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# Anterior eye surface changes following miniscleral contact lens wear

Alejandra Consejo[a,b,c,*], Joséphine Behaegel[c,d], Maarten Van Hoey[a], James S. Wolffsohn[e], Jos J. Rozema[a,c], D. Robert Iskander[b]

[a] Department of Ophthalmology, Antwerp University Hospital, Edegem, Belgium
[b] Department of Biomedical Engineering, Wroclaw University of Science and Technology, Wroclaw, Poland
[c] Department of Medicine and Health Sciences, University of Antwerp, Antwerp, Belgium
[d] Department of Ophthalmology, Brussels University Hospital, Jette, Belgium
[e] School of Life and Health Sciences, Ophthalmic Research Group, Aston University, Birmingham, United Kingdom

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ABSTRACT

*Purpose:* To quantify the effect of short-term miniscleral contact lens wear on the anterior eye surface of healthy eyes, including cornea, corneo-scleral junction and sclero-conjuctival area.

*Methods:* Twelve healthy subjects (29.9 ± 5.7 years) wore a highly gas-permeable miniscleral contact lens of 16.5 mm diameter during a 5-hour period. Corneo-scleral height profilometry was captured before, immediately following lens removal and 3 h after lens removal. Topography based corneo-scleral limbal radius estimates were derived from height measurements. In addition, elevation differences in corneal and scleral region were calculated with custom-written software. Sclero-conjuctival flattening within different sectors was analysed.

*Results:* Short-term miniscleral lens wear significantly modifies the anterior eye surface. Significant limbal radius increment (mean ± standard deviation) of 146 ± 80 µm, ($p = 0.004$) and flattening of −122 ± 90 µm in the sclero-conjuctival area, ($p << 0.001$) were observed immediately following lens removal. These changes did not recede to baseline levels 3 h after lens removal. The greatest anterior eye surface flattening was observed in the superior sector. No statistically significant corneal shape change was observed immediately following lens removal or during the recovery period.

*Conclusions:* Short-term miniscleral contact lens wear in healthy eyes does not produce significant corneal shape changes measured with profilometry but alters sclero-conjuctival topography. In addition, sclero-conjuctival flattening was not uniformly distributed across the anterior eye.

## 1. Introduction

The prescription of scleral contact lenses as well as the number of practitioners who fit scleral contact lenses has notably increased over the last few years [1–3]. Scleral lens prescription and management is no longer limited to highly specialized care centres [4]. 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 irregular corneal optics and in a range of ocular surface diseases [5], including Sjögren's syndrome [6], Steven's Johnson syndrome [7], keratoconus [8] and exposure keratopathy [9]. Additionally, scleral lenses are increasingly being considered for refractive error correction, even in non-compromised eyes [4].

The interaction between the contact lens and the ocular surface is a crucial factor in ensuring the safety and comfort of the contact lens wearer [10,11]. However, information on how ocular surface topography is affected by scleral contact lens wear is scarce. This has traditionally been evaluated with Scheimpflug cameras [12,13,14,15], but the main limitation of this technique is that their range of measurement is essentially restricted to the cornea. Anterior Segment Optical Coherence Tomography (AS − OCT) allows expanding the imaging range to the corneo-scleral transition and sclera, but in this case the analysis is limited to selected meridians [16].

Corneo-scleral profilometry is an accurate technique to measure the cornea and the sclera simultaneously in three dimensions (3D) along all meridians, in a non-contact way [17]. Using this technology, we previously demonstrated that the ocular surface is altered by short-term soft contact lens wear [18]. Contrarily, scleral lenses are hard and larger than soft lenses and rest entirely on the sclera without touching the cornea. Consequently, the rigid material, large size and scleral bearing zone lead us to expect greater changes in ocular surface topography in short-term miniscleral contact lens wear than in short-term soft contact lens wear.

The aim of this work is to determine how much the anterior eye

* Corresponding author at: Department of Ophthalmology, Antwerp University Hospital, Wilrijkstraat 10, 2650, Edegem, Belgium.
*E-mail address:* alejandra.consejo@uza.be (A. Consejo).

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surface is affected by short-term miniscleral contact lens wear in the corneal region, corneoscleral junction and sclero-conjuctival area up to 16 mm diameter.

## 2. 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 explanation of the nature and possible consequences of the study were explained. Participants in this study included 12 young, healthy adult subjects (10 females, two males) aged 29.9 ± 5.7 years old (mean ± standard deviation). This sample size was chosen based on calculations conducted using previous published data on: scleral topography [19], as well as corneal flattening and morphological scleral changes following short-term contact lens wear [12,16]. The latter data suggested that a sample size between 6 and 11 participants would yield a power of 80% power to detect 30 μm morphological changes as a consequence of miniscleral contact lens wear, while the previous published data on scleral topography [19], suggested that a sample size of 10 participants would yield 80% power to detect 40 μm differences in scleral elevation at the 0.05 significance 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 [17]. Prior to inclusion, all subjects were screened to exclude individuals with any contraindications to contact lens wear, such as significant tear film or anterior segment abnormalities. All participants were contact lens neophytes, except for two occasional soft contact lens wearers. These two individuals discontinued lens wear for at least 24 h before participating to minimize the influence 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, as reported by the participants in a background questionnaire.

### 2.1. Contact lens fitting

Contact lens fitting was performed by an experienced optometrist (MVH). The lens design used was the spherical haptic landing zone miniMISA miniscleral lens, provided by Microlens (Arnhem, The Netherlands). The lenses were made of highly gas-permeable materials with a Dk of 125, central thickness of 300 μm, overall diameter of 16.5 mm, inner diameter of 13.0 mm, optical zone radius of 7.8 mm and landing zone radius of 13.5 mm. The lens was placed onto a randomly chosen eye in each participant with preservative free saline and its position was assessed using a slit lamp. If regions of corneal bearing were observed, the sagittal depth of the lens was increased in 125 μm increments and the fit reassessed. Contact lens fitting was conducted on the same day to data collection. If a potential participant was unable to wear the described miniscleral lens, the participant withdrew the study. Corneal clearance was assessed immediately after lens insertion and after 2 h of lens settling [20], using an anterior spectral domain OCT (RTVue, Optovue Inc., Fremont, CA, USA). The callipers within the analysis software were used to determine the distance between 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. Limbal clearance was observed using slit lamp examination.

### 2.2. 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), which is a height profilometer able to measure the corneo-scleral topography far beyond the limbus. To determine surface heights, algorithms used in ESP achieve similar levels of accuracy similar to those reached in keratoscopy-based instruments such as Placido disk videokeratoscopes [17]. Accurate eye surface measurements using the ESP require instillation of fluorescein with a solution more viscous than saline [17]. The BioGlo (HUB Pharmaceuticals) ophthalmic strips were used to gently touch the ocular surface on the upper temporal side. They were impregnated with 1 mg of fluorescein sodium ophthalmic moistened with one drop of an eye lubricant (HYLO-Parin, 1 mg/ml of sodium hyaluronate). Subjects were instructed to open their eyes wide during measurements to ensure full coverage of the corneo-scleral area. Measurements for which part of the corneo-scleral area was covered by the eyelids were excluded.

Baseline measurements were conducted in the morning a minimum of two hours after awakening in order to control the influence of diurnal variations in corneal topography [21], right before contact lenses insertion (0 h, session 1, baseline measurements (MB)). Furthermore, measurements were taken immediately after lens removal following five hours of wear (session 2, M5), and three hours after lens removal (i.e., eight hours after initial lens insertion) (session 3, M8). After lens removal the eye was re-examined using a slit-lamp. Participants continued their normal daily activities between measurement sessions, in most cases standard office and computer work.

### 2.3. Data analysis

Following data acquisition, the raw anterior eye height data (three columns with *X*, *Y*, and *Z* coordinates) was exported from the ESP for further analysis. To ensure that the data was not tilted, a 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 [22]. This correction is necessary to ensure the repeatable demarcation of the corneo-scleral region within different measurements.

Next the limbal transition was calculated in 360 semi-meridians, using a custom-written algorithm, defining the transition as the point corresponding to a certain amount of change in the curvature between cornea and sclera [23]. This was used to determine a best-fit-circle to demarcate 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*. Fig. 1 illustrates an example of the methodology followed.

Further, for each 3D map, the sclera and cornea were automatically separated at the level of the limbus, with a margin of tolerance, based on the results obtained when calculating limbal radius. For both the corneal (0.0–11.0 mm diameter) and sclero-conjuctival region (13.0–16.0 mm diameter) the mean elevation was calculated with custom-written software. The sclero-conjuctival annulus was further divided into four sectors for statistical analysis: superior [45,135]°, inferior [225,315]°, nasal [315,45]° and temporal [135,225]°. Right eyes were corrected for mirror symmetry.

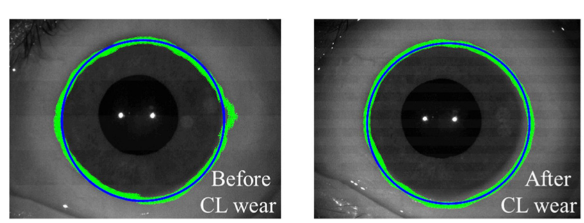


**Fig. 1.** Limbus demarcation points (denoted by green overlapping circles), calculated using [23], and the corresponding circular fit (blue line) for a subject (female, 29 years-old) before miniscleral contact lens (CL) wear and immediately after miniscleral contact lens removal.

**Table 1**
Intra-session comparison of the changes in limbal radius, corneal elevation (0.0–11.0 mm diameter) and sclero-conjuctival elevation (13.0–16.0 mm diameter) due to miniscleral contact lens wear for a 5-hour period (first, third and fifth columns, respectively) and the fellow eye that didn't wear contact lenses (second, fourth and sixth columns, respectively). Measurements were acquired in the early morning before inserting the lenses (MB), immediately after contact lens removal (M5) and three hours after removal (M8).

| | | Limbal radius | | Corneal elevation | | Sclero-conjuctival elevation | |
|---|---|---|---|---|---|---|---|
| | | Under the influence of 5 h miniscleral contact lens wear | Diurnal changes– no contact lens wear (fellow eye) | Under the influence of 5 h miniscleral contact lens wear | Diurnal changes– no contact lens wear (fellow eye) | Under the influence of 5 h miniscleral contact lens wear | Diurnal changes– no contact lens wear (fellow eye) |
| Mean ± SD (mm) | MB | 6.03 ± 0.16 | 6.03 ± 0.14 | −1.12 ± 0.04 | −1.12 ± 0.04 | −3.26 ± 0.13 | −3.28 ± 0.15 |
| | M5 | 6.18 ± 0.12 | 6.03 ± 0.14 | −1.12 ± 0.04 | −1.13 ± 0.04 | −3.38 ± 0.14 | −3.30 ± 0.09 |
| | M8 | 6.08 ± 0.15 | 6.02 ± 0.12 | −1.13 ± 0.04 | −1.13 ± 0.04 | −3.35 ± 0.17 | −3.30 ± 0.16 |
| Testing the difference in limbal radius between sessions (ANOVA test) | MB vs M5 | ***p* = 0.004** | *p* = 0.626 | *p* = 1.000 | *p* = 0.153 | ***p* = 0.003** | *p* = 0.594 |
| | MB vs M8 | *p* = 0.153 | *p* = 0.310 | *p* = 0.060 | *p* = 0.300 | ***p* = 0.045** | *p* = 1.000 |
| | M5 vs M8 | ***p* = 0.026** | *p* = 1.000 | *p* = 0.320 | *p* = 1.000 | *p* = 0.717 | *p* = 1.000 |
| Average increase (µm) (between MB & M5) | | 146 ± 80 | n/a | n/a | n/a | −122 ± 90 | n/a |
| Maximum absolute change (µm) (between MB & M5) | | 340 | n/a | n/a | n/a | −280 | n/a |
| Minimum absolute change (µm) (between MB & M5) | | 20 | n/a | n/a | n/a | −20 | n/a |

n/a : 'non applicable'.
+/- values indicate one standard deviation from the mean.

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 sclero-conjuctival 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.

## 3. Results

It was found that miniscleral contact lens short-term wear had a statistically significant influence on the corneo-scleral area. In particular, limbal radius values and sclero-conjuctival elevation after miniscleral lens wear were found to be statistically significant different from the baseline records (Table 1).

The observed increase in limbal radius was reversed 3 h after contact lens removal for 42% of the participants (5 out of 12). It was assumed that limbal radius had returned to its original size when it was within the range of ± 20 µm from the baseline measurement. This 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. Fig. 2 shows the observed increase in limbal radius for the 12 subjects and compares the results with the fellow eye.

Miniscleral lens wear did not result in significant changes in corneal topography. 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 sclero-conjuctival flattening. The mean elevation change in the 13.0–16.0 mm diameter annulus amounted to −122 ± 90 µm (p = 0.003). A positive statistically significant correlation was found ($R^2 = 0.57$, p = 0.004) between sclero-conjuctival flattening (in absolute value) and limbal radius increase. Sclero-conjuctival flattening did not fully regress to baseline values 3 h after lens removal (−94 ± 108 µm; p = 0.045). Differences within scleral sectors were also found (Fig. 3). 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.

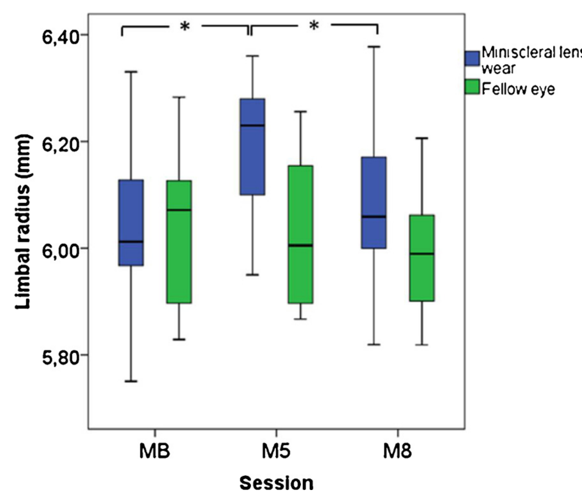


**Fig. 2.** The boxplot illustrates the changes in limbal radius for 12 subjects who participated in the experiment, within the three sessions: before contact lens wear (MB), immediately after contact lens removal (M5) and 3 h after contact lens removal (M8). Blue corresponds with the eye wearing a miniscleral contact lens, green with the fellow eye. Asterisks denote statistically significant difference between sessions. Error bars indicate +/- one standard deviation; N = 12.

The mean initial central corneal clearance was 300 ± 50 µm, which reduced to 229 ± 65 µm after two hours of lens settling. No corneal or conjunctival staining was observed following lens removal. A positive statistically significant correlation was found ($R^2 = 0.42$, p = 0.039) between sclero-conjuctival flattening and central clearance decrease after two hours of lens settling. No correlation was found ($R^2 = 0.05$, p = 0.28) between limbal radius increase and central clearance decrease.

## 4. Discussion

To our knowledge, this is the first study to examine changes, and their recovery, in corneal, corneo-scleral and sclero-conjuctival topography following short-term miniscleral contact lens wear, analysing

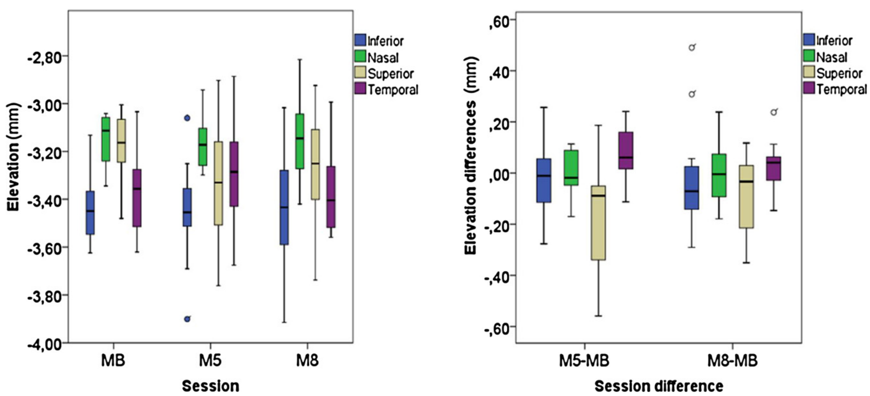


**Fig. 3.** Left: Sclero-conjuctival elevation within sectors for each session. Right: Difference respect to baseline in sclero-conjuctival elevation within sectors. Sessions: Before contact lens wear (MB), immediately after contact lens removal (M5) and 3 h after contact lens removal (M8). Error bars indicate +/- one standard deviation; N = 12.

3D anterior eye surface maps, 360° around. It was found that a relatively short period of miniscleral contact lens wear altered the shape of the anterior eye surface, in particular, limbal radius increase and sclero-conjuctival flattening were observed.

Limbal radius increase after miniscleral contact lens wear amounted, on average, to 146 ± 80 μm. This value is slightly larger than that seen using silicone hydrogel soft contact lenses following the same protocol, which amounted on average to 130 ± 74 μm. [18]. The increase in limbal radius reverted to baseline values three hours after contact lens removal for 42% participants when wearing miniscleral contact lenses, compared to 68% in soft contact lens wearers [18]. This result is in accordance with the previously reported observation that larger limbal radius increases correspond with a longer recovery period [18].

While interactions between lens, eyelid and cornea are associated with forces leading to anterior corneal surface changes [13], no corneal flattening was observed after five hours of miniscleral lens wear. Corneal flattening due to miniscleral contact lens wear was on average −3 ± 17 μm, which was less than the statistically significant value of −30 ± 20 μm reported after three hours of lens wear by Vincent et al. [13]. In another work by the same team, corneal curvature changes following 8 h of miniscleral lens wear was significant respect to baseline [14] but not substantially greater than that observed following 3 h of lens wear [13]. They analysed corneal flattening by means of corneal axial curvature using Scheimpflug imaging, while in this work the height elevation maps using profilometry were examined. These methodological differences could explain the differences found. Another hypothesis to justify the differences found between our work and the earlier works of Vincent et al. is that as ESP requires the instillation of a more viscous drop than saline with sodium fluorescein for data acquisition this could possibly mask subtle corneal changes following lens wear. Furthermore, in a recent work also by Vincent and colleagues [15], posterior corneal curvature was reported to remain stable following 8 h of miniscleral contact lens wear.

Sclero-conjuctival flattening was found to be the most noticeable effect as a consequence of miniscleral contact lens wear. This flattening implies a 3.7 ± 2.7% change from its baseline size. While there was a reduction of this flattening three hours after lens removal, it was still significantly different from baseline values. Furthermore, flattening was not uniformly distributed. Statistical significant differences in sclero-conjuctival flattening were found among the scleral sectors, with the greatest flattening observed in the superior sector (Fig. 3). These findings are in line with a previous work of Alonso-Caneiro and colleagues who investigated scleral thickness following three hours miniscleral contact lens wear using OCT [16]. They reported a significant tissue compression in young healthy eyes, with the greatest thinning observed superiorly and a partial recovery of compression three hours after lens removal. The partial recovery they reported amounted on average to approximately 70% of the total flattening (i.e. 3 h after lens removal 70% of flattening was recovered towards baseline values). Our findings are in line with theirs, since the partial recovery in this study amounts to 77% of the total flattening. Scleral toricity [19,24,25] may result in an uneven distribution of the load for a lens with a spherical landing zone, like the ones used on this experiment, which might contribute to uneven compression across sectors. The orientation of extraocular rectus muscle insertions, eyelid forces and lid position have been designated as potential factors influencing scleral shape [24]. These factors would also influence the changes due to miniscleral lens wear. A recent study also demonstrated regional differences in limbal shape, in which the superior semi-meridian had the shortest radial distance [26]. 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 [27,28], the largest sclero-conjuctival elevation change, as a consequence of miniscleral contact lens wear, was observed in the superior sector. Another factor could be the gravity of the scleral lens, meaning more pressure downwards on the superior sector of the sclera and the limbus.

In the present study, limbal radius increase was found for all but for two, participants. Only one of those two participants was a regular soft contact lens wearer. For these two subjects the limbal radius increase amounted to 20 μm, which is near the instrument's resolution limit. In addition, these two participants were the only ones that did not experience a significant sclero-conjuctival flattening due to miniscleral lens wear. Meanwhile, other participants experienced a limbal diameter increase of over 0.6 mm or scleral flattening by about 300 μm, both of which were undetectable to the examiner using a slit lamp. Furthermore, a significant correlation between sclero-conjuctival flattening and limbal radius increase was observed, suggesting that as a consequence of miniscleral lens wear, the more the sclero-conjuctival area flattens the more limbal radius increases.

A significant correlation was also observed between sclero-conjuctival flattening after 5 h of lens wear and the decrease in corneal clearance after two hours of lens settling, suggesting that the more the clearance decreases the more the sclero-conjuctival area flattens. The role of corneal clearance on scleral tissue was also investigated previously by Alonso-Caneiro and colleagues, who found a weak, non-significant positive correlation between clearance of the lens and scleral tissue thickness thinning following three hours of miniscleral contact lens wear [16].

It is important to note that the results presented need to be put in perspective by considering the instrument's measurement noise. The ESP corneo-scleral topographer 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 [17]. The internal measurement error of the device is therefore small in comparison to the values reported.

The small sample size could be seen as a limitation of the study, despite the prior power analysis. 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 surface abnormalities. An additional limitation of the study is the single lens design. Additional work is necessary to investigate the potential influence of contact lens design on anterior eye surface.

The scleral lenses market has increased tremendously over the last years, partly stimulated by advances in ophthalmic instrumentation. Furthermore, the increase in formal training to expand clinical abilities related to contact lens fitting to both qualified practitioners and at undergraduate levels [3] has facilitated more practitioners to include scleral lenses into their portfolio. Similarly, the expanding governmental regulations that classify trial contact lenses as ‘semi-critical’ in terms of risk for reusable ophthalmic devices might limit in the future the use of trial lenses in clinical practice [29]. This concern also contributed to the expansion of scleral lenses and the interest of practitioners to better understand scleral shape [30]. The asymmetrical nature of the sclera and limbal bearing have been acknowledged as fitting challenges associated with scleral contact lenses [31]. Limbal and scleral shape play a fundamental role on scleral lens design [11,32]. Consequently, gaining knowledge on how the physiology of these structures is affected by scleral lens wear might help practitioners to improve lens fitting process and follow up. It has been shown that short-term miniscleral contact lens wear alters corneo-scleral and sclero-conjuctival topography but no significant corneal shape changes measured with ESP profilometry were observed. Longer studies on both healthy and compromised corneas could further help to elaborate the complete impact that these lenses exert on the anterior surface including corneal topography and physiology.

In conclusion, a relatively short period of optimally fitted miniscleral contact lens wear in healthy eyes, alters corneo-scleral and sclero-conjuctival topography but on average no significant corneal shape changes were found across the central 11 mm, measured with profilometry, for the 12 subjects investigated. Miniscleral contact lens wear results in limbal radius increase and sclero-conjuctival flattening, with the greatest flattening being observed superiorly. Gaining knowledge on the effects of lens settling could help practitioners prevent cases of scleral blanching or discomfort due to an excessive compression of the lens.

## Declarations of interest

None.

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