Daily decisions

Silicone hydrogel or hydrogel?

Whether to fit a silicone hydrogel daily disposable lens or a conventional hydrogel daily disposable is a common dilemma in everyday practice. **David Ruston, Kurt Moody** and **Terri Henderson** review recent studies that may help you decide, and **Simon Donne** describes his own experiences in practice

The transition to silicone hydrogels (SiH) from hydrogel contact lenses has been relatively fast in recent years such that more than half of all soft lenses prescribed worldwide are now SiH lenses.[1] The past decade has also seen a rapid and sustained use of daily disposable (DD) contact lenses, particularly in the UK where they now account for nearly half of all new soft lenses fitted and more than one in three refits.[2]

With both SiH and DD lenses, an important motivator for prescribing and using these lenses is improved ocular health. In the case of SiHs, increased oxygen transmission has been shown to reduce hyperaemia even in daily wear.[3-5] Daily wear with SiHs also reduce symptoms of dryness compared with conventional hydrogel contact lenses.[3,5] Daily disposable lenses, on the other hand, reduce the risk of misuse of lens care systems,[6,7] exposure to contaminated lens cases,[8] and deposit-related complications.[9-11] Furthermore, use of DD lenses has been shown to decrease the ocular symptoms of seasonal allergies.[12]

Aside from improved ocular health, from the patient's point of view the main advantage of DDs is the simplicity and convenience of a fresh, sterile lens every day without the hassles of lens care solutions or storage. Ease of use, and the flexibility of when and where to use these lenses, has no doubt increased the popularity of this lens modality.

In 2008, 1-Day Acuvue TruEye (1DATE) was introduced as the first contact lens combining the advantages of the DD modality with the benefits of an SiH material. Narafilcon A is a material that allows 98 per cent of available oxygen to the central cornea (oxygen flux) and 100 per cent of normal oxygen consumption across the cornea in the open eye.[13] Three years on, SiH DDs are one of the fastest growing sectors in the UK. Industry data show an increase from only 1 per cent of sales value of the DD market in 2008 to 12.9 per cent in the first quarter of 2011, when 1DATE's value share of all spherical DD lenses reached 10.7 per cent.[14] The latest UK prescribing trends data show that 17 per cent of DDs fitted in 2011 are manufactured from SiH materials – a good indication that future market share will continue to rise.[2]

In this article we review the reasons for this success with reference to the clinical performance of 1DATE, how its performance compares with that of hydrogel DDs, and the latest research comparing the lens with a new benchmark – the naked eye.

Clinical performance

Technical features of the 1DATE lens have been described in a series of articles since the lens was first introduced.[15-17] In addition to oxygen performance benefits, the key features of the lens are relatively low modulus (similar to Acuvue Oasys) and mid water content (46 per cent, similar to Acuvue Advance). Hydraclear technology (used in all Acuvue SiH materials), permanently embeds a PVP wetting agent throughout the lens matrix to provide a low coefficient of friction, high lubricity and wettability. Like all Acuvue SiH lenses, 1DATE also incorporates Class I UV protection (>96 per cent UV-A and 100 per cent UV-B). At launch the lens was available in one base curve (8.5mm) and powers from -0.50D to -6.00D. Parameters were extended in 2009 to include a second base curve (9.0mm) and a power range from +6.00D to -12.00D.

Hydrogel wearers

Studies have looked at the clinical performance of 1DATE against that of hydrogel DDs. An early clinical study carried out at five sites in the US compared 1DATE with the hydrogel 1-Day Acuvue lens in 81 current spherical, reusable soft lens wearers (60 per cent were previous SiH users).[18] Subjects were randomly assigned to wear one of the two lens types daily for three months. At the end of the study only 17 per cent of the SiH wearers reported any symptoms compared with 24 per cent of the hydrogel DD wearers. Dryness symptoms were reported by fewer than half as many 1DATE wearers as the hydrogel DD lens wearers (11 per cent vs 23 per cent), with lens awareness noted less frequently in those wearing the SiH lens (2 per cent vs 8 per cent). All subjects were successfully fitted and none of those wearing 1DATE discontinued the study for lens-related reasons.

A more recent study compared the clinical performance of 1DATE with another hydrogel DD, Dailies AquaComfort Plus (nelfilcon A, CIBA Vision).[19] This was a one-week, single-masked, bilateral, parallel group design study conducted at 21 practices in the UK. Subjects were existing, successful daily-wear soft contact lens wearers (hydrogel or SiH). Lens parameters covered the available power range and brands were masked to subjects by over-labelling.

A total of 248 subjects were enrolled, nearly half of whom (42 per cent) were already DD wearers. Of the 1DATE group (n=127), 42 per cent had been using SiH lenses, while 35 per cent of the hydrogel group (n=121) used SiH lenses before the study. All subjects were successfully fitted and dispensed the lens to which they were randomised. Of the subjects enrolled, follow-up data were gathered from 243 subjects (98 per cent).

Subjects who used 1DATE rated various comfort attributes throughout the day significantly higher than those wearing the hydrogel lens (including overall comfort, comfort throughout the day and end of day). The SiH DD lenses also tended to give fewer symptoms and longer comfortable wearing time, as found in other studies in which hydrogel wearing patients were refitted with SiH lenses.[20,21]

Limbal and bulbar hyperaemia were graded significantly lower for subjects wearing the SiH DD (0-4 scale) than those wearing hydrogel DD lenses (Figure 1). These findings were to be expected given the difference in oxygen transmissibility between the lenses. Although the precise mechanisms for ▶

SiH or hydrogel? The practitioner's view

Simon Donne describes his experiences with 1-Day Acuvue TruEye in practice and provides tips for success with the lens

I qualified in the days when patients regularly asked if their lenses would 'last another six months'. Our time was spent managing problems caused by overwear, hypoxia and the wearing of lenses that, frankly, were past their best – the term 'frequent replacement' had not yet been thought of.

For me, the launch of daily disposable lenses provided the ultimate in lens wear. I thought that things couldn't get any better and very quickly a large number of my patients became daily disposable wearers. They were experiencing longer wearing times and fewer problems than their reusable lens-wearing counterparts.

Then came the modern silicone hydrogel lens. Wearers of these lenses tended to be happier than those wearing other materials but therein lay the compromise – my patients were denied either the convenience of daily disposability or the greater oxygen delivery of the silicone hydrogel.

Patients experienced fewer symptoms of dryness and discomfort

The advent of the daily disposable silicone hydrogel lens meant the end of this compromise. As one of the clinical investigators on a UK multi-centre comparative study[19] with 1-Day Acuvue TruEye, I was finally able to offer a lens combining daily disposability with oxygen delivery.

When my patients attended their follow-up appointments I was seeing reduced levels of limbal and bulbar hyperaemia, and lower levels of corneal staining, when compared with daily disposable hydrogel lenses. Patients experienced fewer symptoms of dryness and discomfort, especially at the end of the day, resulting in longer wearing times and a reduced need for rewetting drops. Many reported feeling like they weren't actually wearing any lenses. Their eyes generally looked whiter, confirming in their own minds, as well as in mine, that this was a healthier option.

'Wearing time guilt' was also less of an issue. Patients will often wear lenses for the number of hours that suits them, rather than stick to the wearing schedules you recommend. With silicone hydrogels I'm able to tell them that the lenses can be worn during all waking hours.

It's really powerful to be able to offer a lens that's as comfortable as no lens and that lets through so much oxygen that it doesn't matter whether they're wearing it or not. Patients' comments since being fitted with the lens include remarks such as: 'No more eye tiredness', 'It's really like wearing no lenses' and 'I no longer look like I wear contact lenses'.

The health message can be further reinforced by the Class I UV protection. Some patients may experience no significant difference in terms of comfort and wearing time with differing lens types worn on a contralateral trial but will often be happy to go for a lens that delivers UV protection as well as more oxygen.

Most patients recruited for the study were satisfied with their habitual lenses and hadn't been considering a change. After experiencing the lens many of them upgraded to the new product, which in turn gave me the confidence to recommend it as a first-choice lens to my daily disposable wearers.

The daily disposable SiH lens is a premium product, which I offer at the outset to new patients considering daily disposable lenses. Don't assume patients can't or won't afford it. My practice is not in the most affluent area but I am still able to offer 1-Day Acuvue TruEye as my first-choice daily disposable and patients are happy to pay for the benefits of health and comfort. The oxygen message resonates well with today's health-conscious population. For the more cost-conscious there is the option of a hydrogel lens – many may upgrade at a later date if they feel their lenses are not meeting their lifestyle demands.

In my practice, current lens wearers are offered the chance to trial new products – even if they do not upgrade at the time they will be aware that there is now 'somewhere to go' if they begin to experience problems with their habitual lenses. With new wearers, I highlight the fact that comfort increases as they adapt to the lens and that it's just as comfortable as wearing no lens at all.

Despite the recession my contact lens business is still growing slowly and steadily year on year. Traditionally we think of our competition as other practices, other high-street shops or the internet. I believe we need to get away from discussing lens upgrade costs, and instead encourage patients to compare their eye care outlay with what they might pay for other high-end products such as monthly payments for gym membership, or what they spend on their social life, such as restaurants, cinemas, theatres, etc.

As the optical market place becomes ever more competitive, the way forward, especially for the independent practice such as mine, is to offer premium products combined with a high level of customer service.

Healthy eyes make a healthy practice!.

● Optometrist **Simon Donne** practises in Bedford

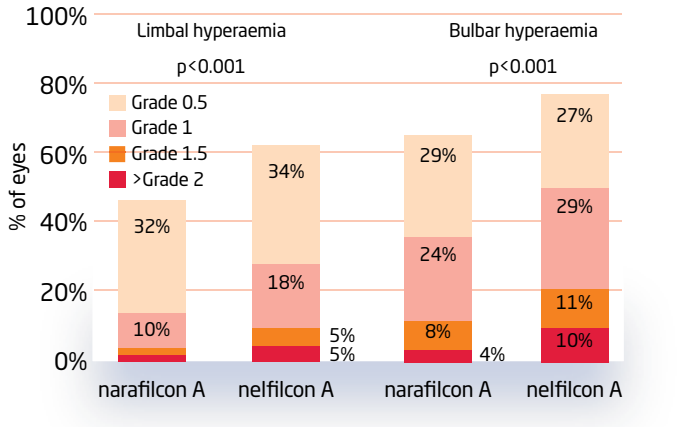

Figure 1 Frequency distribution of limbal and bulbar hyperaemia grades at follow-up visit with narafilcon A (1-Day Acuvue TruEye) and nelfilcon A (Dailies Aqua Comfort Plus)[19]

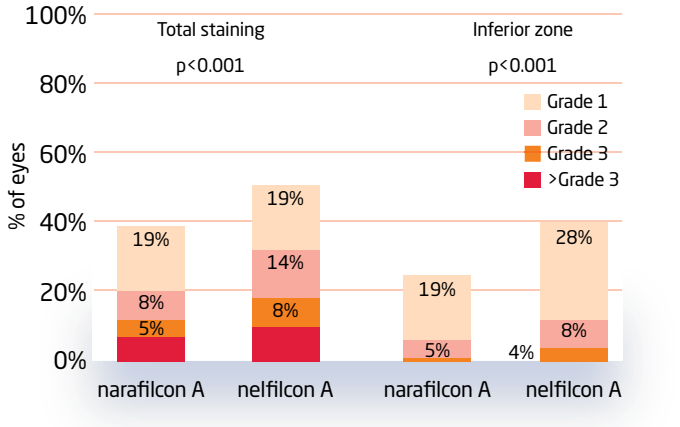

Figure 2 Frequency distribution of total and inferior corneal staining grades at follow-up visit with narafilcon A (1-Day Acuvue TruEye) and nelfilcon A (Dailies Aqua Comfort Plus)[19]

relief of limbal and bulbar redness are not known, reduction in hypoxia has been postulated as a main factor in the change.[22] An alternative explanation in this case might be that the greater lubricity of the SiH DD material resulted in less conjunctival irritation, or that the material's surface properties resulted in a reduction in friction.

There was also significantly less total and inferior corneal staining with the SiH DD compared with hydrogel DD lenses (25 per cent vs 40 per cent Grade 1 or more) (Figure 2). The difference in corneal staining between SiH DD and hydrogel lens wearers was most evident in the inferior cornea. Since most staining in this sector is regarded as desiccation staining, this finding suggests that the difference may have been due to differences in hydration characteristics. *In vitro* testing of hydrogel and SiH lens dehydration has found a high correlation of initial water content to dehydration rate.[23] Thus, the lower water content may yield a more stable hydration state for SiH lenses.

This study demonstrates that while both lenses perform well when refitting a population of existing, soft daily-wear lens users, there are significant performance differences between the two lens types.

New wearers

While these studies have investigated the clinical performance of 1DATE in existing soft lens wearers, the latest UK research examines its use in neophyte wearers. This study, for which one-year data are now available, is unique in comparing the physiological compatibility of the lens with a new benchmark, no lens wear.

Researchers at the University of Manchester enrolled 74 neophyte myopic subjects with no previous contact lens experience in a one-year, parallel group study.[24] Subjects were matched and randomly assigned to wear either 1DATE (n=38) or spectacles (ie no lens wear) (n=36). In the first and fifth weeks of the study, both groups recorded subjective comfort on a 1-5 scale at five times during the day using SMS text messaging (where 1=very uncomfortable and 5=very comfortable). After the fitting and dispensing visit, subjects also made six scheduled visits, at two weeks, one month, three months and then at three-monthly intervals during the year. Biomicroscopy signs (Efron grading scales, 0-4) and subjective response scores were recorded for all subjects at each visit. Investigators recording slit-lamp findings were unaware which group subjects belonged to.

Comfort scores assessed by SMS were statistically equivalent for the 1DATE and non-lens wearing groups and there was a measurable improvement in comfort during the first month of wear for the 1DATE group. SMS scores at five time-points during the day showed that there was no decline in comfort at the end of the day at both weeks 1 and 5 (Figure 3).[25] Mean SMS comfort scores for the 1DATE and non-lens groups at week 1 were 4.11 and 4.25 units respectively, and at week 5 were 4.37 and 4.22 units respectively. For subjective comfort scores recorded at visits, both groups showed improved scores for each of the follow-up visits compared with the initial visit.

There was no significant difference in bulbar or limbal conjunctival hyperaemia, nor in corneal staining, across the study visits or between 1DATE wearers and non-lens wearers (Figure 4). The only difference was for conjunctival staining, where, as might be expected, scores were higher for the lens-wearing group (0.83 vs 0.26 at one year), although absolute levels were low, asymptomatic and did not require clinical management.

The authors observe that long-term assessment of contact lens performance in neophytes in a carefully controlled, fully randomised investigator-masked clinical study perhaps represents the ultimate challenge for a contact lens. This study shows minimal and stable impact on ocular physiology with the 1DATE lens and, for the first time, comfort comparable to the natural eye. The authors also suggest that the use of SMS messaging to understand contact lens comfort is more reliable than the conventional approach where scores are collected at follow-up visits and necessarily rely on subject recollection of lens comfort.[26]

Conclusions

The decision to choose a silicone hydrogel or conventional hydrogel material when fitting daily disposable lenses is a common dilemma in everyday practice. Studies have shown that 1-Day Acuvue TruEye, the world's first silicone hydrogel daily disposable lens, provides wearers with significantly higher levels of comfort, longer comfortable wearing

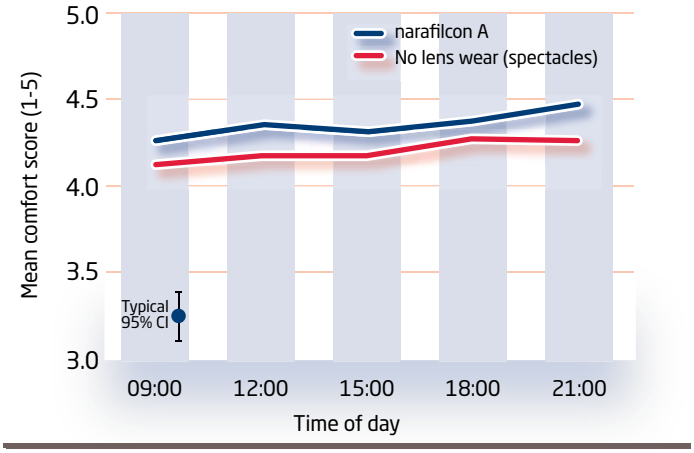

Figure 3 Subjective comfort scores captured via SMS text messaging in week 5 and, at five time points during the day with narafilcon A (1-Day Acuvue TruEye) and no lens wear[25]

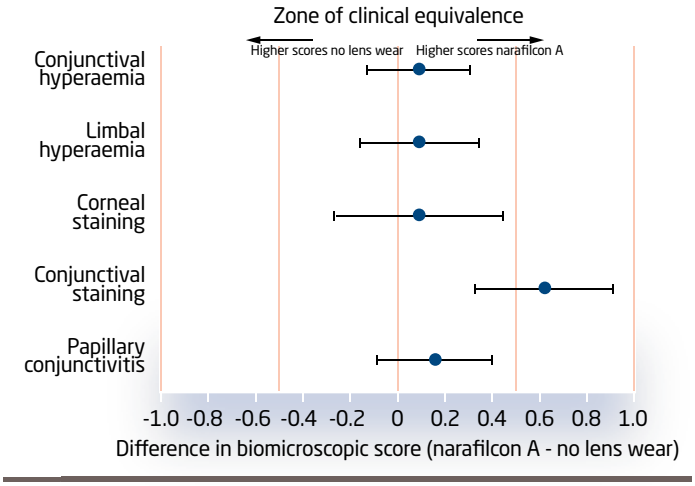

Figure 4 Average differences for the five main biomicroscopic signs at the 12-month visit (clinical equivalence = within 0.5 grading scale units) with narafilcon A (1-Day Acuvue TruEye) and no lens wear[24]

times and improved ocular physiology when compared with hydrogel daily disposable lenses. The latest study in patients new to contact lenses found that 1-Day Acuvue TruEye was equivalent to the non-lens wearing eye for key slit-lamp findings, and there was no significant difference in subjective comfort between wearing the lens and no lens at all. Comfort improved over a year of lens wear and there was no reduction in comfort at the end of the day. Daily disposable lenses made with SiH material give practitioners added flexibility and better performance, meeting the needs of patients interested in the daily disposable modality.

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