

NCC 'Beyond 2020' Paper Abstracts  
Free paper sessions  
Sunday, March 26, 2022 09:30 – 10:30  
Netherlands, Veldhoven, de Koningshof,  
Baroniezaal

**Organization Section:** NCC/ BCLA

**Moderator:** Elizabeth Lumb & James  
Wolffsohn

**Paper Number:** 1

**Presentation time:** 09:30-09:40

**Two-Year Effectiveness Of A Novel  
Spectacle Lens In Young Myopes**

*Debbie Laughton, Joe Rappon, Jay Neitz,  
Maureen Neitz, Thomas Chalberg*

**Purpose:** Onset of myopia is a strong predictor of adult high myopia. Spectacles are an ideal modality for myopia management with young children, but recent studies only include children  $\geq 8$  years old (yo). Novel spectacles that incorporate light scattering features (DOT lenses) are being evaluated in a three-year, randomized, controlled, parallel-group clinical trial with children 6-10 yo. The purpose of this research was to evaluate efficacy of DOT lenses over two years with 6-7 yo subjects.

**Method:** Eligible children (n=256) with myopia were dispensed spectacles at 14 North American sites. Subjects were randomized to receive one of two DOT lens designs or control lenses. Randomization was stratified by age and baseline myopia SER. Myopic progression was evaluated through axial length (AL) change from baseline, and through cycloplegic autorefraction (cSER).

**Results:** A total of 27 six yo and 51 seven yo children were included at baseline, making up 30.4% of the total study population. The mean baseline AL ( $\pm$  SD) was  $23.71 \pm 0.82$ ,  $23.67 \pm 0.69$ , and  $23.93 \pm 0.81$  mm for Test 1, Test 2, and Control, respectively. After 24-months, the mean change from baseline in AL was  $0.50 \pm 0.24$ ,  $0.53 \pm 0.43$ , and  $0.78 \pm 0.30$  mm for Test 1, Test 2, and Control respectively. The mean baseline cSER was  $-1.82 \pm 1.05$ ,  $-1.66 \pm 0.77$ , and  $-1.98 \pm 0.99$  D for Test 1, Test 2, and Control respectively. After 24-

months, the mean change from baseline in cSER was  $-0.58 \pm 0.58$ ,  $-0.78 \pm 1.03$ , and  $-1.34 \pm 0.73$  D for Test 1, Test 2, and Control respectively. The difference in change from baseline cSER between Test 1 and Control was statistically significant. **Conclusions:** Novel spectacle lenses were shown effective in 6 and 7 yo children at reducing myopia progression, which is particularly important given the rapid pace of myopia progression in this age group.

**Research funding received:** This research was funded by SightGlass Vision, Inc. and the authors have financial interests in the company.

**Paper Number:** 2

**Presentation time:** 09:40-09:50

**Comparison of the visual performance of three multifocal lenses used for myopia management**

*Langis Michaud, Camille Leblanc,  
Alexandra Gignac, Mhamed Ouzzani*

**Purpose:** To assess visual acuity, the level of high order aberrations generated and the amplitude of accommodation obtained with 3 multifocal soft lenses in a myopic Caucasian population aged 18-25 years, as well as their subjective evaluation in terms of comfort and quality of vision.

**Method:** Participants were randomly fitted with 3 types of multifocal contact lenses (Senofilcon A - (S) J&J), Omafilcon A (O) and Comfilcon A (C)- (Cooper Vision) used to manage myopia (on/off label). Lens power was selected based on SE auto-refraction. High add power was used (lens C). High contrast visual acuity (ETDRS) was evaluated at distance and at near. Amplitude of accommodation was recorded. High order aberrations were measured for every condition (naked eye, 3 lenses worn). Finally, participants answered a questionnaire about quality of vision and comfort.

**Results:** Clinical population was composed of 23 participants (22.5 years; 17.4% M/82.6%F;  $-2.25D \pm 1.00D$ ) In terms of visual acuity, the only significant

difference was found with the O lens (lower distance VA @  $-0.19 \pm 0.11$ ) than any other lenses vs BCVA ( $-0.24 \pm 0.08$ ). Visual acuity at near and amplitude of accommodation remained unchanged vs single vision correction. HOAs were significantly higher with each of the 3 tested lenses (all over  $0.300 \mu\text{m}$ ) vs naked eye ( $0.014 \pm 0.080$ ). There was no statistical differences between lenses. Subjectively, lens C was preferred for vision and comfort. Lens S came second and lens O was associated with reduced vision and comfort. Consequently, lens C appears to be the best option to manage myopia in young adults. Lens O is considered the last /worst option.

**Conclusions:** Myopia management with multifocal soft lenses give subjective different results based on lens designs. COMfilcon A lens design seems the most valuable option for vision and comfort among tested devices.

**Research funding received:** None

**Paper Number:** 3

**Presentation time:** 09:50-10:00

**Myopia control treatment benefits are retained after discontinuation of a dual focus, myopia control contact lens**

*Elizabeth Lumb, David Hammond, Arthur Bradley, Baskar Arumugam*

**Purpose:** Evaluate myopia progression and eye growth following discontinuation of myopia control therapy with dual-focus daily disposable contact lenses (MiSight 1 day, omafilcon A, CooperVision, Inc; M1D).

**Method:** Following completion of a 6-year study to assess efficacy of M1D, 83 subjects were refitted for one year (year 7) with single vision daily disposable lenses (Proclear 1 day; omafilcon A, CooperVision Inc.; P1D). 43 and 40 subjects had worn M1D lenses for 6 years and 3 years (T6 and T3 groups), respectively. Spherical equivalent refractive error (SERE) and axial length (AL) were monitored during, and after cessation of treatment, and compared to established myopic eye growth models

(Chamberlain et al, ARVO 2021; Arumugam et al, ARVO 2021) to determine if the myopia control benefit was maintained after treatment discontinuation.

**Results:** During year seven, the T3 and T6 groups remained well balanced for mean age,  $16.3 \pm 1.2$  and  $16.1 \pm 1.5$  ( $p=0.55$ ), but because of longer treatment SERE was lower for the T6 than for the T3 group (mean  $\pm$ SD),  $-3.10D \pm 1.15$  and  $-3.85D \pm 1.23$  respectively. Changes (LS mean  $\pm$ SE) in SERE during year 7 were similar for both groups (T6:  $-0.21D \pm 0.035$ , T3  $0.24D \pm 0.036$ ,  $p=0.49$ ) as was axial elongation (T6:  $0.090 \pm 0.013\text{mm}$ , T3  $0.10 \pm 0.013\text{mm}$ ,  $p=0.56$ ). Year seven AL progression was consistent with modelling of age-matched untreated myopic eyes growth of  $0.100 \text{mm/yr}$ .

**Conclusions:** Myopic eye growth returns to average age matched values when discontinuing M1D treatment, revealing that accrued myopia control treatment benefits are retained irrespective of prior treatment duration. These results emphasize the lasting benefits of early M1D treatment for myopia.

**Research funding received:** Study fully sponsored by CooperVision, Inc

**Paper Number:** 4

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

**Measurement of short term choroidal response as a predictor of effectiveness of 3 soft multifocal lenses used for myopia management**

*Langis Michaud, Remy Marcotte-Collard, Justine Renaud, Aulne St-Amant*

**Purpose:** To predict which of the 3 soft MF contact lenses (Omafilcon A-Etafilcon A- Senofilcon A) most used for myopia management has the best myopic control potential based on the choroidal response they generate

**Method:** Each participant was randomly fitted with 3 soft MF lenses which were worn for 30 minutes then assessed. (Omafilcon A lens- My Slight; Senofilcon A - Oasys Presbyopia; Etafilcon A lens- Naturalvue) Every trial was followed by a

resting period (15 minutes) in order to recover. A new baseline value was determined before a new trial. Visual stimulation and environment were controlled during lens wear. OCT measurements (Heidelberg Spectralis) were made with and without lenses on. Pupil diameter was determined prior testing session (photopic). Deep choroidal imagery was analyzed through Matlab's Choroid Segmentation software. A one-factor ANova test followed by Bonferoni's post-hoc analysis was run.

**Results:** 24 participants (12M, 12F, 23.5 years) were enrolled. MEan SE was -2.5D and pupils were 5.1 mm. The difference in total choroidal volume change after wearing O lens (Avg= -0.055um) E lens (Avg = -0.150um) and S lens (Avg=+0.086um) was significant. Post-hoc analysis revealed that E and S, but not O and S, were significantly different. E and O were not considered different as well. S lens wear generated thickening (positive response) on 16 participants and thinning (negative) on 8. O lens gave 10/14. The worst results were obtained with E lens (8/16). Individual results showed that S lens was the best for 14 participants, O lens was first for 4 and E lens for 6. All lenses provided negative results for 2 participants. Results were not explained by the pupil diameter.

**Conclusions:** This study proves that no single lens can manage myopia effectively on every patient. There is an individual response to the lens design. S lens design is found better overall but still 8 participants were better served with other designs. E lens is the best option for 6 and O lens for 4. S lens design is then presumed with the highest potential to manage myopia in a young adult population.

**Research funding received:** None

**Paper Number:** 5

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

**Microbial ingress evaluation of NOVELIA package for Systane Ultra MDPF and Systane Hydration MDPF**

*Paul Shannon, Monica Crary, Cindy McAnally, Brian Patterson, Stephen Shannon*

**Purpose:** Preservative-free products are viable alternatives for individuals who are sensitive, or have reservations about using traditional preservatives. To mitigate microbial growth without the use of preservatives, a multi-dose packaging system must present a physical barrier to contamination throughout the use period. This study evaluates the potential of microbial ingress into Systane Ultra and Systane Hydration presented in the NOVELIA® Multi-Dose Preservative Free package over a 30-day use period.

**Method:** Three challenge methods were evaluated for 30 days per Note for Guidance on In-Use Stability Testing of Human Medicinal Products (CPMP/QWP/2934/99) to simulate consumer use. First, the tip was challenged daily with low levels (102 CFU) of *Brevundimonas diminuta* (ATCC 19146) after actuation to simulate the tip routinely contacting a contaminated surface. After four days of dispensing, the tip was submerged in a high level (106 CFU/mL) susp. of *B. diminuta* and actuated to simulate routine use of the product followed by a gross contamination event similar to falling into a heavily contaminated liquid. Finally, the air-intake vent was challenged by submerging the bottle beyond the air-intake filter into a high level (106 CFU/mL) susp. of *B. diminuta* and actuating to provide an extreme challenge to the physical barrier.

Following each 30-day simulation, internal contents of replicate samples were evaluated for sterility per USP<71>. A passing result indicates the packaging system was able to prevent microbial ingress into the bottle, while a failing result indicates ingress into the packaging system.

**Results:** For all simulations, a passing USP<71> sterility result was obtained following the 30-day use simulations and microbial challenges of the NOVELIA

package.

**Conclusions:** Both Systane Ultra Preservative Free and Systane Hydration Preservative Free, when presented in the NOVELIA package with the PureFlow™ 200 nozzle, remains contaminate-free over a 30-day use period, even when subjected to extreme cases of microbial contamination. Users who suffer from dry eye disease now have the option of Systane Ultra Preservative Free and Systane Hydration Preservative Free in a unique multi-dose package.

**Research funding received:** All research funding from Alcon Laboratories. All authors are Alcon employees.

**Paper Number:** 6

**Presentation time:** 10:20-10:30

**Assessment of Contact Lens Care Products Antimicrobial Efficacy in the Presence of Lehtilcon A Contact Lenses**  
*Manal Gabriel, Rhonda Walters, Elise Miller, Cynthia McAnally, Monica Crary, Paul Shannon*

**Purpose:** The evaluation of the antimicrobial efficacy of contact lens care products (CLC), three multipurpose disinfecting solutions (MPDS) and two hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>) systems in the presence of lehtilcon A contact lenses and manufacturer's lens cases according to ISO 18259. Lehtilcon A is a new silicone hydrogel water gradient contact lens for daily wear with one-month replacement.

**Method:** All CLC products were tested against ISO panel microorganisms plus Fusarium clinical isolates. Lenses were added to lens cases and inoculated to contain approximately 10<sup>x</sup>E5-10<sup>x</sup>E6 CFU/lens. Additionally, for H<sub>2</sub>O<sub>2</sub> systems, two strains of Acanthamoeba trophozoites and cysts (10<sup>x</sup>E4-10<sup>x</sup>E5 cells/lens) were tested using a modified ISO 18259 method. All cases were filled with the appropriate volume of MPDS and H<sub>2</sub>O<sub>2</sub> product, closed and soaked for the 6-hour disinfection time (DT). The solution within the lens case was sampled and survivors quantified. Log reductions (LR) were calculated between Time 0 controls

and test samples recovered at DT.

**Results:** The H<sub>2</sub>O<sub>2</sub> systems showed high efficacy against Acanthamoeba trophozoites (4.9-5.5 LR) and cysts (2.5-3.7 LR) and demonstrated total kill against ISO microorganisms and Fusarium clinical isolates. All MPDS products showed total kill against P. aeruginosa and S. marcescens, 4.9-5.3 LR for S. aureus, and 3.5-4.4 LR for F. keratoplasticum. The MPDS products showed 2.5-3.9 LR against Fusarium clinical isolates.

**Conclusions:** MPDS and H<sub>2</sub>O<sub>2</sub> CLC products demonstrated antimicrobial efficacy against ISO panel microorganisms, clinical isolates of Fusarium and Acanthamoeba trophozoites and cysts in the presence of lehtilcon A contact lenses and manufacturer's lens cases.

**Research funding received:** All research funding from Alcon Laboratories. All authors are Alcon employees

End of session