

PRELIMINARY CLINICAL EXPLORATION OF SCLERAL LENS PERFORMANCE ON HEALTHY EYES

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Abstract

Objectives

The purpose of this study was to evaluate the performance (i.e., vision, comfort and fit) of spherical and front-surface toric scleral lenses in subjects with regular, healthy corneas and regular astigmatism.

Methods

Scleral lenses were fit in the eyes ($n = 16$) of healthy subjects ($n = 9$) with regular corneas, absent of pathology, and studied using an observational, multi-visit design. Lens fit was objectively evaluated by an experienced practitioner. Following 1 month of successful lens wear, participants completed subjective satisfaction surveys regarding the scleral lens wearing experience.

Results

According to participant surveys, spherical and front-surface toric scleral lenses were subjectively preferred over soft toric or gas permeable contact lenses and spectacles in 88% of eyes, including in all eyes ($n = 3$) with only prior history of spectacle wear, but no contact lens wear. Seventy-five percent (75%) of eyes achieved visual acuity of 0.1 logMAR or better and all subjects achieved visual acuity with a scleral lens within 1 Snellen line of spectacle correction. Seventy-five percent of eyes achieved good subjective comfort with a scleral lens, including in all eyes ($n = 3$) with no prior contact lens wear. No participants reported poor subjective vision and/or comfort.

Conclusions

Our findings suggest that subjects preferred the performance of a scleral lens (spherical or front-surface toric) compared to previously worn soft toric or gas permeable contact lenses, including subjects ($n = 2$) with no prior history of contact lens wear. Moreover, scleral lenses may provide a viable, alternative contact lens modality option for patients considering discontinuation of traditional soft toric and/or rigid contact lens wear; so long as the factors associated with hypoxia and increased intraocular pressure remain minimized.

Key Words: scleral lens; scleral contact lens; front-surface toric scleral lens; lens performance; normal eyes; healthy eyes

Scleral lenses are large diameter contact lenses designed to completely vault the cornea and rest on conjunctival and scleral tissue. In the early 16th century, Leonardo DaVinci first conceptualized scleral lenses for the purpose of optically neutralizing the eye within an enclosed liquid reservoir.¹ Early prototypes developed in 1887 by F. A. Müller and A. C. Müller, included thin, lightweight blown-glass lenses without optical correction that demonstrated potential for management of ocular surface disorders.² In 1888, Fick, a German ophthalmologist, first described the concept of scleral lenses with refractive power to correct vision.² Unfortunately, issues of hypoxia during lens wear (i.e., Fick's phenomenon or Sattler's veil)³ and reproducibility constraints of glass material remained problematic and contributed to the temporary decline in scleral lens use. As a result of these clinical limitations, manufacturers transitioned to smaller lens designs, such as rigid corneal contact lenses, made of more durable material, such as polymethyl methacrylate (PMMA). Following years of idleness, Ezekiel⁴ published his landmark 1983 manuscript describing scleral lenses manufactured from material with enhanced oxygen permeability. Rosenthal⁵ and Pullum⁶ proximately followed by establishing scleral lens fabrication and design criteria, fitting techniques and therapeutic indications further facilitating renewed interest in this lens modality.

Indications for scleral lens utilization in clinical practice have experienced tremendous growth in recent years. The early literature (prior to 1983) primarily focused on scleral lens design and fabrication techniques or therapeutic indications.⁷ The main application for scleral lenses, as described at the time, was correction of corneal irregular astigmatism due to corneal ectasia or treatment of ocular surface disease, including compromised corneas.⁷ After 1983, publications described expanded indications and visual/functional outcomes of scleral lens wear.⁷ More recently, indications for scleral lens use in normal, healthy eyes have grown.⁸ Scleral lenses have demonstrated potential for corneas with a normal, prolate shape and conventional refractive

error (i.e., myopia, hyperopia, regular astigmatism and presbyopia) without disease, ectasia, distortion, or irregularities.⁹ To maintain consistency, the term regular cornea will be used henceforth. Although the advantages of scleral lens use in the eyes of patients with irregular corneas and therapeutic indications for ocular surface disease are well documented, studies investigating the performance of scleral lenses for regular corneas remain limited.

The TFOS International Workshop on Contact Lens Discomfort reported that contact lens discomfort is a frequent problem experienced by up to half of current contact lens wearers worldwide; an issue potentially impacting millions.¹⁰ Multiple studies suggest that despite advances in contact lens materials and design, the contact lens dropout rate continues to hover at approximately 15%.¹¹⁻¹⁶ Reasons for dropout from traditional soft and/or rigid contact lens wear are numerous and complex including, but are not limited to: lens discomfort, reduced visual acuity and unacceptable presbyopic correction. Fortunately, contact lens manufacturers have begun to expand and diversify their portfolios by developing novel lens designs to address reported deficits. However, contact lens parameter and performance limitations remain in traditional modalities. Thus, an alternative contact lens modality, such as a scleral lens, may provide a potential option for patients considering discontinuation of traditional contact lens wear.

Scleral lenses present multiple, advantageous characteristics for patients with regular corneas. Scleral lenses efficiently correct high refractive errors, including astigmatism, due to stable optical properties.⁹ Studies have demonstrated that correcting 0.75D or more of astigmatism¹⁷ can significantly improve visual acuity by three to six letters on a Snellen eye chart.¹⁸ This principle is particularly applicable to patients with high astigmatism, as rigid gas permeable contact lenses are preferred to soft toric contact lenses to improve visual outcomes.¹⁹ Scleral lenses also reduce higher order aberrations (HOAs) via enhanced lens parameter customization and improved centration

compared to soft and gas permeable contact lenses. The optic zone diameter of scleral lenses can often be larger than other types of modalities, including corneal gas permeable, soft spherical, soft toric and hybrid contact lenses. Expansion of optic zones are particularly advantageous for patients with larger pupil sizes by reducing visual distortion (i.e., halos and glare) and subsequently improving best-corrected visual acuity.⁹ Although HOAs are more prevalent in patients with irregular corneas and/or lenticular opacities and may compromise visual performance,²⁰ HOAs in regular eyes are often a result of the inherent optics of corrective lenses.⁹ For example, soft contact lenses intrinsically induce HOAs if the lenses are not designed to optically compensate for HOAs.²¹ Also, it is recognized that the post-lens tear fluid reservoir and wavefront-guided optics of scleral lenses compensate for corneal distortion and reduce HOAs.²²

Dry eye disease is one of the most frequent reasons for patient visits to eye care practitioners²³ and a common cause for discontinuation of contact lens wear.¹⁰ Due to the post-lens fluid reservoir, the fluid between the back of the lens and the front of the cornea, scleral lenses uniquely provide continuous hydration to the ocular surface. Thus, scleral lenses have the potential to benefit patients with regular corneas and associated ocular dryness.²⁴ Furthermore, scleral lenses may enhance ocular surface stability in presbyopic patients with regular corneas. Lafosse et al. compared the effect of scleral and corneo-scleral lenses on tear film parameters and central corneal thickness in healthy, presbyopic subjects at baseline, 20 minutes post-insertion and after 8 hours of continuous lens wear.¹⁹ No clinical difference was observed between lenses, including tear osmolarity, throughout a full day of continuous wear.

This study evaluated the performance (i.e., vision, comfort and fit) of spherical and front-surface toric scleral lenses in subjects with regular, healthy corneas.

METHODS

This study was designed as a preliminary observational-cohort, prospective, multi-visit investigation. The protocol was approved by the University of California, Davis Institutional Review Board (IRB) and conformed to the tenets of the Declaration of Helsinki

prior to subject enrollment and data collection. This study enrolled healthy subjects, absent of corneal pathology, including subjects with history of current and/or previous contact lens wear or no history of contact lens wear in accordance to strict inclusion/exclusion criteria. Major exclusion criteria included, but were not limited to, clinically significant ocular surface disease, corneal pathology or irregularity and prior eye surgery (e.g., LASIK, PRK, PK, etc.).

The primary goal of the study was to evaluate the performance of a scleral lens in the eyes of subjects with regular, healthy corneas. The primary outcome measure was subjective satisfaction surveys regarding the scleral lens wearing experience including: Quality of vision, lens comfort, lens awareness, wear time and overall preference of scleral lens compared to a previously favored modality of vision correction (e.g., contact lenses or spectacles). Subjects were instructed to rate responses on a 0 to 10 scale (0 = extremely poor; 10 = extremely good). In addition, subjects were asked to rate the presence/severity of subjective symptoms for each eye on a 0 to 4 scale (0 = absence, 1 = minimal, 2 = mild, 3 = moderate, 4 = severe). Symptoms included: irritation (i.e., dryness, burning, scratching, grittiness, stinging, itching), awareness, redness, cloudy or variable vision, light sensitivity/halos. Subjects were instructed to rate each eye individually.

Secondary outcome variables included objective evaluation of scleral lens fit, including lens position, sagittal depth and edge alignment, ocular surface assessment, including conjunctival injection, conjunctival and corneal staining and corneal edema by an experienced practitioner. The hypothesis was that subjects would subjectively prefer the performance of a scleral lens compared to a soft toric or gas permeable contact lens.

The secondary goal of the study was to evaluate the performance (i.e., vision, comfort and fit) of a front-surface toric scleral lens in the eyes of subjects with regular, healthy corneas and lenticular / residual astigmatism for the use of front-surface toric mini-scleral lenses. The hypothesis was that subjects with lenticular/residual astigmatism for the use of front-surface toric mini-scleral lenses would subjectively prefer the performance of a front-surface toric scleral lens compared to a soft toric or gas permeable lens.

The initial visit was to determine subject eligibility and included a detailed explanation of the procedures, including possible consequences, and signing of the Informed Consent form and Patient Authorization of Use and Release of Health and Research Study Information (HIPAA form). If the subject elected to proceed, detailed medical and ophthalmic history was obtained followed by biomicroscopy examination including evaluation of the eyelids, cornea and conjunctiva, as well as corneal and conjunctival staining. Qualifying subject eyes were diagnostically fit in accordance to manufacturer guidelines using the EasyFit scleral lens diagnostic fitting set (AccuLens, Denver, CO, USA).

Scleral lenses were ordered and dispensed following successful application/removal training with necessary materials and solutions. Subjects were provided with 0.9% preservative-free sodium chloride solution to fill the scleral lens during wear (the only preservative-free application product available at the time of the study), 3% hydrogen peroxide cleaning and disinfecting solution for nightly use (Clear Care® Cleaning and Disinfecting Solution, Alcon, Fort Worth, TX, USA) and an application and removal plunger (DMV® Scleral Cup™, DMV Corporation, Zanesville, OH, USA) along with detailed instructions. Subjects were instructed to proceed with daily wear beginning with 6 hours of wear per day, while increasing two hours of wear time each day, but not to exceed 12 hours total of continuous daily wear. No extended wear was permitted. Subjects were scheduled to return for follow-up in 1 week.

Following 1 week of successful wear, the scleral lens fit, over refraction (spherical and/or spherocylindrical) and ocular surface health, including corneal and conjunctival staining, were evaluated. Scleral lens parameters and prescriptions were modified, as needed, to provide optimal vision, comfort and fit. After 1 month of successful scleral lens wear, subjects completed satisfaction surveys regarding their scleral lens wearing experience. Subjects that overall preferred scleral lens vision and comfort continued with scleral lens wear, while those that did not returned to habitual correction (i.e., spectacle and/or soft/rigid contact lens wear). Data analysis was conducted after subjects completed the study.

RESULTS

Nine ($n = 9$) subjects completed the study. Sixteen ($n = 16$) total eyes were fit with a scleral lens and evaluated. Two ($n = 2$) subjects were fit with a scleral lens in one eye only. The mean objective corneal toricity measured was $2.75D \pm 1.25D$ (range: 1.00D – 5.75D). The mean age was 32.7 ± 15.8 years (range: 20 – 62 years). Sex distribution was 6 females and 3 males. Ethnicities included: 4 Caucasian, 2 Hispanic, 1 African American, 1 Asian, and 1 Other.

Prior to study enrollment, 78% of subjects had a history of previous contact lens wear, including some subjects with a history of multiple contact lens modalities (i.e., soft and/or rigid). Of participants with previous contact lens wear, 78% had worn soft contact lenses while 67% had previously worn soft toric contact lenses. Thirty-three percent (33%) had a history of previous gas permeable contact lens wear. Two ($n = 2$) subjects, three ($n = 3$) total eyes had history of only spectacle wear, but no prior contact lens wear.

Overall, spherical and front-surface toric scleral lenses were subjectively preferred over soft toric or gas permeable contact lenses and spectacles in 88% of eyes, including in all eyes ($n = 3$) with only prior history of spectacle wear, but no contact lens wear. Fifty-six percent (56%) of eyes achieved good vs. fair/poor subjective vision, and 75% of eyes achieved good vs. fair/poor subjective comfort with a scleral lens, including in all eyes ($n = 3$) with no prior contact lens wear (Figure 1). All subjects ($n = 2$) with only prior history of spectacle wear, but no contact lens wear overall subjectively preferred scleral lenses versus spectacles.

No participants reported poor subjective vision and/or comfort in either eye. Seventy-five percent (75%) of eyes achieved visual acuity of 0.1 logMAR or better and all subjects achieved visual acuity with a scleral lens within 1 Snellen line of spectacle correction. Three (3) eyes (19%) required a front-surface toric scleral lens (Table 1).

These eyes measured a subjective spectacle cylinder prescription of 3.25D, 2.50D, and 6.00D and an objective corneal toricity of 2.75D, 3.50D, and 5.75D, respectively. Overall, all 3 eyes subjectively preferred the vision and comfort achieved with a scleral lens compared to a soft toric or gas permeable contact lens.

FIG. 1 Subjective scleral lens vision and comfort preference.

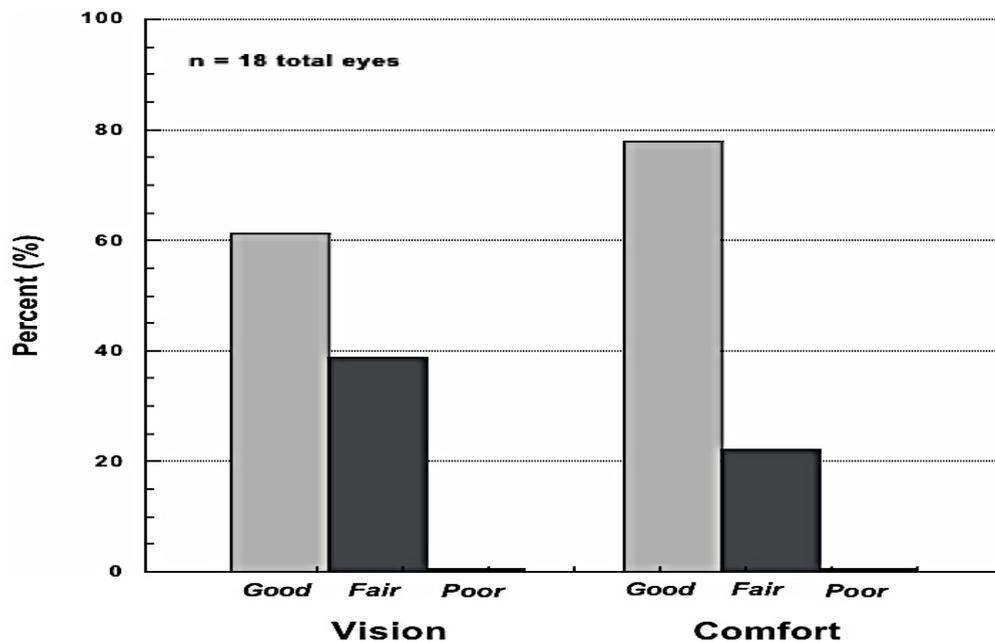


TABLE 1 Front-Surface Toric Scleral Lens Performance

Subject	Final Spectacle Rx	Lenticular / Residual Astigmatism	Final Scleral Lens Rx	Vision	Comfort
1	Pl × 3.25 × 084	2.75D	44.00D (7.67 mm) / 6.75 -0.75 × 166	Good	Good
2	-1.75 +2.50 × 095	3.50D	43.00D (7.84 mm) / + 0.75 -0.75 × 016	Good	Good
3	-3.25 +6.00 × 098	5.75D	42.00D (8.03 mm) / +2.00 -0.75 × 012	Fair	Good

DISCUSSION

The findings of this preliminary investigation suggest that subjects with regular, healthy corneas likely prefer the overall performance of spherical and front-surface toric scleral lenses after 1 month of

wear compared to previously worn soft toric or gas permeable contact lenses and spectacles, as evidenced by objective visual acuity measures and subjective responses from satisfaction surveys. Overall, scleral lenses were subjectively preferred vs. previously favored modality of vision correction (e.g., contact

lenses or spectacles) in 88% of eyes, including all eyes fit with a front-surface toric scleral lens. Seventy-five percent (75%) of eyes achieved visual acuity of 0.1 logMAR or better with a scleral lens and 75% of eyes achieved good vs. fair/poor subjective comfort reported by participants following scleral lens wear (Figure 1, Table 1). Interestingly, only 56% of eyes reported good vs. fair/poor subjective vision. A future investigation with an increased sample size is necessary to validate this discrepancy.

Spherical and front-surface toric scleral lenses demonstrated improved subjective vision and comfort compared to soft toric or gas permeable contact lenses in this study. Stable optical characteristics, including expanded optical zones and limited lens rotation, likely contributed to improved visual quality experienced with a scleral lens.⁹ Large diameter scleral lenses rest on conjunctival rather than corneal tissue, compared to traditional gas permeable contact lenses, contributing to continuous comfort. In addition, the post-lens fluid reservoir of a scleral lens provided constant corneal hydration throughout the duration of wear, limiting dryness symptoms.²⁴ Although this study corroborates subjective preference in overall scleral lens performance, future investigations should consider correlating overall performance of spherical and front-surface toric scleral lenses with other modalities (including soft toric, corneal gas permeable, and hybrid contact lenses) in subjects with regular, healthy corneas with an increased sample size. Furthermore, it will be necessary to objectively quantify both the short and long-term physiological and mechanical impact of scleral lens wear on anterior segment health in the eyes of subjects with regular, healthy corneas before this contact lens modality is accepted as a first-line option in this population.⁷

A common concern among practitioners concerning scleral lens wear are previously reported issues of clinically evident corneal edema due to hypoxia.^{25,26} Although no obvious clinical signs of hypoxia were observed during this investigation, it has been suggested by theoretical models that scleral lens oxygen permeability and fluid reservoir thickness may present barriers to oxygen transmissibility.²⁷ Paugh et al.²⁸ measured reduced tear exchange rates via fluorometry in subjects with scleral lenses, suggesting minimal

possibility of meeting recommended oxygen resupply demands for the anterior segment.^{27,29,30} Vincent et al.³¹ measured trace amounts of central corneal swelling (on average <2%) following 8 hours of mini-scleral lens wear, in young, healthy subjects with regular corneas. Moreover, Giasson et al.³² demonstrated sub-clinical alterations to the apical surface of corneal endothelial cells shortly after scleral lens insertion and a return to baseline following scleral lens removal (i.e., bleb response). Thus, acute hypoxic stress (e.g., sub-clinical corneal edema) may occur throughout the duration of scleral lens wear. Schnornack et al.⁷ noted that practitioners should not assume that all scleral lens designs affect the anterior segment of the eye in the same way. Nevertheless, this potential chronic, long-term impact on corneal permeability (i.e., corneal barrier function), amongst other physiological parameters, is not well understood and warrants further investigation.

The status of the cornea prior to fitting a scleral lens is a critical factor in determining the impact of hypoxic stress, as corneas absent of pathology are more resilient to barrier changes compared to compromised corneas. Traditionally, the potential refractive benefits gained by patients with compromised corneas with a scleral lens have outweighed the potential risks from hypoxic stress.³³ However, this compromise is less apparent in patients with regular, healthy corneas.

In addition, a preliminary study has suggested that increases in intraocular pressure (IOP) occur throughout the duration of scleral lens wear (average 7.0 mmHg increase from baseline) due to excessive suction forces.³⁴ Conversely, Nau et al.³⁵ evaluated IOP via pneumatonometry in 29 neophyte, healthy eyes (test: control) following two hours of small-diameter scleral lens (15 mm Jupiter scleral lens) wear. Measures were collected on the cornea centrally and on the sclera peripherally. In healthy, neophyte eyes, scleral lens wear did not increase IOP after two hours. Also, Vincent et al.³⁶ described changes in IOP after scleral lens wear using an irregular cornea 16.5 mm Paragon Vision Sciences scleral lens design. The initial study measured IOP in seven subjects before and three hours after scleral lens wear with the Ocular Response Analyzer (Reichert). The follow-up study evaluated IOP in five subjects before and eight hours after scleral lens wear with a non-contact tonometer (TX-20P, Canon).

Changes in IOP were found following scleral lens wear to be consistent with normal diurnal fluctuations. Thus, the authors suggested that short-term wear of scleral lenses likely does not elevate IOP, despite superficial tissue compression near the scleral spur.³⁷

The potential consequences of short and long-term IOP elevation during scleral lens wear in regular, healthy eyes remain unknown and require additional studies. Thus, patient selection by an astute practitioner for scleral lens wear is of critical importance to limiting potential complications and ensuring success. Future investigations should seek to establish the incidence and risk factors concerning complications associated with scleral lens wear, as well as evidence-based guidelines for ideal lens fit characteristics.⁷

Furthermore, future studies are needed to understand the potential application of scleral lens use for presbyopia. Scleral lenses may be a viable option for presbyopic patients with either healthy ocular surfaces or with concomitant pathology (e.g., dry eye disease). As previously described, contact lens dropout continues to exist with significant increases occurring around age 42.¹⁰ A multifocal scleral lens that provides acceptable vision at multiple viewing distances may be an option for patients with presbyopia, as scleral lenses bathe and protect the ocular surface helping to manage ocular surface disease.

In conclusion, our findings suggest that subjects preferred the performance of a scleral lens (spherical or front-surface toric) compared to a soft toric or gas permeable contact lens and spectacles. A future investigation with an increased sample size will be necessary to confirm this trend. Moreover, scleral lenses may provide a viable, alternative contact lens modality option for patients with regular, healthy corneas who are considering discontinuation of traditional soft and/or rigid contact lens wear. However, practitioners will need to continue to routinely monitor for potential acute and chronic signs and symptoms associated with, but not limited to hypoxic stress and elevated IOP. It is critical for these factors associated with hypoxia and increased IOP to remain minimized.

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CONFLICTS OF INTEREST

No conflicts for any authors.

PRIOR PRESENTATION

This work has not been presented.

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