Clinical performance of a daily disposable, silicone hydrogel contact lens

David Ruston, Anna Sulley and Kurt Moody

Daily disposable (DD) contact lenses offer considerable convenience, health, vision, comfort and satisfaction benefits[1-9] and are now widely prescribed. Recent data on prescribing trends show that 44% of new fits in the UK are DDs,[10] which is above the global average of 28%, although the proportion of DDs fitted globally varies widely from 4% in Bulgaria to 85% in Qatar. There are now a wide range of parameters and designs available and the combined benefits of convenience and health from the DD modality, and physiological and comfort benefits of a silicone hydrogel (SiH) material[11,12] were realized with the world's first SiH DD contact lens launched in 2008, 1•DAY ACUVUE TruEye (1DAVTE) from Johnson & Johnson Vision Care.[13,14]

1DAVTE parameters and specifications are shown in Table 1. The extensive parameter range offers two base curves to maximise optimal fitting characteristics and a power range from +6.00D to -12.00D to satisfy the majority of spherical refractive errors.

Oxygen performance

Being a SiH lens, 1DAVTE surpasses the performance of a hydrogel lens in a number of areas, such as causing no expected hypoxia-related signs, due to the increased level of oxygen delivery during waking hours. The oxygen transmissibility (Dk/t) of 1DAVTE is 118 x 10-[11] (-3.00DS lens, measured via polarographic method, edge and boundary corrected), and the lens has a Dk/t profile higher than all hydrogel DDs both centrally and peripherally.[15] When considering oxygen flux, 98% of available oxygen reaches the central cornea for daily wear. 1DAVTE also permits total corneal oxygen consumption levels equivalent to no lens wear for daily wear across the entire power range (Figure 1).[15,16,17] The oxygen delivery of the lens is expected to have significant benefits for all patients, particularly those who wear lenses for long or variable hours, or with higher refractive errors.

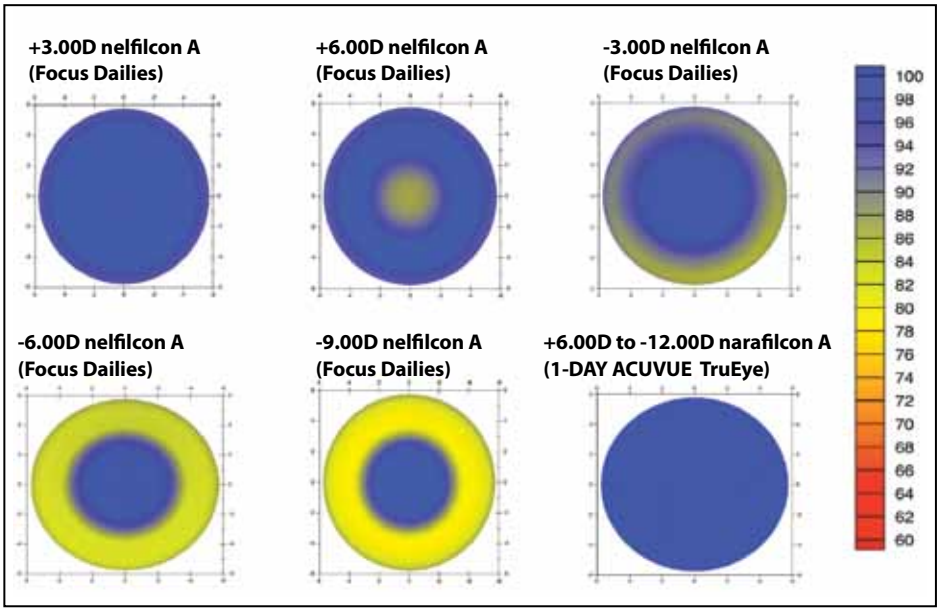

Figure 1
Topographic maps open eye percentage total corneal oxygen consumption for daily disposables (after Brennan[15,16])

Material benefits

1DAVTE uses narafilcon A SiH material and HYDRACLEAR 1 technology, which permanently embeds a wetting agent (polyvinyl pyrrolidone - PVP) throughout the lens matrix. This imparts flexibility, lubricity and moisture retention, without the need for a surface coating or treatment. The PVP attracts water, making 1DAVTE wettable and smooth. The lens has a low coefficient of friction,[15] giving a lubricious lens material for initial comfort, maintained comfort throughout the day, and minimal impact on ocular tissue. There is no release of the internal wetting agent into the ocular environment during lens wear. The modulus of elasticity for 1DAVTE is relatively low and similar to that for ACUVUE OASYS, and with a relatively high water content (46%), similar to ACUVUE ADVANCE; these material properties minimise issues that can potentially affect comfort and mechanical complications when refitting existing hydrogel wearers. Additionally, 1DAVTE offers the benefits of protection from ultraviolet (UV) exposure via a Class I UV blocker, and along with ACUVUE OASYS has the highest UV-blocking of any soft contact lens currently on the market (>96% UV-A and 100% UV-B).[15]

Clinical performance

1DAVTE has technical features to establish it as a premium DD lens: oxygen performance benefits of a SiH material, high lubricity, excellent wettability and UV protection. Information gained since the launch of this lens has shown that it provides excellent on-eye

performance with clinical trial results showing excellent overall and end of day comfort. A twelve-month investigation has recently been completed at Eurolens Research (University of Manchester), which explored these performance characteristics by comparing the comfort and physiological response in neophytes wearing the lens to those wearing spectacles ie comparing 1DAVTE to no lens wear; hypotheses for the study were that subjective comfort over the course of a day and key measures of ocular physiology were equivalent between the two groups. Interim six-month results of the randomized, parallel group study were presented at the American Academy of Optometry meeting in November 2009 and are summarised in this article.[19] This six-month time period is relevant since this is the time when many physiological differences would become evident.

Methodology

Each subject was randomly assigned into either a non-contact lens (spectacle wearing) control group or to 1DAVTE, with subjects being age- and gender-matched. Daily ocular comfort profiles were generated during weeks one and five of the study using SMS messages, sent each day at five specific time points, which has been described as a highly accurate way of obtaining reliable, real time comfort scores;[20] subjects were required to rate their comfort on a "1-5" scale, with a higher score indicating better comfort. Biomicroscopy was performed throughout the study, with ocular physiology graded using an Efron Scale (0-4) and recorded to the nearest 0.1 grade. To ensure investigator masking, a different investigator assessed ocular integrity/response to that who assessed the lens fit, which meant that the former did not know which group each subject was in. Note that since the study commenced in 2008, parameters were limited to availability at the time, which meant that only the 8.5mm base curve and powers of -1.00D to -6.00D were used.

Subject Demographics

Seventy-one subjects were enrolled in the study, with 58 completing up to the six–month stage. Just under half of the subjects (47%) were female. Subjects were between 18 and 51 years of age (mean age of 25.9±7.7 years), with distance sphere refractive error ranging from –1.00D to –6.00D in both eyes, and spectacle astigmatism of 1.00D or less. The average contact lens power dispensed was –2.10±1.50DS, with average spectacle power of the control group being -2.12±1.68DS. All subjects had never worn contact lenses before, had normal and healthy eyes and were correctable to a visual acuity (VA) of 6/9 or better in each eye.

Material (United States Adopted Name)	narafilcon A
Internal wetting agent	Yes, via HYDRACLEAR 1 Technology
Water content (%)	46
Base curves (mm)	8.5, 9.0
Diameter (mm)	14.2
Centre thickness @ –3.00 DS (mm)	0.085
Oxygen transmissibility* @ -3.00DS (× 10^{-9})	118
Oxygen flux (%) **	98
Corneal oxygen consumption (%)	100
Power range	-0.50D to –6.00D (0.25D steps) -6.50D to -12.00 (0.50D steps) +0.50D to +6.00D (0.25D steps)
Ultraviolet (UV) blocking	>96% UV-A, 100% UV-B Class I UV blocker
Inside-out indicator	1-2-3 inversion indicator
Visibility tint	Yes

Table 1
1•DAY ACUVUE TruEye specifications, parameters and key features

* Measured via polarographic method, edge and boundary corrected ** Compared to 100% with no lens wear; through lens centre, -3.00DS lens

Comfort Results

Figure 2 shows the ratings of ocular comfort 1-week and 1-month after fitting 1DAVTE, along with the ratings of the non-lens wearing group. Scores for each group at the five time points ranged from 3.9 to 4.4. Not all subjects responded to all text messages, so the data are reflective of only those who did respond. Two-sided 95% confidence intervals of the difference in least squares means were used to evaluate subjective comfort; the 1-month results were the final comfort data collected. The results show that after one week of wear, lens comfort was consistently at the higher end of the scale throughout the wearing period, and end-of-day comfort (9pm) was equivalent between lens and spectacle wearers. After one month, the adapted 1DAVTE wearer can expect consistent and comfortable wear from morning to night, which was shown to be equivalent to no lens at all, with no decline as the day progressed. Comfort was also shown to improve over the first month of wear for lens wearers, with a significant increase in comfort of about 0.3 units found ($p < 0.0001$), showing an adaptation effect.

Physiology Results

Grading scores of key biomicroscopic ocular physiology measures (limbal and conjunctival hyperaemia, corneal staining and papillary conjunctivitis) are shown in Figure 3. Two-sided 99%

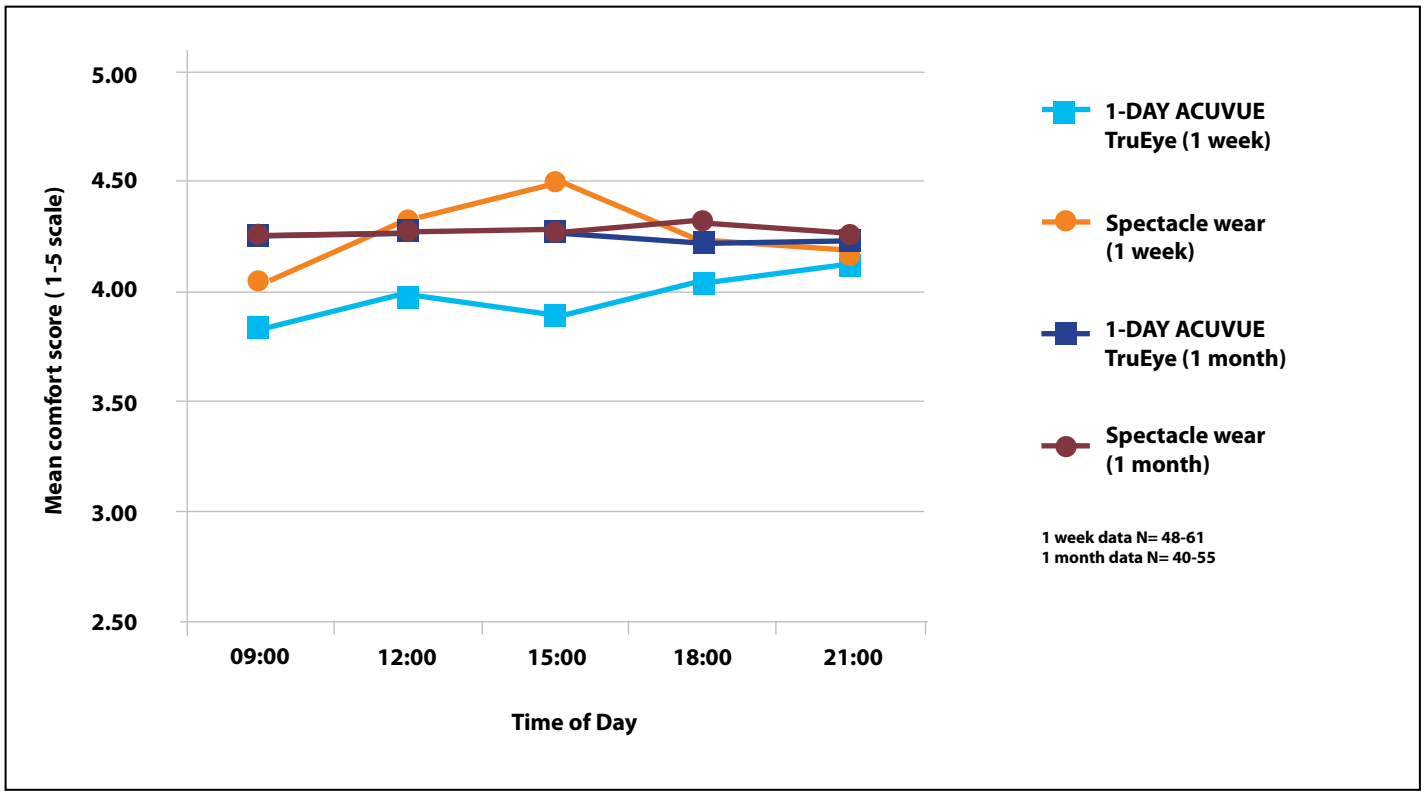

Figure 2
Daily comfort profiles for 1-DAY ACUVUE TruEye and control (spectacle wear) collected via SMS over the course of a day, after one week and one month of daily wear (after Morgan[18])

confidence intervals for the difference in least squares means were used to analyse the physiology data. The results show that ocular physiology was unaffected after six months' of lens wear. Mean biomicroscopic grading scores were consistently low (less than Grade 1.2 in all measures) and the 1DAVTE wearers had equivalent conjunctival and limbal hyperaemia, corneal staining and papillary conjunctivitis to the group of spectacle wearers.

There were low grading scores also, for both groups, for corneal vascularisation, although since there were no eyes with higher than grade 0 for spectacle wearers from one month, and no eyes with higher than Grade 0 for lens wearers from three months, no statistical analysis was done. Conjunctival staining was greater in the lens-wearing group by about half a grade ($p<0.05$) although with a mean absolute level of less than Grade 1 this is of no immediate clinical concern and is often seen in soft contact lens wearers (due to marginal dry eye or mechanical trauma from removal, lens fit, or edge design).

Discussion

One goal of a contact lens manufacturer is to produce a comfortable lens that has minimal impact on the ocular surface while providing optimal optical correction. Comparing lens performance to equivalent subjects who wear spectacles instead of lenses can effectively assess this. It could be said that the control group benefit from their spectacles as a shield to environmental factors and should hence have a high level of ocular surface integrity.

Comfort in the neophytes with 1DAVTE is comparable to that of non-lens wearers and also was maintained throughout the day. Previous reporting of comfort in this manner has shown a reduction in comfort during the day with other contact lenses, even in adapted wearers.[19] An adaptation effect was noted in this study, with

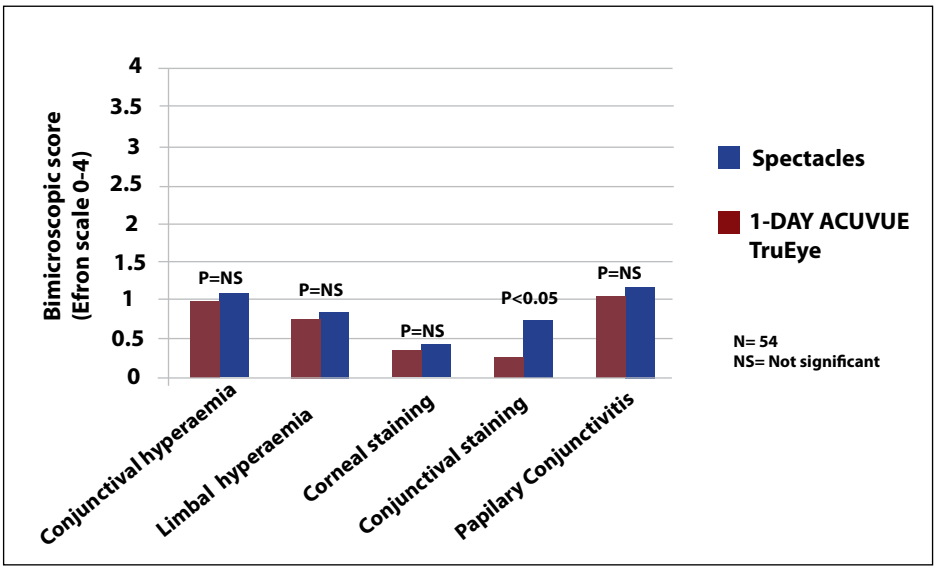

Figure 3
Biomicroscopic scores at six months compared with no lens wear (after Morgan[18])

comfort increasing from weeks one to five, and this would be expected to be greatest for neophyte subjects as opposed to experienced lens wearers.

No significant differences in ocular physiology grading scores were seen in this study, suggesting no signs of hypoxia-mediated problems (conjunctival and limbal hyperaemia; Figure 4), corneal staining or tarsal conjunctival health (papillary changes). This study illustrates that after six months of daily wear, neophyte 1DAVTE wearers have an ocular integrity comparable to no lens wear, leading to, for example, whiter eyes than eyes wearing hydrogel lenses. In addition to the fact there were little differences between the two groups, it should also be noted that the level of ocular and discomfort findings were very low. Typically with this grading scale, Grade 3 and above are considered to be clinically significant, so the very low values observed in this study suggest a positive result from wearing 1DAVTE.

Conclusions

When recommending the optimal contact lens to patients, consideration should be given to both the lens' physiological and comfort performance, in addition to patient satisfaction. 1DAVTE combines the health and comfort benefits of a silicone hydrogel material, with key ocular physiology measures comparable to no lens wear, together with the hygiene and convenience of a daily disposable. This allows practitioners to confidently prescribe contact lenses to a wide range of patients while maintaining ocular health during wear.

The final one-year data of this study will be presented at the BCLA conference at the end of May 2010.

About the authors

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Figure 4

1•DAY ACUVUE TruEye after 8-hours of wear (right image) versus the same non-lens wearing eye prior to fitting (left image) demonstrating no signs conjunctival or limbal hyperaemia

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