The temporal dynamics of miniscleral contact lenses: central corneal clearance and centration

Stephen J Vincent PhD

David Alonso-Caneiro PhD

Michael J Collins PhD

Corresponding author: Stephen J Vincent

Email: sj.vincent@qut.edu.au

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

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Abstract

Purpose: To examine the time course of the reduction in central corneal clearance and horizontal and vertical lens translation (decentration) during miniscleral contact lens wear and the theoretical influence upon the optics of the post-lens tear layer.

Methods: Repeated high-resolution OCT images were captured over an 8 hour period of miniscleral contact lens wear (using a rotationally symmetric 16.5 mm diameter lens) in 15 young, healthy participants with normal corneae. Central corneal clearance and lens decentration were derived from OCT images using semi-automated image processing techniques.

Results: Central corneal clearance decreased exponentially over time, reducing by 76 ± 8 μm over 8 hours. Fifty percent of this reduction occurred within 45 minutes of lens wear and seventy-five percent within 2 hours, with thinning of the post-lens tear layer plateauing 4 hours after lens insertion. Lens translation exhibited a similar pattern of change (0.18 ± 0.04 mm temporal and 0.20 ± 0.09 mm inferior decentration) stabilising 1.5 - 2 hours after insertion. The change in the lens fit over time resulted in a small reduction in the power of the post-lens tear layer (-0.12 ± 0.01 D) and induced a prismatic effect of 0.01 ± 0.16 Δ base out and 0.50 ± 0.19 Δ base down relative to the pupil centre.

Conclusions: For the miniscleral contact lens studied, horizontal and vertical lens decentration followed an exponential decay over 8 hours that plateaued approximately 2 hours after lens insertion, while central post-lens tear layer thinning plateaued after 4 hours of lens wear.

1.0 Introduction

Miniscleral contact lenses are primarily used for the refractive correction of corneal ectasia or high ametropia, and as a therapeutic treatment of chronic ocular surface disease [1]. Due to their sealed nature, there is minimal tear exchange or lens movement upon blinking. The post-lens tear layer neutralises the majority of regular and irregular anterior corneal astigmatism and also provides protection and hydration for the ocular surface. While it is well known that scleral contact lenses gradually “settle back” posteriorly towards the cornea due to compression of the tissues underlying the landing zone [2], there is no consensus on the optimal initial corneal clearance (i.e. the thickness of the post-lens tear layer following lens insertion) to avoid central or limbal corneal touch, to minimise potential corneal hypoxia [3-5], or reduce post-lens tear layer debris or turbidity [6]. The recommended initial corneal clearance varies considerably with manufacturer or practitioner fitting philosophy, the lens type (fenestrated or non-fenestrated) and the ocular condition (ocular surface disease or corneal ectasia).

Prior to the introduction of gas permeable scleral lenses, deep fluid filled chambers were advocated with a central corneal clearance of 500-1500 μm [7]. However, this approach was later substantially revised to provide a central apical clearance of 50-120 μm with the desired final fit incorporating as large a total lens diameter as possible with adequate limbal clearance. Marriot and Woodward [8] suggested that for a settled impression scleral lens, central corneal clearance should remain between 60-80 μm to allow an even flow of tears over the cornea, and promoted greater limbal clearance (i.e. central clearance gradually increasing to a maximum over the limbus) [9]. A similar level of central corneal clearance has been recommended for fenestrated impression (50 μm) [10] or preformed scleral lenses (~70 μm) [11]. For modern non-fenestrated sealed scleral lenses made from gas permeable materials the final recommended central corneal clearance is typically between 100-300 μm ,

with a maximum of 100 μm for fenestrated lenses [12], however lenses can be worn successfully with substantially larger levels of corneal vault [13, 14].

Numerous factors influence the extent of scleral lens settling and consequently the final corneal clearance, including; the capillary attraction of the tears, the weight [12] and diameter [15] of the contact lens, and eyelid forces or morphometry [16]. Resistance from the tissues beneath the landing zone, including the conjunctiva, episclera, Tenon's capsule and the sclera also play a role. Fenestrated lenses made from older gas impermeable materials were thought to sink further into the ocular tissues due to a lack of resistance from an entrapped post-lens tear layer, and when worn on a daily basis, corneal clearance continued to reduce for up to two months [7]. Similarly, preformed scleral lenses yielded greater settling than customised impression lenses (made from a cast of the anterior eye), possibly due to their imperfect alignment with the sclera [11]. However, such claims were formed based upon subjective estimates of apical clearance without objective measurements of the post-lens tear layer (prior to the advent of high resolution anterior segment imaging).

Recent studies of modern highly gas permeable scleral lenses suggest that apical corneal clearance, quantified using optical coherence tomography (OCT), decreases by $\sim 50\text{-}130\text{ }\mu\text{m}$ 8 hours after insertion [15, 17], and up to $\sim 150\text{-}200\text{ }\mu\text{m}$ after one month of lens wear [18]. The change in the thickness of the post-lens tear layer appears to follow a two-stage exponential decay; a rapid initial settling (most noticeable during the first two hours of lens wear) followed by a slower period of settling which appears to plateau 4 hours after lens insertion [15]. In addition to a posterior movement of scleral contact lenses during settling, the lens may gradually translate (decentre) in the horizontal and vertical meridians, and rotate on the eye [19]. The gradual thinning of the post-lens tear layer and the decentration

of the contact lens both have the potential to affect the optical properties of the “tear fluid lens” by altering its refractive power and inducing a horizontal and/or vertical prismatic effect. Decentration of the optic zone relative to the pupil can also induce unwanted higher order aberrations that are not neutralised by the fluid reservoir.

Understanding the temporal dynamics of scleral contact lens settling and centration is of particular importance in order to optimise the lens fit (i.e. informing the target initial apical clearance to allow for lens settling to avoid corneal bearing) and its optical performance (i.e. potential adjustments to account for lens decentration). However, only a limited number of studies have reported in detail on the time course of the change in central corneal clearance during scleral contact lens wear [15, 20], and to date no studies have investigated the typical pattern of lens decentration that occurs over the course of a day. In this study the change in the central corneal clearance and the centration of a 16.5 mm diameter rotationally symmetric miniscleral contact lens was examined over an 8 hour period using high resolution OCT imaging, from which theoretical calculations of the changes in the optics of the post-lens tear layer during lens were derived.

2.0 Methods

Fifteen young, healthy adults (mean age: 22 ± 1 years, 8 female and 7 male) with visual acuity of 0.00 logMAR or better in both eyes were recruited from the staff and students of the Queensland University of Technology (QUT). All participants underwent an initial screening examination to exclude those with any ocular or vision abnormalities, or contraindications to contact lens wear such as significant tear film abnormalities or anterior segment inflammation. Four regular soft contact lens wearers were included, but ceased lens wear for at least 24 hours prior to any experimental measurements. None of the participants

routinely wore rigid contact lenses. Participants had no prior ocular history of injury, surgery or current use of topical medications. The sample size was determined based upon calculations using previously published data on corneal swelling following short-term scleral lens wear, an outcome measure published previously [21]. Several recent studies examining short-term changes in corneal clearance during scleral lens wear have also utilised similar sample sizes of 8-15 participants [15, 17, 20, 22]. This study was approved by the QUT human research ethics committee and followed the tenets of the Declaration of Helsinki.

2.1 Contact lens fitting

Irregular Corneal Design (ICD™ 16.5, Paragon Vision Sciences, USA) miniscleral contact lenses were used in this study (Boston XO material, minimum central thickness of 300 µm overall diameter of 16.5 mm, with a rotationally symmetric posterior surface). The diagnostic contact lens that provided an acceptable fit was determined as per the manufacturers fitting guide. An initial diagnostic lens was chosen based on the corneal sagittal height (measured over a 10 mm chord along the steepest corneal meridian) using a Medmont E300 videokeratoscope (Medmont, Australia). An additional 2400 µm was then added to this measured sagittal height value to extrapolate the corneal sag to a 15 mm chord (the landing zone of the lens) and to allow for ~200-400 µm of initial central corneal clearance. The lens was filled with preservative free saline and sodium fluorescein and inserted into the participants left eye and then assessed with a slit lamp to ensure corneal clearance centrally and at the limbus. If corneal bearing was observed, the sagittal depth of the lens was increased (in 100 µm increments) and reassessed. After an adequate initial fit was obtained, the fit was re-examined after one hour of settling. If corneal bearing was observed after settling, the sagittal depth of the lens was again increased and the process repeated until no evidence of corneal touch was apparent after the recommended one hour trial period.

2.2 Anterior segment imaging

On a separate day following the eligibility screening and trial contact lens fitting, all participants wore the optimal fitting diagnostic lens as determined at the previous study visit for a period of eight hours. The limbal clearance zone, the scleral landing zone, and back vertex power of the lens were not modified. The lens was inserted into the patients left eye with preservative free saline (Lens Plus, AMO) and examined under the slit lamp to ensure the post-lens tear layer was bubble free. To minimise the potential influence of any forces generated during lens application that may theoretically alter the initial lens clearance or rate of lens settling, insertion and removal was performed by the same researcher for each participant. Images of the anterior segment (including the contact lens, post-lens tear layer, and cornea) were captured over the course of the day using a spectral domain OCT (RS-3000, Nidek, Japan). This instrument has an optical transverse resolution of 20 μm and an axial resolution of 5 μm . A high definition 6 mm radial line protocol was used (12 line scans separated by 30 degrees, each consisting of 10 averaged images) centred on the pupil, visualised in the OCT scanning laser ophthalmoscope image during imaging. Three measurements were captured immediately following lens insertion and again after 15, 30, 45, 60, 90, 120, 240 and 480 minutes of lens wear. All participants commenced lens wear between 8-10 AM and ceased lens wear after the final measurement session, 8 hours later, between 4-6 PM.

2.3 Data processing

Following data collection, all raw OCT images obtained at each measurement time point were exported for further analyses. Using custom written software, the anterior and posterior surface of the contact lens, and the anterior corneal surface were automatically segmented (Figure 1). This approach has been described previously for segmentation of the

retina [23] and choroid [24] and utilises graph search theory to identify the particular boundaries of interest. Based on this automatic segmentation, a thickness profile map of the post-lens tear layer was generated, using an interpolation approach from the 12 segmented radial line scans. An experienced observer then visually inspected the three thickness maps generated for each subject at all time points and selected the best quality map with the least number of potential segmentation errors identified by obvious local thickness changes for further manual correction of the automatic layer segmentation of each radial line scan.

Following the inspection of each line scan and the correction of any segmentation errors, the normal (i.e. the point perpendicular to the tangent of the apex of surface of interest in the scan) to the anterior cornea was marked in each radial line scan, and the normal to the anterior surface of the contact lens was marked in both the horizontal and vertical line scans (Figure 1). The central corneal clearance at each time point was calculated by extracting the distance between the posterior surface of the contact lens and the anterior corneal surface at the corneal normal for each line scan and then calculating the average of the ten line scans for each 30° meridian. Lens decentration was quantified by calculating the change in the separation between the normal to the anterior corneal apex and the normal to the apex of the anterior lens surface at each time point for both the horizontal and vertical line scans (i.e. the normal to the surface defined the x,y Cartesian location for both corneal and lens apex).

The repeatability of the methods used to determine the central corneal clearance was assessed by analysing two repeated measures of the post-lens tear layer thickness at the corneal apex as determined by the same experienced observer in each radial line scan of the baseline OCT scans captured immediately after lens insertion for all participants. Similarly, the repeatability of horizontal and vertical decentration data was determined by analysing two repeated measures of the magnitude of decentration after 8 hours of lens

wear. The mean difference and the 95% limits of agreement were determined for central corneal clearance and decentration data using the methods of Bland and Altman [25].

2.4 Optics of the post-lens tear layer

While an over-refraction was not performed on the day of lens wear, the equivalent refractive power of the post-lens tear layer was calculated along the horizontal and vertical meridians at two time points; immediately after lens insertion and following eight hours of lens wear, to investigate the influence of the change in corneal clearance over the course of the day upon the power of the contact lens-tear layer system. This was done by calculating the equivalent power of a thick lens (F_e) using the formula:

$$F_e = F_1 + F_2 - \frac{t}{n} F_1 F_2$$

where F_1 denotes the power of the anterior surface of the fluid lens, F_2 denotes the power of the posterior surface of the fluid lens, t denotes the thickness of the post-lens tear layer in metres, and n denotes the refractive index of the post-lens tear layer (in this case 1.3347 [26]). This approach assumes that the fluid lens formed by the post-lens tear layer is separated from the posterior surface of the contact lens and the anterior cornea by infinitely thin layers of air. F_1 was determined using the known back optic zone radius of the contact lens and F_2 was determined using the radius of curvature along the horizontal and vertical meridians of the anterior cornea obtained from corneal topography measurements captured during the initial trial contact lens fitting procedure.

The theoretical induced vertical and horizontal prismatic effect associated with the lens decentration measured along each meridian was also calculated using the method described by Bennett [27] that accounts for the optical effect of the decentration of the contact lens and

the anterior surface of the post-lens tear layer. The magnitude of the prism induced (P) in prism dioptres is given by:

$$P = c \left[\frac{F_{CL}}{10} + \frac{33.47}{r_2} - \frac{33.47}{r_s} \right]$$

where c denotes the magnitude of lens decentration, F_{CL} denotes the back vertex power of the contact lens in air, r_2 denotes the back optic zone radius of the contact lens, and r_s denotes the radius of curvature of the anterior sclera (with all distances in mm). Bennett used a refractive index of 1.336 for the tears and a 14 mm radius of curvature for the anterior sclera, however, we have used 1.3347 as the known refractive index of the preservative free saline used in this experiment, and a more recent approximation of the radius of curvature of the anterior sclera (13.12 mm) [28].

2.5 Statistical analysis

To examine the statistical significance of the change in central corneal clearance and horizontal and vertical lens decentration during lens wear, a series of repeated measures analysis of variance (ANOVA) were conducted with a within-subject factor of time (0, 15, 20, 45, 60, 90, 120, 240 and 480 minutes following lens insertion). P-values were adjusted using the Greenhouse-Geisser correction to prevent any type I errors if the assumption of sphericity was violated. For ANOVA's with a statistically significant main effect of time, post-hoc pairwise comparisons between time points were conducted using two different approaches for p-value adjustments; the Bonferroni correction and Fisher's Least Significant Difference (LSD). While the Bonferroni correction is a commonly used statistical technique to reduce the likelihood of type I errors associated with multiple comparisons, this conservative approach is not ideal for the current analysis which aims to determine the time point during lens wear at which corneal clearance and lens decentration appears to stabilise (i.e. applying the Bonferroni correction may identify reasonably large clinical changes in

corneal clearance or decentration between time points as not statistically significantly different). Consequently, Fisher's LSD (which effectively does not adjust for multiple comparisons) was also used and the results from both approaches are presented. Pearson's correlation coefficient was used to quantify the association between variables of interest including the initial central corneal clearance, the magnitude of the change in corneal clearance, and the extent of horizontal and vertical lens decentration after 8 hours of lens wear. All statistical analyses were conducted using SPSS software (Version 23) and SigmaPlot (Version 12.5) and the results are reported as the mean or mean difference and the standard error.

3.0 Results

3.1 Measurement repeatability

The mean difference (95% limits of agreement) in central corneal clearance between the two analysed OCT images at the baseline measurement session was 0 μm (-2 to +2 μm). This indicates excellent repeatability and is in close agreement with inter-observer repeatability data for central corneal thickness using the RS-3000 OCT (a 4 μm 95% limit of agreement)[29]. The mean difference (95% limits of agreement) in total lens decentration over 8 hours of lens wear between the two series of analysed OCT images was 0.00 mm (-0.03 to +0.02 mm) for vertical decentration and 0.00 mm (-0.01 to +0.01 mm) for horizontal decentration indicating good repeatability. As expected, the limits of agreement were greater for measures of lens decentration (24 μm for horizontal and 52 μm for vertical) compared to central corneal thickness (4 μm) since the determination of decentration requires the manual selection of two locations within a line scan at two separate time points (baseline and another time point).

3.2 Central corneal clearance

On average, serial OCT measurements were captured immediately following lens insertion and then after 15 ± 1 , 30 ± 1 , 45 ± 1 , 60 ± 1 , 90 ± 1 , 120 ± 1 , 240 ± 2 , and 480 ± 1 minutes of lens wear. Figure 2 displays the change in the thickness of the post-lens tear layer over the course of the day. Corneal clearance varied significantly over time after lens insertion ($p < 0.0001$), with a rapid decrease during the first two hours of lens wear followed by a gradual plateau (asymptote) between 2-8 hours. The clearance data were fitted with a three parameter exponential decay function $y = y_0 + ae^{-bx}$ where y denotes the change in corneal clearance x minutes after lens insertion, and terms a , b and y_0 denote constants. The function $y = -74 + 70e^{-0.01x}$ gave an R^2 value of 0.98. Following 8 hours of lens wear, the post-lens tear layer decreased by $76 \pm 8 \mu\text{m}$ on average, with ~50% of this reduction occurring within the first 45 minutes of lens wear (a mean reduction of $39 \pm 5 \mu\text{m}$) and ~75% within two hours (a mean reduction of $57 \pm 7 \mu\text{m}$). While the central corneal clearance was still decreasing after 8 hours of lens wear, the mean change between 4 and 8 hours was only $3 \pm 4 \mu\text{m}$. Table 1 displays the post-hoc pairwise comparisons, examining the final corneal clearance after 8 hours of lens wear with each other time point. This analysis suggests that the thinning of the post-lens tear layer stabilised (i.e. further reductions were not statistically significant) after 4 hours of lens wear (Fisher's LSD).

3.3 Lens decentration

Lens decentration also exhibited a similar pattern of change (an exponential decay) to corneal clearance values over the course of the day, with the majority of decentration occurring within the first 1-2 hours of lens wear, followed by a gradual plateau thereafter (Figure 3). The magnitude of both horizontal ($p < 0.0001$) and vertical ($p < 0.001$) lens decentration varied significantly with time reaching a maximum after 8 hours of lens wear; a mean horizontal decentration of $0.18 \pm 0.04 \text{ mm}$ temporally and a mean vertical decentration

of 0.20 ± 0.09 mm inferiorly. Three-parameter exponential decay functions were used to describe the change in lens decentration over time; *vertical decentration (mm)* = $-0.20 + 0.21e^{-0.01x}$ ($R^2 = 0.99$), and *horizontal decentration (mm)* = $-0.14 + 0.14e^{-0.03x}$ ($R^2 = 0.86$), where x denotes the time after lens insertion in minutes. While a more complex seven-parameter exponential decay function provided a slightly better fit for the horizontal decentration data ($R^2 = 0.97$), only the three-parameter model is presented to facilitate direct comparison with the vertical decentration data.

Table 2 displays the mean difference in both horizontal and vertical lens decentration at each time point compared to the final decentration values after 8 hours of lens wear. Post-hoc analysis (using Fisher's LSD) suggests that lens decentration stabilises between 90-120 minutes after lens insertion. Approximately 50% of the total lens decentration measured at 8 hours was observed after 30 minutes of lens wear along the horizontal meridian (0.10 ± 0.03 mm, 56% of the total decentration) and after one hour of lens wear along the vertical meridian (0.09 ± 0.07 mm, 46%). This suggests that the temporal dynamics of lens decentration varies slightly along the horizontal and vertical meridians in the initial phase after lens insertion (as evidenced by the different exponential decay fits in Figure 3), but reach a similar endpoint after 8 hours. Examination of the decay constant in each function describing lens decentration (term b), suggests that decentration occurred more rapidly in the horizontal meridian (-0.03) compared to the vertical meridian (-0.01).

3.4 Correlation analyses

A series of correlation analyses were also conducted to explore the relationships between the lens fit immediately after insertion (i.e. the initial central clearance value) and the magnitude of the reduction in the thickness of the post-lens tear layer, and the extent of horizontal and vertical lens decentration. No relationship was observed between the initial

corneal clearance value and the extent of post-lens tear layer thinning after 8 hours of lens wear ($r = 0.31$, $p = 0.26$), or the change in central corneal clearance and the final amount of horizontal ($r = -0.33$, $p = 0.24$) or vertical ($r = 0.11$, $p = 0.69$) decentration. Similarly, the initial central corneal clearance value was not associated with the magnitude of vertical lens decentration ($r = -0.15$, $p = 0.59$), however, a significant negative correlation was observed between initial central corneal clearance and horizontal decentration after 8 hours ($r = -0.64$, $p = 0.01$) indicating that greater clearance immediately following lens insertion was associated with more horizontal lens decentration. Based on an arbitrary split of the participants into “lower” and “higher” initial corneal clearance groups using the mean initial central corneal clearance value ($335 \mu\text{m}$), “lower” central corneal clearance values exhibited significantly less final horizontal decentration ($-0.07 \pm 0.01 \text{ mm}$) compared to “higher” clearance values ($-0.27 \pm 0.05 \text{ mm}$) ($p < 0.02$, unpaired t-test), however vertical decentration was similar between the two groups (lower: $-0.21 \pm 0.07 \text{ mm}$, higher: $-0.20 \pm 0.11 \text{ mm}$, $p = 0.96$).

3.5 Optics of the post lens tear layer

The change in the equivalent power of the liquid lens due to the thinning of the post-lens tear layer over the course of the day was also investigated along both the horizontal and vertical meridians. After 8 hours of lens wear, compared to immediately following lens insertion, the mean change in the equivalent power of the liquid lens was $-0.12 \pm 0.01 \text{ D}$ along both meridians. This small change was highly statistically significant ($p < 0.0001$), but only reached clinically significant levels (more than a 0.125 D change) in seven of the fifteen participants (maximum change -0.21 D). The prismatic effect induced due to lens decentration relative to the corneal normal after eight hours of lens wear was also small; on average $0.38 \pm 0.10 \Delta$ base out and $0.33 \pm 0.15 \Delta$ base down (maximum prism induced 1.08Δ base out and base down). However, after accounting for the horizontal and vertical pupil

offset relative to the centre of the cornea (obtained from the Medmont E300 topography maps) (the pupil centre was on average 0.17 ± 0.04 mm temporal and 0.04 ± 0.03 superior to the corneal centre), the induced prismatic effect relative to the pupil centre reduced to $0.01 \pm 0.16 \Delta$ base out and increased to $0.50 \pm 0.19 \Delta$ base down (maximum prism induced 1.35Δ base out, 1.53Δ base down).

4.0 Discussion

The reduction in central corneal clearance over time followed an exponential decay as expected, with rapid post-lens tear layer thinning observed during the first two hours of wear ($57 \pm 7 \mu\text{m}$, or 75% of the final reduction in clearance), and minimal further reduction between 4 and 8 hours of lens wear ($3 \pm 4 \mu\text{m}$, $p > 0.05$) indicating stabilisation 4 hours after insertion. This time course is consistent with the two-phase decay in corneal vault reported by Kauffman et al [15] for scleral lenses of various design, diameter (14.3 - 18.2 mm) and initial clearance values (125 - 400 μm). The mean change in central corneal clearance after 8 hours of lens wear in our participants ($76 \pm 8 \mu\text{m}$) was similar to previous studies using miniscleral lenses of similar diameter and duration of lens wear; 63 μm for the 16.5-17.5 mm diameter Esclera lens [22] and 96 μm for the 16.5 mm ICD lens [17]. No correlation was observed between the initial central corneal clearance following insertion and the reduction in clearance over time, contrary to a previous report that a greater initial apical clearance was associated with more settling [22]. This is most likely due to the low clearance group (100 - 200 μm initial clearance) influencing this relationship in the previous study [22], whereas in the current study the initial clearance was significantly greater and relatively uniform ($335 \pm 32 \mu\text{m}$).

Mountford [18] reported that following one month of daily ICD 16.5 miniscleral contact lens wear, the mean reduction in apical clearance was 146 μm , approximately double that

observed in our short-term study using the same lens design. This may be partially due to the difference in the two cohorts (normal healthy eyes in the current study compared to a clinical study including patients with various corneal conditions) since eyes fitted with scleral lenses for corneal ectasia have been shown to sink approximately twice as much as eyes fitted for ocular surface disease ($125\text{ }\mu\text{m}$ compared to $68\text{ }\mu\text{m}$ after four hours of lens wear) [14]. This is most likely due to the greater sag and potentially the weight of the lens required to fit some abnormal corneal shapes. However, the duration of lens wear no doubt also plays a role in the extent of lens settling. Bier observed a settling period of 3-8 weeks with an average of one month, if haptic lenses were worn on a full time daily wear basis (with reduced wearing time prolonging the settling period) [7]. Age may also influence the final magnitude of lens settling since conjunctival thickness decreases with age [30, 31], and the superficial layers of the conjunctiva, episclera and Tenon's capsule account for the majority of tissue compression beneath the landing zone [2].

The theoretical change in the refractive power of the post-lens tear layer after eight hours of lens wear was calculated to be $-0.12 \pm 0.01\text{ D}$ on average by using the known BOZR of the contact lens, the radius of curvature of the anterior cornea, the refractive index of the saline solution, and the measured change in the thickness of the post-lens tear layer. This value is in close agreement with the mean over refraction obtained using both objective and subject techniques (a $+0.13 \pm 0.30\text{ D}$ change in best sphere over refraction) following 6-8 hours of lens wear of 15.8 mm diameter miniscleral lens which reduced in central corneal clearance by $80 \pm 20\text{ }\mu\text{m}$ [32]. Our finding is also similar to theoretical calculations using a different approach (Munnerlyn's formula) (a -0.19 D change in the liquid lens after 6 hours of lens wear) for a different scleral lens design (an 18 mm diameter lens) that reduced in central clearance by $70 \pm 10\text{ }\mu\text{m}$ [20]. This magnitude of change over the course of the day is unlikely to be of clinical significance for pre-presbyopic patients; however, changes of 0.25 D may have some minor impact upon near vision for patients with reduced accommodation or

those wearing multifocal corrections. The influence of the change in the optics of the post-lens tear layer may become more apparent over time; for example, Mountford [18] reported a mean reduction in central clearance of 146 μm after one month of ICD miniscleral lens wear, which would equate to a -0.23 D change in the post-lens tear layer (a change of 250 μm would equate to $\sim$ 0.50 D). Consequently, an additional +0.25 D could be incorporated into the final back vertex power of the dispensed lens to compensate for this eventual refractive shift.

Numerous qualitative clinical studies and case reports have commented on the tendency for scleral contact lenses, in particular preformed lenses, to decentre infero-temporally. In a large cohort of scleral lens wearers, Visser et al [19] reported that for a non-rotationally symmetric peripheral design, decentration was most commonly observed in the infero-temporal direction (11.3%), followed by inferiorly (9.4%) and temporally (6.1%). However, these observations were based on slit lamp examination alone. To our knowledge, the current study is the first to accurately quantify the time course and magnitude of miniscleral lens decentration over several hours of lens wear. Significant temporal and inferior decentration (on average 0.18 mm and 0.20 mm respectively) was observed relative to the corneal normal 8 hours after lens insertion (equivalent to a final lens decentration of 0.01 mm temporal and 0.24 mm inferior to the pupil centre) with horizontal and vertical lens translation appearing to stabilise after 2 hours of lens wear (Table 2, Figure 3). Lower initial central corneal clearance values were associated with less horizontal, but not vertical, lens decentration throughout lens wear. For this particular lens design (a rotationally symmetric 16.5 mm diameter miniscleral), horizontal lens decentration may be minimised by fitting with an initial central clearance value of $\sim$ 350 μm or less. However, it should be noted that successful scleral lens wear can be achieved with a wide range of initial clearance values (e.g. up to 1800 μm [14]) dependent upon the total lens diameter and ocular condition treated.

This magnitude of lens decentration will have minimal impact upon vision for standard spherical or aspheric scleral lenses which often have an optic zone diameter of ~10 mm. However, multifocal scleral lenses are becoming a more popular refractive correction for presbyopia, and the optic zone in these lenses can vary substantially from 0.5 to 7 mm in diameter for centre-near designs (in 0.05 to 0.1 mm increments) and are often customised based on the habitual pupil size, or are reduced in size for the dominant eye compared to the non-dominant eye, or for higher powered additions. Alternatively, an annulus of add power may be incorporated in the mid-periphery of the lens (i.e. centre-distance designs). For such presbyopic corrections, lens centration with respect to the pupil will influence visual performance.

Knowledge of scleral lens decentration is also critical for emerging wavefront guided lenses which are customised to correct ocular higher order aberrations arising from the anterior cornea (through the post-lens tear layer), and the posterior cornea and internal optics (using a customised front surface correction) in advanced keratoconus [33, 34]. Sabesan et al [33] reported mean absolute decentration values of 0.27 mm horizontally and 0.88 mm vertically in a small cohort of patients with keratoconus wearing scleral lenses with customised peripheral haptics, which was then accounted for in a customised front surface wavefront design to minimise residual higher order aberrations (i.e. decentring the front surface optics to align with the pupil). Over a one hour period Ticak et al [35] reported a mean horizontal decentration of ~0.1 mm horizontally and ~0.15 mm vertically in four subjects (including one keratoconic) fitted with an 18.1 mm diameter scleral lens with a rotationally symmetric haptic profile. This is similar to our results one hour after lens insertion (0.10 ± 0.03 mm temporal and 0.09 ± 0.07 mm inferior decentration); however, since lens decentration continued to increase until 2 hours after insertion in our participants, trial fittings to quantify the magnitude

of lens decentration to be incorporated in the design of customised higher order aberration front surfaces may need to be conducted for periods of up to 2 hours.

Inferior decentration is thought to be a result of the mass of the lens and potentially eyelid forces or morphometry, whereas temporal decentration is most likely due to the scleral anatomy at the landing zone of the lens (i.e. the nasal sclera is more elevated and has a flatter radius of curvature compared to the temporal sclera along the horizontal meridian [28, 36]). In addition to decentring the optic zone nasally (typically by 1-1.5 mm) as outlined above [33, 34], other potential approaches to increase lens stabilisation include increasing the total lens or optic zone diameter, flattening mid-peripheral/transition curves, changing from a spherical to an aspheric lens design, or incorporating a toric periphery.

While lens decentration can introduce unwanted higher order aberrations due to the mislocation of the anterior lens surface relative to the pupil, the introduction of prism may be more problematic, particularly as a result of inferior decentration due to less tolerance for vertical prismatic imbalance. This may be problematic in patients wearing a monocular scleral lens correction (as the maximum vertical prismatic effect observed in our participants was 1.5 Δ base down), however, since the between eye symmetry for lens decentration is high [35], for patients wearing lenses in both eyes, a base down effect in both eyes will eliminate any significant interocular vertical prismatic imbalance.

A limitation of our study was that limbal corneal clearance values were not measured. Sufficient peripheral corneal clearance is important throughout scleral contact lens wear in order to minimise any adverse mechanical disruption to the limbal stem cells. Future studies examining the change in limbal corneal clearance over time may provide further insights into post-lens tear layer changes in specific regions. This is of clinical interest given that the final

corneal vault in customised scleral lenses with a toric periphery has been shown to vary significantly with corneal location (i.e. reduced superior-nasal clearance and greater inferior-temporal stand-off) [19]. Similarly, rotational lens stability was not measured in the current study since the lenses used were rotationally symmetric without a posterior toric periphery. The use of a relatively small, homogenous sample of participants with healthy eyes is also a limitation since the results cannot be generalised to contact lens wearers with abnormal corneae, or different lens designs. However, our data is in broad agreement with the trends described in previously published settling and decentration data from both normal [15, 17, 20, 32] and keratoconic patients [14, 18, 22, 35] wearing a variety of scleral lenses.

5. Conclusion

Young healthy eyes with normal corneae fitted with a high Dk rotationally symmetric miniscleral contact lens (ICD 16.5) exhibited an exponential decay in central corneal clearance over 8 hours of lens wear which began to plateau 4 hours after lens insertion. Lens translation was minimal over the course of the day (on average ≤ 0.2 mm of horizontal and vertical decentration) and also followed an exponential change over time, beginning to plateau between 1.5 - 2 hours after insertion. For initial miniscleral contact lens trial fittings with the ICD 16.5, the fit should be assessed at least 4 hours after lens insertion to allow for stabilisation with respect to post-lens tear layer thinning and lens decentration, but also reviewed approximately one month after dispensing due to the known increase in settling that occurs during the early period of frequent daily lens wear. While this study provides a comprehensive analysis of the time course of scleral lens settling and decentration for the ICD 16.5 lens, temporal clearance and centration characteristics may vary substantially with both lens design and ocular condition.

Conflicts of interest

The authors have no financial interest in any of the products mentioned in the manuscript.

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Table 1. The mean difference ($\pm$ SE) in central corneal clearance at each time point compared to the final central corneal clearance after 8 hours of lens wear.

Time after lens insertion (minutes)	Mean difference in central corneal clearance compared to 480 minutes (μm)	Post-hoc comparison (p-value)	
		LSD	Bonferroni
0	76 $\pm$ 8	<0.00001*	<0.00001*
15	53 $\pm$ 7	<0.00001*	<0.00001*
30	48 $\pm$ 6	<0.00001*	0.001*
45	37 $\pm$ 7	<0.00001*	<0.01*
60	28 $\pm$ 5	0.0002*	<0.01*
90	21 $\pm$ 5	0.001*	<0.05*
120	18 $\pm$ 5	0.001*	0.05
240	3 $\pm$ 4	0.41	1.00

LSD – Fisher's Least Significant Difference

* Statistically significant difference in central corneal clearance compared to the 8 hour final clearance value. Non-statistically significant differences ($p > 0.05$) indicate stabilisation of the post-lens tear layer thinning.

Table 2. The mean difference ($\pm$ SE) in horizontal and vertical lens decentration relative to the corneal normal at each time point compared to the final decentration values after 8 hours of lens wear.

Time after lens insertion (minutes)	Mean difference in horizontal decentration compared to 480 minutes (mm)	Post-hoc comparison (p-value)		Mean difference in vertical decentration compared to 480 minutes (mm)	Post-hoc comparison (p-value)	
		LSD	Bonferroni		LSD	Bonferroni
0	0.18 $\pm$ 0.04	0.001*	<0.05*	0.20 $\pm$ 0.09	<0.05*	1.00
15	0.12 $\pm$ 0.04	<0.01*	0.27	0.19 $\pm$ 0.06	<0.01*	0.16
30	0.08 $\pm$ 0.04	<0.05*	1.00	0.15 $\pm$ 0.05	<0.05*	0.38
45	0.06 $\pm$ 0.23	<0.05*	0.61	0.12 $\pm$ 0.05	<0.05*	0.98
60	0.07 $\pm$ 0.03	<0.05*	1.00	0.11 $\pm$ 0.04	<0.05*	0.42
90	0.06 $\pm$ 0.04	0.11	1.00	0.07 $\pm$ 0.03	<0.05*	1.00
120	0.07 $\pm$ 0.03	0.07	1.00	0.06 $\pm$ 0.03	0.07	1.00
240	0.04 $\pm$ 0.03	0.29	1.00	0.02 $\pm$ 0.03	0.57	1.00

LSD – Fisher’s Least Significant Difference

* Statistically significant difference in horizontal or vertical lens decentration compared to 8 hour final decentration value. Non-statistically significant differences ($p > 0.05$) indicate lens stabilisation.

Figure 1. An example anterior segment OCT image prior to segmentation (A), and the same scan following segmentation of the layers of interest (B); the anterior surface of the contact lens (pink), the posterior surface of the contact lens (blue), and the anterior corneal surface (green). The yellow lines represent the tangent (solid line) and normal (dashed line) to the apex of the anterior surface of the contact lens and the red lines represent the tangent (solid line) and normal (dashed line) to the apex of the anterior corneal surface within the line scan. The central corneal clearance was calculated as the distance between the posterior surface of the contact lens and the anterior surface of the cornea at the normal to the anterior cornea averaged over twelve line scans. Decentration values were calculated by measuring the change in the distance between the normal to the apex of the anterior corneal surface and the apex of the anterior surface of the contact lens (the distance between the two white arrows) for the horizontal and vertical line scans at each time point.

Figure 2. The mean change in central corneal clearance (the post-lens tear layer thickness) over eight hours of ICD 16.5 miniscleral contact lens wear. The red line indicates the line of best fit and the vertical and horizontal error bars represent the standard error of the mean.

Figure 3. The time course of ICD 16.5 miniscleral vertical (A) and horizontal (B) decentration relative to the corneal normal over eight hours of lens wear. The red line indicates the line of best fit and the vertical and horizontal error bars represent the standard error of the mean. Negative values on the y-axis indicate inferior (A) and temporal (B) decentration respectively.