DAILIES TOTAL1® (delefilcon A) Daily Disposable Contact Lenses

Clinical Science Compendium

Summaries of Peer-Reviewed Clinical Research

Medical Affairs North America

Alcon

INTRODUCTION

At Alcon, our vision care medical device products, such as DAILIES TOTAL1® one-day contact lenses, are designed, manufactured and marketed with a body of science developed through rigorous bench research and clinical studies. As the body of knowledge behind Alcon's products grows, so does the challenge of making our customers aware of its depth. Our medical affairs organization is thus focused on both high-quality data generation and its communication to the clinical community.

High-quality scientific publications are essential to convey the clinical community's knowledge and experience with technology. This clinical science compendium provides a consolidated view of peer-reviewed publications for DAILIES TOTAL1® (delefilcon A) one-day contact lenses.

In addition to exploring this compendium, we encourage you to visit Alcon's Medical Affairs website — AlconScience.com — to learn more about how medical science matters to us. Beyond scientific publications relating to Alcon's portfolio, you will find more information on independent medical education grants, teaching facility equipment placement, and areas of interest for investigator-initiated trials.

METHODOLOGY

The 60 articles summarized in this compendium were identified using the PubMed and Google Scholar databases incorporating the search terms "Dailies Total1®", "delefilcon a", "water gradient contact lens", "Phospholipid in Silicone Hydrogel Contact Lenses" and "water gradient silicone hydrogel." Articles were included when they were published between January 1, 2016 and July 31, 2020 and contained bench and/or clinical research relevant to DAILIES TOTAL1® (delefilcon A) one-day contact lenses and their indicated use in the United States. Only manuscripts published in peer-reviewed journals and available in English were included in this compendium.

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Bench and Clinical Studies

Literature Review

Loading and Release of a Phospholipid from Contact Lenses*

Pitt et al. *Optom Vis Sci.* 2011;88:502-506

OVERVIEW

STUDY DESIGN
Experimental trial to verify that 1,2-dimyristoyl-sn-glycero-3-phosphocholine (DPMC) can be loaded into silicone hydrogel contact lenses and released over time into artificial tear fluid (ATF)

STUDY SITE(S)
Two research centers in the United States

PATIENTS
Not applicable

METHODOLOGY
Lenses were loaded with radiolabeled DMPC. Absorption and elution rate in ATF (n=8) and deionized water (n=4) was assessed at 0, 2, 4, 10, 24, 48 and 72 hours. Lens modulus was measured as stress versus strain in a 2.90 mm wide strip from lens center. Light transmission (610 nm) was used to measure lens visual clarity. Water content was calculated as (hydrated weight – dry weight)/(hydrated weight) x 100%. Wettability was assessed by underwater contact angles of air and octane

LENS TYPE(S)
Silicon hydrogel contact lenses (Alcon/CIBA VISION)

KEY ENDPOINT(S)
DMPC concentration, lens clarity, moduli and water content after contact lens loading; elution in ATF and deionized water

ANALYSIS AND CONCLUSIONS

DMPC can be loaded into silicone hydrogel contact lenses without adversely affecting clarity, surface wettability or modulus. Elution of DMPC was 5 times greater in ATF than in water.

These results support the potential for designing a therapeutic contact lens that can help relieve dry eye syndrome and contact lens-related dry eye.

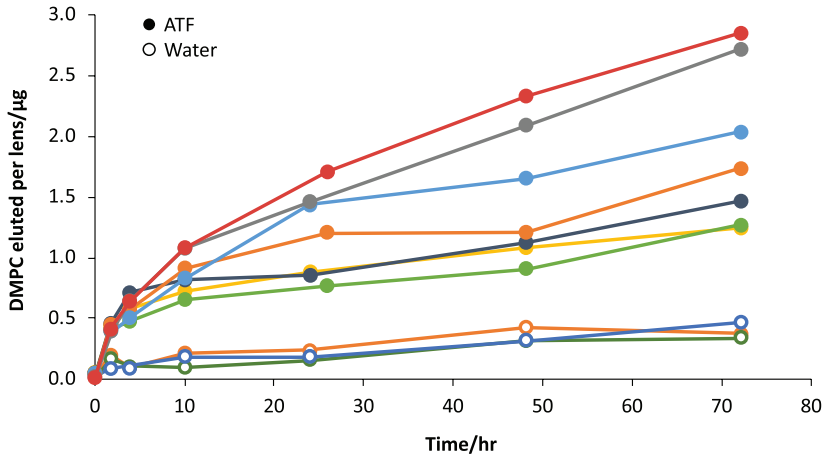
*This study was financially supported by Ciba Vision

STUDY RESULTS

DMPC LOADING, ELUTION, AND LENS PROPERTIES

- Loading lenses with an average (85% CI) of 32.9 ± 0.5 µg/lens did not change its mean water content (33.2 ± 0.6 and 33.2 ± 0.7 for virgin and loaded lenses, respectively)
- There was no statistically significant difference in contact angles of air (40.3 ± 1.4 and 41.7 ± 2.1 for virgin and loaded lenses, respectively) or octane (38.7 ± 1.2 and 38.0 ± 1.7) through the water phase (P>0.2)
- There was no significant difference in light transmission before (95.74 ± 0.21%) and after (95.89 ± 0.19%) loading
- The average lens modulus was 0.71 ± 0.03 MPa before loading and 0.70 ± 0.02 after loading
- DMPC elution into ATF was greater and more variable than into water (**Figure 1**); the mean ± SEM ratio of elution in ATF to water was 4.7 ± 0.7

Figure 1. Elution of 1,2-dimyristoyl-sn-glycero-3-phosphocholine (DPMC) into artificial tear fluid (ATF) and deionized water. Lines are guides to indicate individual lenses.



Transport of Phospholipid in Silicone Hydrogel Contact Lenses*

Pitt et al. *J Biomater Sci Polym Ed.* 2012;23:527-541

OVERVIEW

STUDY DESIGN
Experimental trial to characterize the loading and release of 1,2-dimyristoyl-sn-glycero-3-phosphocholine (DMPC) from a daily silicon hydrogel lens into artificial tear fluid (ATF) of varying phospholipid composition

STUDY SITE(S)
Two research centers in the United States

PATIENTS
Not applicable

METHODOLOGY
Lenses were loaded with radiolabeled DMPC. Absorption and elution in ATF with and without phospholipids was assessed at 0, 2, 4, 10, 24, 48 and 72 hours. Lens modulus was measured as stress versus strain in a 2.90 mm wide strip from lens center. Light transmission (610 nm) was used to measure visual clarity. Water content was calculated as (hydrated weight – dry weight)/(hydrated weight) x 100%.

LENS TYPE(S)
Experimental silicon hydrogel daily wear lenses (Alcon/CIBA VISION)

KEY ENDPOINT(S)
DMPC concentration, lens clarity, moduli and water content after contact lens loading; elution in ATF with and without phospholipids

ANALYSIS AND CONCLUSIONS

This experimental single use silicone hydrogel contact lens can absorb and deliver a phospholipid (DMPC) without changing the modulus or decreasing the clarity and wettability of the lens.

The authors propose that the results support designing a contact lens that could deliver phospholipids over several hours and thus provide relief for eye irritation associated with lack of phospholipids in tears.

*This study was financially supported by Ciba Vision.

STUDY RESULTS

DMPC LOADING AND OPTICAL CLARITY

- Amount of DMPC loaded onto the lenses was a function of the immersion time in a 0.15% DMPC solution; mean average mass values at 30, 60 and 120 seconds of sorption were 23.7, 33.7 and 55.2 µg/lens, respectively
- Addition of up to 55 µg of DMPC per lens did not significantly change the optical clarity (P>0.05); the average moduli of the lenses were not significantly different at the various loading levels (P>0.05)

LENS WETTABILITY AND DMPC ELUTION

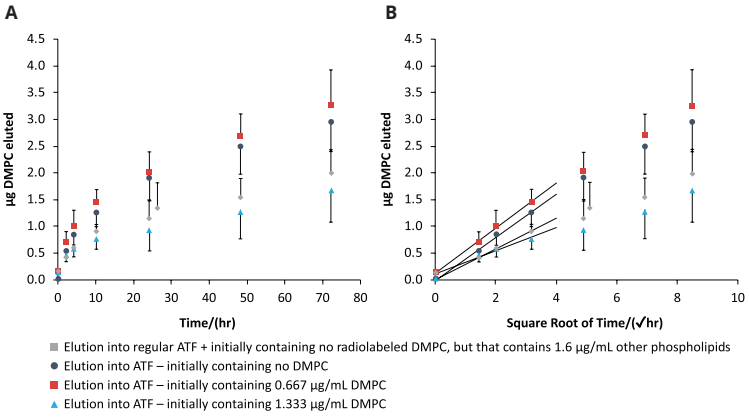
- Although there were some differences in the contact angles with increasing DMPC, the polar components of surface energy remained high and dispersive components remained low (indicating excellent wettability); there was no trend toward decreasing wettability with increased loading; water content (mean ± standard deviation) of lenses did not differ before (33.2 ± 0.6 %) and after (33.2 ± 0.7%) loading for 60 seconds
- Lenses loaded with more DMPC had greater elution into phospholipid-containing ATF: elution of lenses loaded for 120 seconds was significantly greater than that of the other 2 loadings (P>0.05); elution rate was consistent with a diffusion-controlled process (**Figure 1**)

Table 1. Properties of 1,2-dimyristoyl-sn-glycero-3-phosphocholine (DMPC)-loaded contact lenses.

Loading time (s)	Amount DMPC loaded (µg	Light transmission (%)*	Modulus (MPa)†	Contact angle (°C)‡		γd (dyn/cm)	γd (dyn/cm)
				Air	Octane		
0	0	95.74± 0.21	0.71± 0.03	40.3± 1.4	38.7± 1.2	6.3	38.2
30	23.7	95.82± 0.26	0.71± 0.03	42.2± 1.7	38.3± 2.0	5.6	38.5
60	33.7	95.89± 0.19	0.71± 0.02	41.7± 2.1	38.0± 1.7	5.7	38.6
120	55.2	95.79± 0.28	0.71± 0.03	44.3± 1.2	36.7± 1.2	4.6	39.4

** Mean ± standard deviation, n=20*
† Mean ± standard deviation, n=10
‡ Mean ± 95% confidence interval, n>6

Figure 1. Elution of DMPC from lenses into artificial tear fluid (ATF) preloaded with various amounts of 1,2-dimyristoyl-sn-glycero-3-phosphocholine (DMPC). (**A**) Elution vs time. (**B**) Elution vs the square root of time. Error bars represent the magnitude of the 95% confidence intervals (n=4).



In Vitro Power Profiles of Daily Disposable Contact Lenses

Belda-Salmerón et al. *Cont Lens Anterior Eye.* 2013; 36:247-252

OVERVIEW

STUDY DESIGN
Experimental trial to evaluate and compare the distribution of refractive power within the optic zone of different soft contact lenses (CLs) and to investigate the effect of lens decentration on the power profiles

STUDY SITE(S)
Single site in Spain

PATIENTS
Not applicable

METHODOLOGY
Optical power across different aperture diameters of four daily disposable CLs was measured by the Nimo TR1504 instrument. Power data were evaluated when CLs were in centered position and after inducing different amounts of lens decentration

LENS TYPE(S)
DAILIES TOTAL1®; Proclear® 1 day (CooperVision, Inc.); SofLens® daily disposable (Bausch & Lomb); 1-DAY ACUVUE® MOIST® (Johnson & Johnson Vision Care)

KEY ENDPOINT(S)
Refractive power; decentration

ANALYSIS AND CONCLUSIONS

An increase in the refractive power from the lens center toward the periphery with a negligible effect of the decentration was found for all disposable contact lenses studied. Knowledge of power maps allows us to compare differences in the power profiles of contact lenses.

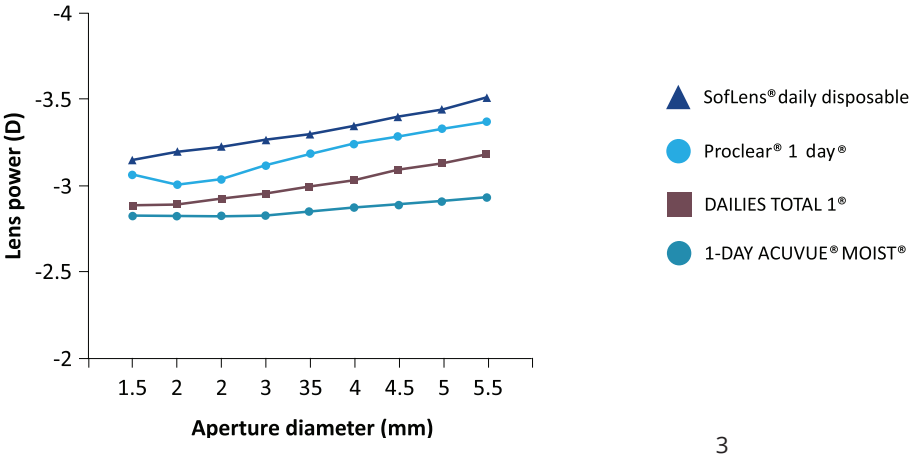
Power profiles may be considered as an essential clinical tool for eye care practitioners to use to select appropriate contact lenses for their patients, as it is based on an understanding of the patients lifestyle and day to day visual tasks, particularly when performed in night lighting conditions.

STUDY RESULTS

POWER PROFILES

- Power profiles for the four daily disposable CLs shows three different behaviors of the CLs tested (**Figure 1**)
  - SofLens® daily disposable and Proclear® 1 day showed over-powered (more negative) outcomes compared to the lens power value on the label for all range of apertures
  - 1-DAY ACUVUE® MOIST® presented slightly under-powered (less negative) values of the labeled power at all points within the optic zone
  - DAILIES TOTAL1® power profile was characterized by under-powered values at small aperture sizes, over-powered values at large apertures, and the designated refraction (-3.00 D) at an aperture diameter of approximately 3.5 mm

Figure 1. Power profiles for the four daily disposable contact lenses (CLs) of -3.00 D used in the study. Each data point represents the mean power value of the three individual CLs measured to characterize each lens type.



EFFECTS OF DECENTRATION

- Study results showed the power curves for the four CLs were somewhat shifted in the negative direction with the increase in decentration
- The clinical effect of decentration does not modify significantly the outcomes reported and no visual change is expected to happen when fitted

Lubricity of Surface Hydrogel Layers*

Dunn et al. *Tribol Lett.* 2013;49:371-378

OVERVIEW

STUDY DESIGN
Experimental study to assess the elastic modulus and deformation behavior of soft surface hydrogel layers

STUDY SITE(S)
Single research center in the United States

PATIENTS
Not applicable

METHODOLOGY
Nanoindentation measurements were made using atomic force microscopy (AFM). Lubricity was measured by a microtribometer (NTR II, CSM Instruments)

LENS TYPE(S)
DAILIES TOTAL1® (delefilcon A)

KEY ENDPOINT(S)
Elastic modulus, deformation behavior, and lubricity

ANALYSIS AND CONCLUSIONS

Nanoindentation measurements revealed an exceedingly soft elastic modulus of ≈25 kPa. Microtribological experiments at low contact pressures (6-30kPa) and at slow sliding speeds (5-200 µm/s) gave average friction coefficients below µ=0.02. At higher contact pressures, friction loops showed a pronounced stick-slip behavior with breakloose or static friction coefficient above µ = 0.5.

The ability of the soft surface hydrogel layers to provide lubricity is dependent on their ability to support the applied pressure without dehydrating. These transitions were found to be reversible and experiments with different radii probes revealed that the transition pressures were on the order of 10-20 kPa.

*This study was financially supported by Alcon.

STUDY RESULTS

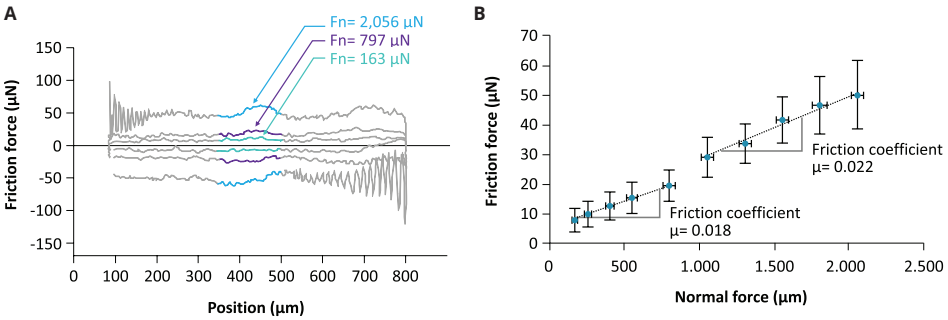
LENS MODULUS

- For colloidal probe indentation depths with the first 200 nm of the surface, an exceedingly low modulus of 0.025 ± 0.007 MPa was fit based on Hertzian contact theory

LENS LUBRICITY

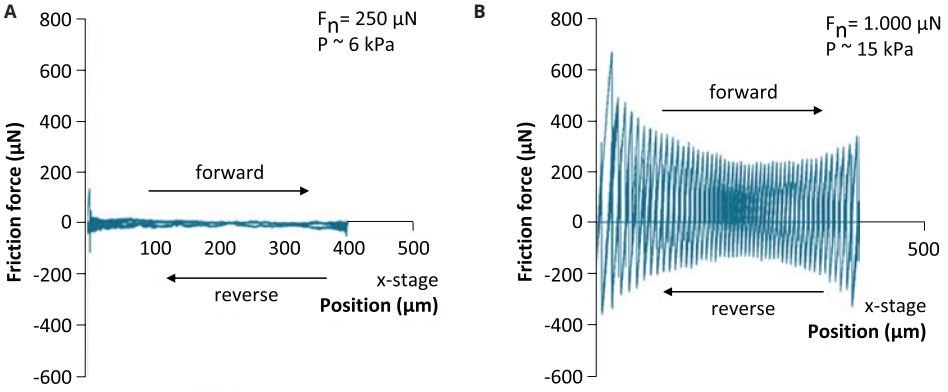
- Friction loops at loads of 163, 797, and 2,056 µN showed that the friction coefficients were on the order of µ=0.02 during the central, free sliding portion of the experiment (**Figure 1A**); at the applied load of 2,056 µN, significant stick-slip behavior was clearly identified during motions initiated at the reversal locations
- The critical transition pressure for the onset of stick-slip motion was determined by systematically increasing the normal force until the friction force response following reversal points changed from smooth sliding to a stick-slip regime
  - For the 1.59-mm radius probe, this was at a critical load of ~1,000 µN (**Figure 1B**); the friction coefficient and associated uncertainties changed from µ = 0.018 ± 0.006 below a normal force of 1,000 lN to µ = 0.022 ± 0.007 above that load; this change in friction response, along with the appearance of stick-slip behavior, indicates two different friction mechanisms in those pressure ranges
- The mechanism underlying the stick-slip behavior is hypothesized to be the result of local contact pressures collapsing the soft surface hydrogel layer and forcing water squeeze-out (**Figure 2**)

Figure 1. (A) Friction loops at loads of 163, 797, and 2056 µN. **(B)** Plot of average friction force and normal force along with associated experimental uncertainties.[1] Slopes, which give characteristic friction coefficients for the low- and high-pressure regimes, are not particularly different within the central 20% of the friction loops as in **(A)**, but are separated based on the observation of persistent stick–slip motions in the reversals.



[1] *Schmitz TL et al. The Difficulty of Measuring Low Friction: Uncertainty Analysis for Friction Coefficient Measurements. J Tribol-T Asme. 2005;127:673-678.*

Figure 2. Friction loops and a hypothesis for the transition in friction behavior. All experiments were performed with a cantilever of 82.65 µN/µm stiffness in the friction direction and 138.6 µN/µm in the normal load direction. **(A)** Friction loop at an applied load of 250 µN shows smooth and very low friction forces. **(B)** Friction loop at an applied load of 1,000 µN reveals significant stick-slip behavior with breakloose friction coefficients on the order of µ=0.6.



Release of Ciprofloxacin and Moxifloxacin From Daily Disposable Contact Lenses From an *In Vitro* Eye Model

Bajgrowicz et al. *Invest Ophthalmol Vis Sci.* 2015; 56:2234-2242

OVERVIEW

STUDY DESIGN
Prospective, open-label study to analyze the release of two fluoroquinolones, ciprofloxacin and moxifloxacin, from conventional hydrogel (CH) and silicone hydrogel (SH) daily disposable contact lenses (CLs)

STUDY SITE(S)
Single site in Canada

PATIENTS
Not applicable, novel *in vitro* eye model

METHODOLOGY
Four (4) CH CLs and three SH CLs incubated in drug solutions for 24 hours, then placed in two release conditions: 1) 4.8 mL phosphate-buffered saline (PBS) vial for 24 hours and 2) *in vitro* eye model with a 4.8 mL flow rate over 24 hours

LENS TYPE(S)
CH CLs [DAILIES® AquaComfort Plus® (nelfilcon A); Proclear® 1 day (omafilcon A; CooperVision, Inc.); 1-DAY ACUVUE® MOIST® (etafilcon A; Johnson & Johnson Vision Care); Biomedics® 1-Day (ocufilcon B; CooperVision, Inc.)]; SH CLs [clariti® 1 day (somofilcon A; CooperVision, Inc.),1-DAY ACUVUE® TruEye® (narafilcon A; Johnson & Johnson Vision Care); DAILIES TOTAL1® (delefilcon A)]

KEY ENDPOINT(S)
Drug release profiles–volume and flow rates; release kinetics

ANALYSIS AND CONCLUSIONS

In a vial, drugs were released rapidly within the first hour. In an *in vitro* eye model that mimics physiological tear volume and flow, drug release from contact lenses was observed at a more constant rate over 24 hours.

Parameters of the release system, the volume and flow rate, have a significant influence on measured release profiles. Under physiological flow, release profiles are significantly slower and constant when compared with release in a vial.

STUDY RESULTS

DRUG RELEASE PROFILE

- Both drugs showed significant differences in the total drug released after 24 hours from the vial compared to the model eye (P<0.001). Release profiles are shown in **Figures 1** and **2.**
- Measurements using either the vial or model eye showed hydroxyethyl methacrylate (HEMA)- based CH lenses released significantly more ciprofloxacin and moxifloxacin compared with SH lenses (P<0.001)
- Both experimental systems showed the materials that released the highest amounts of moxifloxacin were etafilcon A and ocufilcon B followed by omafilcon A
- Materials that released the lowest amount of drug in both systems were nelfilcon A, and all SH lenses
- All lenses containing moxifloxacin remained visually clear throughout all phases of the experiment

DRUG RELEASE KINETICS

- In a large volume vial there were no significant differences in the release between the drugs with both being released rapidly within the first hour
- In the *in vitro* eye model ciprofloxacin had low aqueous solubility and was released at a slow and sustained rate for all lens types over 24 hours. Moxifloxacin had higher solubility, therefore showed a faster drug release
- Ciprofloxacin and moxifloxacin showed the best release profile with CH HEMA-based lenses, however with ciprofloxacin, white drug precipitates formed on the surface of the lenses during the release phase, rendering them opaque
- The SH lenses, although releasing a lower quantity of the drug, appeared to be more suitable for ciprofloxacin, providing sustained release for 24 hours while remaining transparent

Figure 1. Release of ciprofloxacin in PBS vial (**A**) and eye model (**B**).

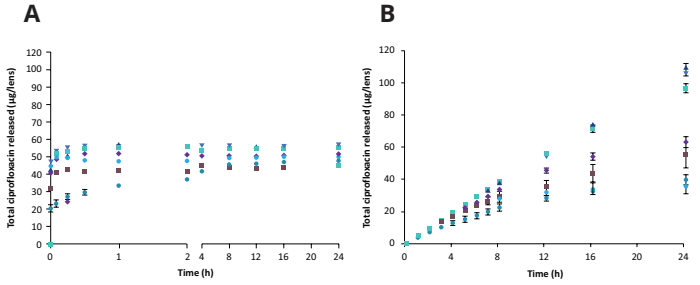
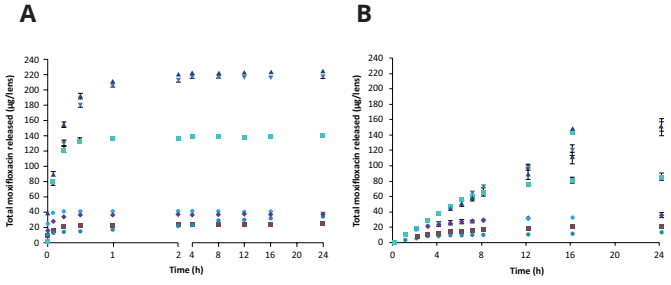


Figure 2. Release of moxifloxacin in PBS vial (**A**) and eye model (**B**).



DAILIES TOTAL1® (delefilcon A) · Biomedics® 1-Day (ocufilcon B) · clariti® 1 day (somofilcon A) · DAILIES® AquaComfort Plus® (nelfilcon A)
Proclear® 1 day (omafilcon A) · 1-DAY ACUVUE® MOIST® (etafilcon A) · 1-DAY ACUVUE® TruEye® (narafilcon A)

Fluorescent Solute-Partitioning Characterization of Layered Soft Contact Lenses

Dursch et al. *Acta Biomaterialia.* 2015; 15:48-54

OVERVIEW

STUDY DESIGN
Experimental study to determine partitioning of aqueous packaging, wetting, and care-solution agents into and out of soft contact lenses (SCLs)

STUDY SITE(S)
Two research centers in the United States

PATIENTS
Not applicable

METHODOLOGY
Two-photon fluorescence confocal laser-scanning microscopy (FCLSM) obtained profiles and partition coefficients of six prototypical fluorescent solutes, and attenuated total-reflectance Fourier-transform infrared spectroscopy (ATR-FTIR) validated the surface water content of DAILIES TOTAL1® lenses. To establish surface-layer charge, partition coefficients and water contents are obtained for aqueous pH values of 4 and 7.4

LENS TYPE(S)
Silicone hydrogel (SiHy) DAILIES TOTAL1® (delefilcon A); SiHy-core O_2OPTIX™ (lotrafilcon B)

KEY ENDPOINT(S)
Uptake profiles and partition coefficients of fluorescent solutes and water content of SCLs

ANALYSIS AND CONCLUSIONS

This study confirmed the layered structure of the DAILIES TOTAL1® lens, consisting of a hydrophilic surface-gel layers of water content near 82% compared with 33% for the SiHy core.

Fluorescent-solute partitioning in soft contact lenses provides information on gel structure and composition, in addition to quantifying uptake and release amounts and rates.

STUDY RESULTS

LENS COMPOSITION

- For the SiHy core of the two lenses, water content did not vary over the range of pH studied
- For the DAILIES TOTAL1® surface layers, water content rose significantly with increased aqueous pH (63% to 82%), indicating a polyelectrolyte gel
- The DAILIES TOTAL1® surface-layer water content was significantly higher than that of the SiHy core, with core gravimetric water content identical to that of O_2OPTIX™
- Fluorescence-confocal-microscopy imaging revealed the layered structure of DAILIES TOTAL1® lenses, with uptake of FITC-dextran4 in the surface-gel layers clearly greater than that in the SiHy core, whereas uptake in O_2OPTIX™ lenses was spatially uniform (**Figure 1**)
- At pH 7.4 (**Figure 2**), DAILIES TOTAL1® lens core partition coefficients were similar to those of the O_2OPTIX™ lens, indicating that the chemical and physical structures of the core of the 2 lenses are similar and confirming the SiHy structure of the DAILIES TOTAL1® core
- In the DAILIES TOTAL1® lens core and O_2OPTIX™ lens, partition coefficients for the positively charged protein FITC-avidin were larger than those of similar-sized FITC-dextran20, but in the DAILIES TOTAL1® surface layer, FITC-avidin partition coefficients were nearly 30 times larger than for FITC-dextran20
- Thus, the surface-gel layers of DAILIES TOTAL1® lenses are anionic, whereas the SiHy cores of both lenses are nonionic at physiological pH
- Both oleophilic solutes exhibited greater-than-unity partition coefficients in the SiHy cores of both lenses, presumably because of strong specific adsorption to silicone moieties

Figure 1. Fluorescence-confocal-microscopy images of fluorescein isothiocyanate (FITC)-dextran4 at equilibrium, (**A**) DAILIES TOTAL1® and (**B**) O_2OPTIX™ lenses.

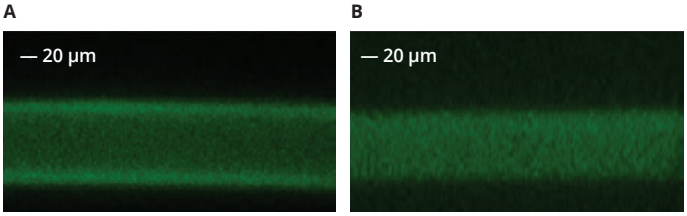
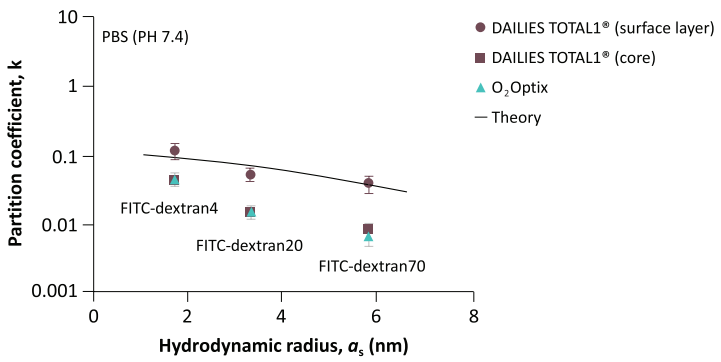


Figure 2. Hydrophilic solute partition coefficients k as a function of hydrodynamic radius as at pH 7.4 for fluorescein isothiocyanate (FITC)-dextran4, FITC-dextran20 and FITC-dextran70 in DAILIES TOTAL1® and O_2OPTIX™lenses.



Extended Elution of Phospholipid from Silicone Hydrogel Contact Lenses*

Pitt et al. *J Biomater Sci Polym Ed.* 2015;26:224-234

OVERVIEW

STUDY DESIGN
Experimental trial to characterize the release of 1,2-dimyristoyl-sn-glycero-3-phosphocholine (DMPC) from a reusable (30-day) lens and the impact on visual clarity

STUDY SITE(S)
Two research centers in the United States

PATIENTS
Not applicable

METHODOLOGY
Lenses were loaded with radiolabeled DMPC and elution rate was assessed in a simulation of 16 hours of wear and 8 hours of cleaning for 30 days

LENS TYPE(S)
Experimental delefilcon 30-day lenses (Alcon/CIBA VISION)

KEY ENDPOINT(S)
DMPC elution after every 16-hour artificial tear fluid and 8-hour cleaning period (Clear Care®, ReNu®, RepleniSH®); lens clarity was quantified as the light transmission at 610 nm

ANALYSIS AND CONCLUSIONS

DMPC elution rates appeared to be a function of the cleaning solution used, with ReNu® and Clear Care® solutions resulting in low amounts of elution and RepleniSH® resulting in much greater elution rates.

There was no visible change in lens clarity after loading DMPC. Additional studies are needed to determine whether the amount of phospholipid release is sufficient to provide ocular comfort.

*This study was financially supported by Ciba Vision.

STUDY RESULTS

DMPC ELUTION

- Loading of 200 µg of radiolabeled DMPC onto lenses resulted in no visible impact in clarity as evidenced by no change in light transmission at 610 nm
- After an initial high elution observed on day 1, the amount of DMPC eluted into artificial tear fluid (16 hour period) was significantly (P>0.05) lower on subsequent days and appeared to be a function of the cleaning system used
- On days 2 through 15, lenses in ReNu®, Clear Care® and RepleniSH® had 16 hour elution means of 1.98, 2.36 and 3.58 µg/lens, respectively; on days 16 through 30 mean elution rates slowed to 1.40, 1.57 and 2.42 µg/lens, respectively (**Figure 1**)
- Nearly half of the DMPC loaded into the lenses was eluted into the artificial tear fluid when the lenses were soaked in RepleniSH®; the mean ± SD cumulative 30-day elution during the 16 hour artificial tear fluid period was 96 ± 6 µg for RepleniSH® compared with 57 ± 8 µg and 67 ± 5 µg for ReNu® and Clear Care®, respectively
- Similarly, mean ± SD elution rates during the 8 hour cleaning period were lowest in ReNu® and Clear Care® solutions (0.053± 0.031 and 0.031 ± 0.016 µg/lens, respectively) compared with RepleniSH® (0.365 ± 0.195 µg/lens) (**Figure 2**)
- Data indicate a fairly constant DMPC release for all 3 cleaning systems; from day 4 to 30, the cumulative release was statistically greater from lenses soaked in RepleniSH® than from those cleaned in the other solutions

Figure 1. Mean mass of 1,2-dimyristoyl-sn-glycero-3-phosphocholine (DMPC) eluted per 16 hour period in artificial tear fluid.

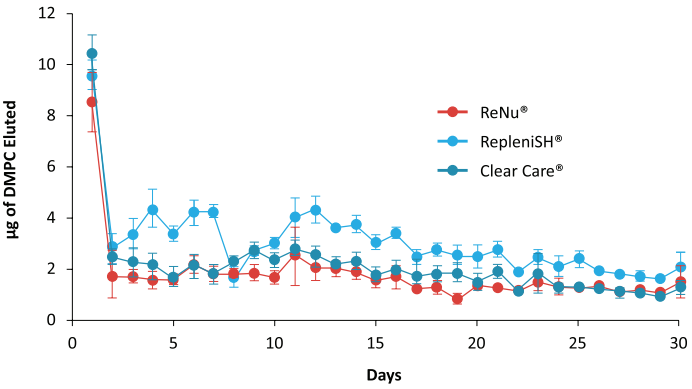
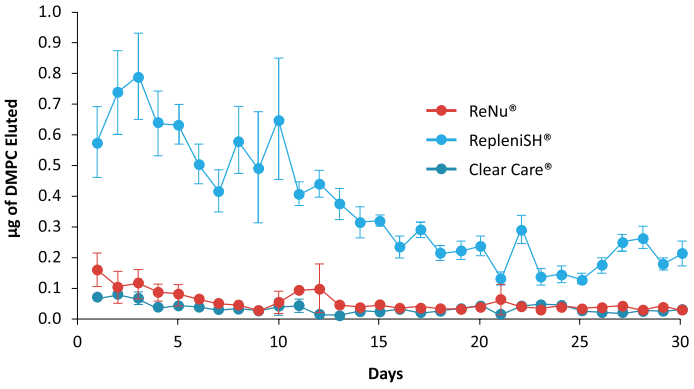


Figure 2. Mean mass of 1,2-dimyristoyl-sn-glycero-3-phosphocholine (DMPC) eluted per 8 hour period in a cleaning solution.



In Vitro Friction Testing of Contact Lenses and Human Ocular Tissues: Effect of Proteoglycan 4 (PRG4)

Samsom et al. *Tribology International* 2015; 9:27-33

OVERVIEW

STUDY DESIGN
Experimental trial to measure the friction of commercially available silicone hydrogel (SiHy) contact lenses (CL) against human cornea and eyelid tissues, and evaluate the ability of proteoglycan 4 (PRG4) to lubricate, and adhere to, SiHy CL

STUDY SITE(S)
Single site in Canada

PATIENTS
Not applicable

METHODOLOGY
Human corneas (age: 45-79); human eyelids (age: 80-91). *In vitro* ocular friction tests were used to evaluate the boundary mode friction of CL and friction-reducing ability of PRG4

LENS TYPE(S)
Two-week SiHy: ACUVUE® OASYS® (senofilcon A; Johnson & Johnson Vision Care). Daily disposable SiHy: DAILIES TOTAL1® (delefilcon A), 1-DAY ACUVUE® TruEye® (narafilcon A; Johnson & Johnson Vision Care)

KEY ENDPOINT(S)
In vitro friction measurements ($\mu_{static, Neq}$) and [$\mu_{kinetic}$]; Western blot PRG4 sorption assay

ANALYSIS AND CONCLUSIONS

The *in vitro* friction test employed in this study effectively measured and distinguished the SiHy contact lens friction coefficients against human eyelid and cornea tissues, and PRG4 functioned as an effective boundary lubricant.

The methods and results of this study provide the framework for future development and assessment of novel low friction contact lens materials and lubricants.

STUDY RESULTS

WEEKLY SIHY CONTACT LENSES

- PRG4 reduced friction on the senofilcon A 2-week SiHy CL; values of $\mu_{static, Neq}$ on both eyelid and cornea were significantly affected by velocity (eyelid: P<0.001; cornea: P<0.001) and PRG4 (eyelid: P<0.001; cornea: P<0.05), with significant interaction (eyelid: P<0.223; cornea: P=0.925)
- $\mu_{static, Neq}$ increased significantly (P<0.05) with increasing effective sliding velocity and PRG4 reduced friction compared to saline at all velocities
- Values of [$\mu_{kinetic}$] remained relatively constant with increasing effective sliding velocity and PRG4 reduced friction compared to saline at all velocities
- PRG4 significantly reduced friction for senofilcon A lenses against both cornea and eyelid tissues

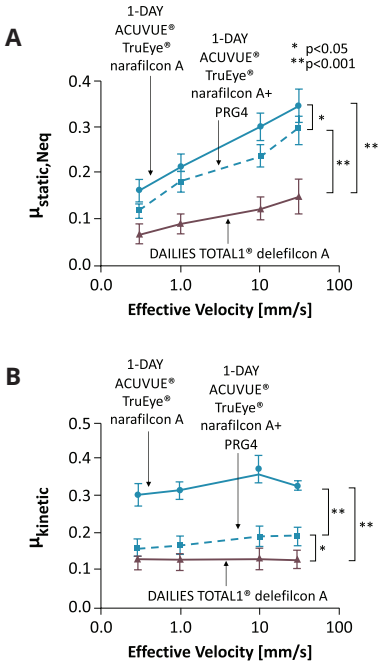
DAILY DISPOSABLE SIHY CONTACT LENSES

- The friction of narafilcon A daily disposable SiHy CL articulated against cornea was higher compared to delefilcon A CL, but could be reduced with PRG4 in solution
- Values of $\mu_{static, Neq}$ were significantly affected by velocity (P<0.001) and lens/lubricant (P<0.001), with no interaction effect (P=0.665)
- $\mu_{static, Neq}$ increased with increasing effective sliding velocity
- PRG4 significantly reduced $\mu_{static, Neq}$ compared to saline for narafilcon A (P<0.05); delefilcon A CL had significantly lower $\mu_{static, Neq}$ than both narafilcon A (P<0.001) and narafilcon A + PRG4 (P<0.001) (**Figure 1**)
- Values of [$\mu_{kinetic}$] were significantly affected by lens/lubricant (P<0.001). PRG4 significantly reduced [$\mu_{kinetic}$] for narafilcon A (P<0.001) and narafilcon A + PRG4 (P<0.05) (**Figure 1**)
- PRG4 reduced friction for the narafilcon A SiHy CL but did not reach the low friction values of the delefilcon A CL alone

WESTERN BLOT PRG4 SORPTION ASSAY

- The Western blot sorption assay results indicated that PRG4 can passively adsorb onto/into SiHy materials, and persist after 3 washes with saline, which is necessary for its ability to function as a boundary lubricant on these materials

Figure 1. Effect of proteoglycan 4 (PRG4) on boundary lubrication at a human cornea-narafilcon A and cornea-delefilcon A biointerfaces. Static (**A**) and kinetic (**B**) friction coefficients in baths of saline and PRG4 at 300 µg/mL in saline for narafilcon A and in a saline bath for delefilcon A.



Evaluation of Surface Water Characteristics of Novel Daily Disposable Contact Lens Materials, Using Refractive Index Shifts After Wear

Schafer et al. *Clin Ophthalmol*. 2015;9:1973-1979

OVERVIEW

STUDY DESIGN
Experimental study to compare surface water characteristics of nesofilcon A (78% water content) and delefilcon A (≥ 80% surface water content; 33% bulk water content) high surface water lenses with etafilcon A (58% water content) lenses before and after 15 minutes of wear

STUDY SITE(S)
Two sites in the United States

PATIENTS
Twenty (20) healthy volunteers

METHODOLOGY
Subjects wore each of the 3 lens types studied in a randomly determined order for 15 minutes. After each wearing, lenses were removed and the surface refractive index (RI) of each lens was immediately measured

LENS TYPE(S)
1-DAY ACUVUE® MOIST® (Johnson & Johnson Vision Care), Biotrue® ONEday (nesofilcon A; Bausch & Lomb), and DAILIES TOTAL1® (delefilcon A)

KEY ENDPOINT(S)
RI of each lens before and after wear

ANALYSIS AND CONCLUSIONS

The surface of the delefilcon A lens quickly dehydrates to behave like its low-water silicone-hydrogel bulk material with respect to surface water content during wear, while both nesofilcon A and etafilcon A lenses maintain their water content during initial wear.

The nesofilcon A lens maintains high surface and bulk water content during wear, important because changes in surface RI due to dehydration are reported to lead to visual aberration affecting user experience.

STUDY RESULTS

LENS SURFACE REFRACTIVE INDEX

- The RI of water is 1.33. Differences between RI before and after wear were significant (P<0.0001) for all lenses (**Table 1**)
  - Delefilcon A lenses had a surface RI of 1.34 prior to wear, but after 15 minutes of wear, the RI increased to 1.43
  - Nesofilcon A lenses had mean RI values of 1.38 for both the unworn and worn lenses etafilcon A lenses also exhibited little change, with mean RI values of 1.41 for the unworn lenses and 1.42 for the worn lenses, respectively

Table 1. Surface refractive indices of contact lenses before and after 15 minutes of wear. The refractive index value for nesofilcon A reported in the table was determined by the test method used in this study, whereas those of etafilcon A and delefilcon A are as reported by their respective manufacturers in regulatory submissions using different test methods.

Lens	Group	N	Minimum	Maximum	Mean	Standard Deviation	Difference (worn–unworn)	*P*-value (*t*-test)
Biotrue® ONEday[1] (nesofilcon A)	Unworn	10	1.374	1.376	1.375	0.0008	0.0064	<0.0001
	Worn	20	1.377	1.385	1.381	0.0021		
					1.375*			
1-DAY ACUVUE® MOIST® (etafilcon A)[2]	Unworn	10	1.403	1.407	1.405	0.0013	0.0123	<0.0001
	Worn	20	1.413	1.431	1.417	0.0046		
					1.40*			
DAILIES TOTAL1® (delefilcon A)[3]	Unworn	10	1.336	1.338	1.337	0.0005	0.0932	<0.0001
	Worn	20	1.425	1.440	1.430	0.0031		
					1.42*			

1. FDA 510(k) Summary K113703. Bausch + Lomb nesofilcon A contact lens. June 5, 2012. 2. FDA 510(k) Summary K113168. Delefilcon A Soft Contact Lenses, 510(k) Summary of Safety and Substantial Equivalence. March 30, 2012. 3. FDA510(k)SummaryK062614.Special510(k) Summary of Safety and Effectiveness. (VISTAKON® (etafilcon A) Soft (hydrophilic) Contact Lens, Clear and Tinted (Visibility and/or Cosmetically) with UV Blocker for Daily Wear). November 1, 2006.

Release of Fluconazole from Contact Lenses Using a Novel *In Vitro* Eye Model

Phan et al. *Optom Vis Sci.* 2016;93:387-394

OVERVIEW

STUDY DESIGN
In vitro study to compare the release of fluconazole from various commercially available daily disposable contact lenses using a novel eye model

STUDY SITE(S)
Research centers in Canada and Poland

PATIENTS
Not applicable

METHODOLOGY
A microfluidic syringe pump was used to simulate tear secretion/flow. Contact lenses (CLs) were incubated in 1.0 mg/mL fluconazole solution for 24 hours, then placed in a phosphate-buffered saline containing vial and in the 3D printed eye model. Samples were taken at specified times over 24 hours

LENS TYPE(S)
Conventional hydrogel (CH) CLs: DAILIES® AquaComfort Plus® (nelfilcon A); Proclear® 1 day (omafilcon A; CooperVision, Inc.); 1-DAY ACUVUE® MOIST® (etafilcon A; Johnson & Johnson Vision Care); Biomedics® 1-Day (ocufilcon B; CooperVision, Inc.). Silicone hydrogel (SH) CLs: clariti® 1 day (somofilcon A; CooperVision, Inc.); 1-DAY ACUVUE® TruEye® (narafilcon A; Johnson & Johnson Vision Care); DAILIES TOTAL1® (delefilcon A)

KEY ENDPOINT(S)
Fluconazole uptake and release from the various lenses tested

ANALYSIS AND CONCLUSIONS

The fluconazole release profile using this novel eye model that mimics physiological tear flow and volume differed from that derived from a static vial-based model and showed sustained release from the contact lenses tested, over 24 hours.

Additional studies are needed to refine this eye model and incorporate further physiologic elements such as blinking motion.

STUDY RESULTS

UPTAKE AND RELEASE

- Fluconazole uptake was higher than the amount released in either the vial or eye model ($P<0.05$)
- CH lenses had significantly higher uptake and release of fluconazole than SH lenses ($P<0.05$); overall, fluconazole release was higher in the vial than in the eye model from etafilcon A, ocufilcon B and delefilcon A CLs ($P<0.001$); there were no differences in the amount of drug released from nelfilcon A, omafilcon A, somofilcon A and narafilcon A CLs ($P>0.05$)
- In the vial model, most fluconazole release occurred within the first 2 to 4 hours, followed by a plateau phase (**Figure 1**), while drug release in the eye model was sustained throughout the 24-hour period (**Figure 2**); the overall drug release is similar for each material
- Fluconazole release was highest for ocufilcon B CLs and lowest for nelfilcon A and narafilcon A CLs, regardless of model

Figure 1. Fluconazole release (mean ± standard deviation) from daily disposable contact lenses, vial model.

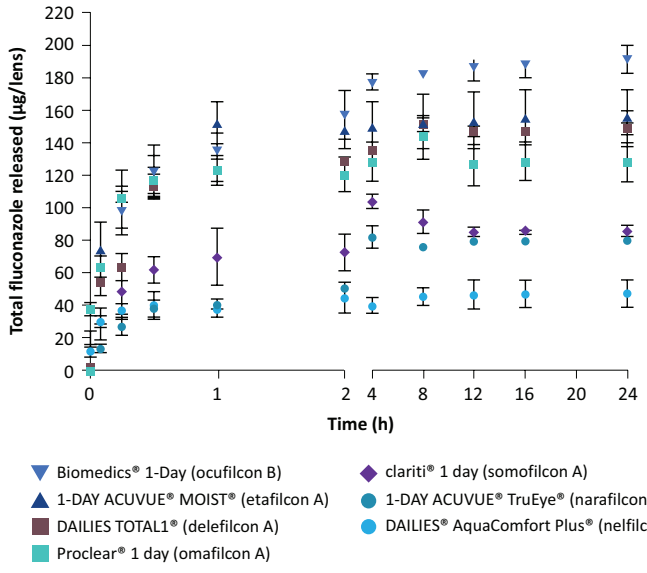
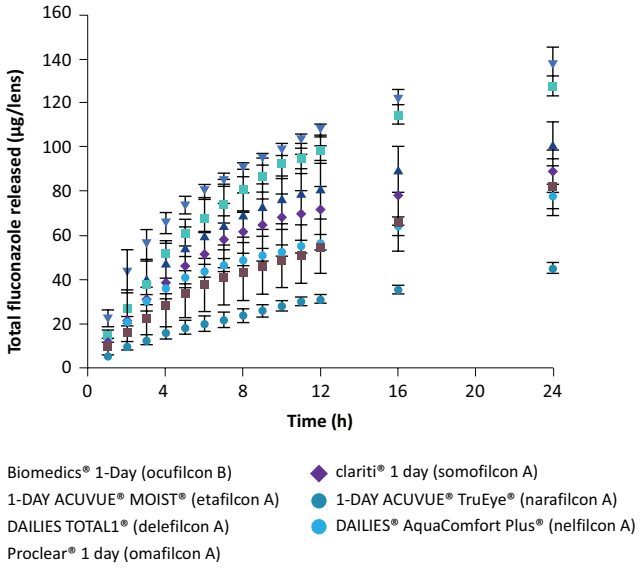


Figure 2. Fluconazole release (mean ± standard deviation) from daily disposable contact lenses, eye model.



Release of Moxifloxacin from Contact Lenses Using an *In Vitro* Eye Model: Impact of Artificial Tear Fluid Composition and Mechanical Rubbing

Phan et al. *Transl Vis Sci Technol.* 2016;5:3

OVERVIEW

STUDY DESIGN
Ocular drug delivery study to evaluate and compare the release of moxifloxacin from daily disposable contact lenses (DD CLs) under various conditions using a novel *in vitro* eye model

STUDY SITE(S)
Academic research center in Canada

PATIENTS
Not applicable

METHODOLOGY
Lenses were incubated in moxifloxacin for 24 hours. Drug release was measured using an *in vitro* model in three experimental conditions: (1) phosphate buffered saline (PBS); (2) artificial tear solution (ATS) containing proteins and lipids; and (3) ATS with mechanical rubbing produced by the device

LENS TYPE(S)
DD conventional hydrogel (CH) CLs: DAILIES® AquaComfort Plus® (nelfilcon A), Proclear® 1 Day (omafilcon A; CooperVision), 1-DAY ACUVUE® MOIST® (etafilcon A; Johnson & Johnson Vision Care), and Biomedics® 1-Day ocufilcon B (CooperVision). Silicone hydrogel (SH) CLs: clariti® 1 day (somofilcon A; CooperVision), 1-DAY ACUVUE® TruEye® (narafilcon; Johnson & Johnson Vision Care) A, and DAILIES TOTAL1® (delefilcon A)

KEY ENDPOINT(S)
Release of moxifloxacin from CL

ANALYSIS AND CONCLUSIONS

Moxifloxacin release from a contact lenses into ATS was lower compared with release into PBS. When mechanical rubbing was introduced, the amount of drug released was increased.

Based on the *in vitro* model used in this study, the release of moxifloxacin can be sustained for up to 24 hours. The drug release profiles are dependent on the properties of the contact lenses. In general, CH lenses released more drugs than SH lenses.

STUDY RESULTS

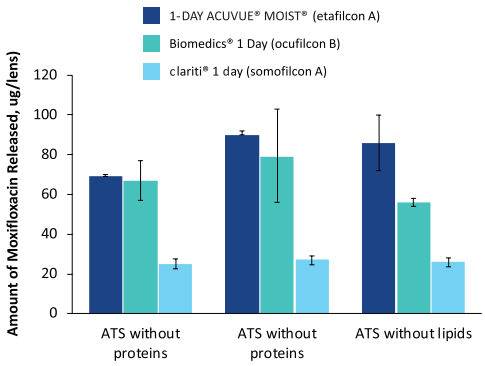
DRUG RELEASE

- Generally, drug release from CLs was sustained over 24 hours for all conditions, and no burst release was observed (P<0.05); conventional hydroxyethyl methacrylate (HEMA)-based hydrogel CLs had a higher drug release than SH CLs (P<0.05) under all conditions (P<0.001) (**Table 1**)
- Higher drug release was observed in PBS than in ATS (P<0.05); for CH CLs, drug release was found to be higher in ATS with rubbing than PBS or ATS (P<0.05); for most lenses, ATS with rubbing produced higher drug release than ATS alone (P < 0.05) (**Table 1**)
- To determine what components in ATS led to the reduction, an experiment was conducted with 2 CH lenses (etafilcon A and ocufilcon B) and 1 SH lens (somofilcon A) in either ATS, ATS without proteins, or ATS without lipids. There were differences in total drug release for the CH lenses between the three solutions (P<0.05), with no conclusive trend (**Figure 1**)
- Materials that released the highest amounts of moxifloxacin were etafilcon A and ocufilcon B, both negatively charged HEMA-based, FDA-group IV materials with high water content, and omafilcon A, a HEMA-based, FDA-group II material with high water content but overall neutral charge; the CLs releasing the lowest amount of drug were nelfilcon A, a polyvinyl alcohol (PVA)-based, FDA group II material with a high water content and neutral charge, and all SH lenses

Table 1. Release (lg/lens) of moxifloxacin after 24 hours from conventional hydrogel (CH) and silicone hydrogel (SH) daily disposable contact lenses (DD CLs) in phosphate buffered saline (PBS), artificial tear solution (ATS), and ATS with mechanical rubbing.

Commercial Name	Material	Moxifloxacin in PBS (µg/lens)	Moxifloxacin in ATS (µg/lens)	Moxifloxacin in ATS +Rubbing (µg/lens)
CH1-Day ACUVUE Moist®	etafilcon A	111.26 ±12.9	96.2 ±4.4	164.3 ± 15.5
CHBiomedics 1 Day®	ocufilcon B	107.5 ±23.4	62.9 ±9.9	158.8 ±24.4
CHProclear 1 Day®	omafilcon A	95.0 ±6.2	75.9 ±7.7	108.4 ±21.8
CHDailies Aqua Comfort Plus®	nelfilcon A	45.1 ±3.6	24.0 ±3.6	40.42 ±2.6
SHclariti 1 Day®	somofilcon A	42.4 ±5.1	28.0 ±3.7	30.6 ±11.3
SHDailies Total 1®	delefilcon A	27.9 ±3.9	16.7 ±3.7	18.07 ±4.3
SH1-DAY ACUVUE TruEye®	narafilcon A	30.2 ±0.8	7.0 ±3.2	28.7 ±6.6

Figure 1. Release of moxifloxacin (lg/lens) in a lipid solution, protein solution, and artificial tear solution (ATS). Values plotted are mean ± standard deviation (SD) for three trials.



Friction Measurements on Contact Lenses in a Physiologically Relevant Environment: Effect of Testing Conditions on Friction

Sterner et al. *Invest Ophthalmol Vis Sci.* 2016;57:5383–5392

OVERVIEW

STUDY DESIGN
In vitro study to characterize the effect of lubricant composition and *in vitro* aging on the coefficient of friction (CoF) of a range of commercially available soft contact lenses (SCLs)

STUDY SITE(S)
Four (4) research sites in Switzerland and the United States

PATIENTS
Not applicable

METHODOLOGY
CoF was characterized by microtribometry against a mucin-coated glass disk. Senofilcon A, etafilcon A, and nelfilcon A lenses were tested with different lubricant solutions, including tear-like fluid (TLF) with proteins and lipids. Reusable and daily disposable lenses were tested before and after exposure to an *in vitro* aging process

LENS TYPE(S)
PureVision™ (balafilcon A; Bausch & Lomb), BIOFINITY® (comfilcon A; CooperVision, Inc.), ACUVUE® 2 (etafilcon A), ACUVUE® OASYS® (senofilcon A), 1-DAY ACUVUE® (etafilcon A), 1-DAY ACUVUE® MOIST® (etafilcon A), 1-DAY ACUVUE® TruEye® (narafilcon A) (all Johnson & Johnson Vision Care), DAILIES® AquaComfort Plus® (nelfilcon A) AIR OPTIX® AQUA (lotrafilcon B), DAILIES TOTAL1® (delefilcon A)

KEY ENDPOINT(S)
Effect of lubricant composition and *in vitro* aging on CoF; CoF data were compared with published data using a different lubricant

ANALYSIS AND CONCLUSIONS

This study indicated that a persistent wetting agent is beneficial in maintaining a low CoF after prolonged simulated wearing.

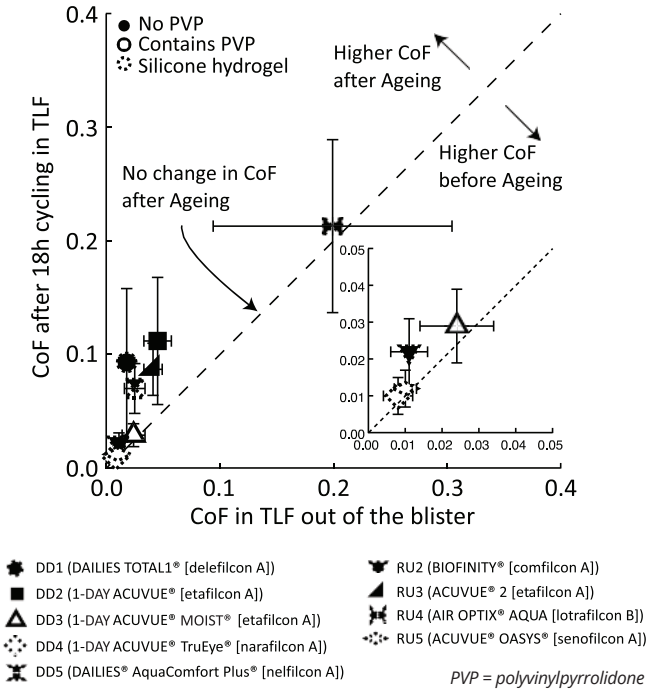
The composition of the lubricant has been shown to affect the CoF values for many soft contact lens materials.

STUDY RESULTS

COEFFICIENT OF FRICTION

- For etafilcon A lenses, the choice of lubricant solution had no significant effect on CoF, with a 0.011 difference (δ) between the highest and lowest CoF values
- A δ of 0.224 was found for nelfilcon A lenses, with higher CoF values in lubricant containing borate buffered saline (BBS) than phosphate buffered saline (PBS) at high and low osmolality for the same protein mixture
- A trend for lower CoFs in TLF was seen for senofilcon A and nelfilcon A lenses
- Comparing the effect of organic content, the CoF in TLF was significantly lower than in TMS-PS ($P<0.05$) for delefilcon A, nelfilcon A, comfilcon A, and etafilcon A (ACUVUE® 2) lenses with no significant difference between the two lubricants for the other lenses
- Delefilcon A, etafilcon A (1-DAY ACUVUE®), nelfilcon A, balafilcon A, comfilcon A, and etafilcon A (ACUVUE® 2) lenses had a significantly higher CoFs after ageing compared with fresh out of the box lenses ($P<0.05$)
- All hydrogel lenses without polyvinylpyrrolidone (PVP; etafilcon A (1-DAY ACUVUE®), nelfilcon A, etafilcon A (ACUVUE® 2)) had higher CoFs after aging; among the three etafilcon A contact lenses, only 1-DAY ACUVUE® and ACUVUE® 2 had an increase in CoF after aging; the same observation held for the SiHy lenses, except for lotrafilcon B lenses
  - Lotrafilcon B and balafilcon A lenses are SiHys lenses with a plasma-treated surface; however, only balafilcon A had a significant increase in CoF after aging ($P<0.05$)
- CoFs of lenses containing PVP as a wetting agent (etafilcon A [1-DAY ACUVUE® MOIST®], narafilcon A, senofilcon A) did not differ between TMS-PS and TLF (**Figure 1**), which may be a consequence of the presence of a polymer brush that prevents deposits from accumulating at the interface

Figure 1. Comparison between the coefficient of friction (CoF) before and after 18 hours of aging. For better readability, data for RU1 balafilcon A are not shown. Among the lenses that have PVP as an embedded wetting agent, none showed an increase in CoF after aging. Error bars: 1 standard deviation (SD).



PVP = polyvinylpyrrolidone

In Vitro Cholesterol Deposition on Daily Disposable Contact Lens Materials*

Walther. *Optom Vis Sci.* 2015; 93:36-41

OVERVIEW

STUDY DESIGN
Experimental trial to analyze effect of incubation times on uptake of cholesterol on silicone hydrogel (SiHy) and conventional hydrogel daily disposable contact lens (CL) materials using an *in vitro* radiochemical detection method

STUDY SITE(S)
Single site in Canada

PATIENTS
Not applicable

METHODOLOGY
Three SiHy and four conventional hydrogel CLs were incubated in an artificial tear solution that contained major tear film components and a portion of radioactive 14C-cholesterol for 2, 6, 12, or 16 hours

LENS TYPE(S)
SiHy: clariti® 1 day (somofilcon A; CooperVision); DAILIES TOTAL1® (delefilcon A); 1-DAY ACUVUE® TruEye® (narafilcon A; Johnson & Johnson Vision Care). Conventional hydrogel: 1-DAY ACUVUE® MOIST® (etafilcon A; Johnson & Johnson Vision Care); Biomedics® 1 day (ocufilcon B) and Biotrue® ONEday (nesofilcon A) (both CooperVision); DAILIES® AquaComfort Plus® (nelfilcon A)

KEY ENDPOINT(S)
Cholesterol deposits on CLs (nanograms/lens)

ANALYSIS AND CONCLUSIONS

This *in vitro* study demonstrated that SiHy contact lenses materials have significantly higher rates of cholesterol deposition than do conventional hydrogel materials, dependent on both the contact lenses type and length of incubation.

These findings may be clinically relevant when selecting contact lenses for patients with tear films that may contain excess lipid; follow-up clinical trials are warranted, particularly in patients with meibomian gland dysfunction.

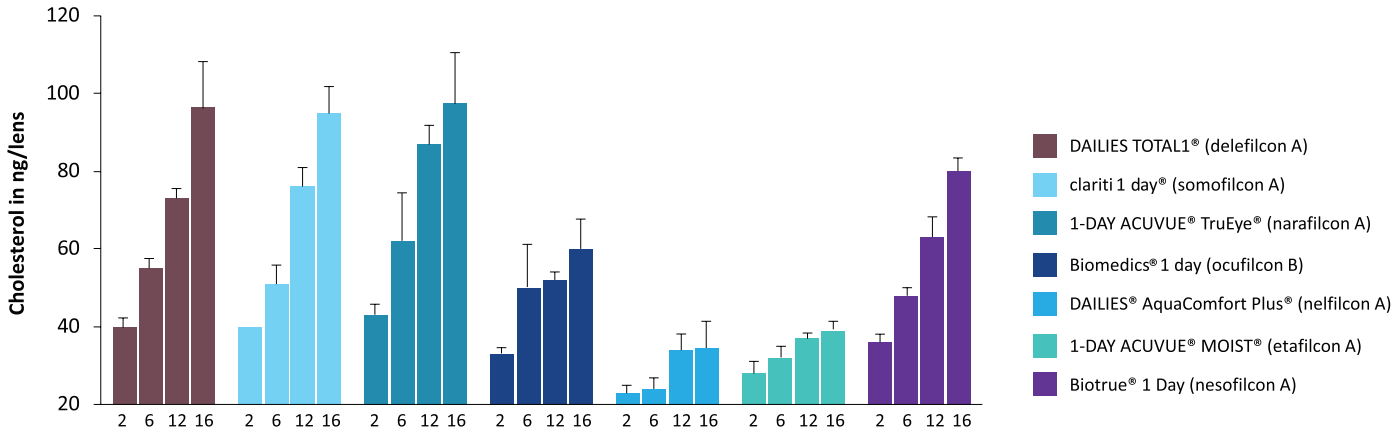
*This study was financially supported by Alcon.

STUDY RESULTS

CHOLESTEROL ACCUMULATION

- Cholesterol accumulation levels by different lens materials for up to 16 hours are shown in **Figure 1**
- Cholesterol deposits were shown to be dependent on both the CL type and length of incubation (P<0.001)
- Increasing time of incubation resulted in increased cholesterol deposition, irrespective of lens material (P<0.001)
- SH lens materials deposited significantly more cholesterol than CH materials (P≤0.033)
  - One exception – there was no significant difference between the lowest-depositing SH material (clariti® 1 day) and the highest depositing CH (Biotrue® ONEday) (P=0.067)
- Among CH materials, a significant difference existed in the amount of cholesterol deposited
  - Biotrue® ONEday > Biomedics® 1 Day (P=0.024); > 1-DAY ACUVUE® MOIST® > DAILIES® AquaComfort Plus® (latter two, not significant, P=0.504)
  - Biomedics® 1 Day deposited more cholesterol than both 1-DAY ACUVUE® MOIST® (P=0.004) and DAILIES® AquaComfort Plus® (P<0.001)

Figure 1. Mean ± standard deviation (SD) total cholesterol uptake on various daily disposable contact lens materials for 16 hours. Lipid quantities were measured using a radiolabel method in which cholesterol was labeled within an artificial tear solution containing a variety of proteins, lipids, and mucin.



Effect of the Surface Layer on Drug Release from Delefilcon-A (Dailies Total1®) contact lenses

Dixon et al. *Int J Pharm.* 2017;529:89-101

OVERVIEW

STUDY DESIGN
Study of drug transport from delefilcon A lenses to determine the impact of this layer on drug transport for both hydrophobic (dexamethasone and cyclosporine A) and hydrophilic (timolol and levofloxacin) drugs

STUDY SITE(S)
Single research center in the United States

PATIENTS
Not applicable

METHODOLOGY
Drugs were loaded into the lens by soaking in aqueous drug solutions followed by release in phosphate-buffered saline. Concentration data during release were fitted to the diffusion equation without considering the surface layer

LENS TYPE(S)
DAILIES TOTAL1® (delefilcon A)

KEY ENDPOINT(S)
Diffusive behavior of both hydrophilic and hydrophobic drugs to study the effect of the high-water content surface layer on drug transport and the effect of vitamin E loading on drug diffusion

ANALYSIS AND CONCLUSIONS

The presence of the thin high water content surface layer has a significant impact on release profiles for hydrophilic drugs. Data showed a good fit with a diffusion control model when release was included as a burst.

The presence of the burst further validates the reported structure of the high water content surface film in DAILIES TOTAL1® lenses. The absence of the burst for hydrophobic drugs shows that the outer layer has very low affinity for these drugs due to its very low polymer fraction. Release duration from DAILIES TOTAL1® was less than with ACUVUE® OASYS® and ACUVUE® TruEye® lenses (previously tested).

STUDY RESULTS

DRUG RELEASE

- Partition coefficients in DAILIES TOTAL1® for levofloxacin and timolol were much smaller than those for dexamethasone and cyclosporine; partition coefficient for DAILIES TOTAL1® lenses was the same magnitude as previously reported for ACUVUE® OASYS® and ACUVUE® TruEye® lenses, but was more similar to TruEye® lenses
- The hydrophilic drugs reached 90% drug release from DAILIES TOTAL1® within 15–20 minutes, while the hydrophobic drugs reached 90% drug release at approximately 7 and 15 hours, respectively (**Figure 1**)
- The correlation coefficients using the burst release were increased to 0.9966 and 0.9921 for timolol and levofloxacin, respectively, improved from the single layer model with correlation coefficients of 0.9643 and 0.9484, respectively (**Table 1**)
- For hydrophilic drugs, no burst release was observed and the partition coefficient is sufficiently small so a perfect sink assumption can be used (**Table 1**), which implies that the concentration in the release medium is negligible; apparently, the surface layer did not significantly impact the drug transport for the hydrophobic drugs
- Compared to ACUVUE® OASYS® and ACUVUE® TruEye®, DAILIES TOTAL1® has a much faster release duration, suggesting that the material used in this lens offers a much lower resistance to diffusion

EFFECT OF VITAMIN E

- Vitamin E incorporation increased the release duration of timolol and levofloxacin to about an hour, or roughly a 5-fold and 3-fold increase in release time, less than other lenses; although the rapid release may be toxic with some drugs, this may be effective for antibiotics

Figure 1. Release profile of drugs from DAILIES TOTAL1®. Percent release is the measured mass released at any time divided by the maximum mass released. For hydrophilic drugs, a majority of the drug is released but for the hydrophobic drugs, a significant portion remains in the lens after equilibrium is reached. Data shown are mean ± standard deviation (N=6).

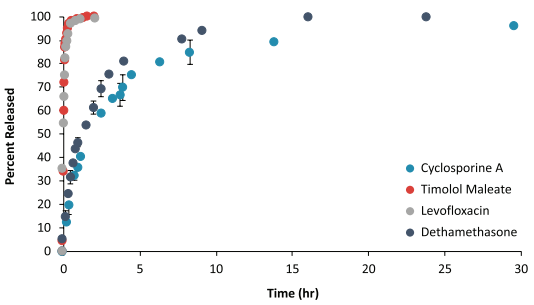


Table 1. Diffusion coefficient (m^2/second) and correlation constants for different models. Data shown are mean ± standard deviation (N=6).

Drug	Single Layer Diffusivity	Correlation Constant R^2	Burst Release Diffusivity	Correlation Constant R^2	Numerical, Non-Perfect Sink Diffusivity	Correlation Constant R^2
Timolol maleate	1.79E-12±8E-14	0.9643	1.53E-12±8E-14	0.9966	-	
Levofloxacin	1.77E-12±2E-14	0.9484	1.25E-12±2E-14	0.9921	-	
Dexamethasone	-	-	-		9.98E-14	0.9869
Cyclosporine	-	-	-		3.19E-14	0.9943

Rapid Loading and Prolonged Release of Latanoprost From a Silicone Hydrogel Contact Lens*

Horne et al. *J Drug Delivery Sci Technol*. 2017; 41:410-418

OVERVIEW

STUDY DESIGN
Experimental study to develop the technology to rapidly load hydrophobic drugs into silicone hydrogel contact lenses for drug delivery

STUDY SITE(S)
Single research center in the United States

PATIENTS
Not applicable

METHODOLOGY
Rapid loading was accomplished in ≤4 minutes by soaking the lens in a solution of the drug in n-propanol, followed by rapid deswelling in water, using latanoprost as an example. The *in vitro* release of this drug into an artificial tear solution was determined over several days

LENS TYPE(S)
DAILIES TOTAL1® (delefilcon A)

KEY ENDPOINT(S)
Methods to load hydrophobic drugs onto silicone hydrogel contact lenses and drug release afterwards

ANALYSIS AND CONCLUSIONS

Using this loading system, the amount of hydrophobic drug placed into the lenses was controllable, with up to 450 mg per lens. Drug loading was proportional to the loading time and to the drug concentration in the solution.

The authors concluded that this method of rapid loading could be more feasible than conventional loading from aqueous solutions, particularly for hydrophobic drugs.

*DailiesTotal1® contact lenses were kindly donated by Alcon

STUDY RESULTS

DRUG LOADING AND RELEASE

- The amount of latanoprost loaded into a contact lens varied with the loading time (60-240 s) and the latanoprost concentration (1-9 mg/mL in n-propanol), suggesting that the loading amount is a linear function of loading time (**Figure 1**)
- Results with normalized data (amount/concentration) suggest that the amount loaded is also proportional to loading concentration
- The linearity of time and loading suggested that the loading mechanism was not solely by diffusion, rather by convective absorption of solution into the lens
- Swelling (by mass) was fairly proportional to time for the first 4 min and thereafter did not appear to increase substantially
- Measurements of lens diameter before swelling and after deswelling show that there was no statistically significant change in lens diameter
- About 78% of the latanoprost taken up into the lens remained in the lens, irrespective of the swelling time or solution concentration
- The data of drug release into artificial tear solution at near body temperature from two values of latanoprost loading (~6:3 and ~ 450 µg /lens) shows that the pattern of release was remarkably similar although the amount of latanoprost differed by two orders of magnitude (**Figure 2**)

Figure 1. Loading of latanoprost into DAILIES TOTAL1® contact lenses as a function of loading time. Insert shows the same data as the large plot, but with a y- axis of the mass of loading divided by loading concentration. Experiments were conducted in 3 different concentrations of latanoprost in n-propanol: 1.0 g/L, 3.0 g/L, and 9.0 g/L. Error bars represent 95% confidence intervals, n = 3.

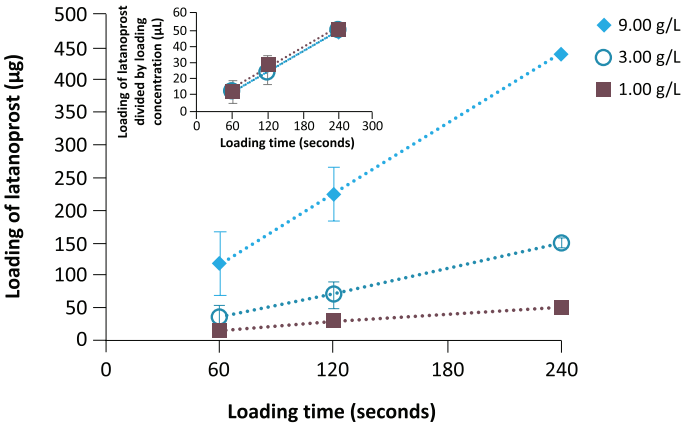
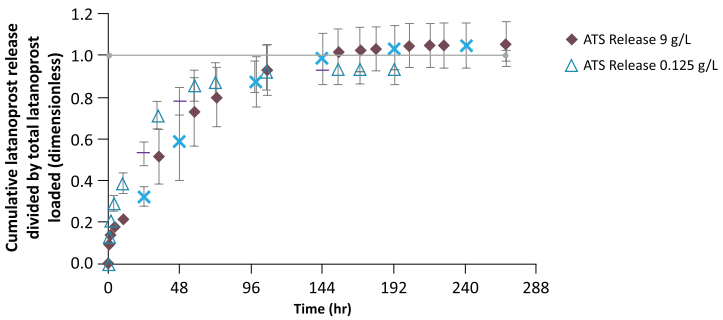


Figure 2. Cumulative fraction of loaded latanoprost released into artificial tears from loaded contact lenses as a function of time. Solid horizontal line indicates the estimated maximum cumulative release of 100%. Experiments were conducted with low and high loading of latanoprost of ~6:3 µg loaded at 0.125 g/L concentration and ~450 µg at 9 g/L concentration. The dashes and x-marks are adapted from the sample taken immediately before transferring the lens to fresh artificial tears.



ATS = artificial tear solution

In Vitro Release of Two Anti-Muscarinic Drugs from Soft Contact Lenses

Hui et al. *Clin Ophthalmol.* 2017; 11:1657-1665

OVERVIEW

STUDY DESIGN
Experimental study to investigate the release of the anti-myopia drugs atropine sulfate and pirenzepine dihydrochloride from commercially available soft contact lenses

STUDY SITE(S)
Research centers in Australia, Poland, and Canada

PATIENTS
Not applicable

METHODOLOGY
Standard ultraviolet absorbance-concentration curves generated for atropine and pirenzepine; contact lenses were loaded by soaking in atropine or pirenzepine solutions; release of the drugs into phosphate-buffered saline was determined over the course of 24 hours

LENS TYPE(S)
1-DAY ACUVUE® MOIST® (etafilcon A) and 1-DAY ACUVUE® TruEye® (narafilcon A) (both Johnson & Johnson Vision Care), Biomedics® 1 Day (ocufilcon B), Proclear® 1 day and Proclear® 1 day Multifocal (omafilcon A), Proclear® Multifocal (omafilcon B), Biofinity® Multifocal (comfilcon A) (all CooperVision), DAILIES TOTAL1® (delefilcon A), Focus® DAILIES® and Focus® DAILIES® Progressive (nelfilcon A)

KEY ENDPOINT(S)
Release of anti-myopia drugs atropine sulfate and pirenzepine dihydrochloride from lenses *in vitro*; effect of drug type, lens material, and loading concentration on drug release; impact of using the multifocal design from lenses formed from the same material

ANALYSIS AND CONCLUSIONS

All lenses showed some degree of drug release when monitored *in vitro*, although the majority released the drugs in an uncontrolled manner.

All lenses, with the exception of narafilcon A material, reached a plateau within 2 hours of release, suggesting that they were unable to sustain drug release into the solution for long periods of time.

STUDY RESULTS

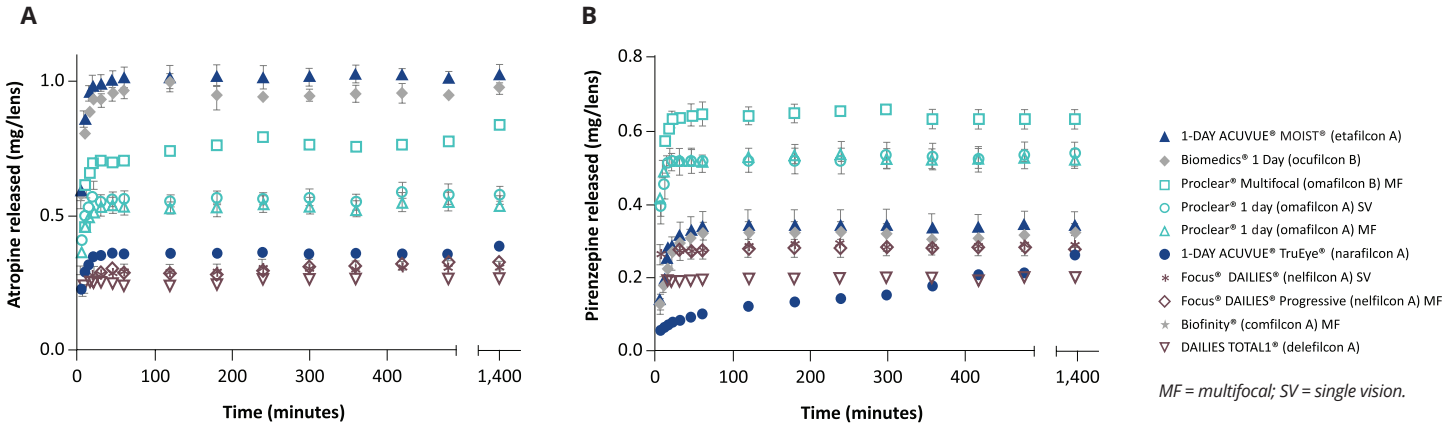
DRUG RELEASE

- There were statistically significant differences in the amount of atropine released (1 mg and 10 mg/mL loaded) over time between the different lens materials ($P < 0.0001$; **Figure 1A**)
- No material demonstrated statistically significant changes in drug release between time points for > 1 hour, with the majority released within the first 20 minutes (10 mg/mL) to 30 minutes (1 mg/mL)
- When loaded with 10 mg/mL of pirenzepine, there was a statistically significant difference between the amount of drug released over time between the different materials ($P < 0.0001$; **Figure 1B**)
- There were statistically significant differences observed between the amount of pirenzepine released from the different materials over time after loading with 1 mg/mL and 10 mg/mL pirenzepine solutions ($P < 0.0001$) (**Figure 1B**)

SINGLE VISION VS MULTIFOCAL LENSES

- The single vision and multifocal versions of Focus® DAILIES® Progressive and Proclear® 1 day showed statistically similar release profiles, implying that the multifocal optical modification has a negligible effect on the drug release kinetics
- While extremely similar to Proclear® 1 day, the slight change in water content and center thickness allowed for statistically significant differences in drug release from Proclear® Multifocal compared with Proclear® 1 day single vision and Proclear® 1 day multifocal materials when loaded with 10 mg/mL solutions of atropine and pirenzepine as well as 1 mg/mL of pirenzepine
- 1-DAY ACUVUE® MOIST® and Biomedics® 1 Day released the greatest overall amount of the two drugs. Silicone hydrogel lenses had less drug release potential compared with non-silicone hydrogel lenses

Figure 1. Atropine release (**A**) and pirenzepine release (**B**) over 24 hours in 4 mL of phosphate-buffered saline (PBS) from contact lenses after 24 hours of uptake in 10 mg/mL atropine solution. Error bars represent standard deviation.



MF = multifocal; SV = single vision.

Raman Imaging of Layered Soft Contact Lenses

Krysztofiak et al. *J Appl Biomater Funct Mater.* 2017; 15:e149-e152

OVERVIEW

STUDY DESIGN
Experimental study to confirm the layered structure of delefilcon A contact lenses (CL)

STUDY SITE(S)
Single site in Poland

PATIENTS
Not applicable

METHODOLOGY
Raman spectroscopy was used to investigate the layered structure of the material, recording depth spectra of the lenses tested; inVia Renishaw Raman microscopy system with a 488nm Ar-Ion laser and 3,000mm-1 grating

LENS TYPE(S)
DAILIES TOTAL1® (delefilcon A)

KEY ENDPOINT(S)
Thickness of surface hydrogel layer on the silicone hydrogel core

ANALYSIS AND CONCLUSIONS

The investigators confirmed the existence of a water gradient at the delefilcon A lens surface of 6um, deemed to be consistant with the manufacturer's data. This study also showed that this technique can be successfully used to measure the thickness of layered materials.

Raman spectroscopy allows for measurement of hydrated and dehydrated samples; therefore, further studies of delefilcon A surface water loss will be valuable.

STUDY RESULTS

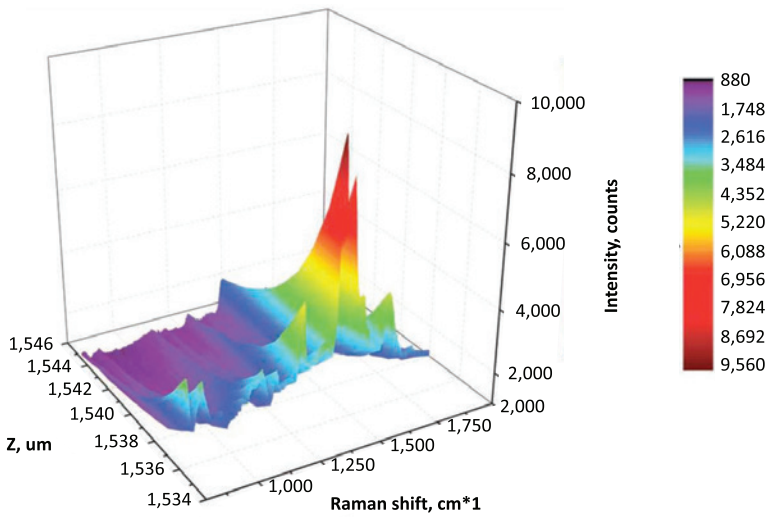
RAMAN SPECTROSCOPY ANALYSIS

- A 3D surface plot shows exemplary results of depth imaging of the delefilcon A sample (**Figure 1**)
- The mean thickness of the hydrogel layer was estimated to be about 6 ± 2 µm, consistent with the manufacturer's data
- Thickness measurements of the surface coating were repeatable irrespective of lens power and position relative to its center

CLINICAL IMPLICATIONS

- Raman examination is performed in air, as opposed to solute partitioning measurements, which are performed in an aqueous environment, and appear to be more accurate

Figure 1. Raman depth imaging of the layered structure of delefilcon A contact lenses.



Composition and Stability of Plasma Polymer Films Exhibiting Vertical Chemical Gradients

Rupper et al. *Langmuir.* 2017; 33:2340-2352

OVERVIEW

STUDY DESIGN
Experimental trial to analyze the composition and stability of highly functional plasma polymer films (PPF) exhibiting a chemical gradient perpendicular to the surface plane

STUDY SITE(S)
Two sites in Switzerland

PATIENTS
Not applicable

METHODOLOGY
Composition of the vertical gradient PPF was determined via analysis of angle-resolved X-ray photoelectron spectroscopy (ARXPS) data and time of flight secondary ion mass spectrometry (TOF-SIMS)

LENS TYPE(S)
Not applicable

KEY ENDPOINT(S)
ARXPS; TOF-SIMS; Oxygen-to-Carbon (O/C) ratios; Water contact angles (WCA)

ANALYSIS AND CONCLUSIONS

Novel vertical chemical gradient structures have been produced by plasma polymerization. The resulting oxygen-containing PPF are composed of a highly cross-linked base layer followed by a thin less cross-linked, but highly functional top layer.

Different aging mechanisms were identified, including a fast hydrophobic recovery, followed by midterm radical reactions and progressive hydrolysis reactions under non-neutral pH conditions. Aging effects in air as well as in aqueous environments under various pH values can be significantly minimized as compared to homogenous or more extended gradient plasma polymer structures.

STUDY RESULTS

COMPOSITION OF VERTICAL GRADIENT STRUCTURES

- The O/C ratios determined from the XPS survey scans are in agreement with those derived from the detail scans of carbon and oxygen peaks; this indicates that degradation during XPS measurement is not an issue
- **Table 1** compares the different PPF before aging – as expected the reference layer exhibits the lowest XPS O/C ratio, whereas the reference oxygen-rich film exhibits the highest O/C ratio. The vertical chemical gradient structures have intermediate O/C ratios

AGING OF VERTICAL GRADIENT STRUCTURES IN AIR

- The O/C ratio is a simple measure for the overall chemical composition, and the water contact angle (WCA) determines the polarity of an aging film
- A comparison of XPS O/C ratio (**Figure 1**) and WCA (**Figure 1**) for the 1 and 2 nm vertical gradient structures and homogenous reference layers as a function of storage time in air can be made
- WCA measured on a reference oxygen-rich or highly cross-linked layer increases monotonically, both vertical gradient structures exhibit an initial increase contact angle and then become hydrophilic after longer air exposure. After air aging, the WCA of the vertical gradient is like the initial value, although the O/C ratio has significantly increased
- In air, the vertical gradient films are stabilized for months

AGING OF VERTICAL GRADIENT STRUCTURES IN AQUEOUS ENVIRONMENTS

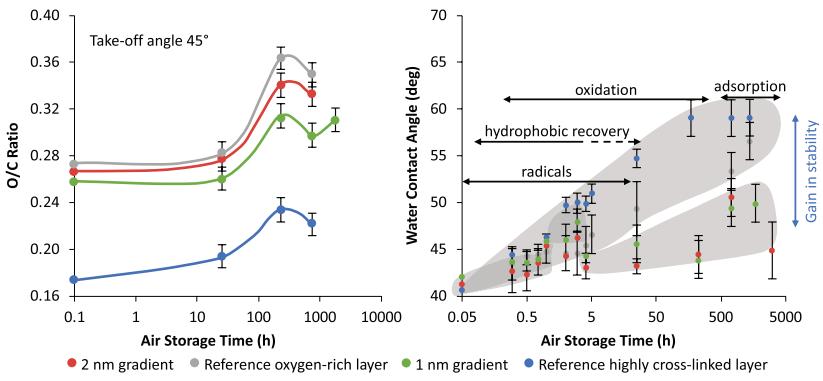
- A comparison of O/C ratio and WCA as a function of the storage time in water at pH≈6.2 was performed. The O/C ratio remains essentially constant for both vertical and chemical gradient structures and for the reference coatings
- In neutral water, the vertical gradient films are stable for at least 1 week

Table 1. Oxygen to carbon ratio (O/C) and percentage content of carbon functional groups of fresh plasma polymer films (PPFs).

	O/C ratio[a]	C–C/C–H[b]	C–O[b]	C=O[b]	O–C=O[b]
Reference highly cross-linked layer	0.175	74.1%	14.7%	7.9%	3.3%
Reference oxygen-rich layer	0.274	68.5%	17.1%	9.7%	4.7%
1 nm vertical gradient film	0.259	70.2%	15.7%	9.5%	4.6%
2 nm vertical gradient film	0.267	70.1%	16.0%	9.2%	4.7%

[a]O/C ratio is determined from the high-resolution C 1s and O 1s XPS spectra.
[b]Percentage of functional groups is determined from the C 1s high-resolution XPS spectrum.

Figure 1. Aging behavior in ambient air for the two investigated vertical gradient structures (1 and 2 nm) as compared to non gradient structures composed of either reference highly cross-linked or oxygen-rich layer material. Oxygen-to-carbon concentration ratio (O/C) and water contact angle (WCA), both as a function of the storage time in air up to over 1000h (logarithmic scale). Error bars for the WCA measurements result from the standard deviation of three measurements. Estimated error for the O/C ratio amounts to ±0.01



Cosmetic Cleansing Oil Absorption by Soft Contact Lenses in Dry and Wet Conditions

Tsukiyama et al. *Eye Contact Lens.* 2017; 43:318-323

OVERVIEW

STUDY DESIGN
Experimental trial to investigate the effects of cosmetic cleansing oil on hydrogel lenses and silicone hydrogel contact lenses (SHCLs) in both wet and dry conditions

STUDY SITE(S)
Single site in Japan

PATIENTS
Not applicable

METHODOLOGY
Hydrogel and SHCLs were immersed in a cleansing oil solution containing Sudan Black B for 5 minutes under wet and dry conditions, excess solution was removed with a multipurpose solution, and lenses were examined using a stereomicroscope to compare brightness

LENS TYPE(S)
Hydrogel CLs: Neo Sight one day Aqua Moist® (polymacon; Aire Inc.); Proclear® 1day (omafilcon A; CooperVision); 1-DAY ACUVUE® MOIST® (etafilcon A; Johnson & Johnson Vision Care); SHCLs: DAILIES TOTAL1® (delefilcon A); AIR OPTIX® AQUA (lotrafilcon B); 2 WEEK Menicon Premio® (asmofilcon A; Menicon); Biofinity® (comfilcon A; CooperVision); ACUVUE® OASYS® (senofilcon A; Johnson & Johnson Vision); 1-DAY ACUVUE® TruEye® (narafilcon A; Johnson & Johnson Vision Care); Medalist FreshFit® (balafilcon A; Bausch & Lomb)

KEY ENDPOINT(S)
Mean brightness; absorption

ANALYSIS AND CONCLUSIONS

The investigators found that hydrogel lenses resisted cosmetic cleansing oil. However, SHCLs had different degrees of lens material-dependent resistance. Various SHCLs absorbed cosmetic cleaning oil increasingly under dry conditions than wet.

The authors emphasized the importance of warnings such as "Take out your contact lenses before removing makeup" or "Wash your hands carefully using soap before handling contact lenses," noting that they should be included with contact lens instructions, and that users should be instructed on contact lens handling and take care.

STUDY RESULTS

MEAN BRIGHTNESS

- Mean brightness change rate (%) before and after testing is shown in **Figure 1**
- The cosmetic cleansing oil was not absorbed by hydrogel lenses under any conditions
- Four of the SHCLs absorbed cosmetic cleansing oil under both wet and dry conditions, whereas asmofilcon A absorbed it only under the dry condition
- Lotrafilcon B and delefilcon A did not absorb cleansing oil even under the dry conditions
- Senofilcon A, narafilcon A, and balafilcon A CLs absorbed more cosmetic cleansing oil under dry conditions than under wet conditions (P<0.01)
- Under wet conditions, balafilcon A CLs absorbed significantly higher amounts of cosmetic cleansing oil than lotrafilcon B CLs (P<0.01)
- Under dry conditions, comfilcon A, senofilcon A, narafilcon A, and balafilcon A lenses absorbed significantly higher amounts of cosmetic cleansing oil than the polymacon, omafilcon A, and etafilcon A hydrogel lenses, and also the delefilcon A and lotrafilcon B SHCLs (P<0.01); asmofilcon A and comfilcon A lenses absorbed significantly less than narafilcon A and balafilcon A lenses (P<0.01)

DEFORMATION SCORES

- The cosmetic cleansing oil was absorbed by some SHLCs; this can contaminate the material and deform the lens
- Polymacon, omafilcon A, and etafilcon A were not deformed by the cleansing oil contaminants under wet or dry conditions
- In the case of SHCLs, there was a difference between wet and dry conditions; delefilcon A, lotrafilcon B, asmofilcon A, and comfilcon A were hardly deformed under wet or dry conditions, senofilcon A lenses and narafilcon A were deformed lightly overall under dry conditions, and balafilcon A lenses were deformed under both wet and dry conditions

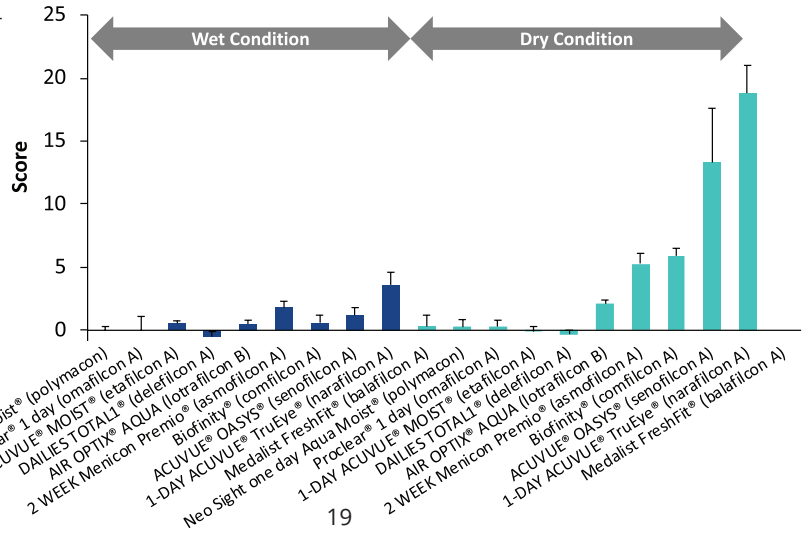


Figure 1. Mean brightness change rate (%) for the entire lens before and after the cleansing oil contamination test.

Reliability of Blotting Techniques to Assess Contact Lens Water Content

Cañadas et al. *Eye Contact Lens.* 2018;44:S227-S232

OVERVIEW

STUDY DESIGN
Experimental study to determine the reliability of wet and modified dry blotting techniques used to assess contact lens (CL) water content (WC) by the gravimetric method, the accuracy of both techniques compared with the nominal WC, and the agreement of both techniques

STUDY SITE(S)
Two research centers in Spain

PATIENTS
Not applicable

METHODOLOGY
Hydrated and dry CL mass values and WC using the gravimetric method were evaluated in daily disposable CLs with 5 lenses per blotting method for each of the 4 brands and 11 back vertex powers tested. Within-subject coefficient of variation (CVw) and intraclass correlation coefficients (ICC) were calculated. Bland-Altman analysis was also performed

LENS TYPE(S)
DAILIES TOTAL1® (delfilcon A); DAILIES® AquaComfort Plus® (nelfilcon A); 1-DAY ACUVUE® TruEye® (narafilcon A: Johnson & Johnson Vision Care); Biotrue® ONEday (nesofilcon A; Bausch & Lomb) with back vertex powers -0.50, -1.00, -2.00, -3.00, -4.00, -5.00, -6.00, +0.50, +1.00, +2.00, and +3.00

KEY ENDPOINT(S)
Variability of both wet and modified dry blotting techniques for removing excess solution, reliability of each technique, accuracy in assessing CL WC compared with the manufactures' values, and agreement between both blotting techniques

ANALYSIS AND CONCLUSIONS

The wet blotting technique was not only more reliable than the modified dry one when obtaining hydrated contact lens mass but also provided more accurate nominal WC measurements.

Agreement between the two blotting techniques was poor.

STUDY RESULTS

DRUG RELEASE PROFILE

- Hydrated CL mass values were significantly different for all the CLs assessed between both blotting techniques (all P≤0.0001; **Table 1**)
- No significant variation in terms of CVw and ICC was found in the reliability among all CL powers evaluated. However, the wet blotting method always had lower variability (better consistency) than the modified dry one
  - The differences in CVw values between the blotting methods were significant for all CLs (P ≤ 0.04). The wet blotting technique yielded higher ICC values for all CLs except for delefilcon A
- Dry CL mass was always slightly higher using modified dry blotting; mean dry CL mass difference between the blotting techniques (wet – modified dry) for delefilcon A (-0.17 mg; 95% CI, -0.56 to 0.22) was not significant; however, mean differences for narafilcon A (-0.33 mg; 95% CI, -0.58 to -0.08), nelfilcon A (-0.36 mg; 95% CI, -0.54 to -0.19), and nesofilcon A (-0.37 mg; 95% CI, -0.71 to -0.02]) were significant (all P ≤ 0.04); there was poor agreement between techniques
- Analysis of blotting technique reliability in terms of CVw and ICC for assessing dry CL mass found no significant variation in reliability among all evaluated CL powers
  - There were no significant differences in CVw values for any CLs between wet and modified dry blotting procedures, except for nelfilcon A (P=0.03); all ICC values were highly consistent (>0.90), except for modified dry blotting procedures with nelfilcon A
- The mean difference between the blotting procedures (wet – dry technique) in CL WC was -15.73% (95% CI, -20.31 to -11.15) for delefilcon A; -11.1% (95% CI, -13.38 to -28.83 for narafilcon A; -6.75% (95% CI, -8.56 to -4.94) for nelfilcon A; and -3.6% (95% CI, -4.77 to -2.42) for nesofilcon A (Table 2); these differences between blotting techniques were statistically significant for all assessed CLs (P≤0.001)

Table 1. Hydrated contact lens mass values for the wet and modified dry blotting techniques.

Contact Lens Material	Blotting Technique	Mean Mass in mg (SD)	95% CI for the Mean Mass (mg)	Range (mg)
DAILIES TOTAL1® (delfilcon A)	Wet Dry	31.64 (1.78) 41.61 (3.98)	30.37-32.91 38.76-44.45	28.74-35.34 34.89-47.38
1-DAY ACUVUE® TruEye® (narafilcon A)	Wet Dry	32.44 (2.46) 41.62 (3.91)	30.79-34.09 39.00-44.25	29.53-38.44 35.00-47.28
DAILIES® AquaComfort Plus® (nelfilcon A)	Wet Dry	25.18 (2.23) 34.52 (3.76)	23.68-26.68 31.99-37.04	22.48-29.46 28.21-39.76
Biotrue® ONEday (nesofilcon A)	Wet Dry	33.13 (4.89) 41.46 (4.96)	29.85-36.42 38.13-44.79	26.42-43.83 34.85-49.53

CI = confidence interval; SD = standard deviation.

Table 2. Contact lens water content values for the wet and dry blotting procedures.

Contact Lens Material (Manufacturer Water Content) (%)	Blotting Technique	Water Content Mean (SD) (%)	95% CI for the Mean Water Content (%)
DAILIES TOTAL1® (delfilcon A) (33)	Wet Dry, lowest value*	31.47 (1.39) 47.20 (5.31), 45.94	30.47-32.47 43.40-51.00
1-DAY ACUVUE® TruEye® (narafilcon A) (46)	Wet Dry, lowest value*	45.37 (1.11) 56.47 (2.62),55.32	44.51-46.22 54.45-58.48
DAILIES® AquaComfort Plus® (nelfilcon A) (69)	Wet Dry, lowest value*	69.70 (0.75) 76.45 (2.72), 76.14	69.20-70.20 74.62-78.28
Biotrue® ONEday (nesofilcon A) (78)	Wet Dry, lowest value*	76.89 (1.30) 80.49 (0.78), 77.99	75.96-77.82 79.93-81.05

CI = confidence interval; SD = standard deviation.
** Lowest (out of the five performed) water content value obtained for the modified dry blotting technique.*

Mechanical Properties of Contact Lens Materials

Kim et al. *Eye Contact Lens.* 2018;44:S148-S156

OVERVIEW

STUDY DESIGN

Experimental study to evaluate the mechanical properties of commonly available soft contact lens materials and compare results using a custom-built microtensometer

STUDY SITE(S)

Two centers in Australia

PATIENTS

Not applicable

METHODOLOGY

The Young modulus, parameters for stress relaxation, and toughness of 18 types of single vision soft contact lenses were measured using a custom-built microtensometer. Five lenses of each type were soaked in standard phosphate-buffered saline and measured at a temperature of 35°C

LENS TYPE(S)

Conventional hydrogel: Biotrue® ONEday (nesofilcon A) and SofLens® Daily (hilafilcon B) (both Bausch & Lomb), DAILIES® AquaComfort Plus® (nelfilcon A), Proclear® (omafilcon B) and Proclear® 1 day (omafilcon A) (both CooperVision), ACUVUE® 2 and ACUVUE® MOIST® 1-DAY (etafilcon A; Johnson & Johnson Vision Care). Silicone hydrogel: ACUVUE® TruEye® 1-DAY (narafilcon A) and ACUVUE® OASYS® (senofilcon A) (both Johnson & Johnson Vision Care), MyDay® (stenfilcon A), Biofinity® (comfilcon A), Avaira (enfilcon A), clariti® 1day (somofilcon A) (all CooperVision), PremiO (asmofilcon A; Menicon), PureVision® 2 (balafilcon A; Bausch & Lomb), DAILIES TOTAL1® (delefilcon A), AIR OPTIX® Aqua (lotrafilcon B), AIR OPTIX® Night & Day® Aqua (lotrafilcon A)

KEY ENDPOINT(S)

Young modulus, parameters for stress relaxation (SR), and toughness; relationships between modulus versus water content and modulus versus toughness

ANALYSIS AND CONCLUSIONS

Using the purpose-built instrument, the mechanical properties, such as the Young modulus, toughness and SR of soft contact lenses were reliably measured.

The modulus data generally agreed with published data from manufacturers and other research groups, with a few exceptions exceeding 15% deviation. The more recently released silicone hydrogel lens types had reduced modulus, approaching that of medium or high water content hydrogel materials.

STUDY RESULTS

LENS MODULUS

- For most of the lenses, the measured stretch moduli were approximately 10% lower compared with the corresponding release modulus
- The measured moduli for silicone hydrogel materials were generally higher compared with the hydrogels, except for the DAILIES® AquaComfort Plus® lenses
- Comparing the nominal manufacturer or published data with moduli measured in this study, the maximum difference was not statistically significant (0.28 MPa; **Figure 1**)
- The relationship between modulus and water content shows that as the water content increases, the modulus tended to decrease for silicone hydrogel lenses (r = 20.750; P = 0.008; **Figure 1**). For hydrogel lenses, the reverse trend was observed with r = 0.553, although this was not statistically significant for measured moduli
- The decay in stress showed a consistent time constant of approximately 10 sec for most of the lenses measured in this study. However, the amplitude constant varied with no obvious trends in the relationship between the time and amplitude constants
- No significant correlation was found between toughness, the area under the curve at breakpoint, and modulus with r = 0.310

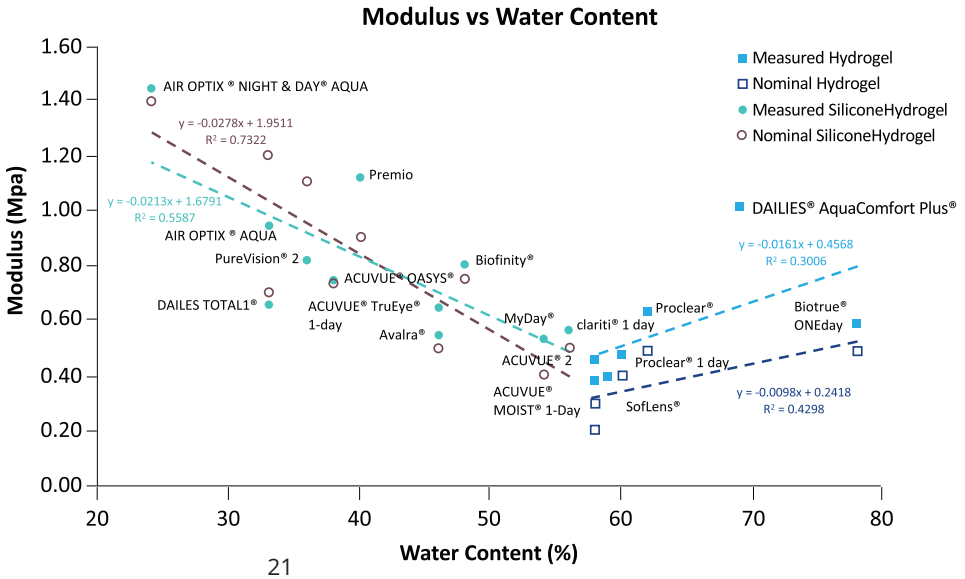


Figure 1. Relationship between measured and nominal modulus and nominal water content. DAILIES TOTAL1® lens plotted against nominal core water content

Elemental Composition at Silicone Hydrogel Contact Lens Surfaces*

Rex et al. *Eye Contact Lens* 2018;44:S221-S226

OVERVIEW

STUDY DESIGN
Experimental trial to analyze the outermost surface composition of silicone hydrogel (SiHy) lenses using X-ray photoelectron spectroscopy (XPS) to understand differences in wettability and potential interactions within an ocular environment

STUDY SITE(S)
Single site in the United States

PATIENTS
Not applicable

METHODOLOGY
Eleven (11) SiHy lenses were soaked for 24 hours in phosphate-buffered saline and dried overnight. XPS was performed at 2 take-off angles, 55°and 75°, to evaluate changes in elemental composition as a function of depth from the surface

LENS TYPE(S)
PureVision® 2 (balafilcon A; Bausch & Lomb); AIR OPTIX® NIGHT & DAY® AQUA (lotrafilcon A); AIR OPTIX® AQUA (lotrafilcon B); ACUVUE® OASYS® (senofilcon A; Johnson & Johnson Vision Care); Biofinity® (comfilcon A; CooperVision; ULTRA® (samfilcon A; Bausch & Lomb); DAILIES TOTAL1® (delefilcon A); 1-DAY ACUVUE® TruEye® (narafilcon A; Johnson & Johnson Vision Care); MyDay® (stenfilcon; CooperVision); clariti® 1 day and clariti® Elite (somofilcon A; CooperVision)

KEY ENDPOINT(S)
Surface silicon content

ANALYSIS AND CONCLUSIONS

Knowledge of lens surface composition is central to the ability to assess and improve the wettability, comfort, and ocular surface compatibility of contact lenses. XPS is a powerful probe of silicone hydrogel surface composition.

Delefilcon A and lotrafilcon A and B exhibiting the lowest silicon contents within the outermost 10.0 nm of the lens surface. Silicon has hydrophobic properties which, when found at the surface, may influence the wettability of the contact lenses and their interaction with the tear film and ocular tissues.

** This study was financially supported by Alcon*

STUDY RESULTS

ELEMENTAL SURFACE COMPOSITION

- The elemental composition of the surface of the 11 SiHy CLs indicate that the lens surfaces possess significant variations in composition, through the relative differences in peak height observed for the different through EPS analysis (**Figure 1**)
- Trends in elemental composition with increasing surface sensitivity across all elements were found, however, was reflected specifically for silicon in **Figure 2**
- Silicon increased in all lenses but delefilcon A (DAILIES TOTAL1®) as a function of decreasing sampling depth
- Silicon content and relative distribution through the near-surface region (~10 nm) of materials varied substantially

Figure 1. Representative X-ray photoelectron spectroscopy (XPS) survey spectra of each lens tested. Carbon 1s, oxygen 1s, and nitrogen 1s are readily apparent in all lenses.

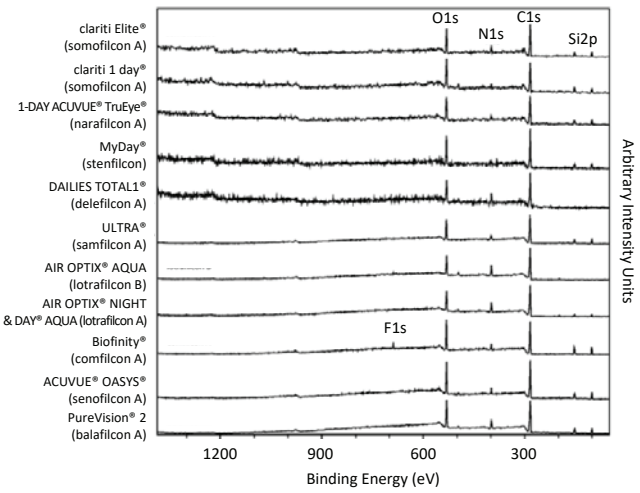
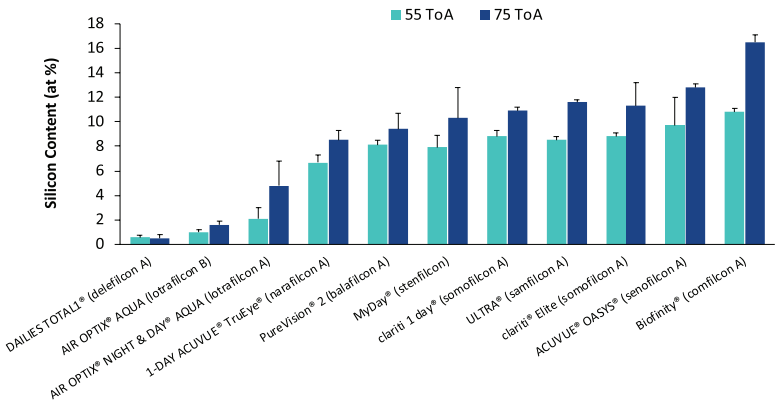


Figure 2. Silicon elemental percentage as a function of take-off angle (TOA) for each lens. Increasing TOA corresponds to a decrease in sampling depth. A TOA of 55" corresponds to approximately 10 nm of sampling depth while a TOA of 75" corresponds to approximately 3 nm. Error bars represent the experimental variation in measured Si intensity across both location and lens sample for each lens type.



Relationship of Water Content with Silicon and Fluorine Contents of Silicone-Hydrogel Contact Lens Materials

Dupre et al. *Eye Contact Lens* 2019; 45:23-27

OVERVIEW

STUDY DESIGN
Experimental study to explore the relationship between silicon (Si) and water (W) content for fourteen silicone hydrogel (SiHy) materials of sixteen commercially available SiHy contact lens brands and the inclusion of fluorine (F) content for three lenses

STUDY SITE(S)
Two research centers in the United States

PATIENTS
Not applicable

METHODOLOGY
W content was obtained gravimetrically for 16 lenses of each SiHy material. Si content was determined using inductively coupled plasma optical emission spectroscopy for four digested lenses of each material. F content was determined using an ion-selective electrode for four combusted lenses of each of the three fluorinated SiHy materials. W and Si contents of the bulk SiHy material of the coated lens was estimated by computational exclusion of the hydrogel layers.

LENS TYPE(S)
AIR OPTIX® AQUA (lotrafilcon B), AIR OPTIX ® Night & Day® (lotrafilcon A), ACUVUE® OASYS® 1-Day (senofilcon A), ACUVUE® ADVANCE (galyfilcon A), ACUVUE® OASYS® (senofilcon A), ACUVUE® TruEye® (narafilcon A), Avaira® UV (enfilcon A), Biofinity® (comfilcon A), clariti® 1 day (somofilcon A), MyDay® (stenfilcon A), ULTRA® (samfilcon A), PureVision® (balafilcon A), PureVision® 2 (balafilcon A), DAILIES TOTAL1® (delefilcon A }, Intelliwave® (efofilcon A; Art Optical), PremiO® (asmofilcon A; Menisoft)

KEY ENDPOINT(S)
Water, silicon, fluorine content and the relationship between them

ANALYSIS AND CONCLUSIONS

There is a negative linear relationship between Si content and W content of clinically prescribed SiHy contact lens materials above 35% W content. The high correlation between Si and W contents is lessened by inclusion of SiHy materials of W content below 35%. The relationship between (Si + F) and water therefore seems to be based on composition rather than structure of available SiHy contact lens materials.

STUDY RESULTS

LENS COMPOSITION

- The negative linear relationship between water and Si content for the 12 lens brands without fluoropolymer or hydrogel surface layers is not as closely followed by 2 lenses containing fluoropolymer (AIR OPTIX® Night & Day® and AIR OPTIX® AQUA), or the DAILIES TOTAL1® lens with a hydrogel surface layer (**Figure 1**)
- The R^2 for the regression line for all 16 brands is 0.7576 (**Figure 1**), whereas the R^2 value for the 12 brands without fluoropolymer or hydrogel surface layers is 0.8869
- Similarly, the R^2 value for the regression line correlating water and hydrated Si content for all 16 brands is 0.8819, whereas the R^2 value for the 12 brands without fluoropolymer or hydrogel surface layers is 0.9263
- The Si + F content is substantially greater than that of Si alone materials, and adding the F content brings the AIR OPTIX ® Night & Day® and AIR OPTIX® AQUA lenses more in agreement with the regression lines
- The overall water content of DAILIES TOTAL1® is greater and its overall Si content is lower when the hydrogel surface layers are included in the calculations; the R^2 of the linear regressions after adding F and adjusting values for the DAILIES TOTAL1® lens are 0.8948 for dry Si + F material and 0.9397 for hydrated Si + F in material
- When the treatments for these SiHy materials were empirically included in the analysis (**Figure 2**), the lenses followed the fundamental negative linear relationships, with hydrated (Si+F) content having the highest R^2 value (0.9397)

Figure 1. Mean silicon content of the dry material versus mean water content of the hydrated material.

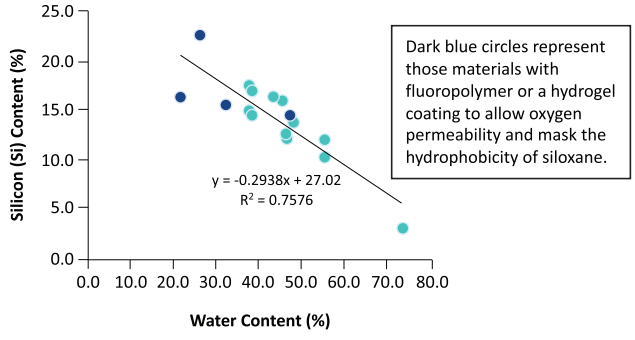
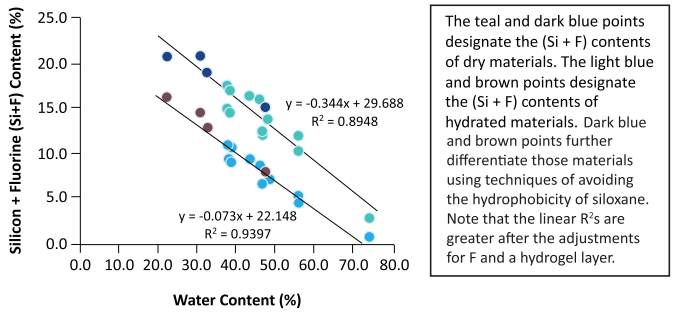


Figure 2. Mean silicon + fluorine (Si + F) content versus mean water content.



Impact of Air Exposure Time on the Water Contact Angles of Daily Disposable Silicone Hydrogels*

Eftimov et al. *Int J Mol Sci.* 2019; 20:1313

OVERVIEW

STUDY DESIGN
Experimental trial examining the wettability of silicone hydrogel (SiHy) contact lens (CLs) and its effects on the pre-lens tear film (PLTF) stability throughout the day

STUDY SITE(S)
Single site in Bulgaria

PATIENTS
Not applicable

METHODOLOGY
Sessile drop and captive bubble setups to study the advancing and receding water contact angles (CA) of four SiHy materials. Sessile drop and captive bubble CA were measured with Contact Angle Meter with Rotable Substrate Holder, Automated Dispenser & Temperature Control HO-IAD-CAM-01B (Holmarc Opto-mechatronics)

LENS TYPE(S)
DAILIES TOTAL1® (delefilcon A)]; ACUVUE® OASYS® 1-Day (senofilcon A; Johnson & Johnson Vision Care), 1-DAY ACUVUE® TruEye® (narafilcon A; Johnson & Johnson Vision Care)); MyDay™ (stenfilcon A; CooperVision, Inc.)

KEY ENDPOINT(S)
Wettability; PLTF; water contact angles (CA)

ANALYSIS AND CONCLUSIONS

The extended desiccation/rehydration cycling increased the differences between the CA of delefilcon A and stenfilcon A compared to senofilcon A and narafilcon A. This suggests that the low Si surface content and the high surface hydration are major determinants of SiHy wettability.

Pre-lens tear film (PLTF) is essential for the comfort of wearers of daily disposable SiHy contact lenses, as it ensures the lubricity and optical quality (i.e., the visual clarity and the refractive index) of the contact lens throughout the day. In turn, contact lens properties, particularly wettability, play a vital role in the stability of the PLTF. If the hydration of the contact lens surface becomes compromised, then PLTF becomes unstable due to dewetting.

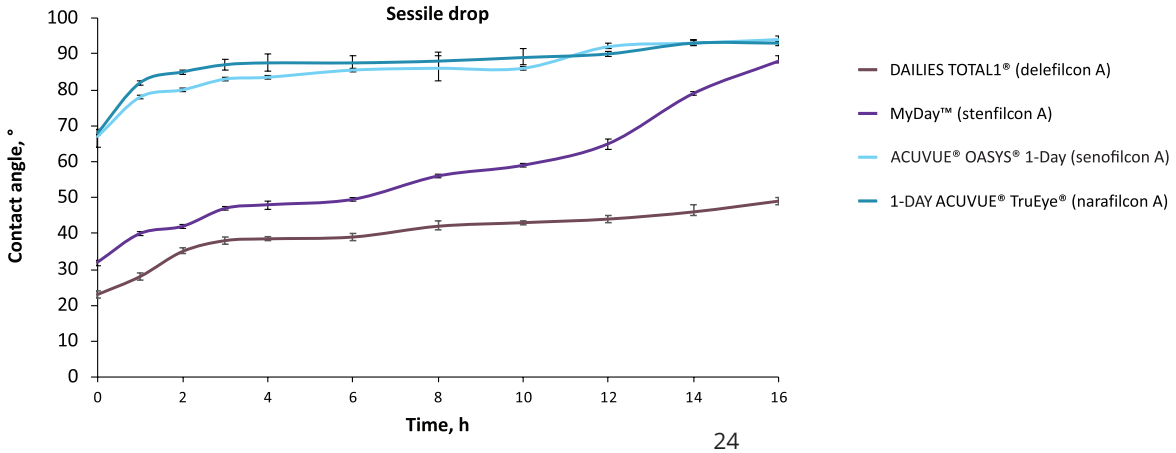
** This study was financially supported by Alcon*

STUDY RESULTS

WETTABILITY

- The dependencies of the advancing water CA of sessile drops over the SiHy materials on the duration of the blink like desiccation/rehydration cycling showed very different performance (**Figure 1**)
  - Narafilcon A and senofilcon A displayed CA of 66.7° and 68.6°, even before air exposure, and the CA rapidly grew to 83.3° for senofilcon A and 87° narafilcon A
  - For both CLs, the CA increased slowly to reach 94.5°for senofilcon A and 93.3° for narafilcon A after 16 hours of desiccation/rehydration cycling
- The advancing water CAs of delefilcon A and stenfilcon A were significantly lower than the ones of narafilcon A and senofilcon A for the entire time scale of exposure to desiccation/rehydration cycling
- The advancing CA, which measures the propensity of the CL surface, proved to be the most sensitive parameter to discriminate between the samples. The order of performance for the entire time scale was delefilcon A>stenfilcon A>senofilcon A>narafilcon A

Figure 1. Dependence of the advancing water contact angle (CA) of sessile drops over silicone hydrogel materials (n=10 for each point) on the duration of the blink like desiccation/rehydration cycling.



Development and Preliminary Evaluation of a System to Rapidly Measure Coefficient of Friction on Soft Contact Lenses

Hook et al. Int *J Ophthalmol Vis Sci.* 2019; 4:88-96

OVERVIEW

STUDY DESIGN
Experimental study to develop an apparatus to rapidly measure coefficient of friction (COF) on soft contact lenses and to determine if COFs measured on two daily-disposable lens models before and after wear are consistent with changes in lens surface morphology observed in parallel atomic force microscopy (AFM) images

STUDY SITE(S)
Two research centers in the United States

PATIENTS
Five (5) patients

METHODOLOGY
Patients each wore the two types of daily disposable contact lenses bilaterally for 4 hours in a randomized order; static and kinetic COFs of lenses worn on left eyes were measured, while lenses worn on right eyes were imaged in parallel by AFM

LENS TYPE(S)
Biotrue® ONEday (nesofilcon A; Bausch & Lomb); DAILIES TOTAL1® (delefilcon A)

KEY ENDPOINT(S)
Comparison of COF measurements to surface topography imaged by AFM and root mean square (RMS) surface roughness

ANALYSIS AND CONCLUSIONS

Static and kinetic COFs measured on delefilcon A were greater than on nesofilcon A lenses. More deposits and greater surface roughness were observed after wear on DAILIES TOTAL1® relative to Biotrue® ONEday lenses.

Parallel AFM images of worn and unworn lenses were not predictive of measured COFs, but increased roughness visible by AFM was consistent with observed increases in COF, although not all increases were statistically significant.

STUDY RESULTS

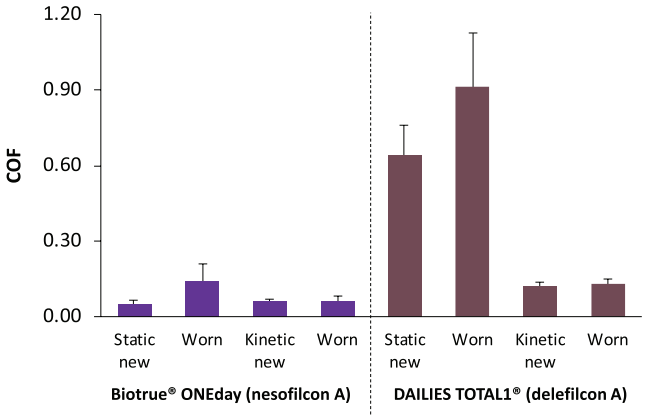
COEFFICIENT OF FRICTION

- Both static and kinetic COFs were greater with DAILIES TOTAL1® than with Biotrue® ONEday (both $P < 0.01$) (**Figure 1**)
- Mean static COF (± standard deviation) with Biotrue® ONEday increased significantly after wear from 0.04 ± 0.02 to 0.14 ± 0.07 ($P < 0.01$); kinetic COF increased after wear from 0.05 ± 0.02 to 0.06 ± 0.02, but the difference was not significant
- Similarly, static COF with DAILIES TOTAL1® increased from 0.64 ± 0.12 to 0.91 ± 0.21 ($P < 0.01$), while kinetic COF on delefilcon A increased from 0.12 ± 0.02 to 0.13 ± 0.02, but the difference was not significant

LENS SURFACE MORPHOLOGY

- Prior to wear, Biotrue® ONEday exhibited a relatively smooth surface lacking distinct features
- After wear, a relatively sparse lens deposit was evident on the topographic image, with disperse, µm-scale material scattered over the surface on the phase image, illustrating areas of the lens where deposits are adhered
- Prior to wear, DAILIES TOTAL1® exhibited a branched, cobblestone-patterned surface morphology
- After wear, this branched morphology was no longer visible, and semi-contiguous, globular, near-confluent lens deposits were observed as islands covering the majority of the lens surface
- The mean RMS surface roughness of Biotrue® ONEday increased from 1.9 ± 0.2 nm to 7.2 ± 3.7 nm after wear ($P = 0.047$)
- The mean RMS surface roughness of DAILIES TOTAL1® decreased from 14.2 ± 5.5 nm to 10.9 ± 4.0 nm after wear but the difference was not significant). The RMS roughness of Biotrue® ONEday was less than that of DAILIES TOTAL1® before wear ($P < 0.01$) but the difference after wear was not significant

Figure 1. Static and kinetic coefficient of friction (COF) of lenses before and after 4 hours of wear. Light grey bars represent unworn lenses. Dark grey bars represent worn lenses.



Deposition of Fluorescently Tagged Lysozyme on Contact Lenses in a Physiological Blink Model

Phan et al. *Eye & Contact Lens*. 2019;00:1-7

OVERVIEW

STUDY DESIGN
In vitro study to visualize deposition of fluorescein isothiocyanate (FITC) lysozyme on daily disposable contact lenses using a novel blink model

STUDY SITE(S)
Single research center in Canada

PATIENTS
Not applicable

METHODOLOGY
Blink speed in an eye model was set at one blink / 10 seconds and a thin layer of fluid was spread over the eyeball surface after each blink. Contact lenses (CLs) were placed in the model for 2 and 10 hours, after which a sample from the center of the CL was examined under a laser scanning microscope. In a second set of experiments, etafilcon A and senofilcon A lenses were incubated 24 hours in the blink model. Four etafilcon A lenses were incubated 2 hours in a vial containing FITC lysozyme solution to compare deposition to the blink model. Lysozyme was chosen as a marker for protein deposition because it is one of the primary depositors on CLs

LENS TYPE(S)
Conventional hydrogel (CH) CLs: DAILIES® AquaComfort Plus® (nelfilcon A); Proclear® 1 day (omafilcon A; CooperVision, Inc.); 1-DAY ACUVUE® MOIST® (etafilcon A; Johnson & Johnson Vision Care). Silicon hydrogel (SH) CLs: clariti® 1 day (somofilcon A; CooperVision, Inc.),1-DAY ACUVUE® TruEye® (narafilcon A; Johnson & Johnson Vision Care); DAILIES TOTAL1® (delefilcon A); ACUVUE® OASYS® (senofilcon A; Johnson & Johnson Vision Care)

KEY ENDPOINT(S)
FITC lysozyme deposition on various daily disposable contact lenses

ANALYSIS AND CONCLUSIONS

FITC lysozyme deposition appeared to be dependent on lens material, with etafilcon A showing the highest deposition at all time points; for most lenses, there was higher deposition at the front of the lens initially but after 10 hours, lysozyme was distributed throughout the bulk of the lens.

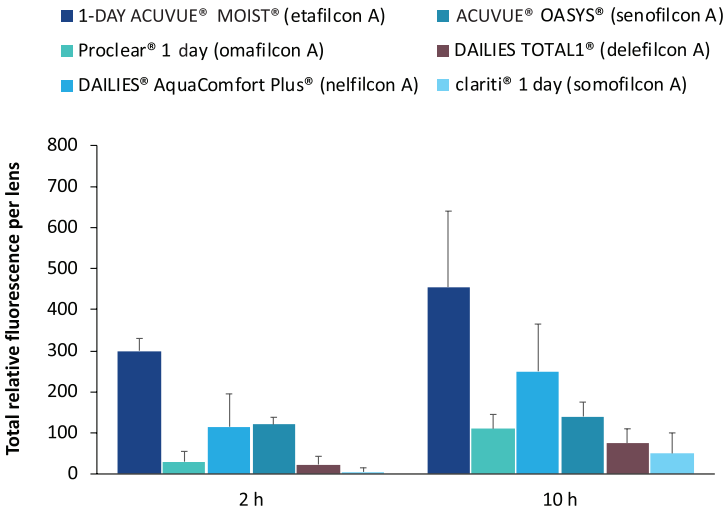
Findings suggest that designing contact lens materials with different surface properties for the frontside and backside of the lens may be beneficial in creating better interactions with the tear film.

STUDY RESULTS

LYSOZYME DEPOSITION

- Total lysozyme deposition increased with increased incubation time for all lenses except somofilcon A, which did not show a significant difference between 2- and 10-hour deposition (P>0.05); the amount of deposition differed among lenses with highest deposition seen in the etafilcon A at all time points (P<0.05)
- At 2 hours senofilcon A and nelficon A had higher deposition than omafilcon A and delefilcon A (P<0.05)
- At 10 hours, there were no significant differences in overall deposition between senofilcon A, nelfilcon A, delefilcon A and omafilcon A (P>0.05) (**Figure 1**)
- CH materials deposited higher amounts of lysozyme than SH materials (P<0.001); although there was greater deposition for etafilcon A at 10 hours (P<0.05), there was no significant difference for senofilcon A (P>0.05)
- Results suggested preferential deposition at the front surface of the lens; this was noted for all but 2 lenses (nelfilcon A and somofilcon A) at 2 hours; at 10 hours, however, omafilcon A, senofilcon A and delefilcon A showed lysozyme deposition throughout the lens after 10 hours

Figure 1. Total relative fluorescence per lens at 2 and 10 hours of incubation.



Novel *In Vitro* Method to Determine Pre-Lens Tear Break-Up Time of Hydrogel and Silicone Hydrogel Contact Lenses

Walther et al. *Cont Lens Anterior Eye.* 2019;42:178-184

OVERVIEW

STUDY DESIGN
Experimental study using an *in vitro* model to determine pre-lens non-invasive break-up time (NIBUT) of contemporary daily disposable contact lenses (DD CL)

STUDY SITE(S)
Single research center in Canada

PATIENTS
Not applicable

METHODOLOGY
DD CLs were incubated in an artificial tear solution. A model blink cell was used to mimic intermittent air exposure. CLs were repeatedly submerged for 3 seconds and exposed to air for 10 seconds over periods of 2, 6, 12, and 16 hours. NIBUTs were determined out of the blister pack (T0) and at the end of each incubation period

LENS TYPE(S)
Silicone hydrogel (SH) DD CLs: DAILIES TOTAL1® (delefilcon A), clariti® 1day (somofilcon A; CooperVision, Inc.), 1-DAY ACUVUE® TruEye® (narafilcon A; Johnson & Johnson Vision Care). Conventional hydrogel (CH) DD CLs: 1-DAY ACUVUE® MOIST® (etafilcon A; Johnson & Johnson Vision Care), Biotrue® ONEday (nesofilcon A; Bausch & Lomb)

KEY ENDPOINT(S)
Use of an *in vitro* model to compare NIBUT for 5 DD CLs

ANALYSIS AND CONCLUSIONS

While NIBUTs of CH materials are longer than those obtained with SH materials immediately out of the blister pack, the NIBUTs obtained for CH and SH DD materials were very similar after tear film exposure.

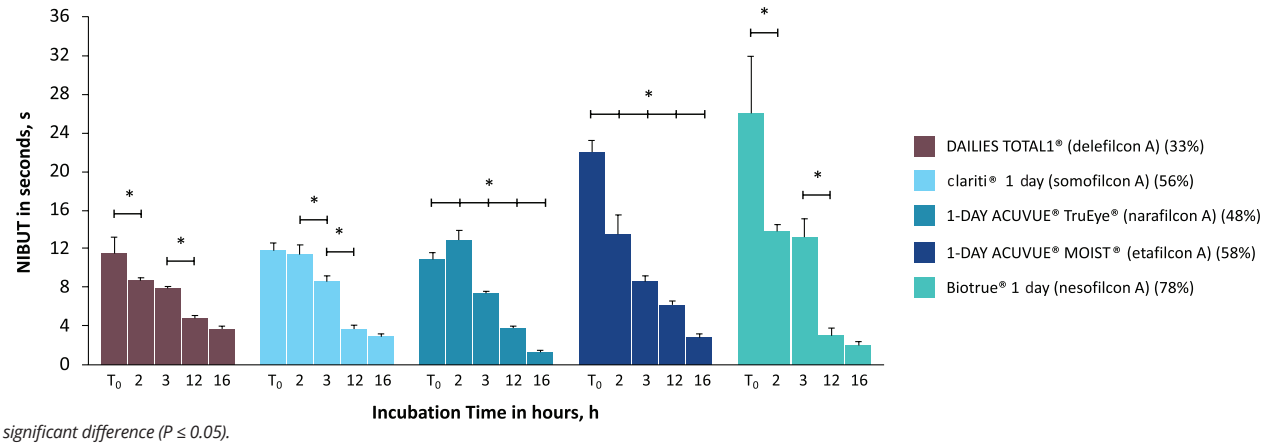
Further work is warranted to determine if a progressive reduction in pre-lens NIBUT occurs over the course of the day and, if so, whether such a difference is mitigated by the materials being worn.

STUDY RESULTS

TEAR FILM BREAK-UP

- NIBUT measurements depended significantly on the duration of incubation, the type of CL material, and the interaction between these factors (all P<0.001); when all time points were pooled for each CL type, CH lenses showed significantly greater NIBUTs than SH lenses (P≤0.001), with no significant difference between the two CH CLs or between the SH CLs
- Nesofilcon A had the longest average NIBUT of all CLs, which was only significant (P≤0.001) compared with the SH materials
- At T_0, the two CH lenses had significantly longer NIBUTs (P≤0.001) than all three SH materials, but no significant difference was found between the individual CH or SH lenses with a NIBUT of 3.6 ± 0.3 seconds, delefilcon A had a significantly longer break-up time after 16 hours (P ≤ 0.001)
- NIBUT significantly decreased (P≤0.002) between T0 and 2 hours for all CLs except for somofilcon A and narafilcon B (**Figure 1**); NIBUT between T0 and 6, 12, and 16 hours was significantly lower for all CLs (P≤0.001)
- For delefilcon A, somofilcon A, and nesofilcon A CLs, the reduction in NIBUTs was statistically significant (P≤0.001) between most time points

Figure 1. Histogram representing the non-invasive break-up time (NIBUT) for five daily disposable contact lens materials for up to 16 hours after incubation in a model blink cell.



** Statistically significant difference (P ≤ 0.05).*

Sagittal Height Differences of Disposable Soft Contact Lenses

Giovanzana et al. *Int Ophthalmol.* 2020; 40:459-465

OVERVIEW

STUDY DESIGN
Experimental study to improve contact lens fitting by using an innovative and simple photogrammetry imaging system to find the sagittal height (SAG) of soft contact lenses

STUDY SITE(S)
Centers in Italy and Romania

PATIENTS
Not applicable

METHODOLOGY
Five (5) lenses each of 11 different types of commercially available soft contact lenses measured by insertion in a polymethyl methacrylate cell with parallel faces containing a solution of saline and fluorescein. Sagittal height (SAG) was calculated using homothetic transformations and data compared with the nominal spherical sagittal height (SAG_SF)

LENS TYPE(S)
High water nonionic hydrogel: Proclear® (omafilcon A; CooperVision), AquaSoft™ All Day (hioxifilcon A), DAILIES® AquaComfort Plus® (nelfilcon A), Biotrue® ONEday (nesofilcon A; Bausch & Lomb), and SofLens® (hilafilcon B). High water ionic hydrogel ACUVUE® (etafilcon A; Johnson & Johnson Vision Care). Silicone hydrogel polymers: 1-DAY ACUVUE® TruEye® (narafilcon A) and ACUVUE® OASYS® (senofilcon A) (both Johnson & Johnson Vision Care), DAILIES TOTAL1® (delefilcon A), clariti® 1 day (somofilcon A) and MyDay™ (stenfilcon A) (both CooperVision)

KEY ENDPOINT(S)
Measured SAG of soft contact lenses and the difference between the SAG and the SAG_SF, which is the calculated sagitta of the back surface of the lens based on the provided package information

ANALYSIS AND CONCLUSIONS

Optical coherence tomography measurement of the eye sagitta over a given chord helped to find the first lens to fit. This is because matching contact lens sagitta and ocular sagitta is the key for a good fitting. The majority of brands use single sphere geometry for the internal surface of disposable soft contact lenses.

STUDY RESULTS

LENS SURFACE ANALYSIS

- Proclear®, AquaSoft™ All Day, Biotrue® ONEday, SofLens®, ACUVUE®, 1-DAY ACUVUE® TruEye®, ACUVUE® OASYS® and clariti® 1 day had a spherical posterior surface, since the mean difference between SAG and SAG_SF was 8 µm with a range of 1 to 24 µm (**Table 1**)
- In contrast, DAILIES® AquaComfort Plus®, DAILIES TOTAL1® and MyDay™ had aspherical posterior surfaces (**Table 1**)
- DAILIES® AquaComfort Plus® and MyDay™ had a measured sagittas lower than their SAG_SFs, 84 µm and 97 µm, respectively. DAILIES TOTAL1® had a measured sagitta 64 µm higher than the SAG_SF
- Lens pairs that passed the t test for comparability (α <0.05) had a difference between each other of less than 17 µm (**Table 2**)

Table 1. Mean sagittal height (SAG), analysis of variance (ANOVA) F, ANOVA P value, and absolute difference between SAG and nominal spherical sagitta (SAG_SF) for the analyzed contact lenses.

Lens	SAG (µm)	SD (µm)	F	*p*-value	SAG–SAG_SF (µm)
oma	3658	38	0.643	0.638	-14
hio	3731	17	0.265	0.896	-16
nel	3450	20	0.532	0.714	-84
nes	3742	20	0.194	0.938	-5
hil	3748	10	0.859	0.508	1
eta	3823	18	1.289	0.309	-4
nar	3828	14	2.283	0.100	1
sen	3907	13	2.020	0.132	3
del	3816	10	1.258	0.319	64
som	3651	10	0.906	0.480	-24
ste	3815	38	1.037	0.413	-97

oma, omafilcon A (Proclear®); **hio**, hioxifilcon A (AquaSoft™ All Day); **nel**, nelfilcon A (DAILIES® AquaComfort Plus®); **nes**, nesofilcon A (Biotrue® ONEday); **hil**, hilafilcon B (SofLens®); **eta**, etafilcon A (ACUVUE®); **nar**, narafilcon A (1 Day ACUVUE® TruEye®); **sen**, senofilcon A (ACUVUE® OASYS®); **del**, delefilcon A (DAILIES TOTAL1®); **som**, somofilcon A (clariti® 1 day); **ste**, stenfilcon (MyDay™)

Table 2. Difference (µm) between the Measured sagittal height (SAG) of contact lenses tested.

	oma	hio	nel	*nes*	hil	eta	nar	sen	del	som	ste
oma	0	73	208	84	90	165	170	249	158	7	157
hio		0	281	11	17	92	97	176	85	80	84
nel			0	292	297	373	378	457	366	201	364
nes				0	6	81	86	165	74	91	73
hil					0	75	80	159	68	97	67
eta						0	5	84	7	172	8
nar							0	79	12	177	13
sen								0	91	256	92
del									0	165	2
som										0	164
ste											0

SD, standard deviation.

Latanoprost Uptake and Release from Commercial Contact Lenses*

Horne et al. *J Biomater Sci Polym Ed.* 2020; 31:1-19

OVERVIEW

STUDY DESIGN
Experimental study to investigate the potential of delivering moderately hydrophobic anti-glaucoma drug latanoprost using commercial silicone hydrogel (SiHy) contact lenses

STUDY SITE(S)
Two research centers in the United States

PATIENTS
Not applicable

METHODOLOGY
Latanoprost was rapidly loaded in 4 minutes by swelling contact lenses in a solution of the drug in n-propanol. A fraction of the drug was radiolabeled to allow measurement of the uptake and subsequent release of drug into artificial tear fluid

LENS TYPE(S)
SiHy: Pure Vision® 2 (balafilcon A: Bausch & Lomb), Biofinity® (comfilcon A; CooperVision), DAILIES TOTAL1® (delefilcon A), ACUVUE® Advance™ (galyfilcon A; Johnson & Johnson Vision Care), AIR OPTIX® (lotrafilcon B). Conventional lens of poly (hydroxyethyl methacrylate): SofLens® 38 (polymacon; Bausch & Lomb)

KEY ENDPOINT(S)
The amount of drug that can be loaded into each type of lens, how fast the drug is released, and how these values are related to the contact lens chemistry

ANALYSIS AND CONCLUSIONS

This study found that much more latanoprost could be loaded into SiHy lenses than a conventional contact lens of poly(hydroxyethyl methacrylate); drug uptake correlated with the amount of swelling in n-propanol, with ACUVUE® Advance™ having the greatest swelling and highest uptake.

Drug uptake in SiHy lenses correlated with favorable solubility parameter interactions between the n-propanol and the lens material.

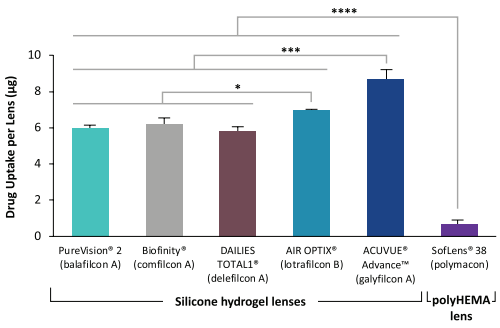
*DailiesTotal1® contact lenses were kindly donated by Alcon

STUDY RESULTS

DRUG LOADING AND RELEASE

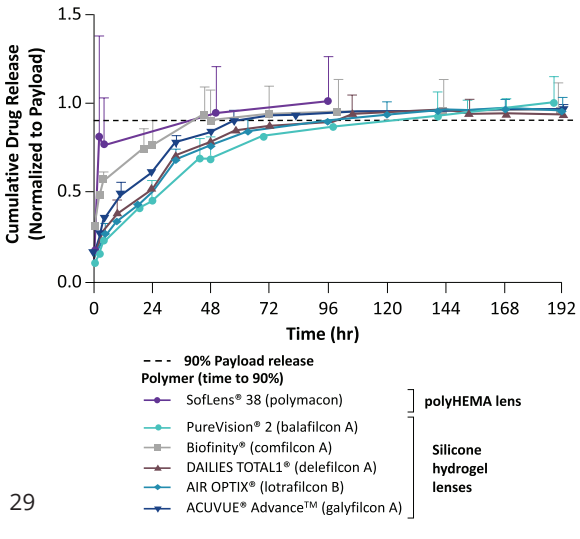
- The 5 SiHy lenses took up a 10-15-fold greater payload of the drug latanoprost than did the pHEMA lens ($P < 0.0001$; **Figure 1**)
- ACUVUE® Advance™ absorbed and retained about 30% more latanoprost than the other SiHy lenses ($P < 0.01$). There was a good correlation between the amount of drug uptake and the swelling in n-propanol ($R = 0.979$)
- When the amount of cumulative release was normalized by the amount loaded, all the SiHy lenses have similar release profiles, releasing around 90% of their latanoprost in about 72 hours
- Drug release decreased over time. The SofLens® 38 lens exhibited burst release over the first 2 hours, while the drug release was generally more prolonged for SiHy lenses. Notably, Pure Vision® 2 delivered drug for 8 days in artificial tears at a dose that is therapeutically greater than or comparable to delivery by eye drops
- To compare release data, the cumulative release profile was divided by the total latanoprost uptake (**Figure 2**)
- All five SiHy have similar sustained release profiles, All the contact lenses released essentially all their loaded latanoprost
- The cumulative release was not linearly proportional to time, but to the square root of time, implicating diffusion as a possible mechanism for the initial latanoprost trans- port from the lens into the artificial tear fluid

Figure 1. Latanoprost drug uptake in commercial contact lenses via swelling for 4 minutes in a solution of 0.125g/L latanoprost in n-propanol. Error bars represent 95% confidence intervals (n=3).



*Post-hoc statistical analysis: *P < 0.05; ***P < 0.001; ****P < 0.0001.*

Figure 2. Normalized cumulative latanoprost release from loaded contact lenses into artificial tear solution. The dotted line represents 90% release, and the values in parentheses indicate times to achieve 90% release. Bars are 95% confidence intervals (n = 3).



Physicochemical Stability of Contact Lenses Materials for Biomedical Applications

Lira et al. *J. Optom.* 2020; 13:120-127

OVERVIEW

STUDY DESIGN
Experimental trial to analyze the physiochemical stability, thermal and water plasticizing effect on transport properties of contact lenses (CL) to verify capacity to maintain the original properties after being dehydrated and rehydrated

STUDY SITE(S)
Single site in Portugal

PATIENTS
Not applicable

METHODOLOGY
CL refractive index (RI), water content (WC) measured using a digital automated refractometer. Chemical structure, and thermal properties were taken new (N), after dehydration (D), and rehydrated (R) by a Fourier Transformed Infrared Spectroscopy (FTIR-ATR) and Differential Scanning Calorimetry (DSC)

LENS TYPE(S)
Daily Disposable CLs: DAILIES TOTAL1® (delefilcon A); Biotrue® ONEday (nesofilcon A; Baush & Lomb). Monthly CLs: AIR OPTIX® AQUA (lotrafilcon B); Biofinity® (comfilcon A; CooperVision, Inc.)

KEY ENDPOINT(S)
Lens physiochemical structure (RI, WC), chemical structure, and thermal properties

ANALYSIS AND CONCLUSIONS

Changes in contact lens materials originated by repeated application and removal, environmental conditions, and dry areas caused by exposure to the environment, can cause permanent deterioration and result in loss of some important features necessary to have a good clinical performance.

There were no significant alterations in the physiochemical structure of the materials after dehydration and rehydration, thus showing good stability of their components.

STUDY RESULTS

PHYSIOCHEMICAL CHANGES

- The FITR spectrum of new, dehydrated, and rehydrated lenses was quite similar for all CLs tested
- As fluctuations in the water content may be related to modifications in the structure and molecular dynamics of the material, the RI and WC of the studied CLs were evaluated under the same conditions with the mean values of both are shown in **Table 1**
- There were no significant changes found in the CLs' chemical structure post dehydration and rehydration (all P>0.05); RI of the delefilcon A CLs was 1.4267 ± 0.0006 and 1.4275 ± 0.0007 under new and rehydrated conditions, respectively; WC of the delefilcon A CLs was 24.10 ± 0.57 % and 23.45 ± 0.64 % under new and rehydrated conditions, respectively (**Table 1**)
- RI and WC of the rehydrated CLs did not vary significantly from the initial CL (P>0.05) and thermal properties also confirm that the behavior did not change
- The glass-transition temperature decreased with increased WC as shown in **Table 2**

Table 1. Mean values of refractive index and water content and statistical significance.

		RI (N)	RI (R)	p	WC (N) (%)	WC (R) (%)	p
Biotrue® ONEday	Nesofilcon	1.3726 ± 0.0003	1.3729 ± 0.0003	0.285	78.37 ± 0.21	78.03 ± 0.38	0.180
DAILIES TOTAL1®	Delefilcon A	1.4267 ± 0.0006	1.4275 ± 0.0007	0.180	24.10 ± 0.57	23.4 5± 0.64	0.180
AIR OPTIX® AQUA	Lotrafilcon B	1.4218 ± 0.0001	1.4219 ± 0.0002	0.593	28.57 ± 0.15	28.20 ± 0.10	0.109
Biofinity®	Comfilcon A	1.4045 ± 0.0005	1.4056 ± 0.0004	0.109	47.9 ± 0.20	47.27 ± 0.15	0.109

RI (N): refractive index (new lens); RI (R): refractive index (rehydrated lens); WC (N): water content (new lens); WC (R): water content (rehydrated lens).

Table 2. Glass transition temperature (Tg) and water content of lenses.

	DAILIES TOTAL1® (delefilcon A)	Biotrue® ONEday (nesofilcon A)	Biofinity® (comfilcon A)	AIR OPTIX® AQUA (lotrafilcon B)
Water content (%)	33-80	78	48	33
Tg (°C)	17.26	24.86	27.05	27.43

Interaction Between Siloxane-Hydrogel Contact Lenses and Eye Cosmetics: Aluminum as a Marker of Adsorbed Mascara Deposits

Zeri et al. *Polym Polym Compos.* 2020; online May 7, 2020

OVERVIEW

STUDY DESIGN
Experimental and clinical trial to investigate the presence of mascara deposits on polymeric siloxane-hydrogel contact lenses (CL) after *in vivo* 8 hours of wear and to compare the affinity to mascara of two siloxane-hydrogels through *in vitro* contamination tests

STUDY SITE(S)
Single site in Italy

PATIENTS
Eight (8) subjects – females aged 18-30 years, habitual CL wearers with no allergies or ocular pathologies

METHODOLOGY
Scanning electron microscopy (SEM) and energy-dispersive X-ray spectroscopy (EDX) were carried out on new CLs, CLs exposed *in vitro* to non-waterproof blue mascara, and CLs worn for 8 hours by mascara wearers; images by an optical microscope were acquired and processed on new CLs and CLs treated *in vitro*

LENS TYPE(S)
DAILIES TOTAL1® (delefilcon A); OPEN 30 (filcon V; Safilens)

KEY ENDPOINT(S)
EDX; SEM; *in vitro* contamination tests

ANALYSIS AND CONCLUSIONS

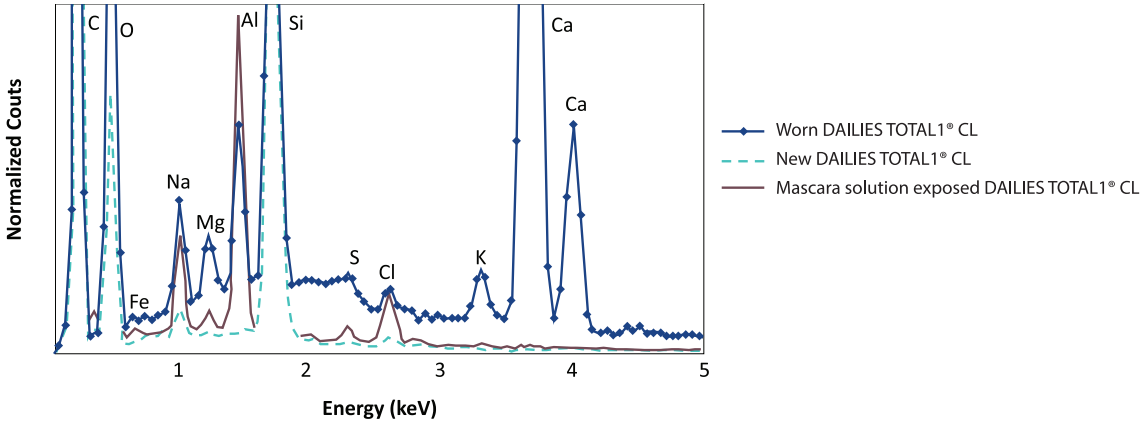
In this observational study, deposits of aluminum (a marker of deposit of mascara on contact lenses) were detected on all investigated contact lenses after 8 hours of wear, more marked than for the components of the tear film.

STUDY RESULTS

SEM/EDX/OPTICAL MICROSCOPY OBSERVATIONS

- Mascara deposits were seen on the surface of CLs exposed to mascara solution *in vitro* as well as those work for 8 h; due to the high concentration of mascara found within *in vitro* solutions, deposits on the corresponding CLs were more frequent than deposits on worn CLs
- **Figure 1** shows the representative EDX profiles
- The most important difference between the new CLs on one side and, on the other side, CLs treated *in vitro* or worn for 8 h, was the appearance of the following peaks:
  - Iron at 0.705 keV
  - Magnesium at 1.253 keV
  - Sulfur at 2.307 keV
  - Al peak at 1.486 keV (very intense)
- Iron, magnesium, sulfur, and aluminum were attributable to mascara because they were present on both worn CLs and CLs treated *in vitro*, but not new CLs
- SEM whiteish deposits and EDX intense peak of aluminum were identified in all samples both after *in vitro* treatment and after 8 h wear for both DAILIES TOTAL1® and OPEN 30 CLs
- DAILIES TOTAL1® CLs showed an affinity for the mascara more than two times higher than the OPEN 30 CLs; this is attributable to the different properties of the surface layer of the two types of CLs

Figure 1. EDX profiles obtained by directing the electrons toward the smooth surface of a new delefilcon A CL (dotted line), towards deposits observed by SEM on a DAILIES TOTAL1® CL exposed to mascara solution (continuous line), and toward deposits observed by SEM on a worn DAILIES TOTAL1® CL (continuous line with diamonds).



CL: contact lens; EDX: energy dispersive spectroscopy; SEM: scanning electron microscopy.

Diurnal Variations in Visual Performance for Disposable Contact Lenses

Belda-Salmerón et al. *Optom Vis Sci.* 2013;90:682-690

OVERVIEW

STUDY DESIGN
Bilateral, prospective double-blind, randomized, comparative daily wear, controlled study to compare the visual performance and variation over time provided by different daily disposable contact lenses

STUDY SITE(S)
Single center in Spain

PATIENTS
Fifteen (15) myopic habitual contact lens wearers (30 eyes) aged 20-35 years with monocular best-corrected visual acuity (VA) of 20/20 or better; twelve (12) wore monthly soft contact lenses and three (3) wore daily disposable contact lenses

METHODOLOGY
Visual performance was evaluated by visual acuity (VA) and contrast sensitivity (CS) in subjects fitted with each of seven soft contact lenses. VA was measured at low- (10%), medium- (50%), and high- (100%) contrast levels and CS was measured for 10 (low), 20 (medium), and 25 (high) cycles/degree (cpd) spatial frequencies

LENS TYPE(S)
DAILIES TOTAL1® (delefilcon A); DAILIES® AquaComfort Plus® (nelfilcon A); 1-DAY ACUVUE® TruEye® (narafilcon A; Johnson & Johnson Vision Care), 1-DAY ACUVUE® MOIST® (etafilcon A; Johnson & Johnson Vision Care); SofLens® daily disposable (hilafilcon B; Bausch & Lomb), Proclear® 1 day (omafilcon A; CooperVision); clariti® 1 day (filcon II 3; Sauflon Pharmaceuticals)

KEY ENDPOINT(S)
Visual acuity, contrast sensitivity before fitting and at 2-hour intervals during a 12-hour period of continuous wear

ANALYSIS AND CONCLUSIONS

Contact lens characteristics such as material and water content, among other factors, may be the cause of the differences in visual performance between contract lenses and over time.

The effect was more pronounced with low-contrast VA and higher spatial-frequency CS.

STUDY RESULTS

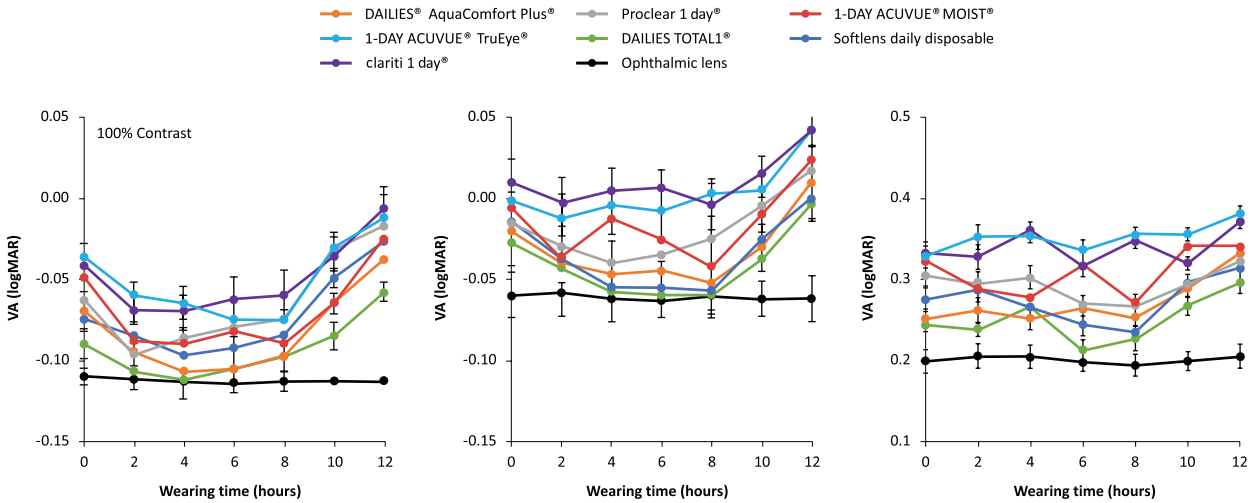
VISUAL ACUITY

- Greater VA differences across lenses were observed at low contrast levels and with increasing wear time (**Figure 1**)
- Lower contrast worsened VA. There was a significant interaction between contact lens type and wear time at all contrast levels (P<0.001). There were no significant differences in VA between contact lenses, only differences between all lenses and no lens at 10 hours with low-contrast and at 12 hours with all levels of contrast

CONTRAST SENSITIVITY

- Higher spatial frequencies were associated with lower CS values and greater differences between lens types
- Differences in CS between contact lenses were revealed at all spatial frequencies (all P<0.001). The interaction between lens type and wearing time at 10- and 20-cpd spatial frequencies were significant (P=0.04 and P<0.001, respectively)

Figure 1. Visual acuity (VA; logMAR) results for a 3-mm pupil, 100% (left), 50% (middle), 10% (right) contrast level. Each data point represents the mean value across all patients obtained for that particular lens type, ophthalmic lens condition, and wearing time.



A Multi-Country Assessment of Compliance with Daily Disposable Contact Lens Wear*

Dumbleton et al. *Cont Lens Anterior Eye.* 2013; 36:304-312

Lens Fit

Practitioner-Reported Outcomes

Patient-Reported Outcomes

OVERVIEW

STUDY DESIGN
Survey to assess compliance with, and re-use of, daily disposable contact lenses

STUDY SITE(S)
Sites in Australia, Norway, United Kingdom, United States

PATIENTS
Eight hundred and five (805) current contact lens wearers ≥18 years of age who had worn daily disposable contact lenses for at least 6 months

METHODOLOGY
Patients completed lens wearing history survey, ranking of various aspects related to daily disposable contact lens wear, lens wearing patterns, behavior and reasons related to re-use, comfort ratings; compliance defined as replacing lenses at an interval equal to the Manufacturer Recommended Replacement Frequency (i.e. re-use was considered to be non-compliant)

LENS TYPE(S)
Conventional hydrogel: DAILIES® AquaComfort Plus® (nelfilcon A); SofLens® daily disposable (hilafilcon B; Bausch & Lomb); Proclear® 1 day (omafilcon A; CooperVision); 1-DAY ACUVUE® MOIST® (etafilcon A; Johnson & Johnson Vision Care); Biomedics® 1 day (ocufilcon B; CooperVision). Silicone hydrogel: clariti® 1 day (somofilcon A; CooperVision),1-DAY ACUVUE® TruEye® (narafilcon A; Johnson & Johnson Vision Care); DAILIES TOTAL1® (delefilcon A)

KEY ENDPOINT(S)
Compliance with daily lens use and factors related to lens wear and lens re-use

ANALYSIS AND CONCLUSIONS

33% of patients reported some type of non-compliant behavior. Compliance was not different between hydrogel and silicon hydrogel lenses.

This study highlights the need for continued counseling of patients on the importance of appropriate lens wear and replacement of lenses.

* This study was funded by Alcon

STUDY RESULTS

COMPLIANCE

- The most commonly used lenses were DAILIES® AquaComfort Plus® worn by 364 participants (45%) and 1-DAY ACUVUE® MOIST® worn by 141 participants (18%); silicon hydrogel contact lenses were worn by 115 participants (14%)
- Overall, 59% of participants reported wearing their daily disposable lenses 7 days per week; mean wearing time was 13.8 ± 2.8 hours (range 2–23 hours)
- Re-use of daily disposable lenses was reported by 9% of participants. The frequency of non-compliance was lowest in Norway (4%), followed by the UK (7%), US (12%) and Australia (18%)
- Most (64%) participants report re-using lenses for one day, while 27% re-used their lenses for between 2 and 6 more days; the reasons for re-use are to save money, running out of lenses, and no risk in reusing lenses.
- Overnight wear of daily disposable contact lenses was reported by 28% of participants, with a higher proportion found among those <25 years of age (48%) compared with those ≥ 24 years old (24%) and no significant difference among different lens types
- There were no factors such as age, gender or lens material that differentiated those individuals who were compliant with daily disposal of their lenses and those who were not

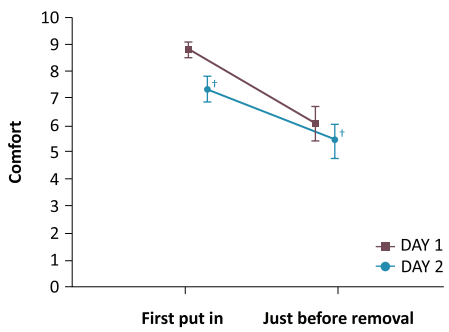
COMFORT

- Participants were asked to rank their comfort on a scale of 0 (very poor) to 10 (excellent) at various points during the day; there was a significant decrease in comfort during a one-day period with new lenses (P<0.001) (**Table 1**)
- Participants who re-used lenses reported comfort rating that were significantly lower than those with new lenses (**Figure 1**)

Table 1. Comfort ratings reported by survey participants. Ratings based on a scale where 0=very poor and 10=excellent.

Country	New - on insertion	Halfway through day	Later in day	Prior to removal
Australia	8.5 ± 1.4	8.2 ± 1.5	6.7 ± 2.4	6.1 ± 2.8
US	9.2 ± 2.0	8.5 ± 1.5	6.9 ± 2.2	6.2 ± 2.6
UK	8.8 ± 1.3	8.6 ± 1.6	6.9 ± 2.2	6.2 ± 2.8
Norway	8.8 ± 1.3	8.8 ± 1.4	7.2 ± 1.9	6.4 ± 2.4
All	8.9 ± 1.3	8.6 ± 1.5	7.0 ± 2.4	6.2 ± 2.6

Figure 1. Comfort ratings for new and re-used daily disposable contact lenses. Ratings based on a scale where 0=very poor and 10=excellent.



** P=0.001 Tukey HSD, all comparisons P<0.001*

Comfort Response of Three Silicone Hydrogel Daily Disposable Contact Lenses*

Lens Comfort

Patient-reported Outcomes

Varikooty et al. *Optom Vis Sci.* 2013; 90:945-953

OVERVIEW

STUDY DESIGN
Prospective, randomized, bilateral, crossover trial to evaluate subjective ocular comfort across the day with three silicone hydrogel daily disposables (SHDDs) in a group of adapted contact lens (CL) wearers

STUDY SITE(S)
Single site in Canada

PATIENTS
One hundred and four (104) subjects completed the study (51 asymptomatic, 53 symptomatic); 29 males, 75 females; aged 17-51 years (mean 27 ± 9 years)

METHODOLOGY
Asymptomatic or symptomatic subjects with end-of-day (EOD) dryness with habitual CLs) wore three SHDDs, each for three days. On day 2, wearing time and comfort were recorded. Comfort was analyzed across the day (up to 8 hours, 8-12 hours), and a new variable ("cumulative comfort") was calculated for EOD

LENS TYPE(S)
DAILIES TOTAL1® (DT1; delefilcon A); clariti® 1 day (C1D; filcon II3; CooperVision); 1-DAY ACUVUE® TruEye® (AVTE; narafilcon A; Johnson & Johnson Vision Care)

KEY ENDPOINT(S)
Wearing time (WT); cumulative comfort (CC)

ANALYSIS AND CONCLUSIONS

All three SHDDs had average WTs of 12 hours or longer for 1 day. Combined with high oxygen transmissibility of silicone hydrogel materials and the convenience and other benefits of a daily disposable modality, SHDDs are a valuable option for practitioners to consider for their patients.

Cumulative comfort may be a valuable new metric to assess ocular comfort during the day.

*This study was financially supported by Alcon.

STUDY RESULTS

WEARING TIME

- The mean WT for asymptomatic and symptomatic subjects, was 14.0 and 12.7 hours, respectively (P<0.001)
- One hundred and four (104) subjects wore all 3 SHDDs for at least 8 hours, whereas 74 subjects wore them for 12 hours or longer

COMFORT RATING

- On average, ocular comfort was rated higher in the asymptomatic group throughout the day (least square mean (LSM) 92.0 vs 85 in the symptomatic group; P<0.001) and the was a significant difference between comfort ratings at 8 hours as compared to 12 hours (P<0.01)
- For both asymptomatic and symptomatic groups combined, ocular comfort was rated lower with CD (LSM 84.0) lens compared with DT1 lens (LSM 88.0) (P=0.012)

Table 1. Ratings of comfort at insertion, at 4 hours, 8 hours, and 12 hours, and at the end of the day (EOD) (Day 2).

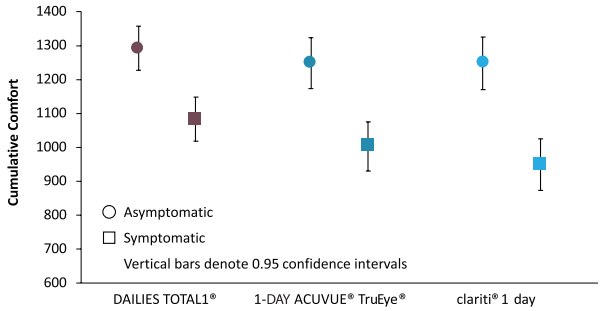
Lens		Mean±SD				
		Insertion	4 h	8 h	12 h	EOD
Asymptomatic group N=51 except at 12 h	DAILIES TOTAL1®	93±9	95±9	93±10	89±14 n=49	84±16
	clariti® 1 day	91±12	93±10	90±12	85±16 n=48	81±18
	1-DAY ACUVUE® TruEye®	89±18	93±10	91±11	88±15 n=47	86±15
Symptomatic group N=53 except at 12 h	DAILIES TOTAL 1®	91±10	90±9	84±12	79±16 n=45	74±16
	clariti® 1 day	88±12	83±12	75±19	71±18 n=40	63±20
	1-DAY ACUVUE® TruEye®	89±12	85±16	79±19	76±17 n=38	70±22

- There was no statistically significant difference in comfort rated between the DT1 lens and AVTE lens (LSM 85.0) (P>0.05) (**Table 1**)

CUMULATIVE COMFORT

- As a result of differences in WT between the groups, post hoc CC scores were calculated with the results shown in **Figure 1**
- Mean CC was higher in the asymptomatic group (1,261 ± 59) compared with the symptomatic group (1,009 ± 58; P<0.001) and higher for DT1 (1,184 ± 258) than C1D (1,094 ± 318; P=0.002) and AVTE (1,122±297; P=0.046)
- The difference in CC between the AVTE and C1D lenses was not statistically significant (P>0.05)

Figure 1. Mean ± 95% confidence interval cumulative comfort (CC) for the asymptomatic and symptomatic groups.



European survey of contact lens wearers and eye care professionals on satisfaction with a new water gradient daily disposable contact lens

Perez-Gomez I[†], Giles T[†]. *Clin Optometry.* 2014;6:17-23

Lens Fit

Lens Comfort

Practitioner-Reported Outcomes

Patient-Reported Outcomes

OVERVIEW

STUDY DESIGN
Survey of European eye care professionals (ECPs) to determine real-world experience with delefilcon A daily disposable contact lenses

STUDY SITE(S)
Study involved 24 ECPs from 16 European countries

PATIENTS
Two hundred and eighty (280) male and female current CL wearers ≥18 years of age

METHODOLOGY
Survey was conducted between November 2011 and April 2012 to assess ECP attitudes and patient satisfaction with delefilcon A lenses. Patients completed a questionnaire at baseline and after 2 weeks of wear. ECPs were surveyed at baseline and after fitting 5-10 patients/at 3 months

LENS TYPE(S)
DAILIES TOTAL1® (delefilcon A)

KEY ENDPOINT(S)
Survey questions (5-point scale) addressing dryness or discomfort, end of day dryness, perception of wearing the lenses and all-day comfort and moistness

ANALYSIS AND CONCLUSIONS

Overall, patients preferred delefilcon A daily disposable contact lens over their previous habitual contact lenses.

ECPs also rated perceived comfort, ease of fit and vision as better with delefilcon A contact lenses vs other daily disposable contact lenses.

[†]Inma Pérez-Gómez and Tim Giles are employees of Alcon

STUDY RESULTS

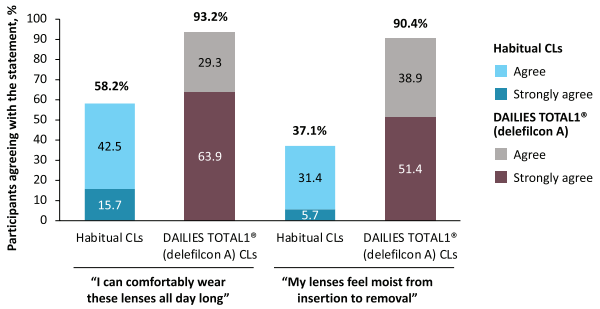
PATIENT EXPERIENCE

- Most patients (77%) were female and between the age of 21 and 39 years. Dryness and/or discomfort was reported by 176 (62.9%) of patients at baseline
- There was a 78.9% reduction in the proportion of patients reporting end-of-day dryness with delefilcon A compared with their habitual CLs (14.3% [n=40] vs 67.9% [n=190]; P<0.0001)
- Patients reporting their lenses feel like new rose from 43.9% (n=122) to 97.5% (n=272; P<0.0001) and 90.4% (n=253) of participants indicated that they sometimes forgot they were wearing delefilcon A CLs compared to 51.8% (n=145) who said the same about their habitual CL (P<0.0001)
- There was a 60.1% increase in the proportion of patients reported being able to comfortably wear their lenses all day for delefilcon A CLs vs their habitual CLs; additionally, there was a 143.3% increase in the proportion of participants who reported their lenses remain moist from insertion to removal (**Figure 1**)
- There was a 46.6% increase in the proportion of patients who had clear vision until the end of the day and nearly twice as many agreed that their lenses felt comfortable at the end of the day when using delefilcon A CLs (**Figure 2**)
- Overall, 81.8% (n=229) of participants preferred delefilcon A CLs to their habitual CLs

ECP EXPERIENCE

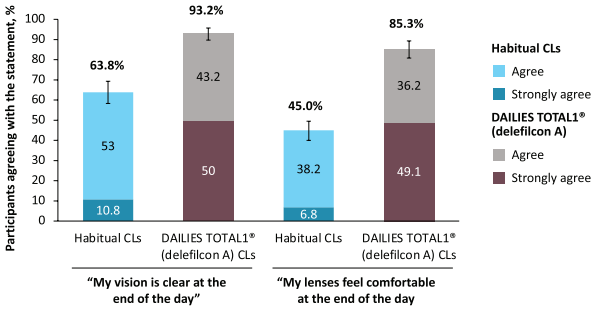
- All ECPs agreed that the perceived comfort with delefilcon A CLs was better than that with other daily disposable lenses and all stated they would recommend them to colleagues and view the lenses as a welcome addition to their business
- The majority (80% [n=19]) of ECPs stated their patients' vision was better with delefilcon A than with other daily disposable CLs and nearly all (95.8% [n=23]) said delefilcon A CLs were easy to fit

Figure 1. Participant experiences of all-day comfort and moistness with delefilcon A daily disposable and habitual contact lenses (CLs). Error bars represent 95% confidence intervals.



** P<0.0001 for habitual CLs versus delefilcon A CLs for participants' agreement with both statements.*

Figure 2. Participant end-of-day vision and comfort with delefilcon A daily disposable and habitual contact lenses (CLs). Error bars represent 95% confidence intervals.



** P<0.0001 for habitual CLs versus delefilcon A CLs for participants' agreement with both statements.*

Assessment of Corneal Morphological Changes Induced by the Use of Daily Disposable Contact Lenses

Del Águila-Carrasco et al. *Cont Lens Anterior Eye* 2015; 38:28-33

OVERVIEW

STUDY DESIGN
Prospective open-label randomized controlled trial to assess the effect of different disposable soft contact lenses (CLs) upon corneal thickness, and upon anterior and posterior corneal curvatures using a dual-Scheimpflug imaging-based device

STUDY SITE(S)
Single site in Spain

PATIENTS
Twenty-eight (28) left eyes from 28 patients – 11 male,17 female; aged 21-36 years (mean 25.7 ± 5.1 years)

METHODOLOGY
Patients wore four different disposable soft CLs on four different days. Pachymetry maps and keratometry values were obtained before and after 8 hours of lens wear. Measurements were also recorded without any CL use on a given day

LENS TYPE(S)
DAILIES TOTAL1®; Proclear® 1 day (CooperVision, Inc.); clariti® 1 day (CooperVision, Inc.); 1-DAY ACUVUE® MOIST® (Johnson & Johnson Vision Care)

KEY ENDPOINT(S)
Corneal thickening; anterior and posterior corneal curvature

ANALYSIS AND CONCLUSIONS

Wearing daily disposable soft contact lenses induces changes in corneal morphology, whose magnitude and pattern depend on lens type. Corneal morphology results differed from the non-contact lens condition. DAILIES TOTAL1® was the contact lens yielding values most similar to the non-contact lens scenario, followed by Proclear® 1 day lens. clariti® 1 day lens showed the largest difference from the non-contact lens condition.

The magnitude of the changes introduced using soft contact lenses over the 8-hour wearing period was small. Also, variations on corneal parameters appear to depend on the type of contact lens used.

STUDY RESULTS

CORNEAL THICKENING

- A repeated-measures analysis of variance (ANOVA) revealed that both types of CL and corneal zone (central and peripheral annulus) had a significant effect in corneal thickness after 8 h of lens wear (P<0.001 and P=0.012, respectively)
- The mean change in corneal thickness with each of the four CLs is shown in **Figure 1** and **Table 1**

ANTERIOR AND POSTERIOR CORNEAL CURVATURE

- Anterior and posterior curvature data were averaged from the values given by the Galilei G4
- Repeated measures ANOVA indicated that the type of lens had a significant effect on the change of both curvatures (P=0.031 and P=0.005, respectively)
- Anterior corneal curvature changes were slight and pair-wise comparison revealed that 1-DAY ACUVUE® MOIST® and Proclear® 1 day introduced significant changes in anterior corneal curvature (P<0.05)
- Posterior corneal curvature showed a steepening, and the comparison with the baseline days data revealed that all the contact lenses used in this study, except for the DAILIES TOTAL1® caused significant changes (P<0.05) in this curvature
- No associations can be found between the changes in corneal thickness and changes in corneal anterior curvature (R^2=0.17; P>0.05). There was a strong negative, but non-significant correlation between changes in mean corneal thickness and posterior corneal curvatures (R^2=0.95; P=0.058)

Figure 1. Variation in corneal thickness (%) experienced by each of the four quadrants of the cornea for each contact lens under study.

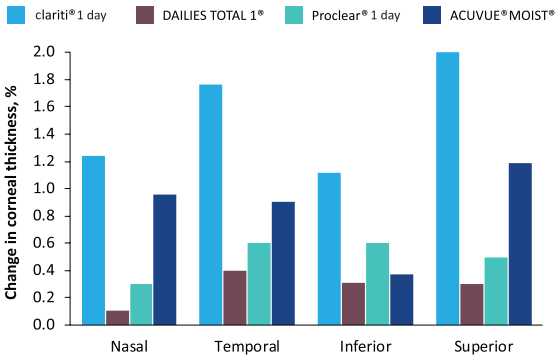


Table 1. Central and peripheral corneal thickness variation for all of the contact lenses under study.

Lens type	Central mean change (µm)	Peripheral mean change (µm)
ACUVUE® MOIST®	5.6 ±3.0[a] (p=0.02)	7.3 ±3.7[a] (p=0.01)
DAILIES TOTAL1®	1.8 ±1.5 (p=0.11)	3.9 ±2.1 (p=0.09)
clariti® 1 day	8.9 ±2.8[a] (p<0.01)	10.1 ±4.6[a] (p<0.01)
Proclear® 1 day	5.0 ±2.9[a] (p=0.03)	4.3 ±3.0[a] (p=0.02)

** Values that revealed significant changes from baseline after a pair-wise comparison was performed.*

Assessment of Corneal Thickness and Tear Meniscus During Contact Lens Wear*

Anatomical Outcomes

Clinical Signs

Del Águila-Carrasco et al. *Cont Lens Anterior Eye.* 2015; 38:185-193

OVERVIEW

STUDY DESIGN
Prospective open-label randomized controlled trial to assess the effect of seven different daily disposable contact lenses (CLs) upon corneal thickness and tear meniscus volume (TMV) by using optical coherence tomography (OCT)

STUDY SITE(S)
Single site in Spain

PATIENTS
Thirty-four (34) left eyes from 34 patients – 15 male,19 female; aged 23-34 years (mean 25.4±1.94 years)

METHODOLOGY
Patients wore seven types of daily disposable soft CLs each for 12 hours. Central and mid-peripheral corneal thickness and lower TMV were measured using an OCT device during CL wear at 4-hour intervals. Measurements were also recorded without any CL worn during a day

LENS TYPE(S)
DAILIES TOTAL1® (delefilcon A), DAILIES® AquaComfort Plus® (nelfilcon A); Proclear® 1 day (omafilcon A; CooperVision, Inc.); clariti® (filcon II3; Sauflon); 1-DAY ACUVUE® TruEye® (narafilcon A; Johnson & Johnson Vision Care); ACUVUE® (etafilcon A; Johnson & Johnson Vision Care); SofLens® (hilafilcon B; Bausch & Lomb)

KEY ENDPOINT(S)
Corneal thickening; TMV

ANALYSIS AND CONCLUSIONS

OCT made it possible to evaluate both corneal thickness variations and TMV changes because of contact lens wear.

For all the lenses under study, the changes found in corneal thickness, curvature, and volume were quite small and are not likely to affect vision performance or comfort.

** This study was financially supported by Alcon*

STUDY RESULTS

CORNEAL THICKENING

- An illustration of the change in corneal thickness caused by each type of daily disposable CL after the whole diurnal wearing period, **Figure 1** shows for each evaluated lens, the variation in corneal thickness during the whole period of measurements (12 hours)
- For both central corneal thickness and mid-peripheral corneal thickness, delefilcon A, omafilcon A, and nelfilcon A showed the lowest variation
- Hilafilcon B showed the highest variation for central corneal thickness and etafilcon A for the mid-peripheral cornea
- Delefilcon A was the lens that showed the most similar behavior to the naked eye
- No CL studied induced a percentage variation in corneal thickness above 1.5%

TEAR MENISCUS VOLUME (TMV)

- When a subject wore no CL, TMV remained almost unchanged over the 12 hours (**Figure 2**)
- Wearing CLs, regardless of type, led to a decrease in TMV relative to the no-CL scenario (**Figure 2**)
- A two-way repeated measurements analysis of variance (ANOVA) showed that the type of CL and wearing time, both had a significant impact on the change in TMV ($P<0.05$)
- Delefilcon A was the lens that caused the smallest drop in TMV ($P=0.007$)

Figure 1. Variation in corneal thickness for each contact lens under study after 12-h wearing period. Center of the cornea (left) and the mid-periphery (right).

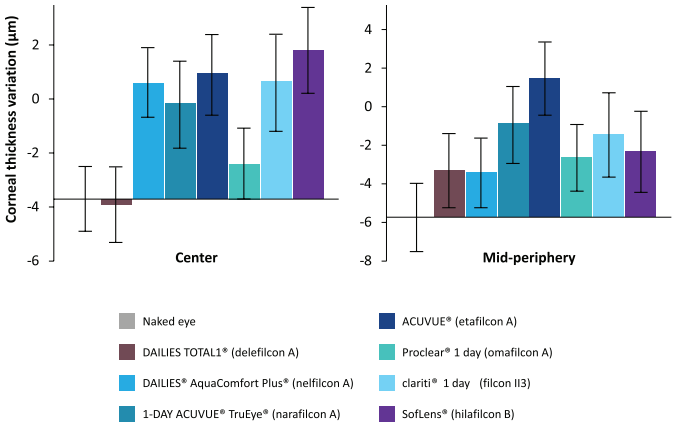
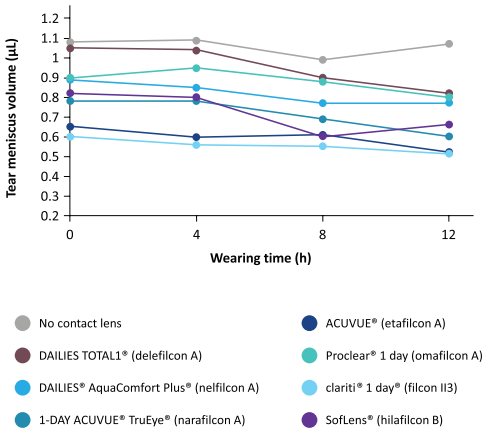


Figure 2. Tear Meniscus Volume (TMV) values as a function of the wearing time (hours) for each contact lens under study and the no-contact lens scenario.



Assessment of Modifications in Thickness, Curvatures, and Volume Upon the Cornea Caused by Disposable Soft Contact Lens Wear

Del Aguila-Carrasco et al. *Eur J Ophthalmol.* 2015; 25:385-390

OVERVIEW

STUDY DESIGN
Prospective noninvasive study to assess the effect of various disposable contact lenses on corneal parameters

STUDY SITE(S)
Single center in Spain

PATIENTS
Twenty-one (21) eyes from 21 healthy subjects, aged 21 to 34 years

METHODOLOGY
Pachymetry, curvature maps and corneal volume measures were obtained from the right eye of subjects prior to lens insertion and after 8 hours of lens wear; a 3-day recovery period was implemented in between trials with individual lenses

LENS TYPE(S)
Conventional hydrogel: DAILIES® AquaComfort Plus® (nelfilcon A), SofLens® daily disposable (hilafilcon B; Bausch & Lomb); Silicone hydrogel: DAILIES TOTAL1® (delefilcon A), 1-DAY ACUVUE® TruEye® (narafilcon A; Johnson & Johnson Vision Care)]

KEY ENDPOINT(S)
Corneal thickness, anterior and posterior curvature and volume as assessed by the Pentacam HR (Oculus) non-invasive optical diagnostic system

ANALYSIS AND CONCLUSIONS

Changes in corneal thickness, curvature and volume vary with the type of contact lens used. However, changes induced over the 8-hour period were small and not likely to affect vision or comfort.

STUDY RESULTS

CORNEAL THICKNESS

- The mean diurnal change in corneal thickness for the non-contact lens condition showed a significant thinning of -3.1 ± 2.0 µm (P = 0.032) in the central corneal region and -6.0 ± 3.8 µm (P = 0.005) in the peripheral annular corneal region
- All lenses caused changes in corneal thickening, anterior and posterior curvatures and corneal volume and the type of lens had a significant effect on these changes
- The greatest thickening in the central (1.3 ± 0.3%) and peripheral (1.8 ± 0.5%) cornea was seen with the ACUVUE® TruEye® lens and the smallest with DAILIES TOTAL1® lens (0.2 ± 0.1% central, 0.6 ± 0.2% peripheral)
- Changes in corneal thickening were significantly different from baseline with all lenses at all corneal zones, with the exception of the central cornea after use of the DAILIES TOTAL1® lens (**Figure 1**)

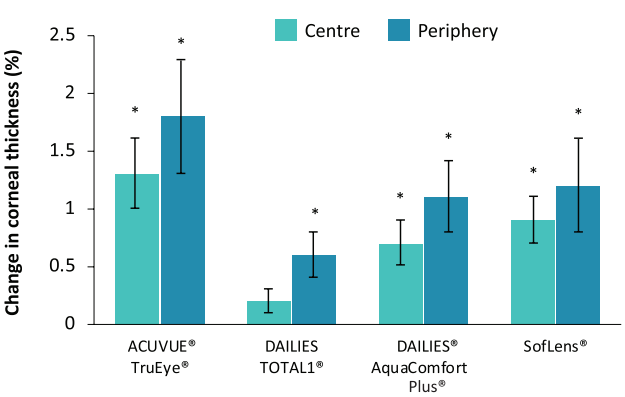
CORNEAL CURVATURE

- All lenses caused a flattening of the anterior corneal curvature; the greatest change was seen with ACUVUE® TruEye® (0.39 ± 0.10%) and the smallest with DAILIES TOTAL1® (0.13 ± 0.04%)
- Steepening in the posterior corneal curvature was caused by all lenses; the greatest modification in this parameter occurred with SofLens® (0.48 ± 0.12% P = 0.039), and the smallest modification occurred with DAILIES® AquaComfort Plus® (0.13 ± 0.05%) (**Figure 2**)

CORNEAL VOLUME

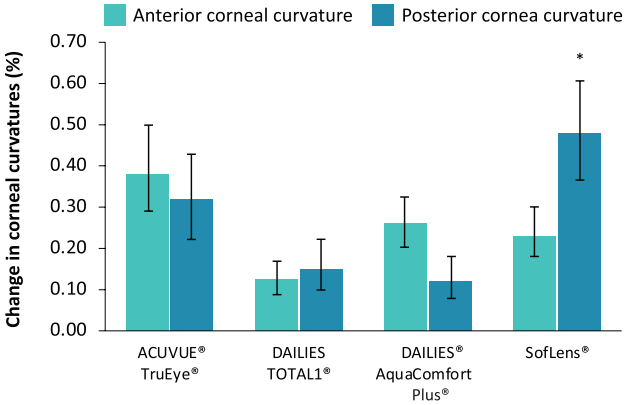
- Changes in corneal volume relative to the non-contact lens scenario were 0.2 ± 0.4 mm^3 for DAILIES TOTAL1®, 0.5 ± 0.2 mm^3 for DAILIES® AquaComfort Plus®, 0.8 ± 0.3 mm^3 for SofLens®, and 1.0 ± 0.3 mm^3 for ACUVUE® TruEye®
- The change caused by the DAILIES TOTAL1® lens was the only one that was not significant (P>0.05)

Figure 1. Changes in corneal thickness (%) from baseline.



**Change is statistically different from no lens*

Figure 2. Percent change from baseline in anterior and posterior corneal curvature.



**Change is statistically different from no lens*

The Influence of End of Day Silicone Hydrogel Daily Disposable Contact Lens Fit on Ocular Comfort, Physiology and Lens Wettability

Wolffsohn et al. *Cont Lens Anterior Eye.* 2015;38:339-344

Lens Fit
Lens Comfort
Clinical Signs
Patient-Reported Outcomes

OVERVIEW

STUDY DESIGN
Randomized crossover study to quantify the end-of-day silicone-hydrogel daily disposable contact lens fit and its influence of on ocular comfort, physiology, and lens wettability

STUDY SITE(S)
Three centers in the United Kingdom

PATIENTS
Thirty nine (39) patients who wore soft contact lenses (mean age of 22.1 ± 3.5 years)

METHODOLOGY
Patients wore each of 3 silicone-hydrogel daily-disposable contact lenses for one week. Lens fit was assessed using a digital video slit-lamp at 8, 12, and 16 hours after lens insertion

LENS TYPE(S)
1-DAY ACUVUE® TruEye® (narafilcon A; Johnson & Johnson Vision Care, clariti® 1 day (filcon II 3; CooperVision, DAILIES TOTAL1® (delefilcon A)

KEY ENDPOINT(S)
Lens fit, hyperemia, non-invasive tear break-up time, tear meniscus height, and comfort (10-point scale; 1=poor; 10-excellent) at all time points, corneal and conjucntival staining upon lens removal

ANALYSIS AND CONCLUSIONS

Among the lenses tested, objective lens fit changed between 8 hours and 12 hours of lens wear.

The weak correlation in individual lens fit between brands indicates that fit is dependent on more than ocular shape. Consequently, substitution of a different lens brand with similar parameters will not necessarily provide comparable lens fit.

STUDY RESULTS

LENS FIT

- Movement on blink ranged from 0.06 to 1.73 mm with no difference with time after insertion (8 hours: 0.34 ± 0.24mm; 12 hours: 0.35 ± 0.28mm; 16 hours: 0.36 ± 0.28 mm; P=0.670); the narafilcon A lenses moved further on blink than the other lens brands (delefilcon A: 0.33 ± 0.21 mm; narafilcon A: 0.41 ± 0.34 mm; filcon II 3: 0.33 ± 0.25 mm; P=0.046)
- Lag on horizontal excursions ranged from −7 to 215%. Lag reduced towards the end of the day (8 hours: 77.3 ± 52.3%; 12 hours: 69.2 ± 31.1%; 16 hours: 70.1 ± 36.5%; P=0.046); all lens brands had a similar lag
- Lens push-up recovery speed ranged from 0.0 to 3.4 mm/s; lenses had a faster recovery speed after either 12 hours (0.76 ± 0.44 mm/s) or 16 hours (0.73 ± 0.40 mm/s) of wear compared with 8 hours (0.61 ± 0.41 mm/s; P = 0.041); recovery speed following push-up was similar between lens brands

LENS COMFORT

- Lens fit was generally not correlated with subjective comfort (**Table 1**)
- The change in lens fit between 8 and 12 hours of wear and between 8 and 16 hours of wear did not correlate with change in comfort over these times

CLINICAL SIGNS

- Lens fit was generally not correlated with bulbar or limbal hyperemia
- Lens fit was generally not correlated with end of day corneal or conjunctival staining, non-invasive lens surface break-up time, or tear meniscus height

Table 1. Effect of lens fit (correlation coefficients) on comfort and relationship between lens brands (N=39). No correlations were significant at the P < 0.01 statistical level.

	1-DAY ACUVUE® TruEye® (narafilcon A)			DAILIES TOTAL1® (delefilcon A)			clariti® 1 day (filcon II 3)			Comfort between brands		
Time (h)	Blink	Lag	Push-up	Blink	Lag	Push-up	Blink	Lag	Push-up	Delefilcon vs narafilcon	Narafilcon vs filcon II 3	Delefilcon vs filcon II 3
8 h	0.119	−0.346	0.106	−0.091	−0.11	0.148	0.244	−0.012	0.250	−0.047	0.048	0.029
12 h	0.121	−0.104	0.066	−0.130	−0.11	−0.020	0.163	−0.095	0.232	0.014	0.089	0.094
16 h	−0.060	0.127	0.217	−0.163	−0.14	0.253	0.032	0.051	0.027	0.262	0.390	−0.059

Crossover Evaluation of Silicone Hydrogel Daily Disposable Contact Lenses*

Lens Comfort

Visual Acuity

Clinical Signs

Wolffsohn et al. *Optom Vis Sci.* 2015; 92:1063-1068

OVERVIEW

STUDY DESIGN

Prospective, randomized, masked, crossover trial to assess the surface tear breakup time and clinical performance of three daily disposable silicone hydrogel contact lenses (CL) over 16 hours of wear

STUDY SITE(S)

Single site in the United Kingdom

PATIENTS

Thirty-nine (39) patients - 18 male, 21 female; mean 22.1 ± 3.5 years

METHODOLOGY

Patients bilaterally wore 3 different CLs in the 1-week trial. Tear film was assessed by the tear meniscus height, ocular/CL surface temperature dynamics, and lens surface noninvasive breakup time at 9, 12, and 16 hours of wear. Clinical performance and ocular physiology were assessed by subjective questionnaire, high-/low-contrast logMAR acuity, and bulbar and limbal hyperemia grading. Corneal and conjunctival staining were assessed after lens removal

LENS TYPE(S)

DAILIES TOTAL1® (delefilcon A); clariti® 1 day (filcon II3; CooperVision); 1-DAY ACUVUE® TruEye® (narafilcon A; Johnson & Johnson Vision)

KEY ENDPOINT(S)

Tear meniscus height (TMH); tear breakup time; corneal staining; tear film stability; bulbar hyperemia; ocular surface temperature; subjective questionnaire; comfort

ANALYSIS AND CONCLUSIONS

Daily disposable contact lenses supported high levels of comfort throughout the day in a young, healthy population. There were differences in on-eye wettability and ocular physiology between lens brands, even after just 1 week of wear.

Tear breakup time over the contact lens surface differed between lens types and may have a role in protecting the ocular surface.

*This study was financially supported by Alcon.

STUDY RESULTS

WEAR TIME

- All patients completed the wearing schedule of 16 hours on the assessment days; there was no difference between the lens brands in the number of days or hours they were worn; no adverse events were reported in the study

TEAR FILM STABILITY AND MENISCUS HEIGHT

- Delefilcon A demonstrated a longer non-invasive breakup time (NIBUT) (13.4 ± 4.4 seconds) than filcon II-3 (11.6 ± 3.7 seconds); P<0.001) and narafilcon A (12.3 ± 3.7 seconds); P<0.001) CLs (**Figure 1**)
- A greater TMH (0.35 ± 0.11 mm) was shown with delefilcon A than filcon II-3 (0.32 ± 0.10 seconds; P=0.016) CLs
- Time was not a significant factor for pre-lens tear film stability (F=0.594; P=0.555) or TMH (F=0.632; p=0.534) across all lens brands

CLINICAL PERFORMANCE AND OCULAR PHYSIOLOGY

- Lens brand did not affect temperature (F=1.220; P=0.308), but it decreased toward the end of the day (F=19.497; P<0.001)
- Bulbar and limbal hyperemia were minimal and not different between the lenses
- There was a significant difference in corneal fluorescein staining on lens removal after 16 hours of wear (P=0.004), with delefilcon A CLs causing less staining (0.7 ± 0.05 Efron grade) than falcon II-3 (1.1 ± 0.7; P<0.001) and narafilcon A (0.9 ± 0.7; P=0.031) CLs
- Comfort, quality of vision, visual acuity and contrast acuity, and limbal grading were similar between the lens brands but decreased with time during the day (P<0.05) (**Figure 2**)

Figure 1. Noninvasive tear breakup time (NIBUT) for delefilcon A, narafilcon A, and falcon II 3 CLs. N=39; error bars = 1 standard deviation.

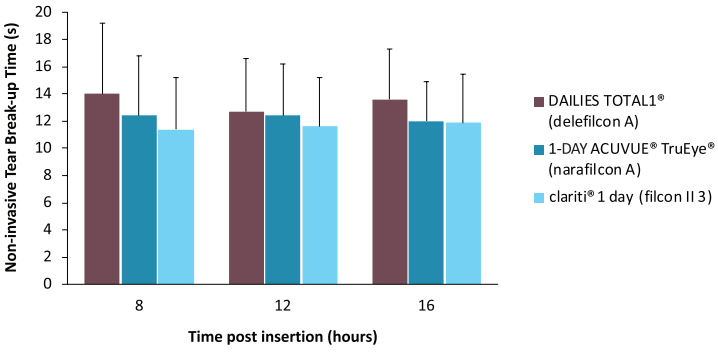
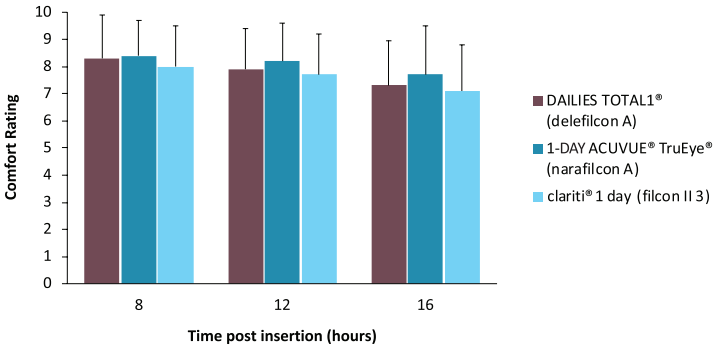


Figure 2. Subjective comfort ratings for the delefilcon A, narafilcon A, and falcon II 3 contact lenses. N=39; error bars = 1 standard deviation.



Comparing Two Different Daily Disposable Lenses for Improving Discomfort Related to Contact Lens Wear*

Patient-Reported Outcomes

Lens Comfort

Clinical Signs

Michaud and Forcier. *Cont Lens Anterior Eye.* 2016;39:203-239

OVERVIEW

STUDY DESIGN
Multicenter, crossover, study to compare two daily disposable contact lenses to reduce lens-induced discomfort (CLD)

STUDY SITE(S)
Three (3) private clinics (PC) and one university reference center (UC) in Canada

PATIENTS
Seventy-six (76) habitual monthly or 2-week contact lens wearers who reported CLD at least 3 times per week

METHODOLOGY
Patients wore nelfilcon A then delefilcon A, for one month each (group A), or vice-versa (group B), and clinical signs and symptoms were evaluated

LENS TYPE(S)
Daily disposable (DD) DAILIES® AquaComfort Plus® (nelfilcon A) and DAILIES TOTAL1® (delefilcon A)

KEY ENDPOINT(S)
Tear break-up time (TBUT), corneal staning (CS), and conjunctival staining (CJS) at every visit. Symptoms, via the validated CLDEQ-8(R) and non-validated Université de Montréal (UM) questionnaire

ANALYSIS AND CONCLUSIONS

Delefilcon A lenses improved comfortable period of wear by 3 hours or 22% (vs baseline with habitual contact lenses) in symptomatic contact lens wearers.

** This study was funded by Alcon Vision, LLC.*

STUDY RESULTS

LENS COMFORT

- Total hours of wear did not vary significantly from baseline (BL) with either study lens; the daily number of comfortable hours of wear increased from BL by almost one hour with nelfilcon A lenses (7.6 ± 2.3 hours to 8.5 ± 2.6 hours; P=0.394) and 3.1 hours with delefilcon A lenses (7.6 ± 2.3 hours to 10.7 ± 3.0 hours; P=0.031), a gain of 22%
- Initial comfort at BL decreased during the evening (from 1.7 ± 0.6 to 3.2 ± 1.0) (**Figure 1**) -
  - Nelfilcon A lenses did not improve this outcome (1.9 ± 0.9 morning: 3.3 ± 1.1 evening)
  - Patients wearing delefilcon A lenses had increased comfort vs BL in the afternoon (P = 0.006), lasting during the evening (P = 0.000), subjects, in general, remained "very comfortable" or "comfortable" during all the wearing hours (1.2 ± 0.5 – 2.1 ± 1.0)

LENS PREFERENCE

- At the end of the study, 78.8% of patients preferred delefilcon A lenses (P<0.001), 13.2% chose nelfilcon A lenses, while 7.9% decided to keep their BL lenses
- At BL, average usage of comfort drops was 0.8 ± 1.6 drops/day: this did not change significantly with nelfilcon A lenses (0.6 ± 1.1; P=0.198), but improved significantly with delefilcon A lenses (0.2 ± 0.6; P=0.03); at BL, 35.7% of patients used comfort drops during wear; this was unchanged with nelfilcon A lenses (32.3%), but decreased by more than 50% with delefilcon A lenses (14.3%)
- A significantly higher number of patients rated delefilcon A lenses as excellent (67.4%) vs BL (23.2%) and nelfilcon A (12.5%; P=0.000; **Figure 2**); the only factor found to explain the differences in CLDEQ© scores was the tested lens (P<0.001), with delefilcon A lenses having a major effect (P<0.001) that nelfilcon A lenses did not (P=0.397)

TEAR BREAK UP

- TBUT was similar to BL to the end of the study regardless of lenses tested; nelfilcon A lens wearers were more at risk of developing light to moderate conjunctival staining compared with those wearing delefilcon A lenses by a factor of 14.3 (95% confidence interval [CI] 3.103-66.126)
- After one month of wear, nelfilcon A lens wearers were 8 times more likely to show increased corneal staining than delefilcon A wearers (odds ratio 8.754; 95% CI 2.181-35.146)

Figure 1. Daytime comfort using Université de Montréal Questionnaire (1 = very comfortable, 2 = comfortable, 3 = slightly uncomfortable, 4 = uncomfortable, 5 = very uncomfortable).

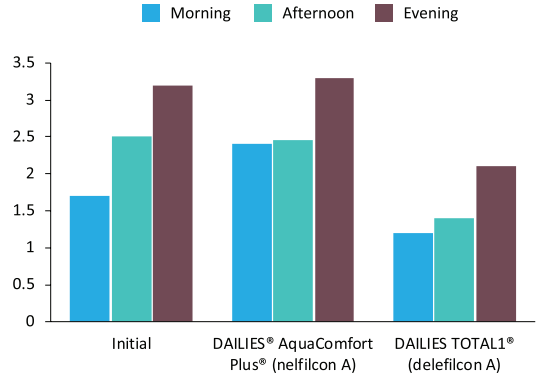
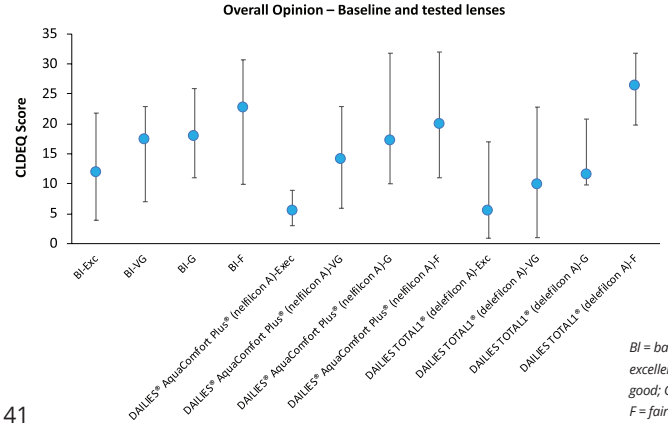


Figure 2. Subjective overall opinion of lenses vs Contact Lens Dry Eye Questionnaire (CLDEQ©) scores.



Bl = baseline; Exc = excellent; VG = very good; G = good; F = fair

Comparison of Silicone Hydrogel and Hydrogel Daily Disposable Contact Lenses

Diec et al. *Eye Contact Lens.* 2018;44:S167-S172

Visual Acuity
Patient-reported Outcomes
Lens Comfort
Clinical Signs
Lens Fit

OVERVIEW

STUDY DESIGN
Retrospective analysis of five open-label 3-month trials to compare subjective, objective, and safety performance of silicone hydrogel (SiHy) daily disposable contact lenses (DDCLs) versus hydrogel (Hy) DDCLs

STUDY SITE(S)
Single research center in Australia

PATIENTS
A total of 201 patients (174 unique patients), >18-years old; established CL wearers and neophytes. Patients were allowed to enroll in more than one trial with a 2-week washout period between trials

METHODOLOGY
Participants wore study lenses for 3 months, for a minimum of 5 days/week and 6 hr/day; visits were at baseline, 2 weeks, 1 and 3 months. Comfort, adverse events , physiological variables, and wearing time were compared between groups

LENS TYPE(S)
SiHy: DAILIES TOTAL1® (delefilcon A); clariti® 1 day (somofilcon A; CooperVision); 1-DAY ACUVUE® TruEye® (narafilcon A; Johnson & Jonson Vision Care). Hy: Proclear® 1 day (omafilcon A; CooperVision); DAILIES® AquaComfort Plus® (nelfilcon A)

KEY ENDPOINT(S)
Subjective comfort (1-10 sclae), adverse events, physiological response (CCLRU; 0-4 sclae), wearing time at each study visit

ANALYSIS AND CONCLUSIONS

Although some statistical significance was found between the groups, these differences were within measurement error.

Neither SiHy nor Hy material type showed superiority in comfort and adverse event rates were low with both material types. Choice of material is a patient and practitioner preference; however, for patients at risk of hypoxia-related complications, SiHy materials should be considered.

STUDY RESULTS

VISUAL ACUITY

- There was a statistically significant difference at all visits between the SiHy and Hy DDCL groups for monocular high-contrast visual acuity (SiHy: -0.057 ± 0.10 logMAR; Hy: -0.061 ± 0.10 logMAR; P=0.001), monocular low-contrast visual acuity (SiHy: 0.251 ± 0.12 logMAR; Hy: 0.233 ± 0.12 logMAR; P<0.001), and binocular high-contrast visual acuity (SiHy: -0.127 ± 0.07 logMAR; Hy: -0.134 ± 0.07 logMAR; P<0.001)
- Differences in visual acuity between groups were within measure-ment error, with an average difference of <1 letter in all instances

CLINICAL SIGNS

- There was a significant increase in limbal redness in the Hy DDCL group compared with the SiHy DDCL group (P<0.001) (**Table 1**) and a significant difference within the Hy group (P<0.001) there was no significant difference within the SiHy group (P=0.08)
- Conjunctival staining and indentation significantly increased in the SiHy DDCL group compared with the Hy DDCL group (P<0.001) (**Table 1**)
  - There was a significant difference within the Hy group for both variables (P<0.001), with nelfilcon A showing a greater increase from baseline than omafilcon A, and within the SiHy group for both variables, with somofilcon A showing the greatest increase from baseline
- There was a significant increase in upper palpebral roughness in the SiHy DDCL group vs the Hy DDCL group (P=0.042; **Table 1**). For all other physiological variables, there were no statistically significant differences between groups

LENS FIT

- There were no significant differences between the SiHy and Hy DDCL groups in lens movement, lens lag, and lens tightness (all P>0.1)
- There were statistically significant differences in lens centration with less horizontal decentration (SiHy: 0.0001 ± 0.03 mm Hy: 0.011 ± 0.05 mm; P=0.003) and less vertical decentration in the SiHy group (SiHy: -0.028 ± 0.07 mm Hy: 0.041 ± 0.08 mm; P=0.001); mean difference between groups for lens centration was <0.02 mm

LENS WEAR TIME

- There was no significant difference between SiHy and Hy in average daily wear time (11.39 ± 2.9 vs 11.0 ± 3.2 h), comfortable daily wear time (9.8 ± 3.4 vs 9.1 ± 3.7 h), or comfort on insertion (8.4 vs 8.3), during the day (8.5 vs 8.3), or at end of day (7.3 vs 7.2)

Table 1. Ocular physiological variables, showing the difference for all lens wearing visits from the baseline visit. Grades based on a 0 to 4 grading scale. Results are given as mean ± standard deviation. Negative values indicate that the actual grading of the variable was lower at the lens wearing visits compared with baseline.

Physiological Variable	SiHy DDCL	Hy DDCL	*P*
Bulbar redness	0.11±0.46	0.12±0.42	0.08
Limbal redness	0.02±0.47	0.18±0.38	<0.001*
Corneal staining	0.14±0.74	0.10±0.76	0.94
Conjunctival staining†	0.48±0.92	0.07±0.75	<0.001*
Conjunctival indentation†	0.62±1.11	-0.02±0.59	<0.001*
Upper palpebral redness	0.01±0.45	0.00±0.43	0.63
Upper palpebral roughness	-0.09±0.52	-0.03±0.55	0.042*

** Statistically significant P value.*
† Differences driven by the somofilcon A lens in the SiHy lens group.

Subjective Ratings and Satisfaction in Contact Lens Wear

Patient-reported Outcomes

Lens Comfort

Diec et al. *Optom Vis Sci.* 2018;95:256–263

OVERVIEW

STUDY DESIGN

Retrospective analysis was performed on two clinical trials, each testing a different contact lens (CL) over 3 months, to understand the relationship between subjective ratings and satisfaction with CL wear

STUDY SITE(S)

Single research center in Australia

PATIENTS

Fifty nine (59) myopic patients >18-40 years old who were either experienced or neophyte contact lens wearers; 30 wore somofilcon A and 29 wore delefilcon A lenses

METHODOLOGY

Subjective ratings (numerical rating scale 1 to 10) collected at baseline, 2 weeks, 1 month, and 3 months included comfort (insertion, during day, end of day), vision clarity, and binary response for satisfaction with comfort and vision (yes/no). Willingness to continue with trial CL was obtained at completion

LENS TYPE(S)

DAILIES TOTAL1® (delefilcon A); clariti® 1 day (somofilcon A; CooperVision)

KEY ENDPOINT(S)

Subjective ratings for comfort upon insertion, comfort during the day and at end of day, dryness at end of day, and clarity of vision

ANALYSIS AND CONCLUSIONS

Satisfaction in contact lens wear is influenced by both comfort and vision. A higher rating for comfort during the day compared with end of day was necessary for participants to attain satisfaction.

Participants appeared to accept that a level of discomfort is unavoidable toward the end of the day, but this did not necessarily translate to them being dissatisfied.

STUDY RESULTS

- Delefilcon A proved significantly more comfortable than somofilcon A upon insertion (P=0.009), during the day (P=0.02), and at the end of the day (P=0.038) (**Table 1**); there was no difference between lenses for clarity of vision (P=0.55) and no significant interaction between lenses and visits for any subjective variable (P≥0.17)
- Percentage of participants satisfied with comfort ranged from 79 to 91% over the trial; more participants were satisfied with comfort wearing delefilcon A compared with somofilcon A lenses (93% vs. 80%, P=0.015), and between age ranges (P=0.028), with those in the 36-40-year age group having the lowest percentage satisfied with comfort (58% vs 82-93% in other age groups)
- Overall satisfaction with vision was high (96%), with no significant differences in percentage of participants satisfied with vision between visits (P=0.52), CL brands (P=0.71), or based on age (P=0.94)
- There was no significant association of comfort on insertion with comfort satisfaction (odds ratio 1.2; P=0.299); comfort during the day (odds ratio 2.1; P<0.001) and end of day (odds ratio 3.4, P<0.001) was associated with satisfaction with comfort
- Participants consistently satisfied with overall comfort generally had higher average ratings compared with those who were not, with a trend for the inconsistent raters toward an increase in the ratings over time (**Table 2**); those consistently satisfied with their overall vision also generally had higher average ratings compared with those who were not
- Of all participants, 80% expressed their willingness to continue to wear the trialed CLs
  - Of those who were satisfied with both comfort and vision, 86% were willing to continue wearing them, but this dropped to 50% if either comfort or vision was unsatisfactory and further reduced to 0% if both features were unsatisfactory
  - Comfort during the day was the only subjective rating that was associated with "continue to wear" outcome (odds ratio 2.3; 95% confidence interval 1.3 to 4.3)

Table 1. Mean subjective ratings for each contact lens and visit (1 to 10 numerical rating scale with 1-point steps).

Subjective variable	Visit	DAILIES TOTAL1® (delefilcon A) (mean±SD)	clariti® 1 Day (somofilcon A) (mean±SD)	*P* (between lenses)	*P* (between lenses and visits)
Comfort upon insertion	2 wk 1 mo 3 mo	8.2±1.6 8.6±1.1 8.4±1.2	7.4±1.8 7.4±1.4 7.8±1.4	**.009***	.40
Comfort during day	2 wk 1 mo 3 mo	8.2±1.6 8.6±1.1 8.4±1.2	7.6±1.5 7.6±1.5 8.0±0.9	**.002***	.17
Comfort at end of day	2 wk 1 mo 3 mo	8.2±1.6 8.6±1.1 8.4±1.2	6.2±1.3 6.3±1.5 6.6±1.6	**.038***	.47
Clarity of vision	2 wk 1 mo 3 mo	8.2±1.6 8.6±1.1 8.4±1.2	7.7±1.7 8.0±1.3 8.2±1.3	**.55**	.95

Table 2. Mean ratings for each subjective variable for participants who reported consistent satisfaction with their overall comfort and who reported inconsistent satisfaction with comfort at every visit.

Subjective variable	Visit	Consistently satisfied with comfort (mean±SD)	Not consistently satisfied with comfort (mean±SD)
Comfort upon insertion	2 wk 1 mo 3 mo	7.8±1.7 8.1±1.3 8.0±1.3	7.6±1.9 7.8±1.5 8.3±1.2
Comfort during day	2 wk 1 mo 3 mo	8.4±1.0 8.4±1.1 8.3±0.9	7.2±1.8 7.5±1.6 8.0±0.9
Comfort at end of day	2 wk 1 mo 3 mo	7.2±1.4 7.4±1.5 7.3±1.3	5.3±1.6 5.6±1.3 5.6±1.3
Clarity of vision	2 wk 1 mo 3 mo	8.0±1.6 8.1±1.2 8.3±1.2	7.4±2.0 7.9±1.4 8.3±1.2

** Statistically significant P value*

SD = standard deviation.

Performance Evaluation of Delefilcon a Water Gradient Daily Disposable Contact Lenses in First-Time Contact Lens Wearers*

Marx et al. *Cont Lens Anterior Eye.* 2018; 41:335-341

Lens Fit
Lens Comfort
Practitioner-Reported Outcomes
Patient-Reported Outcomes
Visual Acuity

OVERVIEW

STUDY DESIGN
Prospective, open-label, single-arm, two-week trial, to evaluate the tolerability of and subject and investigator satisfaction with delefilcon A daily disposable contact lenses (CL) in first-time CL wearers

STUDY SITE(S)
Multiple sites in Europe – 8 investigators from 8 private practices in Germany, Spain, Norway, Sweden, and Denmark

PATIENTS
Ninety-eight (98) patients – 49 male, 49 female; aged 14-43 years (mean 24.8 ± 7.6 years)

METHODOLOGY
Assessments were made at dispensing and at weeks 1 and 2; subject-reported outcomes included comfort, quality of vision, convenience, and intent to purchase; investigator-reported outcomes included slit-lamp biomicroscopy findings and lens fitting

LENS TYPE(S)
DAILIES TOTAL1® (delefilcon A)

KEY ENDPOINT(S)
Safety (adverse events (AEs)) and tolerability; subjective assessment of vision, comfort, convenience, and satisfaction; investigator assessment of ease of fit

ANALYSIS AND CONCLUSIONS

The investigators concluded that practitioners can expect favorable outcomes, with minimal risk of unexpected safety concerns, when transitioning first-time contact lens wearers from spectacles to delefilcon A daily disposable contact lenses.

** This study was financially supported by Alcon*

STUDY RESULTS

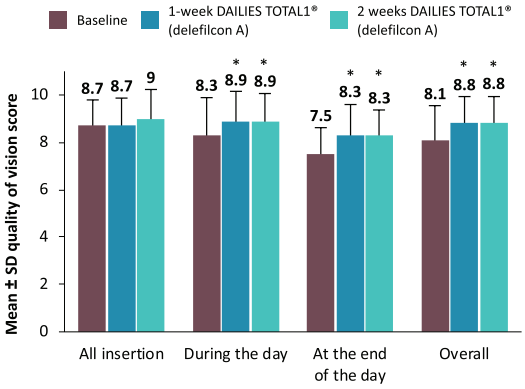
SAFETY

- Ninety-two (92) subjects completed the study, with the other six discontinuing, five for AEs and one who withdrew voluntarily
- No serious AEs were observed,two of which were related to study lenses (severe contact lens discomfort); all AEs resolved, except the subject who had a fall unrelated to the study and was lost to follow-up

SUBJECT- AND INVESTIGATOR-REPORTED OUTCOMES

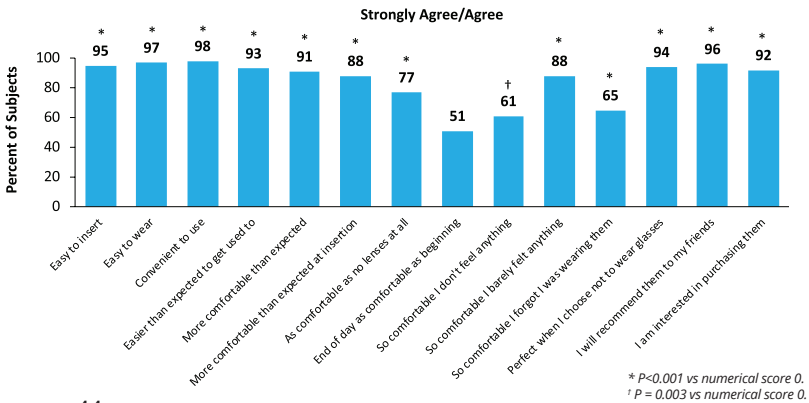
- Mean scores for subject reported quality of vision (**Figure 1**) and ocular comfort were significantly higher with delefilcon A CL than with habitual spectacles during the day, at the end of the day, and overall (all P≤0.02)
- When comparing ocular comfort while wearing spectacles at baseline and after wearing CLs on Day 14, 59% of subjects agreed or strongly agreed that their overall ocular comfort was better with contact lenses (P=0.01), and 36% agreed or strongly agreed that their eyes were less tired at the end of the day with CLs
- Subject-reported outcomes also included the following (as shown in **Figure 2**):
  - 91% of subjects reported that their study lenses were more comfortable than expected
  - 98% agreed that they were convenient to use
  - 92% were interested in purchasing the lenses (all P<0.001)
- Subjects reported average daily contact lens wearing times of 11.8 ± 2.5 h at one week and 12.0 ± 2.3 h at two weeks and average daily comfortable lens wearing times of 10.3 ± 3.2 h and 10.4 ± 2.8 h, respectively.
- Investigators agreed or strongly agreed that study lenses were easy to fit for 98% of subjects

Figure 1. Mean subject reported quality of vision with spectacles (baseline visit) and contact lenses (one and two-week visits) in the per-protocol population (n=92). Results reported on a scale of 1 (poor) to 10 (excellent).



** P≤0.001 vs. baseline.*

Figure 2. Subject reported outcomes of lens convenience, comfort, satisfaction, and purchase intent (per-protocol population, n=92) after wearing DAILIES TOTAL1® (delefilcon A). Shown are the proportion of subjects who responded "strongly agree" or "agree".



** P<0.001 vs numerical score 0.*
† P = 0.003 vs numerical score 0.

Quantification of contact lens wettability after prolonged visual device use under low humidity conditions*

Anatomical Outcomes

Clinical Signs

Patient-Reported Outcomes

Guillon et al. *Cont Lens Anterior Eye.* 2019;42:386-391

OVERVIEW

STUDY DESIGN
Prospective open-label randomized controlled trial to investigate the impact of challenging environmental conditions on wettability of four daily disposable silicone hydrogel (SiHy) contact lenses (CL)

STUDY SITE(S)
Single site in the United Kingdom

PATIENTS
Sixty-four (64) subjects (32 habitual delefilcon A users;32 habitual somofilcon A users); 19 male, 45 female; mean age 33.8±9.7years (range 19-56 years)

METHODOLOGY
Habitual delefilcon A and somofilcon A wearers were tested with their habitual CLs and with stenfilcon A and narafilcon A CLs. Videos were captured using non-invasive Tearscope illumination after 3 hours (h) of conventional wear and 3 h of computer use at 20% relative humidity (RH)

LENS TYPE(S)
DAILIES TOTAL1® (delefilcon A); clariti® 1 day (somofilcon A; CooperVision, Inc.); MyDay™ (stenfilcon A; CooperVision, Inc.); 1-DAY ACUVUE® TruEye® (narafilcon A; Johnson & Johnson Vision Care)

KEY ENDPOINT(S)
Wettability; non-invasive break-up time (NIBUT); minimum protected area (MPA) of the lens surface by tear film; dehydration speed (DS) over the interblink period after exposure to 20% RH

ANALYSIS AND CONCLUSIONS

Delefilcon A contact lenses performed better than stenfilcon A and narafilcon A after 6 hours of wear including 3 hours intensive visual tasks under challenging environmental conditions.

Delefilcon A demonstrated superior on-eye wetting properties compared with the other two contact lenses, including longer time with full tear film coverage, greater resistance to dehydration once a break has occurred and greater surface coverage at the time of the blink, clinically corroborating the superiority of delefilcon A *in vitro*.

* *This study was financially supported by Alcon*

STUDY RESULTS

NON-INVASIVE BREAK UP TIME (NIBUT)

- After wearing their habitual lenses for 10 ± 3 days, the mean ± SD NIBUT following exposure to 20% RH for 3 h was 9.2 ± 11.1 s in habitual wearers of delefilcon A lenses and 6.2 ± 5.7 s in habitual wearers of somofilcon A lenses (**Figure 1 A&B**)
- Habitual delefilcon A wearers NIBUT was longer with delefilcon A (9.2 s) than stenfilcon A (6.3 s, P=0.052) and narafilcon A (5.1 s, P=0.006) (**Figure 1A**)

MINIMUM PROTECTED AREA (MPA)

- Mean MPA was significantly higher with delefilcon A (95.4%) than stenfilcon A (84.4%, P=0.002) and narafilcon A (82.9%, P=0.006)
- For habitual somofilcon A wearers, mean MPA was lower for narafilcon A (76.2%) than for somofilcon A (89.0%, P<0.001) but not stenfilcon A (88.4%, P=0.748)

DEHYDRATION SPEED (DS)

- Mean DS was lower with delefilcon A (0.28mm2/s) than stenfilcon A (0.81 mm2/s, P=0.002) and narafilcon A (0.60 mm2/s, P=0.056) (**Figure 2 A**)
- For habitual somofilcon A wearers, mean DS was higher for narafilcon A (0.96mm2/s) than somofilcon A (0.60mm2/s, P=0.029) but not stenfilcon A (0.051 mm2/s, P=0.701) (**Figure 2 B**)

Figure 1. Mean ± standard deviation (SD) non-invasive break-up time (NIBUT) in habitual wearers of (**A**) delefilcon A and (**B**) somofilcon A lenses after exposure to 20% relative humidity while wearing habitual, stenfilcon A, and narafilcon A lenses. T-bars represent the 95% confidence intervals.

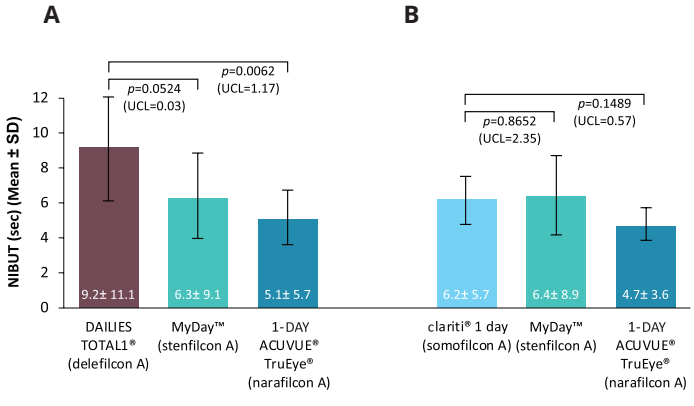
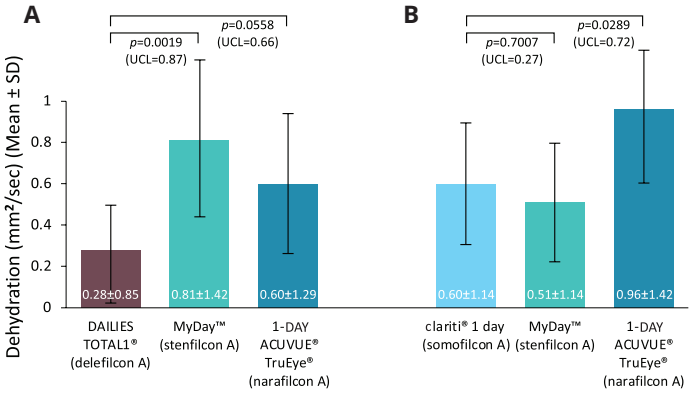


Figure 2. Mean ± standard deviation (SD) dehydration speed in habitual wearers of (**A**) delefilcon A and (**B**) somofilcon A lenses after exposure to 20% relative humidity while wearing habitual, stenfilcon A, and narafilcon A lenses. T-bars represent the 95% confidence intervals.



UCL, upper limit of the 95% confidence interval of the least square mean difference (Study CL- Habitual CL)

Response of the Aging Eye to First Day of Modern Material Contact Lens Wear

Lafosse et al. *Eye Contact Lens.* 2019;45:40-45

OVERVIEW

STUDY DESIGN
Prospective, randomized study to investigate the ocular surface of an aged population wearing a daily disposable contact lens (CL) over their 1st day of wear

STUDY SITE(S)
Centers in Spain and the United Kingdom

PATIENTS
Forty (40) eyes from 40 presbyopic, neophyte CL wearers with average age of 50.0 ± 4.4 years

METHODOLOGY
Patients were fitted with a daily CL. Tear osmolarity, tear meniscus area (TMA), and ocular surface aberrations (total higher-order root mean square [RMS]) were assessed at baseline, at 20 minutes, and after 8 hours of wear. Fluorescein corneal and conjunctival staining and tear breakup time (TBUT) were performed at baseline and after 8 hours

LENS TYPE(S)
DAILIES TOTAL1® (delefilcon A)

KEY ENDPOINT(S)
Tear osmolarity, TMA, RMS ocular surface aberrations, corneal and conjunctival staining, and TBUT

ANALYSIS AND CONCLUSIONS

Delefilcon A contact lens insertion induces an initial decrease in tear film (TF) stability observed by osmolarity values rising after 20 minutes of wear; this did not impact tear meniscus metrics and seemed to be transitory.

Ocular surface aberrations remained largely stable from contact lens insertion, demonstrating an even repartition of TF over the contact lens material surface.

STUDY RESULTS

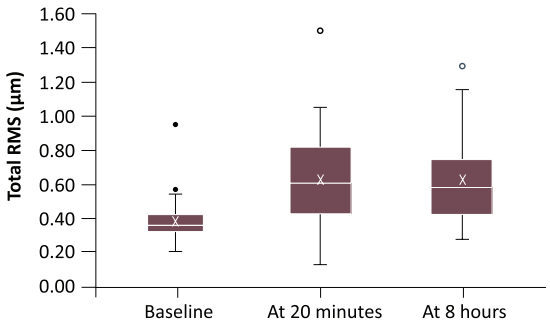
TEAR OSMOLARITY, SURFACE ABERRATIONS, AND BREAKUP

- Osmolarity showed significant changes between baseline and 20 min (P = 0.02; **Table 1**), but not between baseline and 8 hours. Tear meniscus area values diminished across the day but the difference was not statistically significant
- Ocular surface higher-order RMS aberrations showed a statistically significant increase between baseline and 20 minutes and between baseline and 8 hours (both P ≤0.001), with no statistically significant changes found between 20 minutes and 8 hours (**Table 1; Figure 1**)
- TBUT worsened from baseline to after 8 hours of CL wear (P < 0.05; **Table 1**)
- No statistically significant differences were found between the measurements at baseline and after 8 hours of CL wear regarding fluorescein corneal and conjunctival staining (**Table 1**), which means that even if osmolarity was altered, it was not clinically significant because there was no significant cellular damage

Table 1. Comparison of the objective measurements of the neophyte contact lens wearers at the initial visit and 20 minutes and 8 hours after DAILIES TOTAL1® lens Insertion. Values are mean ± standard deviation.

	Baseline (t_0)	At 20 min (t_1)	At 8 hr (t_2)	*P*
Abberations (µm)	0.38 ± 0.21	0.61 ± 0.04	0.64 ± 0.41	(t_0)/(t_1) P<0.01 (t_1)/(t_2) P<0.71
Osmolarity (mOsm/L)	306.93 ± 2.32	312.43 ± 2.42	310.40 ± 2.26	(t_0)/(t_1) P<0.02 (t_0)/(t_2) P<0.09 (t_1)/(t_2) P<0.71
TMA (mm^2)	0.020 ± 0.003	0.019 ± 0.002	0.017 ± 0.003	P=0.061
TBUT (s)	10.4 ± 0.4	—	9.0 ± 0.3	P<0.01

Figure 1. Box plot of root mean square (RMS) aberration at baseline and 20 minutes and 8 hours of DAILIES TOTAL1® lens wear. Medians are shown for each plot, quartiles are shown as boxes, ranges as whiskers, and outliers as dots.



Assessing a Modified Fitting Approach for Improved Multifocal Contact Lens Fitting*

Merchea† et al. *Cont Lens Anterior Eye*. 2019; 42:540-545

Lens Fit

Practitioner-Reported Outcomes

Patient-Reported Outcomes

Safety

OVERVIEW

STUDY DESIGN
Prospective, randomized, subject masked trial to compare the effectiveness of a modified and previous fitting guide for multifocal (MF) contact lenses that share a common optical design, with three soft contact lenses (CL) brands

STUDY SITE(S)
Multiple global sites –20 investigators: 14 in the United States, 3 in the United Kingdom, 3 in Canada

PATIENTS
One hundred seventy seven (177) presbyopic patients – 29 male, 154 female; aged 40-65 years (mean 50.4 ±6.7 years) refractive range: sphere -9.75 to +5.25 D, cylinder of -0.75 to ≤+0.75 D. ADD +0.50 to +2.50 D

METHODOLOGY
Sites were randomly assigned to use the modified or previous fitting guide. Subjects were randomized to either lotrafilcon B MF (n=62), nelfilcon A MF (n=57), or delefilcon A MF (n=58). Study lenses were worn 10 ± 3 days

LENS TYPE(S)
AIR OPTIX® AQUA (lotrafilcon B); DAILIES TOTAL1® (delefilcon A); DAILIES® AquaComfort Plus® (nelfilcon A)

KEY ENDPOINT(S)
Number of CLs required to fit each eye at Visit 1; efficacy of modified vs. previous fitting guides; ease of fit by eye care practitioner; subjective vision; safety (adverse events (AEs))

ANALYSIS AND CONCLUSIONS

The study showed that the modified fitting guide was superior to the previous guide and required fewer lenses to successfully fit each presbyopic patient.

Findings indicate that the modified fitting guide improves the efficiency of fitting presbyopic contact lens wearers with all Alcon MF lenses. The increased efficiency will benefit eye care professionals (ECPs), possibly by reducing chair time and potentially reducing the costs of fitting MF lenses. Furthermore, the need for fewer trial lenses may enhance subject confidence in their ECPs and the performance of their MF contact lenses.

* *This study was funded by Alcon Vision, LLC.* †*Mo Merchea is an employee of Alcon*

STUDY RESULTS

FITTING ASSESSMENTS

- The modified fitting guide directs ECPs to add +0.25D binocularly after determining the vertex-corrected, least minus / most plus, spherical equivalent distance prescription
- The mean ± standard deviation (SD) number of lenses required to fit each eye using the modified and previous fitting guides were 1.2 ± 0.5 and 1.4 ±0.5, respectively
- The least-squares mean difference (0.2) met predetermined criteria for superiority of the modified fitting guide
- At the fitting visit, 82.8% (164/198) and 65.1% (105/166) of presbyopic eyes were fit with one pair of MF lenses using the modified and previous guides, respectively, and 98.0% (194/198) of eyes were fit with MF lenses using the modified guide (**Figure 1**)
- More ECPs rated ease of fit as a 9 or 10 for the modified than for the previous fitting guide (63.6% (7/11) vs 33.3% (3/9) (**Figure 2**)

VISUAL OUTCOMES AND SAFETY

- At both the initial and successful fittings, mean scores for near vision were comparable for lenses fitted using the modified and previous fitting guides; comparisons between the fitting guides for intermediate and distance vision show a similar pattern
- Mean vision scores quality scores at the successful fit visit included 8.3 ± 1.6 (modified guide) and 8.3 ± 1.5 (previous guide), during driving; 8.2 ± 1.7 (modified guide) and 8.0 ± 1.6 (previous guide) during computer use; and 8.0 ± 2.0 (modified guide) and 7.7 ± 1.8 (previous guide) during tablet/mobile phone use
- No serious AEs were reported during this study; overall, 19 eyes in 13 subjects experienced 22 ocular non-serious AEs during the study; were all mild and resolved.
- The most common ocular AEs were eye allergy, eye irritation, and ocular discomfort

Figure 1. Percentage of eyes requiring one, two, or three multifocal (MF) lenses for a successful visit at Visit 1 (screening/fitting visit) using the modified and previous MF Fitting Guides.

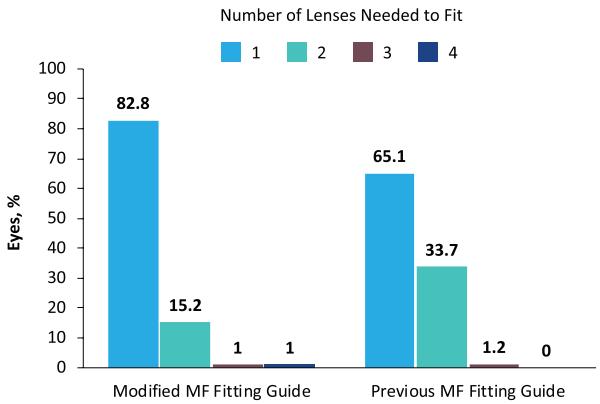
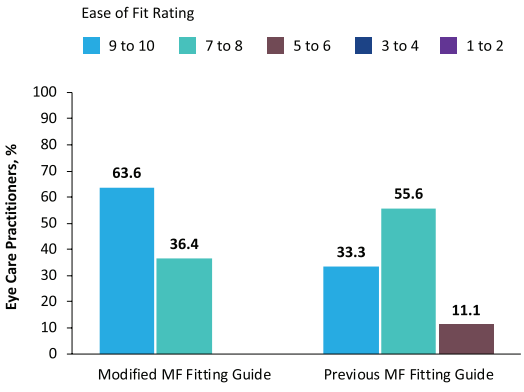


Figure 2. Ease of fit ratings by eye care practitioners using a 10-point scale ranging from 1 (difficult) to 10 (easy) with the modified and previous multifocal (MF) fitting guides.



Evaluation of the Ocular Surface in Different Contact Lens Replacement Schedules

Muhafiz et al. *Cornea* 2019; 38:587-594

OVERVIEW

STUDY DESIGN
Prospective study to evaluate the effects of different contact lens (CL) replacement schedules and different CL materials on the ocular surface and tear function

STUDY SITE(S)
Academic centers in Turkey

PATIENTS
Seventy-one (71) subjects who had not previously worn CLs

METHODOLOGY
Daily disposable hydrogel CLs were given to group 1 (n = 22), daily disposable silicone hydrogel CLs were given to group 2 (n = 25), and reusable silicone hydrogel CLs were given to group 3 (n = 24) with a multipurpose solution for lens cleaning and disinfection

LENS TYPE(S)
Daily disposable hydrogel 1-DAY ACUVUE® MOIST (etafilcon A; Johnson & Johnson Vision Care), daily disposable silicone hydrogel DAILIES TOTAL1® (delefilcon A), monthly reusable silicone hydrogel PureVision® 2 (balafilcon A; Bausch & Lomb)

KEY ENDPOINT(S)
Tear function tests, inflammatory cytokine [interleukin (IL)-6, IL-8, IL-17A, and matrix metalloproteinase (MMP)-9] levels, and impression cytology using the Nelson grading system

ANALYSIS AND CONCLUSIONS

There was an increase in some proinflammatory cytokines from the basal values on the ocular surface and a series of cellular changes in the conjunctiva related to contact lens wear.

The wear of daily disposable contact lenses caused less changes to the ocular surface and less increase in proinflammatory cytokine levels than the monthly reusable lens in this study.

STUDY RESULTS

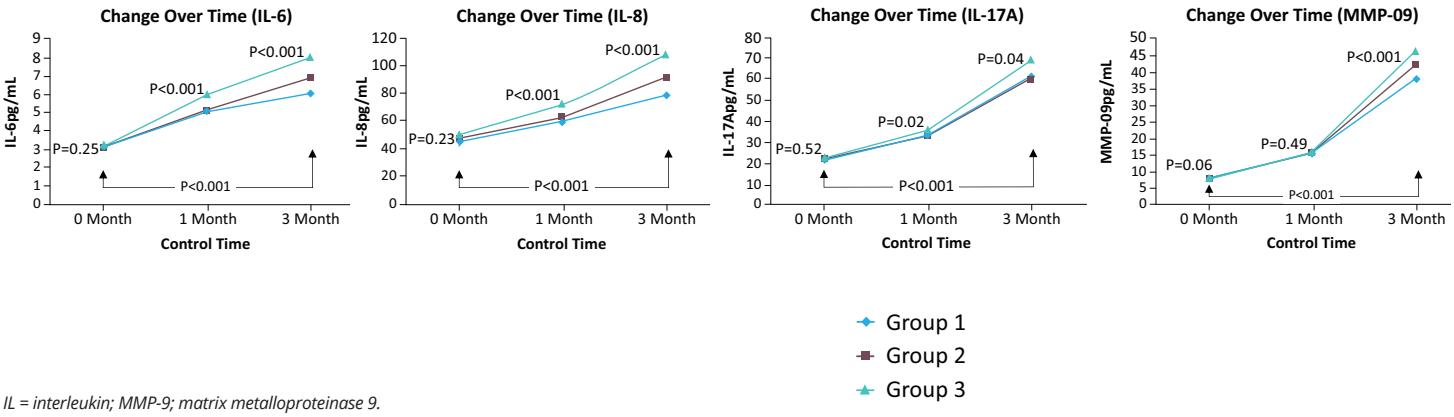
TEAR ANALYSIS

- At the end of the first and third months of CL usage, no significant differences in tear function tests were observed between groups (P>0.05)
- A decrease over time was noted for the Schirmer test in group 1 (P = 0.01), tear breakup time (TBUT) in group 2 (P = 0.01), and an increase in the Ocular Surface Disease Index (OSDI) score (P = 0.05), a reduction in the TBUT, (P = 0.02) and Schirmer test (P = 0.03) in group 3
- After one month, a significant difference between groups was observed for levels of IL-6, IL-8, and IL-17A in tears, with the highest levels in group 3 and the lowest levels in group 1 (all P < 0.05), with no difference in MMP-9 levels (P=0.49) (**Figure 1**)
- After three months, a significant difference between groups was observed for levels of all the inflammatory cytokines examined, with the highest levels seen in group 3 and the lowest in group 1 (all P < 0.05; **Figure 1**)
- A significant progression was observed in the Nelson grades in all 3 groups (all P < 0.05); no progression to Nelson grade 3 was observed in groups 1 and 2, whereas 23.5% of group 3 had progressed to Nelson grade 3

GOBLET CELL ANALYSIS

- After 3 months, a significant reduction was seen in goblet cell density in all 3 groups (P < 0.05)
- An increase was noted in the rate of snake-like nuclei seen in all 3 groups, with a significant difference only in group 2 (P = 0.04)

Figure 1. Changes occurring over time in the levels of cytokines in tears. The standard deviations shown for Group 1 were similar for the other study groups. P<0.05 was considered statistically significant.



IL = interleukin; MMP-9; matrix metalloproteinase 9.

A 12-Month Prospective Study of Tear Osmolarity in Contact Lens Wearers Refitted with Daily Disposable Soft Contact Lenses

Clinical Signs

Lens Comfort

Patient-Reported Outcomes

Garaszczuk et al. *Optom Vis Sci* 2020; 97:178-185

OVERVIEW

STUDY DESIGN

Prospective, longitudinal study to assess changes in tear osmolarity and ocular symptoms over a period of 12 months following refitting contact lens wearers with daily disposable contact lenses

STUDY SITE(S)

Research center in Poland

PATIENTS

Fifty (50) healthy young habitual contact lens wearers age 21 to 37 years, 32 (64%) habitually wore monthly lenses, 15 (30%) wore fortnightly lenses, and 3 (6%) wore daily disposable contact lenses that were different from the study lens on a daily basis for at least 8 hours per day for a year or more

METHODOLOGY

Patients refitted with either DAILIES TOTAL1® or Proclear® daily disposable soft contact lenses. The Ocular Surface Disease Index (OSDI) and Contact Lens Dry Eye Questionnaire (CLDEQ-8) used to assess patient-reported ocular symptoms and contact lens discomfort, respectively

LENS TYPE(S)

SiHy: DAILIES TOTAL1® (delefilcon A). Hy: Proclear® (omafilcon A; CooperVision)

KEY ENDPOINT(S)

Changes in tear osmolarity and ocular symptoms experienced during the wear of daily disposable lenses across a period of 12 months

ANALYSIS AND CONCLUSIONS

Refitting habitual resuable contact lens wearers with daily disposable contact lenses was demonstrated to lower tear osmolarity in the study.

STUDY RESULTS

LENS COMFORT

- No statistically significant difference was noted in the OSDI across study visits (**Table 1**); however, a statically significant difference in the OSDI was noted between baseline and the post-study visits ($P < 0.001$)
- No statistically significant difference in the CLDEQ-8 was found between the habitual contact lens wear comfort and study lens wear across the study

TEAR OSMOLARITY

- A downward trend of tear osmolarity was noted over the time course of the study for both eyes (**Table 2**), readings for all patients were comparable with healthy non-contact lens wearers at the end of the study
- Statistically significant differences in tear osmolarity were noted over the time course of the study and between baseline and the 3-, 6- and 12-month visits for both, the right and the left, eyes
- Low osmolarity was maintained after 12 months of wearing daily disposable soft contact lenses; the values at the post-study visit were significantly lower than those at the baseline visit for both eyes (both $P < 0.0001$)
- A significant decrease in tear osmolarity was also apparent for the initially symptomatic (OSCI ≥13) group for the right ($P = 0.003$] and the left eye ($P = 0.01$), and asymptomatic (OSDI <13) group for the right eye only ($P = 0.002$)
- Patients who demonstrated initially increased osmolarity (hyperosmolarity, ≥316 mOsm/L for at least one eye, n = 10) exhibited the most apparent decrease in tear osmolarity

Table 1. Subject-reported ocular symptoms.

	OSDI (−)				
	Baseline	3 mo	6 mo	12 mo	Post-study
Mean ± SD	13.3 ± 11.4	11.2 ± 11.0	11.9 ± 8.8	12.2 ± 11.3	5.1 ± 7.6
Median	10.4	7.6	8.3	9.1	2.1
Range	[0.0, 47.7]	[0.0, 52.1]	[0.0, 37.5]	[0.0, 59.1]	[0.0, 31.3]

	CLDEQ-8 (−)				
	Habitual lens	3 mo	6 mo	12 mo	
Mean ± SD	8 ±6	7± 4	7 ±4	6±4	
Median	7	6	6	6	
Range	[0, 22]	[0, 17]	[0, 21]	[0, 19]	

CLDEQ-8 = 8-item Contact Lens Dry Eye Questionnaire;
OSDI = Ocular Surface Disease Index (mild, 13-22; moderate, 23-32; severe, ≥33).

Table 2. Tear osmolarity values. Tear osmolarity ≥316 mOsm/L corresponds to a state of hyperosmolarity.

	Baseline	3 mo	6 mo	12 mo	Post-study
Tear osmolarity (m0sm/L)					
Right eye mean ± SD	304 ± 9	301 ± 10	298 ± 7	296 ± 8	293 ± 8
Left eye mean ± SD	303 ± 7	300 ± 9	297 ± 8	296 ± 7	292 ± 9
Tear osmolarity in initially asymptomatic subjects (OSDI <13; n = 31)					
Right eye mean ± SD	304 ± 8	303 ± 9	298 ± 8	296 ± 7	295 ± 8
Left eye mean ± SD	302 ± 7	299 ± 7	296 ± 7	296 ± 7	292 ± 9
Tear osmolarity in initially symptomatic subjects (OSDI ≥13; n = 19)					
Right eye mean ± SD	305 ± 10	298 ± 10	297 ± 6	296 ± 9	290 ± 6
Left eye mean ± SD	304 ± 9	300 ± 12	298 ± 8	295 ± 7	291 ± 8

Tear Film Characteristics During Wear of Daily Disposable Contact Lenses

Montani and Martino. *Clin Ophthalmol.* 2020;14:1521-1531

OVERVIEW

STUDY DESIGN
Prospective open-label unmasked non-randomized simultaneous comparative cross-over study to evaluate changes induced over time by three daily disposable (DD) contact lenses

STUDY SITE(S)
Single site in Italy

PATIENTS
Forty-six (46) new and habitual contact lens wearers (spherical refractive error < ± 3.50 D; astigmatism < 0.75 D

METHODOLOGY
Patients wore a nesofilcon A lens in the right eye and a delefilcon A lens in the left eye for one week, then vice-versa after 3-day washout period. Clinical signs were measured at baseline and on day 1 at 20 minutes and on day 7 after ≥8 hours of wear

LENS TYPE(S)
Biotrue® ONEday (nesofilcon A; Bausch & Lomb), DAILIES TOTAL1® (delefilcon A), MyDay™ (stenfilcon A; CooperVision)

KEY ENDPOINT(S)
Tear meniscus height (TMH), pre-lens non-invasive tear break-up time (NIBUT), tear film osmolarity, and objective quality of vision (OQV; changes in objective scatter index (OSI), stability index (SI), and fluctuation index (FI)

ANALYSIS AND CONCLUSIONS

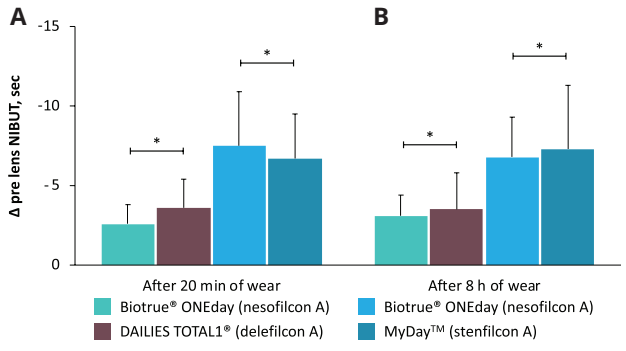
Compared to delefilcon A and stenfilcon A silicone hydrogels, nesofilcon A hydrogel lenses, despite their high water content, showed a lower reduction of tear meniscus height after 8 hours of wear, even though there were no significant differences between lenses in tear film osmolarity in this study.

STUDY RESULTS

TEAR FILM AND OBJECTIVE QUALITY OF VISION

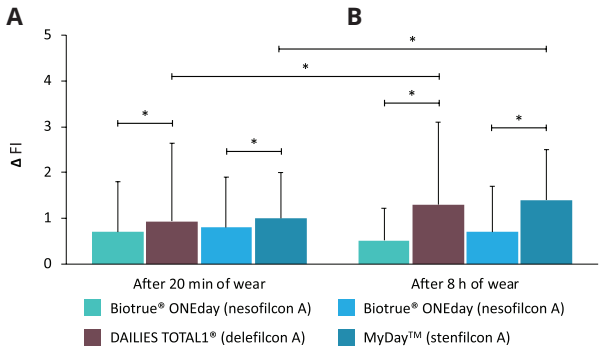
- Differences in baseline measurements for TMH, NIBUT, TO, FI and SI between eyes were not statistically significant (all P>0.05)
- Compared with baseline, TMH showed a significant reduction with delefilcon A (P=0.03) and stenfilcon A (P=0.02) lenses after 8 hours wear, but not at 20 minutes wear (P>0.05); nesofilcon A lenses did not show a significant reduction of TMH vs baseline at either time point (P>0.05)
- For all lenses, pre-lens NIBUT compared to baseline was significantly reduced at both time points (all P<0.05), but did not change significantly between time points (**Figure 1**); the reduction was significantly lower with nesofilcon A compared with the other lenses (P<0.05)
- TO did not change significantly from baseline for any lens (all P>0.05)
- OSI changes over time vs baseline were similar for all materials, although nesofilcon A had a lower increase after 10 seconds measured at 20 minutes and after 7 seconds measured at 8 hours (P<0.05); delefilcon A and stenficon A lenses presented significant increases after 8 hours of wear (P<0.05)
- Relative to baseline, FI was significantly increased for all lenses (all P<0.05); mean changes from baseline were significantly lower with nesofilcon A versus the other 2 lenses at both time points (all P<0.05) (**Figure 2**)
- Compared with baseline, SI was significantly increased for all lenses for both time points (all P<0.05); the SI change vs baseline with nesofilcon A was significantly different from stenfilcon A lenses but not delefilcon A after 8 hours of wear (P<0.05)

Figure 1. Comparison of mean changes in pre-lens non-invasive break-up time (NIBUT) from baseline at 20 minutes and 8 hours of wear. (**A**) Nesofilcon A (Biotrue® ONEday) vs. delefilcon A (DAILIES TOTAL1®). (**B**) Nesofilcon A (Biotrue® ONEday) vs stenfilcon A (MyDay™). Error bars indicate standard deviation and negative results a reduction with respect to baseline.
Adapted from Montani and Martino. *Clin Ophthalmol.* 2020;14:1521-153.



** All differences significant at α = 0.05 for the comparisons shown between the overhead bars*

Figure 2. Comparison of mean changes in fluctuation index (FI) from baseline induced by the hours of wear at 20 minutes and after 8 hours of wear. (**A**) Nesofilcon A (Biotrue® ONEday) vs. delefilcon A (DAILIES TOTAL1®). (**B**) Nesofilcon A (Biotrue® ONEday) vs stenfilcon A (MyDay™). Error bars indicate standard deviation and negative results a reduction with respect to baseline.
Adapted from Montani and Martino. *Clin Ophthalmol.* 2020;14:1521-153.



** All differences significant at α = 0.05 for the comparisons shown between the overhead bars*

Corneal Epithelial Thickness and Corneal Curvature Changes During the Day: The Effects of Daily Disposable Contact Lens Wear

Turhan et al. *Cont Lens Anterior Eye.* 2020;43:389-394

OVERVIEW

STUDY DESIGN
Randomized crossover study to evaluate the changes in corneal epithelial thickness and corneal anterior and posterior curvatures during the day and the effect of wearing daily disposable (DD) soft contact lenses (SCLs)

STUDY SITE(S)
Single center in Turkey

PATIENTS
Thirty-two (32) healthy volunteers without history of CL wear

METHODOLOGY
At baseline, keratometry and corneal and epithelial thickness were measured by optical coherence tomography in the morning and after 8 hours. Each patient was wore one of four DD CLs in random order on different days, with 3 days of no wear between contact lens types. Measurements were repeated prior to contact lens wear and after eight-hours of wear

LENS TYPE(S)
DAILIES TOTAL1® (delefilcon A), DAILIES® AquaComfort Plus® (nelfilcon A), 1-DAY ACUVUE® TruEye® (narafilcon A; Johnson & Johnson Vision Care), and Biotrue® ONEday (nesofilcon A; Bausch & Lomb)

KEY ENDPOINT(S)
Changes in corneal epithelial thickness and corneal anterior and posterior curvatures during the day and after wearing DD SCLs

ANALYSIS AND CONCLUSIONS

Corneal and epithelium thickness were not affected by DD soft contact lenses, whereas corneal thickness decreased in the natural diurnal variation.

The steepening of the anterior corneal surface might be masked by DD contact lenses despite the diurnal changes in the anterior topographic indices being significantly steepened. No significant difference was found in either diurnal changes or contact lens wearing in posterior corneal curvature.

STUDY RESULTS

CORNEAL THICKNESS AND CURVATURE

- With regard to diurnal changes, the anterior curvature topographic indices significantly steepened (Kflat: P<0.0001; Ksteep: P<0.0001; Kmax: P=0.04), whereas posterior curvature topographic indices remained unchanged (Kflat: P=0.07; Ksteep: P=0.16; Kmax: P=0.06)
- The mean diurnal change in corneal thickness showed significant thinning in the central (−5.5 ± 18.7 µm, P=0.034) and the temporal (−7.1 ± 18.5 µm, P=0.04) corneal regions, with no significant thinning in the nasal corneal region (−6.4 ± 18.4 µm, P=0.08)
- No significant diurnal thinning in the corneal epithelium was observed in any of the five different zones (central, nasal, temporal, inferior, and superior)
- Regardless of the lens type, CL wear had no effect on the anterior (mean data in **Table 1**) and posterior curvature or the corneal (mean data in **Table 2**) and epithelial thickness. There was no significant difference in the epithelial thickness among the DD CL groups (all P>0.05)

Table 1. Anterior curvature changes with daily disposable contact lens (DD CL) wear.

Scheimpflug-based Device Anterior Curvature (D)					
		DAILIES Total1®	DAILIES® Aqua Comfort Plus ®	1-DAY ACUVUE® TruEye®	Biotrue® ONEday
Kflat Mean ± SD Median (CI)	Before lens insertion	41.6 ± 1.2 41.7 (40.8 to 42.5)	41.7 ± 1.0 41.9 (41.0 to 42.5)	41.7 ± 1.0 41.6 (41.2 to 42.1)	41.9 ± 1.0 41.8 (41.5 to 42.5)
	After the 8-h wearing	41.5 ± 1.0 41.5 (40.9 to 42.3)	41.6 ± 1.0 41.6 (41.0 to 42.4)	41.7 ± 0.9 41.7 (41.2 to 42.1)	41.8 ± 1.0 41.6 (41.4 to 42.5)
Ksteep Mean ± SD Median (CI)	Before lens insertion	42.4 ± 1.2 42.8 (41.8 to 43.0)	42.6 ± 1.2 42.7 (41.9 to 43.3)	42.4 ± 1.0 42.5 (42.0 to 43.0)	42.5 ± 1.1 42.3 (41.9 to 43.1)
	After the 8-h wearing	42.3 ± 1.8 42.6 (41.4 to 43.1)	42.6 ± 1.0 42.6 (41.8 to 43.2)	42.4 ± 0.9 42.4 (42.0 to 43.0)	42.5 ± 1.1 42.3 (42.0 to 43.2)
Kmax Mean ± SD Median (CI)	Before lens insertion	43.8 ± 1.4 44.0 (43.1 to 45.1)	43.9 ± 1.5 43.9 (42.7 to 45.1)	43.9 ± 1.3 43.8 (43.3 to 44.6)	43.9 ± 1.2 43.9 (43.5 to 44.5)
	After the 8-h wearing	43.6 ± 1.2 43.6 (42.9 to 44.3)	44.1 ± 1.3 44.3 (43.3 to 45.1)	44.2 ± 0.9 44.1 (43.8 to 44.8)	44.2 ± 1.0 44.0 (43.5 to 44.8)

CI = confidence interval; D = diopter; SD = standard deviation.
P > 0.05 paired-sample t-test

Table 2. Corneal thickness changes with daily disposable contact lens (DD CL) wear.

Corneal Thickness (µm)					
		DAILIES Total1®	DAILIES® Aqua Comfort Plus ®	1-DAY ACUVUE® TruEye®	Biotrue® ONEday
Central Sector Mean ± SD Median (CI)	Before lens insertion	533.1 ± 28.8 531.0 (518.0 to 554.0)	536.5 ± 34.2 533.5 (521.5 to 557)	549.3 ± 36.8 557.0 (522.5 to 570.0)	543.3 ± 37.0 543.0 (517.0 to 570.0)
	After the 8-h wearing	529.4 ± 27.7 528.0 (510.0 to 552.0)	531.0 ± 29.9 532.0 (515.0 to 549.5)	543.4 ± 36.8 541.0 (517.0 to 569.0)	541.7 ± 38.1 530.5 (513.0 to 571.0)
Nasal sector Mean ± SD Median (CI)	Before lens insertion	557.8 ± 29.6 554.0 (540.5 to 570.0)	554.6 ± 36.4 555.0 (539.5 to 573.5)	573.8 ± 39.9 574.0 (548.5 to 594.0)	562.5 ± 39.1 555.5 (539.0 to 595.0
	After the 8-h wearing	552.4 ± 28.2 548.5 (531.0 to 576.0)	547.8 ± 32.9 544.5 (534.5 to 567.9)	567.6 ± 42.0 562.5 (540 to 589.0)	559.6 ± 37.4 555.5 (537.0 to 568.0)
Temporal Sector Mean ± SD Median (CI)	Before lens insertion	537.6 ± 28.8 538.0 (522.5 to 554.0)	548.7 ± 34.2 545.0 (528.5 to 568.0)	554.3 ± 36.4 560.0 (525.5 to 583.0)	552.6 ± 37.7 554.5 (523.0 to 573.0)
	After the 8-h wearing	535.1 ± 29.6 539.0 (517.5 to 552.0)	543.1 ± 28.0 540.0 (527.5 to 558.0)	551.6 ± 36.5 554.5 (521.0 to 577.0)	553.6 ± 44.1 534.0 (520.0 to 587.0)

CI = confidence interval; SD = standard deviation.
P > 0.05 paired-sample t-test

Comparison of Tear Film Surface Quality Measured *in Vivo* on Water Gradient Silicone Hydrogel and Hydrogel Contact Lenses.

Lens Properties

Patient-Reported Outcomes

Lens Comfort

Szczesna-Iskander. *Eye Contact Lens.* 2014; 40:23-27

OVERVIEW

STUDY DESIGN
Prospective, randomized, single-blind study to assess, *in vivo*, the pre lens tear film surface quality (TFSQ) of a new contact lens in comparison with that of another daily disposable lens from the same manufacturer

STUDY SITE(S)
Single site in Poland

PATIENTS
Eleven (11) subjects – 3 male, 8 female; aged 23-36 years (mean 29.1 ± 4.1 years)

METHODOLOGY
Subjects wore two pairs of hydrogel and silicone hydrogel lenses on two nonconsecutive days. Noninvasive lateral shearing interferometry (LSI) was used to analyze the pre lens tear film and distinguish between the different contact lens materials. Measurements were taken in natural blinking conditions after 6 hours of wear and subjective comfort was evaluated

LENS TYPE(S)
Silicone hydrogel: DAILIES TOTAL1® (delefilcon A); hydrogel: DAILIES® AquaComfort Plus® (nelfilcon A)

KEY ENDPOINT(S)
TFSQ; contact lens water content; subjective comfort assessment

ANALYSIS AND CONCLUSIONS

The investigators concluded that although pre lens TFSQ is not always directly proportional to the lens water content, the results of the *in vivo* study showed that the new water gradient silicone hydrogel material (delefilcon A) had less impact on TFSQ the hydrogel lens (nelfilcon A).

STUDY RESULTS

TEAR FILM SURFACE QUALITY (TFSQ)

- The presence of both lenses resulted in a TFSQ reduction as compared to the bare eye condition
- A smaller, yet significant (P<0.012) change in TFSQ was introduced by the water gradient silicone hydrogel material (25 ± 5%) than the high-water content hydrogel material (38 ± 7%) (**Figure 1**)
- There were three subjects for whom the TFSQ decline was lower for nelfilcon A than for delefilcon A, however the difference in the decline was less than 3%
- A significant correlation between the TFSQ results of the two lenses was found (R=0.8; P<0.003), indicating high linearity of the measurement methodology concerning the tested lens material

SUBJECTIVE COMFORT ASSESSMENT

- All but one subject assessed the lens comfort as better for the water gradient silicone hydrogel lens (delefilcon A); lower values for discomfort (3.0 ± 1.0 median ± (median absolute deviation)) were achieved for the water gradient silicone hydrogel lens than for the high water content hydrogel lens (5.0 ± 1.8) (**Figure 2**)
- The correlation of subjective comfort in lenses was lower than for TFSQ and was not statistically significant (R=0.06; P=0.054)

Figure 1. Box and whisker plot of the decline in the average pre lens tear film surface quality (TFSQ) with respect to that of the precorneal tear film

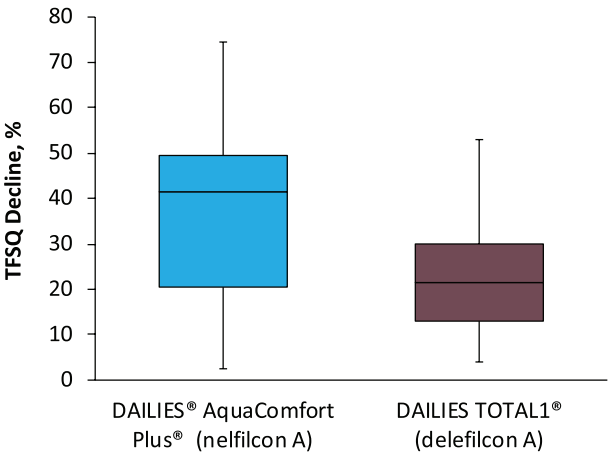
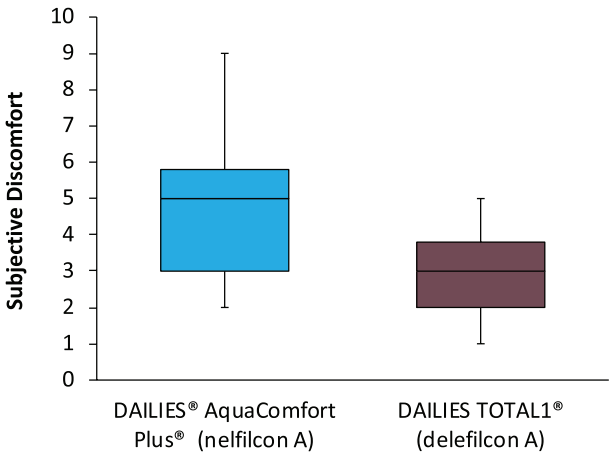


Figure 2. Box and whisker plot of subjective discomfort on lenses.



Clinical Performance of Three Silicone Hydrogel Daily Disposable Lenses

Lens Properties

Clinical Signs

Varikooty et al. *Optom Vis Sci.* 2015; 92:301-311

OVERVIEW

STUDY DESIGN
Prospective, randomized, bilateral, crossover trial to determine the clinical performance of three silicone hydrogel daily disposable contact lenses (SiHy DDCLs)

STUDY SITE(S)
Single site in Canada

PATIENTS
One hundred and four (104) subjects completed the study - 51 asymptomatic, 53 symptomatic; 29 male, 75 female; aged 17-51 years (mean 27± 9 years)

METHODOLOGY
Subjects wore SiHy DDCLs for three consecutive days; the order of lens wear was randomized, with at least 1 -day washout between

LENS TYPE(S)
DAILIES TOTAL1® (delefilcon A); clariti® 1 day (somofilcon A; CooperVision); 1-DAY ACUVUE® TruEye® (narafilcon A; Johnson & Johnson Vision Care)

KEY ENDPOINT(S)
Non-invasive tear breakup time (NITBUT); wettability; corneal staining; conjunctival staining; conjunctival indentation

ANALYSIS AND CONCLUSIONS

Each of the three SiHy DDCLs performed well. DAILIES TOTAL1® had the longest NITBUT and greatest wettability, while clariti® 1 day had the most conjunctival staining and conjunctival indentation.

There was no difference between asymptomatic and symptomatic wearers regarding ocular response and clinical performance of the lenses. The study findings suggest that SiHy DDCLs may be an excellent contact lens replacement schedule for symptomatic patients.

STUDY RESULTS

CLINICAL PARAMETERS

- The mean NITBUT was ~ 1 second longer with DAILIES TOTAL1® (5.8 ±2.7 seconds) than with clariti® 1 day (4.8 ±2.0 seconds) and 1-DAY ACUVUE® TruEye® (4.9 ±2.4 seconds) (P<0.01) **Figure 1**
- Wettability of all three CLs was good – DAILIES TOTAL1® (0.40 ±0.45) was graded marginally better than the other CLs (clariti® 1 day - 0.67 ±0.57: 1-DAY ACUVUE® TruEye® 0.75±0.62) (both P<0.01) **Figure 2**
- On day 3, eyes wearing 1-DAY ACUVUE® TruEye® had significantly more dehydration-induced corneal staining compared to DAILIES TOTAL1® (1-DAY ACUVUE® TruEye®, 24%; DAILIES TOTAL1®, 11%; P<0.01)
- After 8 hours, conjunctival staining was different between CLs; this may be considered clinically relevant as a staining grade of greater than 35 (0 to 100 scale) was seen in 31% of eyes wearing clariti® 1 day as compared to 0% DAILIES TOTAL1® and less than 1% of 1-DAY ACUVUE® TruEye®
- Conjunctival indentation was more prevalent with the clariti® 1 day lenses (n=70) compared with DAILIES TOTAL1® (n=1, P<0.01) and 1-DAY ACUVUE® TruEye® (n=11; P<0.01)
- There were no differences between asymptomatic and symptomatic lens wearers for any of the clinical parameters (NITBUT, wettability, corneal staining, conjunctival staining, conjunctival indentation; all P>0.05)

Figure 1. Noninvasive tear breakup time (NIBUT) results at each visit. Vertical bars denote 0.95 confidence intervals.

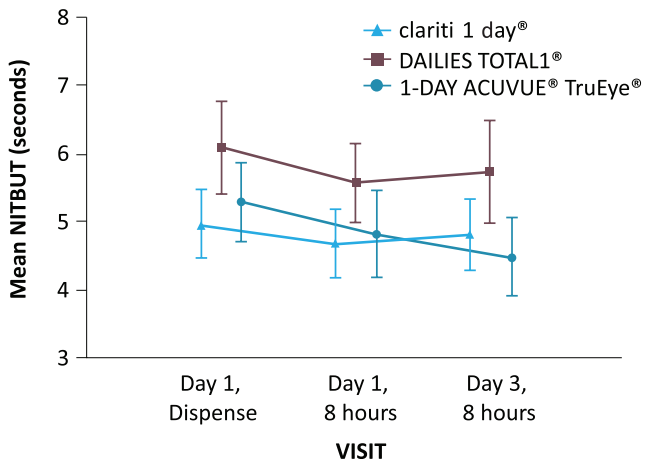
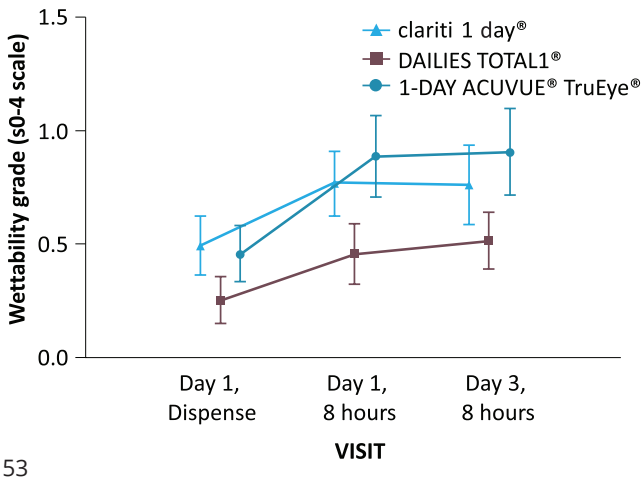


Figure 2. Wettability results at each visit (0 = excellent, 4 = severely reduced; 0.25 steps); vertical bars denote 0.95 confidence intervals.



The Effect of Temperature on Soft Contact Lens Diameter

Lens Properties

Lens Fit

Young et al. *Eye Contact Lens.* 2016; 42:298-302

OVERVIEW

STUDY DESIGN
Experimental trial to evaluate room temperature to eye temperature shrinkage in a representative sample of contemporary spherical soft contact lenses (CL)

STUDY SITE(S)
Single site in the United Kingdom

PATIENTS
Not applicable

METHODOLOGY
Reusable and daily disposable (DD) lens types in three powers were measured for total diameter at RT (20°C±1°C) and ET (34°C±1°C). CL diameter measurements were undertaken after equilibration in ISO saline in a temperature-controlled lens analyzer. Theoretical changes in base curve radii were also calculated

LENS TYPE(S)
Twenty-four (24) DD and reusable CLs (10 hydrogel and 14 silicone hydrogels [SiHy]) (**Table 1**)

KEY ENDPOINT(S)
Room temperature, eye temperature, contact lens diameter, base curve radius

ANALYSIS AND CONCLUSIONS

All of the spherical soft contact lenses analyzed in this study showed reduction in diameter when raised from room temperature to eye temperature.

STUDY RESULTS

DIAMETER MEASUREMENTS

- All lens types showed a reduction in diameter when raised from room temperature to eye temperature; there was a wide range of change between the different CLs tested (**Table 1**)
- The greatest mean changes with SiHy and hydrogel CLs were with Avaria® (Δ0.33mm) and SofLens® DD (Δ0.69mm), respectively
- The smallest mean changes with SiHy and hydrogel CLs were with 1-DAY ACUVUE® TruEye® (Δ0.04mm) and SofLens 38® (Δ0.11mm), respectively

Table 1. Temperature-induced Diameter Changes (±SD) and Shrinkage Factors

Lens Brand	Diameter Measured at 24˚C61˚C (mm)	Diameter Measured at 34˚C61˚C (mm)	Mean Reduction (mm)	Shrinkage Factor (%)
Daily disposables				
1-DAY ACUVUE® TruEye®	14.24±0.03	14.20±0.02	0.04	0.997
1-DAY ACUVUE® MOIST	14.01±0.02	13.69±0.02	0.32	0.977
Biotrue® ONEDay	14.23±0.03	13.62±0.03	0.61	0.957
clariti® 1 day	13.99±0.11	13.74±0.15	0.25	0.982
Dailies® All day Comfort	13.91±0.03	13.62±0.06	0.30	0.978
Dailies® AquaComfortPLUS®	13.97±0.03	13.64±0.02	0.34	0.976
Dailies Total1®	14.18±0.11	14.04±0.07	0.14	0.990
MyDay®	14.15±0.02	13.86±0.02	0.30	0.979
Proclear® 1 day	14.30±0.01	14.15±0.04	0.15	0.990
SofLens® daily disposable	14.00±0.02	13.31±0.02	0.69	0.951

All changes were statistically significant (P<0.0001).

- A significant negative correlation (r=-0.62, P=0.0009) was found between the shrinkage factor and lens water content; the CLs with the highest water content tended to show the greatest shrinkage
- The range in eye temperature diameters was nearly 1.0 mm, whereas the range of calculated eye temperature base curves was slightly more than 0.5 mm, showing the wide range of lens designs in contemporary soft CLs

Lens Brand	Diameter Measured at 24˚C61˚C (mm)	Diameter Measured at 34˚C61˚C (mm)	Mean Reduction (mm)	Shrinkage Factor (%)
Reusables				
ACUVUE® 2	13.81±0.02	13.59±0.02	0.23	0.984
ACUVUE® ADVANCE	14.01±0.02	13.74±0.03	0.27	0.981
ACUVUE® OASYS®	14.00±0.00	13.90±0.00	0.10	0.993
Air OPTIX® Aqua	14.28±0.06	14.09±0.08	0.19	0.987
Air OPTIX® Night & Day®	13.86±0.04	13.75±0.04	0.11	0.992
Avaira®	14.21±0.09	13.87±0.07	0.33	0.977
Biofinity®	14.16±0.04	13.86±0.02	0.30	0.979
clariti®	14.03±0.09	13.79±0.15	0.24	0.983
PremiO	14.18±0.03	14.00±0.01	0.18	0.987
Proclear®	14.19±0.04	14.03±0.04	0.17	0.988
PureVision® 2	14.03±0.04	13.89±0.04	0.14	0.990
SofLens® 38	13.88±0.08	13.77±0.08	0.11	0.992
SofLens® 59	14.24±0.04	13.62±0.03	0.62	0.957
Ultra™	14.2±0.01	14.06±0.02	0.14	0.990

Comfort, Ocular Dryness, and Equilibrium Water Content Changes of Daily Disposable Contact Lenses

Lens Comfort

Lens Properties

Insua Pereira et al. *Eye Contact Lens.* 2018;44:S233-S240

OVERVIEW

STUDY DESIGN
Contralateral open trial to evaluate the level of comfort and ocular dryness during wear with six daily disposable contact lenses (DDCL) and determine the changes in contact lens equilibrium water content (EWC) resulting from their wear

STUDY SITE(S)
Single center in Portugal

PATIENTS
Twenty seven (27) normal, healthy patients, mean age of 28.2 ± 7.5 years; three subjects were fitted with contact lenses for the first time

METHODOLOGY
Patients were randomly fitted with six DDCL. Comfort and ocular dryness sensation was recorded by the participants at 11 AM and 5 PM over 10 days of contact lens wear using visual analogue scales (0–10). Refractive index of DDCLs was accessed via digital automated refractometer

LENS TYPE(S)
MyDay™ (stenfilcon A; CooperVision), DAILIES TOTAL1® (delefilcon A), DAILIES® AquaComfort Plus® (nelfilcon A), 1-DAY ACUVUE® TruEye® (narafilcon A; Johnson & Johnson Vision Care), Biotrue® ONEday (nesofilcon A; Bausch & Lomb), Proclear® (omafilcon A; CooperVision)

KEY ENDPOINT(S)
Levels of comfort and ocular dryness, retention of initial water content with wear, and the relationship between EWC changes, comfort, and ocular dryness

ANALYSIS AND CONCLUSIONS

Comfort was slightly higher for delefilcon A and narafilcon A lenses and these lenses wearers also reported less ocular dryness.

Omafilcon A, narafilcon A, and nesofilcon A demonstrated an EWC decrease after lens wear. However, no significant correlations were found among change in EWC, comfort, and dryness ratings. Overall, all the contact lenses performed well during the 10 days of wear.

STUDY RESULTS

LENS COMFORT AND DRYNESS

- Comfort decreased after 6 hours of lens wear (P=0.002) and dryness increased in the same period (P<0.001). Mean afternoon ratings (5 PM) were lower than the morning (11 AM) ratings for all lenses. Comfort ratings were slightly higher for delefilcon A and narafilcon A lenses (both P=0.010) (**Table 1**)
- Users of delefilcon A (P=0.009) and narafilcon A (P=0.010) lenses experienced less dryness than other users
- A direct correlation was found between the comfort and dryness ratings (r = 0.816, P<0.001)
- The refractive index of narafilcon A (P=0.022), nesofilcon A (P=0.020), and omafilcon A (P < 0.001) lenses increased after being worn. Delefilcon A showed a reduction in the refractive index of the lenses used by the participants (P < 0.001)

LENS WATER CONTENT

- There was a pronounced water content reduction for omafilcon A (26.7 ± 2.0%, P = 0.002), narafilcon A (24.4 ± 1.5%, P = 0.008), and nesofilcon A (21.7 ± 0.5%, P = 0.003). Delefilcon A lenses behaved differently, with a higher EWC for the worn lenses compared with its initial value (+4.1 ± 1.8%, P<0.001)
- No significant correlations were found between change in EWC and comfort and change in EWC and ocular dryness ratings

Table 1. Values of statistical significance resulting from the comparison of comfort ratings between lenses at 11 AM and 5 PM.

Contact Lenses	MyDay™ (stenfilcon A)		DAILIES TOTAL1® (delefilcon A)		DAILIES® AquaComfort Plus® (nelfilcon A)		1-DAY ACUVUE® TruEye® (narafilcon A)		Biotrue® ONEday (nesofilcon A)		Proclear® (omafilcon A)	
	11 AM	5 PM	11 AM	5 PM	11 AM	5 PM	11 AM	5 PM	11 AM	5 PM	11 AM	5 PM
MyDay™ (stenfilcon A)	—	—										
DAILIES TOTAL1® (delefilcon A)	0.411	0.281	—	—								
DAILIES® AquaComfort Plus® (nelfilcon A)	0.447	0.169	0.137	0.032	—	—						
1-DAY ACUVUE® TruEye® (narafilcon A)	0.682	0.858	0.781	0.371	0.207	0.091	—	—				
Biotrue® ONEday (nesofilcon A)	0.348	0.101	0.079	0.010	0.929	0.825	0.192	0.010	—	—		
Proclear® (omafilcon A)	0.230	0.215	0.044	0.044	0.791	0.930	0.108	0.057	0.965	0.965	—	—

** Statistically significant difference (P<0.05) when ratings are compared between lenses.*

Association Between Ocular Surface Temperature and Tear Film Stability in Soft Contact Lens Wearers

Lens Properties

Clinical Signs

Itokawa et al. *Invest Ophthalmol Vis Sci.* 2018; 59:771-775

OVERVIEW

STUDY DESIGN
Prospective, double-blind, non-interventional study to investigate the correlation between the changes in the ocular surface temperature (OST) and tear film stability over soft contact lenses (SCLs)

STUDY SITE(S)
Single site in Japan

PATIENTS
Twenty (20) eyes from 20 SCL wearers (20 males aged 20-35 years (mean 34.4 ± 4.1 years))

METHODOLOGY
OST was measured every second for 10 seconds without blinking. Noninvasive tear break-up time (NIBUT) and tear interference patterns on the contact lenses (TIPCL) were measured using tear film interferometry. Parameters were measured before and 15 minutes of SCL wear

LENS TYPE(S)
DAILIES TOTAL1® (delefilcon A); 1-DAY ACUVUE® MOIST® (etafilcon A with polyvinylpyrrolidone (PVP)); 1-DAY ACUVUE® (etafilcon A) (Johnson & Johnson Vision Care); Ever Color 1 Day Decolog® (polymacon; Aisei Co. Ltd.)

KEY ENDPOINT(S)
OST at defined time points and ΔOST (difference in OST from 0 to 10 seconds); tear film stability (NIBUT, TIPCL)

ANALYSIS AND CONCLUSIONS

These study results suggest that silicone hydrogel delefilcon A could maintain OST better than conventional hydrogel lenses as well as tear film stability. Changes in OST over soft contact lenses were related to tear film stability.

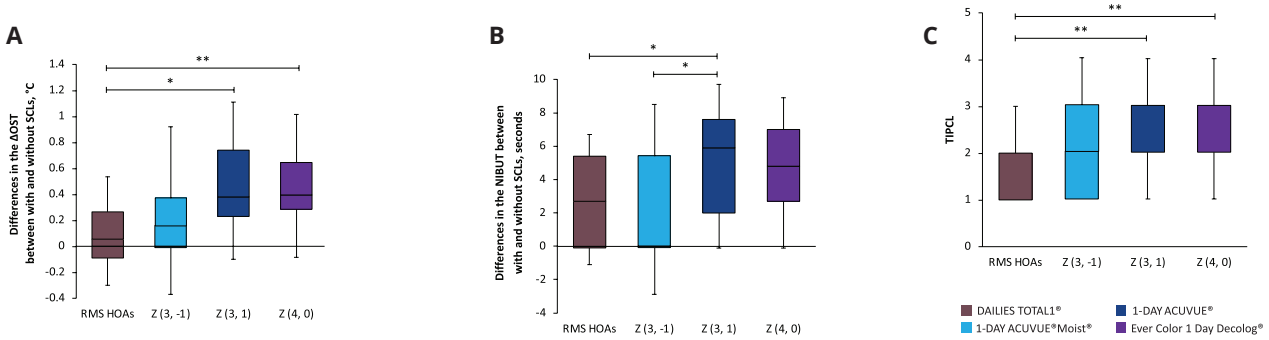
Study limitations included the limited number of subjects, evaluation of only a single silicone hydrogel contact lens, and measurement of NIBUT out to only 10 seconds. It is suggested that longer soft contact lenses wear before measurement allows for adjustment of the soft contact lenses to the subject's ocular surface, so a longer wear period prior to measurement might affect OST or NIBUT.

STUDY RESULTS

OCULAR SURFACE TEMPERATURE AND TEAR FILM STABILITY

- ΔOST was correlated significantly with NIBUT at baseline (no SCL; Spearman r=0.411, P<0.01) and over SCLs (Spearman r =0.642, P<0.01)
- In each SCL group (n=20), the correlation coefficients of the delefilcon A, etafilcon A with PVP, etafilcon A, and polymacon SCLs were 0.747 (P<0.01); 0.618 (P<0.01); 0.428 (P=0.05); and 0.510 (P<0.05), respectively, indicating the same tendency as the overall results
- Regarding the interferometry pattern, the ΔOSTs for all SCLs were significantly negatively correlated (Spearman r=-0.636, P<0.01) with the TIPCL
- Differences in OST with and without delefilcon A, etafilcon A with PVP, etafilcon A, and polymacon SCLs were 0.15 ± 0.33°C, 0.22 ± 0.33°C, 0.46 ± 0.33°C, and 0.50 ± 0.35°C, respectively
  - Delefilcon A ΔOST was significantly smaller (P<0.05 and P<0.01, respectively, Tukey HSD test) than those of etafilcon A and polymacon (**Figure 1A**)
- Differences in ΔOST with and without delefilcon A, etafilcon A with PVP, etafilcon A, and polymacon SCLs were 2.6 ± 2.6 s, 2.3 ± 3.6 s, 5.3 ± 3.2 s, and 4.8 ± 2.8 s, respectively
  - Delefilcon A and etafilcon A with PVP ΔOST were significantly smaller (P<0.05 for both comparisons, Tukey HSD test) than with etafilcon A (**Figure 1B**)
- TIPCL with delefilcon A, etafilcon A with PVP, etafilcon A, and polymacon lenses were 1.7 ± 0.9, 2.1 ± 1.0, 2.7 ± 0.9, and 2.8 ± 1.0, respectively
  - Delefilcon A lens TIPCL was significantly smaller (P<0.01 for both comparisons, Tukey HSD test) than those of etafilcon A and polymacon (**Figure 1C**)

Figure 1. Differences in ocular surface temperature (ΔOST) and non-invasive tear break-up time (NIBUT) between soft contact lens (SCL) wear and no SCL wear. (**A**) The difference in ΔOSTs between with and without the delefilcon A lens is significantly smaller than with the etafilcon A and polymacon lenses. (**B**) The difference in NIBUTs with the delfilcon A and etafilcon A with PVP lenses are significantly smaller than with the etafilcon A lens. (**C**) Tear interference patterns on the contact lens (TIPCL) grade of the delefilcon A lens was significantly smaller than those of etafilcon A and polymacon.



* P<0.05, Tukey HSD test ** P<0.01, Tukey HSD test

Non-Invasive Pre-Lens Tear Film Assessment with High-Speed Videokeratoscopy

Llorens-Quintana et al. *Cont Lens Anterior Eye.* 2018; 41:18-22

Lens Properties

Anatomical Outcomes

Clinical Signs

OVERVIEW

STUDY DESIGN

Prospective, double-blind trial to (1) evaluate the effect of two types of daily contact lens (CL) on the tear film characteristics and establish whether it is dependent on the pre-corneal tear film and (2) to determine the sensitivity of the method in differentiating between CL materials on the eye

STUDY SITE(S)

Single site in Poland

PATIENTS

Fifty-four (54) patients — 19 male, 35 female; mean age: 25.5 ± 4.3 years

METHODOLOGY

High-speed videokeratoscopy recordings analyzed using a custom-made automated algorithm. Baseline measurements, in suppressed and natural blinking conditions, were taken before subjects were fitted with two different daily CLs and after four hours of CL wear

LENS TYPE(S)

DAILIES TOTAL1® (delefilcon A; Proclear® (omafilcon; CooperVision, Inc.)

KEY ENDPOINT(S)

CL material differentiation; tear film kinetics; non-invasive tear film assessment

ANALYSIS AND CONCLUSIONS

The investigators concluded that by non-invasively measuring tear film kinetics with high-speed videokeratoscopy, it is possible to differentiate between two contact lens types *in vivo* (in eyes) even when the two contact lenses are quite similar.

The authors suggested that it would be appropriate to rethink the protocol for contact lens fitting, including an objective, quantitative assessment of tear film quality with thecontact lens on the eye as an additional test.

STUDY RESULTS

TEAR FILM QUALITY

- A significant decrease in pre-lens tear film quality with respect to the baseline pre-corneal tear film quality was found for break-up time (BUT), tear film surface quality (TFSQ), breaks feature indicator (BFI) and the percentage of analyzed area with breaks (AAB) for both lenses (**Table 1**)
- There was a significant decrease in these parameters in natural blinking conditions (NBC), as well as a decrease in the number of blinks and the mean quality in the build-up phase
- There was a statistically significant difference between the two CLs in TFSQ, BFI, and AAB, for the pre-lens tear film in suppressed blinking conditions (SBC), indicating that these three parameters are the most sensitive and able to differentiate between the function of both lenses; these differences were not found in NBC

NON-INVASIVE TEAR FILM ASSESSMENT

- An objective "best lens choice," based on the pre-lens tear film quality was made using the majority voting scheme (**Table 2**)
- Based on this objective choice, DAILIES TOTAL1® (delefilcon A) performed better in 57.4% of the cases whereas the expert clinician prescribed it for 67.3% of the subjects; coincidence between objective and clinician choice was 52.7%
- No statistically significant correlation was found between the baseline pre-corneal and pre-lens tear film quality for any of the parameters for either NBC or SBC conditions

Table 1. Median values [inter-quartile ranges] for all parameters considered in SBC. Right: P values of the hypothesis test for between visits comparisons (same eye) and between eyes comparisons (same visit).

	Pre-corneal tear film		Pre-lens tear film		P value between visits		P value between eyes	
	OD	OS	OD (DAILIES TOTAL1®)	OS (Proclear®)	OD	OS	Pre-corneal tear film	Pre-lens tear film
BUT (s)	16.47 (10.40)	14.20 (11.15)	8.88 (6.97)	7.88 (9.27)	<0.001*	<0.001	0.796	0.786
TFSQ	41.32 (16.75)	46.50 (37.93)	86.15 (57.74)	114.26 (120.25)	0.001	0.001	0.333	0.007*
BFI	33.85 (21.81)	39.59 (34.76)	97.13 (76.16)	133.91 (174.24)	<0.001	0.001	0.555	0.011*
DFI	55.80 (39.36)	50.32 (44.77)	45.34 (36.76)	48.77 (35.35)	0.786	0.505	0.816	0.455
BLD	42.67 (32.24)	42.67 (33.05)	48.82 (44.25)	50.33 (53.98)	0.276	0.702	0.887	0.387
%AAB	3.62 (1.64)	3.63 (2.78)	8.75 (4.94)	11.39 (10.87)	<0.001	<0.001	0.449	0.033*
% AAD	5.33 (4.63)	5.25 (4.29)	6.28 (5.98)	5.59 (4.98)	0.058	0.714	0.326	0.629

BUT = break up time; TFSQ = tear film surface quality; BFI = breaks feature indicator; DFI = distortions feature indicator; BLD, build-up; %AAB = percentage of analyzed area with breaks; %AAD = percentage of analyzed area with distortions.
**Statistically significant difference for a significance level of 0.05.*

Table 2. Contingency table showing the results of the frequency distribution of the considered variables for the objective best lens choice.

		Final objective best lens choice		
		DAILIES TOTAL1® (delefilcon A)	Proclear® (omafilcon A)	Total percentage
Best TFSQ choice	L1	31	3	63%
	L2	0	20	37%
Best BFI choice	L1	30	0	55.6%
	L2	1	23	44.4%
Best AAB choice	L1	26	3	53.7%
	L2	5	20	46.3%
DFI		**57.4%**	**42.6%**	

TFSQ = tear film surface quality; BFI = breaks feature indicator; AAB = analyzed area with breaks

Impact of Contact Lens Material and Design on the Ocular Surface

Lens Properties

Clinical Signs

Ruiz-Alcocer et al. *Clin Exp Optom.* 2018;101:188-192

OVERVIEW

STUDY DESIGN
Three-week crossover study to evaluate the impact on the ocular surface of a daily disposable hydrogel contact lens with high water content compared with two silicone hydrogel daily disposable lenses of lower water content

STUDY SITE(S)
Two academic centers in Spain

PATIENTS
Twenty (20) eyes of 20 patients aged 20 to 35 years who were not regular contact lens wearers

METHODOLOGY
Contact lens thickness was measured to assess material stability during daily wear. Tear film osmolarity, tear meniscus area, and central corneal thickness were measured to assess the ocular surface. Optical quality was analyzed for all cases by wavefront aberrometry

LENS TYPE(S)
Biotrue® ONEday (nesofilcon A; Bausch & Lomb) hydrogel contact lens and DAILIES TOTAL1® (delefilcon A) and MyDay™ (stenfilcon A; CooperVision) silicone hydrogel lenses

KEY ENDPOINT(S)
Contact lens thickness, tear film osmolarity, tear meniscus area, and central corneal thickness, wavefront aberrations

ANALYSIS AND CONCLUSIONS

In spite of having the thinnest lens and the highest water content, the hydrogel lens (nesofilcon A) resisted dehydration and did not significantly impact tear film and corneal swelling after one day of use in first-time wearers in this study.

STUDY RESULTS

LENS PROPERTIES

- The nesofilcon A lens was thinner than the other two lenses (P<0.001) with no differences between the stenfilcon A and the delefilcon A lenses. The thickness of the three lenses did not change as a factor of time (P = 0.799), and no interaction was found between time of use and the lens used (P = 0.200).

CLINICAL SIGNS

- No differences in tear film osmolarity values, tear meniscus area, or central corneal thickness were found based on the lens used or length of time of use, with no interaction found between the two factors (all P>0.05) **(Table 1)**

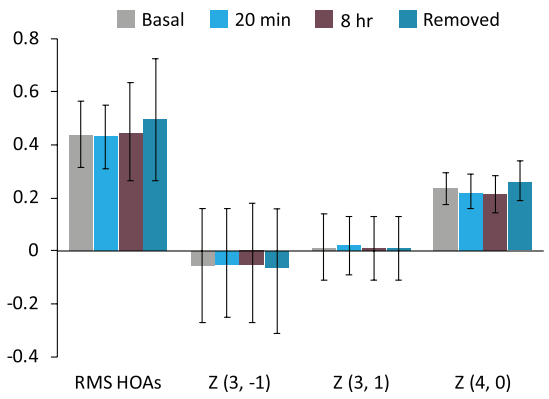
WAVEFRONT ABERRATIONS

- No significant variations were observed in the root-mean-square of high-order abberrations, horizontal and vertical coma, and spherical aberration for any of the lenses as a factor of the different time periods (all P>0.05) **(Figure 2)**

Table 1. Mean tear film osmolarity and meniscus volume at 20 minutes and 8 hours after lens insertion (Adapted from Ruiz-Alcocer et al. *Clin Exp Optom.* 2018;101:188-192)

		Delefilcon A		Stenfilcon A		Nesofilcon A	
Lens Time	**Basal**	**20 min**	**8 hrs**	**20 min**	**8 hrs**	**20 min**	**8 hrs**
Mean (SD) tear film osmolarity (mOsm/L)	299.4 (6.5)	297.2 (7.6)	300.5 (11.4)	297.3 (7.9)	300.4 (9.3)	296.9 (11.1)	297.2 (10.1)
Mean (SD) tear meniscus volume (mm³)	NA	0.014 (0.007)	0.013 (0.006)	0.011 (0.004)	0.011 (0.004)	0.013 (0.007)	0.011 (0.006)

Figure 2. Wavefront aberration values for DAILIES TOTAL1®. Root-mean-square of high order aberrations (RMS HOAs), vertical coma (Z(3, −1)), horizontal coma (Z(3, 1)) and spherical aberration (Z(4, 0)). Optical quality parameters were measured at 4 different times: before insertion of the lens, 20 minutes, and 8 hours after insertion, and when the lens was removed.



DAILIES TOTAL1® (delefilcon A)

Performance of Daily Disposable Contact Lenses in Symptomatic Wearer

Nick et al. *J Cont Lens Res Sci.* 2020;4: e1-e11

Lens Properties
Lens Comfort
Visual Acuity
Patient-reported Outcomes
Lens Fit

OVERVIEW

STUDY DESIGN
Multicenter, open-label, randomized, crossover study to evaluate the performance of delefilcon A water gradient and narafilcon A silicone hydrogel daily disposable contact lenses (CLs) in symptomatic soft CL wearers

STUDY SITE(S)
Eight (8) sites in Europe; two in Finland, three in Germany, and three in the United Kingdom

PATIENTS
One hundred twenty-one (121) soft CL wearers with symptoms of CL discomfort with mean age 34.0 ± 10.4 years

METHODOLOGY
CL wearers were randomized to delefilcon A (n =60) or narafilcon A (n=61) for 2 weeks, followed by the alternate lens for 2 weeks

LENS TYPE(S)
DAILIES TOTAL1® (delefilcon A), 1-DAY ACUVUE® TruEye® (narafilcon A; Johnson & Johnson Vision Care)

KEY ENDPOINT(S)
End of day (EOD) comfort, EOD dryness, and quality of vision rated by patients and fit, surface deposits, and surface wettability rated by investigators

ANALYSIS AND CONCLUSIONS

DAILIES TOTAL1® lenses showed superior subjective outcome ratings compared with 1-DAY ACUVUE® TruEye® lenses for comfort, dryness, quality of vision, daily wear time (DWT) and comfortable DWT.

As indicated by investigator ratings, DAILIES TOTAL1® also had better lens surface attributes, including fewer surface deposits and superior wettability, than did 1-DAY ACUVUE® TruEye®.

STUDY RESULTS

PATIENT-REPORTED OUTCOMES

- After 2 weeks, EOD comfort, dryness, and quality of vision scores were higher for DAILIES TOTAL1® than for 1-DAY ACUVUE® TruEye® (all P<0.0001) (**Figure 1**)
- Patient ratings of lens comfort throughout the day, consistent lens comfort and quality of vision from day to day, and dryness also favored DAILIES TOTAL1® (all ratings P < 0.0001)

WEAR TIME

- Average daily wear time (P = 0.001) and average comfortable daily wear time (P < 0.0001) were significantly longer for DAILIES TOTAL1® than for 1-DAY ACUVUE® TruEye®
- At the end of the study, patients preferred DAILIES TOTAL1® for all 8 questions regarding comfort, dryness, and visual quality over the 1-DAY ACUVUE® TruEye® lenses (all P < 0.0001)

LENS FIT AND PROPERTIES

- Overall lens fit assessed by investigators was reported as 'optimal' for 90.6% of eyes fitted with DAILIES TOTAL1® compared with 52.1% of eyes fitted with 1-DAY ACUVUE® TruEye®
- For centration, 94.4% of DAILIES TOTAL1® lenses were reported to be 'centered' compared with 82.5% of 1-DAY ACUVUE® TruEye® lenses
- The proportions of lenses with no visible front-surface deposits and no dry/non-wetting areas on their surfaces were approximately two-fold higher for DAILIES TOTAL1® than for 1-DAY ACUVUE® TruEye® (**Figure 2**). A higher percentage of DAILIES TOTAL1® lenses than narafilcon A lenses had no visible back-surface deposits
- The investigators' overall impression of surface wettability after 2 weeks of lens wear was significantly better for DAILIES TOTAL1® (P < 0.0001)

Figure 1. Mean ± standard deviation patient-reported end of day (EOD) comfort, EOD dryness, daytime quality of vision, and nighttime quality of vision (10-point rating scale), after 2 weeks of delefilcon A (DAILIES TOTAL1®) and narafilcon A (1-DAY ACUVUE® TruEye®) lens wear.

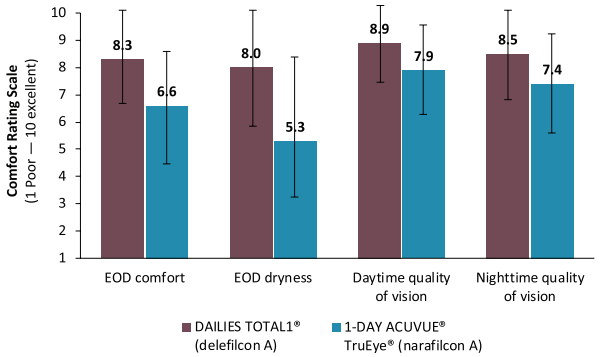
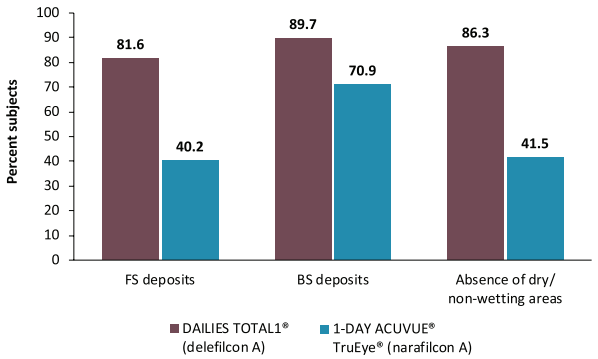


Figure 2. AInvestigator-reported percentage of wearers of delefilcon A (DAILIES TOTAL1®) and narafilcon A (1-DAY ACUVUE® TruEye®) lenses with no visible front surface (FS) deposits, no visible back surface (BS) deposits, and no dry / non-wetting areas.



Literature Review

A Decade of Silicone Hydrogel Development: Surface Properties, Mechanical Properties, and Ocular Compatibility

Tighe. *Eye Contact Lens.* 2012; 39:4-12

OVERVIEW

STUDY DESIGN
An overview of aspects of surface and mechanical behavior of SiHy lens materials that are likely to be influential in the eye, and discussed how these aspects relate to ocular compatibility of the lenses

METHODOLOGY
Literature review

LENS TYPE(S)
SiHy: PureVision® 2 (balafilcon A: Bausch & Lomb; AIR OPTIX® Night & Day® (lotrafilcon A); AIR OPTIX® AQUA (lotrafilcon B); ACUVUE® ADVANCE® (galyfilcon A) and ACUVUE® OASYS® (senofilcon A) (both Johnson & Johnson Vision Care); Biofinity® (comfilcon A) and Avaira® (enfilcon A) (both CooperVision); clariti® (somofilcon A; CooperVision); CVUE® Advanced HydraVUE™ (efrofilcon A; Unilens); DAILIES TOTAL1® (delefilcon A)

KEY ENDPOINT(S)
Dynamic mechanical properties; vitronectin; kinins

ANALYSIS AND CONCLUSIONS

The ocular environment is dynamic, leading to cumulative effects of shear-dependent mechanical and frictional response.

There is growing evidence that the dynamics of the consequent lens–eye interactions have specific biochemical consequences and that the locus of these effects relates to sites of tissue–material interactions.

STUDY RESULTS

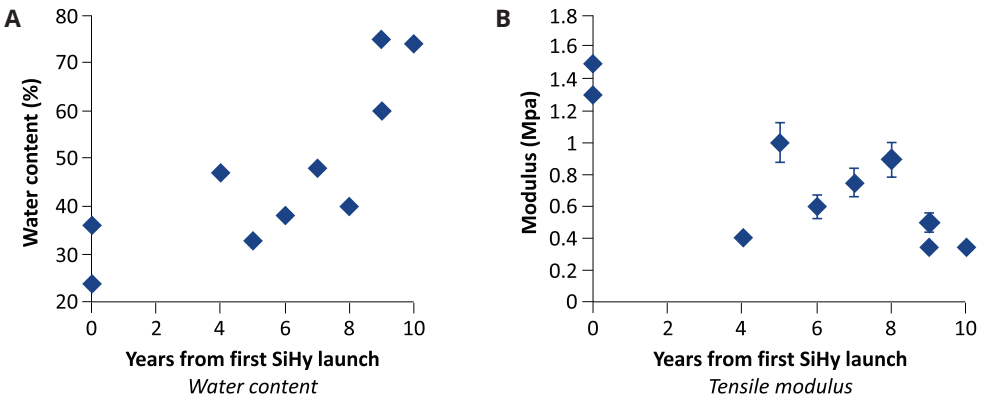
SILICONE HYDROGEL DEVELOPMENT

- There has been a considerable broadening in the range of commercial silicone hydrogel lenses over the past decade. Over this period, water content of the lenses has increased (24%–74%) and modulus has dramatically decreased (1.4–0.3 MPa) (**Figure 1**)
- In addition, the hysteresis (advanced receding) values of coated SiHy have significantly reduced from (lotrafilcon A, >40°) to (delefilcon A, <10°)
- Although water content, surface properties, and mechanical properties of the lenses have changed, there has not been an equally dramatic and progressive improvement in comfort

SURFACE PROPERTIES

- The silicon-oxygen bond is the major characteristic of SiHy that advantageously confers higher oxygen permeability; because of their inherent mobility, silicon-oxygen chains will always find their way to the surface
- SiHy lenses behave like very low water content hydrogel lenses, helping to explain why SiHy lenses show much lower levels of protein adhesion than do conventional hydrogels with similar water contents
- SiHy lenses have greater shear-dependent elastic response than do conventional hydrogels and lower coefficients of friction that offsets this elastic effect to some extent

Figure 1. Properties of emerging SiHy lenses as a function of time from first SiHy launch: (**A**) water content, (**B**) tensile modulus.



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Notes

Notes

See product instructions for complete wear, care and safety information. Rx only

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