Assessing Additional Sources of Front Toric Cylinder in the Bitoric Scleral Lens Fitting Process

STATE UNIVERSITY OF NEW YORK
COLLEGE OF OPTOMETRY

Sharon P. Keh, OD, FAAO
SUNY College of Optometry, New York, New York, United States

INTRODUCTION

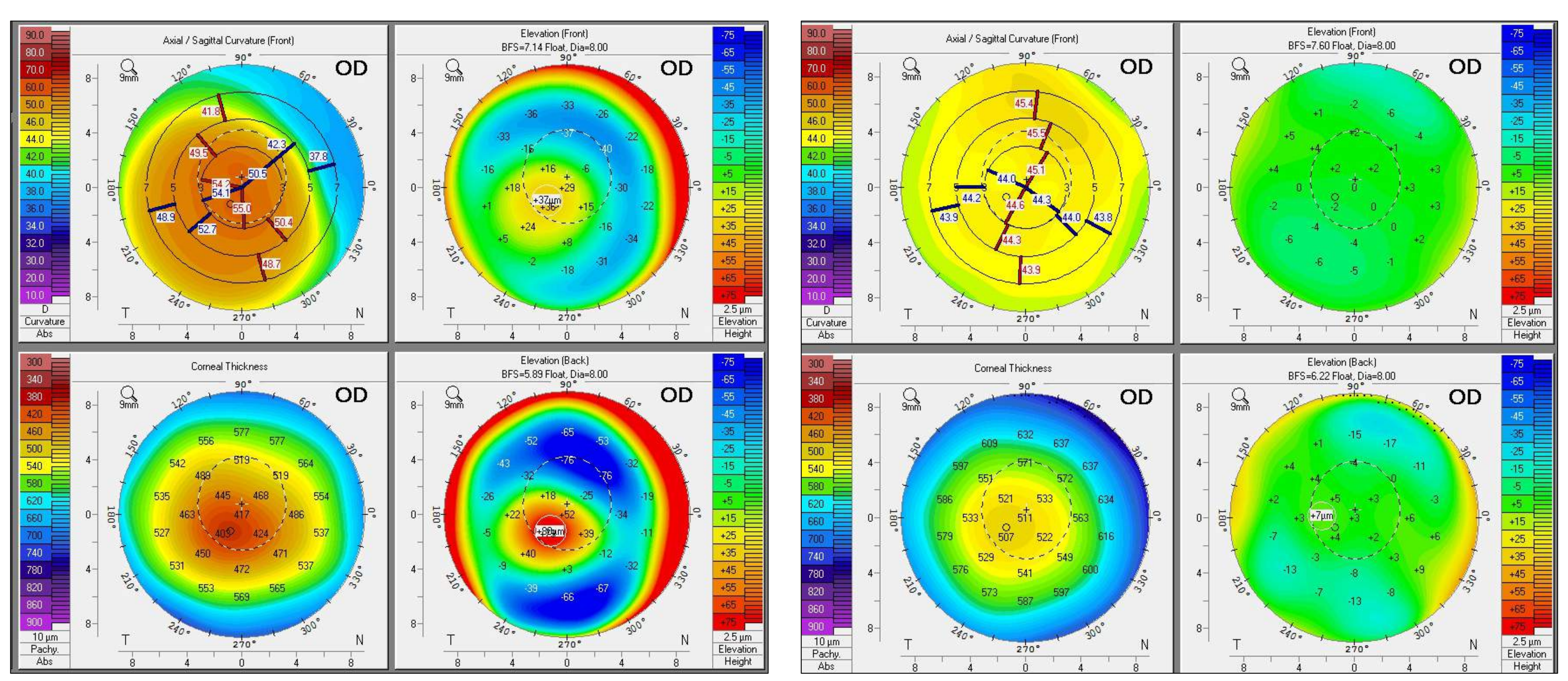
Scleral lenses vault over the most diseased of corneas filling in irregularity with pre-filled saline. With the advent of devices mapping sclera-corneal topography, practitioners are gaining invaluable knowledge regarding scleral shape and, therefore, the fitting of these lenses.[9] Dr. DeNaeyer and colleagues collected data from 152 eyes of prospective scleral lens patients and found that only 8 (5.7%), of the plots were primarily spherical.[4] In light of this information, SynergEyes and other specialty contact lens companies have proactively created fitting sets with scleral toricity built into each of their diagnostic lenses. Aligning the back toricity to the non-rotationally asymmetric sclera allows for: better anterior segment health as fewer areas of localized compression are formed and better vision as locking in the scleral toricity allows for exact alignment of the front toric astigmatic correction.[9]

When refitting patients into scleral lenses or even when changing to a different scleral lens design, an interesting personal observation our clinic has made is that patients often require front astigmatic correction (of different amounts and direction) to obtain their best-corrected visual acuity, even if their previous lens was not bitoric. We propose that other factors may be contributing to that sphero-cylindrical over-refraction beyond internal astigmatism and flexure including: torsion on a toric sclera and excessive or minimal central clearance.

METHODS

This was a prospective, single site, non-dispensing pilot study with two visits. This study used the SynergEyes VS diagnostic fitting set with 8 extension lenses that increased the standard fitting set's parameters. The extension set matched all parameters of the fitting set and varied only in scleral landing zone toricity and sagittal depth for purposes of this study.

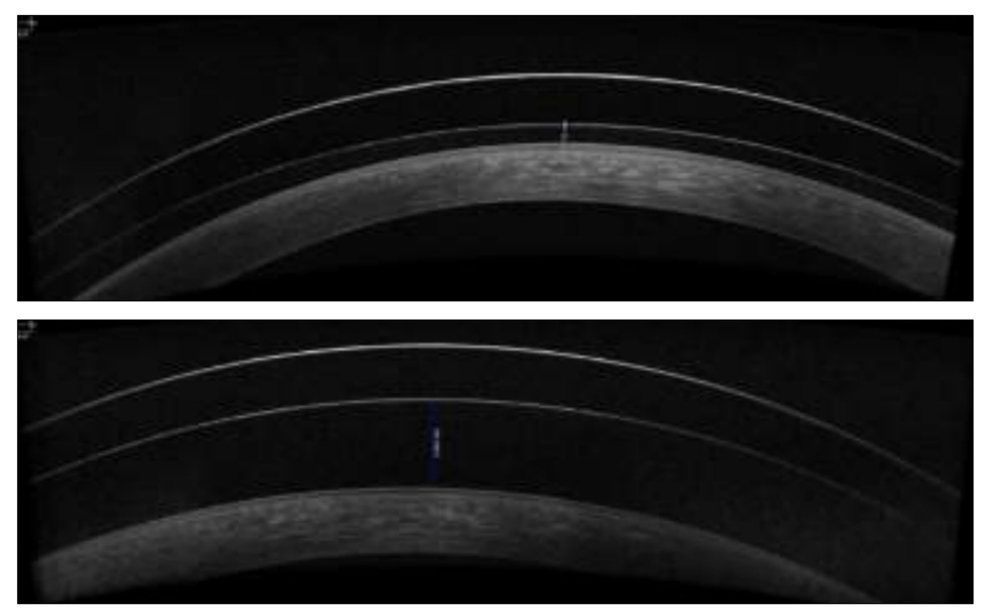
Up to 15 subjects were recruited in the normal cornea group and 15 subjects in the irregular cornea group. Enrollment closed when 10 subjects per group had completed the study. At Visit 1, baseline Pentacam measurement, corneal health and refractive data were attained. The eye with more corneal astigmatism based on Pentacam measurement was selected for scleral lens fitting and all lenses were fit on this eye. If the amount of corneal astigmatism was equal between the two eyes, the left eye was selected.



The SynergEyes VS fitting guide recommends starting with the same first diagnostic lens regardless of corneal shape –3600µmsag, 36 flat, 42 steep SLZ. An initial fit assessment was performed immediately upon insertion to ensure that the fitting relationship was suitable.

First, the scleral landing zone was checked for alignment. If the initial trial lens had excessive scleral lift off in all quadrants, the scleral landing zone was tightened to 38 flat, 44 steep. If the initial trial lens had excessive scleral blanching in all quadrants, the scleral landing zone was flattened to 34 flat, 40 steep. All changes maintained the same degree of toricity (6 degrees). The central relationship was estimated by comparing the tear film thickness to the known center thickness of the trial lens. If the initial trial lens had touch (i.e. insufficient apical clearance), the sagittal depth was increased to 4000µm. If the initial trial lens had excessive apical clearance (estimated to be greater than a 2:1 ratio when comparing the tear film to thickness of the lens), the sagittal depth was decreased to 3400µm.

The selected lens became the reference lens for all modifications moving forward. While this lens settled for 30 minutes, auto-refraction, anterior segment Optical Coherence Tomography (OCT), and centration measurements were obtained over the lens. Over-refraction was performed once the lens has settled fully. The second and third lenses maintained all the same parameters as the reference lens but had 200µm less sag followed by 200µm more sag. All testing was repeated over each lens. At Visit two, 2 additional lenses were trialed with varying SLZ values whilst maintaining the sag of the reference lens. The first lens at Visit 2 was 38 flat, 38 steep SLZ (i.e. 0 degrees of scleral toricity). The second lens' SLZ was 32 flat, 40 steep (i.e. 8 degrees of scleral toricity). No other parameters were altered. All over-contact lens tests were repeated over each lens.



RESULTS

Twenty-four subjects were enrolled in the study. Ten normal cornea subjects and ten irregular cornea subjects completed the study. Nine right eyes and eleven left eyes were tested. The normal cornea group had an average HVID of 12.07mm and the irregular cornea group had an average HVID of 12.60mm as measured by Pentacam. Topographic analysis of the normal cornea group exhibited less front surface astigmatism, 0.94D at steep axis 90.86deg; the irregular group had an average of 4.80D difference between the steep and flat meridians of the anterior surface of the cornea at steep axis of 78.41degrees. Posterior surface astigmatism exhibited a similar trend, more back surface astigmatism in the irregular cornea group 0.94D, 0.32D for the normal, but steep axes were similar − 87.46deg for the irregular group and 80.68deg for the normal group.

Nine of the subjects utilized the sponsor-recommended initial sag of 3600µm as the reference lenses, another nine subjects needed a drop in initial sag to continue (3400 µm) and two subjects needed additional sag and used 4000µm as the reference lens. None of the reference lens SLZ's need to be adjusted due to inadequate fitting relationships. All lenses settled for a minimum of 30 minutes with the exception of one lens which was removed earlier due to subject discomfort. Tear film thickness as measured by anterior segment OCT for all five lenses tested for all subejcts ranged from 23 to 945µm. Auto-Keratometry over the scleral contact lens was considered flexure if >0.50DC. Twenty five percent of lenses did exhibit flexure, interestingly most often with Lens 5 which had the greatest amount of posterior toricity built into the lens. After Lens 5, Lens 2 and 4 exhibited the most amount of flexure − the lenses with the least amount of sagittal depth and the lens with spherical posterior toricity respectively. Interestingly, despite the flexure measured by Auto-K, the over-refractions over these lenses were 62.5% spherical or had less residual astigmatism than K's would predict.

STATISTICAL ANALYSIS

For each outcome, a combined analyses and a subsequent stratified analysis by group (normal and irregular) were performed. Each analyses used repeated measures analysis with compound symmetry, modeling the correlation between lens numbers. For each analyses, "Lens 1" was utilized as the reference level but pairwise comparisons between least-square adjusted means were conducted. This analysis was conducted in SAS Version 9.4 at the 0.05 level of significance.

Three Rx outcomes were analyzed − sphere, cylinder and axis. For each outcome, no particularly statistically significant difference was noted of lens 2-5 to lens 1 nor all pairwise differences in the combined analyses. However, in the stratified analyses by group, there was a significant difference in the normal group only for: between lens 2 with 3 ($p<0.0129$) which varied by 400um of sag and 2 and 5 ($p<0.0357$) for sph, between lens 3 and 4 ($p<0.0434$) for cyl and between lens 2 and 5 for axis ($p<0.0267$) which varied by degrees of scleral toricity (6 degrees vs. 8). It seems at least lens 5 was having significant differences in the normal group with lens 2 and 3 in general.

CONCLUSION

These results suggest that over-refraction, regardless of tear film thickness (ranging from 23 to 945 um) and posterior toricity (from 0 to 8 degrees) of the scleral lens, remains fairly stable at the same diameter with the same lens type. Clinically speaking, this may improve efficiency for practitioners trialing many lenses in-office. This also supports the supposition that tear film power is of minor importance when calculating final lens power.

Further analysis of the data is required to better understand torsion of the scleral lens on the conjunctiva (based on rotation marker) and the subsequent over-refraction axis and/or cylindrical power. In addition, calculating the power and contribution of back-surface astigmatism in overall power would be worthwhile. Study design was limited as there was no objective measure of scleral lens alignment beyond the initial practitioner observation. Finally, centration in relation to residual astigmatism and flexure needs further investigation.

REFERENCES

1. "Scleral Contact Lenses − SynergEyes VS." *https://synergeyes.com/professional/specialty–contact–lenses–scleral–vs/*. Accessed 17 November 2017.
2. "Scleral lens fit scale." *https://ferris.edu/HTMLS/colleges/michopt/vision–research–institute/pdfs–docs/Scleral–lens–fit–scales_v2.pdf*. Accessed 14 December 2017.
3. Benjamin W J.EOP and Dk/L: the quest for hyper transmissibility. Journal of the American Optometric Association
4. DeNaeyer, Gregory, et al. "Qualitative Assessment of Scleral Shape Patterns Using a New Wide Field Ocular Surface Elevation Topographer." Journal of Contact lens Research and Science 1.1 (2017): 12–22.
5. Dorronsoro, Carlos, et al. "On–eye measurement of optical performance of rigid gas permeable contact lenses based on ocular and corneal aberrometry." Optometry & Vision Science 80.2 (2003): 115–125.
6. Kojima, R. Eye shape and scleral lenses. Contact Lens Spectrum. 2013 Apr 01
7. Lemp MA . Report of the National Eye Institute/Industry Workshop on Clinical Trials in Dry Eye. CLAO J. 1995;21:221−232.[PubMed]
8. Miller, Joseph M. "Clinical applications of power vectors." Optometry & Vision Science 86.6 (2009): 599–602.
9. van der Worp E. A Guide to Scleral Lens Fitting, Version 2.0. Forest Grove, OR: Pacific University; 2015. Available from: http://commons.pacificu.edu/mono/10/.

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