueous production stops
E During sleep the eyelids exert pressure on the lens

The deadline for response is January 14

Answers – Module EW2 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.