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

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A B S T R A C T

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 h 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 h. Fifty percent of this reduction occurred within 45 min of lens wear and seventy-five percent within 2 h, with thinning of the post-lens tear layer plateauing 4 h 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 h 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 h that plateaued approximately 2 h after lens insertion, while central post-lens tear layer thinning plateaued after 4 h of lens wear.

1. 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 and 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 and 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].

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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 ~50–130 μm 8 h after insertion [15,17], and up to ~150–200 μm 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 h 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 h period using high resolution OCT imaging, from which theoretical calculations of the changes in the optics of the post-lens tear layer during lens wear were derived.

2. 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 h 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°, 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 min of lens wear. All participants commenced lens wear between 8 and 10 AM and ceased lens wear after the final measurement session, 8 h later, between 4 and 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 (Fig. 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