The influence of centre thickness on miniscleral lens flexure

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ARTICLE INFO

ABSTRACT

Purpose: To examine the influence of centre thickness upon miniscleral lens flexure and the association between the magnitude of in-vivo lens flexure and scleral toricity.

Methods: In-vivo lens flexure was measured using a videokeratoscope in 9 healthy young participants (25 ± 4 years) with normal corneae fitted with ICD 16.5 miniscleral lenses (hexafocon B material) with centre thicknesses of 150, 250, and 350 μm. Scleral toricity was determined from sagittal height data over a 15 mm chord obtained from a corneo-scleral topographer.

Results: On average, lens flexure increased with decreasing centre thickness, but remained < 0.50 D (mean increase < 0.25 D, p = 0.63). Scleral toricity was positively correlated with in-vivo flexure for the 150 μm (r = 0.77, p = 0.02) and 250 μm (r = 0.72, p = 0.03) lenses. Using a group mean split, eyes with > 200 μm scleral toricity exhibited greater in-vivo flexure than eyes with < 200 μm (0.40 D more, averaged across all lenses, p = 0.02), and this effect was greatest for the 150 μm lens (0.61 D more, p = 0.04).

Conclusions: Decreasing the centre thickness from 350 μm to 150 μm resulted in < 0.25 D increase in lens flexure for a high Dk and low modulus material. Scleral toricity > 200 μm was associated with more in-vivo lens flexure. When intentionally reducing scleral lens centre thickness to enhance oxygen transmissibility, customised back surface designs may be required to minimise in-vivo flexure in eyes with > 200 μm scleral toricity at a 15 mm chord.

1. Introduction

It is well established that spherical corneal rigid contact lenses may flex slightly during wear, as a result of eyelid forces, and return to a non-flexed state between blinks. The magnitude of lens flexure is influenced by a number of factors, including corneal shape (with more corneal astigmatism associated with greater flexure), the fitting relationship between the back optic zone radius and the anterior corneal surface (with steeper fitting lenses typically resulting in more flexure [1–3]), the back optic zone diameter (with larger diameters generating more flexure [4]), and the lens material and thickness (with higher Dk materials [5,6], and thinner lenses more susceptible to flex [7]). To date, no studies have reported on the nature of flexure during scleral lens wear, but presumably the magnitude of lens flexure is similarly governed by factors such as the lens thickness, the total lens diameter, the modulus of the lens material, and the fitting relationship between the lens haptic zone and the underlying topography of the scleral tissue.

While several clinical studies have demonstrated that minimal corneal oedema occurs during short-term high Dk sealed miniscleral lens wear in young healthy eyes (typically 1–2%) [8–10], reducing the centre thickness of a scleral lens will increase the transmission of oxygen to the cornea, even for highly permeable materials [11]. This may be of particular benefit for eyes with reduced endothelial cell counts [12,13]. However, scleral lenses with a reduced central thickness may flex on-eye resulting in unwanted residual astigmatism and higher order aberrations or permanent lens warpage due to routine handling. Consequently, most scleral lenses are manufactured with a centre lens thickness between 300–500 μm; however, the centre thickness will vary with the total lens diameter and the required back vertex power. Similar to corneal rigid lenses, flexure associated with scleral lenses can be minimised by increasing the centre or junctional thickness at the edge of the optic zone, or by utilising an asymmetric back surface design (e.g. a toric periphery, or quadrant specific design) to improve alignment with the underlying rotationally asymmetric sclera. The aim of this study was to systematically investigate the influence of centre lens thickness upon measurements of in-vivo and in-vitro miniscleral

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Table 1
Parameters of the miniscleral lenses used in this study.

Nominal values			Measured values				
BOZR (mm)	BVP (D)	CT (μm)	BOZR (mm)	BVP (D)	CT (μm)	12 mm T (μm)	16.5 mm T(μm)
7.46	−1.00	150	7.47	−0.75	163 ± 11	183 ± 14	215 ± 18
7.46	−1.00	250	7.46	−0.75	264 ± 4	282 ± 14	305 ± 12
7.46	−1.00	350	7.46	−0.75	362 ± 0	366 ± 6	372 ± 11
7.46	−1.00	450	7.46	−0.75	448 ± 3	433 ± 9	421 ± 13

BOZR - back optic zone radius, BVP - back vertex power, CT mean ± SD centre thickness, 12 mm T - mean ± SD thickness across the central 12 mm, 16.5 mm T - mean ± SD thickness across the entire lens.

lens flexure and examine the association between the magnitude of in-vivo lens flexure and both corneal and scleral toricity, while controlling for potential confounding factors.

2. Methods

2.1. Contact lenses

Four ICD 16.5 miniscleral lenses were ordered with the same aspheric back optic zone and central radius (7.46 mm), sagittal depth (4200 μm over a 15 mm chord), peripheral (T1) and limbal (T2) clearance zones (50 and 45 degree tangents respectively), back vertex power (-1.00 D) and total diameter (16.5 mm) (Capricornia Contact Lenses, Brisbane, Australia). The lenses were manufactured in hexafocon B material (Dk 141) with nominal central thickness values of 150 μm, 250 μm, 350 μm, and 450 μm. The nominal and measured parameters for each lens are summarised in Table 1. The centre and average thickness values for each lens were determined using an OCT imaging technique described previously [13]. The back optic zone radii and back vertex powers were confirmed using a radiuscope and vertometer respectively.

2.2. Measurement sampling

A Placido ring videokeratoscope was used for all measures of lens flexure (E300 corneal topographer, Medmont, Melbourne, Australia). In order to determine the minimum number of videokeratoscope images required to reliably measure the curvature of the anterior surface of the miniscleral lenses, a pilot study was conducted using the lenses with 150 μm and 450 μm centre thickness. Each lens was positioned in a customised 3D-printed lens holder (Fig. 1A) with the back lens surface coated with lissamine green to enable visualisation and detection of the projected Placido rings from the topographer onto the anterior contact lens surface (Fig. 1B). The lens holder was mounted in front of the instrument cone of the videokeratoscope and twenty consecutive topography maps were acquired (with the contact lens removed from the lens holder and repositioned between each measurement). The raw data from each of the twenty topography maps for each lens were then exported from the instrument for further analysis using customised software. Each of the twenty axial curvature maps acquired for each lens were converted to axial power maps using the keratometric corneal refractive index of 1.3375, similar to previous studies assessing rigid lens flexure using keratometers or videokeratoscopes [2–7]. The best-fit spherocylinder that describes the anterior contact lens surface was calculated using an established technique [14] over a 1 mm and a 6 mm analysis diameter. The mean astigmatic component of the best-fit spherocylinder (lens flexure) was then calculated when including all twenty topography maps in the analysis for each lens, and again when including between 2–19 randomly selected topography maps. The mean difference, the 95% limits of agreement, and the exact 95% confidence interval of the limits of agreement [15] were calculated for each analysis including a reduced number of topography maps (2–19 maps) compared to an assumed gold standard of 20 topography maps.

Fig. 2 displays the mean difference in the astigmatic component of the best-fit spherocylinder of the anterior surface of the contact lens determined by averaging a number of topographical maps (from 2 to 19 maps) in comparison to the average obtained from the analysis including twenty topography maps (data for both 150 μm and 450 μm centre thickness lenses and the 1 mm and 6 mm diameters have been combined for simplicity, as the analyses showed similar trends). While the mean difference was relatively similar if either 2 or 19 topography maps were used to calculate the magnitude of lens flexure, in comparison to 20 maps, if 10 or more topography maps were used to determine the average, the 95% limits of agreement and exact 95% CI of the LoA's decreased significantly. The mean difference of 10 averaged topography maps compared to the assumed gold standard of 20 averaged maps was 0.00 D (95% LoA -0.01 to 0.01 D, 95% CI outer bounds of the LoA -0.03 to 0.03 D). Consequently, for the remaining experiments outlined below which involved videokeratoscopy of miniscleral lenses in the lens holder (in-vitro) or on eye (in-vivo), 10 topography maps were obtained and averaged.
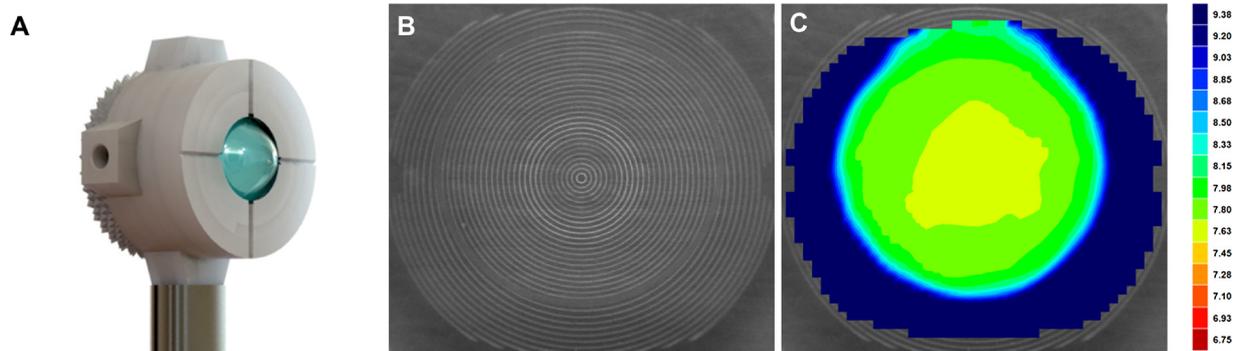

Fig. 1. (A) The 3D printed customised lens holder with an ICD 16.5 miniscleral lens in place with the back surface coated with lissamine green to aid visualisation of the Placido ring pattern. (B) An example of the Placido ring pattern imaged on the anterior contact lens surface. (C) An example axial curvature map (scale in mm) obtained from the Medmont E300 corneal topographer displaying minimal in-vitro flexure.
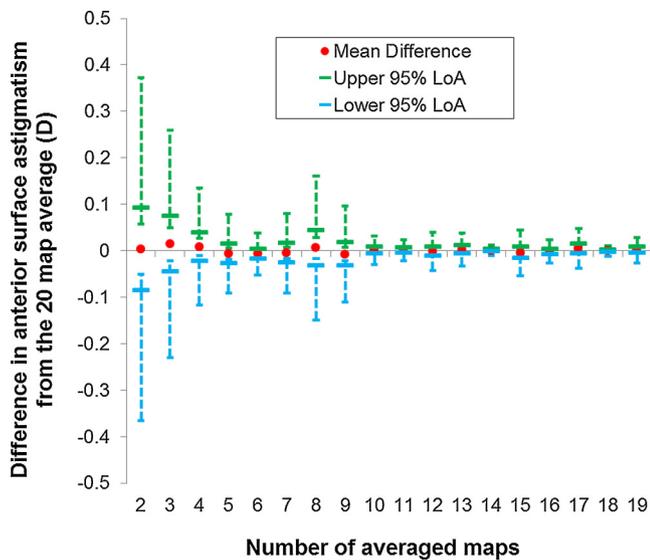
Fig. 2. The mean difference (red circles) in the astigmatic component of the best-fit spherocylinder of the anterior surface of the miniscleral lens when averaging between 2 and 19 randomly selected topography maps in comparison to an average of 20 topography maps. The upper (green bars) and lower (blue bars) 95% limits of agreement (LoA) are also displayed, along with the corresponding 95% exact confidence intervals of the upper and lower bounds of the 95% LoA (dashed lines). The use of 10 or more topography maps to calculate anterior surface lens flexure substantially reduced the measurement variability.

2.3. Duration of lens wear

Given that modern miniscleral lenses settle into the tissues of the anterior eye [16], most notably during the first 90 min of wear [17,18], a pilot study was conducted on one participant to examine the change in lens flexure during the first 2 h of lens wear. The participant was fitted with the ICD 16.5 miniscleral lens described in Table 1 (150 μm centre thickness). This lens was selected since a thinner lens should theoretically induce greater in-vivo flexure. Ten topography images were captured immediately after lens insertion and every fifteen minutes for the first hour of lens wear, then every thirty minutes during the second hour of lens wear. While in-vivo lens flexure increased by 0.20 D during the first 15 min of lens wear, between 15 min to 2 h after insertion the flexure remained stable (varying by less than ± 0.06 D), consistent with previous temporal flexure data for high Dk corneal rigid lenses [6]. For example, the spherocylinder measured over a 6 mm diameter following 15 min of lens wear ($+49.39/-0.35 \times 125$) did not change significantly after two hours of lens wear ($+49.41/-0.40 \times 118$). Therefore, for all measurements of in-vivo flexure, the miniscleral lenses were worn for 15 min prior to capturing topography measurements.

2.4. The influence of centre thickness upon lens flexure

2.4.1. Participants

This study was approved by the Queensland University of Technology human research ethics committee and followed the tenets of the Declaration of Helsinki. All participants provided informed consent. Nine participants were recruited with a mean age of 25 ± 4 years (7 female, 2 male and 6 Caucasian, 3 East Asian). This sample size was chosen based on previous samples used in studies of corneal rigid lens flexure using a similar repeated measures experimental design, in which the sample size ranged from 5 to 14 participants [3,5–7,19]. Prior to inclusion in the study, all subjects were screened for any contraindications to contact lens wear. The participants had healthy eyes and normal corneae, with visual acuity of at least 0.00 logMAR in each eye and no history of previous ocular disease of surgery. Six of the

participants were soft contact lens wearers, but ceased lens wear 24 h prior to data collection to minimise the influence of contact lens wear upon corneal and scleral topography measurements [20].

2.4.2. Corneal and scleral topography

Since the ICD 16.5 miniscleral lenses used in this experiment all had a sagittal depth of 4200 μm over a 15 mm chord, sagittal height data obtained from a videokeratoscope (E300 corneal topographer, Medmont) over a 10 mm chord was also used as an initial screening to assess suitability for inclusion. Four central topography images of the left eye were captured and averaged. Based on the manufacturer's lens fitting guide, 2400 μm was added to this 10 mm mean sagittal height value to extrapolate the height to a 15 mm chord (the landing zone of the lens) and to allow for sufficient central corneal clearance following lens settling. Measures of scleral topography were also captured using a corneo-scleral topographer (Eye Surface Profiler, Eaglet Eye, The Netherlands). Fifteen images of the left eye were captured; five in primary gaze with normal eyelid position, five with upper eyelid retraction, and five with lower eyelid retraction. The meridional height data along four principal meridians (nasal-temporal, superior-inferior, superotemporal-inferonasal, and superonasal-inferotemporal) were exported for analysis.

2.4.3. Miniscleral lens fitting assessment

For this aspect of the experiment, only the three thinner lens designs (centre thickness 150 μm, 250 μm, 350 μm) were used since significant flexure is unlikely to be observed with a lens with centre thickness of 450 μm. The lenses were soaked in conditioning solution (Boston Advance, Bausch and Lomb) for twenty-four hours prior to the measurement session. The order of lens wear was randomised, since each participant wore the three lenses during the same measurement session on the same day, and each lens was fitted to the left eye only. Each lens was inserted with preservative free saline and sodium fluorescein and assessed using a slit lamp to ensure there was no corneal bearing or bubbles within the post-lens tear layer. If adequate corneal clearance was observed, central corneal clearance was quantified using a high resolution OCT imaging protocol (Spectralis, Heidelberg Engineering, Germany) consisting of three vertical line scans (encompassing a 30° x 1° area, with the line scan comprised of the average of 30 B scans). Central corneal clearance was measured as the distance from the posterior contact lens surface to the anterior corneal surface along the normal to the tangent of the corneal apex from the line scan closest to the reflex from the anterior surface of the contact lens.

2.4.4. In-vivo and in-vitro lens flexure

Permanent warpage of each contact lens was estimated by measuring the in-vitro lens flexure, immediately prior to each in-vivo measurement session for each subject. Ten topography images of the anterior lens surface were captured with the lens mounted in the lens holder (with the instrument axis aligned with the vertex normal of the contact lens) using the method outlined in Section 2.2. Following lens insertion and a 15 min settling period for each lens, 10 topography images were captured using the videokeratoscope and exported for analysis (in-vivo lens flexure). Lubricating drops were applied in the case of reduced surface wettability during over-topography measurements.

2.4.5. Data analysis

As outlined in Section 2.2, the best-fit spherocylinder that describes the anterior lens surface was calculated using an established technique [14] over a 6 mm analysis diameter based on the average of 10 axial power maps for in-vivo and in-vitro measures obtained for each subject and lens. Mean axial power maps were generated for each lens to provide a dioptric representation of in-vivo flexure. The anterior surface of the scleral lens was also modelled as a single refractive surface optical system (hexafocon B refractive index of 1.424) to derive the

wavefront error from the averaged videokeratoscope elevation data for each subject and each lens thickness [21,22]. The optical path distance (the difference between the marginal rays and chief ray) for each point on the surface was calculated using three-dimensional ray tracing, and the wavefront was fitted with a sixth-order Zernike polynomial expansion over a 6 mm diameter centred on the instrument axis. Meridional scleral height data exported from the scleral topographer were averaged and analysed over a 15 mm chord (the landing zone of the ICD 16.5 miniscleral lens) after combining data extracted from topography maps with lid retraction, to ensure sufficient scleral coverage, using a similar approach to DeNaeyer et al. [23]. Scleral toricity was defined as the greatest difference in scleral sagittal height between two perpendicular meridians [24].

2.4.6. Statistical analysis

A series of repeated measures analysis of variance (ANOVA) were used to compare measurements of anterior surface astigmatism (for in-vitro and in-vivo measures of lens flexure), higher order aberration terms (individual Zernike coefficients and RMS values), and the initial level of central corneal clearance between the three lenses (150 μm, 250 μm, and 350 μm centre thickness). A repeated measures ANOVA was also used to examine the magnitude of in-vivo lens flexure between the three lenses with a between-subject factor of scleral toricity (based on a mean split of scleral toricity; 198 ± 140 μm [i.e. 200 μm]). P-values were adjusted using the Greenhouse-Geisser correction to prevent type I errors, if the assumption of sphericity was violated, and significant main effects were investigated using Bonferroni corrected post-hoc comparisons. Pearson's correlation analysis was used to examine the relationship between corneal and scleral toricity, and the magnitude of in-vivo lens flexure. Statistical analyses were conducted using SPSS software (Version 25) and the results are reported as the mean ± the standard deviation.

3. Results

3.1. Corneal astigmatism and scleral toricity and sagittal depth

The mean anterior corneal astigmatism over a 6 mm diameter was 1.19 ± 0.56 D (range 0.29–2.10 D) and the mean corneal sagittal height over a 10 mm chord was 1710 ± 71 μm (range 1640–1878 μm). The mean scleral toricity over a 15 mm chord length was 198 ± 140 μm (range 31–424 μm).

3.2. Central corneal clearance

The mean central corneal clearance was similar for each lens worn; 150 μm centre thickness (278 ± 97 μm clearance), 250 μm centre thickness (278 ± 98 μm clearance), and 350 μm centre thickness (268 ± 114 μm clearance) (p = 0.53). The mean within-subject difference in corneal clearance between the three lenses was 0 ± 10 μm, and the mean maximum absolute difference between the three lenses was 38 ± 19 μm.

3.3. In-vitro lens flexure measurements

Measures of in-vitro flexure, an estimate of permanent lens flexure (i.e. warpage), are displayed in Fig. 3 for each subject and the three different lenses worn. In-vitro flexure varied significantly over the course of the study (i.e. prior to each in-vivo measurement session, p < 0.001). However, the observed changes were small in magnitude for each lens and did not progressively increase as a function of lens handling and lens wear (i.e. with increasing subject number). The slope of the dashed lines in Fig. 3, which represent the line of best fit for in-vitro flexure as the experiment progressed, are positive but very close to zero (slopes ranging from 0.00 to 0.005 D/subject) indicating minimal permanent lens warpage (less than 0.05 D).
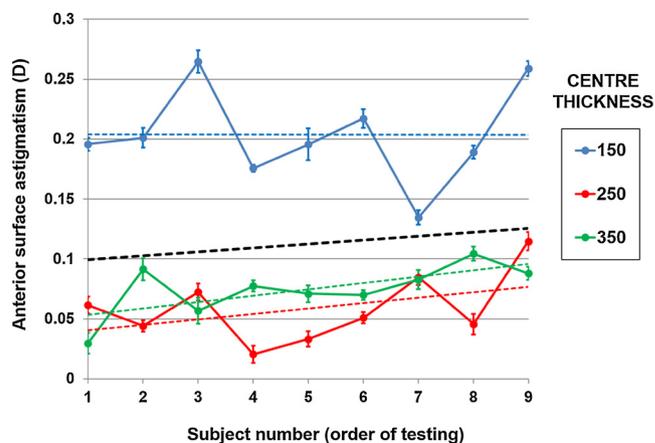

Fig. 3. The mean astigmatic component of the best-fit spherocylinder of the anterior surface for each miniscleral lens (blue 150 μm centre thickness, red 250 μm, green 350 μm) measured in-vitro prior to in-vivo measurements for subjects 1–9 in the order of testing, displaying the change in lens flexure (an estimate of permanent warpage) over the course of the study. The coloured dashed lines represent the line of best fit for each individual lens and the black dashed line represents the average change across all three lenses. The line of best fit for the average change across all lenses (black dashed line) is y = 0.003x + 0.1 (r = 0.48). Error bars represent one standard deviation of the mean.
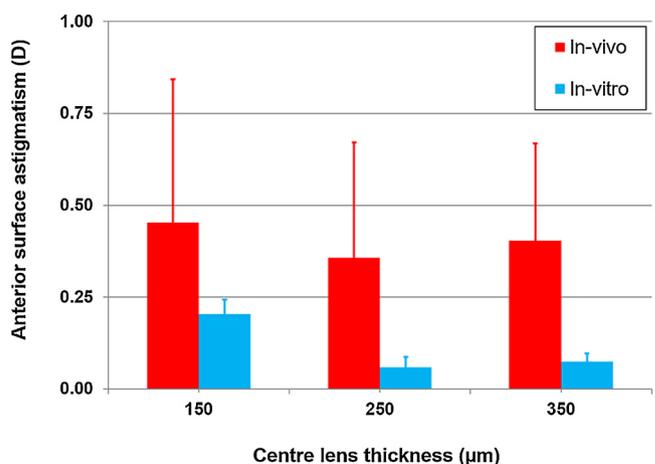

Fig. 4. The mean astigmatic component of the best-fit spherocylinder of the anterior surface for the miniscleral lenses of varying centre thickness measured in-vivo (red) and in-vitro (blue) prior to capturing the in-vivo measurements. Error bars represent one standard deviation of the mean.

As anticipated, in-vitro lens flexure varied with centre thickness (p < 0.001). The 150 μm lens displayed greater anterior surface astigmatism (0.20 ± 0.04 D) compared to both the 250 μm lens (0.06 ± 0.03 D) and the 350 μm lens (0.08 ± 0.02 D) (Fig. 4), however, the magnitude of in-vitro flexure was not significantly different between the 250 μm and 350 μm lenses (p = 0.71). The maximum in-vitro flexure values observed for each lens (0.26 D, 0.11 D, and 0.10 D for the 150 μm, 250 μm, and 350 μm lenses respectively) were small and would be considered clinically insignificant (i.e. unlikely to cause a significant reduction in vision).

3.4. In-vivo lens flexure measurements

Measures of in-vivo lens flexure are displayed in Fig. 4, along with the average in-vitro flexure data. Fig. 5 displays the average axial power maps for each lens demonstrating the change in in-vivo lens flexure with decreasing centre thickness. Surprisingly, anterior surface
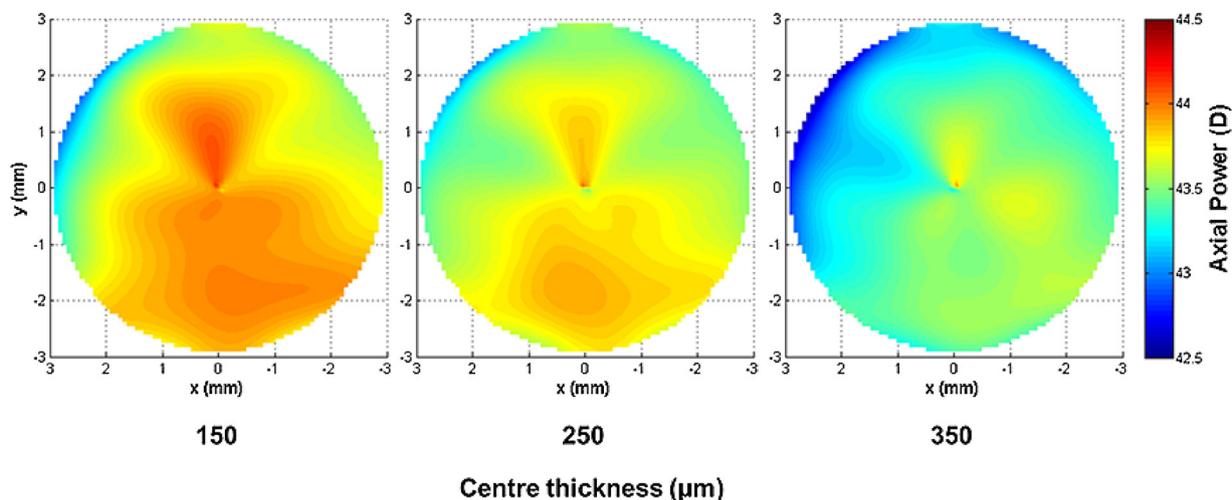
Fig. 5. Average axial power maps for each lens demonstrating a small non-significant increase in in-vivo lens flexure with decreasing centre thickness. Axial power maps provide a dioptric representation of curvature rather than the refractive value of the anterior contact lens surface.

astigmatism did not vary significantly with centre lens thickness for measures of in-vivo lens flexure (p = 0.63). The maximum in-vivo lens flexure values were observed for the thinnest lens (150 μm lens, maximum flexure 1.16 D), followed by the 250 μm lens (maximum flexure 1.12 D) and the 350 μm (maximum flexure 0.85 D), however, on average, the magnitude of the in-vivo flexure was less than 0.50 D.

3.5. In-vivo higher order aberrations

The in-vivo higher order aberration profile extracted from the corneal over-topography height data was stable across the three lenses. Repeated measures ANOVA revealed no significant effect of lens thickness upon the individual Zernike term coefficients (3rd to 6th orders inclusive) or RMS values (all p > 0.05), except for horizontal coma (Z [3,1]) (p = 0.002), with the 350 μm lens displaying more horizontal coma (0.110 ± 0.034 μm) compared to the 250 μm lens (0.032 ± 0.021 μm, p = 0.03) and the 150 μm lens (0.065 ± 0.025 μm, p = 0.04).

3.6. Influence of scleral toricity

A weak negative correlation was observed between the magnitude of corneal and scleral toricity which did not reach statistical significance (r = -0.42, p = 0.26). There was no association between the magnitude of corneal astigmatism and the magnitude of in-vivo lens flexure for any of the three scleral lenses (all p > 0.05). However, significant positive associations were observed between scleral toricity and in-vivo lens flexure for the 150 μm lens (r = 0.77, p = 0.02) and the 250 μm lens (r = 0.72, p = 0.03), but not the 350 μm lens (r = 0.53, p = 0.14) (Fig. 6). Fig. 7 displays the in-vivo lens flexure for each lens based on a mean split of scleral toricity (200 μm). Averaged across the three lenses, eyes with > 200 μm of scleral toricity (mean 313 ± 118 μm) exhibited more flexure (0.62 ± 0.34 D) compared to eyes with < 200 μm of scleral toricity (mean 106 ± 71 μm) (0.23 ± 0.15 D) (p = 0.02). This finding was primarily due to the difference in lens flexure between the two scleral toricity groups for the 150 μm lens (> 200 μm; 0.79 ± 0.36 D, < 200 μm; 0.18 ± 0.07 D, p = 0.04). No statistically significant variations were observed in the higher order aberration profile with respect to scleral toricity (all p > 0.05).

4. Discussion

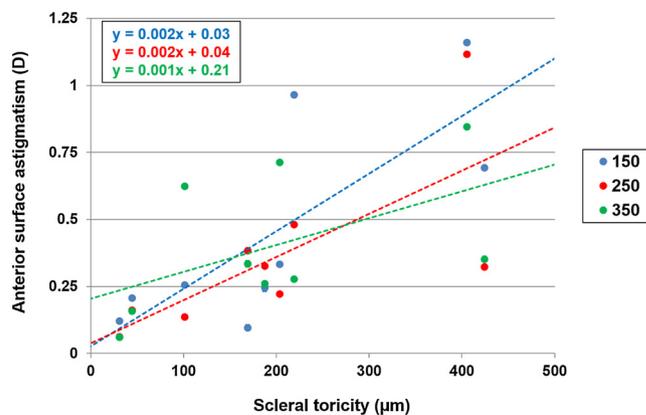This is the first study to systematically investigate the influence of

Fig. 6. Anterior surface astigmatism (in-vivo lens flexure) as a function of scleral toricity measured over a 15 mm chord length (the landing zone of the ICD 16.5 miniscleral). For the 150 μm and the 250 μm lens a statistically significant positive correlation was observed between scleral toricity and in-vivo lens flexure.

miniscleral lens centre thickness upon measures of in-vivo anterior surface lens flexure while controlling for numerous potential confounding variables such as the back optic zone radius and diameter, total lens diameter, peripheral curves and tangents, lens material, and permanent lens warpage, in order to isolate the effect of lens centre thickness upon flexure. The central corneal clearance was also kept relatively constant for each lens that was worn, since post-lens tear surface tension forces are thought to influence corneal rigid lens flexure [25]. The hexafocon B material was specifically chosen for this study due to its high oxygen permeability (Dk 141), low modulus (1161 MPa, compared to 2432 MPa for PMMA), and known propensity to flex during scleral lens wear and handling. However, in our participants, minimal in-vivo flexure was observed for all lenses (mean flexure < 0.50 D, Fig. 4).

The magnitude of in-vivo lens flexure observed in the current study (mean 0.40 ± 0.32 D, range 0.06–1.16 D across all lenses), was slightly less than the flexure reported previously in studies of thick (~170 μm) high Dk corneal rigid lenses (~0.6 to 0.9 D) [6], most likely due to the difference in the central thickness and the peripheral thickness profile for larger diameter scleral lenses. Only small, non-statistically significant differences in in-vivo lens flexure were observed between the three scleral lenses of varying centre thickness (mean differences of less than 0.12 D that would be not be considered
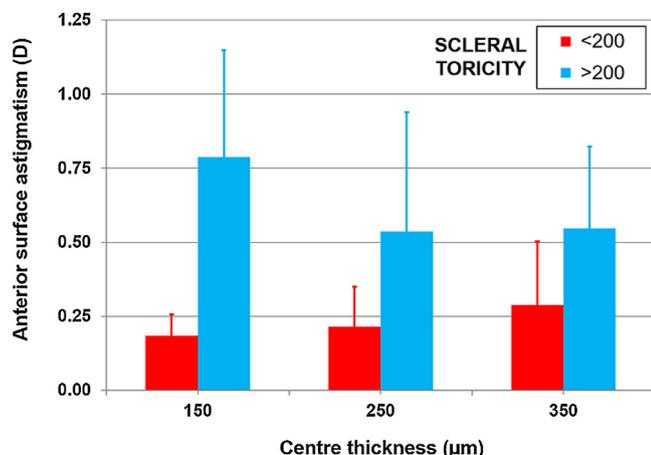
Fig. 7. Anterior surface astigmatism (in-vivo lens flexure) as a function of scleral toricity measured at a 15 mm chord length (the landing zone of the ICD 16.5 minisceral) based on a mean split of the data (mean scleral toricity 198 ± 140 μm). Averaged across all lenses, eyes with > 200 μm scleral toricity (blue) exhibited significantly greater in-vivo lens flexure compared to eyes with < 200 μm scleral toricity (red) (0.40 D greater, p = 0.02), primarily due to the difference in lens flexure between the two groups for the 150 μm lens (> 200 μm; 0.79 ± 0.36 D, < 200 μm; 0.18 ± 0.07 D, p = 0.04). Error bars represent one standard deviation of the mean.

clinically significant) (Fig. 4). A greater amount of in-vitro lens flexure was observed for the thinnest lens (150 μm), most likely due to a small amount of pressure exerted on the edge of the lens when positioned in the lens holder. This suggests that not surprisingly, minisceral lens designs of reduced centre thickness (150 μm) may be more susceptible to flexure due to handling and cleaning procedures, however Fig. 3 shows that in-vitro measures of flexure remained stable for this lens throughout the study indicating minimal permanent warpage.

Anterior surface higher order aberrations induced by scleral lens decentration or flexure are important considerations for the design of customised wavefront guided lenses to correct residual internal aberrations arising from the posterior cornea (e.g. significant coma in keratoconus) [26]. Surprisingly, the in-vivo higher order aberration profile of the anterior lens surface remained stable across the three lenses with varying centre thickness. The only individual Zernike coefficient that varied significantly with changes in the centre thickness was horizontal coma, which was ~1.5 to 3.5 times greater for the 350 μm lens compared to the thinner lenses. Collins et al. [7] observed the opposite trend for 9.5 mm diameter corneal rigid lenses, with a reduction in higher order aberrations (RMS values) and flexure with increasing lens centre thickness for both PMMA and hexafocon A materials. It is difficult to directly compare the results from this previous study due to the difference in lens thickness (centre lens thickness 60–170 μm [7] compared to 150–350 μm in the current study), lens designs and the aberrations measured. However, the increased coma with the thicker lens observed in the current study is most likely the result of slight horizontal lens decentration during the initial settling period, or lens tilt with respect to the measurement axis of the corneal topographer, rather than an increase in lens flexure.

Our participants with healthy eyes displayed normal corneal sagittal height data, a relatively low level of corneal astigmatism, and rotationally asymmetric scleral sagittal height data over a 15 mm chord. The magnitude of scleral toricity observed in the current study (mean 198 ± 140 μm) was slightly greater than that observed by Ritzmann et al. [24] who examined a larger sample of young healthy adults using OCT imaging (159 ± 85 μm), but applied the same definition and chord length to define scleral toricity. No association was observed between the magnitude of corneal astigmatism and scleral toricity, or corneal astigmatism and in-vivo lens flexure, which suggests that unlike

corneal rigid lenses, corneal astigmatism is not a useful clinical indicator of potential in-vivo lens flexure for scleral lenses.

Despite the limited sample size, a significant positive correlation was observed between scleral toricity and in-vivo lens flexure for the 150 μm (r = 0.77, p = 0.02) and 250 μm (r = 0.72, p = 0.03) lenses, which diminished to non-significant levels for the 350 μm lens (Fig. 6). This indicates that for scleral lenses with a reduced centre thickness of 150 μm and 250 μm, scleral toricity significantly influences in-vivo lens flexure. This is clearly illustrated in Fig. 7 which highlights the difference in in-vivo flexure for the three lenses based on a mean split of scleral toricity. Eyes with > 200 μm of scleral toricity over a 15 mm chord, exhibited more in-vivo lens flexure compared to those with < 200 μm scleral toricity, which diminished as centre thickness increased. Similar to eyes with moderate corneal astigmatism (~2.50 D) that require a back surface toric or bitoric design to optimise the fit and minimise flexure for corneal rigid lenses, there is most likely a threshold of scleral toricity which indicates the need for a back surface toric haptic or quadrant specific design to minimise in-vivo flexure and optimise centration, particularly for thinner lens designs. Data from the current study indicates that this value may be approximately a 200 μm difference in the sagittal height of perpendicular meridians measured at the landing zone of the intended lens (in this case a 15 mm chord). However, examination of the in-vivo lens flexure induced in a much larger sample of eyes with a wider range of scleral toricities and using various lens designs, would be required to more accurately estimate this threshold. A larger sample size may also reveal statistically significant differences in lens flexure between identical designs of varying centre thickness due to a reduction in variance, however, given the limited mean difference observed between the lenses used in the current study (< 0.10 D), this is unlikely to alter the clinical implications. Clinical studies suggest that refitting patients from rotationally symmetric spherical back surface minisclerals into toric back surface haptic designs not only improves lens stability and centration, but can minimise local conjunctival blanching or post-lens tear layer air bubbles due to poor alignment, resulting in modest increases in subjective comfort levels and wearing time [27].

A limitation of the current study was the use of a single lens design (ICD 16.5) with only one sagittal depth (4200 μm), which restricted our sample to participants with relatively normal eyes. Keratoconic or postgraft eyes fitted with scleral lenses of greater sagittal depth may manifest greater levels of in-vivo lens flexure, particularly since keratoconic eyes display a greater asymmetry in the scleral height profile between principal meridians compared to normal eyes [28]. However, since scleral lenses of greater sagittal depth required for the correction of advanced keratoconus are typically associated with greater minus back vertex powers, and consequently increased junctional thickness [13], the relationship between scleral asymmetry and in-vivo flexure in keratoconic eyes will also be influenced by the lens back vertex power and the peripheral lens thickness profile. Although only one minisceral lens design was used in this study, similar results would be expected for other designs of similar total lens diameter, as different lens designs of similar total diameter display similar thickness profiles, that primarily vary with back vertex power (e.g. the Rose K2 XL 14.6 mm diameter semi-scleral design and the ICD 16.5 mm diameter minisceral [13]). The short duration of lens wear is another potential limitation, since the reduction in apical clearance of the ICD 16.5 (and presumably lens stabilisation) plateaus after 2 h of lens wear [17].

In conclusion, a small clinically insignificant increase in in-vivo and in-vitro anterior surface lens flexure was observed when the centre thickness of the ICD 16.5 minisceral was decreased from 350 μm to 150 μm (< 0.25 D increase in flexure), while controlling for other confounding variables. However, eyes with scleral toricity of > 200 μm displayed significantly greater in-vivo flexure (0.40 D more flexure averaged across all lenses) compared to eyes with < 200 μm scleral toricity, most notably for the 150 μm centre thickness lens (0.62 D more flexure). Decreasing the centre thickness of minisceral lenses may be a

valid clinical approach to increase oxygen transmission to the cornea, however, back surface toric haptics or quadrant specific designs may be required for eyes with > 200 μm of scleral toricity at the anticipated lens landing zone to improve the alignment of the haptic with the underlying sclera and minimise in-vivo lens flexure and decentration.

Acknowledgements

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