Clinical Evaluation of Scleral Lenses Using a Trial Lens Calculator on Normal Eyes

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Introduction

Scleral gas permeable contact lenses are proving to play a role in managing conditions that involve “normal corneas” such as ocular surface disease, high ametropia, anisometropia, and presbyopia. As the indications for scleral lenses and the number of practitioners fitting them increase, the demand for lens designs that are simple and efficient to fit is also increasing. A calculator to select the initial lens and determine diagnostic fitting could improve the process.

This study was designed to evaluate the effectiveness and accuracy of a lens calculator in selecting a trial lens and predicting the resultant central vault. It was approved by the IRB at Ferris State University.

Methods

A diagnostic fitting set of the 15.7mm diameter REO 5 scleral lens was provided by Valley Contax, along with the lens calculator software application. 35 healthy subjects were included in the study. Inclusion criteria was a normal refractive error (+/-20.00D with up to 10.00D of refractive astigmatism) and normal ocular health with no history of ocular disease or surgery. Subjects were evaluated with visual acuity testing, manifest refraction, and corneal topography. Out of 70 eyes, 11 were excluded for not meeting inclusion criteria.

At the initial visit, the subject’s average keratometry and average corneal eccentricity were entered in the lens calculator, which selected a lens to place on eye. The suggested lens was then fitted on eye, assessed for an initial central vault of 200-300 microns, and left for 20 minutes to settle. Visual acuity and over-refraction were performed, along with OCT imaging of central vault, limbal vault, and landing profile. A custom lens was then ordered using the data. At follow-up, the ordered lenses were fitted onto the subject’s eye(s) and allowed to settle for four hours. Repeat measurements from the initial visit were then taken. Subjects were also asked to rate the comfort of each eye during lens wear.

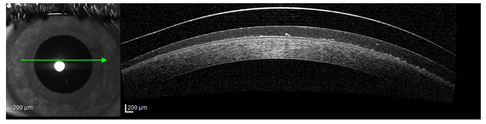

Image 1: Heidelberg Spectralis horizontal scan demonstrating vault over central cornea

Results

For the purposes of this study, a central corneal clearance (vault) of 200 to 300 microns after settling was considered optimal. Of the 59 eyes initially fit, 1 eye was excluded as an outlier. Of the 58 eyes evaluated, 6 of those eyes needed to be refit due to an initial central clearance of less than 100 microns. The estimated clearance from the calculator was compared to the measured clearance using a Heidelberg Spectralis AS-OCT. The clearance was divided into the three categories listed (Chart 1).

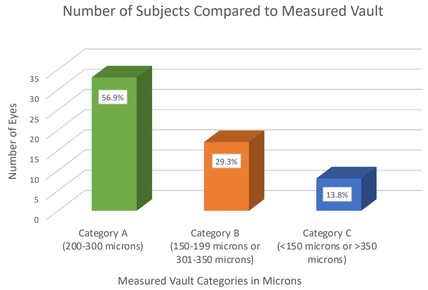

Chart 1: Measured central vault

To evaluate the calculator accuracy in predicting vault, the numerical difference between the estimated vault and the actual measured vault was evaluated. This data was divided into the three categories listed in Chart 2 below. Of the 58 eyes fit with lenses using the calculator, 33 (56.9%) were in category A, 20 (34.5%) were in category B, and 5 (8.6%) were in category C. The calculator predicted a vault within 100 microns of the actual measured amount for 89.8% of the lens fits.

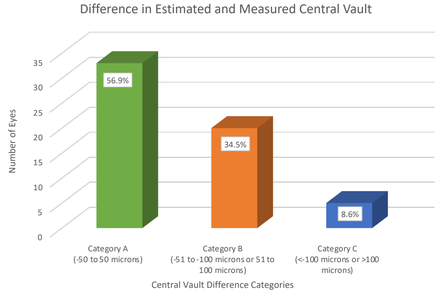

Chart 2: Difference in estimated vs. measured vault

Lens centration was also evaluated, with the majority located centrally or slightly inferior temporal, as shown in Chart 3. A total of 52 lenses did not require a refit. Those subjects were asked for initial comfort ratings with 86.6% reporting that the lenses were comfortable (Chart 4).

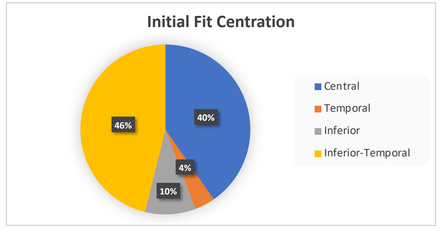

Chart 3: Initial fit centration characteristics

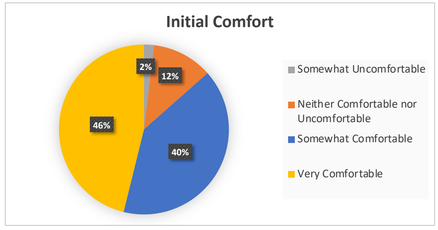

Chart 4: Initial comfort ratings of ordered lenses

Discussion & Conclusion

With 89.8% of lens fits falling within 100 microns of the predicted values, this study demonstrates that this calculator can be utilized to predict initial central vault in the studied scleral lens. The widely suggested “ideal” scleral lens vault is around 200-300 microns, with a minimum of around 100 microns[1]. The results of this study show 86.2% of the lenses demonstrated between 150-350 microns of central vault.

The lens fits in this study also show centration patterns typical of scleral lenses in clinical practice, with 86% of lenses located centrally or slightly inferior temporal. The study also collected data regarding limbal vault and edge profiles in all four quadrants. The results of this analysis are still underway and will be reported in the future.

As more practitioners are fitting scleral lenses on ”normal corneas,” they desire a simpler fitting process for these patients. A calculator like this could be easily incorporated into clinical practice. The provider would enter a few key points of patient data to select an appropriate starting lens out of a diagnostic set. This study indicates that the selected lens will provide an appropriate vault on the first try in most cases, which could improve efficiency and reduce the need for multiple diagnostic lenses in the fitting process.

Corneal diameter has been shown to play a significant role in sagittal depth of an eye[2]. Future analysis of this calculator will include a measurement of horizontal visible iris diameter (HVID), as well as its impact on determining when a lens diameter other than 15.7mm in this scleral design is indicated.

References:
1. Hall, L. What You Need to Know About Sagittal Height and Scleral Lenses. Contact Lens Spectrum, Volume 30, Issue May 2015, page(s): 26-28, 30, 32, 34
2. van der Worp E. A Guide to Scleral Lens Fitting [monograph online]. Forest Grove, OR: Pacific University; 2010.

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