

New insights into the long-term success of etafilcon A daily disposable contact lenses

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The latest findings with the 1-DAY ACUVUE® MOIST family support the significant role for hydrogel daily disposables in contemporary contact lens practice. Dr Noel Brennan and David Ruston report

KEY POINTS FROM THE LATEST PUBLISHED CLINICAL STUDIES:

- Corneal oxygen consumption with etafilcon A lenses (Dk/t of 25.5 units centrally) is the same (100%) as with lotrafilcon A lenses (Dk/t of 175) under open-eye conditions,⁷ and there is a small and probably clinically irrelevant difference in limbal hyperaemia.⁸
- Refitting SiHy wearers with 1-DAY ACUVUE® MOIST MULTIFOCAL (etafilcon A) results in minimal impact to ocular physiology along with high levels of overall comfort and vision satisfaction.¹⁰
- Recently reported results for adverse events contribute further evidence to support the safety profile of daily disposables in general and etafilcon A in particular.^{15,18,19}
- etafilcon A DDs are associated with a lower risk of corneal infection than other DDs evaluated.²⁰

Daily disposable (DD) contact lenses continue to gain widespread acceptance with patients and with eye care practitioners. Worldwide around four in 10 soft lenses fitted in 2017 (37%) were for daily replacement.¹ In the UK, the latest data for 2017 show that DDs accounted for two-thirds of new soft lens fits (66%).²

Although more DD options in silicone hydrogel (SiHy) materials are now available, the proportion of SiHys prescribed in this category still lags behind the proportion of reusable lenses that are SiHy.¹

The enduring satisfaction with hydrogel materials relies heavily on their performance. In a recent clinical study comparing lenses made from SiHy and hydrogel materials, Diec *et al*³ reported there were 'no clinically significant differences in physiological variables, vision and contact lens fitting characteristics' between the materials.

'Neither material type was shown to be superior in comfort,' these authors say. They conclude that the outcomes 'suggest that the choice of material for this modality [DD] may be based on patient and practitioner preference.'

DDs manufactured from etafilcon A – the 1-DAY ACUVUE® MOIST family – are the number one DD contact lens brand globally and provide the most optical parameters available of any soft contact lens brand in a daily replacement modality, to satisfy the vision needs of spherical, astigmatic and presbyopic patients.^{4,5}

The continuing success of etafilcon A DDs has been reflected in positive reports on safety outcomes and ocular health with these lenses.⁶ New studies with the 1-DAY ACUVUE® MOIST family are now emerging that support the excellent record of etafilcon A DD lenses for successful wear with minimal problems (see panel).

Focus on what matters

Despite this proven success, some eye care practitioners may still have concerns about fitting hydrogels for new wearers or refitting SiHy wearers into hydrogels. The belief that SiHy materials *per se* are healthier than hydrogels may be driven by the perception that 'the higher the oxygen transmissibility (Dk/t) the better'.

Indeed, it is known that as Dk/t increases, other measures of oxygen that are more clinically relevant – such as anterior corneal oxygen flux (the amount of oxygen that passes through a unit area of lens in a given time) or oxygen consumption by the cornea (a direct index of corneal oxygen metabolism) – quickly plateau (Figure 1).⁷

At a Dk/t of approximately 20 units, the central cornea gets all the oxygen it needs for normal functioning in the open-eye state. Therefore, corneal oxygen consumption with etafilcon A lenses (Dk/t of 25.5 centrally) is the same as with lotrafilcon A lenses (Dk/t of 175) under open-eye conditions, despite their very different lab-based transmissibility measurements.⁷

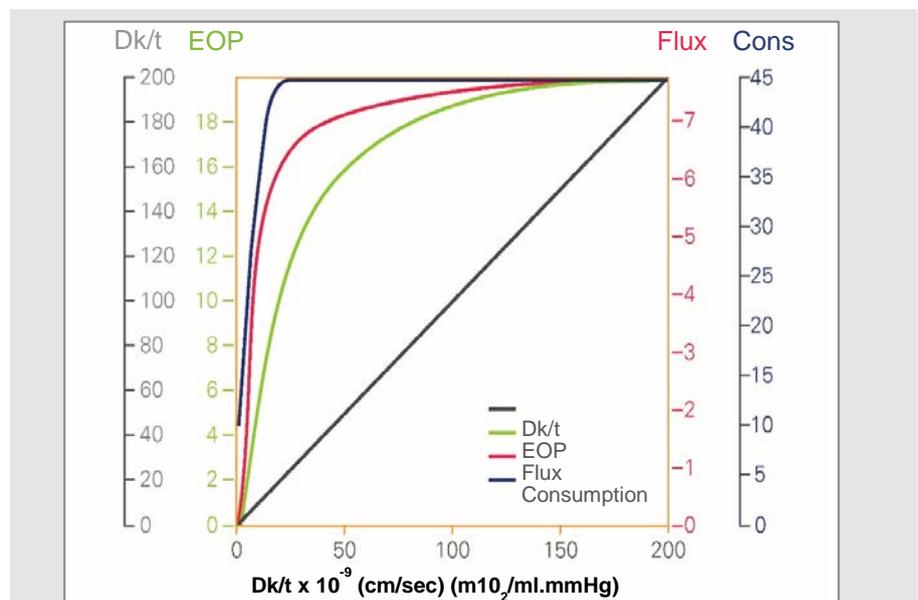


Figure 1. Combined graph showing Dk/t, EOP, anterior corneal oxygen flux (µl/cm²h) and consumption (nl/cm³sec) as a function of Dk/t for the open eye⁷

In fact, the only solid evidence of a benefit from a central Dk/t >20 is a small and likely not clinically relevant reduction in limbal hyperaemia,⁸ and a reduction in peripheral corneal swelling, which may be important for patients who are predisposed to vascularisation with the thicker designs of some toric lenses.⁹

There are patients who do better in high Dk/t SiHy lenses (although, in most cases, this is probably not due to increased oxygen supply), just as there are patients who do better in hydrogels. Prescribing according to patient needs and comfort preferences is more likely to lead to success than arbitrarily emphasising one characteristic – Dk/t – that has relatively little impact on performance and no positive impact on comfort.

Switching to hydrogels

A recent study, conducted at the Center for Contact Lens Research at the University of Waterloo, examined physiological response and clinical performance in subjects switched from their usual SiHy lenses to 1-DAY ACUVUE® MOIST MULTIFOCAL.¹⁰

Subjects here were 39 habitual SiHy lens wearers (14 hyperopes, 25 myopes) of SiHy multifocals, monovision and spherical lenses. A majority (70%) wore reusable SiHy multifocals. The mean age of the subjects was 54.5±7 years. Ocular physiology was assessed at baseline and at 4 weeks after 6 hours of open-eye wear. Success factors such as visual acuity, subjective comfort and vision were evaluated.

No clinically significant differences in ocular physiological responses to lens wear were found between baseline habitual reusable SiHy wear and after 4 weeks of open-eye DD wear of 1-DAY ACUVUE® MOIST MULTIFOCAL lenses.

Importantly, comfort and performance were superior with the hydrogel lens. After 4 weeks of 1-DAY ACUVUE® MOIST MULTIFOCAL wear, the overall CLUE comfort score (Contact Lens User Experience¹¹ – a composite index of multiple comfort questions, validated by the US Food & Drug Administration Guidance on Patient Reported Outcomes¹²) was significantly higher (72.2 vs 62.1) than at baseline and

more subjects agreed with the statement ‘these lenses were comfortable at the end of the day’ (82% vs 69%).

Key clinical signs

The study reveals similarly positive results for these two key clinical signs of hypoxic stress: corneal swelling and limbal hyperaemia. After 6 hours of lens wear, for each of four corneal locations corneal thickness at day 28 and baseline (SiHy wear) was clinically equivalent (Figure 2), and for hyperopes and hyperopes alike.¹⁰

This result is important when considering whether to recommend 1-DAY ACUVUE® MOIST MULTIFOCAL to existing SiHy wearers in the presbyopic age group.

Findings for limbal hyperaemia provide even more confidence for practitioners. There was no significant clinical difference in mean bulbar conjunctival hyperaemia with 1-DAY ACUVUE® MOIST MULTIFOCAL compared to the habitual SiHy lenses (Figure 3).¹⁰

In fact, the levels of mean bulbar as well as mean limbal hyperaemia at day 28 compared to baseline were equivalent. Again, the same was true in both hyperopes and myopes. The levels of hyperaemia observed were consistent with that seen in non-lens wearing adults (≤Grade 1).

Taking the stress test

Previous studies of these two key clinical signs of hypoxia have provided

reassurance that there is more to ocular health than Dk/t and demonstrated the excellent performance of etafilcon A.

In the first study researchers compared open-eye corneal swelling between 1-DAY ACUVUE® MOIST and no lens.¹³ This study involved 24 patients using the etafilcon A DD or no lens, with a minimum 24-hour washout period between visits.

After 8 hours of open-eye wear, central and peripheral corneal swelling along the horizontal meridian with 1-DAY ACUVUE® MOIST was <1.5%, clinically equivalent to that observed with no lens. Conjunctival hyperaemia was also clinically unremarkable under both conditions.

A second study compared these same signs of hypoxic stress in 36 habitual contact lens wearers after 7 days’ wear of three lens types: etafilcon A (ACUVUE® 2 control), and the SiHys lotrafilcon B (Air Optix® Aqua) and comfilcon A (Biofinity®).¹⁴ Central corneal thickness and limbal hyperaemia were measured 2 hours after waking and after 6-8 hours’ wear.

The etafilcon A lens resulted in corneal de-swelling throughout the day, as did the SiHy lenses, and was within 0.85% mean swelling of the SiHys. Overall (and by quadrant) mean limbal hyperaemia with etafilcon A was within a 0.5 grade step of that induced by the SiHys. Equivalence of etafilcon A with respect to the two SiHy lenses for these key measures of hypoxic stress was demonstrated.

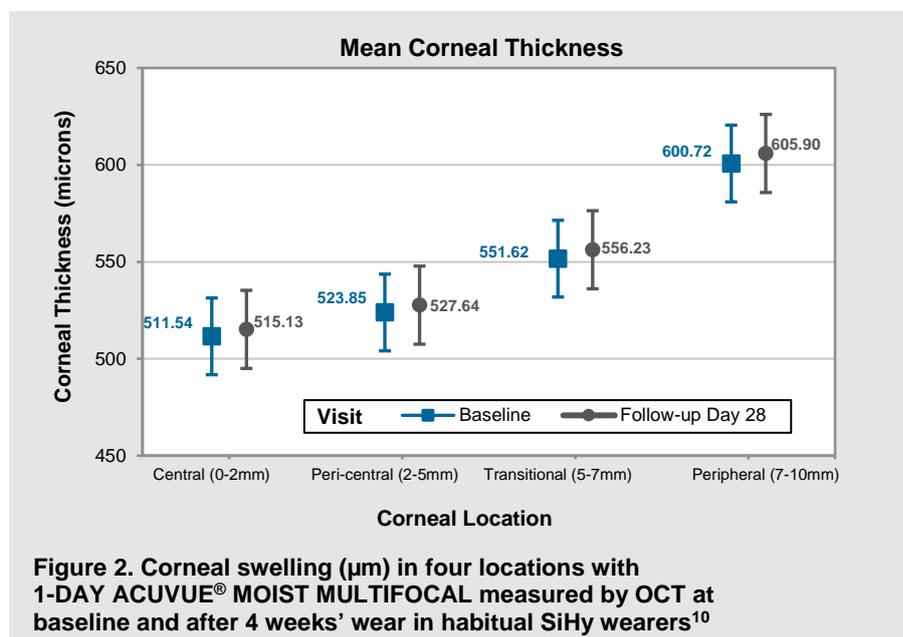


Figure 2. Corneal swelling (µm) in four locations with 1-DAY ACUVUE® MOIST MULTIFOCAL measured by OCT at baseline and after 4 weeks’ wear in habitual SiHy wearers¹⁰

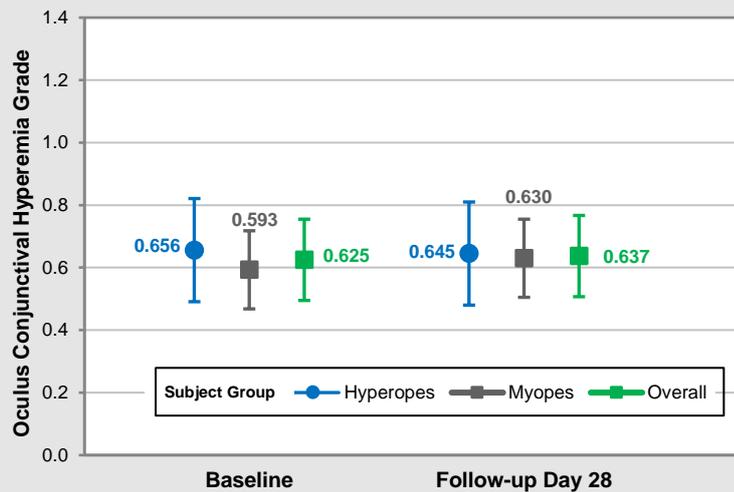


Figure 3. Mean limbal conjunctival hyperaemia with 1-DAY ACUVUE® MOIST MULTIFOCAL at baseline and after 4 weeks' wear in habitual SiHy wearers¹⁰

Three lenses compared

One further study has looked at these same measures with three different ACUVUE® Brand lenses.⁸ A total of 120 subjects were randomised to wear each lens type: etafilcon A (1-DAY ACUVUE® MOIST), narafilcon A (1-DAY ACUVUE® TruEye®) and the reusable senofilcon A lens (ACUVUE OASYS®), all worn on a DD regime.

Ocular physiology – including limbal hyperaemia – and lens performance data were collected during 3 months' wear. Subjects were instructed to wear lenses at least 8 hours a day and at least 6 days a week.

While the SiHy lenses did result in statistically lower limbal hyperaemia scores, the difference was 0.2 units on a 0-4 grading scale. It is generally accepted that a difference of 0.5, or even 0.25 units, represents clinical significance. No other ocular physiology variable – including vascularisation – showed significant differences.

Positive safety outcomes

If ocular physiology findings for etafilcon A DDs are reassuring, results for the safety profile of these lenses are also very positive.

The TEMPO study measured the incidence of adverse events by post-market surveillance registry of wearers fitted with 1-DAY ACUVUE® MOIST.¹⁵

This 12-month observational study of 570 patients (equivalent to 471 patient years of lens wear), found there were no symptomatic corneal infiltrative events (CIEs) or other serious adverse events (AEs) (0.0%/year) and only three non-serious events (0.6%/year).

This observational/surveillance registry relied on patient reports of symptomatic adverse events that led them to seek clinical care. The results should be considered in conjunction with other clinical results on the safety and efficacy of DD etafilcon A contact lenses, which also generally show low rates of such events. It should be noted that although no symptomatic infiltrative events were reported in the TEMPO study, such events can occur with DD lenses, including 1-DAY ACUVUE® MOIST, as noted in the product labelling.

The overall CIE rates found in the TEMPO registry are significantly lower than found in previous reusable lens studies, such as an annualised incidence of 4.0% in a retrospective chart review of mainly daily wear hydrogel and SiHy wearers, and 5.0% in a prospective trial with daily wear reusable SiHys.^{16,17}

Additional analysis of the TEMPO study has since explored the influence of age on performance outcomes.¹⁸ Among 86 wearers aged over 40 (24% men, age 50.2±7.1 years) completing the registry, 76% were new to DDs and 8% were neophytes.

Existing contact lens wearers older than 40 years experienced many benefits from refitting with 1-DAY ACUVUE® MOIST. Changing to the hydrogel DD significantly improved overall opinion of contact lenses, improved dry eye symptoms (CLDEQ-8 scores), and maintained average and comfortable wear time.

Low adverse events

Rates of other AEs in the TEMPO registry were also very low in comparison with prior studies using different designs or other modalities.

This finding is supported by an independent, retrospective analysis that looked at 28 lens/solution combinations, each tested on approximately 40 patients wearing lenses on a daily wear basis for a 3-month period.¹⁹ Lenses were frequent replacement and DDs, hydrogels and SiHys. Solutions included hydrogen peroxide and multipurpose.

The overall AE rate was 3.6 events per 100 participant-months. Rates were low for the four DD lenses tested and significantly lower in DDs compared with reusable daily wear lenses, at 3.1 vs 10.9. The only lens in the study that did not have any reported AEs was 1-DAY ACUVUE® MOIST, although the study did not show statistically significant differences between the DDs evaluated.

Lower incidence of microbial keratitis (MK)

A new study of MK in DD wearers helps build further confidence on safety outcomes with etafilcon A DDs in particular.

A two-year case control study at Moorfields Eye Hospital in the UK and a one-year national surveillance study in Australia and New Zealand identified new cases of contact lens-related MK in wearers using DD and other soft contact lenses.²⁰ Self-administered (cases) or telephone-administered (controls) questionnaires were used to identify potential risk factors for MK, expressed as an odds ratio (OR).

A total of 963 DD wearers were identified, from which 67 MK cases and 374 controls were sampled. Independent risk factors for all and for

moderate/severe MK were: wearing contact lenses every day vs less frequent use (OR 10.4x), any overnight wear (OR 1.8x), less frequent hand washing (OR 1.8x) and smoking (OR 1.3x).

But the study also found that risk varied with DD lens type and it would seem that certain DDs had lower rates. Using etafilcon A as the referent, a nelfilcon A DD had an OR of 3.98 for all presumed MK (and 4.83 for moderate/severe MK), and a hilafilcon B DD had an OR of 2.06 (and 2.61 respectively) (Figure 4).

The authors observe that 'it is unclear why certain DDs are protective for the risk of infection,' and that 'some types of DD are more difficult to remove than others, which may increase the risk of mechanical complications.' They conclude that lens type, material properties and design are likely to play a role in the aetiology of MK in the DD modality.

These results add to the analysis of a previous case-control study of MK rates in the UK that again found differences between DDs, again citing handling difficulty as a possible cause and the nelfilcon A lens as more difficult to remove than the etafilcon A lens.²¹

It is important to note that both the nelfilcon A (FOCUS® DAILIES®) lenses and etafilcon A (1-DAY ACUVUE®) have altered since these studies were conducted. The nelfilcon A lenses now have a larger base curve and diameter with two added wetting agents. 1-DAY ACUVUE® (etafilcon A) has since been replaced by 1-DAY ACUVUE® MOIST, having the same base material and design with the addition of polyvinylpyrrolidone (PVP).

For patients with sensitivities

While vision, comfort and health are at the core of every fit, the 1-DAY ACUVUE® MOIST family is an excellent option for patients who experience ocular sensitivities and want to comfortably enjoy everyday activities. Half of all contact lens wearers (52%) say their eyes feel sensitive,²² which may be described as irritation, redness, stinging.²³ Additionally, etafilcon A has been shown to improve comfort in wearers who have

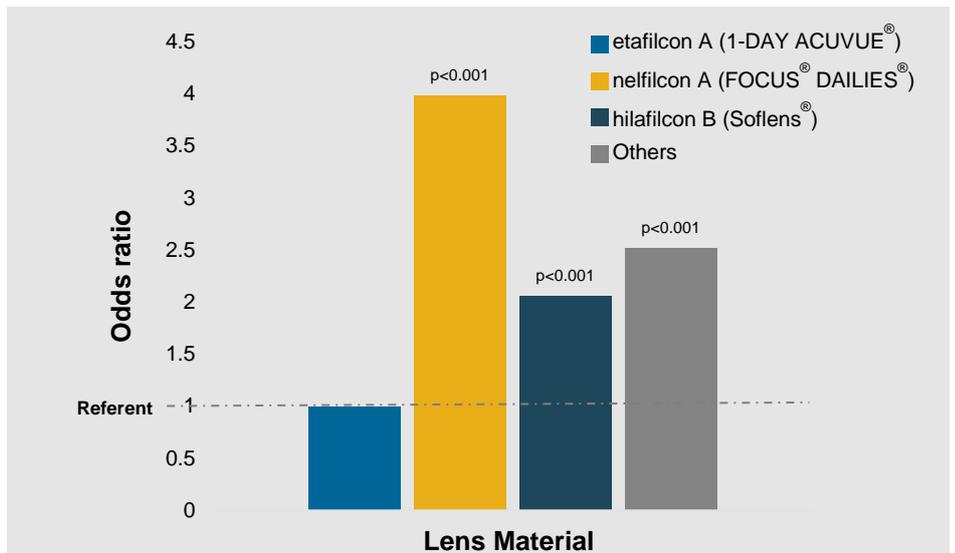


Figure 4. Additional risk factors for all presumed microbial keratitis identified by multiple logistic regression analysis²⁰

ocular allergy²⁴ compared to a new pair of their habitual reusable lenses.

The unique properties of etafilcon A contribute to patient comfort. LACREON® Technology permanently embeds a water-holding ingredient, and PVP enhances moisture retention and reduces friction.²⁵ For the 1-DAY ACUVUE® MOIST family, the highest concentrations of PVP are at the lens surfaces (within 10µm),²⁶ where the eye interacts with the lens and thereby benefits most. The result is a long-lasting 'cushion' of moisture from the core to the surface.

Etafilcon A also helps maintain lysozyme in its natural state, selectively and rapidly attracting a significant amount of enzyme. This has been shown *in vitro* to help maintain low levels of inflammatory biomarkers that can lead to irritation.^{27,28} Other attributes of the 1-DAY ACUVUE® MOIST family include low modulus, the INFINITY EDGE™ design and Class 2 UV-Blocking.

CONCLUSIONS



- Both SiHy and high-quality hydrogel contact lenses can provide adequate oxygen for healthy daily wear. Both materials will likely continue to play an important role in contemporary contact lens practice.
- Etafilcon A hydrogel DD lenses have an excellent record for comfortable, successful wear with an excellent safety profile. These lenses have minimal impact on ocular physiology and supply sufficient oxygen levels for open-eye daily wear. Many studies have now shown that these lenses are associated with low rates of CIEs, adverse events and infections.
- With evidence from recent studies – added to the unique material properties of etafilcon A – eye care practitioners can continue to recommend the 1-DAY ACUVUE® MOIST family to their patients with confidence.

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* **Class 2:** Must transmit less than 50% of UVA and 5% of UVB. UV-blocking percentages are based on an average across the wavelength spectrum. Helps protect against transmission of harmful UV radiation to the cornea and into the eye.

WARNING: UV-absorbing contact lenses are NOT substitutes for protective UV-absorbing eyewear such as UV-absorbing goggles or sunglasses, because they do not completely cover the eye and surrounding area. You should continue to use UV-absorbing eyewear as directed. **NOTE:** Long-term exposure to UV radiation is one of the risk factors associated with cataracts. Exposure is based on a number of factors such as environmental conditions (altitude, geography, cloud cover) and personal factors (extent and nature of outdoor activities). UV-blocking contact lenses help provide protection against harmful UV radiation. However, clinical studies have not been done to demonstrate that wearing UV-blocking contact lenses reduces the risk of developing cataracts or other eye disorders. Consult your eye care practitioner for more information.

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