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A Comparison of Three Methods to Increase Scleral Contact Lens On-eye Stability

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Abstract

Purpose—To: 1) quantify on-eye rotational and translational stability of three scleral contact lens stabilization methods and 2) model the variation in visual acuity when these movements occur in a wavefront-guided correction for highly aberrated eyes.

Methods—Three lens stabilization methods were integrated into the posterior periphery of a scleral contact lens designed at the Visual Optics Institute. For comparison, a lens with no stabilization method (rotationally symmetric posterior periphery) was designed. The lenses were manufactured and lens movements were quantified on eight eyes as the average standard deviation of the observed translations and rotations over 60 minutes of wear. In addition, the predicted changes in acuity for 5 eyes with keratoconus wearing a simulated wavefront-guided correction (full correction through the fifth order) were modeled using the measured movements.

Results—For each lens design, no significant differences in the translation and rotation were found between left and right eyes, and lenses behaved similarly on all subjects. All three designs with peripheral stability modifications exhibited no statistically significant differences in translation and rotation distributions of lens movement and were statistically more stable than the spherical lens in rotation. When the measured movements were used to simulate variation in visual performance, the three lenses with integrated stability methods showed a predicted average loss in acuity from the perfectly aligned condition of approximately 0.06 logMAR (3 letters), compared to the loss of over 0.14 logMAR (7 letters) for the lens with the spherical periphery.

Conclusions—All three stabilization methods provided superior stability, as compared to the spherical lens design. Simulations of the optical and visual performance suggest that all three stabilization designs can provide desirable results when utilized in the delivery of a wavefront-guided correction for a highly aberrated eye.

Keywords

scleral contact lens; stability; wavefront error; visual performance

INTRODUCTION

Scleral contact lenses are an increasingly attractive option for patients who exhibit contact lens intolerance or reduced visual performance with conventional corneal contact lenses.¹ The improved comfort and vision associated with scleral contact lenses has driven their increased popularity, with scleral contact lenses now accounting for ~10% of the gas permeable (GP) market.² From a clinician's point of view, scleral contact lenses are particularly useful when treating eyes with highly aberrated optics, such as in keratoconus, corneal trauma, and poor corneal refractive surgery outcomes.²⁻⁹ Due to the fact that ocular aberration in these eyes originates from morphological distortion of the cornea, the benefit of the scleral contact lenses comes equally from their ability to improve the optical performance (through a rigid first optical surface) and to increase comfort during lens wear (due to its weight bearing on the conjunctiva that covers the sclera).

In addition to their current clinical utility, scleral lenses are also being used as a platform to implement custom wavefront-guided corrections for highly aberrated eyes, resulting in reduced levels of higher order aberration and visual image quality typical of normal, uncorrected eyes.^{10,11} However, unlike a typical scleral contact lens intended to correct defocus, a wavefront-guided contact lens must remain well-aligned to the underlying optical components of the eye.¹²⁻¹⁵ Failure to align a wavefront-guided correction (which incorporates higher order aberration compensation in addition to the sphero-cylindrical correction) leads to the induction of complex, unintended wavefront errors that, depending on their magnitude, can be optically devastating.¹³

Several approaches have been utilized to examine the impact associated with the movement of wavefront-guided contact lenses. Work by Guirao et al.^{13,14} examined the impact of decentration on the optical performance of a wavefront guided lens. Their work advocated correcting a portion of each Zernike term, such that there would always be a benefit in the presence of the expected rotation and translation. Shi et al.¹⁵, building on the work of Guirao et al., examined the impact of movement on resultant performance, with the goal of identifying a correcting aberration structure that provided 1) a specific level of visual performance improvement and 2) kept that performance within a defined level of variation. In addition, Shi et al.^{15,16} evaluated the consequence of the observed lens movement in terms of its impact on visual image quality instead of wavefront error. The choice to evaluate the impact in terms of visual image quality was based on evidence in the literature that root mean square (RMS) wavefront error is relatively poorly correlated with visual acuity¹² and that measured change in visual quality metrics (in particular visual Strehl ratio and neural sharpness) are highly correlated to a measured change in visual performance as measured by acuity in the presence of keratoconus (KC) aberrations.^{17,18}

Given the need to register the optics of a wavefront-guided scleral contact lens with the underlying optics of the eye, the purpose of this study was two-fold:

- 1) quantify on-eye rotational and translational stability of three scleral contact lens stabilization methods and;

- 2) model the variation in visual acuity expected when these movements occur in wavefront-guided corrections for highly aberrated eyes.

METHODS

The study adhered to the tenets of the Declaration of Helsinki and received approval by the Institutional review boards of the University of Houston. Signed informed consent was obtained from all participating subjects.

Basic VOI scleral contact lens design

A custom scleral contact lens fitting set designed and manufactured at the Visual Optics Institute (VOI) was used as a platform for implementing the stability methods evaluated in this study. The VOI trial scleral contact lens set consists of a series of lenses implemented in Boston XO gas permeable contact lens material with an 18.1 mm diameter and 0.45mm center thickness. Custom lens design software (CLD) implemented by the University of Houston, College of Optometry Core Programming Module was used to design the lenses. The fitting lenses were similar in all respects to the test lenses, except for the magnitude of the toricity incorporated into the peripheral landing zone. The level of toricity in the fitting lenses was less than in the level of toricity in the toric test lenses, but by definition more than the spherical test lens. The posterior periphery of the scleral contact lens (from a diameter of 14.1mm to the edge of the scleral contact lens) is defined as the combined scleral landing zone. This zone is the main point-of-contact of the contact lens with the conjunctiva covering the sclera of the eye, and it is where the stability methods described here are implemented in the lens. This zone incorporates an edge lift starting 0.50mm from the lens edge, which is intended to support tear exchange and application of an edge radius connecting the anterior and posterior surfaces of the scleral contact lens.

Initial fitting of the scleral contact lens

The following fitting procedure was executed on each eye of each subject enrolled in the study. The initial fitting of the VOI scleral lens attempted to achieve the same four goals common to all scleral contact lens fitting sets: 1) eliminate interaction of the scleral contact lens with the limbus; 2) eliminate vessel impingement at the scleral contact lens margin; 3) exhibit movement on scleral contact lens push up and 4) achieve central corneal clearance between the contact lens and cornea; After being filled with non-preserved saline and fluorescein the lens was placed on the eye and allowed to settle for 30 minutes. All subjects were deemed to successfully meet criteria 1) – 3) given the planned duration of the experiment. If, after the settling period the lens did not meet criterion 4), the clinician chose an alternate lens from the fitting set (an alternate base curve radius). The fitting process was repeated until a successfully fit scleral contact lens was identified.

The position of the lens on the eye was captured using a digital imaging system (Sarver and Associates, Cookeville, TN) and quantification of lens movement was performed with custom software developed at The University of Houston, College of Optometry (Lens Auto Tracker (LAT) which allows the user to determine the scleral lens' misalignment with respect to the center of the pupil (translation and rotation). Following a phoropter-based

over-refraction, the fitting scleral contact lens was removed and the anterior cornea was assessed for staining, impression rings, and signs of superficial disruption.

Altering the basic trial lens design to include stabilization methods

Three unique lens stabilization methods were integrated into the posterior periphery of the scleral contact lens. In addition, a spherical lens with no stabilization method was designed. All four designs incorporated the subject's spherical equivalent over-refraction. The four lens designs for an individual eye have the same macro properties and the differences in the lenses manifest only in the posterior periphery (the portion of the design that include the stability methods). The four lens designs can be described as follows:

Design 1: Spherical Lens Design (SLD): The SLD lens includes no stabilization method in the lens periphery and is rotationally symmetric.

Design 2: Deep Toric Lens Design (DTLD): This design alters the posterior periphery by introducing toricity defined by orthogonal radii of curvature of 11.75mm and 13.00mm.

Design 3: Deep Toric with Sinusoidal Cleats (DTSC): This design integrates a 50 μ m amplitude sinusoidal pattern that repeats 8-fold around the circumference of the DTLD lens design.

Design 4: Deep Toric with Blended Sinusoidal Cleats (DTBSC): This design takes the DTSC lens design and incorporates automated dampening of the sinusoidal pattern toward the lens edge, forming a rotationally symmetric lens profile at the edge of the lens.

The rotational placement of the DTLD, DTSC and DTBSC stabilization methods was based on the rotational misalignment data that was recorded in the presence of the fitting lens. Said differently, if the fitting scleral contact lens tended to be rotated on average, that misalignment was compensated in subsequent lens iterations by rotating the design of the anterior surface with respect to the posterior surface.

Manufacture processes common to all lenses

All contact lens designs used in this experiment were manufactured in-house at The Visual Optics Institute using a DAC 2XALM OTT ophthalmic lens lathe (DAC International, Carpinteria, CA). Each lens was finished using Larsen anterior/posterior polishers RP202/ARP102CRN and a Larsen edger EP202 (Larsen Equipment, Seattle WA).

Subjects

Both eyes of four subjects (ages 25, 38, 41 and 64) participated in this study. All subjects had normal systemic health and none were habitual scleral contact lens or rigid corneal lens wearers. Ocular health was normal in all but one subject, with moderate keratoconus OU, as defined by sim K values in the Collaborative Longitudinal Evaluation of Keratoconus (CLEK) study.¹⁹

Quantification of on-eye stability of a scleral contact lens

To minimize the influence of any one lens on the on-eye behavior of a subsequent lens, the testing of each of the 4 lens designs was separated by at least 7 days. The following procedure was performed for each lens on each eye of each subject. The visit was initiated with recording of entering acuity, removal of habitual correction (if any), and slit lamp examination. Subjects were dilated with 1% tropicamide and 2.5% phenylephrine. The study lens was inserted and oriented such that the horizontal alignment marks were positioned horizontally (see Figure 1). The lens-eye system was examined under slit lamp after 60 minutes of wear, and if the lens had rotated during settling, it was manually rotated such that the horizontal marks were again horizontal. Every 20 minutes from that point (three total imaging sessions), a series of 7 images (1 frame/second) was recorded using the digital imaging system. The lens was then removed, followed by slit lamp examination and visual acuity measurement with the subject's habitual correction (if any).

The quantification of lens movement was performed with custom software developed at The University of Houston, College of Optometry, which quantified the location of the lens (x,y) with respect to the pupil center. The rotation of the lens was also calculated from the position of the alignment marks at 3 and 9 o'clock. Figure 1 shows one frame of the analysis software. Here the pupil center (faint purple '+') and lens center (faint blue '+') slightly displaced down and to left of pupil center) can be seen near the center of the pupil of the eye.

In Figure 1, the 6 purple boxes placed on the pupil border are fit with an ellipse, the center of which identifies the pupil center (purple '+'). The blue '+' marks the lens center of the scleral contact lens and the position of the lens center and pupil center are used to calculate translation (x and y) of the scleral lens with respect to the pupil center. The angle formed by the red box around the mark at roughly 180° (left) and the blue box around the box at roughly 0° (right) is used to calculate rotation of the scleral contact lens (θ) with respect to the horizontal. In total, for each lens evaluated, there were 21 images for each subject (3 measurement time periods * 7 images per measurement). Average standard deviation (sum of n standard deviations divided by n) across all eyes of x , y and θ were compared using pairwise t-tests with a Bonferroni correction for multiple comparisons.

Calculating predicted variation in visual acuity

Of equal interest to the variation in the physical position that the lens experienced on the eye is the impact on visual performance caused by this level of movement. To gain insight into the potential visual impact of this level of movement, the predicted change in acuity as a function of movement was modeled. The calculated level of residual aberration that would result when 5 keratoconic eyes wore a wavefront guided correction (full correction through the fifth order) with the movement characteristics quantified above on the two keratoconic eyes enrolled in this study was used in this modeling exercise. For this model, it was assumed (but not proven) that the lens would behave similarly on other highly aberrated eyes as the two eyes with keratoconus measured here. The visual image quality metric visual Strehl, which has previously been demonstrated to be well-correlated with change in acuity

by Ravikumar et al.^{17,18}, was used to quantify the predicted change in visual acuity that would be experienced in the presence of these movements.

RESULTS

For each lens design, no significant differences in the translation and rotation were found between left and right eyes or between subjects. Therefore, the data for both eyes of all subjects were pooled in the final analysis. For each stability method, the variation in scleral lens position over time was quantified as the average standard deviation of the observed translational (x , y) errors (in mm), and the average standard deviation of the rotational (θ) errors (in degrees ($^{\circ}$)). With this metric, lower values of x , y and θ represent a more stable lens. Figures 2 and 3 report average standard deviation for horizontal and vertical movement, respectively, with Figure 4 reporting average standard deviation for rotation.

Statistical differences were observed only in the rotation associated with the varied stabilization methods as reported in Table 1 below.

These results demonstrate that all three designs with peripheral stability modifications (DTLD, DTSC and DTBSC) are similarly stable (i.e. no significant differences across these three designs) and all are shown to be more stable than SLD for rotation.

Figure 5 plots the predicted loss in visual acuity associated with the movements of the SLD, DTLD, DTSC and DTBSC lens designs on the two eyes with keratoconus in the study. In the three lens designs with a stability method designed in the the posterior periphery of the lens, all show a predicted average loss in acuity given the measured movements (from the perfectly aligned condition) of approximately 0.06 logMAR (3 letters) with a predicted variation ($2 \times SD$) of 0.04 logMAR (4 letters). This is in contrast to the the loss of 0.14 logMAR for the spherical SLD design (7 letters) which is accompanied by a variation of 0.16 logMAR (8 letters). Said succinctly, the lenses with stabilization methods are predicted to provide more stable acuity when used in conjunction with a wavefront guided correction.

DISCUSSION

Toric fitting designs exist in commercial scleral lenses and are used currently to improve lens fits in cases where a spherical lens results in an unacceptable fit. Toric peripheral curves will align naturally on a toric scleral surface and are associated with patient-perceived improvement in comfort.²⁰

Accounting for the movement of the lens is critical in the design of a wavefront-guided correction, and the design process of the scleral contact lens allows for compensation of average positional offsets. If a fitting scleral contact lens tended to be rotated on average, that misalignment can be compensated in subsequent lens iterations by rotating the design of the anterior surface with respect to the posterior surface, as was done in the design of the DTLD, DTSC and DTBSC lenses here, which were based on data associated with the fitting lens. Therefore, the true measure of stability that is critical for wavefront-guided lens success is precision (the variation in movement about the final orientation). With increased

stability, there is the possibility for reduced lens movement and reduced tear exchange. Future investigations will examine the relationship between movement and physiological acceptance of the scleral lens.

Scleral contact lenses have been successfully integrated with wavefront-guided optics by several laboratories, and have been shown to improve optical quality to levels seen in the typical eye.^{10,11} However this level of performance requires that the wavefront-guided correction remain aligned with the underlying WFE of the eye. Here three separate stabilization designs (DTLD, DTSC and DTBSC) were evaluated and compared to the traditional spherical lens with no stabilizing methods (SLD). The DTLD lens included a simple toric periphery and is simpler in design than the DTSC and DTBSC designs, and therefore meets the additional, and more practical requirement of being most easily manufactured. The simulations performed give further weight to the idea that since the DTLD is predicted to provide the same change in visual performance (here, change in acuity) as the more complicated DTSC and DTBSC, the DTLD is the most attractive of the three designs for planned wavefront-guided scleral contact lens research. While a single toric magnitude was used here, a patient-specific level of toricity in the peripheral posterior of the lens may be beneficial.

CONCLUSION

All three stabilization methods (DTLD, DTSC, DTBSC) provided superior stability compared to the spherical lens (SLD). Simulations of the optical performance suggest that all three stabilization designs DTLD, DTSC and DTBSC will provide desirable results when deploying a wavefront-guided correction for the highly aberrated eye, whereas the traditional spherical design studied here will not. The DTLD is a likely candidate for use in future wavefront-guided lens work, as it is the simplest of the three to manufacture.

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Figure 1.

Example of one frame of the digital image data utilized to calculate rotation and translation of the scleral contact lens on the eye. The faint blue '+' represents the geometric center of the lens determined from the lens symmetric black alignment marks within the red and blue boxes located roughly at 0° and 180° . The faint purple '+' represents the center of the pupil determined from the purple circle at the pupil border.

Figure 2.

Average standard deviation of the horizontal misalignment (in mm) for the 4 different scleral contact lens stabilization designs: spherical lens design (SLD), deep toric lens design (DTLD), deep toric with sinusoidal cleats (DTSC), deep toric with blended sinusoidal cleats (DTBSC). Error bars represent ± 1 SD. Table 1 below reports statistical 382 comparisons across the lens types.

Figure 3.

Average standard deviation of the vertical misalignment (in mm) for the 4 different scleral contact lens designs: spherical lens design (SLD), deep toric lens design (DTLD), deep toric with sinusoidal cleats (DTSC), deep toric with blended sinusoidal cleats (DTBSC). Error bars represent ± 1 SD. Table 1 below reports statistical comparisons across the lens types.

Figure 4.

Average standard deviation of the rotational misalignment (in °) for the 4 different scleral contact lens designs: spherical lens design (SLD), deep toric lens design (DTLD), deep toric with sinusoidal cleats (DTSC), deep toric with blended sinusoidal cleats (DTBSC). Error bars represent ± 1 SD. Table 1 below reports statistical comparisons across the lens types.

Figure 5. Simulated loss of acuity (logMAR) associated with on-eye movement of a scleral contact lens as compared to perfect alignment. Error bars represent ± 1 SD. The optical aberrations used to model this data were collected on 5 eyes with keratoconus wearing scleral contact lenses.

Table 1

Statistically lower variability (i.e. a more stable lens design) in the design listed in columns (vertical) as compared to the design listed in the row.

	SLD	DTLD	DTSC	DTBSC
SLD		rotation (p = 0.001)	rotation (p = 0)	rotation (p = 0.001)
DTLD			-	-
DTSC				-
DTBSC				

Data is for measurements recorded over 60 minutes (paired t-test $p < 0.05$ with Bonferroni correction).