Anterior eye surface changes following miniscleral contact lens wear

INTRODUCTION

The prescription of scleral contact lenses as well as the number of practitioners who fit scleral contact lenses has notably expanded over the last years [Hartan, 2017][Nau, 2017] [Vicent, 2018]. Nowadays scleral lens prescription and management is no longer limited to highly specialized care centres [Schornack, 2015]. Significant improvements in visual acuity, vision-related quality of life and ocular surface integrity have been repeatedly reported as a consequence of scleral contact lens wear in cases of corneal ectasia and ocular surface disease [Schornack, 2014][Visser, 2007][Lee, 2013][Arumugam, 2014][Ortenberg, 2013][Koppen, 2018]. Additionally, scleral lenses are increasingly being considered for refractive error correction even in non-compromised eyes [Schornack, 2015].

The interaction between the contact lens and the ocular surface is a crucial factor in assuring the safety and the comfort of the contact lens wear [Jones, 2013][Fadel, 2018]. However, information on how the entire topography of the ocular surface is affected by scleral contact lens wear is scarce. The effect of scleral contact lens wear on corneal shape has been traditionally evaluated with Scheimpflug cameras [Vincent, 2014][Soeters, 2015][Vincent, 2016]. The main limitation of these techniques is that their range of measurement is restricted to the cornea. Anterior segment Optical Coherence Tomography (OCT) allows to expand the imaging range to the corneo-scleral transition and sclera, but the analysis is limited to selected meridians. [Alonso-Caneiro, 2016]

Corneo-scleral profilometry has recently proven to be an accurate technique to measure the cornea and the sclera simultaneously in 3-dimensions (3D) 360˚ around, in a non-contact way

[Iskander, 2016]. Using this technology, we investigated in a previous work that the ocular surface is altered by short term soft contact lens wear [Consejo CL, 2017]. Scleral lenses are hard and larger than soft lenses, they rest entirely on the sclera, without touching the cornea. Consequently, due to the rigid material, larger size and bearing zone we expect to observe greater changes in ocular surface topography as a consequence of short-term miniscleral contact lens wear than that observed when analysing short-term soft contact lens wear.

The aim of this work is to describe and quantify how much the whole anterior eye surface is affected by short-term miniscleral contact lens wear. Alterations in corneal region, corneoscleral junction and sclera up to 16 mm diameter are considered in this study.

METHODS

This study was approved by the Antwerp University Hospital Research Ethics Committee and adhered to the tenets of the Declaration of Helsinki. All subjects gave written informed consent to participate after the nature and possible consequences of the study were explained. Participants in this study included 12 young, healthy adult subjects (10 females, 2 males) aged 29.9 ± 5.7 years old (mean ± SD). This sample size was chosen based on calculations conducted using previous published data on: scleral topography [Consejo EVER, 2017] and also corneal flattening and morphological scleral changes following short-term contact lens wear [Vicent, 2014] [Alonso-Caneiro, 2014]. The later data suggested that a sample size between 6 and 11 participants would yield 80 % power to detect 30 µm morphological changes as a consequence of miniscleral contact lens wear, while the previous published data on scleral topography, [Consejo EVER, 2017], suggested that a sample size of 10 participants would yield 80% power to detect 40 µm differences in scleral elevation at the 0.05 significant level. This value was chosen according to the inherent noise of the measuring device in the corneo-scleral peripheral area. The utilized corneo-scleral topographer was proved to provide below 40 µm error for an extended measurement area of 16 mm diameter in calibrated artificial surfaces.[Iskander, 2016] 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). All the participants but two were contact lens neophytes. Those two participants were occasional soft contact lens wearers, but discontinued lens wear for 24 hours prior to commencing the study, to minimize the effects of soft lens wear on the ocular surface. 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, specified by the participants as a part of a background questionnaire.

Contact lens fitting

Contact lens fitting was performed by an experienced optometrist (MVH). The lens designed used was the miniMISA miniscleral lens, provided by Microlens (Arnhem, The Netherlands). The lenses were made of highly gas-permeable materials (Dk = ___), __ µm central thickness, and had a diameter of 16.5 mm. The lens was inserted into the patients left eye with preservative free saline and assessed using a slit lamp. If regions of corneal bearing were observed, the sagittal depth of the lens was increased (in 100 µm increments) and the fit reassessed. Corneal clearance was assessed immediately after lens insertion and 2 hours after lens settling, [Vicent, 2017] using an anterior spectral domain OCT (RTVue, Optovue Inc., Fremont, CA, USA). The callipers within the analysis software were used to determine the position of the back surface of the miniscleral contact lens and the anterior surface of the cornea to provide a measure of the central corneal clearance at the position of the corneal reflex. The mean initial central corneal clearance was 276 ± 26 µm , that was reduced to 225 ± 23 µm after lens settling following 2 hours of miniscleral lens wear.

Data collection

The study was conducted over three sessions on the same day. Each session included six measurements from each eye with a corneo-scleral profilometer (Eye Surface Profiler (ESP), Eaglet Eye BV, Netherlands), a height profilometer with the potential to measure the corneo-scleral topography far beyond the limbus. To determine surface heights, algorithms used in ESP achieve similar levels of accuracy to those reached in keratoscopy based instruments such as Placido disk videokeratoscopes [Iskander, 2016]. Accurate measurements of anterior eye surface using ESP require instillation of fluorescein with a more viscous solution than saline [Iskander, 2016]. The BioGlo (HUB Pharmaceuticals) ophthalmic strips were used to gently touch the upper temporal ocular surface. They were impregnated with 1 mg of fluorescein sodium ophthalmic moisten with one drop of an eye lubricant (HYLO-Parin, 1mg/ml of sodium hyaluronate). Subjects were instructed to open their eyes wide prior the measurements with ESP to insure full coverage of the corneo-scleral area. Measurements in which the corneo-scleral area was covered by eyelids were excluded.

Baseline measurements were conducted in the morning with a minimum of two hours after awakening in order to control the influence of diurnal variation [Read, 2005] and before contact lenses insertion (0h, session 1, baseline measurements (MB)). Measurements were also acquired immediately post lens removal following 5 hours of wear (session 2, M5) and 3 hours after lens removal (i.e., 8 hours after initial lens insertion) (session 3, M8). Following lens removal the corresponding eye was re-examined using a slit-lamp to assess the anterior eye. Participants were continuing their normal daily activities between the measurement sessions that constituted office/computer work.

Data analysis

Following data acquisition, the raw anterior eye height data (three columns with *X*, *Y*, and *Z* coordinates) was exported from ESP for further analysis. To ensure that the data is not tilted, the realignment was performed by first calculating a geodesic (straight line that joins two points in a given surface) of specific distance from the apex, fitting a 3D plane to the geodesic, and then correcting the data with the estimated tilt. This correction is necessary to ensure the repeatable demarcation of the corneo-scleral region within different measurements.

First, limbal transition was calculated in 360 semi-meridians, using a custom written algorithm, as the point corresponding to a certain amount of change in the curvature between cornea and sclera [Consejo, 2016]. Further, a best-fit-circle was estimated using the points which demarcated the anterior limbus surface in each semi-meridian. The planar radius of this circle was termed the planar corneo-scleral limbal radius, or shortly the *limbal radius*.

Secondly, for each 3D map, the sclera and cornea were automatically separated at the level of the limbus, with a certain margin of tolerance, based on the results obtained when calculating limbal radius. Mean elevation of corneal (0.0-11.0 mm diameter) and scleral region (13.0-16.0 mm diameter) was calculated with custom made software. Scleral annulus was further divided into four sectors for statistical analysis: superior [50,130]˚, inferior [230,310]˚, nasal [40,320]˚ and temporal [140,220]˚. Right eyes were corrected for mirror symmetry.

The statistical analysis was performed using SPSS software for Windows version 24.0 (SPSS Inc., Chicago, Illinois, United States). The Shapiro-Wilk test was used to test the distribution type

(Gaussian or non-Gaussian) of all continuous variables. Normality of all sets of data was not rejected ($p > 0.05$). The ANOVA-repeated-measurements test (adjustment for multiple comparisons: Bonferroni) was performed to ascertain whether there was a change in limbal radius between sessions. The same test was performed to assess whether there was a change in the mean corneal and scleral elevation between sessions. Mauchly's test of sphericity indicated that the assumption of sphericity had not been violated in any ANOVA case under analysis. The level of significance was set to 0.05.

RESULTS

All data reported in this section are given for correctly fitted miniscleral contact lenses that did not induce any noticeable physiological signs in slit lamp examination. It was found that miniscleral contact lens short-term wear had a statistically significant effect on the corneo-scleral area. In particular, values in limbal radius (Table 1) and scleral elevation after miniscleral lens wear were found to be statistically significant different from baseline records.

Table 1. Limbal radius comparison intra session under the influence of wearing miniscleral contact lens during 5 hours period (first column) and without wearing contact lenses, fellow eye (second column). Baseline measurements were acquired in the early morning (MB); immediately after contact lens removal (M5) and three hours after removal (M8); in the same time interval measurements data was acquired for the fellow eye. Data was obtained with ESP and processed with a custom made algorithm. [Consejo, 2016] 'n/a' stands for 'non applicable'.

		Limbal radius under the influence of 5 hour miniscleral contact lens wear	Diurnal changes in limbal radius – no contact lens wear (fellow eye)
Mean ± SD (mm)	MB	6.03 ± 0.16	6.03 ± 0.14
	M5	6.18 ± 0.12	6.03 ± 0.14
	M8	6.08 ± 0.15	6.02 ± 0.12
Testing the difference in limbal radius between sessions	MB vs M5	***p* = 0.004**	*p* = 0.626
	MB vs M8	*p* = 0.153	*p* = 0.310
	M5 vs M8	***p* = 0.026**	*p* = 1.000
Average increment (µm) (between MB & M5)		146 ± 80	n/a
Maximum absolute change (µm) (between MB & M5)		340	n/a
Minimum absolute change (µm) (between MB & M5)		20	n/a

The observed increment in limbal radius was reversed 3 hours after contact lens removal for 42% of the participants (5 out of 12). It was assumed that limbal radius comes back to its original size when it is within the range of ± 20 µm from the baseline measurement. That range was chosen according to the lateral resolution of the instrument. The mean difference between M8 and MB limbal radius amounted to 50 ± 60 µm. Figure 1 shows the observed increment in limbal radius for the 12 subjects and compares the results with the fellow eye.

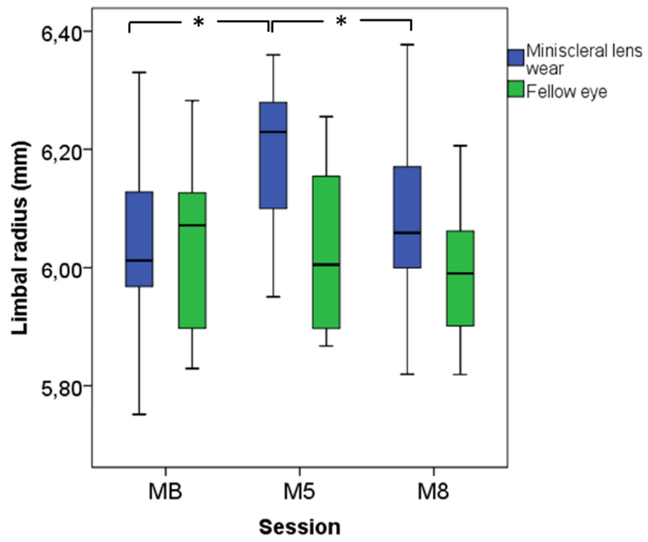

Figure 1. The boxplot illustrates the changes in limbal radius for 12 subjects who participated in the experiment, within the three sessions: before contact lens wear (MB), immediately after contact lens removal (M5) and 3 hours after contact lens removal (M8). Blue color corresponds to the eye which wore a miniscleral contact lens, while green color corresponds to the fellow eye. Asterisks denote statistically significant difference between sessions. For details see text.

Miniscleral lens wear did not result in significant corneal flattening. The group change over a 11.0 mm corneal diameter was –3 ± 17 µm immediately after lens removal (p=1.000), which coincides with the results obtained for the fellow eye between M5 and MB, –4 ± 11 µm (p=0.153). Contrarily, miniscleral lens wear resulted in significant scleral flattening. The group change over the scleral region under analysis (13.0-16.0 mm diameter) amounted to −122 ± 90 µm ($p=0.003$), which did not completely regressed to baseline values 3 hours after lens removal, –94 ± 108 µm ($p=0.045$). Differences within scleral sectors were also found (Figure 2). Within sessions two-way ANOVA test revealed differences between inferior and nasal ($p<<0.001$), inferior and superior ($p=0.021$) and nasal and temporal ($p=0.001$) sectors.

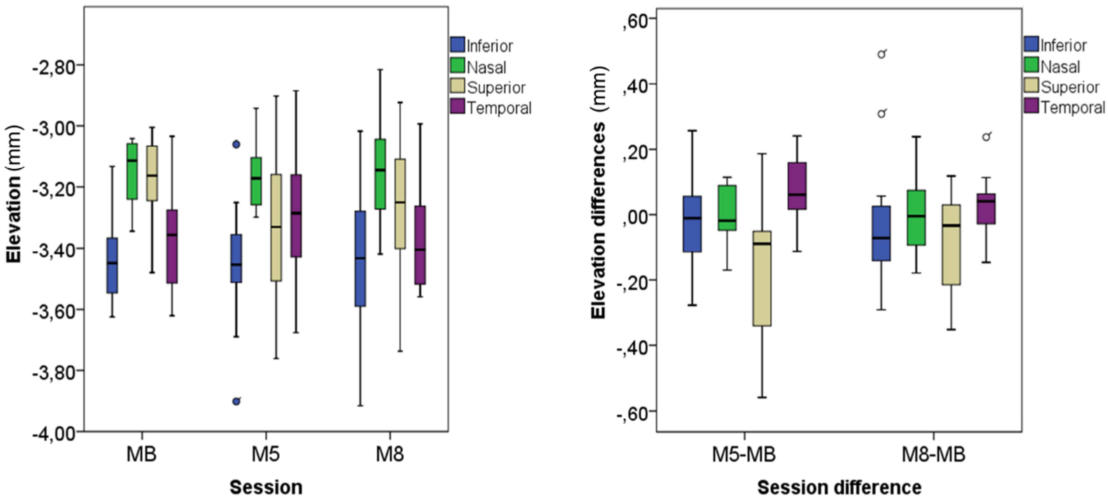

Figure 2. Left: Scleral elevation within sectors for each session. Right: Difference respect to baseline in scleral elevation within sectors. Sessions: Before contact lens wear (MB), immediately after contact lens removal (M5) and 3 hours after contact lens removal (M8).

A positive statistically significant correlation was found ($R^2 = 0.567$, $p = 0.004$) between scleral flattening (in absolute value) and limbal radius increment, suggesting that as a consequence of miniscleral lens wear, the more the sclera flattens the more limbal radius increments.

Statistical power post-hoc estimation was made. The analysis was conducted for 80% power at the 5% alpha level. For a sample size of 12 subjects, differences in limbal radius of 60 µm and differences in scleral flattening of 40 µm could be differentiated.

DISCUSSION

To our knowledge, this is the first study to examine changes, and their recovery, in corneal, corneo-scleral and scleral topography following short-term miniscleral contact lens wear, analysing 3D anterior eye surface maps, 360˚ around. In this study it was found that a relatively short-term of miniscleral contact lens wear modifies the shape of the anterior eye surface. In particular, limbal radius increment and scleral flattening were observed as a consequence of miniscleral contact lens wear.

Limbal radius increment after miniscleral contact lens wear amounted, on average, to 146 ± 80 µm. This value is slightly larger than that obtained when following the same protocol using silicone hydrogel soft contact lenses, 130 ± 74 µm. [Consejo CL, 2017]. The observed increment in limbal radius was reversed 3 hours after contact lens removal for 42% participants when wearing miniscleral contact lenses, and 68 % participants when wearing soft contact lenses. This result is in accordance with the previously reported observation that the more the limbal radius increments, the longer it takes for the effect to be reversed [Consejo CL, 2017].

The magnitude of corneal flattening as a consequence of miniscleral contact lens wear, which amounted, on average, to –3 ± 17 µm was smaller than that previously reported by Vincent and colleagues which amounted, on average, to – 30 ± 20 µm [Vincent, 2014], who found statistical significant differences in corneal shape following miniscleral lens wear. They analysed corneal flattening by means of corneal axial curvature using scheimpflug imaging, while in this work we examined height elevation maps using profilometry. This methodological differences could justify the differences found. In addition, in their work they took into account the diurnal fluctuations in all corneal parameters measured. However, we did not find a statistical significant difference between the control eye and the eye in which the lens was worn. Our findings are in accordance with a more recent work, also by Vicent and colleagues [Vicent, 2016], in which posterior corneal curvature was reported to remain stable following 8 hours of miniscleral contact lens wear.

Scleral flattening was found to be the most noticeable effect as a consequence of contact lens wear. This flattening amounted, on average, to −122 ± 90 μm (p=0.003), implying a 3.7 ± 2.7 % change from its original (baseline) size. This flattening was reduced 3 hour after lens removal, it amounted, on average, to −94 ± 108 μm. However, it was still significantly significant different from baseline values. In a previous work, Alonso-Caneiro and colleagues investigated scleral thickness following 3 hours miniscleral contact lens wear using OCT. [Alonso-Caneiro, 2016] They reported a mean decrease in thickness of −24 ± 4 μm, which diminished 3 hours after lens removal, but was still significantly thinner relative to baseline. Our findings on scleral topography change as a consequence of 5 hours of miniscleral lens wear are in line with their results.

Scleral flattening as a consequence of miniscleral lens wear was not uniformly distributed 360˚ around. Statistical significant differences in scleral flattening were found among sectors, being the superior sector the most affected by miniscleral lens wear (Figure 2). Scleral toricity [Consejo EVER, 2017][Ritzmann, 2017][Bandlitz, 2017] may result in an uneven distribution of the load for a spherical lens design, like the ones used on this experiment, which might consequently contribute to uneven compression across quadrants. Orientation of extraocular rectus muscle insertions, eye lid forces and lid position have been designated as potential factors influencing scleral shape [Ritzmann, 2017]. Likely, these factors would also influence the effect of wearing miniscleral contact lenses. In a recent work on limbal shape differences in radial distance among quadrants were found, being the superior semimeridian the shortest.[Consejo JCRS, 2017] This difference was justified by the effect of the eyelid pressure on this area. We conjecture that, precisely due to the eye lid forces and position, [Read, 2006][Read, 2007] the greatest changes in scleral shape as a consequence of miniscleral contact lens wear was observed in the superior sector.

The interaction of scleral contact lenses with the anterior eye surface and the influence they have on the physiological processes of corneal tissue is fundamental to ensure a safe wear. Static theoretical models, that did not account for dynamic tear changes that occur during lens wear, have been proposed regarding the oxygen supply to the cornea during scleral lens wear. [Michaud, 2012] [Compan, 2014][Jaynes, 2015]. Based on theoretical calculations, it was suggested that the higher the Dk value, the better in terms of minimizing hypoxia-induced corneal swelling as a consequence of contact lens wear. Recently, a number of short-term clinical studies have attempted to quantify corneal hypoxic changes as a result of scleral lens wear (high Dk). [Vincent, 2014][Compan, 2014][Frisani, 2015]. The results from these works suggested that modern high Dk miniscleral contact lenses, do not induce clinically significant corneal edema following short term of scleral lens wear. Miniscleral contact lenses used during this study met this requirement. However, different reaction and corneal response to contact lens wear depending on the distance from its center could be expected because contact lens thickness is usually not uniform.

Note that the results presented need to be put in perspective by considering the instrument's measurement noise. The ESP corneo-scleral topographer used for data acquisition has been demonstrated to provide an RMS error of < 10 µm for the central 8 mm area of a calibrated artificial surface and < 40 µm for an extended measurement area of 16 mm.[Iskander, 2016] Our analysis was performed for an area with a diameter of 0 – 16 mm. It is worth noting that the internal measurement error of the device is minor in comparison to the values reported.

The small sample size could be seen as a limitation of the study, besides the prior power analysis, confirmed by the post hoc test. All participants were young and healthy with normal cornea and sclera, and no history of ocular disease or scleral lens wear. Consequently, the results must be interpreted with caution and may not be applicable for older patients or those with ocular disease or abnormal anterior eye surface.

The market on scleral lenses has tremendously increased over the last years. Advances in ophthalmic instrumentation played a key role in that expansion. Also, the rise of formal pathways to undertake training to expand clinical capabilities related to contact lens fitting not only for qualified practitioners but also at undergraduate level [Vicent, 2018] has facilitated that more practitioners included scleral lenses in their portfolio. Similarly, the expanding governmental regulations that might limit the use of trial lenses in clinical practice, [Lian, 2017] is another reason that has contributed to the expansion of scleral lenses. The asymmetrical nature of the sclera or limbal bearing have been acknowledged as fitting challenges associated with scleral contact lenses [Walker, 2016]. Limbal and scleral shape play a fundamental role on scleral lens design [Fadel, 2018]. Consequently, gaining knowledge on how the physiology of these structures is affected by scleral lens wear might help practitioners in the fitting process and follow up.

In the present study, limbal radius increment was found for all, except for two, participants. For those two subjects the limbal radius increment of 20 µm was at the resolution limit of the instrument. In addition, those two participants were the only ones that did not experience a significant scleral flattening as a consequence of miniscleral contact lens wear. These results remark the importance of lens-subject biocompatibility. It is important to notice that in some of the studied cases more than 0.6 mm increment in limbal diameter or 300 μm scleral flattening were found and these changes were unavailable to the examiner using a slit lamp.

CONCLUSION

Short-term miniscleral contact lens wear alters corneo-scleral and scleral topography but do not produce significant corneal shape changes. Gaining knowledge on the effects of lens settling, could help the practitioner prevent cases of scleral blanching or discomfort due to an excessive compression of the lens.

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