Scleral lens wear following penetrating keratoplasty: changes in corneal curvature and optics

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Abstract

Purpose: Visual rehabilitation following penetrating keratoplasty is the primary indication for approximately 15% of all scleral lens fittings. Since corneal biomechanics are altered following penetrating keratoplasty, the aim of this study was to quantify changes in anterior corneal optics following short-term scleral lens wear in eyes with corneal grafts.

Methods: Scheimpflug images were obtained before and after a period of scleral lens wear (mean 6.3 ± 1.4 h), from eyes that had previously undergone penetrating keratoplasty (10 eyes of nine participants, mean age 31 ± 9 years). Corneal power and thickness data were examined over the central 6 mm, including regional analyses of the central (0–3 mm) and the mid-peripheral cornea (3–6 mm annulus) using customised software to determine corneal power vectors M (best fit sphere), J0 (90/180 astigmatism) and J45 (45/135 astigmatism). Anterior corneal aberrations were extracted using corneal elevation data.

Results: Corneal power vector J45 increased following lens wear (by 0.22 ± 0.05 D, p = 0.003) across the central 6 mm, while M displayed regional variations following lens wear indicating larger changes further from the corneal centre (p = 0.004). The change in corneal power vector M was also correlated with the magnitude of central corneal swelling (r = 0.65, p = 0.04). The anterior corneal aberration terms of oblique astigmatism, horizontal coma, and spherical aberration also varied following lens wear (all p ≤ 0.01). The mean change in the corneal spherocylinder derived from the elevation data following lens wear was +0.14/−0.54 for a 6 mm corneal diameter.

Conclusions: Clinically significant alterations in anterior corneal topography and higher order aberrations were observed following short-term scleral lens wear in eyes that had undergone penetrating keratoplasty. Spherocylindrical changes were approximately double the magnitude and more oblique in orientation compared to previous reports of healthy eyes. Changes in corneal power vector M may be related to epithelial corneal oedema.

Introduction

Both soft1 and rigid2 corneal contact lenses can alter corneal topography, dependent upon the lens design,3 the fitting relationship with the anterior corneal surface,4 and the duration of lens wear.5 Even appropriately fitted scleral lenses, which do not contact the cornea, have been shown to alter corneal curvature and optics in healthy6,7 and keratoconic eyes8,9 following short periods of lens wear. These changes are thought to arise from either the post-lens fluid reservoir suction forces generated beneath a sealed scleral lens, or due to compression of the conjunctival and scleral tissue adjacent to the limbus10 that indirectly alters the corneal shape. Earlier work suggested changes in keratometry
values were associated with corneal oedema during scleral lens wear, but more recent studies have not observed this association.

While the primary indication for scleral lens fitting is the refractive correction of corneal ectasia, approximately 15% of scleral lens fits are for the correction of significant irregular astigmatism following penetrating keratoplasty. In such cases, a scleral lens is an ideal optical correction since the lens is very stable and can vault the graft-host interface, unlike corneal rigid lenses, minimising potential mechanical irritation from lens movement or bearing and reducing the potential for graft rejection or failure. Contact lens correction of monocular corneal graft patients is particularly useful, due to the large degree of anisometropia often induced, and subsequent aniseikonia with full spectacle prescription.

The aim of the current study was to quantify the magnitude of change in anterior corneal curvature and optics following a short-period of scleral lens wear in eyes that had previously undergone penetrating keratoplasty and were dissatisfied with other optical corrections. Understanding the nature of the changes in the curvature and optics of the anterior cornea following scleral lens wear is of particular relevance to contact lens practitioners refitting existing scleral lens wearers, and ophthalmic surgeons considering procedures to reduce post-operative ametropia in eyes following penetrating keratoplasty (e.g. topography-guided LASIK or PRK, or cataract surgery).

Methods

Nine participants (mean age 31 ± 9 years, five females and four males) who had previously undergone penetrating keratoplasty for keratoconus were recruited from patients that presented to a hospital based contact lens clinic for scleral lens fitting. This study was approved by the Narayana Nethralaya Institutional Review Board and adhered to the tenets of the Declaration of Helsinki. Written informed consent was obtained from all participants.

An anterior segment examination was conducted to confirm suitability for inclusion with no contraindications to scleral lens wear. Keracare (www.acculens.com) scleral diagnostic contact lenses were used to determine the optimal fitting trial lens. These are non-fenestrated lenses made from roflufocon D (Dk of 100 and 250 µm centre thickness) with a standard spherical landing zone. Scleral lens assessments were conducted by a single experienced optometrist following the manufacturer’s recommended fitting approach. Lenses were applied with saline and sodium fluorescein and assessed using a slit-lamp biomicroscope to ensure an initial post-lens fluid reservoir thickness of ~250 to 300 µm (judged by comparison with the lens centre thickness). The haptic fit was then assessed to ensure there were no obvious changes in conjunctival tissue or vasculature. If the central clearance and haptic alignment were acceptable, the lens was allowed to settle for 1 h and was then reassessed to ensure that the lens remained centred, vaulted the cornea, and the post-lens fluid reservoir was free of air bubbles.

At least 1 week later, a second visit was scheduled, and habitual contact lens wearers were advised to discontinue lens wear for at least 10 days prior to this visit. Corneal curvature, power, elevation, and thickness data were obtained using Pentacam Scheimpflug imaging (www.pentacam.com) before and immediately following a period of scleral lens wear of at least 4 h (mean wearing time 6.3 ± 1.4 h, range 4–8.5 h). The scleral lens worn was the optimal fitting diagnostic lens determined in the trial fitting at the previous study visit. Three repeated measures were obtained before and after lens wear and data were exported from the Pentacam in a square grid format with data point spacing of 0.1 mm for analysis using customised software.

Data analysis

Since measurements were obtained from both right (7) and left (3) eyes, all left eye data were rotated around the vertical midline to ensure all maps were oriented as right eyes to avoid potential errors associated with enantiomorphism during the analysis. The three measurements obtained for each participant at each time point were averaged using the customised software. Averaged pre-lens wear maps were subtracted from the averaged post-lens wear maps for each participant to generate difference maps. Data analysis was confined to the central 6 mm of the cornea to exclude any peripheral regions with missing data.

The best fit corneal spherocylinder was calculated from anterior axial power maps (derived from the corneal elevation data) using a least squares fitting approach with the surface referenced to the videokeratoscope axis. The corneal spherocylinder was converted to power vectors M (best sphere), J0 (astigmatism at 90/180°), and J45 (astigmatism at 45/135°). A root mean square error term was also calculated as a measure of topographic irregularity (i.e. a quantification of by how much the cornea deviates from a perfect spherocylinder). The anterior corneal wavefront across the central 6 mm centred on the instrument axis was generated from the anterior corneal elevation data using a three dimensional ray tracing technique with the image plane set as the circle of least confusion using a wavelength of 555 nm. Zernike polynomials were fitted to the wavefront up to and including the eighth radial order, however, data is only reported up to the 4th order, since these terms have the greatest impact upon vision. Dioptric power maps were generated as described by Iskander et al.
Statistical analyses

A series of repeated measures analysis of variance (RM-ANOVA) were used to examine the change in various corneal parameters following lens wear. The normality of the data was confirmed using the Kolmogorov-Smirnov test, and violations of sphericity were adjusted using the Greenhouse-Geisser correction. The variation in the change of anterior axial curvature across the central cornea following lens wear was examined using an RM-ANOVA with two within subject factors of corneal segment (eight 45 degree segments) and location (the central 0–3 mm, and the mid-peripheral 3–6 mm) (Figure 1). The change in corneal parameters M, J0, J45, and the spherocylinder root mean square (RMS) following lens wear were also investigated using a RM-ANOVA across the central 6 mm (within subject effect of time, pre and post lens wear) and also as a function of corneal location (additional within subject effect comparing the central 0–3 mm and the mid-peripheral 3–6 mm). Changes in anterior corneal higher order aberrations across a 6 mm diameter were also examined using an RM-ANOVA for individual Zernike coefficients (2nd to 4th radial order), and RMS terms (2nd to 4th order RMS, higher order (HO) RMS, and total RMS). Bonferroni corrected post-hoc comparisons were conducted for any significant main effects and interactions with multiple comparisons. Pearson’s correlation was used to assess the association between the magnitude of central corneal swelling with corneal vectors M, J0 and J45 (all using a 6 mm diameter). All statistical analyses were performed using IBM SPSS statistical software v. 25 (https://www.ibm.com/analytics/spss-statistics-software).

Results

Spherocylinder analysis (central 6 mm)

Averaged across the central 6 mm, only corneal power vector J45 varied significantly following lens removal (F = 16.09, p = 0.003) (−0.22 ± 0.05 D change) (Table 1). The mean spherocylindrical corneal change based on the axial power data was +0.12/−0.43 × 130, from +52.43/−4.76 × 114 prior to lens wear to +52.52/−5.12 × 115 immediately after lens removal. The magnitude of change in corneal vector M was positively correlated with the magnitude of total corneal swelling (r = 0.65, p = 0.04).

Anterior corneal axial power regional analysis

Figure 2 highlights the change in anterior axial corneal curvature following lens wear. The RM ANOVA for regional variations in the change in anterior axial corneal power revealed no significant effect of corneal zone (F = 1.55, p = 0.17), but a significant effect of radius (F = 8.12, p = 0.02) indicating that the change in axial corneal power following lens wear was similar across each segment examined, but significantly greater further from the central cornea; −0.04 ± 0.19 D change for the central 0–3 mm region compared to a −0.40 ± 0.08 D change for the mid-peripheral 3–6 mm annulus.

Corneal annuli (0–3 and 3–6 mm)

The best-fit spherical corneal power (M) varied significantly with location (F = 15.29, p = 0.004; 2.14 ± 0.55 D greater in the mid-periphery compared to centrally) averaged across both time points, as did the spherocylinder RMS (F = 22.44, p = 0.001); 1.34 ± 0.28 D greater in the mid-periphery compared to centrally) (Table 2). An effect of lens wear was observed for J45 only (as observed in the corneal diameter analysis described above), and a corneal location by time interaction was also observed for power vector M (F = 9.83, p = 0.01) indicating that greater changes were observed in the mid-periphery following lens wear.

Table 1. Mean ± S.E. corneal parameters from the axial power data before and after lens wear averaged across the central 6 mm.

|                | Pre     | Post    | p-value |
|----------------|---------|---------|---------|
| M (D)          | 50.05 ± 0.84 | 49.96 ± 0.73 | 0.61    |
| J0 (D)         | −1.61 ± 0.83  | −1.65 ± 0.78  | 0.76    |
| J45 (D)        | −1.75 ± 0.76  | −1.96 ± 0.80  | 0.003   |
| Spherocyl-RMS (D) | 4.10 ± 0.60  | 4.07 ± 0.62  | 0.71    |

p-value denotes the pre vs post lens wear comparison across the central 6 mm from the repeated measures analysis of variance (RM-ANOVA). Bold value denotes P < 0.05.
wear compared to centrally (central change 0.10 ± 0.23 D and mid-peripheral change −0.28 ± 0.14 D).

Anterior corneal aberrations

Dioptric power maps generated from the wavefront fitted to the anterior corneal elevation data before and after lens wear are displayed in Figure 3 and the individual Zernike coefficients for radial orders 2–4 are displayed in Figure 4. Statistically significant changes following lens wear were observed for terms $Z(2,−2)$ oblique astigmatism ($F = 11.18$, $p = 0.009$; pre lens wear $−3.60 ± 1.60$ µm, post lens wear $−4.00 ± 1.58$ µm), $Z(3,1)$ horizontal coma ($F = 10.77$, $p = 0.01$; pre lens wear 0.641 ± 0.328 µm, post lens wear 0.344 ± 0.348 µm), and $Z(4,0)$ primary spherical aberration ($F = 10.75$, $p = 0.01$; pre lens wear 1.206 ± 0.206 µm, post lens wear 1.071 ± 0.200 µm). Other individual Zernike terms coefficients or RMS values (2nd to 8th order, higher order, and total RMS) did not vary with lens wear ($all p > 0.05$).

Discussion

This is the first study to examine the effects of short-term scleral lens wear upon corneal parameters in post-penetrating keratoplasty eyes. Statistical and clinically significant changes were observed in anterior corneal topography immediately following lens removal, most notably an increase in corneal parameter $J_{45}$ (i.e. an increase in oblique astigmatism of ~0.50 DC), with greater changes in corneal power vector $M$ observed further from the corneal centre, towards the graft-host junction (Tables 1 and 2). While several studies have reported the changes in healthy and keratoconic eyes following scleral lens wear (typically a central and superior corneal flattening), eyes with corneal grafts appear to respond differently to scleral lens wear. The optical changes observed in the current study were larger than those reported previously following short-term scleral lens wear in healthy eyes. For example, the mean change in the spherocylinder correction derived from the dioptric power maps (based on corneal elevation data) was +0.14

Table 2. Mean ± S.E. corneal parameters from the axial power data before and after lens wear for central (0–3 mm) and mid-peripheral (3–6 mm) corneal regions.

|                | 0–3 mm          | 3–6 mm          | $p$-value          |
|----------------|-----------------|-----------------|--------------------|
|                | Pre             | Post            | Pre               | Post               | Time  | Region | Time × Region |
| $M$ (D)        | 48.85 ± 0.95    | 48.95 ± 0.81    | 51.18 ± 0.82      | 50.90 ± 0.74       | 0.63  | 0.004  | 0.01          |
| $J_{0}$ (D)    | −1.61 ± 0.86    | −1.70 ± 0.86    | −1.62 ± 0.80      | −1.60 ± 0.72       | 0.76  | 0.80   | 0.48          |
| $J_{45}$ (D)   | −1.65 ± 0.70    | −1.99 ± 0.78    | −1.84 ± 0.83      | −1.94 ± 0.81       | 0.003 | 0.70   | 0.15          |
| Spherocyl-RMS (D) | 1.51 ± 0.20    | 1.53 ± 0.27    | 2.43 ± 0.34       | 2.57 ± 0.42        | 0.94  | 0.001  | 0.18          |

$p$-values from the repeated measures analysis of variance (RM-ANOVA): Time denotes the pre versus post lens wear comparison averaged across both regions, Region denotes the comparison between the central 0–3 mm and the mid-peripheral 3–6 mm region averaged across both time points, and Time × Region denotes the comparison of the variation in each parameter following lens wear between the central 0–3 mm and the mid-peripheral 3–6 mm region. Bold values denote $P < 0.05$.  

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DS/−0.54 DC for a 6 mm diameter (Figure 3), compared to +0.02 DS/−0.15 DC to +0.10 DS/−0.20 DC for 6–8 mm corneal diameters and wearing times of 3–8 h in previous studies of healthy eyes using the same analysis.6,7 The larger topographical changes observed in this study may be related to changes in corneal biomechanics following surgery, since post-penetrating keratoplasty eyes display reduced corneal resistance and hysteresis in comparison to healthy controls.27 The nature of the change in corneal optics also appears to differ, with normal eyes displaying an increase in with/against the rule astigmatism (x 90/180)6,7 compared to an increase in oblique astigmatism (x 45/135) in post-graft eyes, possibly due to the nature of the underlying natural corneal astigmatism. Epithelial oedema may also play a role in these optical changes, which is often observed in post-graft eyes.28,29 The total corneal oedema averaged across the central 6 mm was correlated with the magnitude of anterior corneal surface change (corneal

Figure 3. The group mean dioptric power maps generated from the wavefront fitted to the corneal elevation data before lens insertion, immediately following lens removal, and the difference (post minus pre lens wear maps). The scale for all maps is in dioptries and varies for lower order (2nd radial order only, top row), higher order (3rd to 8th radial order, middle row) and all Zernike terms (2nd to 8th radial order, bottom row). Note all left eyes have been rotated around the vertical axis and each map is presented in a right eye orientation (positive x axis denotes nasal and positive y axis denotes superior). The pre and post lens wear scale differs from the difference map scale.
vector $\mathbf{M}$, $r = 0.65$, $p = 0.04$), however, no significant correlations were observed between corneal oedema and the magnitude of change in astigmatic power vectors. The magnitude of epithelial tissue swelling cannot be extracted from Scheimpflug images, which is a limitation of the current study. Optical coherence tomography can be used to reliably detect low level epithelial oedema during scleral lens wear,\(^3\) which may provide further insights in future research. Previous studies of both scleral\(^6,7\) and corneal rigid lens\(^3\) wear have not observed a correlation between corneal oedema and anterior surface curvature changes in healthy eyes, most likely because corneal swelling is primarily stromal\(^3\) and in the posterior direction\(^3\)–\(^3\) (i.e. the anterior chamber depth decreases with swelling) for neophyte and adapted lens wearers and in animals. However, this may not be the case in eyes that have undergone penetrating keratoplasty.

The changes observed in anterior corneal shape following lens wear in this study have implications for practitioners relying upon topography measurements obtained shortly after scleral lens removal. This is a common situation in clinical practice when patients present wearing their habitual lenses due to their reliance on the device for functional vision. Accurate measurement of corneal topography is required when refitting an existing scleral lens wearer into a smaller diameter corneal rigid lens or customising the back-surface profile of a scleral lens to optimise the lens fit or vision. Topography or wavefront guided LASIK to correct residual ametropia following penetrating keratoplasty would also be affected by such scleral lens induced corneal changes. For example, wavefront guided surgery based on the corneal Zernike coefficients that varied significantly in this study, would result in incorrect estimates on average of $\sim11\%$ for $Z(2,-2)$ oblique astigmatism and $Z(4,0)$ spherical aberration, and $46\%$ for $Z(3,1)$ horizontal coma (Figure 4). Therefore, although appropriately fitted scleral lenses do not contact the anterior corneal surface, ideally, scleral lens wear must be ceased for a period of time before obtaining corneal topography. The optimum time out of scleral lenses is unknown, however, Vincent \textit{et al}\(^6\) reported that three hours after scleral lens removal in young healthy eyes the change in the sphero-cylinder derived from the corneal wavefront had only reduced by half. This previous regression data may not be applicable to eyes with corneal grafts, since the magnitude of change observed in the anterior corneal sphero-cylinder in the current study was on average approximately double compared to previous studies of healthy eyes.

Several guidelines exist regarding the cessation of contact lens wear for pre-operative corneal imaging for refractive surgery candidates. This is particularly important since many procedures aim to minimise higher order aberrations through a wavefront or topography guided approach.\(^3\)\textit{4},\textit{35} For example, the United States Food and Drug Administration recommends two weeks without soft contact lens wear prior to an initial assessment, three weeks for toric soft or rigid gas permeable (RGP) (presumably corneal) lenses, and 4 weeks for polymethyl methacrylate (PMMA) lenses.\(^3\)\textit{6} The preferred practice pattern for the American Academy of Ophthalmology is three days to two weeks without soft contact lens wear, and discontinuation of soft torics and rigid lenses for “a longer period”\(^3\)\textit{7}. Previous studies examining the stability of corneal topography in refractive surgery candidates following the cessation of contact lens wear have found that the majority of eyes exhibit stable parameters following one to two weeks out of soft lenses and two to 5 weeks out of rigid corneal lenses.\(^3\)\textit{8}–\textit{40} However, Wang \textit{et al}\(^3\)\textit{8} found that $7\%$ of long-term contact
lens wearers displayed persistent corneal warpage which took substantially longer to resolve dependent upon the lens type and wearing modality, on average; four weeks for soft sphere daily wear, 7 weeks for soft torics, 11 weeks for corneal RGP’s, and 13 weeks for soft extended wear. Presumably, the above recommendations for the cessation of RGP wear refer to corneal lenses, which are typically fitted to align with the anterior corneal surface with a certain degree of bearing, in contrast to scleral lens fitting. Further work is still required regarding the minimum required time out of scleral lenses for a range of ocular conditions. To date only Soeters et al9 have examined corneal recovery in regular scleral lens wearers with keratoconus and observed ~0.5–1.00 D of central corneal steepening following cessation of lens wear for at least 1 week.

Limitations of the current study include the small sample size, the use of a single lens design in neophyte scleral lens wearers and the relatively short period of lens wear on a single day, particularly since 50% of post-penetrating keratoplasty patients wear scleral lenses for 10 or more hours per day,41 or two to seven days per week for between 6 and 18 h per day.42 The inclusion of both eyes in the data analyses from one participant may potentially inflate the degrees of freedom and result in a type I error, due to the high degree of symmetry between the fellow eyes.33 However, removal of the second eye from this one participant that had minimal impact upon the results. For the corneal parameter analysis (Table 2), there were no changes in which metrics varied significantly, only small changes in significant p-values (e.g. the vector M region p-value changed from 0.004 to 0.001 and the time J45 p-value changed from 0.003 to 0.005). For the higher-order aberration (HOA) analysis, removal of the additional eye also resulted in small changes in the p-values for Z(2,−2) from 0.009 to 0.008 and Z(3,1) and Z(4,0) both from 0.01 to 0.02. The correlation analysis of corneal oedema and power vector M was also unchanged.

In conclusion, clinically significant changes in anterior corneal topography and higher order aberrations were observed following short-term scleral lens wear in eyes that had undergone penetrating keratoplasty. Changes in the anterior corneal spherocylinder were approximately double the magnitude and more oblique in orientation compared to changes observed previously in healthy eyes. Although appropriately fitted scleral lenses do not contact the anterior corneal surface, practitioners should be mindful of the potential impact of these transient changes with respect to rigid lens fitting and refractive outcomes.

**Conflicts of interest**

The authors report no conflicts of interest and have no proprietary interest in any of the materials mentioned in this article. This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

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