2020 AND BEYOND:
are hydrogel daily disposables still relevant for contemporary contact lens practice?

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Introduction

With the growth in availability and use of silicone hydrogel (SiHy) materials over the last twenty years, are hydrogels still relevant for contemporary clinical practice? Euromonitor data confirms 32% of fits were into SiHy materials in the United States in 2018.[1] That still leaves a very significant proportion of fits involving hydrogel daily disposables (DDs). Those new and refits into hydrogel DDs add to the established widespread global use of this material, a fact illustrated by 1-DAY ACUVUE® MOIST remaining the number one selling DD contact lens (CL) brand in the world.‡

Factors contributing to successful contact lens wear

Comfort, vision and health are often used to describe the main areas of performance deemed most important in relation to achieving successful CL wear. Table 1 summarizes some perceptions that maybe held with regard to hydrogel DD lenses, along with published evidence of their clinical performance.

Comfort and vision

In terms of comfort and vision performance, evidence suggests that eye care professionals (ECPs) can continue to include 1-DAY ACUVUE® MOIST in their thinking when considering lens choice for their patients. In fact, in 13 clinical studies posted on www.clinicaltrials.gov, 1-DAY ACUVUE® MOIST Brand contact lenses have never been beaten in comfort in its category,† or in vision.§

Health: corneal oxygenation

There is considerable evidence that 1-DAY ACUVUE® MOIST, being a thin mid-water content lens, does not produce clinically significant levels of corneal edema. The work of Szczotka-Flynn,[5] assessed corneal responses during fitting of low to moderate myopes into one hydrogel (1-DAY ACUVUE® MOIST) and two common SiHy materials for daily wear. Central corneal thickness measurements were performed with a very precise optical low coherence reflectometry biometer at least 2 hours after waking and at the end of 6-8 hours of wear on day 1 and day 7 of each lens type. Statistically, non-inferiority of the hydrogel material was judged, with respect to the other two lens types, if the corneal swelling was within 1.5%. Knowing that the normal non-lens wearing cornea thins throughout the day, the study results were reassuring in that all three lens types demonstrated no impediment to this normal deswelling process. In particular, the hydrogel lens demonstrated about 0.3% deswelling which was within the non-inferiority margin of the two other silicone hydrogel lens types as seen in Figure 1. Additional work with 1-DAY ACUVUE® MOIST supports these findings showing central corneal edema clinically equivalent to no lens wear after 8 hours,[6] and central and peripheral swelling equivalent to SiHy wear after 6 hours. [7]

Peripheral hypoxic stress was quantified by assessing limbal hyperemia. Consistent with the corneal swelling data, limbal hyperemia with all lenses was negligible and non-inferiority assumptions were met between the hydrogel lens and the two other lens types.

While there might be concern that these results do not reflect the level of corneal edema after a full day's wear as the measurements were taken after 6-8 hours of wear, the benchmark work of Holden *et al* shows that when subjects are exposed to the levels of oxygen present (as under the contact lenses evaluated) corneal swelling peaks after 2 hours and plateaus thereafter.[18] Thus, the time period over which this investigation into corneal edema was carried out is more than sufficient.

Health: corneal infiltrative events

The TEMPO study measured the incidence of adverse events by post-market surveillance registry of wearers fitted with 1-DAY ACUVUE® MOIST.[11]

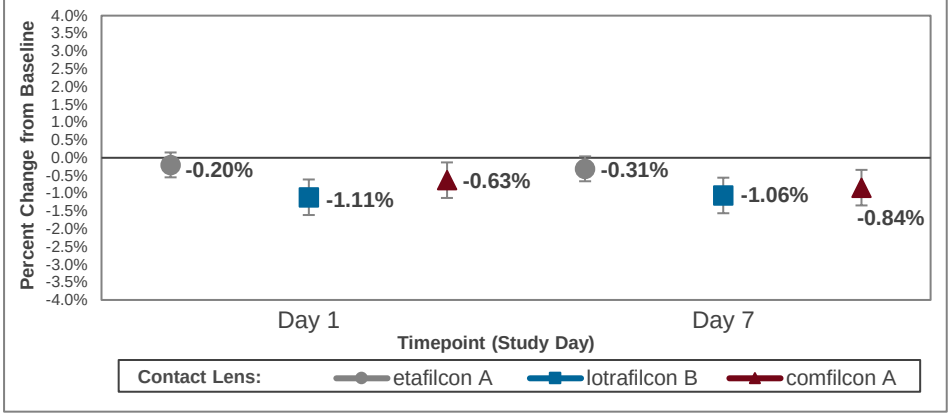
Table 1: Clinical performance of hydrogel lenses – separating fact from perceptions

Area of potential concern	Perception	Evidence
Comfort	SiHy DDs are always more comfortable than hydrogel DDs	Multiple studies show no clear evidence for this,[2-4] and one study shows a hydrogel DD CL more comfortable than some SiHy DDs.[4]
Corneal oxygenation	Unacceptable levels of corneal swelling in daily wear	Multiple recent investigations show clinically insignificant degrees of corneal edema in daily wear, both centrally and peripherally (maximum difference <1.5%) [5-7]
Limbal hyperemia	Marked ocular redness due to peripheral hypoxia	Multiple studies show either no or no clinically significant increase (<0.5 grade on 0-4 scale).[5,7-9]
Neo-vascularization in long-term wearers	A common issue indicating unhealthy CL wear	The authors have not seen any clinical evidence in over 30 years history of the use of mid-water content thin hydrogels. A recent study cited as evidence of an issue,[10] defines neo-vascularization as vessel extension of 0.5mm or more when 0.5mm is half of grade 1 (<1mm) on the Efron scale and rated as not clinically significant.
Safety	Hydrogel DD lenses are less safe than SiHy DDs, especially if wearer naps or wears overnight.	In major studies,[11,12] etafilcon A lenses (1-DAY ACUVUE® MOIST) were associated with no or minimal symptomatic corneal infiltrative events or other serious adverse events. No difference in MK rates between hydrogel and SiHy in daily wear or overnight wear.[13-16] In fact, etafilcon A shown to be associated with lower risk of MK than other materials.[17]

*Dr. Robin Chalmers is a paid consultant of Johnson & Johnson Vision Care, Inc.

‡JJV data on file 2019. Source: Euromonitor International Limited; based on research conducted in August 2019; "world" and "globally" represent markets accounting for 80.8% of total daily disposable contact lenses in 2018 (retail sales). Claim effective starting August 10th, 2019. † JJV data on file 2020. In 13 clinical studies posted on www.clinicaltrials.gov, 1-DAY ACUVUE® MOIST Brand FAMILY (spherical, astigmatism, and multifocal) contact lenses has never been beaten in comfort in its category. www.clinicaltrials.gov is a website maintained by the NIH. The 13 clinical studies evaluated subjective comfort as a primary or secondary endpoint for 1-DAY ACUVUE® MOIST Brand FAMILY contact lenses with LACREON® technology. Category is defined as hydrogel daily disposable contact lenses. Review conducted as of June 24, 2020. §JJV Data on file 2019. In 17 clinical studies posted on www.clinicaltrials.gov, 1-DAY ACUVUE® MOIST Brand FAMILY (spherical, astigmatism, and multifocal) Contact Lenses with LACREON® technology has never been beaten in vision. www.clinicaltrials.gov is a website maintained by the NIH. The 17 clinical studies evaluated objective and subjective vision as a primary or secondary endpoint for 1-DAY ACUVUE® MOIST Brand FAMILY Contact Lenses with LACREON® technology. Review conducted as of Aug 6, 2019.

Figure 1: Percentage change in corneal thickness from baseline following 6-8 hours wear of hydrogel and SiHy lenses[6]



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 (0.0%/year) and only three non-serious events (0.6%/year).^

Additional analysis of the TEMPO study has since explored the influence of age on performance outcomes.[19] 86 wearers aged over 40 completed the registry, with 76% new to DDs and 8% new to CLs completely. Existing CL wearers older than 40 years experienced many benefits from being refitted with 1-DAY ACUVUE® MOIST. Changing to the hydrogel DD significantly improved their overall opinion of CLs, improved dry eye symptoms as quantified by the CLDEQ-8 questionnaire,[20] and maintained average and comfortable wear time. When the younger age of the sample was analyzed using data from subjects less than 18 years old, 1-DAY ACUVUE® MOIST was the only CL to have shown zero symptomatic events in teens in this 1-year observational study.[21]

Conclusion

1-DAY ACUVUE® MOIST remains the number 1 selling DD CL brand in the world,‡ and for good reason. They have an excellent safety profile,[11] are the only DD lenses shown to have zero adverse events in teenagers in the year long TEMPO study,[21] are unbeaten in comfort in their category,† as well as unbeaten in vision,§ offer a full family of lenses to satisfy most patients' needs, and create clinically insignificant corneal edema and hyperemia during daily wear.[5-9]

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IMPORTANT SAFETY INFORMATION.
ACUVUE® Brand Contact Lenses are indicated for vision correction. As with any contact lens, eye problems, including corneal ulcers, can develop. Some wearers may experience mild irritation, itching or discomfort. Lenses should not be prescribed if patients have any eye infection, or experience eye discomfort, excessive tearing, vision changes, redness or other eye problems. Consult the package insert for complete information. Complete information is also available from Johnson & Johnson Vision Care, Inc., by calling 1-800-843-2020, or by visiting www.jnjvisionpro.com.

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^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 1-DAY ACUVUE® MOIST, 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.

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