Initial Evaluation of Quadrant-Specific, Data-Based Scleral Lens Design: Indications and Previous Contact Lens Experience

Muriel Schornack OD[1], Karen Carrasquillo OD[2]

[1]Mayo Clinic, Rochester, MN, [2]Boston Foundation for Sight, Needham, MA

schornack.muriel@mayo.edu

Purpose

- To identify indications for scleral lens wear in patients who were fit with a quadrant-specific, data-based scleral lens design.
- To describe previous contact lens wearing experience of patients who were fit with this lens design.

Introduction

Increased interest in clinical use of scleral lenses has inspired new fields of research into anterior ocular contour. Studies have shown that the sclera is not rotationally symmetrical (1), yet most diagnostic scleral lens fitting sets feature spherical haptics only, even though toric or quadrant-specific haptics can be incorporated into customized lens designs.

Lack of correspondence between the contour of the ocular surface and the scleral lens haptic complicates the fitting process. Iterative changes in haptic design are often necessary to achieve adequate conjunctival/scleral alignment. These changes require the fabrication of multiple lenses during the fitting process. Studies have reported an average of 1.5 to 3.2 lenses (range 1-8) per eye needed in order to complete a scleral lens fit (2, 3).

Iterative fitting processes also create a longer learning curve for practitioners learning to fit scleral lenses. In a study by Macedo-de-Araugo et al, practitioners demonstrated significant improvements in fitting efficiency over the course of their first 140 fits (4).

Misalignment between lens haptic and the ocular surface may cause discomfort for patients wearing scleral lenses. Furthermore, lens stability may be compromised, which could negatively impact quality of vision (particularly with front surface toric lenses). Poor vision or comfort may lead to discontinuation of lens wear, even in patients who could otherwise benefit from use of scleral lenses.

The lens design evaluated here was based upon data gathered from over 7,000 eyes that were fit with PROSE lenses at the Boston Foundation for Sight. Data from these lenses was analyzed, and diagnostic lenses were designed to provide reasonable conjunctival/scleral alignment.

Methods

Study Design:

- Multi-center retrospective chart review
  - Study design was reviewed and approved by Mayo Clinic IRB
  - Data was collected using REDCap (housed at Mayo Clinic)
  - 6 practices (academic medical centers, private practices)
  - Each practitioner fit the lenses according to his/her own fitting philosophy regarding lens diameter, corneal clearance, and limbal clearance
  - Data were collected on all patients for whom a scleral lens fit or refit using the study lens design was initiated between January 1, 2016 and March 31, 2017

Data Collected:

- Age
- Gender
- Laterality of scleral lens fitting
- Indication for scleral lens wear
- Previous contact lens history
  - For patients who had worn scleral lenses previously, reason for refitting was also collected, if available.
- Conclusion of fitting process (complete/incomplete)

Statistical Analysis:

- Descriptive statistics are reported

Results

Overall Demographics

| 75 patients (89 eyes)	Age: 45 [16] years (mean [SD]), range 17-77 years	46 male (61%) 29 female (39%)

Outcome of Fitting Process

Fit was completed in 57 patients (76% of total patients enrolled)	• Bilateral fits were accomplished in 32 patients • Right eye only was fit in 14 patients • Left eye only was fit in 11 patients

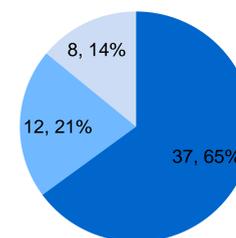### Indications for Scleral Lens Wear

Corneal Irregularity:
Specific Conditions (# of patients)
- Keratoconus (23)
- Penetrating keratoplasty (9)
- Pellucid marginal degeneration (6)
- S/P refractive surgery (3)
- S/P corneal infection (3)
- S/P ocular trauma (2)
- Irregular astigmatism (2)
- Corneal dystrophy (1)
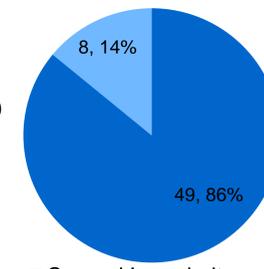
Ocular Surface Disease:
Specific Conditions (# of patients)
- Exposure keratopathy (2)
- Sjogren's syndrome (2)
- Neurotrophic keratopathy (1)
- GVHD (1)
- S/P excision of lacrimal gland (1)
- S/P refractive surgery (1)

Pie chart: Corneal Irregularity 49, 86%; Ocular Surface Disease 8, 14%

Habitual Correction Worn at the Time of Initiation of Study Lens Fit

Pie chart: Contact Lenses 37, 65%; Spectacles 12, 21%; No Correction 8, 14%

Previous contact lens modalities (# of patients):
- Scleral lenses of another design (27)
- Corneal rigid gas permeable lenses (6)
- Hybrid lens (1)
- Silicone hydrogel lens (1)
- Hydrogel lens (1)
- Piggyback lens system (1)

Reason for Fitting/Refitting into Study Lens

Study lens was first option considered (7)	Inadequate vision with previous correction (23)	Inadequate comfort with previous lenses (20)	Inadequate fit with previous lenses (6)	Inadequate surface protection (1)

Conclusions

- General indications for scleral lens wear in this population correspond to distribution of indications reported for general populations.
- Approximately 50% of patients had worn scleral lenses previously, but were unable to achieve adequate vision, comfort, or physiological fit with previous lenses.
- Quadrant-specific, data-driven scleral lens design may allow patients who have been previously unsuccessful with scleral lenses to reap the benefits of scleral lens therapy.

References

1. DeNaeyer G, et al. (2017). Qualitative assessment of scleral shape patterns using a new wide field ocular surface elevation topographer. Journal of Contact Lens Research and Science **1**(1).
2. Schornack MM, Patel SV (2010). Scleral lenses in the management of keratoconus. Eye Contact Lens **36**(1): 39-44.
3. Pecego M, Barnett M, Mannis MJ, Durbin-Johnson (2012). Jupiter scleral lenses: the UC Davis Eye Center experience. Eye Contact Lens **38**(3): 179-182.
4. Macedo-de-Araujo RJ, van der Worp E, Gonzalez-Meijome JM (2019). Practitioner learning curve in fitting scleral lenses in irregular and regular corneas using a fitting trial. BioMed Research International: 5737124.

Support

Disclosure