

GSLs 2024

Free Paper Session

Moderator – Eef van der Worp, BOptom, PhD

Presenters: Evan Elam, BA; Daddi Fadel, DOptom; Randy Kojima; Langis Michaud, OD, MS; Kishan Patel, OD

Description: This free paper session will have 5 different short presentations on studies and projects in contact lenses and related subjects presented by separate clinicians and researchers, ranging in topics from keratoconus, scleral lenses, corneal GP lenses, symptomatic soft lens wearers, myopia management and optical aberration control

Learning objectives:

- Understanding lower and higher order aberration manufacturing methods and its application for scleral lenses
- Understanding if and how if scleral lenses (with and without surface treatment) can improve ocular comfort and reduce dryness in symptomatic soft lens wearers
- To understand corneal topography of the irregular shaped eye and how corneal GP lenses could be adapted to improve the overall lens fit
- To understand and define the limits of the peripheral retinal that responds to the optical defocus used in myopia management
- To understand the creation and use of a clinical grading scale to evaluate scarring in keratoconus patients

Quantifying the Variability in Aberration Structure for Two Methods of Wavefront-guided Lens Manufacture – Evan Elam, BA

PURPOSE: Wavefront-guided scleral lenses (WFGSLs) correct both lower order aberration (LOA) and higher order aberration (HOA). All past demonstrations of WFGSLs have relied on a common manufacture method, which requires the wavefront correction to be integrated into the design of a traditional scleral lens prior to lens manufacture. A novel method of manufacture (NMM) for WFGSL would rely on carving the wavefront correction into the anterior surface of a previously manufactured spherical scleral lens, which would allow wavefront correction to be applied to any scleral lens with a predictable on-eye orientation. The purpose of this study was to compare the variability in aberration structures observed within the established method of manufacture (EMM) and NMM methods of WFGSL manufacture.

METHODS: Four unique WFGSL designs were chosen for evaluation in this study. Two duplicates of each design were manufactured using both the EMM and NMM (4 designs x 2 duplicates x 2 methods of manufacture), resulting in a total of 16 test lenses. Two additional spherical lenses were manufactured as controls. All lenses were optically profiled over a 7-mm pupil diameter and the aberrations were represented with a 2nd-10th radial order Zernike polynomial. The

variability within each manufacture method was calculated as the difference in the Zernike representation of each unique WFGSL design after subtracting control aberrations, and summarized as lower order (LO) root mean square (RMS) and higher order (HO) RMS. The average level of HORMS of the population over a 7mm pupil ($0.64\text{ }\mu\text{m}$) was used as a benchmark.

RESULTS: Average LORMS and HORMS difference between the first and second build of the EMM lenses was $0.13\pm0.08\text{ }\mu\text{m}$ and $0.14\pm0.04\text{ }\mu\text{m}$, respectively. Average LORMS and HORMS difference between the first and second build of the NMM lenses was $0.27\pm0.13\text{ }\mu\text{m}$ and $0.13\pm0.08\text{ }\mu\text{m}$, respectively. The variability induced by the two methods was not statistically different for LORMS ($p=0.24$) or HORMS ($p=0.92$). The maximum variability in HORMS for the EMM and NMM were $0.17\text{ }\mu\text{m}$ and $0.24\text{ }\mu\text{m}$, respectively. No variability within the repeated build of a lens exceeded the typical eye benchmark ($0.64\text{ }\mu\text{m}$) for HOA for either method of manufacture.

CONCLUSION: Utilizing the NMM does not induce variability in the manufacturing process beyond what is already observed in the EMM. Future directions will explore the clinical viability of this novel manufacture method.

The Use of Scleral Lenses to Manage Dry Eye Symptoms in Habitual Soft Lens Wearers

Daddi Fadel, DOptom

PURPOSE: To determine if scleral lenses (SLs) with and without Hydra-PEG coating can improve ocular comfort and reduce dryness in symptomatic soft lens wearers.

METHODS: This prospective, randomized, double-masked, 1-month bilateral cross-over, daily wear study recruited symptomatic soft lens wearers who presented with healthy eyes and a CLDEQ-8 score ≥ 12 with their habitual contact lens (hab-CL). Eligible participants were fit with SLs (Onefit MED, CooperVision, Inc.) and wore these with and without HydraPEG coating (coated (C-SL) / uncoated (U-SL)) in a randomized order for 1 month per pair. Participants completed a CLDEQ-8 and rated comfort, vision clarity, dryness, and handling after each 1-month wear period using a 0-10 scale (10=best) and these data were compared between study SLs and to their hab-CL.

RESULTS: Twenty participants (16F:4M), mean age 29.3 ± 12.4 years [18-64 years] completed the study. The mean refraction of the right eye was Sph $-4.69\pm3.42\text{DS}$ [-15.25 to -0.50DS] and Cyl $-0.84\pm0.79\text{DC}$ [0.00 to -2.75DC]. At 1 month, the CLDEQ-8 score improved with both study SLs in comparison to hab-CL ($p<0.01$) and the C-SL performed slightly better than the U-SL ($p=0.04$) (hab-CL: 20.6 ± 2.8 , C-SL: 13.4 ± 5.3 , U-SL: 14.8 ± 4.5). End of day contact lens comfort and dryness ratings were similar between study SL ($p>0.05$) and both were rated better compared to hab-CL ($p<0.01$) (Comfort: hab-CL: 4.9 ± 1.4 , C-SL: 8.0 ± 1.1 , U-SL: 7.6 ± 1.2 ; Dryness: hab-CL: 4.1 ± 1.9 , C-SL: 7.9 ± 1.1 , U-SL: 7.5 ± 1.2). Vision clarity ratings were better with C-SL compared U-SL ($p=0.01$) or

hab-CL ($p=0.02$), but no difference was seen between hab-CL and U-SL ($p=0.51$) (hab-CL: 6.9 ± 1.9 , C-SL: 8.3 ± 1.4 , U-SL: 7.4 ± 1.6). For CL handling at insertion, the hab-CL were rated slightly better than the U-SL ($p=0.01$) and similar to C-SL ($p=0.21$), while removal was rated similarly for hab-CL and both SLs ($p>0.05$). At study exit, 9 of the 20 participants requested the SL details to be shared with their eye care professional because they wanted to continue wearing these SLs in future.

CONCLUSIONS: Switching symptomatic soft lens wearers into scleral lenses improved comfort and reduced dryness symptoms after 1 month of wear, with little reduction in ease of lens handling. Subjective ratings were similar with uncoated and HydraPEG-coated scleral lenses, with the latter providing slightly better visual clarity.

Peripheral Corneal Elevation in Keratoconic Eyes **Randy Kojima**

Purpose: Historically, corneal GP lenses played a significant role with the keratoconic and irregular shaped eye in order to provide functional vision¹. Although scleral lenses have revolutionized diseased and asymmetric eye fitting, corneal gas permeable lenses continue to be required and play an important role in specialty lens practice². This study set out to understand the topography of the irregular shaped eye and how corneal GP lenses could be adapted to improve the overall fit.

Methods: This retrospective study evaluated consecutive keratoconus patients who presented for specialty contact lens fitting. Inclusion criteria required quality topographies with $>8\text{mm}$ of corneal coverage circumferentially (Medmont Topographer). 74 eyes on 48 patients were analyzed using the elevation map display. Then the axis with the most symmetric elevation across a single meridian was determined. This was defined to be quadrants 1 and 3 (180° apart). Quadrant 2 and 4 were perpendicular to the symmetric meridian. Elevation values were collected at each of the 4 quadrants which were 90° separated from the adjacent data point. Discussion: After analyzing the elevation in the four zones, Quadrants 1 & 3 show the least asymmetry with an average differential in height of 49.6 ± 40.8 microns (Range: 2-171 microns). Quadrants 2 and 4 exhibit a significantly greater degree of asymmetry with a mean differential in height of 252.4 ± 158.2 microns (Range: 3 – 712).

Results: These findings might suggest that most keratoconic eyes have a meridian where the lens can land on opposing points using a relatively symmetric surface. However, along the axis of greatest elevation change (Quadrants 2 & 4), different sagittal depths may be required to manage the high positive and high negative elevations along the same meridian. Additionally, when categorizing the peripheral elevation of each of the 74 subjects, three were determined to be symmetric. One subject was determined to be toric in nature and the remaining 70 were best described as asymmetric surfaces at a 4mm hemi-chord.

Conclusion: This study has found that the keratoconic eye exhibits significantly different elevation in three of four quadrants for the vast majority of cases. Therefore, corneal GP lens

alignment may be improved with an asymmetric, rather than symmetric or toric landing for most eyes. In vivo testing should be performed, guided by topographical lens construction.

Define the Extent of Peripheral Retina Contributing to Myopic Control Using Electroretinography and Biometry

Langis Michaud, OD, MS

Purpose: To attempt to define the limits of the retinal periphery that responds to the optical defocus used in myopia management.

Methods: This presentation combines two studies conducted in a group of myopic young adults. Firstly, axial length was measured along the horizontal meridian (up to 20 deg, N and T) and vertical meridian (10 deg, S and I) using an optical biometer, modified to allow pivoting. In a second phase, the retinal response to 3 soft +10D add multifocal contact lens designs with different optic zones was investigated using electroretinography, specifically global flash mfERG. Both studies were performed under pupil dilation (tropicamide 1%).

Results: Study 1 included 53 participants (83% F; 25.6 + 2.7 years). Results show horizontal symmetry of axial length up to 20° eccentricity horizontally and 10° vertically. The relationship between axial length and refraction showed high correlation up to 20 degrees from the macula. This correlation is lost over 20 degrees. Study 2 enrolled 27 different participants (62%F, 28.6 ± 4.2 years). The results of this phase show that the amplitude of the direct wave is not affected by lens design. However, the amplitude of the induced wave is significantly reduced when the optical zone is going smaller. This difference is present at a retinal eccentricity of 15.5° to 24.0°, which is then considered to be the most sensitive to myopic defocus. These combined results indicate that the peripheral retina most sensitive to defocus is located between 10 and 20 degrees from the macula, more likely between 15 and 20 degrees. This angle corresponds to a distance of 5.5 mm, which is equivalent to the macular area. These results confirm those of Smith, who also suggested that the most sensitive retina lies in this zone, around 12 to 20 degrees.

Conclusion: The peripheral retina was identified early on as being responsible for the regulation of ocular growth, without defining its extent. These two studies suggest that the most sensitive area of the retina to defocus lies between 15 and 20 degrees from the fovea. The symmetry of the retina, and the extent of the macular area may explain the limits of this zone. These results can influence the way medical devices are designed, so as to optimize the presence of defocus in the most sensitive area of the retina.

Creation of a Clinical Grading Scale to Evaluate Scarring in Keratoconus Patients

Kishan Patel, OD

Purpose:

Corneal scarring, especially in cases of keratoconus, receives little attention in corneal and contact lens textbooks. Corneal scarring may be seen as haze or opacification and limits the

ability of the cornea to focus light. Debilitating glare that is induced by scarring further deteriorates vision. In keratoconus scarring is a sign associated with progression of the disease, but it has consistently not been included or emphasized in the staging of keratoconus. A reason scarring has received little attention is the absence of a useful clinical scarring guide. Today corneal scarring in keratoconus is the leading indicator for the need of a corneal transplant surgery and, for this reason, we need to explore ways to make scar manifestations a more detailed part of the overall disease assessment. The intent of the present study was to introduce a subjective clinical grading scale to better detail disease status and progression.

Methods:

Ten patients with and without existing scarring due to keratoconus, who had signed a University Human Subject Committee approved consent form, had corneal transparency graded on a 5-point scaling system where 0 is normal and transparent and 4 being opaque. This corneal scarring scale was designed to describe the density alongside the horizontal and vertical locations of the scarring. A biomicroscope using a halogen light source was used to examine the cornea. In addition, anterior segment photos were obtained and best corrected VA determined.

Results:

Evaluation of the patients showed VA – ranging from 20/20 to CF at 1 foot and a scarring grade range of 2 patients with grade 0, 3 at grade 1, 2 at grade 2, 1 at grade 3, and 2 at grade 4. Anterior segment photography was used to confirm grading.

Conclusion:

The impact corneal scarring has on a patient's vision cannot be understated, as the recorded VAs show. This new clinical scarring guide was able to make a more detailed assessment of patients' status and was able to discriminate between each point in the range of the grading scale. Our future research on scar assessment will add an objective component, a densitometer, to further assess this crucial manifestation of disease severity and progression.