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Scleral lens influence on corneal curvature and pachymetry in keratoconus patients

Nienke Soeters[a,*], Esther Simone Visser[a,b,1], Saskia M. Imhof[a], Nayyirih G. Tahzib[c]

[a] Department of Ophthalmology, University Medical Center Utrecht, Utrecht, The Netherlands
[b] Visser Contact Lens Practice, Nijmegen, The Netherlands
[c] Zonnestraal Eye Hospital Amersfoort, Amersfoort, The Netherlands

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ABSTRACT

Objectives: To investigate the influence of full scleral lenses on corneal curvature and pachymetry in keratoconus patients.
Methods: In this intervention study, 20 eyes of 14 patients were measured by Scheimpflug imaging (Pentacam HR, Oculus) at two time points: directly and ≥1 week after scleral lens removal. Steep, flat and maximal keratometry (K_{steep}, K_{flat} and K_{max}) and optical pachymetry were analyzed. A generalized estimating equation analysis was performed to correct for paired eyes.
Results: Directly after scleral lens removal, all three curvature parameters were significantly flatter compared to ≥1 week after scleral lens removal. Average K_{steep} was 0.7 diopter (D) lower ($P < 0.001$), average K_{flat} was 0.5 D lower ($P = 0.037$) and average K_{max} was 1.1 D lower ($P < 0.001$). Directly after scleral lens removal, average optical pachymetry was ±2.5% higher ($P < 0.001$) compared to ≥1 week after scleral lens removal.
Conclusions: Although scleral lenses do not mechanically touch the cornea, curvature and pachymetry seem to be influenced by scleral lens wear in keratoconus patients. The duration of these changes remain unclear.

1. Introduction

Ectatic corneal disorders, such as keratoconus, often result in visual complaints related to the irregular cornea and resulting astigmatism. In mild to moderate disease, corneal contact lenses (soft, rigid, piggy-back and hybrid) have been employed to correct or neutralize the irregular cornea and thereby improve vision. For contact lens intolerant patients or moderate to severe cases of irregular astigmatism that cannot be corrected with corneal contact lenses, scleral lenses offer an alternative. These lenses have been used since the introduction by Fick and Muller in the 1880s [1,2]. The development of gas-permeable (GP) materials and innovations in the design (such as toric and tangential designs), led to a decrease in corneal hypoxia and increased comfort [3,4]. Scleral lenses rest on the bulbar conjunctiva and sclera and vault the cornea; the fluid layer between the lens and cornea both neutralizes the irregular astigmatism and hydrates and protects the corneal surface. Therefore, scleral lenses can be used to provide mechanical protection, relief of symptoms as in dry eyes or to facilitate corneal healing. The main application of scleral lens use is optical correction of the irregular surface, with corneal ectasia being the primary cause [5–7].

It is well known that corneal curvature can be influenced by corneal contact lenses due to mechanical corneal rubbing or hypoxia [8–15]. Reports on temporary keratometry changes induced by soft or RGP contact lens wear show variable results; both steepening and flattening of normal corneas have been reported. The timing of corneal recovery after discontinuation of corneal contact lenses is variable per contact lens type. Duration of corneal contact lens wear seems proportional to the required time for topography stabilization [16].

Corneal curvature changes following (short term) miniscleral lens wear have been reported recently in healthy subjects, but at this moment, we are not certain of the corneal effects of full scleral lenses in patients with keratoconus [17]. The fact that there is no mechanical contact between a scleral lens and the

* Corresponding author at: Department of Ophthalmology, HP E03.136, University Medical Center Utrecht, Heidelberglaan 100, 3508 GX Utrecht, The Netherlands. Tel.: +31 088 755 1683; fax: +31 088 755 5417.
E-mail address: N.Soeters@umcutrecht.nl (N. Soeters).
[1] E.S. Visser is co-owner of Visser Contact Lens Practice, Nijmegen, The Netherlands.

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Table 1
Scleral lens fitting classification by Visser et al.

Characteristic	Grade −2 unacceptable	Grade −1 acceptable	Grade 0 optimal	Grade +1 acceptable	Grade +2 unacceptable
Central corneal clearance	Corneal contact	≤0.1 mm	0.1–0.3 mm	>0.3 mm to ≤0.5 mm	>0.5 mm
Limbal corneal clearance	Circumcorneal limbal contact	Circumcorneal <0.05 mm	0.05–0.2 mm	Circumcorneal >0.2 mm to ≤0.3 mm	Circumcorneal >0.3 mm
Scleral (haptic) fit	Circumcorneal blanching	Segmented/slight blanching	Scleral alignment	Slightly increased edge clearance	Increased edge clearance, with possible trapped air bubbles
Lens movement (push-up test)	Lens suction	Reduced	Gentle	Increased	Excessive
General lens fit			Optimal	Acceptable	Unacceptable

cornea could lead to the assumption that corneal curvature is not influenced by this lens type. Changes in both corneal topography and corneal thickness can occur during scleral lens wear. Topographic changes might be induced by fluid pressure behind the scleral lens or by corneal swelling due to hypoxia following scleral lens wear. Besides hypoxia-induced corneal swelling, another hypothesis for increased pachymetry during scleral lens wear is the absence of lid wiper contact and chafing of the surface epithelium during blinking [18].

Keratoconus patients are often highly dependent on their lenses and have suboptimal vision with spectacles. Therefore, they are often reluctant to remove their lenses for topography measurements which aim to monitor the keratoconus progression. In cases of progressive keratoconus, corneal crosslinking (CXL) can be performed in order to stabilize the cornea [19–21]. However, since one of the most important inclusion criteria for CXL includes a recent documented topographic progression [20], accurate topography readings are essential in these patients. In most studies, patients who wear corneal contact lenses are requested to discontinue their lens wear for a certain period of time prior to topography measurements, in order to avoid bias in corneal curvature determination. For scleral lenses, there is no defined consensus on this topic.

In this study, we investigated the influence of full scleral lenses on corneal curvature and pachymetry in patients with keratoconus. A confirmation of the hypothesis that scleral lenses do not manipulate corneal curvature would be valuable for keratoconus patients and would implicate that scleral lens discontinuation could be avoided prior to examinations.

2. Methods

All keratoconus patients who visited our outpatient clinic at the University Medical Center Utrecht (UMCU) were asked to discontinue their full scleral lenses (size 18–22 mm) at least 1 week before baseline Scheimpflug imaging. For this study, patients were requested to discontinue their scleral lens wear right before CXL treatment, in order to repeat Scheimpflug imaging directly after scleral lens removal.

Inclusion criteria were: keratoconus, scleral lens wear for at least 3 months and discontinuation of scleral lens wear at least 1 week before Scheimpflug imaging. Excluded were patients who wore an inadequately fitted scleral lens and patients with unreliable Scheimpflug images. Scleral lens parameters and fitting were assessed at Visser Contact Lens Practice ($n = 18$) or requested for and supplied by an external contact lens institution ($n = 2$). A standard classification method was used to grade the scleral lens fitting characteristics [6], which was revised after new insights (Table 1): corneal clearance, limbal clearance, scleral fit, lens movement and general lens fitting. Grade 0 was considered ‘optimal’, grade 1 ‘acceptable’ and grade 2 ‘unacceptable’. All scleral lenses consisted of one of the following materials: Boston Equalens II (Oprifocon A, Dk 85 (Polarographic ISO/Fatt method)), Boston XO2 (Hexafocon B, Dk 161 (non-edge corrected ISO/Fatt method)), Boston XO (Hexafocon A, Dk 100) (Polarographic ISO/Fatt method) which were manufactured by the Polymer Technology Corporation, Bausch & Lomb, Wilmington, MA, USA.

Data were collected after approval of the Medical Ethics Committee of the UMCU. Written informed consent was conducted in accordance to UMCU guidelines.

All measurements were acquired from a rotating Scheimpflug device (Pentacam HR, Oculus Wetzlar, Germany) and performed by the one and the same optometrist. Quality of the measurement was checked, and one high quality examination (valid data >85%) per eye was used for analysis.

2.1. Statistics

A sample of at least 18 eyes was required to detect a difference of 1.0 D between the mean K_{max} at two time points and to achieve a power of 0.8 with a significance level of 0.05. Normal distribution of the data was confirmed by the Shapiro–Wilk test of normality. Generalized estimating equations with statistical correction to test for correlations between paired eyes were used to analyze the differences between variables at two time points. A P-value <0.05 was considered statistically significant.

3. Results

In this study, 24 eyes of 17 patients were enrolled, 10 were female, 7 were male. Mean age was 30 years (range 19–49). Pentacam imaging was performed directly after scleral lens removal and ≥1 week after scleral lens removal.

After exclusions (1 patient showed an improperly fitted scleral lens with a corneal touch in both eyes, in 1 patient the Scheimpflug images were unreliable and of 1 patient the external scleral lens fitting characteristics could not be obtained), 20 eyes of 14 patients were analyzed. Of these 20 patients, 6 patients (11 eyes) discontinued scleral lenses for 2 weeks and in 8 patients (9 eyes) lenses were discontinued for 1 week. In 16 out of 20 eyes, both measurements were assessed at a consistent time of day, with a mean difference of 49 min (range 11–129). The mean difference in time of day in the other 4 eyes was 293 min (range 194–342 min).

Results are listed in Table 2.

Directly after scleral lens removal, all 3 curvature parameters were significantly flatter compared to measurements when scleral lenses were removed for ≥1 week. Average K_{steep} was 0.7 diopters (D) lower ($P < 0.001$), average K_{flat} was 0.5 D lower ($P = 0.037$) and average K_{max} was 1.1 D lower ($P < 0.001$). Directly after scleral lens removal, average optical pachymetry was ±2.5% higher ($P < 0.001$) than ≥1 week after scleral lens removal.

Table 3 shows the scleral lens fitting results. All components were graded as optimal or acceptable (grade 0 or 1).