

NCC 'Beyond 2020' Paper Abstracts  
Free paper sessions  
Monday, March 27, 2022 13:30 – 14:30  
Netherlands, Veldhoven, de Koningshof,  
Baroniezaal

**Organization Section:** NCC/ BCLA

**Moderator:** Sebastian Marx & James  
Wolffsohn

**Paper Number:** 1

**Presentation time:** 13:30-13:40

**Morphology and Mechanical Properties  
of Biomimetic Engineered Surface on  
Lehfilcon A Contact Lenses**

*James Wu, Charlie Shi, Vinay Sharma,  
George Yao*

**Purpose:** Lehfilcon A is a new silicone hydrogel (SiHy) material with surface modification of a cross-linkable bioinspired 2-methacryloyloxyethyl phosphorylcholine (MPC) polymer to mimic the surface morphology and properties of corneal tissue. This study was designed to characterize the unique surface structure and mechanical properties of lehfilcon A, which might contribute to the outstanding on-eye performance of this new contact lens.

**Method:** The surface morphology of human corneas and lehfilcon A contact lenses were imaged using environmental scanning electron microscopy (ESEM), atomic force microscopy (AFM), and scanning transmission electron microscopy (STEM). The surface modulus of human corneas and lehfilcon A contact lenses (n=3 each) were measured via AFM nanoindentation.

**Results:** Similar to the glycocalyx structure on human corneal tissue, a distinctive layer of hydrated MPC polymer on the lehfilcon A lens surface was clearly observed in ESEM, AFM, and STEM images. The surface modulus of the new lehfilcon A contact lens was  $0.037 \pm 0.008$  MPa, which was comparable to that of human cornea,  $0.050 \pm 0.022$  MPa (n=3, p>0.05) measured by AFM nanoindentation method.

**Conclusions:** The surface morphology and mechanical properties of lehfilcon A

contact lens were similar to those of human corneal tissue. These results demonstrated that lehfilcon A contact lenses not only mimicked the glycocalyx structure on the corneal surface, but also closely matched the surface softness of the human cornea, which may enhance tear film stability and reduce contact stress on the ocular surface.

**Research funding received:** N/A

**Paper Number:** 2

**Presentation time:** 13:40-13:50

**Clinical Performance of a Novel Toric  
Silicone Hydrogel Contact Lens**

*Carles Otero, Lakshman Subbaraman,  
Britt Gustafson, Susan Whaley, Bradley  
Giedd*

**Purpose:** To obtain on-eye clinical performance data and assess contact lens alignment and fit characteristics of a novel toric silicone hydrogel contact lens (verofilcon A) for astigmatism.

**Method:** In this prospective, open-label, single-arm, bilateral, multicenter clinical study eyes of healthy participants were fitted with verofilcon A contact lenses. The study evaluated lens alignment and fit characteristics. Lens alignment was determined in terms of the percentage of lenses with axis orientation within  $\pm 5^\circ$ ,  $\pm 10^\circ$ , and  $\pm 20^\circ$  from the intended  $90^\circ$  axis; and lens oscillation with blink on a 4-point scale (none,  $<3^\circ$ ,  $3^\circ$  to  $5^\circ$ , and  $>5^\circ$ ). The lens fit characteristics were recorded in terms of lens position and movement. Safety endpoints assessed include adverse events (AEs), device deficiencies, and biomicroscopy findings.

**Results:** A total of 39 subjects (78 eyes; mean (SD) age, 34.1 (10.8) years; female, 66.7%) were exposed to study lenses. The mean (SD) lens settling time was 40.1 (56.8) seconds. At 10 minutes, the proportions of lenses orienting within  $\pm 20^\circ$ ,  $\pm 10^\circ$ , and  $\pm 5^\circ$  from the intended axis were 100%, 98.7%, and 89.7%, respectively. The mean (SD) absolute axis orientation at 2 minutes was 2.7 (3.6) degrees. The majority of lenses (98.7%) had less than  $5^\circ$  of oscillation or no

oscillation with blink. All lenses studied achieved optimal or acceptable fit (optimal, 88.5%; acceptably tight, 6.4%; and acceptably loose, 5.1%) and optimal or acceptable centration (optimal, 97.4%; and acceptable decentration, 2.6%). There were no AEs, device deficiencies, or clinically relevant changes to biomicroscopic findings.

**Conclusions:** The novel toric verofilcon A contact lens showed optimal alignment and fit without any safety concerns. Owing to the unique material features, advanced surface technology, optimal lens alignment, and fitting characteristics of this lens, it could offer astigmatas a better contact lens wearing experience.

**Research funding received:** Alcon

**Paper Number:** 3

**Presentation time:** 13:50-14:00

**Clinical Performance Evaluation of New Lehtilcon A Monthly Replacement Silicone Hydrogel Toric Contact Lenses**

*Carles Otero, Vidhya Subramanian, Stephen Montaquila, Britt Gustafson, Susan Whaley*

**Purpose:** The lehtilcon A toric lens is a new monthly replacement water gradient contact lens with CELLIGENT™ Technology, indicated for the optical correction of refractive ametropia with astigmatism. It utilizes the proven Precision Balance 8|4™ design. This study evaluated the on-eye performance of fit and rotational stability characteristics of the new lehtilcon A toric lens.

**Method:** In this study, 69 subjects (mean age 37.5±13.2 years), who were adapted wearers of soft contact lenses having cylindrical correction between -0.75D and -1.75D at axis 90° or 180° (±10°), wore lehtilcon A toric lenses bilaterally for approximately 1 hour. The percentage of lenses with axis orientation within ±10° of the intended 90° axis at 10 minutes; axis orientation at 3 and 10 minutes; lens oscillation with blink; and rotational recovery time following 30° nasal and temporal manual dislocation were

evaluated. Overall lens fit characteristics of movement and position were also assessed. Subjective ratings of insertion and overall comfort were measured (on a 1 to 10 scale).

**Results:** At 10 minutes after insertion, 94.9% of lenses had axis orientation within ±10° of the intended 90° axis. Mean (SD) absolute axis orientation was 3.0° (4.8°) at 3 minutes and 3.2° (6.2°) at 10 minutes after lens insertion. 97.8% lenses oscillated ≤5° with blink. Mean time for rotational recovery was 63.3 seconds and 44.9 seconds, after 30° temporal and nasal manual dislocations respectively. Lens movement and centration was assessed to be optimal or acceptable for all (100%) lehtilcon A toric lenses. Both insertion and overall comfort had a mean subjective rating score of ≥ 9.0.

**Conclusions:** The lehtilcon A toric lenses exhibited good axis orientation, on-eye rotation stability and optimal fit. These characteristics along with excellent comfort ratings, provides a promising new toric lens option for astigmatas in the monthly replacement modality.

**Research funding received:** Alcon

**Paper Number:** 4

**Presentation time:** 14:00-14:10

**Performance and environmental perceptions of a novel toric hydrogel contact lens**

*Neema Ghorbani-Mojarrad, Lindsay Rountree, Louise Terry, Neil Retallic, Katharine Evans*

**Purpose:** To investigate the performance and environmental perceptions of a novel Flat Pack toric daily disposable (TDD) contact lens compared to traditional blister packaged lenses, in a randomised-crossover trial.

**Method:** Methods: Forty habitual toric lens wearers (33% male, aged 25.8±6.5 years) were fitted with a brand-masked Flat Pack TDD: Hioxifilcon A (Miru 1day Flat Pack Toric), and a brand-masked TDD control lens: either Nelfilcon-A (Dailies Aqua Comfort Plus) or Etafilcon-A (1-day

Acuvue Moist). Objective lens performance (fit, vision quality, rotation recovery) was assessed at fitting by an unmasked investigator, after which participants wore the two lenses for 3 days each in a randomised order, with >24-hour wash-out period between. Subjective measures (comfort, vision, handling), environmental perceptions, and overall lens preference were assessed by questionnaire.

**Results:** Results: Lens fitting measures were similar for all lenses. Subjective comfort, particularly end of day comfort, was greater with Hioxifilcon-A ( $7.3 \pm 1.9$  versus  $6.3 \pm 2.0$ , scored out of 10), whilst subjective visual performance was greater with the control lenses ( $8.1 \pm 1.24$  versus  $7.1 \pm 2.2$ , scored out of 10). These differences did not reach statistical significance. Distance VA was better with the control lenses ( $p < 0.05$ ), but only by one LogMAR letter. Most participants (70%) preferred the Flat Pack packaging compared to a traditional blister pack. For overall lens preference, Hioxifilcon-A was the most popular (60% of participants). 95% of participants indicated that environmental impact of contact lenses is important/extremely important, and 100% recognized that the Flat Pack packaging had the smaller environmental impact.

**Conclusions:** Conclusion: Overall, all lenses performed well, and to similar levels. Subtle differences in vision quality may be due to the different optical designs. The overall preference for Hioxifilcon-A may indicate that wearers prioritise comfort and other factors over vision. This study demonstrated that environmental credentials are important to contact lens wearers, and may influence overall lens preference and choice.

**Research funding received:** Funding and consumables for this project was provided by Menicon Co., Ltd., Japan. Project methodology, results, and analysis were designed and completed by the

researchers, with no interference from funding bodies.

**Paper Number:** 5

**Presentation time:** 14:10-14:20

**Change in objective ocular redness and symptoms after refit of weekly and monthly lenses into a water-gradient daily disposable lens material**

*Sebastian Marx, Stefan Schwarz, Katharina Keller, Wolfgang Sickenberger*

**Purpose:** Primary objective of the study is the evaluation of change in ocular redness when a water gradient DD SiHy Lens (Delefilcon A) is refitted to 2-4 week CL wearers.

**Method:** 52 habitual, asymptomatic, full time SCL wearers with spherical correction were enrolled in a prospective single center study. At the baseline visit bulbar and limbal redness were measured objectively using the Oculus K5M Redness-Scan mode. Lens care type, comfort ratings and staining data was captured as well. Comfort after insertion, during the day as well as the end of day comfort was obtained using a 101 point visual analog scale. The comfort rating were averaged in this abstract. A wash out phase of  $6 \pm 1$  days was conducted in which the subjects didn't wear any lenses before Delefilcon A lenses were dispensed at visit 2 for a wearing period of  $26 \pm 5$  days. A follow up visit was planned after  $6 \pm 1$  days from V2 and a final visit after additional  $20 \pm 4$  days. During visit 2, 3 and 4 the same objective measurements were carried out and corresponding subjective data was captured. Wilcoxon signed rank test and t-test for paired samples were used for the statistical analyses.

**Results:** 50 subjects completed the study. Following results, refer to the right eyes only. Objectively measured bulbar redness decreased by 0.11 ( $p=0.012$ ) from baseline in comparison to the final visit. In the same period limbal redness reduced by 0.20 ( $<0.001$ ), corneal staining by 0.24 ( $p=0.014$ ) and conjunctival staining by 0.16 ( $p=0.046$ ). In contrast to the

objective findings, subjective ratings increased. The averaged comfort rating with habitual lenses was 79.29, after the wash out phase with no lens wear 85.91, during the first follow up visit with Delefilcon A lenses 86.83 and at the final visit 89.12.

**Conclusions:** Although the difference is small in context of our classic subjective grading habits, which uses fully grades in 1.0 steps, the Oculus K5M was able to detect fine graduated differences in the cohort of non-symptomatic wearers, which didn't show high redness scores. Delefilcon A material delivers benefits to wearers in form of reduced bulbar and limbal redness, reduced corneal and conjunctival staining and increased wearing comfort.

**Research funding received:** The IIT study # 43410197 was fully funded by Alcon Inc.

**Paper Number:** 6

**Presentation time:** 14:20-14:30

**Performance evaluation of two toric multifocal contact lenses available in different parameter increments**

*Doerte Luensmann, Sarah Guthrie, Jill Woods, Jose Vega, Gary Orsborn*

**Purpose:** Toric multifocal contact lenses (TMFCLs) offer vision correction to the astigmatic presbyopic population. The vision outcome was determined in existing soft lens wearers when fit with two TMFCLs, available in different parameter steps; 5 vs 10-degree axis increments and 6 vs 2 near adds.

**Method:** In a multisite, prospective, randomised, participant-masked, 1-month crossover, bilateral dispensing study, habitual soft lens wearers  $\geq 42$  years old with minimum 0.75DC astigmatism were fit with two monthly replacement, silicone hydrogel TMFCLs (comfilcon A (com-A); CooperVision, samfilcon A (sam-A); Bausch & Lomb). The manufacturer's fitting guides were followed, and lens prescriptions were optimised after 3-7 days of wear, before the 1-month wear period. Vision outcomes included visual acuity (LogMAR), 3-point ratings

(met/exceeded or did not meet my needs), and 5-point preference ratings (strongly/slightly prefer lens 1 or 2, no preference).

**Results:** Fifty-six participants age  $53.6 \pm 8.6$  years were included in the analysis (OD mean( $\pm$ SD): sph  $-2.47D(\pm 2.38)$ , cyl  $-1.27D(\pm 0.47)$ , add  $1.88D(\pm 0.48)$ ). For com-A axes ending in 5 degrees were chosen for 47% of eyes and each add power was prescribed. After one month, LogMAR acuity was similar for both lens types for distance, intermediate and near ( $p > 0.05$  for all). On days 7, 14 and 28 participants rated that com-A met their needs better for 'Overall speed and ability to change focus between distances', 'Vision stability throughout the day' and 'Overall vision clarity' ( $p < 0.05$  for all); other ratings showed no difference between lenses. A preference was found for com-A for vision clarity for 'intermediate tasks' ( $p = 0.03$ ), 'near tasks' ( $p = 0.01$ ), 'during digital device use' ( $p < 0.01$ ) and for 'overall vision clarity' ( $p = 0.01$ ). No preference was indicated for distance tasks ( $p > 0.05$ ).

**Conclusions:** The higher accuracy of prescribing for com-A due to the 5-degree axis steps and the 6 near adds may have contributed to the better vision outcomes reported with com-A.

**Research funding received:** This research was funded by CooperVision.

End of session