Contact Lens & Anterior Eye 38 (2015) 294–297

Contents lists available at ScienceDirect

Contact Lens & Anterior Eye

journal homepage: www.elsevier.com/locate/clae

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

ARTICLE INFO

Article history:
Received 19 October 2014
Received in revised form 12 February 2015
Accepted 6 March 2015

Keywords:
Keratoconus
Scleral lens
Topography
Keratometry
Pachymetry

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.

http://dx.doi.org/10.1016/j.clae.2015.03.006
1367-0484/

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).

Table 2
Mean keratometry and pachymetry before and after scleral lens removal ($n = 20$).

Time point	K_{steep} diopter	K_{flat} diopter	K_{max} diopter	CCT pupil µm
Directly after scleral lens removal	51.9 ± 5.0	47.5 ± 4.3	57.0 ± 6.7	488 ± 47
≥1 week after scleral lens removal	52.6 ± 5.2	48.0 ± 4.7	58.1 ± 6.8	475 ± 44
P value[a]	<0.001[*]	0.037[*]	<0.001[*]	<0.001[*]
95% CI diff	−1.2 to −0.3	−0.9 to 0.0	−1.6 to −0.6	8 to 19

K_{steep} = steepest central keratometry value; K_{flat} = flattest central keratometry value; K_{max} = maximal keratometry value; CCT = corneal thickness (pachymetry); 95% CI diff = 95% confidence interval of the difference.

[a] Generalized estimating equations analysis with correction for paired eyes; total number of paired eyes in the analysis is 6.

[*] Statistically significant.

Table 3
Scleral lens fitting, $n = 20$ eyes.

Grade	−2	−1	0	1	2
Central corneal clearance	0	2	12	6	0
Limbal corneal clearance[a]	0	0	16	3	0
Scleral (haptic) fit	0	0	16	4	0
Movement	0	0	18	2	0
General lens fit	0	0	15	5	0

Grade −2 or 2 = unacceptable; grade −1 or 1 = acceptable; grade 0 = optimal.

[a] In one patient, limbal corneal clearance was not graded.

4. Discussion

To the best of our knowledge, this is the first report to show the influence of full scleral lenses on corneal curvature and pachymetry in patients with keratoconus. In this study, we found a difference in curvature and pachymetry directly after scleral lens removal compared to ≥1 week of scleral lens removal.

The sample size of this relevant and clinically oriented study was small, no control group was available and measurements at only two time points were assessed. Additional information on scleral lens influence at more than two time points (for instance at 1, 2 and 3 days after lens discontinuation) may have provided more information on the duration of curvature and pachymetry changes induced by scleral lens wear. This was desirable, yet difficult to implement in daily practice.

Our topography and pachymetry measurements were performed by Scheimpflug (Pentacam) imaging, which is considered to be a highly reliable device to measure keratometry and pachymetry in keratoconic corneas [22,23]. The repeatability of measurements with the Pentacam is high and in a study by Koller et al. [24] the standard deviation of repeated K_{max} ranged from 0.017 to 0.039 mm with a mean of 0.024 mm, which corresponds to a mean of approximately 0.1 D.

In a report of 1982 by Kiely et al. [25] in 21 healthy subjects without lens wear, it was shown that pachymetry changes during the day were correlated with keratometry: increased pachymetry after awakening was associated with central corneal flattening. This is in line with the outcome in our keratoconus group: compared to >1 week of scleral lens removal, K_{steep}, K_{flat} and K_{max} were slightly but significantly lower directly after scleral lens removal, in addition to significant corneal swelling. Similar results were shown in a recent report on corneal changes during 3 h of miniscleral lens wear in healthy subjects. However, there was no association between pachymetry change and the anterior corneal curvature change, following lens wear. In their study, the timing of the measurement sessions was matched to allow for confounding influence of diurnal variation. In our study, in 4 eyes there was a disparity in time of measurement, which was not accounted for [17].

Corneal swelling is the principal objective method to determine hypoxia [26]. Physiologic overnight swelling (without lens wear) is approximately 4.5–5.5%, shows recovery during the first waking hours and then varies throughout the day [27,28]. Although the small sample size in our study limited the ability to make definite data interpretations, the significant ±2.5% increase in pachymetry directly after scleral lens removal in keratoconic corneas was in line with studies in healthy eyes. Pachymetry changes after scleral lens wear have been reported by Mountford et al. [29], showing an increase in pachymetry by 0.98 µm per hour with scleral lenses of highly GP material fitted on eight healthy subjects. Pullum and Stapleton [30] described a less than 3% corneal swelling in four healthy subjects with scleral lenses. Depending on the thickness of the fluid layer between lens and cornea, a corneal swelling of 1.5–4% in eight healthy subjects was reported recently by Compañ et al. [32] When comparing scleral lens Dk, it seems that Pullum and Stapleton used lower scleral lens Dk's, and the group of Compañ et al. used comparable Dk's compared to our study. The limited temporary increase in pachymetry in our study group was not expected to cause adverse physiological corneal responses; however, individual hypoxia responses may differ. In general, it is recommended to restrict hypoxia-induced swelling by application of highest Dk available materials and minimizing both lens thickness and the fluid layer between lens and cornea [31,32]. The thickness of the fluid layer between lens and cornea was not investigated in this study.

Another explanation for temporary corneal swelling during scleral lens wear could be the elimination of the eyelid influence on epithelial thickness. The thickness of the epithelium is suggested to decrease by 'wiping' of the eyelid on the apex of keratoconus [18]. This effect of corneal thinning by chafing of epithelium during blinking is diminished by vaulting of the scleral lens over the cornea, which allows the corneal epithelium to regain its thickness.

Temporary corneal changes induced by scleral lens wear are of great importance for the clinician when evaluating patients for possible keratoconus progression and assessment of a CXL indication. Corneal changes caused by scleral lens wear, including corneal flattening and swelling, can lead to an underestimation of the level of keratoconus and missing progressive cases.

In conclusion, although there is no mechanical contact between a scleral lens and the cornea, small but statistically significant changes in corneal curvature and thickness were noted 1–2 weeks after discontinuation of full scleral lens wear in patients with keratoconus. These changes suggest that accurate assessment of topographic keratoconus progression in patients who wear scleral lenses require the discontinuation of lens wear for some period of time prior to evaluation. The exact duration of the time necessary to allow for reversal of scleral lens-induced corneal changes is unknown, and warrants further study.

Conflict of interest

None of the authors had a conflict of interest in the outcomes of this study.

Acknowledgments

N. Soeters was supported by the following foundations: Dr. F.P. Fischer Stichting (Amersfoort, The Netherlands) and Stichting Nederlands Oogheelkundig Onderzoek (SNOO) (Rotterdam, The Netherlands) that contributed through UitZicht. The funding organizations had no role in the design or conduct of this research. They provided unrestricted grants.

References

[1] Fick AE. A contact-lens, 1888 (translation). Arch Ophthalmol 1988;106:1373–7.
[2] Müller A. Brillenglaser und Hornhautlinsen, Part III. Inaugural Dissertation zur Erlangung des Doktorgrades der Universität Kiel; 1889. p. 18–26.
[3] Ezekiel D. Gas-permeable haptic lenses. J Br Contact Lens Assoc 1983;6:158–61.
[4] Visser E-S, Linden van der BJ, Otten HM, Van der Lelij A, Visser R. Medical applications and outcomes of bitangential scleral lenses. Optom Vis Sci 2013;90:1078–85.
[5] Tan DT, Pullum KW, Buckley RJ. Medical applications of scleral contact lenses: 1. A retrospective analysis of 343 cases. Cornea 1995;14:121–9.
[6] Visser E, Visser R, van Lier HJJ, Otten HM. Modern scleral lenses part I: clinical features. Eye Contact Lens 2007;33:13–20.
[7] Van der Worp E, Bornman D, Ferreira DL, Faria-Ribeiro M, Garcia-Porta N, González-Meijome JM. Modern scleral contact lenses: a review. Contact Lens Anterior Eye 2014;37:240–50.
[8] Tyagi G, Collins M, Read S, Davis B. Regional changes in corneal thickness and shape with soft contact lenses. Optom Vis Sci 2010;87:567–75.
[9] Ruiz-Montenegro J, Mafra CH, Wilson SE, Jumper JM, Klyce SD, Mendelson EN. Corneal topographic alterations in normal contact lens wearers. Ophthalmology 1993;100:128–34.
[10] Yeniad B, Yiğit B, Işsever H, Közer Bilgin L. Effects of contact lenses on corneal thickness and corneal curvature during usage. Eye Contact Lens 2003;29:223–9.
[11] Liu Z, Pflugfelder SC. The effects of long-term contact lens wear on corneal thickness, curvature, and surface regularity. Ophthalmology 2000;107:105–11.
[12] Miller D. Contact lens-induced corneal curvature and thickness changes. Arch Ophthalmol 1968;80:430–2.
[13] Pratt-Johnson JA, Warner DM. Contact lenses and corneal curvature changes. Am J Ophthalmol 1965;60:852–5.
[14] Høvding G. Variations of central corneal curvature during the first year of contact lens wear. Acta Ophthalmol 1983;61:117–28.
[15] Sanaty M, Temel A. Corneal curvature changes in soft and rigid gas permeable contact lens wearers after two years of lens wear. CLAO J 1996;22:186–8.
[16] Tsai PS, Dowidar A, Naseri A, McLeod SD. Predicting time to refractive stability after discontinuation of rigid contact lens wear before refractive surgery. J Cataract Refract Surg 2004;30:2290–4.
[17] Vincent SJ, Alonso-Caneiro D, Collins MJ. Corneal changes following short-term miniscleral contact lens wear. Contact Lens Anterior Eye 2014;37:461–8.
[18] Reinstein DZ, Gobbe M, Archer TJ, Silverman RH, Coleman DJ. Epithelial, stromal, and total corneal thickness in keratoconus: three-dimensional display with artemis very-high frequency digital ultrasound. J Refract Surg 2010;26:259–71.
[19] Spoerl E, Huhle M, Seiler T. Induction of cross-links in corneal tissue. Exp Eye Res 1998;66:97–103.
[20] Wollensak G, Spoerl E, Seiler T. Riboflavin/ultraviolet-a-induced collagen crosslinking for the treatment of keratoconus. Am J Ophthalmol 2003;135:620–7.
[21] Wollensak G, Spoerl E, Seiler T. Stress-strain measurements of human and porcine corneas after riboflavin–ultraviolet-A-induced cross-linking. J Cataract Refract Surg 2003;29:1780–5.
[22] De Sanctis U, Loiacono C, Richiardi L, Turco D, Mutani B, Grignolo FM. Sensitivity and specificity of posterior corneal elevation measured by Pentacam in discriminating keratoconus/subclinical keratoconus. Ophthalmology 2008;115:1534–9.
[23] Kamiya K, Ishii R, Shimizu K, Igarashi A. Evaluation of corneal elevation, pachymetry and keratometry in keratoconic eyes with respect to the stage of Amsler–Krumeich classification. Br J Ophthalmol 2014;98:459–63.
[24] Koller T, Iseli HP, Hafezi F, Vinciguerra P, Seiler T. Scheimpflug imaging of corneas after collagen cross-linking. Cornea 2009;28:510–5.
[25] Kiely PM, Carney LG, Smith G. Diurnal variations of corneal topography and thickness. Am J Optom Physiol Opt 1982;59:976–82.
[26] Holden BA, Mertz GW. Critical oxygen levels to avoid corneal edema for daily and extended wear contact lenses. Invest Ophthalmol Vis Sci 1984;25:1161–7.
[27] Harper CL, Boulton ME, Bennett D, Marcyniuk B, Jarvis-Evans JH, Tullo AB, et al. Diurnal variations in human corneal thickness. Br J Ophthalmol 1996;80:1068–72.
[28] Mertz GW. Overnight swelling of the living human cornea. J Am Optom Assoc 1980;51:211–4.
[29] Mountford J, Carkeet N, Carney L. Corneal thickness changes during scleral lens wear: effect of gas permeability. Int Contact Lens Clin 1994;21(1–2):19–22.
[30] Pullum KW, Stapleton F. Scleral lens induced corneal swelling: what is the effect of varying Dk and lens thickness? Contact Lens Assoc Ophthalmol 1997;23:259–63.
[31] Michaud L, van der Worp E, Brazeau D, Warde R, Giasson CJ. Predicting estimates of oxygen transmissibility for scleral lenses. Contact Lens Anterior Eye 2012;35:266–71.
[32] Compañ V, Oliveira C, Aguilella-Arzo M, Molla S, Peixoto-de-Matos SC, Gonzalez-Méijome JM. Oxygen diffusion and edema with modern scleral rigid gas permeable contact lenses. Invest Ophthalmol Vis Sci 2014;2012:1–30.