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Morphological changes in the conjunctiva, episclera and sclera following short-term miniscleral contact lens wear in rigid lens neophytes

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ABSTRACT

Purpose: To quantify the influence of short-term wear of miniscleral contact lenses on the morphology of the corneo-scleral limbus, the conjunctiva, episclera and sclera.
Methods: OCT images of the anterior eye were captured before, immediately following 3 h of wear and then 3 h after removal of a miniscleral contact lens for 10 young (27 ± 5 years) healthy participants (neophyte rigid lens wearers). The region of analysis encompassed 1 mm anterior, to 3.5 mm posterior to the scleral spur. Natural diurnal variations in thickness were measured on a separate day and compensated for in subsequent analyses.
Results: Following 3 h of lens wear, statistically significant tissue thinning was observed across all quadrants, with a mean decrease in thickness of $-24.1 \pm 3.6\ \mu m$ ($p < 0.001$), which diminished, but did not return to baseline 3 h after lens removal ($-16.9 \pm 1.9\ \mu m$, $p < 0.001$). The largest tissue compression was observed in the superior quadrant ($-49.9 \pm 8.5\ \mu m$, $p < 0.01$) and in the annular zone 1.5 mm from the scleral spur ($-48.2 \pm 5.7\ \mu m$), corresponding to the approximate edge of the lens landing zone. Compression of the conjunctiva/episclera accounted for about 70% of the changes.
Conclusions: Optimal fitting miniscleral contact lenses worn for three hours resulted in significant tissue compression in young healthy eyes, with the greatest thinning observed superiorly, potentially due to the additional force of the eyelid, with a partial recovery of compression 3 h after lens removal. Most of the morphological changes occur in the conjunctiva/episclera layers.

1. Introduction

Miniscleral contact lenses are manufactured from rigid gas permeable (RGP) polymers with an overall diameter of 14–17 mm [1,2] and are of particular benefit to patients with corneal conditions including corneal ectasia (e.g. keratoconus), a history of penetrating keratoplasty, surface irregularity or contact lens intolerance associated with severe dry eye [3–5]. The lenses are designed to vault the cornea and limbus, with the haptic landing zone bearing entirely on the sclera and overlying ocular tissues [6]. The corneal vaulting results in the formation of a tear fluid reservoir (the post-lens tear layer) between the lens and the cornea, which can lead to optical, biomechanical and physiological advantages for the underlying cornea compared to other forms of contact lenses [7–10].

The distance between the posterior surface of the contact lens and the anterior surface of the cornea (i.e. the apical clearance) depends on the corneal geometry (primarily the corneal sagittal depth) and the lens design, and is routinely evaluated as part of the fitting procedure. The amount of apical corneal clearance is known to change over time, as the lens “settles” into the eye. The reduction in apical clearance during lens wear has been documented in various studies using both miniscleral and full scleral lens designs [11–14], with the majority of lens settling occurring within the first three to four hours following insertion [13]. This change in apical clearance following initial lens insertion may potentially be associated with tissue compression in the region of lens bearing (i.e. the landing zone of the lens).

Caroline and Andre [11] reported an average reduction in apical clearance of 96 μm (range 70–180 μm) following eight hours of lens wear for a 16.5 mm diameter miniscleral lens in 15 subjects with normal corneas. Using a similar lens diameter, Mountford [14] found the average lens settling after one month of lens wear to be

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146 μm (range 106–186 μm) for a large cohort of 392 patients with various corneal conditions and lens designs. Michaud [12] also evaluated scleral lens settling in 23 subjects after a 6 h period of wear for a 14.3 mm diameter lens and observed a mean decrease in apical clearance of 75 μm. More recently, Kauffman et al. [13] reported on the lens settling for three different lens designs, which included two miniscleral (14.3 mm and 15.8 mm) and a full scleral design (18.2 mm), over an eight hour period for seven subjects with normal corneas. The magnitude of lens settling varied with each design, ranging from 88 to 133 μm. The reported changes in corneal clearance follow an exponential decay, with the majority of change occurring within the first 2 h of lens wear and no significant differences (i.e. a plateau in corneal clearance) approximately 4 h after lens insertion [13].

While the decrease in apical lens clearance over time is commonly observed in clinical practice, no study has measured the changes in the morphology of the ocular tissues surrounding the landing zone of scleral lenses. In this study, we used spectral domain optical coherence tomography to assess the short-term effect of 3 h of miniscleral contact lens wear on the morphology of the corneo-scleral limbus, the conjunctiva/episclera and sclera and their recovery over the subsequent 3 h. Image analysis methods were developed to allow repeated quantitative measurements at the same location on the ocular surface.

2. Methods

Participants were recruited from the staff and students of the Queensland University of Technology (QUT) Faculty of Health in Brisbane, Australia. Approval from the University Human Research Ethics Committee was obtained before commencement of the study, and subjects gave written informed consent to participate. All subjects were treated in accordance with the declaration of Helsinki.

The study participants included 10 young, healthy adult subjects (6 females, 4 males) between 21 and 33 years (mean ± SD age: 27 ± 5 years) with best corrected visual acuity of 0.00 logMAR or better. Prior to commencement of the study, all subjects were screened to exclude those with any contraindications to contact lens wear (i.e. significant tear film or anterior segment abnormalities). None of the subjects were previous rigid contact lens wearers and four of the subjects who were part-time soft contact lens wearers discontinued lens wear for 24 h prior to commencing the study. This should have allowed any substantial effects of soft lens wear on the morphology of the cornea and sclera to resolve [15]. Participants had no prior history of eye injury, surgery or current use of topical ocular medications.

2.1. Limbal and scleral imaging

The Spectralis optical coherence tomographer (OCT) with anterior segment module (Spectralis, Heidelberg Engineering, Heidelberg, Germany) was used to obtained cross sectional images of the corneoscleral limbus, conjunctiva/episclera and sclera from four different quadrants (superior, inferior, nasal and temporal). This instrument uses a super luminescent diode of central wavelength 870 nm, which provides images with an axial resolution of 3.9 μm and transversal resolution of 14 μm, with a scanning speed of 40,000 A-scans per second. A high resolution volumetric scanning protocol was used (8.3 × 2.6 mm) consisting of 21 B-scans (each separated by 124 μm). The short wavelength of the instrument allows for high resolution imaging, however it does provide less imaging depth compared to longer wavelength systems. To compensate for this, images were obtained using the enhanced depth imaging (EDI) mode that optimises the posterior scleral interface. The instrument utilizes a confocal scanning laser ophthalmoscope (SLO) to automatically track the eye in real-time, and this function was active during the examination to achieve an average of 15 images per B-scan. A total of three volumetric scans were captured for each quadrant for each of the measurement sessions. Only images with a scan quality index of >20 dB were included in the analysis (mean value 39.3 ± 3.9 dB).

While the instrument can track the eye during image acquisition to allow for precise alignment and averaging of B-scans which reduces noise and improves contrast, the instrument's "auto-rescan" function, which automatically registers repeated scans taken at different times to the same location during acquisition, is only available for posterior segment imaging and not anterior segment imaging. Thus, during acquisition, care was taken to position the volume scan in approximately the same limbal location (i.e. 3, 6, 9 and 12 o'clock) for all repeated measurements. Custom written software was developed to use the SLO image to accurately align OCT images between each measurement session for each participant and this procedure is described in the following section. The software was validated in terms of the observer's repeatability, showing that on average there was no difference in the selected B-scan between the repetitions.

The OCT instrument used in this study is limited by a maximum imaging depth of 1.9 mm. To optimise image quality, subjects maintained a fixed head position in the chin rest while looking peripherally to external LED fixation targets placed about 30° off-axis at different locations to facilitate the imaging of different scleral quadrants. This ensured that the measured region (i.e. the tissue surface) was quasi-perpendicular to the instrument, and minimised the depth to the posterior sclera, resulting in enhanced contrast across the horizontal scan.

2.2. Experimental procedure

The study protocol was conducted over three separate days; day one for general ophthalmic screening and miniscleral contact lens fitting and two additional days of data collection. On the second day, OCT diurnal measurements were taken without contact lens wear and on the third day the OCT measurements were taken before and after contact lens wear. Prior to the OCT measurements, corneal topography and thickness (Pentacam HR system, Oculus, Germany) were also captured at each measurement session to examine any corneal effects of lens wear and these changes have been reported elsewhere [16].

Initial baseline measurements were obtained in the morning (0 h, session 1) and then repeated 3 h (session 2) and 6 h later (session 3). On the second day, the subject did not wear a contact lens and the natural diurnal variations of the combined conjunctiva/episcleral thickness and scleral thickness were recorded. On the third day, the subjects wore an optimal fitting miniscleral contact lens in their left eye only, with measurements collected in the morning before the lens was inserted (0 h, session 1), immediately after lens removal following 3 h of wear (session 2) and finally 3 h after lens removal (i.e. 6 h after initial lens insertion) (session 3).

The timing of the measurement sessions on days two and three were matched for each participant to minimize any potential confounding influence due to diurnal variations in the morphology of the anterior eye [17] and were scheduled between 9:00 and 11:00 AM (session 1), 12:00 and 2:00 PM (session 2) and 3:00 and 5:00 PM (session 3). Between measurement sessions, participants were free to go about their daily activities, however, most remained in our laboratory engaged in computer based work or study. Measurements on day two (no lens wear day) were conducted at least 12 h after the initial contact lens fitting (on