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Wavefront-Guided Scleral Lens Correction in Keratoconus

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Abstract

Purpose—To examine the performance of state-of-the-art wavefront-guided scleral contact lenses (wfgSCLs) on a sample of keratoconic eyes, with emphasis on performance quantified with visual quality metrics; and to provide a detailed discussion of the process used to design, manufacture and evaluate wfgSCLs.

Methods—Fourteen eyes of 7 subjects with keratoconus were enrolled and a wfgSCL was designed for each eye. High-contrast visual acuity and visual quality metrics were used to assess the on-eye performance of the lenses.

Results—The wfgSCL provided statistically lower levels of both lower-order RMS ($p < 0.001$) and higher-order RMS ($p < 0.02$) than an intermediate spherical equivalent scleral contact lens. The wfgSCL provided lower levels of lower-order RMS than a normal group of well-corrected observers ($p < < 0.001$). However, the wfgSCL does not provide less higher-order RMS than the normal group ($p = 0.41$). Of the 14 eyes studied, 10 successfully reached the exit criteria, achieving residual higher-order root mean square wavefront error (HORMS) less than or within 1 SD of the levels experienced by normal, age-matched subjects. In addition, measures of visual image quality (logVSX, logNS and logLIB) for the 10 eyes were well distributed within the range of values seen in normal eyes. However, visual performance as measured by high contrast acuity did not reach normal, age-matched levels, which is in agreement with prior results associated with the acute application of wavefront correction to KC eyes.

Conclusions—Wavefront-guided scleral contact lenses are capable of optically compensating for the deleterious effects of higher-order aberration concomitant with the disease, and can provide visual image quality equivalent to that seen in normal eyes. Longer duration studies are needed to assess whether the visual system of the highly aberrated eye wearing a wfgSCL is capable of producing visual performance levels typical of the normal population.

Keywords

scleral contact lens; aberration; visual quality metrics; keratoconus

Scleral contact lenses were the first form of contact lens correction successfully demonstrated, and Pearson et. al. report almost simultaneous demonstrations by Fick, Kalt

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and Mueller in the late 1880s.[1-3] With the introduction of hydrogel soft contact lenses, gas permeable lens prescription (including scleral contact lenses) reduced as a proportion of the overall contact lens market.[4] However, the unique properties of scleral lenses (large diameter, vaulting of the central cornea and the formation of a pre-corneal tear reservoir) have led to renewed specialty application in today'ss clinic.[5-12] In particular, clinicians are finding utility in treating abnormal corneal conditions such as pellucid marginal degeneration, keratoconus, dry eye syndrome, post-LASIK ectasia and non-healing epithelial defects.[5-12] In the case of the highly aberrated keratoconic eye, practicing clinicians report that scleral contact lenses are finding success due to the combined potential of improved optics, vision and comfort.

Rigid gas-permeable lenses reduce higher-order wavefront error associated with keratoconus.[13-19] However, during rigid gas-permeable lens wear, the residual higher-order aberrations remain elevated, as compared to normal eyes.[13-19] In this feature issue of *Optometry and Vision Science*, Yang et al. show that for a sample of 20 keratoconic eyes, the correction of residual aberration results in an improvement in contrast sensitivity at low (2 $^{c}/_{d}$) and intermediate (4, 8 and 16 $^{c}/_{d}$) spatial frequencies.[20] The authors of that work suggest custom contact lenses as a method to achieve this additional reduction in aberration.[20] The literature currently contains several demonstrations of customized contact lenses that specifically target higher-order aberration.[21-26] For customized higher-order compensating optics to perform optimally, they must be integrated into a stable lens platform and properly aligned to the underlying optical errors. When a lens is not stable or is misaligned, aberration correction is reduced, and can actually lead to an *increase* in higher-order aberration and a reduction in visual performance.[27-29]

Work by Sabesan et al. on severe keratoconus subjects demonstrated that higher-order RMS was reduced and both visual acuity and contrast sensitivity improved with wavefront-guided scleral contact lenses (wfgSCLs).[26] They also noted that while improved, visual performance did not reach levels seen in individuals that habitually experience normal levels of higher-order aberration.

When judging the performance of a wavefront-guided contact lens (regardless of modality), higher-order RMS (HORMS) is a logical metric of optical performance, as these lenses are specifically designed to target higher-order aberrations. In terms of real-world visual performance, HORMS is not an optimal predictor of performance, as it does not consider the contribution of lower-order aberrations (residual uncorrected sphere and cylinder) nor does it consider the interaction between individual aberration terms.[30-31] The literature now contains several descriptions of optical quality metrics that examine the interaction of individual terms and the impact on visual performance.[32-40] Three metrics: light in the bucket, visual Strehl ratio and neural sharpness, have been shown to be well-correlated with changes in optical performance in keratoconus.[40] All three are based on retinal image quality and two of the three incorporate neural weighting functions. Their mathematical formulation (briefly presented here) was previously detailed by Thibos et al.[33]

The formulation for light in the bucket (LIB) is given in Equation 1. As described by Thibos et al.,[33] LIB calculates the percentage of total energy in a normalized point spread function falling in an area defined by the core of a diffraction limited PSF for the same pupil diameter. In essence, it is a measure of compactness of the PSF.

$$LIB=\int_{DLcore} PSF_N\left(x,y\right)dxdy \quad (1)$$

Visual Strehl ratio computed in the spatial domain (VSX) is given in Equation 2. As described by Thibos et al.,[33] VSX is calculated as the inner product of the PSF with a neural weighting function (inverse of contrast sensitivity function), normalized to the diffraction-limited case. VSX attempts to include both optical quality (represented by the PSF) with the efficiency of the visual system at processing the image formed on the retina (represented mathematically by the neural weighting function N).

$$VSX=\frac{\int_{psf} PSF\left(x,y\right)N\left(x,y\right)dxdy}{\int_{psf} PSF_{DL}\left(x,y\right)N\left(x,y\right)dxdy} \quad (2)$$

Neural sharpness (NS) is given in Equation 3. As described by Thibos et al.,[33] this metric was conceptualized by Williams as a way, much like VSX, to capture the effectiveness of a PSF for stimulating the neural portion of the visual system by using a Gaussian weighting function.[34]

$$NS=\frac{\int_{psf} PSF\left(x,y\right)g\left(x,y\right)dxdy}{\int_{psf} PSF_{DL}\left(x,y\right)g\left(x,y\right)dxdy} \quad (3)$$

VSX and NS both neurally weight the PSF, albeit with different weighting functions. As described by Thibos et al.,[33] the main difference in the weighting functions being that the weighting function of VSX contains an inhibitory surround outside the PSF core, whereas the weighting function for NS has no such inhibitory surround.

The current experiment focuses on the optical quality achieved with scleral contact lenses by reporting metrics of image quality calculated from the combined residual lower-order and higher-order aberrations, using these metrics that are highly correlated with visual acuity in keratoconus.[40] Results are compared to similar values for the well-corrected normal population. Importantly, this report also details the clinical process utilized in dispensing wfgSCLs as envisioned by the investigators; this description is included for the interest of the contact lens practitioner that may be interested in fitting these lenses in the future.

PURPOSE

The purposes of this manuscript were: 1) To quantify visual performance and residual aberration in keratoconus subjects wearing wavefront-guided scleral contact lenses designed to correct subject-specific lower-and higher-order aberration, 2) To use optical quality metrics to report the efficacy of wavefront-guided corrections for reducing whole eye aberrations and comparing resultant image quality to normative levels and 3) to describe the clinical process utilized in dispensing wavefront-guided scleral contact lenses, as envisioned by the investigators of the current experiment.

METHODS

The study adhered to the tenets of the Declaration of Helsinki and received approval from the institutional review board of the University of Houston. Signed informed consent was obtained from each subject prior to their participation in this study.

Seven keratoconic subjects (fourteen eyes) were enrolled. Both eyes of each subject were included in this study for two reasons. First, clinically, both eyes of a single subject would be fit, and a major goal of this work was to describe a clinical process for dispensing these lenses. This would require fitting both eyes. Second, the asymmetry of the disease makes each eye a unique fitting challenge, increasing knowledge associated with fitting KC eyes with wfgSCLs. Each subject participated in three study visits, during which logarithm of the minimum angle of resolution (logMAR) visual acuity (VA) and wavefront error were assessed independently in each eye. In brief, the first visit was a baseline evaluation of the subject used to record subject history and to identify scleral lens fitting parameters from a trial lens set. These parameters were used to design an aspheric scleral contact lens whose optics were defined from the spherical equivalent over-refraction (seSCL). The second visit was used to collect on-eye temporal lens stability data and wavefront error data while wearing the seSCL, which is needed to design a wfgSCLs (2nd – 5th order correcting). The third visit was used to evaluate the on-eye optical and visual performance while wearing the wfgSCL. The detailed method for each visit is described below.

Visit 1: Trial Lens Evaluation

High contrast logMAR visual acuity was assessed monocularly using paper charts with a luminance of 253 $^{cd}/_{m^2}$. (acuity testing was conducted at these conditions for every visit). Three charts were used to avoid memorization and allow for an average to be computed. In this visit, testing was performed through the subject'ss habitual correction and an ocular and systemic health history was obtained. The inclusion criteria of the study (Table 1) were assessed based on steep K, disease severity based on the CLEK study criteria, and habitual forms of correction (Table 2). In general, the eyes studied were moderate to severe keratoconic eyes. The form of correction varied significantly, with no correction and soft, hybrid, rigid gas permeable and scleral forms of correction being represented. Measures of wavefront error with the habitual correction are not available for this sample, as the habitual correction did not, in all cases, provide useful data over a 6mm pupil. This is not uncommon when highly aberrated eyes attempt to make due with soft lens corrections or when rigid gas permeable lenses decenter inferiorly on the eye, and do not fully cover the dilated pupil.

Subjects that met the inclusion criteria were fitted with 18.2 mm trial scleral contact lenses designed and manufactured at the Visual Optics Institute (VOI). A key parameter for the trial set is the inclusion of a posterior surface scleral toric landing zone in the lens periphery to rotationally stabilize the lens during wear.

Two clinicians with experience in scleral contact lens fitting participated in the research. Clinicians selected an initial lens from the trial set based on simulated keratometry values (SimKs) determined from corneal topography, where the trial lens base curve was intended to provide roughly 200 - 300μm of corneal vault centrally, as assessed with a slit lamp with sodium fluorescein present in the tear reservoir. After 30 minutes of settling, the trial lens was assessed on the eye for corneal vault, limbal clearance, lens movement on push-up/blink and absence of blanching of the blood vessels under the lens at the lens margin. Once the best-fitting trial lens was identified from the trial set, a phoropter-based over-refraction was performed. On-eye lens rotation at this step was quantified with a slit lamp by examining the orientation of five alignment marks that are designed onto the anterior surface of the lens. This gross examination allows for quantification of the on-eye rotation of the lens, which is compensated in the seSCL by compensatory rotation of the toric periphery of the posterior lens. A subset of these marks is visible in Figure 1.

Design and Manufacture of seSCL—The parameters defining the successful trial lens and spherical equivalent over-refraction were entered into Custom Lens Design (CLD) software (University of Houston College of Optometry Core Programming Module, Houston, TX). The seSCLs studied here used the standard method of providing a new first optical surface and index-matching consistent with all rigid lens treatments. The resulting design produced anterior and posterior lens profiles for an aspheric scleral contact lens that incorporated a spherical equivalent correction for the eye under study. This step produces a lens that is closer in weight distribution to the final wfgSCL (described below) than the trial lens. Given that the optics of the seSCL are designed from a spherical equivalent over-refraction, this lens is not designed for the purpose of optimizing lower-order correction. It is more accurately described as an intermediate lens between the trial lens and the wfgSCL. The degree of rotation measured with the trial lens was also entered into the CLD software to ensure appropriate rotation of the posterior scleral toric landing zone was achieved, as predictable and accurate alignment of the seSCL, with respect to the eye, is required to appropriately position the wavefront-guided design in the next lens iteration. The seSCL lens design mimicked the macro properties used in the definition of the appropriate trial lens, with the added benefits of compensation of the spherical equivalent refractive error and compensation for the on-eye lens rotation measured after trial lens settling.

The anterior and posterior lens profiles generated by CLD served as cutting routines to manufacture the seSCL. Cutting of anterior and posterior surfaces of the lens was performed with a 2X-ALM OTT ophthalmic lens lathe (DAC International, Carpinteria, CA), manufactured from 21 mm diameter Boston XO lens blanks (Bausch and Lomb, Rochester NY).[41] The Dk value of the material is reported by the manufacturer to be 100 (www.bausch.com), and the intended center lens thickness of all lenses manufactured was 0.45mm. Alignment marks were placed on the anterior surface of the seSCL at 0°, 90°, 180°, 270° and 330° 3.2 mm from the lens edge with the pneumatic milling tool that is integrated into the DAC 2X-ALM ophthalmic lens lathe. The lens was finished using Larsen anterior/posterior polishers RP202/ARP102CRN and a Larsen edger EP202 (Larsen Equipment, Seattle, WA).

Visit 2: seSCL Evaluation

Each study eye'ss pupil was dilated with 1 drop 1% tropicamide and 1 drop 2.5% phenylephrine . After reaching full dilation, the seSCL was inserted and allowed to settle on the eye for 30 minutes. Wavefront aberration data were recorded through the eye-lens system using a COAS HD wavefront sensor (Abbott Medical Optics, Albuquerque NM). At each point where wavefront error was recorded, three separate measures were recorded and averaged over a 7 mm pupil diameter, defining the wavefront - compensating optical zone. For each individual measure, the instrument was aligned to the subject'ss eye, the subject asked to blink and open their eye wide, and the measurement was recorded. Immediately following capture, the spot diagrams were examined to assure there was no occlusion of any portion of the Shack-Hartmann image by an eyelid, eyelashes or debris on the ocular surface. Immediately following measurement of the wavefront error, on-eye translation (x,y) and rotation (theta) of the seSCL was recorded using custom-built Modular Ophthalmic Measurement System, MOMS, (Sarver and Associates, Carbondale, IL.). Movement was recorded once a second for 10 seconds. The average rotation and translation for the lens over that period was calculated and used to represent the position of the lens on the eye. Prior to recording movement data, the instrument was aligned to the subject'ss eye, the subject was asked to blink and open their eye. The subject was allowed to blink during the measurement as needed, and data where a blink was captured were discarded. Figure 1 provides an example of the offset between the pupil center (central cross) with respect to the geometric center of the lens (cross displaced inferiorly and to the right). In Figure 1 below, 4 of the 5 black alignment marks are visible.

The images of the scleral lens on the eye were processed with custom software LensAutoTracker v1.2.5 (University of Houston College of Optometry Core Programming Module, Houston, TX), which provides statistics associated with the rotation and translation of the lens with translational accuracy of ±0.02mm and rotational accuracy of ±0.5°. The mean x,y offsets produced from this measurement are used to decenter the wavefront-compensating optical zone on the anterior contact lens surface. The rotation of the lens on the eye is also calculated from the peripheral rectangular search boxes over two of the lens alignment marks, and is used to further rotate the posterior toric landing zone. When both rotation and translation are taken into account, the wavefront-compensating patch is positioned in front of the pupil, registering the wavefront-guided optical zone with the wavefront of the eye.

Design and Manufacture of seSCL—In designing the wfgSCL, the method employed was to start with the seSCL, and make only changes that would allow for placement of the wavefront-guided patch and correct orientation of the lens on the eye. The physical parameters that were used in the design of the seSCL (radii of curvature, diameter of each zone of the lens, posterior surface toric amplitude and orientation, power of the lens, desired center thickness), along with the wavefront aberration data and decentration data were entered into CLD. A 2^{nd}-5^{th} order masking function was applied to the Zernike data in CLD. Second through 5^{th} order correction was chosen based on prior simulation work suggesting a return to normal levels of high-contrast visual acuity in mild-moderate keratoconus subjects with this level of correction.[42] All wavefront-guided customization of the optics were incorporated into the design of the anterior surface of the lens. The anterior and posterior lens profiles generated by CLD served as cutting routines to manufacture the wfgSCL. The lens manufacturing and finishing process for the wfgSCL is identical to that described above for the seSCL evaluated in Visit 2.

Visit 3: Evaluation of Wavefront Guided Scleral Contact Lens

The wfgSCL was placed on the eye. After a settling period of 30 minutes, high contrast visual acuity was assessed with habitual pupils through the wfgSCL using three logMAR acuity charts. The lens was removed, and the eye'ss pupil dilated with 1 drop 1% tropicamide and 1 drop 2.5% phenylephrine . After reaching full dilation, the wfgSCL was reinserted and allowed to re-settle on the eye. Wavefront aberration data were recorded through the eye-lens system using the COAS HD wavefront sensor.

Evaluating Optical Performance with Metrics of Image Quality—Residual wavefront error data with the wfgSCL were entered into GetMetrics v2.5 metrics calculator (developed from a co-operation between Dr. Larry Thibos, our lab and The University of Houston College of Optometry'ss Core Programming Module, Houston, TX). Wavefront error data for two hundred normal, well-corrected eyes adjusted to 555 nm from the Thibos well-corrected data set [43] were also processed with GetMetrics. The majority of the subjects in this normative dataset were between the ages of 22-35 years, similar in age to the current cohort, which was composed of subjects aged 24-42. Three image quality metrics (logVSX, logNS and logLIB) that have been shown to be highly correlated with visual acuity were extracted from the metrics output

RESULTS

Comparison of Habitual logMAR Visual Acuity Measures in this Sample to the Larger Keratoconic Population

Monocular logMAR VA in the presence of each subjects habitual correction was better than 20/40 in all eyes (0.30 logMAR) (Table 3). This is comparable to, but better than, the visual acuity reported by the Collaborative Longitudinal Evaluation of Keratoconus (CLEK) study sample, where 63% of subjects had entrance acuity of 20/40 or better in both eyes.[44] For the CLEK sample, the number increases to 78% achieving 20/40 in both eyes under best corrected conditions. In general, it can be said that the subjects enrolled in the current study achieve what is clinically considered reasonable high contrast visual acuity in the presence of this disease. However, it cannot be classified as a normal level of acuity, as normal age-matched acuity for this cohort is ~20/15.[45]

Spherical Scleral Contact Lens and Wavefront-Guided Scleral Contact Lens Optical Performance

Residual lower-order errors with the seSCL and wfgSCL are reported in Figure 2. The residual lower-order aberration in well-corrected normal eyes as reported by Thibos et al.[43] is also reported for comparison. The residual higher-order errors are reported in Figure 3. In both Figures 2 and 3, a 6 mm pupil is chosen as a common pupil size for comparison across subjects.

T-tests were used to compare the levels of lower-order RMS (LORMS) and HORMS with the seSCL and wfgSCL, as well as the seSCL and wfgSCL to the normal control data. The wfgSCL provided statistically lower levels of both LORMS ($p<0.001$) and HORMS ($p<0.02$) than the seSCL lens. In addition, the wfgSCL provided lower levels of LORMS than the normal group ($p<0.001$). However, the wfgSCL does not provide less HORMS than the normal group ($p=0.41$).

The fact that the wfgSCL provided better lower-order aberration compensation than the seSCL (Figure 2) was to be expected, as the wfgSCL mimicked the seSCL in design, except for the optics, which were designed to compensate for the residual aberration measured while wearing the seSCL. The seSCL contained a spherical equivalent correction based on subjective refraction, as is commonplace when dispensing corrections for highly aberrated eyes, while the wfgSCL contained this baseline level of defocus correction, plus objective lower- and higher-order wavefront compensation. For 13 of 14 eyes, the level of lower-order RMS is reduced from the seSCL (light gray bars) to the wfgSCL (dark gray bars bars).

Residual higher-order errors for a 6 mm pupil diameter, and age matched higher-order aberration data reported previously by Applegate et al. are also provided for each subject for comparative purposes (Figure 3).[46] The age-matched data is important in examining the efficacy of the correction. The elevated levels of HORMS seen in the seSCL (light gray bars) are expected, as it is known that conventional rigid gas permeable corrections do not completely mask the higher-order aberration present in keratoconic eyes.[13-19] Presumably the same is true for clinically available scleral contact lenses. In the sample under study here, the seSCL provides mean HORMS levels consistent with that of the age-matched normal population in 4 of 14 eyes (both eyes of subjects S5 and S7). This is in contrast to the performance of the wfgSCL, where 10 of the 14 eyes perform optically better than or equal to (within 1 SD) the age-matched normal level. Interestingly, four eyes of two subjects (S4OD, S4OS, S7OD, S7OS) experience HORMS levels above this range, and in 3 of the 4, above that experienced with the seSCL. For the remainder of the analysis, the 10 eyes achieving the study exit criteria of HORMS less than or within 1 SD of an age-matched mean are considered (opinion on the failure of the 4 lenses is included in the discussion).

Comparison is now made to the optical performance of the normal population using image quality metrics. To construct a normative distribution of values for the metrics used here, logVSX, logNS and logLIB were calculated for a sample of 200 well-corrected eyes from 100 subjects reported by Thibos et al.[43] These metrics consider the entire wavefront, and do not separate terms by lower- and higher-order, as is done with LORMS and HORMS. The individual metric values for the 10 eyes meeting the exit criteria of HORMS less than or within 1 SD of the age-matched normal were plotted (gray bars) along with normative metric values generated for subjects in the Thibos dataset (black bars). The results for all 3 metrics are that the resulting image quality is consistent with that associated with normal eyes (Figures 4A-C). Comparing any given metric value for any given study eye to the distribution of normal metric values, it is clear that the wfgSCL provides the eye with visual image quality consistent with normal eyes, suggesting that adaptation to the new retinal image may lead to further improvements in visual performance. The three metrics reported here have previously been found to be well correlated with visual performance in keratoconus.[40]

Comparison of Habitual logMAR VA to WFG Visual Performance

On average, the 10 eyes gain 1.5 lines of acuity with the wfgSCL compared to the habitual lens (Figure 5). Average high contrast logMAR VA for the cohort with the wfgSCL was -0.01 logMAR (~20/20 Snellen). While the gains in acuity compared to habitual correction are substantial, all 10 study eyes have poorer VA compared with age-matched normal levels, even though residual higher-order aberrations are within 1 SD of normal mean values. This is in agreement with prior reports by Sabesan et al.[26]

DISCUSSION

The method described in this paper details a process to manufacture individualized, wfgSCL for highly aberrated eyes (here, using keratoconic subjects). In general, the process is successful in reducing higher-order aberrations. However, when compared to conventional contact lens practice, this success comes at a cost of time and resources of both the subject (patient) and the clinician. This is due to the current procedures and measurements required to obtain the data needed to successfully manufacture the lenses, which requires repeated subject visits. The 3-visit process affords the designers the opportunity to build the seSCL lens that is well aligned on the eye and provides reasonable lower-order correction prior to attempting to target the higher-order wavefront error in the eye with the wfgSCL. In other words, the seSCL step allows the designers to consider problems associated with lower-order aberration and lens rotation first, facilitating success of the final wfgSCL.

The entrance criteria for this study excluded subjects with corneal scarring, which is a common clinical finding in subjects with KC. The deleterious effects of scarring are not directly correctable with conventional optics available in the clinic, or the wavefront-guided optics being discussed here. The presence of scarring will, depending on its severity, 1) hamper the ability to provide optimal refractive correction and 2) limit the absolute levels of visual performance achievable with any form of correction, including wfgSCLs.

The result of executing this process in this cohort was 10/14 of the keratoconic eyes enrolled achieved HORMS levels within 1 SD or below age-matched normal levels. This is in contrast to HORMS reduction in the case of the seSCL, which does not directly target the higher-order aberrations in the eyes. The seSCLs studied here use the standard method of providing a new first optical surface and index-matching consistent with all rigid gas permeable lens treatments, resulting in only 4/14 of the eyes achieving higher-order RMS levels within 1 SD or below the levels of a normal population. In terms of higher-order RMS reduction, it can be said that the level of aberration present is reduced with the wfgSCL. This is also reflected in the optical quality values of the metrics logVSX, logNS and logLIB, which are distributed within normal levels of optical performance in the presence of the wfgSCL for the 10 eyes achieving the exit criteria.

While encouraging, optical performance evaluated alone is only important to the subject (patient) if it is accompanied by an improvement in visual performance. Here, comparison of VA is made to the habitual correction worn by the subject. While it is agreed that the habitual correction worn by the subjects entering the study is not necessarily an optimal correction, it is reflective of the efforts of clinicians to provide the patients with the best optical correction that is clinically possible. In this cohort, average entrance acuity with the habitual correction was consistent with (slightly better than) previous reports of habitual correction in the keratoconus population.[44] On average, subjects acutely gained 1.5 lines of acuity with the wfgSCL. This is consistent with the finding of Sabesan et al. that demonstrated 1.9 lines improvement with the custom wavefront-guided lens.[26] In the current experiment, the average high contrast acuity was -0.01 logMAR with the wfgSCL. This is better than that reported by Sabesan et al. (0.21 logMAR). However, this may be due to the severity of the keratoconus affecting the eyes studied, as evidenced by the average entrance visual acuity: 0.4 logMAR of the Sabesan et al.[26] subjects and 0.14 logMAR in the current study. High contrast visual acuity of subjects in the current study did not reach age-matched normal levels, and on average was 1 line worse than normative values. This finding is consistent with reports in the literature that custom corrected keratoconus subjects perform worse than normal subjects with comparable levels of residual aberrations.[47]

While the results are encouraging, in 4 eyes of 2 subjects, the wfgSCL failed to reduce higher-order aberration, and in 3 of these eyes, the lenses actually induced higher-order aberration compared to the seSCL. This finding highlights the complexity of the process. Of note, temporal lens stability and repeatable lens positioning remain challenges. In cases where a stable lens is not achieved, correction of the optics literally remains a ‘moving target’ with the wavefront-compensating optical zone misaligned from the designed orientation, inducing higher-order aberration. Clinically speaking, unstable wfgSCLs do not provide the benefit for which they were designed. If they were being dispensed clinically, they would require a redesign of the macro-properties of the lens to provide a more stable platform for the wavefront-guided correction, or abandonment of the custom method in favor of more conventional modes of correction. Lens instability can also impact the efficacy of the designed wavefront correction; if the lens is unstable during capture of the wavefront and alignment data, the designed wavefront-compensating optical zone would not reflect the true aberration structure of the eye.

There are several hurdles remaining to effectively translate wavefront guided lenses into clinical practice. One such hurdle is the complexity of the combined fitting/design/manufacture process. This process demands specialized instrumentation, assuring, at least in the near future, wavefront-guided lenses in the form described here will be delivered and studied at centers with specialized capabilities. While the acuity gains seen here and in other studies are modest, it has been shown that gains continue over time as the subject adapts to the improved retinal image afforded by a custom scleral contact lens.[48] Further, visual benefit not apparent through the measure of visual acuity may be equally, if not more important to the patient. For example, preliminary data from one subject in a companion study currently being executed in our laboratory suggests gains in stereoacuity over the time course of days in the presence of the wfgSCL.

On a more qualitative note, patients in this study did offer comments about the performance of the lenses. For instance, subjects routinely commented that they appreciated the improved ‘sharpness’ of their vision, with one commenting that the effect was most notable in the presence of a dilated pupil. When KC subjects are dilated, the impact of residual uncorrected WFE can be devastating, even with the habitual correction in place. The wavefront guided lens reduces the deleterious impact of these residual aberrations and improves the quality of vision even at large pupil diameters.

If the goal of the growing body of research into custom correction of highly aberrated eyes is clinical translation, the projected cost (both to the patient and doctor) associated with the lenses must also be reduced. When one steps out of the research laboratory and into the daily lives of the clinician and patient, cost becomes a significant factor driving choices related to correction. It is not a stretch to equate cost with access to care (for the patient) or a willingness to invest in the time and tools to deliver that care (for practitioners), and this particular hurdle must be lowered. It is clear that this population is demanding more complete forms of optical correction. As the performance of the lenses continues to improve and the methods required to prescribe them become more accessible in the clinical environment, it is anticipated that their cost will decrease and accessibility will increase, perhaps one day transforming them from classification as ‘novel’ forms of correction to ‘standard’ forms of correction. The promise of this type of correction is the potential for improved vision, improved comfort and longer wearing time for the patient with highly aberrated eyes, which could significantly lessen the burden of the disease.

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REFERENCES

1. Pearson RM. Kalt, keratoconus, and the contact lens. Optom Vis Sci. 1989; 66:643–6. [PubMed: 2677884]
2. Pearson RM, Efron N. Hundredth anniversary of August Müller's inaugural dissertation on contact lenses. Surv Ophthalmol. 1989; 34:133–41. [PubMed: 2686057]
3. Pearson RM. Karl Otto Himmler, manufacturer of the first contact lens. Cont Lens Anterior Eye. 2007; 30:11–6. [PubMed: 17110156]
4. Efron N. Obituary--rigid contact lenses. Cont Lens Anterior Eye. 2010; 33:245–52. [PubMed: 20674469]
5. Foss AJ, Trodd TC, Dart JK. Current indications for scleral contact lenses. CLAO J. 1994; 20:115–8. [PubMed: 8044976]
6. Cotter JM, Rosenthal P. Scleral contact lenses. J Am Optom Assoc. 1998; 69:33–40. [PubMed: 9479934]
7. Pullum K, Buckley R. Therapeutic and ocular surface indications for scleral contact lenses. Ocul Surf. 2007; 5:40–8. [PubMed: 17252164]
8. Pullum KW, Whiting MA, Buckley RJ. Scleral contact lenses: the expanding role. Cornea. 2005; 24:269–77. [PubMed: 15778597]
9. Romero-Rangel T, Stavrou P, Cotter J, Rosenthal P, Baltatzis S, Foster CS. Gas-permeable scleral contact lens therapy in ocular surface disease. Am J Ophthalmol. 2000; 130:25–32. [PubMed: 11004256]
10. Jacobs DS, Rosenthal P. Boston scleral lens prosthetic device for treatment of severe dry eye in chronic graft-versus-host disease. Cornea. 2007; 26:1195–9. [PubMed: 18043175]

11. Shepard DS, Razavi M, Stason WB, Jacobs DS, Suaya JA, Cohen M, Rosenthal P. Economic appraisal of the Boston Ocular Surface Prosthesis. Am J Ophthalmol. 2009; 148:860–8. e2. [PubMed: 19781684]
12. Gumus K, Gire A, Pflugfelder SC. The impact of the Boston ocular surface prosthesis on wavefront higher-order aberrations. Am J Ophthalmol. 2011; 151:682–90. e2. [PubMed: 21269603]
13. Kosaki R, Maeda N, Bessho K, Hori Y, Nishida K, Suzaki A, Hirohara Y, Mihashi T, Fujikado T, Tano Y. Magnitude and orientation of Zernike terms in patients with keratoconus. Invest Ophthalmol Vis Sci. 2007; 48:3062–8. [PubMed: 17591874]
14. Thibos LN, Hong X. Clinical applications of the Shack-Hartmann aberrometer. Optom Vis Sci. 1999; 76:817–25. [PubMed: 10612402]
15. Munson K, Hong X, Thibos LN. Use of a Shack-Hartmann aberrometer to assess the optical outcome of corneal transplantation in a keratoconic eye. Optom Vis Sci. 2001; 78:866–71. [PubMed: 11780663]
16. Choi J, Wee WR, Lee JH, Kim MK. Changes of ocular higher order aberration in on- and off-eye of rigid gas permeable contact lenses. Optom Vis Sci. 2007; 84:42–51. [PubMed: 17220777]
17. Jinabhai A, Radhakrishnan H, Tromans C, O'Donnell C. Visual performance and optical quality with soft lenses in keratoconus patients. Ophthalmic Physiol Opt. 2012; 32:100–16. [PubMed: 22268571]
18. Marsack JD, Parker KE, Pesudovs K, Donnelly WJ 3rd, Applegate RA. Uncorrected wavefront error and visual performance during RGP wear in keratoconus. Optom Vis Sci. 2007; 84:463–70. [PubMed: 17568315]
19. Negishi K, Kumanomido T, Utsumi Y, Tsubota K. Effect of higher-order aberrations on visual function in keratoconic eyes with a rigid gas permeable contact lens. Am J Ophthalmol. 2007; 144:924–9. [PubMed: 17949670]
20. Yang B, Liang B, Liu L, Liao M, Li Q, Dai Y, Zhao H, Zhang Y, Zhou Y. Contrast sensitivity function after correcting residual wavefront aberrations during RGP wear. Optom Vis Sci. 2014; 91:XXX–XX.
21. Katsoulos C, Karageorgiadis L, Vasileiou N, Mousafeiropoulos T, Asimellis G. Customized hydrogel contact lenses for keratoconus incorporating correction for vertical coma aberration. Ophthalmic Physiol Opt. 2009; 29:321–9. [PubMed: 19422564]
22. Marsack JD, Parker KE, Applegate RA. Performance of wavefront-guided soft lenses in three keratoconus subjects. Optom Vis Sci. 2008; 85:E1172–8. [PubMed: 19050464]
23. Marsack JD, Parker KE, Niu Y, Pesudovs K, Applegate RA. On-eye performance of custom wavefront-guided soft contact lenses in a habitual soft lens-wearing keratoconic patient. J Refract Surg. 2007; 23:960–4. [PubMed: 18041254]
24. Sabesan R, Jeong TM, Carvalho L, Cox IG, Williams DR, Yoon G. Vision improvement by correcting higher-order aberrations with customized soft contact lenses in keratoconic eyes. Opt Lett. 2007; 32:1000–2. [PubMed: 17375181]
25. Chen M, Sabesan R, Ahmad K, Yoon G. Correcting anterior corneal aberration and variability of lens movements in keratoconic eyes with back-surface customized soft contact lenses. Opt Lett. 2007; 32:3203–5. [PubMed: 17975644]
26. Sabesan R, Johns L, Tomashevskaya O, Jacobs DS, Rosenthal P, Yoon G. Wavefront-guided scleral lens prosthetic device for keratoconus. Optom Vis Sci. 2013; 90:314–23. [PubMed: 23478630]
27. Applegate RA, Marsack JD, Sarver EJ. Noise in wavefront error measurement from pupil center location uncertainty. J Refract Surg. 2010; 26:796–802. [PubMed: 20954688]
28. Jinabhai A, Neil Charman W, O'Donnell C, Radhakrishnan H. Optical quality for keratoconic eyes with conventional RGP lens and simulated, customised contact lens corrections: a comparison. Ophthalmic Physiol Opt. 2012; 32:200–12. [PubMed: 22512372]
29. Guirao A, Williams DR, Cox IG. Effect of rotation and translation on the expected benefit of an ideal method to correct the eye's higher-order aberrations. J Opt Soc Am (A). 2001; 18:1003–15.
30. Applegate RA, Marsack JD, Ramos R, Sarver EJ. Interaction between aberrations to improve or reduce visual performance. J Cataract Refract Surg. 2003; 29:1487–95. [PubMed: 12954294]

31. Pepose JS, Applegate RA. Making sense out of wavefront sensing. Am J Ophthalmol. 2005; 139:335–43. [PubMed: 15733998]
32. Chen L, Singer B, Guirao A, Porter J, Williams DR. Image metrics for predicting subjective image quality. Optom Vis Sci. 2005; 82:358–69. [PubMed: 15894912]
33. Thibos LN, Hong X, Bradley A, Applegate RA. Accuracy and precision of objective refraction from wavefront aberrations. J Vis. 2004; 4:329–51. [PubMed: 15134480]
34. Williams, DR. Subjective image quality metrics from the wave aberration.. Paper presented at the 4th International Congress of Wavefront Sensing and Aberration Free Refractive Correction; San Francisco, CA. 2004; Available at: http://cfao.ucolick.org/pubs/presentations/eyedesign/07_Metrics_DW.pdf.
35. Cheng X, Bradley A, Thibos LN. Predicting subjective judgment of best focus with objective image quality metrics. J Vis. 2004; 4:310–21. [PubMed: 15134478]
36. Marsack JD, Thibos LN, Applegate RA. Metrics of optical quality derived from wave aberrations predict visual performance. J Vis. 2004; 4:322–8. [PubMed: 15134479]
37. Schoneveld P, Pesudovs K, Coster DJ. Predicting visual performance from optical quality metrics in keratoconus. Clin Exp Optom. 2009; 92:289–96. [PubMed: 20082622]
38. Ravikumar A, Applegate RA, Shi Y, Bedell HE. Six just-noticeable differences in retinal image quality in 1 line of visual acuity: toward quantification of happy versus unhappy patients with 20/20 acuity. J Cataract Refract Surg. 2011; 37:1523–9. [PubMed: 21782097]
39. Ravikumar A, Sarver EJ, Applegate RA. Change in visual acuity is highly correlated with change in six image quality metrics independent of wavefront error and/or pupil diameter. J Vis. 2012; 12:11. [PubMed: 22984224]
40. Ravikumar A, Marsack JD, Bedell HE, Shi Y, Applegate RA. Change in visual acuity is well correlated with change in image-quality metrics for both normal and keratoconic wavefront errors. J Vis. 2013; 13:28. [PubMed: 24281244]
41. [December 22, 2013] Bausch and Lomb data on Boston XO. Available at: http://www.bausch.com/en/ecp/our-products/contact-lenses/gp-lens-materials/boston-xo/.
42. Marsack JD, Pesudovs K, Sarver EJ, Applegate RA. Impact of Zernike-fit error on simulated high- and low-contrast acuity in keratoconus: implications for using Zernike-based corrections. J Opt Soc Am (A). 2006; 23:769–76.
43. Thibos LN, Hong X, Bradley A, Cheng X. Statistical variation of aberration structure and image quality in a normal population of healthy eyes. J Opt Soc Am (A). 2002; 19:2329–48.
44. Zadnik K, Barr JT, Edrington TB, Everett DF, Jameson M, McMahon TT, Shin JA, Sterling JL, Wagner H, Gordon MO. Baseline findings in the Collaborative Longitudinal Evaluation of Keratoconus (CLEK) Study. Invest Ophthalmol Vis Sci. 1998; 39:2537–46. [PubMed: 9856763]
45. Elliott DB, Yang KC, Whitaker D. Visual acuity changes throughout adulthood in normal, healthy eyes: seeing beyond 6/6. Optom Vis Sci. 1995; 72:186–91. [PubMed: 7609941]
46. Applegate RA, Donnelly WJ 3rd, Marsack JD, Koenig DE, Pesudovs K. Three-dimensional relationship between high-order root-mean-square wavefront error, pupil diameter, and aging. J Opt Soc Am (A). 2007; 24:578–87.
47. Sabesan R, Yoon G. Visual performance after correcting higher order aberrations in keratoconic eyes. J Vis. 2009; 9:6, 1–10. [PubMed: 19757884]
48. Sabesan R, Yoon G. Perceptual learning after correcting the eye's aberration with adaptive optics. Invest Ophthalmol Vis Sci. 2013:54. ARVO E-Abstract 1282.

SYNOPSIS

Scleral contact lenses, which were first demonstrated in the late 1800s, are finding renewed application in specialty cases such as keratoconus due to advantageous properties such as the vaulting of the cornea and the resulting pre-corneal tear layer. This study examines the performance of state-of-the-art custom wavefront-guided scleral contact lenses on a sample of keratoconic eyes, with emphasis on performance quantified with visual quality metrics. The study also provides a detailed discussion of a process for design, manufacture and application of wavefront-guided scleral contact lenses.

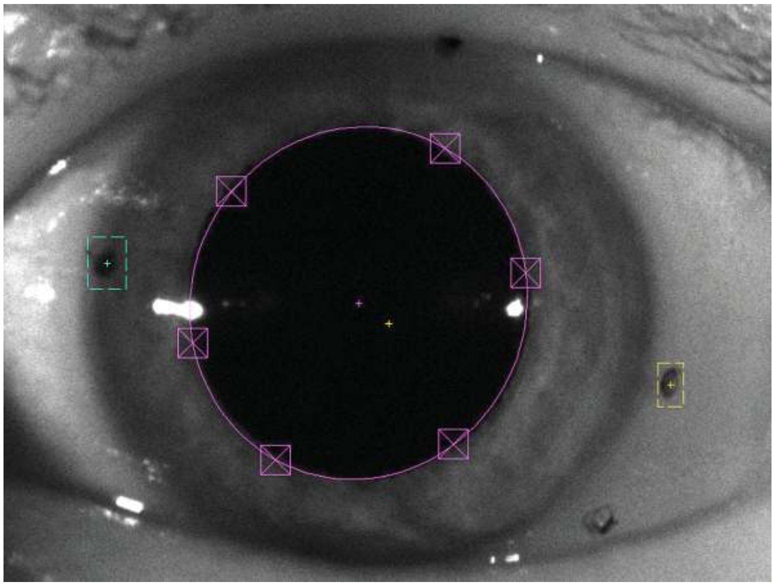

Figure 1.

Lens offset on the eye, captured with the Modular Ophthalmic Measurement System. The central cross within the pupil represents the center of the pupil, while the cross decentered inferior and to the right represents the geometric center of the lens. In this image, four of the five alignment marks on the surface of the lens are visible). One of the 5 marks (pictured lower right) is at a unique angular orientation, allowing determination of the orientation of the lens during wear. A color version of this figure is available online at www.optvissci.com.

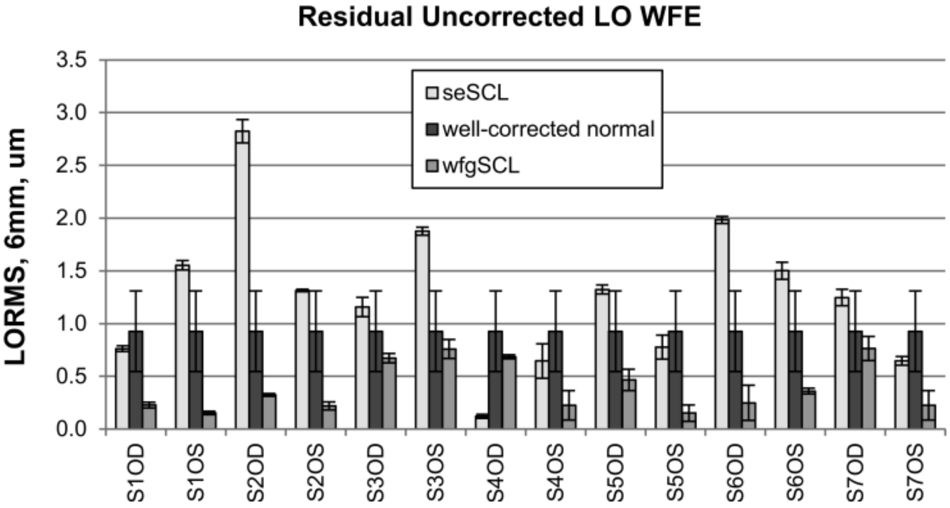

Figure 2.

Mean uncorrected lower-order RMS measured over a 6 mm pupil while wearing the spherical equivalent scleral contact lens (light gray bars) and wfgSCL(gray bars). Residual lower-order RMS reported in the Thibos et al.[43] well-corrected dataset is also presented (dark gray bars).

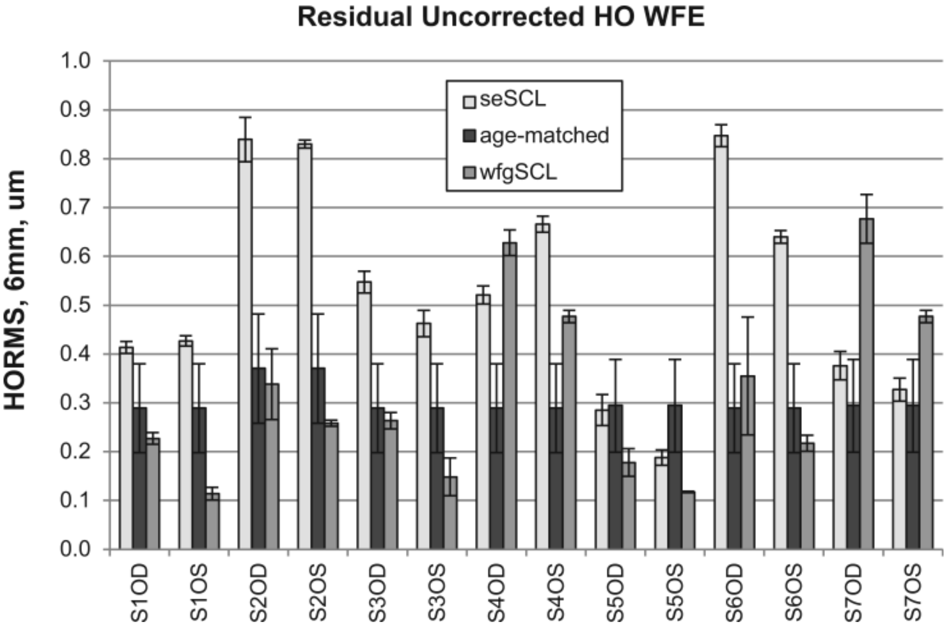

Figure 3.

Mean uncorrected higher-order RMS measured over a 6 mm pupil while wearing the spherical equivalent scleral contact lens (light gray bars) and wfgSCL(gray bars). Age-matched higher-order RMS from Applegate et al.[46] is also presented (dark gray bars).

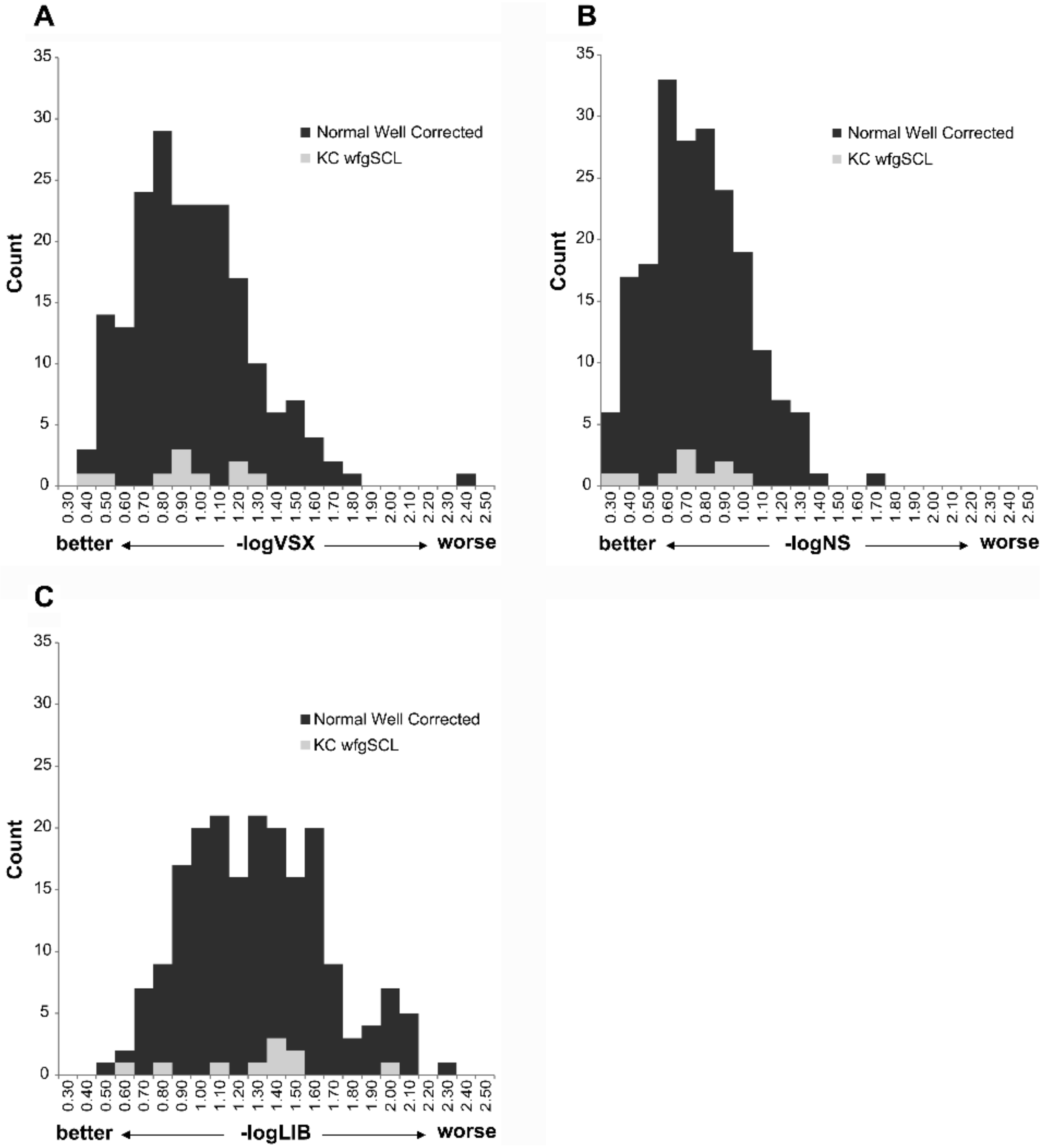

Figure 4.

Well-corrected normal values of logarithm of the visual strehl (logVSX) (4a), logarithm of the neural sharpness (logNS) (4b) and logarithm of light in the bucket (logLIB) (4c) plotted with values generated from the residual aberration measured during wfgSCL wear for the 10 eyes that met the exit criterion. For all 3 metrics, the wfgSCL-corrected eyes provide optical performance comparable to those in the normal, well corrected population.

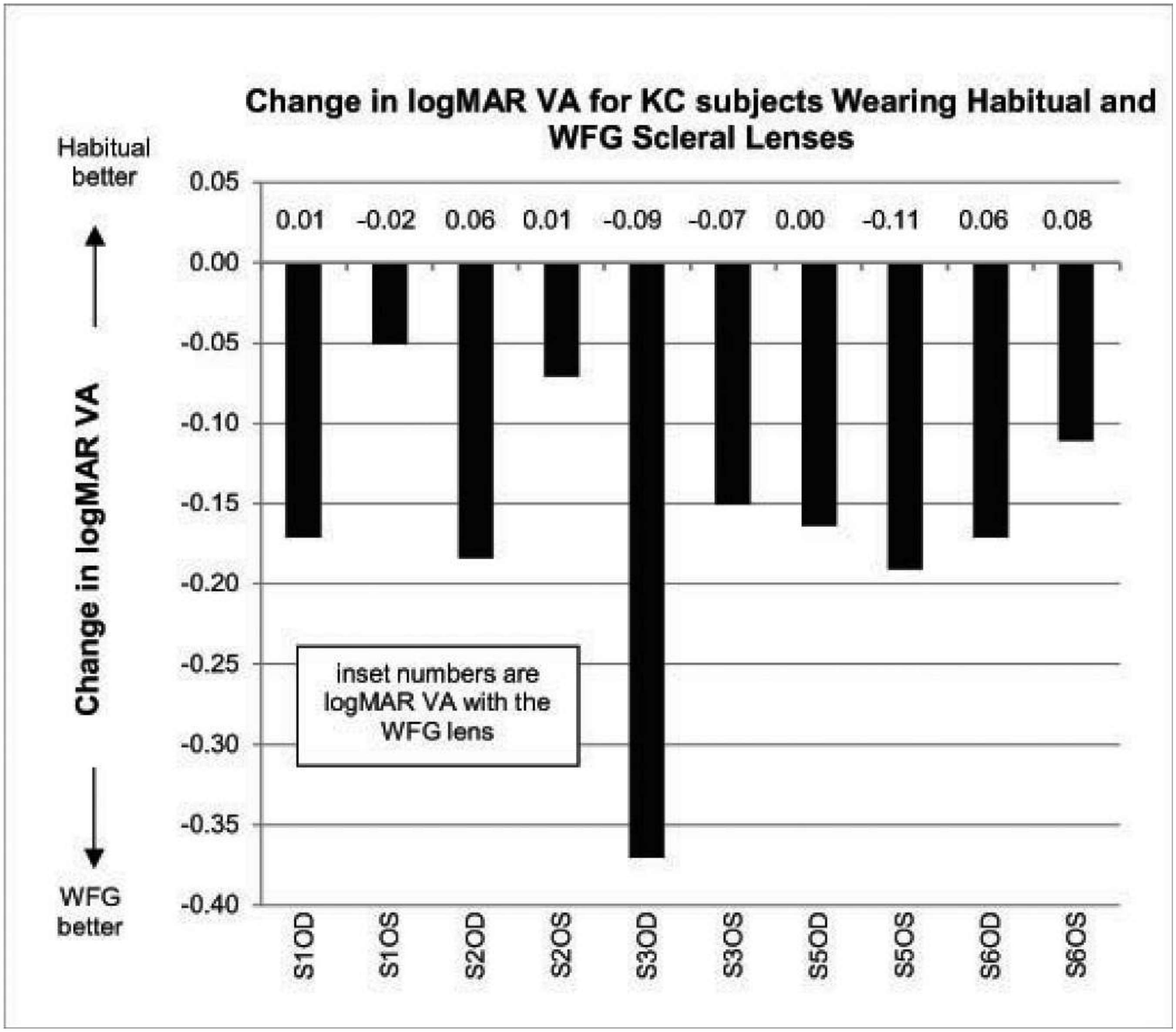

Figure 5.

The improvement in high contrast logMAR VA for 10 eyes from the habitual to wavefront-guided scleral contact lens (wfgSCL). Inset numbers above each bar indicate levels of VA achieved with the wfgSCL.

Table 1

Inclusion criteria used for this study.

Study Inclusion Criteria
1. Clinical diagnosis of keratoconus.
2. Uncorrected higher-order RMS levels above age-matched normal levels.
3. Free of corneal scarring in the central 7mm.
4. Free of additional ocular disease and prior corneal surgery.
5. Free of systemic disease that would confound the visual measurements.

Table 2

Steep K, Disease Severity and Habitual Correction. The steep K values (determined from topography), Collaborative Longitudinal Evaluation of Keratoconus severity score and habitual mode of correction are reported for each eye enrolled in the study.

	OD			OS		
Subject	**Steep K (D)**	**CLEK Severity**	**Habitual Correction**	**Steep K (D)**	**CLEK Severity**	**Habitual Correction**
S1	51.4	moderate	soft CL	50.65	moderate	soft CL
S2	58.2	severe	RGP	55.3	severe	RGP
S3	57.9	severe	soft CL	57.0	severe	soft CL
S4	49.0	moderate	RGP	54.3	severe	RGP
S5	51.2	moderate	scleral CL	45.1	moderate	none
S6	57.0	severe	hybrid CL	56.3	severe	hybrid CL
S7	56.0	severe	RGP	51.5	moderate	RGP

Table 3

Habitual Visual Acuity. The habitual entrance visual acuity was better than 20/40 (0.30 logMAR) in all eyes. One eye performs at or better than 0.00 logMAR, (20/20 Snellen).

	S1	S2	S3	S4	S5	S6	S7	AVG	STDEV
OD	0.18	0.24	0.28	0.16	0.23	0.22	0.01	0.14	0.10
OS	0.03	0.07	0.08	0.08	0.19	−0.03	0.17		

Table 4

LogMAR visual acuity with the wfgSCL by eye, as well as the age-matched normative values reported by Elliott et al.[45]

WFG	**S1**	**S2**	**S3**	**S5**	**S6**	**AVG**	**STDEV**
OD	0.01	0.06	−0.09	0.00	0.06	−0.01	0.07
OS	−0.02	0.01	−0.07	−0.11	0.08		
Age-matched	−0.14 ± 0.07	−0.13 ± 0.05	−0.14 ± 0.07	−0.16 ± 0.06	−0.13 ± 0.06		