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Scleral lens centration: The influence of centre thickness, scleral topography, and apical clearance

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ABSTRACT

Purpose: To investigate the effect of lens centre thickness (and mass) upon short-term horizontal and vertical scleral lens decentration, and the association between both scleral topography and apical clearance, with lens decentration.

Methods: Lens decentration was measured using over-topography data from 9 healthy young participants (25 ± 4 years) with normal corneae fitted with ICD 16.5 scleral lenses (hexafocon B material) with centre thicknesses of 150, 250, and 350 μm , while controlling for other lens parameters. Scleral toricity and elevation were determined from sagittal height data over a 15 mm chord obtained from a corneo-scleral topographer and central apical clearance was quantified using anterior segment optical coherence tomography.

Results: The mean lens decentration was 0.55 ± 0.19 mm temporally and 0.84 ± 0.35 mm inferiorly, which did not vary significantly with centre thickness ($p > 0.05$). The mean nasal-temporal asymmetry in scleral elevation data was substantially greater ($619 \pm 67 \mu\text{m}$) compared to the vertical meridian ($369 \pm 57 \mu\text{m}$) ($p < 0.01$), and this variation in scleral topography along the horizontal meridian was associated with the magnitude of horizontal lens decentration ($r = 0.68$, $p = 0.04$). Greater initial central apical clearance was associated with more inferior lens decentration ($r = -0.78$, $p = 0.01$).

Conclusion: Lens centre thickness and mass did not significantly influence centration. Horizontal lens decentration was associated with the nasal-temporal asymmetry in scleral elevation, while vertical lens decentration correlated with initial central apical clearance. Factors affecting scleral lens centration may vary between the horizontal and vertical meridians.

1. Introduction

The centration and movement of a corneal rigid contact lens is influenced by a range of factors including eyelid tension and morphology, lid-lens interactions, and gravitational and post-lens tear layer fluid forces [1–3]. Numerous modifiable parameters also play a role in lens stabilisation such as the total diameter, back vertex power (BVP), back optic zone radius (BOZR) and thickness profile, all of which influence the centre of gravity [4,5]. Previous work has shown that when the centre of gravity of a contact lens is located more posteriorly (i.e. further into the eye), lens centration and stability improves. For corneal rigid lenses: thinner, higher minus powered lenses, a steeper BOZR, and larger total diameter result in a more posteriorly-located centre of gravity (when controlling for other variables); with changes in the total lens diameter having the greatest effect upon the centre of gravity [5]. The extent of apical clearance will also influence the position of the

rigid lens centre of gravity relative to the cornea, and therefore may also affect centration. This is particularly relevant for scleral contact lenses, since the central apical clearance may be substantially greater (over 1000 μm in some cases) compared to corneal rigid lenses ($\sim 10 \mu\text{m}$) [6].

Many modern scleral lenses are sealed systems, with minimal or no tear exchange or lens movement. However, lens settling occurs over the course of the day, which is observed clinically as a reduction in apical clearance [7–9] and compression of the tissue underlying the lens haptic [10,11]. Scleral lens decentration may also be observed, most commonly infero-temporally, for both rotationally [7,11] and non-rotationally symmetric landing zones [12,13]. Inferior decentration has been attributed to lens mass or eyelid morphology [14], whereas it has been hypothesised that temporal decentration is likely a result of asymmetries in scleral anatomy (i.e. the sclera is typically flatter and more elevated nasally compared to temporally) [15].

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Corneal rigid lens or scleral lens decentration can adversely affect visual outcomes since a non-uniform distribution of the post-lens tear layer induces a prismatic effect, which may disrupt binocularity [6,7], and decentration of the anterior contact lens surface relative to the pupil generates residual astigmatism and higher-order aberrations (typically horizontal or vertical coma) [16]. Minimising scleral lens decentration is important for multifocal corrections for presbyopia and wavefront guided front surface lenses designed to correct residual higher order aberrations (primarily the posterior corneal, internal and residual anterior corneal) in keratoconus [17–20]. Scleral lens decentration may also result in an inappropriate lens fit and subsequent undesirable physiological ocular changes. This can include insufficient limbal clearance leading to corneal touch or excessive conjunctival impingement [21,22] which may necessitate lens modifications such as incorporating a toric or customised landing zone, despite adequate vision, to improve comfort and extend wearing time.

Currently, only two studies have examined potential factors associated with scleral lens decentration, with greater initial apical clearance and scleral toricity both associated with greater decentration of rotationally symmetric haptic lens designs [7,11]. These previous studies utilised a variety of scleral lenses with different overall diameter, BOZR, BVP, and thickness profiles across participants. The primary aim of this study was to examine the influence of lens thickness (and consequently mass) upon scleral lens decentration while controlling for other potential confounding variables such as lens wearing time, BVP, BOZR, and central apical clearance. A secondary aim was to investigate potential factors associated with horizontal and vertical decentration.

2. Methods

2.1. Scleral lenses

Three scleral lenses of 150, 250 and 350 μm nominal centre thickness were used (ICD design, Capricornia Contact Lenses, Brisbane, Australia). The centre lens thickness was measured using an OCT imaging approach described previously [23] and each lens was weighed three times to the nearest 0.1 mg using an analytical balance (Pioneer, Ohaus Corp., USA). All other lens parameters were held constant (total diameter 16.5 mm, back optic zone radius 7.46 mm, 4200 μm sagittal depth over a 15 mm chord, back vertex power -1.00 D, material hexafocon B).

2.2. 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. The participant characteristics have been described previously [24]. Briefly, nine participants were recruited with a mean age of 25 ± 4 years (7 female, 2 male and 6 Caucasian, 3 East Asian); a sample size comparable to previous studies (8–12 participants) investigating corneal rigid lens centration using a similar repeated measures experimental design [1,5,25]. All subjects were screened for any contraindications to contact lens wear and 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 or surgery. Six of the participants were soft contact lens wearers, but ceased lens wear 24 h prior to data collection [26]. The other participants did not wear contact lenses.

2.3. Corneal and scleral topography

Since the scleral lenses all had a sagittal depth of 4200 μm over a 15 mm chord, sagittal height data obtained from a videokeratoscope (E300 corneal topographer, Medmont, Australia) over a 10 mm chord was used as an initial screening to assess suitability for inclusion. Scleral topography was also captured using a corneo-scleral

topographer (Eye Surface Profiler, Eaglet Eye, The Netherlands). Fifteen images of the left eye were obtained; 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. Scleral lens fitting assessment

The lenses were soaked in conditioning solution (Boston Advance, Bausch and Lomb) for 24 h prior to the measurement session and were worn for 15 min prior to capturing a series of 10 over-topography measurements. The order of lens wear was randomised using a Latin square design, and each participant wore the three lenses during the same measurement session on the same day (separated by at least ten minutes), fitted to the left eye only. Lubricating drops were applied to improve anterior lens surface wettability if required. Central apical clearance was quantified using a high resolution optical coherence tomographer (Spectralis, Heidelberg Engineering, Germany). Three vertical line scans were captured (encompassing a $30^\circ \times 1^\circ$ area, with each line scan consisting of 30 averaged B scans) and apical clearance was measured as the distance from the posterior 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 scleral lens.

2.5. Data analysis

Tangential power over-topography maps were analysed to estimate lens decentration relative to the pupil centre as described previously [27]. Using the Medmont Studio software, a single observer manually fitted an ellipse to the pupil and the region of topographical change concentric with the front optic zone, in four tangential power maps for each lens. The location of the centre of the pupil and front optic zone ellipse were extracted relative to the vertex normal and scleral lens (front optic zone) decentration relative to the pupil centre was then calculated as the difference between the pupil and optic zone centres relative to the vertex normal.

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 scleral lens) after combining data extracted from topography maps with lid retraction. Scleral toricity was defined as the greatest difference in scleral sagittal height between two perpendicular meridians [24,28]. The difference in scleral elevation was also calculated along the four principal meridians over a 15 mm chord (e.g. the difference in scleral height at a 7.5 mm radius in the nasal and temporal quadrant along the horizontal meridian).

2.6. Statistical analyses

Measurement error was quantified using the method of Bland and Altman [29] to calculate the within-subject standard deviation. A repeated measures analysis of variance (ANOVA) was used to compare both horizontal and vertical scleral lens decentration across the three lenses (150 μm , 250 μm , and 350 μm centre thickness). Pearson's correlation analysis was used to examine the relationship between lens decentration and scleral toricity, intrameridian scleral height differences, and central apical clearance. For correlation analyses, decentration data were averaged across the three lenses per participant ($n = 9$ instead of $n = 27$) to avoid artificial inflation of r and p -values (type I error). Statistical analyses were conducted using SPSS software (Version 25).

Table 1

Horizontal and vertical scleral lens decentration relative to the pupil centre for scleral lens designs of different lens centre thickness. Positive values denote temporal and superior decentration.

LENS CENTRE THICKNESS (μm)		MASS (mg)	DECENTRATION (mm)	
Nominal	Measured		Horizontal	Vertical
150	163 \pm 11	79.4 \pm 0.1	0.52 \pm 0.20	-0.80 \pm 0.35
250	264 \pm 4	109.8 \pm 01	0.58 \pm 0.15	-0.86 \pm 0.36
350	362 \pm 0	121.6 \pm 0.2	0.53 \pm 0.24	-0.85 \pm 0.40

3. Results

3.1. Measurement error

When three decentration values were calculated for each participant (one for each lens derived from four measures of decentration along each meridian per lens) the within-subject standard deviation for horizontal and vertical measures of decentration was 0.07 and 0.11 mm respectively. When a single decentration value was calculated per

participant based on the average across the three lenses (derived from four measures of decentration along each meridian per lens) the within-subject standard deviation for horizontal and vertical measures of decentration was 0.04 and 0.07 mm respectively.

3.2. Decentration

The mean horizontal and vertical decentration, averaged across all lenses, was 0.55 \pm 0.19 mm temporally and 0.84 \pm 0.35 mm inferiorly. There was no significant difference in the magnitude of horizontal ($p = 0.38$) or vertical lens decentration ($p = 0.28$) as a function of lens thickness (or mass) (Table 1), and the magnitude of horizontal and vertical decentration were not correlated for each lens thickness value (all $p > 0.05$).

3.3. Scleral toricity and height

Over a 15 mm chord diameter, the mean scleral toricity was 198 \pm 47 μm , range 31–424 μm . The mean difference in scleral height along the horizontal meridian (619 \pm 67 μm , range 416–1077 μm , with greater elevation nasally compared to temporally), was

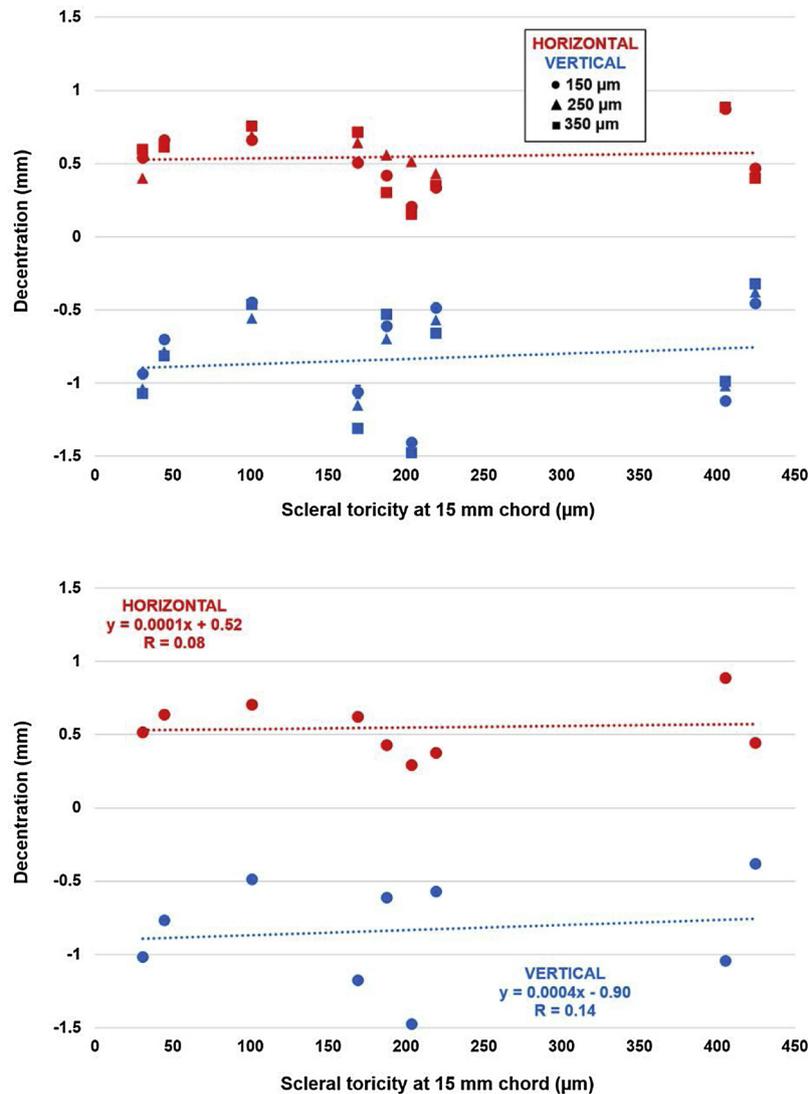


Fig. 1. Top: Horizontal and vertical scleral lens decentration for each lens (150, 250 and 350 μm centre thickness) as a function of scleral toricity at a 15 mm chord. Bottom: Horizontal and vertical scleral lens decentration averaged across all lenses as a function of scleral toricity at a 15 mm chord. No significant associations were observed between the magnitude of scleral toricity and lens decentration along either meridian ($p > 0.05$). Positive y-values denote temporal (horizontal, red line) and superior (vertical, blue line) decentration.

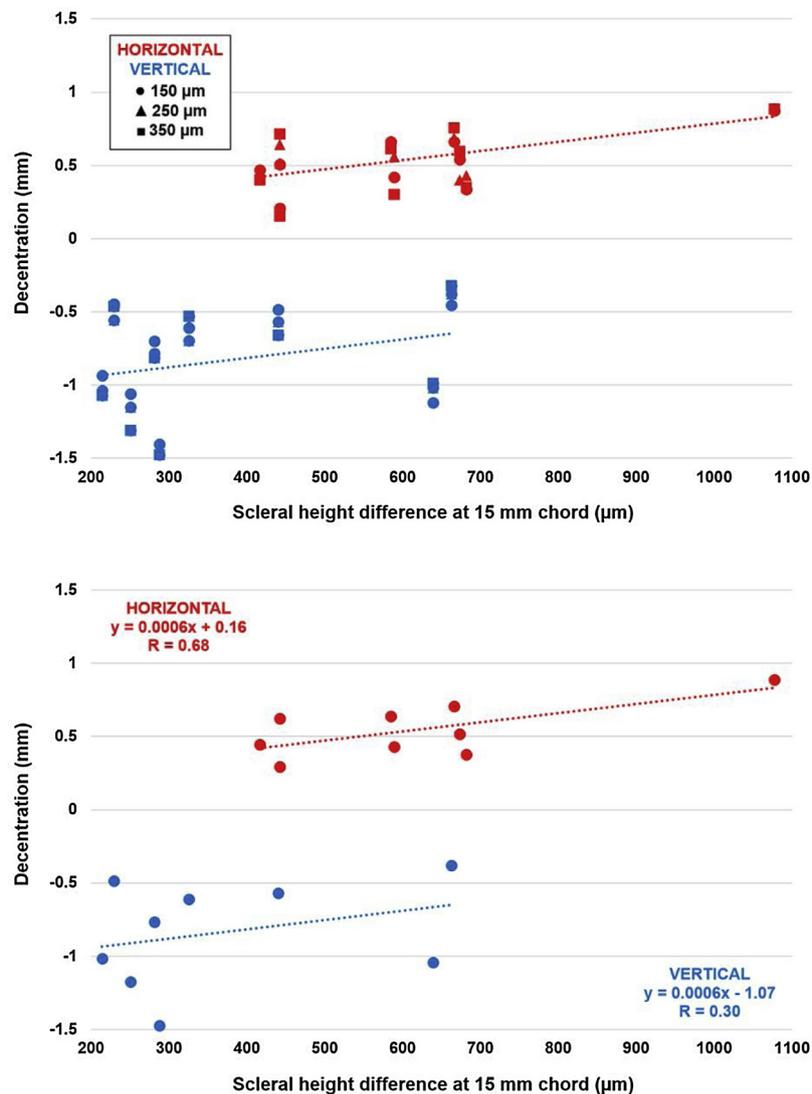


Fig. 2. Top: Horizontal and vertical scleral lens decentration for each lens (150, 250 and 350 µm centre thickness) as a function of the difference in scleral height at a 15 mm chord along the same meridian. Bottom: Horizontal and vertical scleral lens decentration averaged across all lenses as a function of the difference in scleral height at a 15 mm chord along the same meridian. A greater difference between nasal and temporal scleral elevation was associated with more temporal lens decentration ($r = 0.68$, $p = 0.04$). Positive y-values denote temporal (horizontal, red line) and superior (vertical, blue line) decentration.

significantly greater than the variation observed along the vertical meridian ($369 \pm 57 \mu\text{m}$, range 214–662 µm, with greater elevation superiorly compared to inferiorly) ($p = 0.01$). There was no association between horizontal ($r = 0.08$, $p = 0.84$) or vertical lens decentration ($r = 0.14$, $p = 0.72$) with the magnitude of scleral toricity (Fig. 1). However, a significant association was observed between the magnitude of horizontal lens decentration and the scleral height difference along the horizontal meridian ($r = 0.68$, $p = 0.04$), but not for vertical decentration and vertical scleral height differences ($r = 0.30$, $p = 0.43$) (Fig. 2), or oblique principal meridians.

3.4. Central apical clearance

There was no association between central apical clearance and horizontal lens decentration ($r = 0.20$, $p = 0.61$), however, there was a strong correlation between central vault and vertical decentration ($r = -0.78$, $p = 0.01$) indicating greater inferior decentration with higher initial apical clearance (Fig. 3).

4. Discussion

The mean lens decentration in our participants (averaged across the three lenses of different thickness) after 15 min of wear was 0.55 ± 0.19 mm temporally and 0.84 ± 0.35 mm inferiorly, which is in broad agreement with previous reports; mean decentration values ranging from 0.1 to 0.5 mm horizontally and 0.2 to 0.9 mm vertically [7,19,30]. Decentration data is difficult to compare across studies due to numerous methodological differences including the lens parameters and wearing time, the scleral anatomy of the participants, and the method used to quantify decentration. Nonetheless, our results are most similar in magnitude, direction and sample variation (comparing standard deviations) to those of Hastings et al. [17] who recently reported mean decentration values of approximately 0.48 ± 0.15 mm temporally and 0.48 ± 0.24 mm inferiorly (based on data presented to offset the optic zone to compensate for lens decentration) in keratoconic patients fitted with a 17–18.1 mm total diameter lens with a toric haptic zone worn for 30 min.

Interestingly, no significant variation in lens centration was observed for the same lens design with increasing centre lens thickness (from 150 to 350 µm for a -1.00 D BVP) and the associated increase in

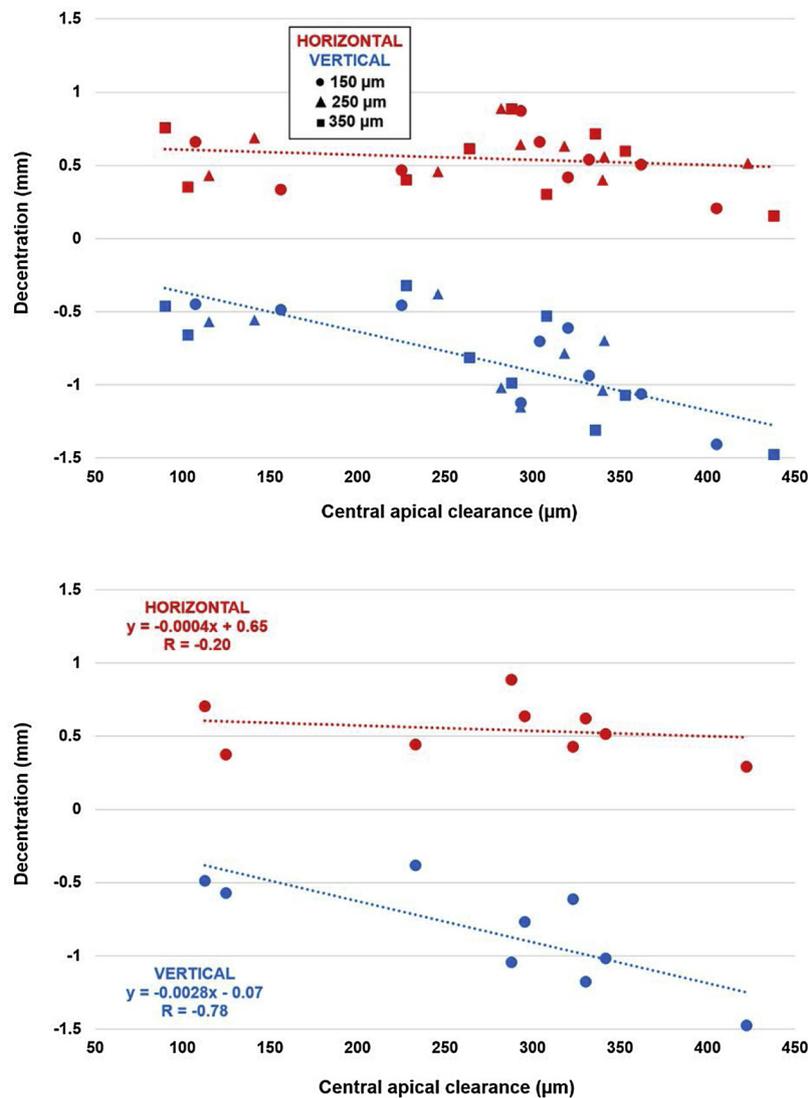


Fig. 3. Top: Horizontal and vertical scleral lens decentration for each lens (150, 250 and 350 µm centre thickness) as a function of central corneal clearance. Bottom: Horizontal and vertical scleral lens decentration averaged across all lenses as a function of central corneal clearance. Greater initial apical clearance was associated with more inferior lens decentration ($r = -0.78$, $p = 0.01$). Positive y-values denote temporal (horizontal, red line) and superior (vertical, blue line) decentration.

mass (from 80 to 122 mg, a 53% increase). Carney et al. [31] reported a similar finding for corneal rigid lenses of 120–180 µm centre thickness. For both high and low riding corneal RGP's, lens mass (10–17 mg, 70% variation) was not associated with horizontal or vertical centration, however the centre of gravity was, although this effect diminished with increasing lens mass. Although the dynamic forces at play during scleral lens wear are most likely to be vastly different compared to corneal rigid lenses (e.g. in comparison to Carney et al. [31] the scleral lenses used in this study were up to 3x thicker and 12x heavier), this similar finding between the two studies of minimal influence of lens mass suggests that perhaps other factors such as the centre of gravity are more detrimental to decentration for all types of contact lenses.

Examining decentration data for each participant and lens ($n = 27$), or averaging the data across the three lenses per participant ($n = 9$), revealed significant associations between initial central apical clearance and vertical lens decentration ($r = -0.78$, $p = 0.01$, $n = 9$). This means that a more anteriorly positioned centre of gravity of the scleral lens relative to the cornea resulted in greater inferior lens decentration. This is consistent with previous work examining corneal rigid lenses [5,31] and scleral lenses [11] and suggests that a first step for practitioners to minimise vertical scleral lens decentration is to move the scleral lens centre of gravity more posteriorly by reducing apical

clearance. In a previous study using OCT imaging to quantify scleral lens decentration [7], greater initial central apical clearance was associated with greater horizontal decentration (not vertical) after 8 h of lens wear, however further analysis of this data following 15 min of lens wear revealed no significant correlations. This is likely due to differences in individual participant and lens fitting characteristics, such as scleral topography, initial apical clearance and the magnitude of lens settling or tilt [32].

In the current study, the variation in the scleral height profile along the horizontal meridian was $\sim 1.7x$ greater than that observed along the vertical meridian. This is consistent with OCT profiling by Ritzmann et al. [28], who reported the variation in scleral elevation along the horizontal meridian was $\sim 1.95x$ greater than the vertical meridian over a 15 mm chord diameter (averaged across right and left eyes), and Consejo et al. [33] who observed $1.91x$ greater variation horizontally compared to vertically over a 15–16 mm chord analysis (averaged across both eyes). These anatomical variations in scleral elevation along the horizontal meridian explained 68% of the variation observed in horizontal scleral lens decentration, however, no association was observed between vertical scleral elevation asymmetry and vertical lens decentration. Consejo et al. [11] used a different approach to assess scleral lens decentration, by quantifying the location of tissue

compression (i.e. change in the scleral height profile) relative to the position of the theoretical proximal edge of the lens landing zone with no decentration following 5 h of scleral lens wear, but still found a very similar association between scleral asymmetry and lens decentration ($r = 0.71$) as observed in the current study. The results from the current study suggests that horizontal lens decentration is largely influenced by the horizontal scleral elevation profile, while vertical lens decentration is primarily governed by apical clearance (the position of the scleral lens centre of gravity relative to the cornea). However, since the scleral elevation profile can vary substantially between individuals [34], and fellow eyes [28,33], currently a scleral lens assessment in-vivo is required to examine the how the interaction between anatomical factors and other forces ultimately influence centration.

An advantage of the repeated measures study design used in this experiment is that potentially confounding lens variables were carefully controlled (e.g. corneal clearance, BVP, BOZR) in order to isolate the effect of lens thickness or mass upon centration. However, it is difficult to generalise these results to a wider clinical population since only a single rotationally symmetric lens design of fixed diameter was examined. Additionally, this study only included participants with healthy corneas. Although corneo-scleral limbal angles [35] and scleral thickness values [36] are similar between keratoconics and healthy age-matched controls, the findings from the current study may not translate to populations with advanced corneal disease which often requires scleral lenses with larger diameters and greater sagittal depth. Further studies including lens designs with a wide range of overall diameters, BVP's (particularly higher plus powered lenses), and central apical clearance values are required to improve the understanding of the interaction between lens fitting parameters, scleral shape, and lens decentration.

5. Conclusion

When controlling for confounding factors of BOZR, BVP, and central corneal clearance, altering scleral lens centre thickness, and therefore mass, did not significantly affect decentration. Horizontal lens decentration was associated with the difference in scleral elevation along the horizontal meridian at the proximal edge of the lens landing zone (greater differences in scleral elevation resulting in greater temporal lens decentration). Vertical lens decentration was significantly associated with initial central apical clearance (higher initial central clearance values resulting in greater inferior lens decentration), most likely due to an anterior shift in the centre of gravity of the scleral lens relative to the cornea. Factors affecting scleral lens centration appear to vary between the horizontal and vertical meridians.

Declaration of Competing Interest

The authors have no competing interests to declare.

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