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Corneal changes following short-term miniscleral contact lens wear

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ABSTRACT

Purpose: To examine the influence of short-term miniscleral contact lens wear on corneal shape, thickness and anterior surface aberrations.
Methods: Scheimpflug imaging was captured before, immediately following and 3 h after a short period (3 h) of miniscleral contact lens wear for 10 young (mean 27 ± 5 years), healthy participants. Natural diurnal variations were considered by measuring baseline diurnal changes obtained on a separate control day without contact lens wear.
Results: Small but significant anterior corneal flattening was observed immediately following lens removal (overall mean 0.02 ± 0.03 mm, $p < 0.001$) which returned to baseline levels 3 h after lens removal. During the 3 h recovery period significant corneal thinning (−13.4 ± 10.5 μm) and posterior surface flattening (0.03 ± 0.02 mm) were also observed (both $p < 0.01$). The magnitude of posterior corneal flattening during recovery correlated with the amount of corneal thinning ($r = 0.69$, $p = 0.03$). Central corneal clearance (maximum tear reservoir depth) was not associated with corneal swelling following lens removal ($r = -0.24$, $p > 0.05$). An increase in lower-order corneal astigmatism $Z(2,2)$ was also observed following lens wear (mean −0.144 ± 0.075 μm, $p = 0.02$).
Conclusions: Flattening of the anterior corneal surface was observed immediately following lens wear, while 'rebound' thinning and flattening of the posterior surface was evident following the recovery period. Modern miniscleral contact lenses that vault the cornea may slightly influence corneal shape and power but do not induce clinically significant corneal oedema during short-term wear.

1. Introduction

Miniscleral contact lenses, a sub-group of scleral contact lenses with a total lens diameter between 15 and 18 mm which rest entirely upon the sclera [1], are sealed to the anterior eye with minimal movement upon blinking or ocular versions. They are primarily used for the correction of irregular corneal optics commonly encountered in keratoconus, keratoglobus or following penetrating keratoplasty, as the post-lens tear layer (the fluid reservoir between the posterior lens and anterior cornea) effectively neutralises the majority of corneal astigmatism [2]. More recently, scleral lenses have also been utilised as a therapeutic intervention in cases of ocular surface disease (e.g. exposure keratopathy [3], Sjogren's syndrome [4], Steven–Johnson's Syndrome [5]) by providing the cornea with continual hydration during lens wear without evaporation.

Previously, scleral lens fitting was largely empirical and primarily relied upon practitioner interpretation of haptic (landing zone) vascular compression of the bulbar conjunctiva. However, advances in anterior eye imaging with corneal topography and optical coherence tomography have resulted in a more reliable and accurate fitting process and along with improved lens designs this has led to a subsequent increase in scleral contact lens prescribing [1].

Scleral lenses are typically significantly thicker (up to 1300 μm central thickness for full scleral lenses [6]) than corneal rigid gas permeable (RGP) lenses (~140–180 μm [7]), to avoid on eye and handling flexure. Consequently, to counteract this increased thickness, modern scleral lenses are manufactured from highly permeable materials to maximise oxygen transmission to the cornea. This is particularly important since scleral lenses do not move upon blinking to allow freshly oxygenated tears to replenish the post-lens tear layer. The post-lens tear layer varies in depth with lens design, corneal shape and practitioner fitting philosophy and may act as a further barrier to atmospheric oxygen reaching the cornea [8]. Despite these potential hypoxic factors of increased lens thickness, minimal tear exchange and the presence of a thick

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post-lens tear layer, there are few clinical reports of significant corneal oedema associated with modern scleral lens wear.

A limited number of studies have attempted to quantify the corneal response following scleral lens wear. In an early study using full scleral lenses, Bleshoy and Pullum [9] reported on corneal oedema in a single subject following 5 h of sealed scleral contact lens wear using an RGP material with a Dk of 24. Central lens thickness was varied from 180 to 500 μm and corneal swelling increased slightly with increasing lens thickness from 3.6% to 4.8% centrally and 4.6–5.3% in the periphery (although these central and peripheral zones were not defined). More recently, Pullum and Stapleton [10] assessed central corneal swelling for four subjects following 3 h of sealed scleral lens wear while varying lens thickness and oxygen permeability. Up to 8% corneal swelling was observed for a scleral lens of 1200 μm thickness with a Dk of 32, which reduced as lens thickness was reduced and Dk increased.

Other studies have examined fitting characteristics (e.g. apical clearance [11]) and visual or ocular outcomes (improved acuity [12], lens tolerance [12] and complications [13,14]) in relation to scleral contact lenses. In this study, the physiological changes in corneal characteristics (biometrics and optical properties including anterior higher order aberrations) associated with modern miniscleral contact lens wear were assessed in addition to the recovery of these induced changes. Scheimpflug imaging was used to investigate the influence of short-term miniscleral contact lens wear on healthy, young subjects with normal corneae (i.e. without keratoconus or corneal abnormalities including ocular surface disease) over a substantially larger corneal region than previously examined.

2. Methods

This study was approved by the Queensland University of Technology (QUT) human research ethics committee and followed the tenets of the Declaration of Helsinki. All subjects gave written informed consent to participate. The study participants included 10 young, healthy adult subjects (6 females, 4 males) recruited from the QUT School of Optometry and Vision Science aged between 21 and 33 years (mean ± SD age: 27 ± 5 years) with visual acuity of 0.00 logMAR or better. This sample size was chosen based on calculations conducted using previous published data on corneal swelling following short-term scleral lens wear, which suggested that a sample size between 6 and 12 participants would yield 80% power to detect 2% corneal oedema [10] (or a 3 μm increase in central corneal thickness [15]) at the 0.05 significance level. 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). Four of the subjects were part time soft contact lens wearers but discontinued lens wear for 24 h prior to commencing the study, to minimise the effects of soft lens wear on the cornea. None of the subjects were previous rigid contact lens wearers. Participants had no prior history of eye injury, surgery or current use of topical ocular medications.

2.1. Experimental overview

The influence of short-term miniscleral contact lens wear (3 h duration) upon measures of anterior and posterior corneal topography, corneal thickness and anterior corneal aberrations was examined using Scheimpflug imaging. The study was conducted over three separate days; day 1 involved an ophthalmic screening and miniscleral contact lens fitting, day 2 included baseline diurnal corneal measurements obtained without contact lens wear and day 3 involved the capture of corneal measurements before and after contact lens wear.

On day 2, baseline measurements were obtained without contact lens wear, in the morning (0 h, session 1) and then repeated 3 h (session 2) and 6 h later (session 3). On day 3, the subjects wore an optimal fitting miniscleral contact lens (according to the manufacturers fitting guide) 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 for days two and three were matched for each participant to allow for the control of the confounding influence of diurnal variation [16] during analysis and were scheduled between 9:00 and 11:00 AM (session 1), 12:00–2:00 PM (session 2) and 3:00–5:00 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. Baseline measurements (day 2) were conducted at least 12 h after the initial contact lens fitting (on day 1) to minimise the potential influence of any ocular surface changes associated with the fitting process. Day 3 was scheduled within one week of day 2 to limit the influence of monthly cyclical changes upon corneal biometrics [17].

Following the removal of the lens on day 3, each participants left eye was re-examined using a slit lamp biomicroscope to assess the anterior eye. The Efron grading scale for contact lens complications [18] was used by the same examiner to quantify conjunctival (inferior, superior, nasal and temporal) and corneal (inferior, superior, nasal, temporal and central) fluorescein staining to the nearest 0.1 scale unit.

2.2. Contact lens assessment

The contact lenses used in this study were Irregular Corneal Design (ICD™ 16.5, Paragon Vision Sciences, USA) non-fenestrated miniscleral lenses made from hexafocon A material (Boston XO) with a Dk of 100×10^{-11} (cm^2/s) (ml O_2/mL × mmHg), central thickness of 300 μm and overall diameter of 16.5 mm. The optimal fitting contact lens was determined according to the manufacturers fitting guide. In brief, the initial diagnostic lens was selected based on the participants corneal sagittal height measured over a 10 mm chord (along the steepest corneal meridian) using a videokeratoscope (E300, Medmont, Australia) which was then extrapolated to a 15 mm chord (i.e. the distance to the landing zone of the ICD lens). The lens was inserted into the patients left eye with preservative free saline and sodium fluorescein and assessed using a slit lamp biomicroscope. If an air bubble was present, the lens was removed and reinserted. The fluorescein pattern was assessed to ensure adequate central and limbal corneal clearance. If regions of corneal bearing were observed, the sagittal depth of the lens was increased (in 100 μm increments) and the fit reassessed. After an adequate fit was obtained, the lens was then allowed to settle for 1 h, and was re-examined using the slit lamp. The final fluorescein pattern for all subjects showed central corneal clearance (sufficient to obscure visualisation of the pupil and iris features with sodium fluorescein), slight superior mid-peripheral to peripheral pseudo-bearing (an apparent area of bearing that disappeared on downward gaze) and sodium fluorescein "bleed" beyond the limbus onto the conjunctiva. Conjunctival blood vessels were examined under white light within the scleral landing zone to ensure there was no restriction or blanching of the vessels due to excessive peripheral seal off. The contact lens fit was assessed by the same examiner during the trial lens fitting (with sodium fluorescein) and on the day of lens wear (without sodium fluorescein) to ensure a well centred fit without any air bubbles. After 1 h of lens settling, the corneal clearance was measured using an anterior spectral domain optical coherence tomographer (Spectralis, Heidelberg, Germany). A