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The time course and nature of corneal oedema during sealed miniscleral contact lens wear

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Abstract

Purpose: To examine the magnitude and time course of central epithelial, stromal and total corneal thickness changes during sealed miniscleral contact lens wear and the influence of initial central corneal clearance upon these thickness changes.

Methods: High-resolution OCT images were captured over an 8 hour period of miniscleral lens wear in 15 young, healthy participants with normal corneae. Corneal thickness data were derived from OCT images using semi-automated techniques.

Results: Changes in stromal and total corneal thickness followed a similar pattern, with oedema first detected 15 minutes after lens insertion (0.47 ± 0.09% increase in stromal and total corneal thickness, both $p < 0.01$) which peaked after 90 minutes (1.36 ± 0.24% increase in stromal and 1.18 ± 0.20% increase in total corneal thickness, both $p < 0.01$) and decreased thereafter. Epithelial thickness decreased to a minimum thickness 480 minutes after lens insertion (2.38 ± 0.70% decrease, $p < 0.05$). The maximum change in epithelial, stromal, and total corneal thickness values were not associated with the initial central clearance or the extent of lens settling (all $p > 0.05$). Greater initial central corneal clearance resulted in less oxygen reaching the cornea (~2% less) based on published data, which manifested as ~0.5% more central corneal oedema.

Conclusions: Central stromal and total corneal thickness increased rapidly following lens insertion and peaked after 90 minutes, while central epithelial thickness gradually decreased throughout lens wear. Greater initial central clearance resulted in reduced corneal oxygen delivery, which had minimal short-term impact upon healthy eyes.

1.0 Introduction

The symptoms of scleral contact lens induced corneal oedema were first described by Muller following his experimentation with glass haptics in the 1880's [1], however the physiological mechanism underlying Sattler's Veil (epithelial oedema) remained elusive and was fiercely debated for the next half a century [2]. Early clinical attempts to delay the inevitable, but highly variable onset of corneal haze, included fitting slightly flat or loose in the haptic zone to encourage tear exchange at the expense of comfort, and altering the composition or pH of the post-lens fluid reservoir [3]. These approaches to minimising corneal oedema were unpredictable, and until "ventilated" (fenestrated) scleral lenses were introduced and much later oxygen permeable RGP sclerals [4], patients often removed their lenses for extended periods throughout the day to restore vision.

Although the oxygen permeability of rigid lens materials has improved substantially in recent years, there is still debate surrounding the corneal oxygen requirements for successful scleral contact lens wear; particularly since modern sealed scleral lenses are manufactured with a minimum centre thickness typically ≥ 300 μm to minimise lens flexure, exhibit limited to no tear exchange following lens settling, and the relatively thick post-lens tear layer itself may inhibit oxygen transmission to the cornea. However, despite these potential barriers to atmospheric oxygen, a number of short-term clinical studies have confirmed that modern highly oxygen permeable scleral contact lenses worn on a daily wear basis, typically induce ≤ 2% of total corneal oedema in young healthy eyes [5–8]. These studies have quantified the change in the total corneal thickness using optical coherence tomography (OCT) or Scheimpflug imaging following a specified period of lens wear, typically after lens removal to facilitate imaging. Consequently, the time course (both the onset and recovery) and nature (epithelial and/or stromal) of scleral lens induced corneal oedema has not been investigated in detail.

Studies using soft contact lenses, eyelid closure, or gases of varying oxygen concentration suggest that the cornea swells rapidly under hypoxic conditions and stabilises after 2-4 hours dependent upon the extent of the hypoxic stress [9–11]. However, the onset of corneal oedema during scleral lens wear may differ substantially to oedema associated with soft contact lenses or corneal RGP's, given the lack of tear exchange in a sealed system and the dynamic thinning of the post-lens tear layer associated with scleral lens landing zone settling into the underlying conjunctiva and episclera [12]. Pullum et al [13] examined the time course of corneal oedema in a single sealed PMMA scleral lens wearer and observed no swelling after 1 hour of lens wear, followed by a steady increase to 8% after 3 hours which then plateaued, suggesting that the post-lens tear layer may provide a reservoir of oxygen during the first hour after lens insertion.

Theoretical models of oxygen diffusion and scleral lenses have utilised a resistance in series approach [14] based on Fatt's [15] earlier modelling of piggyback systems (soft and rigid contact lenses worn in combination), or have also taken into consideration the oxygen consumption of each corneal layer [16,17]. These models suggest that scleral lenses should be fitted with minimal central and limbal clearance (e.g. not exceeding 200 µm and 50-60 µm respectively [14]) to maximise the overall Dk/t of the scleral lens system [14] or the tear layer oxygen tension [17] to minimise potential anterior segment hypoxia. However, clinical case series of patients with both ocular surface disease and corneal ectasia suggest that modern highly oxygen permeable scleral contact lenses can be worn successfully and provide good vision and comfort with substantially greater levels of apical clearance (e.g. 600 to 1000 µm central vault) [18,19]. A small number of studies have systematically examined the influence of altering apical clearance upon scleral lens induced corneal oedema, typically in young participants with keratoconus [5] or healthy corneae [6,20]. These studies have utilised a repeated measures design to control for confounding variables such as lens design (e.g. thickness, oxygen permeability, peripheral seal off or tear exchange), individual variations in

the corneal response and wearing time, and suggest that modifying the apical clearance does not substantially alter the magnitude of corneal oedema following 3-8 hours of lens wear. Esen and Toker [5] observed no significant difference in the extent of corneal swelling after 8 hours of lens wear in keratoconic patients fitted with low (100-200 μm) medium (200-300 μm) or high (>300 μm) apical clearance (less than 4 μm or ~0.9% difference in oedema between the various clearance groups), and observed a trend towards greater levels of oedema with lower levels of apical clearance also reported in other short-term studies [7,8]. Arlt [6] also found only 0.5% more oedema in young patients fitted with over 600 μm of central clearance (2.1% swelling) compared to the same miniscleral lens fitted with only 200 μm of central clearance (1.6% swelling). However in one study [20], a larger apical clearance (350 μm) was associated with significantly more corneal oedema (~2% greater) than a lower clearance (150 μm). The methodology of this particular study differs somewhat from other studies that report no significant effect of altering corneal clearance [5,6] since a smaller diameter scleral lens was used (15.5 mm), the clearance values were estimated subjectively, and corneal thickness was measured using a manual ultrasound pachymeter rather than high resolution OCT.

In the current study the change in central corneal thickness (epithelial, stromal, and total corneal thickness) was measured using high resolution OCT imaging over an 8 hour period of sealed miniscleral lens wear to examine the time course and nature of the induced corneal swelling and the influence of central corneal clearance. The change in total corneal thickness was also compared to previously published data to estimate oxygen delivery to the cornea during scleral lens wear.

2.0 Methods

The details of the study participants, contact lens fitting process, imaging procedures and

experimental design have been described previously [21] and are summarised below. 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 Queensland University of Technology (QUT). Participants underwent a 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 wore rigid contact lenses. Participants had no prior ocular history of injury, surgery or current use of topical medications. 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

Participants were fitted with Irregular Corneal Design (ICD™ 16.5, Paragon Vision Sciences, USA) sealed miniscleral contact lenses (Boston XO material, minimum central thickness of 300 µm and overall diameter of 16.5 mm). The diagnostic contact lens that provided an acceptable fit was determined as per the manufacturers fitting guide and the limbal clearance zone, the scleral landing zone, and back vertex power of the lens were not modified. The initial diagnostic lens was selected 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 to extrapolate the corneal sag to a 15 mm chord (the landing zone of the lens) and to allow for ~200-400 µm of 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 central and limbal corneal clearance. 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 and 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 one hour of settling.

2.2 Anterior segment imaging

On a separate day, participants wore the optimal fitting diagnostic lens for a period of eight hours. The lens was inserted into the patients left eye with preservative free saline and a bubble free post-lens tear layer. Corneal thickness measurements were captured over the course of the day using a spectral domain OCT (RS-3000 Advance, Nidek, Japan) with a digital axial resolution of 4 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. Three measurements were captured immediately following lens insertion and again after 15 ± 1, 30 ± 1, 45 ± 1, 60 ± 1, 90 ± 1, 120 ± 1, 240 ± 2 and 480 ± 1 minutes of lens wear. 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

The raw OCT images obtained at each measurement time point were exported for further analyses. The posterior surface of the contact lens, the anterior and posterior boundaries of the corneal epithelium and the posterior corneal boundary (endothelium) were automatically segmented using customised software. This approach has been described previously for the segmentation of anterior [21], and posterior ocular structures [22]. Based on this automatic segmentation, thickness profile maps of the post-lens tear layer, corneal epithelium and total cornea were generated, using an interpolation approach from the 12 radial line scans. An experienced observer then visually inspected these thickness maps generated for each

subject at each time point and selected the best quality map with the least number of 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 manual correction of any segmentation errors within the boundaries of interest, the normal of the anterior epithelial surface (i.e. the point perpendicular to the tangent of the anterior corneal apex) was marked in each radial line scan. The central epithelial, stromal, and total corneal thickness values were calculated at each time point by extracting the axial distance between the relevant segmented boundaries averaged over the central 4 mm (centred at the normal) for each line scan and then calculating the average of the 12 line scans. A 4 mm diameter was chosen due to a small number of OCT images affected by vignetting. Central corneal clearance was calculated as the mean distance between the posterior surface of the contact lens and the anterior corneal surface at the corneal normal, averaged over the 12 line scans.

2.4 Statistical analysis

To examine the statistical significance of the change in central epithelial, stromal and total corneal thickness, 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) and a between subject factor of initial central corneal clearance based on a mean split of the central corneal clearance data immediately after lens insertion (mean initial clearance of all subjects 335 ± 46 μm; mean “lower” clearance group 225 ± 21 μm [n =7], mean “higher” clearance group 431 ± 26 μm [n = 8]). For ANOVA’s with a statistically significant main effect or interaction, post-hoc pairwise comparisons between time points were conducted using a Bonferroni correction. Pearson’s correlation analysis was also used to examine the association between each of the following thickness changes during lens wear;

the maximum total corneal oedema, the maximum stromal oedema, and the maximum epithelial thinning with both the initial central corneal clearance value (immediately following insertion) and the magnitude of lens settling (the reduction in central corneal clearance over the 8 hour wearing time).

The repeatability of the OCT segmentation method used to determine central corneal thickness was assessed by analysing two repeated measures of the epithelial, stromal, and total corneal thickness averaged over the central 4 mm (derived from the 12 line scans for each participant) as determined by the same experienced observer for the baseline OCT scans captured immediately after lens insertion. The mean difference and the 95% limits of agreement were determined using the methods of Bland and Altman [23]. To estimate the oxygen partial pressure (and oxygen tension) beneath the sealed miniscleral contact lenses, total corneal swelling over the 8 hour period for all subjects and the "lower" and "higher" clearance groups were compared to previously published data (extracted using WebPlotDigitizer) of corneal swelling in response to gases of varying oxygen concentrations [9]. All statistical analyses were conducted using SPSS software (Version 23) 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) between the two analysed OCT images at the baseline measurement session was 0 µm (-1 to +2 µm) for the epithelium, -1 µm (-3 to +2 µm) for the stroma, and 0 µm (-2 to +2 µm) for the total cornea. This indicates excellent repeatability with the 95% limits of agreement for each corneal thickness measurement less than the axial resolution of the instrument, and is in close agreement with inter-observer

repeatability data for total central corneal thickness using the RS-3000 OCT in normal corneae (a 4 µm 95% limit of agreement) [24].

3.2 Change in central corneal thickness

Figure 1 displays the change in the thickness of the epithelium, stroma and total cornea averaged over the central 4 mm for the 8 hour period of lens wear. Central thickness values varied significantly over time following lens insertion ($p < 0.0001$ for the epithelial, stromal, and total corneal thickness). A statistically significant increase in total corneal thickness was observed 15 minutes following lens insertion (0.47 ± 0.09% swelling, $p = 0.006$) which stabilised 45 minutes after insertion at 1.01 ± 0.14% (i.e. subsequent measurements were not statistically different from this value) and peaked after 90 minutes of wear (1.18 ± 0.20% swelling). After the peak total corneal thickness swelling at 90 minutes, a gradual thinning was observed at the 120, 240, and 480 minute time points. The stromal thickness data displayed a very similar trend to the total corneal thickness data over the 8 hours of lens wear; a statistically significant increase in stromal thickness was observed 15 minutes following lens insertion (0.47 ± 0.09%, $p = 0.004$), which stabilised 45 minutes after insertion at 1.10 ± 0.15%, peaked after 90 minutes of wear (1.36 ± 0.24%), and gradually thinned thereafter. The epithelial thickness data displayed a significantly different pattern of change over the 8 hour period of lens wear. While the epithelium swelled slightly during the first 30 minutes of lens wear (0.56 ± 0.30% $p > 0.05$), from 45 minutes after lens insertion, the epithelial thickness continued to decrease, stabilising after 90 minutes (0.88 ± 0.35% thinning) and reaching a maximum thinning after 480 minutes (2.38 ± 0.70% thinning, $p < 0.05$).

3.3 Effect of central corneal clearance and lens settling

No significant correlations were observed between any of the thickness changes and the

baseline central corneal clearance or the magnitude of lens settling (all $p > 0.05$). Repeated measures ANOVA revealed no statistically significant effect of initial central corneal clearance (i.e. central clearance or central clearance by time interaction) upon epithelial ($p = 0.77$), stromal ($p = 0.20$) or total corneal thickness ($p = 0.13$) changes observed during lens wear (Figure 2). Averaged across all time points, the "higher" initial clearance group displayed slightly greater, but clinically insignificant, thickness changes compared to the "lower" initial clearance group (0.77 ± 0.60% less epithelial thinning, 0.20 ± 0.30% more stromal thickening and 0.25 ± 0.28% more total corneal thickening in the "higher" initial clearance group). The difference in peak oedema between the two clearance groups after 90 minutes of lens wear was less than 0.5% for both stromal and total corneal oedema.

3.4 Oxygen tension and central corneal clearance

Figure 3 displays the change in total corneal thickness for all subjects (panel A) and the "higher" and "lower" central corneal clearance groups (panel B) over the 8 hours of lens wear plotted against previously published data of the corneal response in healthy young adults during exposure to gases of 7.5% and 10.1% oxygen concentration (oxygen partial pressures of 55 mmHg and 74.1 mmHg respectively) [9]. The magnitude and time course of the corneal response averaged across all subjects (Figure 3A), appears to follow the trends reported for total corneal thickness changes in response to oxygen concentrations of 7.5% and 10.1%. Figure 3B highlights that the corneal response observed in the "lower" initial clearance group displayed a similar time course and magnitude of oedema to the 10.1% oxygen concentration data, while for the "higher" initial clearance group, the total corneal oedema data was more closely aligned with the 7.5% oxygen data.

4.0 Discussion

The mean peak total corneal oedema observed in our subjects after 90 minutes of sealed miniscleral lens wear (1.18 ± 0.20%) is consistent with a number of previous studies also using high resolution imaging techniques to quantify corneal thickness changes following 3-8 hours of high Dk scleral lens wear in young participants (typically between 1-2% swelling) [5–8]. Lafosse et al [25], however, recently reported corneal oedema of 5.1% after 8 hours of 18 mm diameter high Dk (100) scleral contact lens wear. This significantly greater level of oedema compared to previous studies [5–8] is most likely due to the older patient cohort (mean age 54 years) with a presumably slightly reduced endothelial cell count (~6% reduction has been reported between 30 and 50 years of age [26], and is possibly also a consequence of the baseline corneal thickness measures being captured without the scleral lens on eye compared to subsequent thickness measures obtained through the lens on eye (i.e. a potential magnification effect), or the lower axial resolution of the OCT used (18 µm) [27]. Interestingly, Lafosse et al [25] observed a significant increase in oedema between 20 minutes and 8 hours of lens wear (~3.8%), whereas in our study, corneal oedema had returned to 0.49% after 8 hours (originally 0.47% oedema after 15 minutes). This implies an impaired endothelial pump mechanism in their older cohort of unadapted lens wearers compared to the younger participants included in previous studies (mean ages ranging from 22-34 years) [5–8].

The timing and magnitude of the onset (first observed 15 minutes after lens insertion), peak (90 minutes) and plateau or diminishing (after 90 minutes) of corneal oedema was very similar based on measures of stromal and total corneal thickness, suggesting that corneal oedema induced by modern scleral contact lenses is primarily stromal in nature. This is in contrast to early clinical reports of oedema associated with low or non-oxygen permeable scleral lens materials in which corneal oedema was thought to be primarily epithelial in nature based largely on macroscopic external observation [28] and subjective reports of visual disturbance later attributed to epithelial cell swelling and separation [29].

Since a plateau in both stromal and total corneal oedema was observed after 45 minutes of lens wear in our participants (i.e. oedema did not increase significantly after this time point), corneal oedema measured 45-60 minutes after lens insertion, a typical period of lens settling used in clinical practice prior to reassessing corneal clearance, may provide practitioners with a reasonable estimate of the anticipated peak/end of day oedema during lens wear. However, this estimate may vary with patient age [25], and will most likely overestimate the peak oedema in contact lens neophytes prior to adaptation [30,31]. A plateau in corneal oedema during lens wear suggests a balance has been reached between the rate of production and elimination of lactic acid within the stroma [32] and is typically observed after 2-4 hours of hypoxia induced by older low Dk soft contact lens materials, or exposure of the eye to lowered concentrations of oxygen [9,10]. The rapid plateau observed in the current study for measures of stromal and total corneal oedema is most likely due to the lower level of corneal hypoxic stress associated with high Dk modern scleral lens materials (<2% oedema, despite no tear exchange) compared to older studies (inducing more than 8% oedema) [9,10]. In contrast to Pullum et al [13], who measured the time course of corneal oedema in a single sealed PMMA scleral lens wearer, we did not observe a delay in the onset of oedema during the first hour of lens wear, but a rapid increase and plateau (Figure 1) which may be a result of the differences in lens materials, the experimental design between the two studies, or the higher resolution instrumentation used to quantify corneal thickness changes in the current study. The gradual thinning of the corneal epithelium observed during lens wear (2.38 ± 0.70% thinning after 8 hours) most likely reflects the natural diurnal change in the epithelium over the course of the day and is consistent with the time course and magnitude of the natural fluctuations in the epithelial thickness without contact lens wear (2.5% epithelial thinning 8 hours after waking [33]).

Comparison of our total corneal swelling data to a previously published study [9] examining the corneal response in healthy individuals to various oxygen concentrations over an 8 hour

period (Figure 3) revealed that the magnitude and time course of total corneal oedema observed in subjects fitted with greater initial clearance (mean 431 ± 26 µm) was comparable to a ~7.5% oxygen concentration, while the corneal changes observed in subjects fitted with lower initial corneal clearance (mean 225 ± 21 µm) approximated the response to an oxygen concentration of ~10.1%. This is in close agreement with a recent study [34] that measured oxygen tension beneath scleral lenses of varying central clearance after five minutes of wear. For a lens material with central thickness of ~320 µm and Dk of 141 (compared to 300 µm and Dk 100 in our study) and low and high corneal clearance values of 240 µm and 430 µm (compared to 225 µm and 431 µm in our study), Giasson et al [34] reported oxygen tensions of 9.1% for the lower clearance condition and 6.2% for the higher clearance condition. Our data confirms and extends these findings, by providing further clinical insight regarding the magnitude of the difference in corneal oedema as a result of such difference in oxygen concentration; a ~0.25% difference between the two initial clearance groups averaged over the entire day, or a ~0.50% difference in peak oedema observed 90 minutes after lens insertion. While this small difference in corneal oedema would be considered clinically insignificant in healthy eyes, minimising corneal clearance may be important for eyes with compromised corneal endothelial cell function to minimise potential hypoxic stress. In comparison to recent theoretical models of oxygen delivery during scleral contact lens wear, our data most closely agrees with a lower total corneal Dk model of 24.7 Fatt units [35] adopted by Compan et al [16]. Other models appear to underestimate the oxygen tension within the post-lens tear layer or reaching the cornea during scleral lens wear to varying extents for different clearance values [17,20].

A methodological limitation of the current study is the digital axial resolution (4 µm) of the OCT used to quantify the thickness of the epithelium, stroma and total central cornea. While other studies have used anterior segment OCT's with a greater axial resolution (~3 µm) [36,37] to examine thickness changes in various corneal layers, we utilised an imaging protocol that

included an average of 10 B-scans per radial line scan to improve image quality and reported the data averaged over the central 4 mm of the 12 line scans following manual correction of segmentation errors by a single observer. This approach yielded small standard errors (Figure 1) and a high degree of reproducibility less than the axial resolution of the OCT. The use of a mean split to define the "lower" and "higher" initial central corneal clearance groups is a design limitation since a repeated measures approach (using the same 15 participants fitted with lenses yielding different apical clearance values on separate experimental days) would reduce inherent individual variability between subjects (reducing the standard error), however, the mean difference between clearance groups would be unlikely to change substantially and is consistent with recent studies examining the influence of apical clearance upon central corneal oedema [5,6]. Another limitation is the inclusion of young patients with healthy eyes only, which limits the ability to generalise our results to patients with abnormal corneae or reduced endothelial cell counts such as older cohorts or eyes with corneal transplants. The use of a single lens design means this data is only directly applicable to the ICD 16.5 miniscleral contact lens, however, the trends observed with respect to the time course, nature and magnitude of corneal oedema and the influence of initial central corneal clearance are most likely broadly translatable to all sealed miniscleral contact lenses made from highly oxygen permeable materials.

While the change in total corneal thickness measured during scleral lens wear allowed a direct comparison to previously published data of the corneal response to gases of various oxygen concentrations [9], the lack of serial high resolution measures of corneal thickness obtained on a separate day without lens wear to account for the natural diurnal thinning of the cornea means that the afternoon measurements (240 and 480 minutes after lens insertion) underestimate the true amount of oedema induced by lens wear. We have previously published the natural diurnal variation in corneal thickness and optics of the same cohort of subjects included in the current study based on Scheimpflug imaging [8,38] captured between

8-10 AM and 8 hours later between 4-6 PM over larger corneal diameters. Reanalysis of this data over the central 4 mm (the same region used for our OCT analysis in the current study) revealed that the mean total corneal thinning over the course of the day was 0.89 ± 0.23%. The black cross displayed in Figure 1 denotes the magnitude of total corneal oedema after 8 hours of lens wear when accounting for the natural diurnal thinning of the cornea (1.38 ± 0.24%), which is similar to the peak observed after 90 minutes of lens wear (1.18 ± 0.20%) without correction for diurnal variation.

5. Conclusion

Young healthy eyes with normal corneae fitted with a high Dk sealed miniscleral contact lens (ICD 16.5) displayed small but highly significant variations in epithelial, stromal, and total corneal thickness during lens wear. Corneal oedema was primarily stromal in nature, rapid in onset and peaked 60-90 minutes after lens insertion (<1.5% swelling) before stabilising. The total corneal swelling observed after an hour of sealed scleral lens wear provides a reasonable estimate of end of the day oedema (after 8 hours) in healthy eyes. Based on comparisons to previously published data, greater initial central corneal clearance (> 335 µm compared to < 335 µm) resulted in a reduction in oxygen reaching the cornea (~7.5% compared to ~10.1%), however, this manifested as a small 0.5% increase in corneal oedema. Further studies examining older eyes or post-graft corneae with reduced endothelial cell counts are required to improve the understanding of the influence of central corneal clearance on corneal hypoxia.

Conflicts of interest

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

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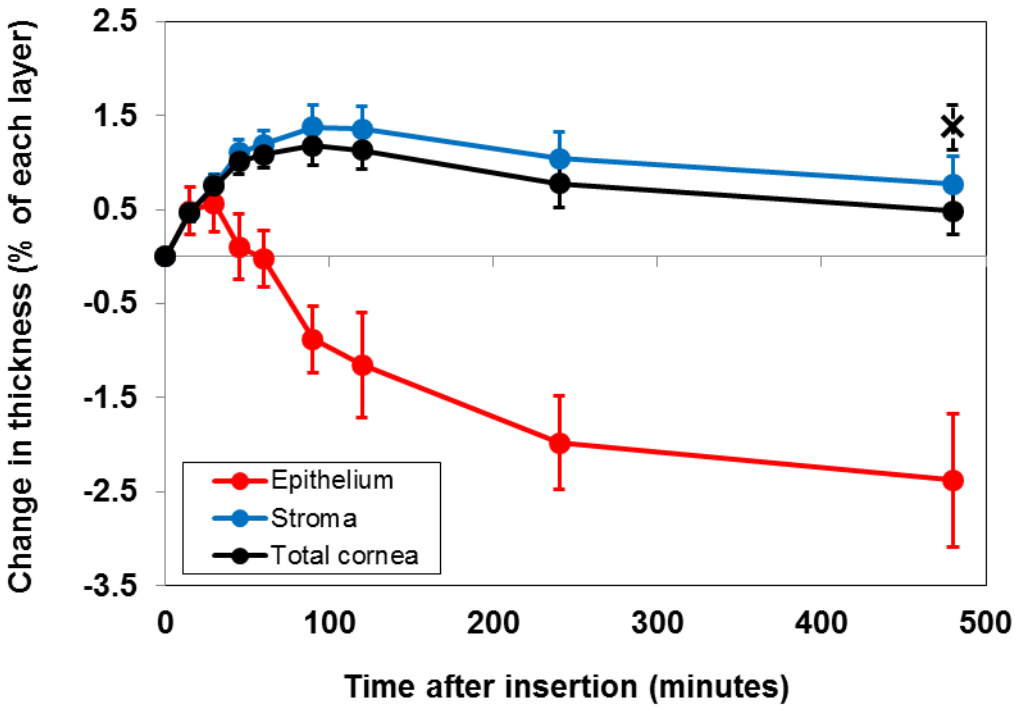

Figure 1. The mean change in corneal thickness over eight hours of ICD 16.5 miniscleral contact lens wear averaged over the central 4 mm for the total cornea (black), stroma (blue) and epithelium (red). The black cross denotes the magnitude of change in total corneal thickness after accounting for natural diurnal thinning at the eight hour time point. The error bars represent the standard error of the mean.

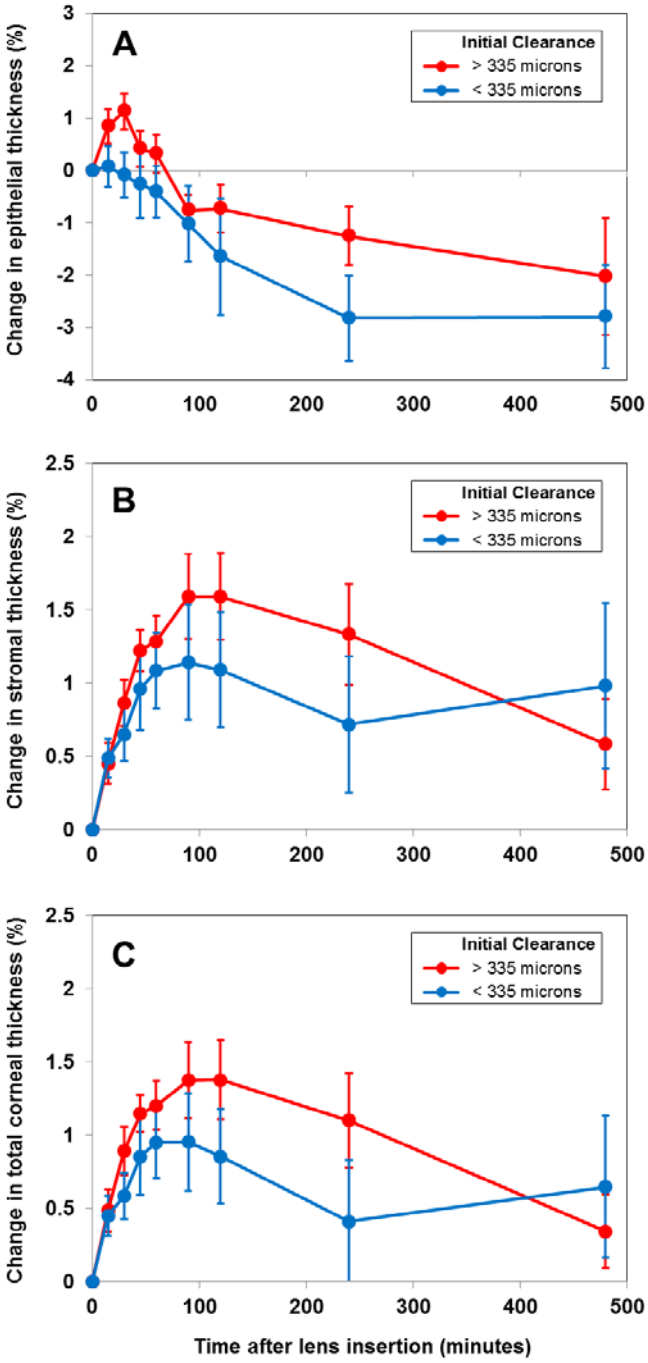

Figure 2. The mean change in epithelial thickness (A), stromal thickness (B), and total corneal thickness (C) averaged over the central 4 mm for high (> 335 µm, red) and low initial clearance (< 335 µm, blue) groups. The error bars represent the standard error of the mean.

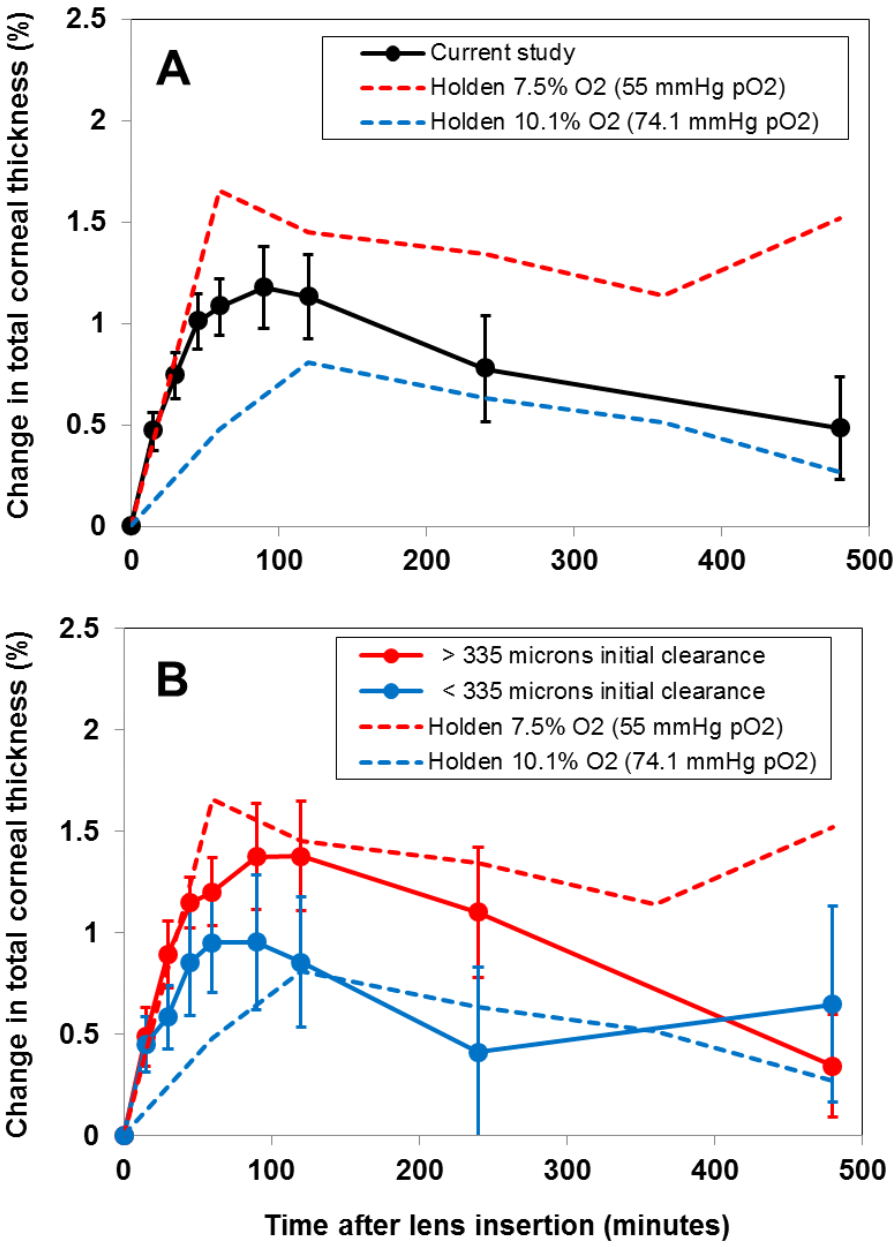

Figure 3. The mean change in total corneal thickness over the 8 hour period of lens wear for all subjects (A) and the "lower" and "higher" initial corneal clearance groups (B) (solid lines). Error bars represent the standard error of the mean. The dashed lines represent previously published data [9] of corneal thickness changes in healthy young adults exposed to gas mixtures of varying oxygen concentrations (red 7.5% oxygen, blue 10.1% oxygen).