Silicone hydrogel performance across recommended replacement intervals

Sheila Hickson-Curran highlights the results of a recent multi-centre clinical study that evaluated subjective and objective differences between two reusable silicone hydrogel lenses with different replacement intervals

Replacement intervals for soft contact lenses have dropped from a year or more in the 1970s to typically four weeks or less with contemporary lenses. Given that several on eye studies have shown a relationship between shorter replacement intervals and lower complication rates,[1,2,3] a two-week replacement cycle may offer physiological, vision and comfort advantages over a four-week cycle. However, no large clinical studies involving silicone hydrogel lenses have been performed to test this hypothesis.

In vitro studies also suggest that the performance of silicone hydrogel contact lenses may decline over time,[4,5] but clinical studies are needed to confirm this hypothesis.

A study, recently conducted in the US, was designed to test two silicone hydrogel contact lenses with different replacement intervals and compare their performance, as well as to determine how each lens' performance changes over the manufacturer's recommended life of the lens.

Leading silicone hydrogel lenses studied

In a multicentre, subject-masked study, 18- to 45-year-old successful spherical soft contact lens wearers were randomised to wear either a senofilcon A lens with a recommended replacement interval of two weeks (Acuvue Oasys with Hydraclear Plus, Johnson & Johnson Vision Care) or a lotrafilcon B lens with a recommended replacement interval of one month (Air Optix Aqua, Alcon). All subjects signed written informed consent forms, and the study received Institutional Review Board (IRB) approval and was registered on www.clinicaltrials.gov.[6]

Rex Features

Lens performance changes over the wear schedule

Baseline measurements were taken with subjects wearing their habitual lenses; subjects were instructed to have worn their lenses for at least one hour prior to this visit. Subjects were then randomly assigned to one of the two lens groups; lenses were dispensed in the practice in a masked fashion. Subjects did not see the lens blister or box and were unaware of the replacement interval of the lens worn. Each investigational site dispensed both types of lenses. All lenses were worn bilaterally on a daily wear schedule.

Subjects used their habitual care system for lens cleaning and disinfection; if subjects were habitually using an inappropriate care system or no care system, they were issued Complete Multi-Purpose Solution Easy Rub Formula (Abbott Medical Optics).

All subjects were evaluated at the baseline/dispensing, one-week, and two-week follow-up visits; lotrafilcon B lens wearers were also evaluated at four weeks. Key clinical measurements included visual acuity, pre-ocular tear film and lens fit assessments, front surface wetting, slit lamp findings (including staining), deposits, and subject questionnaires. A telephone survey was administered at one and two weeks (for both groups) and at four weeks (for the lotrafilcon B lens wearers) to gather subjective data about the study lenses.

Investigators used fluorescein, blue light, and a yellow filter to assess corneal and conjunctival staining. Corneal staining was graded according to the National Eye Institute (NEI) reference scale (0 to 3 in each peripheral quadrant and 0 to 3 centrally, for a maximum total score of 15). Conjunctival staining was graded in each quadrant (superior, inferior, nasal, temporal) on a 0 to 4 scale (0 = none, 4 = severe). Investigators determined lens surface wettability based on the appearance of the lens surface and the drying time; results were reported on a 0 to 4 scale (0 = very poor, 4 = excellent). Investigators also scanned the lens surface for the presence of film deposits and recorded these findings using a 0 to 4 scale (0 = no film, 4 = heavy film visible to the naked eye).

A modified contact lens dry eye questionnaire (CLDEQ8) was administered at the two-week visit to assess symptoms of dryness and discomfort.[7] Frequency of dryness and frequency of discomfort were measured using a five-point scale

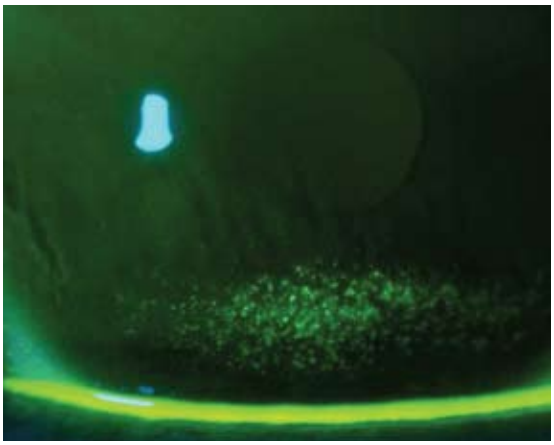
(0 = never, 4 = constantly); intensity of end-of-day (EoD) dryness and intensity of EoD discomfort were measured using a five-point scale (from 5 = very intense to 1 = not at all intense).

Descriptive statistics were generated for all per-protocol subjects. For key variables, a linear mixed model was used to analyse trends between lens modalities and visits, with modality, visit, site, and the interactions of modality with visit and modality with site as fixed effects and subject as a random effect. For other variables, a similar mixed model, excluding the visit term, was used to analyse trends between modalities at the two-week visit. A p-value ≤0.05 was taken to indicate a significant difference.

Subjects

In all, 379 subjects were enrolled at 24 investigational sites across the US. Sixty-nine per cent of the subjects were female (68 per cent of those randomised to wear senofilcon A, 70 per cent of those randomised to wear lotrafilcon B). The study population was aged 18 to 45 years with an average age of 29.5 ± 6.9 years (senofilcon A group 29.7 ± 7.0 years, lotrafilcon B group 29.3 ± 6.9 years). Sixty-five per cent of the subjects habitually wore silicone hydrogel contact lenses, the remainder habitually wore hydrogel contact lenses.

Approximately half the subjects (195, 51 per cent) were assigned to the lotrafilcon B lens group; the remaining subjects (184, 49 per cent) received senofilcon A lenses. There were no significant differences in baseline characteristics between the two groups.



Inferior corneal staining

Nineteen subjects (5 per cent) discontinued during the study: eight for lens-related reasons (six in the lotrafilcon B group and two in the senofilcon A group), three for non-lens-related reasons (one in the lotrafilcon B group and two in the senofilcon A group), and eight were lost to follow up (five in the lotrafilcon B group and three in the senofilcon A group).

Eleven adverse events were recorded during the study: eight (73 per cent) were lens-related and three (27 per cent) were non-lens-related. Of the eight lens-related adverse events, seven occurred in the lotrafilcon B group; one of these (a corneal ulcer) was a serious adverse event.

In all but four lenses, investigators judged lens fit as acceptable at the two-week visit; all four of the unacceptable fits occurred in the lotrafilcon B group.

Differences in performance

Mean high-contrast visual acuity (VA) was within one letter of 6/6 for both lens modalities. However, subjects reported better subjective visual quality with the senofilcon A lenses (p = 0.021). Subjective vision assessments at one and two weeks also showed significantly better performance with the senofilcon A lenses, both in terms of overall quality of vision (p = 0.047 at one week; p = 0.017 at two weeks) and on a number of sub-scales, including 'clarity of vision while driving at night' and 'fluctuating vision'.

Subjects reported significantly better overall comfort with the senofilcon A lenses than with the lotrafilcon B lenses at dispensing, one week, and two weeks. When investigators administered the dry eye questionnaire (CLDEQ8) at two weeks, the senofilcon A group had significantly better ratings for frequency of dryness (p = 0.0001), intensity of end of day (EoD) dryness (p = 0.0001), frequency of discomfort (p = 0.0011), and intensity of EoD discomfort (p = 0.0008).

There were also differences between the two lenses in subject ratings of EoD comfort. This measure was significantly higher with the senofilcon A lenses than with the lotrafilcon B lenses (p = 0.0005). In addition, subjects rated the senofilcon A lenses as having significantly higher EoD comfort compared to the lotrafilcon B lenses at one week (p = 0.0010) and two weeks (p = 0.0002).

In addition to measuring comfort and vision, this study also assessed limbal, bulbar, and palpebral hyperaemia; upper palpebral roughness; and corneal and conjunctival staining. Overall statistical analyses found no significant differences between groups for any of these measures.

When just the two-week data were analysed, however, some significant differences were evident; limbal, bulbar, and palpebral hyperaemia were all higher in the lotrafilcon B lens group (p = 0.041, p = 0.042, and p = 0.041, respectively), as were upper palpebral roughness (p = 0.048), conjunctival staining (p = 0.043), and

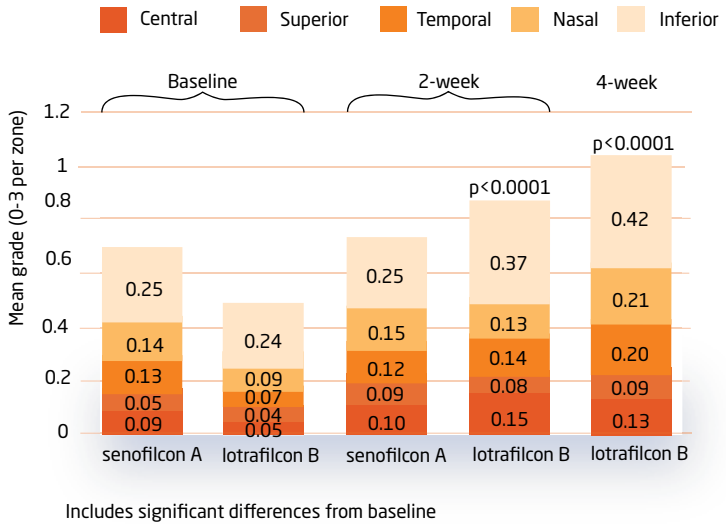


Figure 1 Corneal staining – In the lotrafilcon B lens group, corneal staining significantly increased between baseline and two weeks and between two weeks and four weeks; the senofilcon A lenses did not demonstrate a significant difference between baseline and two weeks

corneal staining (p = 0.024; Figure 1).

Overall, investigators graded front surface wetting as significantly better for the senofilcon A lenses compared to the lotrafilcon B lenses (p = 0.0054). There were no significant differences between the groups in film deposits.

Differences in performance over time

Both lenses showed a significant decline in vision quality between dispensing and one week (p = 0.013 for senofilcon A; p <0.0001 for lotrafilcon B, Figure 2). In the senofilcon A group, quality of vision did not change significantly for the remainder of the wear cycle. In the lotrafilcon B group, subjective quality of vision continued to decline significantly between one and two weeks (p = 0.022) but did not change significantly between two and four weeks.

Looking at how comfort changed over time, subjects reported that the senofilcon A lenses were similarly comfortable between dispensing and one week, but there was a significant decline in overall comfort between one week and two weeks (p = 0.0058). In contrast, the lotrafilcon B lenses showed a significant decline in comfort between dispensing and one week (p <0.0001) and between one week and four weeks (p = 0.0092, Figure 3). There was, however, no significant decline between two weeks and four weeks.

Subjects reported that the performance of the senofilcon A lenses on EoD comfort at one week was about the same as with their habitual lenses and did not change significantly between one and two weeks. In the subjects allocated to wear lotrafilcon B lenses, EoD comfort at one week was significantly lower than was EoD comfort with their habitual lenses (p <0.0001), and it declined significantly between one week and four weeks (p = 0.0079, Figure 4).

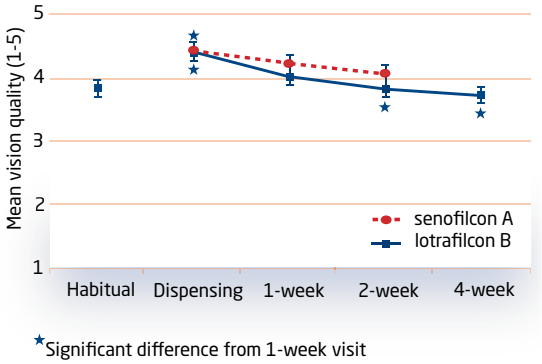


Figure 2 Quality of vision – both the senofilcon A and lotrafilcon B lenses showed a decline over time

Both groups showed significant reductions in front surface wetting between dispensing and two weeks (p <0.0001 for both groups), and in the lotrafilcon B group there was also a further decline in front surface wetting between two weeks and four weeks (p = 0.0001, Figure 5). There was also a significant increase in film deposits between two weeks and four weeks in the lotrafilcon B group (Figure 6).

The investigators also found significant changes in slit-lamp findings over time. In the senofilcon A lens group, limbal hyperaemia, bulbar hyperaemia, palpebral hyperaemia, and upper palpebral roughness were significantly reduced (indicating improvement) between baseline and two weeks, while conjunctival staining significantly increased between baseline and two weeks. In the lotrafilcon B lens group, palpebral hyperaemia and upper palpebral roughness decreased significantly between baseline and two weeks, but both measures then increased to near baseline levels by four weeks; corneal and conjunctival staining significantly increased between baseline and two weeks, and corneal staining continued to increase between two weeks and four weeks (Figure 1).

Implications for clinical practice

When the two lens groups were compared over all time points, significant differences were found in quality of vision, overall comfort, EoD comfort, and front surface wetting. The differences in comfort and EoD comfort seem particularly noteworthy because lens-associated discomfort is the leading cause of contact lens dropout.[8]

Given that good wettability is essential for optimum contact lens performance, the difference in front surface wetting may help to partly explain the comfort findings. Not only is good wetting necessary to allow the eyelids to move smoothly and comfortably over the lens,[9,10] but wettability also helps to promote an intact tear film, which may contribute to the observed difference in quality of vision.[11,12] Other lens properties such as modulus, coefficient of friction (CoF) and design features such as edge profile are key to lens comfort, some of which (CoF), can be influenced by wear.[13]

The study found that comfort declined in both lens groups across the wear cycle, although there was a difference in when this decline occurred. In the senofilcon A lenses,

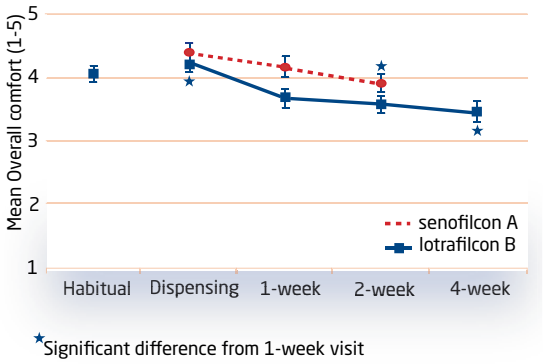


Figure 3 Overall comfort – both the senofilcon A and lotrafilcon B lenses showed a decline over time

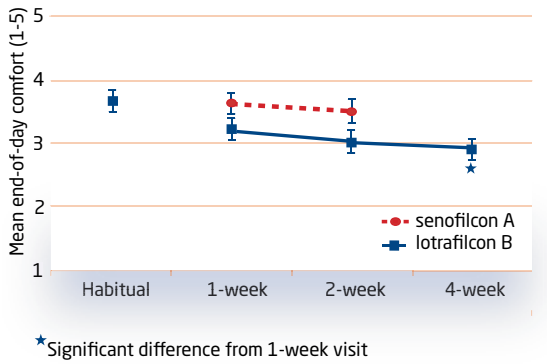
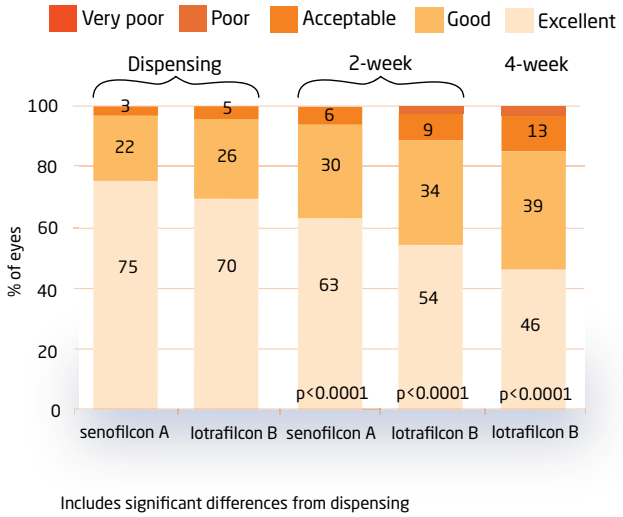
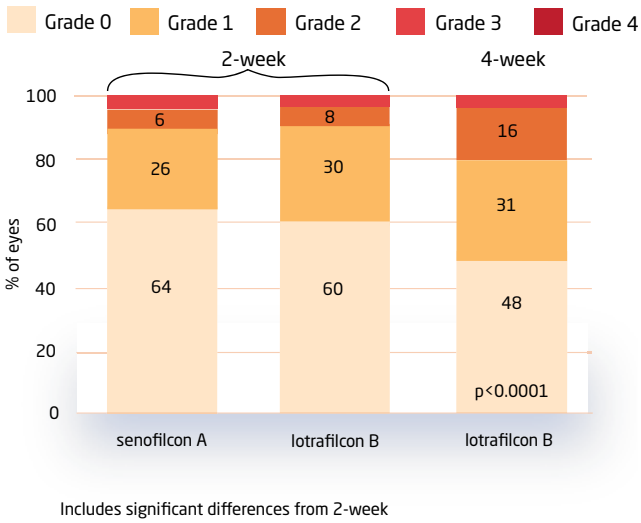


Figure 4 End of day (EoD) comfort – in the lotrafilcon B lens group, EoD comfort declined significantly between one week and four weeks; in the senofilcon A lens group, no significant difference was observed between one week and two weeks



Includes significant differences from dispensing

Figure 5 Front surface wetting declined significantly over time in both lens groups



Includes significant differences from 2-week

Figure 6 Film deposits – in the lotrafilcon B lens group, these increased significantly between two weeks and four weeks

which are designed for two-week replacement, comfort at one week was not significantly different from comfort at dispensing, but comfort declined significantly between one week and two weeks; in the lotrafilcon B lenses, which are designed for monthly replacement, comfort at one week was significantly lower than at dispensing and declined further between one week and four weeks.

While these findings may help to shed light on how the recommended replacement interval affects lens performance, this study has limitations that must be considered. Specifically, this study evaluated only one lens for each replacement interval and collected data over only one cycle of wear. Differences in the habitual care systems used by study subjects may have contributed to specific findings, although the mix of care systems was similar in both groups with most subjects using branded multipurpose solutions and about one in 10 using peroxide disinfection. The robust study design and sample size allows for small differences in performance to be detected.

Although statistically significant, some differences were clinically small. A study like this allows an overview of what may occur with a sample of normal lens wearers. Small differences between lenses evaluated may be diminished in some populations, but could be magnified when patients with less-than-optimal ocular physiology, tear film characteristics, or hygiene habits wear lenses in a non-study situation.

Areas of future study may include a wider range of lenses, evaluating wearers over a longer period, or evaluating the performance of the same material over two weeks versus four-week replacement.

Our study provides some information that may help to guide clinical practice. Because of overall differences in performance between the two lens modalities and differences in how lens performance changes over time, the senofilcon A lenses showed better clinical performance for several measures. These data suggest that clinicians should consider the appropriate replacement interval, in addition to lens choice, when prescribing lenses to a given patient.

Acknowledgement
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