Corneal changes following short-term miniscleral contact lens wear

Stephen J Vincent PhD
David Alonso-Caneiro PhD
Michael J Collins PhD

Corresponding author: Stephen J Vincent

Affiliation for all authors:
Contact Lens and Visual Optics Laboratory, School of Optometry and Vision Science
Queensland University of Technology

Address for correspondence:
Contact Lens and Visual Optics Laboratory, School of Optometry and Vision Science
Queensland University of Technology
Room D513, O Block, Victoria Park Road, Kelvin Grove 4059
Brisbane, Queensland, Australia
Phone: 617 3138 0415, Fax: 617 3138 5880

Word count: 4939, Number of Figures: 2, Number of Tables: 1
Email: sj.vincent@qut.edu.au
Abstract

Purpose: To examine the influence of short-term miniscleral contact lens wear on corneal shape, thickness and anterior surface aberrations.

Methods: Scheimpflug imaging was captured before, immediately following and 3 hours after a short period (3 hours) of miniscleral contact lens wear for 10 young (mean 27 ± 5 years), healthy participants. Natural diurnal variations were considered by measuring baseline diurnal changes obtained on a separate control day without contact lens wear.

Results: Small but significant anterior corneal flattening was observed immediately following lens removal (overall mean 0.02 ± 0.03 mm, p < 0.001) which returned to baseline levels three hours after lens removal. During the three hour recovery period significant corneal thinning (-13.4 ± 10.5 μm) and posterior surface flattening (0.03 ± 0.02 mm) were also observed (both p < 0.01). The magnitude of posterior corneal flattening during recovery correlated with the amount of corneal thinning (r = 0.69, p = 0.03). Central corneal clearance (maximum tear reservoir depth) was not associated with corneal swelling following lens removal (r = -0.24, p > 0.05). An increase in lower-order corneal astigmatism Z(2,2) was also observed following lens wear (mean -0.144 ± 0.075 μm, p = 0.02).

Conclusions: Flattening of the anterior corneal surface was observed immediately following lens wear, while ‘rebound’ thinning and flattening of the posterior surface was evident following the recovery period. Modern miniscleral contact lenses that vault the cornea may slightly influence corneal shape and power but do not induce clinically significant corneal oedema during short-term wear.

Keywords: Miniscleral contact lens, corneal thickness, corneal topography, corneal aberrations, post-lens tear layer
Introduction

Miniscleral contact lenses, a sub-group of scleral contact lenses with a total lens diameter between 15-18 mm which rest entirely upon the sclera,[1] are sealed to the anterior eye with minimal movement upon blinking or ocular versions. They are primarily used for the correction of irregular corneal optics commonly encountered in keratoconus, keratoglobus or following penetrating keratoplasty, as the post-lens tear layer (the fluid reservoir between the posterior lens and anterior cornea) effectively neutralises the majority of corneal astigmatism.[2] More recently, scleral lenses have also been utilised as a therapeutic intervention in cases of ocular surface disease (e.g. exposure keratopathy,[3] Sjogren’s syndrome,[4] Steven-Johnson’s Syndrome[5]) by providing the cornea with continual hydration during lens wear without evaporation.

Previously, scleral lens fitting was largely empirical and primarily relied upon practitioner interpretation of haptic (landing zone) vascular compression of the bulbar conjunctiva. However, advances in anterior eye imaging with corneal topography and optical coherence tomography have resulted in a more reliable and accurate fitting process and along with improved lens designs this has led to a subsequent increase in scleral contact lens prescribing.[1]

Scleral lenses are typically significantly thicker (up to 1300 μm central thickness for full scleral lenses[6]) than corneal rigid gas permeable (RGP) lenses (~140-180 μm[7]), to avoid on eye and handling flexure. Consequently, to counteract this increased thickness, modern scleral lenses are manufactured from highly permeable materials to maximise oxygen transmission to the cornea. This is particularly important since scleral lenses do not move upon blinking to allow freshly oxygenated tears to replenish the post-lens tear layer. The post-lens tear layer varies in depth with lens design, corneal shape and practitioner fitting philosophy and may act as a further barrier to atmospheric oxygen reaching the cornea.[8] Despite these potential hypoxic factors of increased lens thickness, minimal tear exchange
and the presence of a thick post-lens tear layer, there are few clinical reports of significant corneal oedema associated with modern scleral lens wear.

A limited number of studies have attempted to quantify the corneal response following scleral lens wear. In an early study using full scleral lenses, Bleshoy and Pullum[9] reported on corneal oedema in a single subject following five hours of sealed scleral contact lens wear using an RGP material with a Dk of 24. Central lens thickness was varied from 180 to 500 μm and corneal swelling increased slightly with increasing lens thickness from 3.6 to 4.8% centrally and 4.6 to 5.3% in the periphery (although these central and peripheral zones were not defined). More recently, Pullum and Stapleton[10] assessed central corneal swelling for 4 subjects following three hours of sealed scleral lens wear while varying lens thickness and oxygen permeability. Up to 8% corneal swelling was observed for a scleral lens of 1200 μm thickness with a Dk of 32, which reduced as lens thickness was reduced and Dk increased.

Other studies have examined fitting characteristics (e.g. apical clearance[11]) and visual or ocular outcomes (improved acuity,[12] lens tolerance[12] and complications[13, 14]) in relation to scleral contact lenses. In this study, the physiological changes in corneal characteristics (biometrics and optical properties including anterior higher order aberrations) associated with modern miniscleral contact lens wear were assessed in addition to the recovery of these induced changes. Scheimpflug imaging was used to investigate the influence of short-term miniscleral contact lens wear on healthy, young subjects with normal corneae (i.e. without keratoconus or corneal abnormalities including ocular surface disease) over a substantially larger corneal region than previously examined.

**Methods**

This study was approved by the Queensland University of Technology (QUT) human research ethics committee and followed the tenets of the Declaration of Helsinki. All subjects gave written informed consent to participate. The study participants included 10
young, healthy adult subjects (6 females, 4 males) recruited from the QUT School of Optometry and Vision Science aged between 21 and 33 years (mean ± SD age: 27 ± 5 years) with visual acuity of 0.00 logMAR or better. This sample size was chosen based on calculations conducted using previous published data on corneal swelling following short-term scleral lens wear, which suggested that a sample size between 6-12 participants would yield 80% power to detect 2% corneal oedema[10] (or a 3 µm increase in central corneal thickness[15]) at the 0.05 significance level. Prior to commencement of the study, all subjects were screened to exclude those with any contraindications to contact lens wear (i.e. significant tear film or anterior segment abnormalities). Four of the subjects were part time soft contact lens wearers but discontinued lens wear for 24 hours prior to commencing the study, to minimise the effects of soft lens wear on the cornea. None of the subjects were previous rigid contact lens wearers. Participants had no prior history of eye injury, surgery or current use of topical ocular medications.

Experimental overview

The influence of short-term miniscleral contact lens wear (3 hours duration) upon measures of anterior and posterior corneal topography, corneal thickness and anterior corneal aberrations was examined using Scheimpflug imaging. The study was conducted over three separate days; day one involved an ophthalmic screening and miniscleral contact lens fitting, day two included baseline diurnal corneal measurements obtained without contact lens wear and day three involved the capture of corneal measurements before and after contact lens wear.

On day two, baseline measurements were obtained without contact lens wear, in the morning (0 hours, session 1) and then repeated 3 hours (session 2) and 6 hours later (session 3). On day three, the subjects wore an optimal fitting miniscleral contact lens (according to the manufacturers fitting guide) in their left eye only, with measurements collected in the morning before the lens was inserted (0 hours, session 1), immediately after
lens removal following 3 hours of wear (session 2) and finally 3 hours after lens removal (i.e. 6 hours after initial lens insertion) (session 3).

The timing of the measurement sessions for days two and three were matched for each participant to allow for the control of the confounding influence of diurnal variation[16] during analysis and were scheduled between 9:00-11:00 AM (session 1), 12:00-2:00 PM (session 2) and 3:00-5:00 PM (session 3). Between measurement sessions, participants were free to go about their daily activities, however, most remained in our laboratory engaged in computer based work or study. Baseline measurements (day two) were conducted at least 12 hours after the initial contact lens fitting (on day 1) to minimise the potential influence of any ocular surface changes associated with the fitting process. Day three was scheduled within one week of day two to limit the influence of monthly cyclical changes upon corneal biometrics.[17]

Following the removal of the lens on day three, each participants left eye was re-examined using a slit lamp biomicroscope to assess the anterior eye. The Efron grading scale for contact lens complications[18] was used by the same examiner to quantify conjunctival (inferior, superior, nasal and temporal) and corneal (inferior, superior, nasal, temporal and central) fluorescein staining to the nearest 0.1 scale unit.

**Contact lens assessment**

The contact lenses used in this study were Irregular Corneal Design (ICD™ 16.5, Paragon Vision Sciences, USA) non-fenestrated miniscleral lenses made from hexafcon A material (Boston XO) with a Dk of 100 x 10^{-11} (cm^2/sec) (ml O_2/ml x mmHg), central thickness of 300 μm and overall diameter of 16.5 mm. The optimal fitting contact lens was determined according to the manufacturers fitting guide. In brief, the initial diagnostic lens was selected based on the participants corneal sagittal height measured over a 10 mm chord (along the steepest corneal meridian) using a videokeratoscope (E300, Medmont, Australia) which was then extrapolated to a 15 mm chord (i.e. the distance to the landing zone of the ICD lens).
The lens was inserted into the patients left eye with preservative free saline and sodium fluorescein and assessed using a slit lamp biomicroscope. If an air bubble was present, the lens was removed and reinserted. The fluorescein pattern was assessed to ensure adequate central and limbal corneal clearance. If regions of corneal bearing were observed, the sagittal depth of the lens was increased (in 100 μm increments) and the fit reassessed. After an adequate fit was obtained, the lens was then allowed to settle for one hour, and was re-examined using the slit lamp. The final fluorescein pattern for all subjects showed central corneal clearance (sufficient to obscure visualisation of the pupil and iris features with sodium fluorescein), slight superior mid-peripheral to peripheral pseudo-bearing (an apparent area of bearing that disappeared on downward gaze) and sodium fluorescein “bleed” beyond the limbus onto the conjunctiva. Conjunctival blood vessels were examined under white light within the scleral landing zone to ensure there was no restriction or blanching of the vessels due to excessive peripheral seal off. The contact lens fit was assessed by the same examiner during the trial lens fitting (with sodium fluorescein) and on the day of lens wear (without sodium fluorescein) to ensure a well centred fit without any air bubbles. After one hour of lens settling, the corneal clearance was measured using an anterior spectral domain optical coherence tomographer (Spectralis, Heidelberg, Germany). A high resolution corneal volumetric scan protocol was used (15 x 10 degrees, 8.3 x 5.5 mm) consisting of 21 B scans (each separated by 277 μm) centred on the corneal reflex visualised in the scanning laser ophthalmoscope image. The callipers within the analysis software were used to mark the position of the back surface of the miniscleral contact lens and the anterior surface of the corneal epithelium to provide a measure of the central corneal clearance at the position of the corneal reflex. The mean final central corneal clearance was 403 ± 204 μm. Alterations to the tangent curve of the limbal clearance zone or the edge lift of the scleral landing zone were not required to obtain an adequate fit, so during the experiment all participants wore the diagnostic trial lens which provided an optimal fit.

**Anterior segment imaging**
The Pentacam HR system (Oculus, Wetzlar, Germany) which uses a rotating Scheimpflug camera (a digital camera with a slit illumination system) was used to evaluate the anterior and posterior corneal curvature and corneal thickness at each measurement session. A total of 5 error free measurements were captured using the 25 picture 3D scan mode, which provides 25 cross-sectional images of the anterior eye. This instrument has been shown to be highly repeatable for measures of central[19] and peripheral[19, 20] corneal thickness and anterior[21] and posterior[22] corneal topography including subtle corneal changes following contact lens wear[23], while reports concerning the repeatability of anterior higher order corneal aberrations vary depending on the individual aberrations examined.[24, 25]

Data analysis

Following data collection, the raw corneal curvature, elevation and pachymetry data from all five measurements on each participant (for each time point) were exported from the Pentacam for further analysis. The pupil offset (the geometric offset between the pupil centre and the centre of the topography map centre) was also recorded for each measurement. Using custom written software, the five maps obtained for each participant were averaged for each time point. The baseline data obtained on day 2, without contact lens wear, was then used to calculate the normal diurnal change in each corneal parameter (thickness, anterior and posterior curvature and elevation) at each afternoon measurement time point (sessions 2 and 3) relative to the morning measurement (session 1). This was done by subtracting the session 1 mean measurement (9:00-11:00 AM) from the session 2 mean measurement (12:00-2:00 PM) and likewise, the session 1 mean measurement (9:00-11:00 AM) from the session 3 mean measurement (3:00-5:00 PM) for each participant.

The same procedure was then used to examine the influence of short-term miniscleral contact lens wear upon the corneal parameters. The mean session 1 (day 3) data (prior to lens insertion) was subtracted from both the session 2 (day 3) mean data (immediately following lens removal) and also the session 3 (day 3) data (following 3 hours recovery) for
each participant. To eliminate the potential confounding influence of diurnal variations, the normal diurnal fluctuations calculated from the day 2 baseline data were also subtracted to generate ‘difference’ data (the change in corneal parameters immediately following lens removal and 3 hours after lens removal) which represents changes due to lens wear only. All analysis presented refers to these data that have been corrected for normal diurnal variations in corneal parameters.

The average maps from all the subjects were further analysed in order to study the regional distribution of corneal change. The average corneal thickness and anterior/posterior curvatures were calculated for each subject within both central (0-3 mm) and peripheral (3-6 mm) annular corneal zones and inferior and superior regions within these central and peripheral zones. The corneal elevation data from the Pentacam was also analysed to determine the anterior corneal wavefront over a 6 mm analysis diameter using a three dimensional ray tracing procedure described previously.[26] The wavefront was centred on the line of sight by using the pupil offset values from the pupil detection function in the Pentacam as the reference axis for the wavefront. The image plane was at the circle of least confusion and the wavelength used was 555 nm. Zernike wavefront polynomials were fitted to the wavefront error (up to and including the eighth radial order) and expressed using the double index notation (Optical Society of America [OSA] convention[27]). This procedure was conducted for the five topography measurements per participant (at each time point on each day of testing) and the mean calculated. While an eighth order polynomial expansion was used to optimise the fit to the corneal elevation data, statistical analysis was restricted to 2nd to 4th order terms, since these aberrations have the greatest influence upon optical quality.[28]

To examine the statistical significance of changes due to short term miniscleral contact lens wear, a repeated measures analysis of variance (ANOVA) was used with corneal zone (central and peripheral) and region (superior and inferior) as within-subject factors for analysis of changes in corneal thickness and curvature. For the analysis of anterior surface
aberrations, a repeated measures ANOVA was also conducted, examining the wavefront over a 6 mm corneal diameter. Degrees of freedom were adjusted using Greenhouse-Geisser correction to prevent any type 1 errors, where violation of the sphericity assumption occurred. Bonferroni adjusted post-hoc pair-wise comparisons were carried out for individual comparisons. Pearson’s correlation coefficient was used to quantify the association between the changes in corneal thickness and anterior and posterior curvature changes in the central and peripheral corneal regions and the change in corneal parameters with the central corneal clearance (i.e. the thickness of the post-lens tear layer). All statistical analyses were conducted with SPSS (version 21.0) statistical software.

Results

Trace levels of corneal and conjunctival fluorescein staining were observed following lens wear. Immediately after lens removal the mean (± SD) grade of conjunctival staining was; 0.3 ± 0.4 inferiorly, 0.3 ± 0.5 superiorly, 0.3 ± 0.5 nasally and 0.3 ± 0.4 temporally, while the mean grade of corneal staining was; 0.5 ± 0.7 inferiorly, 0.2 ± 0.4 superiorly, 0.2 ± 0.3 nasally and 0.4 ± 0.6 temporally. No central corneal staining (grade 0.0 ± 0.0) was observed in any participant following lens wear. Low grade corneal and conjunctival staining of this severity (i.e. less than grade 1.0) is considered clinically insignificant and typically does not require intervention.[18]

Corneal thickness

Figure 1A displays the group mean change in corneal thickness immediately following and three hours after lens removal relative to pre-lens wear pachymetry measurements after accounting for diurnal fluctuations. There was no evidence of clinically significant corneal swelling following three hours of lens wear with a mean increase in corneal thickness over a 6 mm diameter of 5.0 ± 17.9 μm (0.85% swelling) (p > 0.05). The greatest magnitude of corneal swelling (~8 μm or 1.4%) was observed in the inferior cornea (3-6 mm annulus) (Table 1). However, significant thinning relative to baseline corneal thickness was observed
three hours following lens removal (13.4 ± 10.5 μm, 2.3% thinning, p < 0.01). Small variations observed between corneal regions (inferior-superior and central-peripheral) did not reach statistical significance suggesting a largely symmetrical or uniform corneal response (Table 1).

**Anterior corneal curvature**

Miniscleral lens wear resulted in significant anterior corneal flattening, primarily in the vertical meridian (Figure 1B). The group mean change over a 6 mm corneal diameter was 0.02 ± 0.03 mm immediately following lens removal (p < 0.001), which regressed to baseline curvature values three hours later (0.00 ± 0.02 mm mean change from baseline). Anterior corneal flattening was slightly greater in the superior cornea (0.03 ± 0.03 mm) compared to the inferior cornea (0.02 ± 0.03 mm) possibly due to forces associated with the upper eyelid, however, this regional difference was not statistically significant (p > 0.05). Similarly, the magnitude of the difference in change between the central and peripheral corneal regions did not reach statistical significance (Table 1).

**Posterior corneal curvature**

Conversely, posterior corneal curvature remained stable following lens wear, with a mean group change immediately after lens removal of 0.01 ± 0.03 mm (p > 0.05). Greater changes in posterior curvature were observed centrally (0-3 mm, 0.01 ± 0.03 mm) compared to peripherally (3-6 mm, 0.00 ± 0.03 mm), but did not reach statistical significance (Table 1, Figure 1C). Three hours after lens removal, significant posterior corneal flattening was observed (0.03 ± 0.02 mm over a 6 mm diameter, p < 0.01). This posterior flattening was positively correlated with the rebound corneal thinning also observed during the recovery period (r = 0.69, p = 0.03).

**Anterior corneal aberrations**
Analysis of the change in each individual Zernike coefficient up to and including the fourth order revealed that only Z(2,2) (lower order horizontal/vertical astigmatism) underwent a statistically significant change immediately following miniscleral lens wear (-0.144 ± 0.075 μm) and three hours after lens removal (0.214 ± 0.064 μm) (p = 0.02). Third and fourth order higher aberration terms (or 3rd and 4th order RMS values) remained stable over time (p > 0.05). Figure 2 displays the mean group change in lower and higher order anterior corneal aberrations immediately after lens removal and following 3 hours recovery, represented as Zernike refractive power maps[29] derived from the change in the anterior corneal wavefront. The mean change in the anterior corneal sphero-cylinder following lens removal was +0.10/-0.20 x 108, which reduced to +0.05/-0.09 x 163 following 3 hours recovery. The smallest anterior surface sphero-cylinder change observed in an individual participant was +0.05/-0.03 x 64, while the largest was +0.36/-0.67 x 116, with four of the ten participants exhibiting a refractive power change greater than 0.50 DC (as determined from the change in the wavefront).

Discussion

This is the first study to examine regional changes, and their recovery, in corneal thickness and anterior and posterior curvature following short-term miniscleral contact lens wear. All participants had normal corneae and consequently a somewhat larger than usual post-lens tear layer (mean central corneal clearance 403 ± 204 μm) compared to patients with corneal abnormalities, but a similar clearance for patients fitted with scleral lenses for ocular surface disease[11]. Importantly, the measurements reported in this study have taken into account the diurnal fluctuations in all corneal parameters measured (thickness, curvature and anterior higher order aberrations) for each participant.

There was no evidence of either central (0-3 mm diameter, 0.82% thickness increase) or peripheral corneal oedema (3-6 mm annulus, 0.87% thickness increase) following 3 hours of miniscleral lens wear. However, three hours after lens removal, corneal thickness was
significantly reduced in both central (2.29%) and peripheral (2.26%) regions compared to baseline (p < 0.01). The small variations observed between corneal regions (inferior-superior and central-peripheral) did not reach statistical significance suggesting a largely symmetrical corneal response with respect to thickness changes. While the superior cornea may be more prone to oxygen deprivation during contact lens wear due to the position of the upper eyelid, the corneal swelling observed immediately following lens removal was greatest inferiorly. The magnitude of corneal swelling observed averaged over the central 6 mm (mean 5 ± 17 μm) following three hours of lens wear was similar to that reported by Mountford et al[15] following short-term full scleral lens wear (121 Dk, 800 μm centre lens thickness) of approximately 1 μm swelling per hour of lens wear.

The statistically significant corneal thinning (or ‘de-swelling’) observed three hours after lens removal to levels below the baseline corneal thickness (referred to as corneal ‘overshoot’) has been observed previously in response to a hypoxic corneal environment following both soft[30] and rigid[31] lens wear or overnight eyelid closure.[32] This response is poorly understood but is thought to be due to corneal hydration factors including tear film evaporation rates and endothelial fluid influx or ion pump capacity.[33, 34] While statistically or clinically significant corneal oedema was not observed following lens removal, the corneal thinning overshoot observed during the follow up period suggests that the cornea was possibly recovering from subclinical hypoxic stress.

Michaud et al[8] recently modelled the oxygen transmissibility of scleral contact lenses taking into consideration lens thickness, oxygen permeability of the lens material and the post-lens tear layer thickness. The authors calculated that a scleral contact lens with a Dk of 100, lens thickness of 300 μm and central corneal vault of 400 μm (similar to the lens and mean fitting characteristics in our study) would yield a predicted oxygen transmissibility of 12.5 Fatt Dk/t units which would not satisfy the Holden-Mertz criterion for successful daily lens wear (i.e. hypoxic-related corneal swelling >4% would be induced[35]). However, clinically or statistically significant corneal swelling was not observed following short-term lens wear in
our participants with healthy corneae. There was also no correlation between apical corneal clearance (i.e. the maximum depth of the tear reservoir) and the change in corneal thickness following lens removal for the central ($r = -0.25$, $p > 0.05$) or peripheral corneal regions ($r = -0.23$, $p > 0.05$). This lower than predicted level of swelling may be due to some level of tear exchange occurring beneath the lens.

Prolonged hypoxic stress as a result of miniscleral contact lens wear (associated with a thick and stagnant post-lens tear layer) could potentially lead to a loss of corneal transparency and an inflammatory response including limbal neovascularisation, however, such complications are uncommon in modern scleral lens wear. Tan et al[13] reported on adverse events associated with fenestrated PMMA scleral lens wear with corneal neovascularisation and oedema the most common complications, occurring in 13.3% and 7.4% of patients respectively. However, a more recent retrospective analysis of 97 scleral lens wearers (using contemporary highly permeable RGP materials with an oxygen transmissibility of 97 or 125 x $10^{-11}$ Fatt Units), reported a failure rate of only 1.3% as a direct result of corneal oedema or neovascularisation.[36] This study of long-term scleral lens wearers (2-71 months duration) is in general agreement with our short-term findings that oxygen supply to the cornea during high Dk miniscleral lens wear is sufficient to avoid clinically significant corneal oedema.

Relatively few studies have reported on the change in corneal curvature following scleral lens wear. In a single subject, Bleshoy and Pullum[9] observed a small but consistent flattening of the principal corneal meridians following a short period of lens wear (0.14 mm for the flattest meridian and 0.01 mm for the steepest meridian) for the same sealed scleral lens design of varying central thickness. However, following only 5 of hours lens wear, central keratometry mires often appeared distorted and corneal striae were observed along with mild superficial central staining. Murphy et al[37] also examined the effect of brief (30 minutes) wear of scleral search coils; a scleral lens annulus imbedded with a wire coil commonly used to record eye movements.[38] Small changes in central corneal curvature
were observed following lens wear; typically less than 0.05 mm, but in some cases as large as 0.1 mm. A slight flattening of the vertical meridian was typically observed (potentially due to eyelid pressure on the annulus) and a somewhat smaller steepening of the horizontal meridian. These studies suggest that subtle changes in central corneal curvature may occur following the use of contact lenses that primarily interact with the peripheral cornea, conjunctiva and sclera and are consistent with our findings of a flattening of the anterior corneal surface (primarily in the vertical meridian, superior corneal region) following miniscleral lens wear. Since there was no association between the change in corneal thickness and the change in anterior corneal curvature following lens wear, and given that changes in corneal curvature associated with hypoxia are typically restricted to the posterior corneal surface,[39, 40] the anterior surface changes observed in our participants were most likely due to forces associated with the interaction between the upper eyelid, the lens and the cornea. Previous work has shown that eyelid forces upon the cornea during near work (without contact lens wear) typically result in topographical changes in the superior cornea (similar to the region of superior corneal flattening in Figure 1B) and optical changes primarily along the vertical meridian.[26, 41] Significant flattening of the posterior cornea was observed during the recovery period and was associated with rebound corneal thinning which is consistent with previous findings of posterior corneal steepening as a result of central corneal swelling during soft and rigid lens wear,[42] although no significant corneal swelling was observed following miniscleral lens wear in the current study (less than 1% over the central 6 mm).

Since scleral lenses significantly improve best-corrected visual acuity by effectively neutralising irregular astigmatism and higher order aberrations,[43] to our knowledge, no studies have examined the change in corneal or ocular aberrations following the removal of scleral lenses. A small but statistically significant increase in a lower order corneal aberration Z(2,2) (horizontal/vertical astigmatism) was observed over a 6 mm diameter, which returned to baseline levels within three hours of lens removal. Similarly, Tyagi et
al[44] observed a significant increase in total ocular lower order (2nd order) RMS values following PMMA lens wear, which the authors attributed to central corneal swelling, anterior surface steepening and posterior flattening. The magnitude of the change in mean anterior corneal refractive power observed in our study would have minimal impact upon vision following lens wear (particularly since the spherical equivalent of the mean change was close to plano i.e. +0.10/-0.20 x 108). However, following longer duration wearing times, such changes may be exacerbated by eyelid pressure and may temporarily degrade vision quality following lens removal in patients without refractive corneal anomalies who wear miniscleral lenses.

This is the first study to examine the influence of short-term miniscleral lens wear upon corneal thickness, anterior and posterior curvature and higher order aberrations over a large analysis diameter while accounting for the natural diurnal variations in these parameters. Corneal changes were examined following a three hour period of lens wear since the cornea appears to reach a steady state of swelling after three hours of RGP or hydrogel lens wear.[45, 46] However, examination of the cornea following a longer wearing time would provide more clinically relevant information since the oxygen dissolved in the post-lens tear layer would most likely dissipate after a longer period. Greater changes in corneal parameters may be observed following longer periods of lens wear, or in patients with compromised corneae who often require scleral contact lenses (e.g. severe ocular surface disease or post penetrating keratoplasty). Longer term studies, over months or years, examining both healthy eyes and eyes with corneal pathology are required to understand the influence of extended periods of miniscleral lens wear on corneal physiology and optics.

**Conclusion**

A small amount of flattening of the anterior corneal surface was observed immediately following short-term miniscleral contact lens wear, while 'rebound' thinning and flattening of the posterior surface was evident after the three hour recovery period following lens removal.
Corneal changes observed over the central 6 mm following lens removal and recovery were largely symmetrical between inferior and superior and central and peripheral zones. Modern high Dk miniscleral contact lenses, in conjunction with a moderate post-lens tear layer, do not induce clinically significant corneal oedema following three hours of lens wear as predicted by recent theoretical modelling.

**Acknowledgements**

This study was partially funded by a QUT Institute of Health and Biomedical Innovation Vision Domain Development Grant.
References


<table>
<thead>
<tr>
<th>Analysis</th>
<th>Time after removal (hours)</th>
<th>Region</th>
<th>Corneal thickness (µm)</th>
<th>Anterior axial curvature (mm)</th>
<th>Posterior axial curvature (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total 0-6 mm diameter</strong></td>
<td>0</td>
<td>Total</td>
<td>5.0 ± 17.9</td>
<td>0.02 ± 0.03***</td>
<td>0.01 ± 0.03</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Superior</td>
<td>3.2 ± 18.0</td>
<td>0.03 ± 0.03*</td>
<td>0.01 ± 0.03</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Inferior</td>
<td>6.8 ± 18.0</td>
<td>0.02 ± 0.03</td>
<td>0.00 ± 0.04</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Total</td>
<td>-13.4 ± 10.5**</td>
<td>0.00 ± 0.02</td>
<td>0.03 ± 0.02**</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Superior</td>
<td>-15.0 ± 11.0**</td>
<td>0.00 ± 0.02</td>
<td>0.02 ± 0.03</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Inferior</td>
<td>-11.9 ± 10.2**</td>
<td>0.00 ± 0.02</td>
<td>0.03 ± 0.04*</td>
</tr>
<tr>
<td><strong>Central 0-3 mm diameter</strong></td>
<td>0</td>
<td>Total</td>
<td>4.6 ± 17.6</td>
<td>0.02 ± 0.04*</td>
<td>0.01 ± 0.03</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Superior</td>
<td>3.5 ± 17.6</td>
<td>0.04 ± 0.04*</td>
<td>0.02 ± 0.06</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Inferior</td>
<td>5.8 ± 17.8</td>
<td>0.01 ± 0.04</td>
<td>0.01 ± 0.04</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Total</td>
<td>-12.9 ± 10.3**</td>
<td>0.00 ± 0.02</td>
<td>0.03 ± 0.02**</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Superior</td>
<td>-13.9 ± 10.8**</td>
<td>0.01 ± 0.03</td>
<td>0.03 ± 0.04</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Inferior</td>
<td>-11.8 ± 9.8**</td>
<td>0.00 ± 0.02</td>
<td>0.03 ± 0.05</td>
</tr>
<tr>
<td><strong>Peripheral 3-6 mm annulus</strong></td>
<td>0</td>
<td>Total</td>
<td>5.4 ± 19.2</td>
<td>0.03 ± 0.02***</td>
<td>0.00 ± 0.03</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Superior</td>
<td>2.9 ± 18.5</td>
<td>0.03 ± 0.02***</td>
<td>0.00 ± 0.04</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Inferior</td>
<td>7.9 ± 18.4</td>
<td>0.03 ± 0.02***</td>
<td>0.00 ± 0.03</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Total</td>
<td>-14.0 ± 10.8**</td>
<td>0.00 ± 0.02</td>
<td>0.02 ± 0.02**</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Superior</td>
<td>-16.1 ± 11.3**</td>
<td>0.00 ± 0.02</td>
<td>0.02 ± 0.03*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Inferior</td>
<td>-11.9 ± 10.7**</td>
<td>0.00 ± 0.02</td>
<td>0.03 ± 0.03</td>
</tr>
</tbody>
</table>

Values where a pairwise comparison revealed a statistically significant change from baseline measurements (*p < 0.05, **p < 0.01, ***p < 0.001). A positive value represents corneal thickening or flattening, and a negative value represents corneal thinning or steepening.
Figure 1. The group mean change in (A) corneal thickness (mm), (B) anterior corneal curvature (mm) and (C) posterior corneal curvature (mm) immediately following and 3 hours after miniscleral lens removal relative to baseline (pre-lens wear). Note: diurnal fluctuations in corneal thickness and curvature have been accounted for in the analysis.
**Figure 2.** The group mean change in the anterior corneal wavefront immediately following and 3 hours after miniscleral lens removal relative to baseline (pre-lens wear); (A) lower order (B) higher order and (C) lower and higher terms represented as Zernike refractive power maps. Note: diurnal fluctuations in the anterior corneal wavefront have been accounted for in the analysis.