

# **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

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

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

32

### 33 **METHODS**

34 This study was approved by the Antwerp University Hospital Research Ethics Committee and  
35 adhered to the tenets of the Declaration of Helsinki. All subjects gave written informed consent to  
36 participate after the nature and possible consequences of the study were explained. Participants in  
37 this study included 12 young, healthy adult subjects (10 females, 2 males) aged  $29.9 \pm 5.7$  years  
38 old (mean  $\pm$  SD). This sample size was chosen based on calculations conducted using previous  
39 published data on: scleral topography [Consejo EVER, 2017] and also corneal flattening and  
40 morphological scleral changes following short-term contact lens wear [Vicent, 2014] [Alonso-  
41 Caneiro, 2014]. The later data suggested that a sample size between 6 and 11 participants would  
42 yield 80 % power to detect 30  $\mu\text{m}$  morphological changes as a consequence of miniscleral  
43 contact lens wear, while the previous published data on scleral topography, [Consejo EVER,  
44 2017], suggested that a sample size of 10 participants would yield 80% power to detect 40  $\mu\text{m}$

45 differences in scleral elevation at the 0.05 significant level. This value was chosen according to  
46 the inherent noise of the measuring device in the corneo-scleral peripheral area. The utilized  
47 corneo-scleral topographer was proved to provide below 40  $\mu\text{m}$  error for an extended  
48 measurement area of 16 mm diameter in calibrated artificial surfaces.[[Iskander, 2016](#)] Prior to  
49 commencement of the study, all subjects were screened to exclude those with any  
50 contraindications to contact lens wear (i.e., significant tear film or anterior segment  
51 abnormalities). All the participants but two were contact lens neophytes. Those two participants  
52 were occasional soft contact lens wearers, but discontinued lens wear for 24 hours prior to  
53 commencing the study, to minimize the effects of soft lens wear on the ocular surface. None of  
54 the subjects were previous rigid contact lens wearers. Participants had no prior history of eye  
55 injury, surgery or current use of topical ocular medications, specified by the participants as a part  
56 of a background questionnaire.

### 57 *Contact lens fitting*

58 Contact lens fitting was performed by an experienced optometrist (MVH). The lens designed  
59 used was the miniMISA miniscleral lens, provided by Microlens (Arnhem, The Netherlands).  
60 The lenses were made of highly gas-permeable materials ( $Dk = \_\_\_$ ),  $\_\_\_ \mu\text{m}$  central thickness,  
61 and had a diameter of 16.5 mm. The lens was inserted into the patients left eye with preservative  
62 free saline and assessed using a slit lamp. If regions of corneal bearing were observed, the sagittal  
63 depth of the lens was increased (in 100  $\mu\text{m}$  increments) and the fit reassessed. Corneal clearance  
64 was assessed immediately after lens insertion and 2 hours after lens settling, [[Vicent, 2017](#)] using  
65 an anterior spectral domain OCT (RTVue, Optovue Inc., Fremont, CA, USA). The callipers  
66 within the analysis software were used to determine the position of the back surface of the  
67 miniscleral contact lens and the anterior surface of the cornea to provide a measure of the central

68 corneal clearance at the position of the corneal reflex. The mean initial central corneal clearance  
69 was  $276 \pm 26 \mu\text{m}$ , that was reduced to  $225 \pm 23 \mu\text{m}$  after lens settling following 2 hours of  
70 miniscleral lens wear.

#### 71 *Data collection*

72 The study was conducted over three sessions on the same day. Each session included six  
73 measurements from each eye with a corneo-scleral profilometer (Eye Surface Profiler (ESP),  
74 Eaglet Eye BV, Netherlands), a height profilometer with the potential to measure the corneo-  
75 scleral topography far beyond the limbus. To determine surface heights, algorithms used in ESP  
76 achieve similar levels of accuracy to those reached in keratometry based instruments such as  
77 Placido disk videokeratoscopes [Iskander, 2016]. Accurate measurements of anterior eye surface  
78 using ESP require instillation of fluorescein with a more viscous solution than saline [Iskander,  
79 2016]. The BioGlo (HUB Pharmaceuticals) ophthalmic strips were used to gently touch the upper  
80 temporal ocular surface. They were impregnated with 1 mg of fluorescein sodium ophthalmic  
81 moisten with one drop of an eye lubricant (HYLO-Parin, 1mg/ml of sodium hyaluronate).  
82 Subjects were instructed to open their eyes wide prior the measurements with ESP to insure full  
83 coverage of the corneo-scleral area. Measurements in which the corneo-scleral area was covered  
84 by eyelids were excluded.

85 Baseline measurements were conducted in the morning with a minimum of two hours after  
86 awakening in order to control the influence of diurnal variation [Read, 2005] and before contact  
87 lenses insertion (0h, session 1, baseline measurements (MB)). Measurements were also acquired  
88 immediately post lens removal following 5 hours of wear (session 2, M5) and 3 hours after lens  
89 removal (i.e., 8 hours after initial lens insertion) (session 3, M8). Following lens removal the  
90 corresponding eye was re-examined using a slit-lamp to assess the anterior eye. Participants were

91 continuing their normal daily activities between the measurement sessions that constituted  
92 office/computer work.

### 93 *Data analysis*

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

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

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

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

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

120

## 121 RESULTS

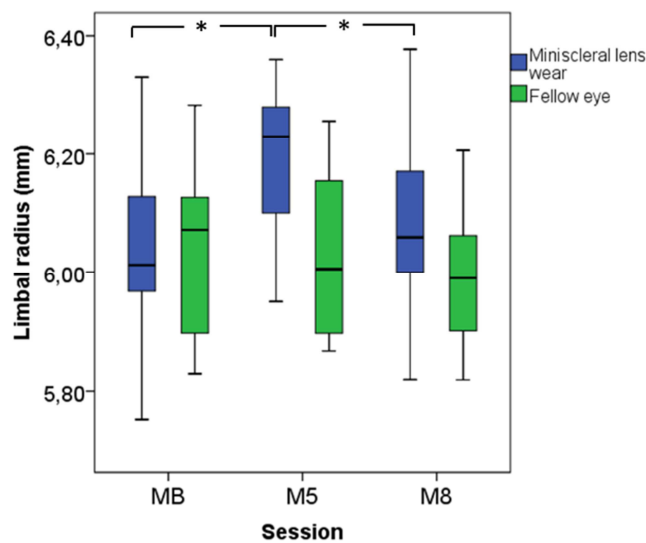
122 All data reported in this section are given for correctly fitted miniscleral contact lenses that did  
 123 not induce any noticeable physiological signs in slit lamp examination. It was found that  
 124 miniscleral contact lens short-term wear had a statistically significant effect on the corneo-scleral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

127 **Table 1.** Limbal radius comparison intra session under the influence of wearing miniscleral contact lens during 5  
 128 hours period (first column) and without wearing contact lenses, fellow eye (second column). Baseline measurements  
 129 were acquired in the early morning (MB); immediately after contact lens removal (M5) and three hours after removal  
 130 (M8); in the same time interval measurements data was acquired for the fellow eye. Data was obtained with ESP and  
 131 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 $\pm$ SD (mm)	MB	6.03 $\pm$ 0.16	6.03 $\pm$ 0.14
	M5	6.18 $\pm$ 0.12	6.03 $\pm$ 0.14
	M8	6.08 $\pm$ 0.15	6.02 $\pm$ 0.12
Testing the difference in limbal radius between sessions	MB vs M5	<b><math>p = 0.004</math></b>	$p = 0.626$
	MB vs M8	$p = 0.153$	$p = 0.310$
	M5 vs M8	<b><math>p = 0.026</math></b>	$p = 1.000$
Average increment ( $\mu\text{m}$ ) (between MB & M5)		146 $\pm$ 80	n/a
Maximum absolute change ( $\mu\text{m}$ ) (between MB & M5)		340	n/a
Minimum absolute change ( $\mu\text{m}$ ) (between MB & M5)		20	n/a

132

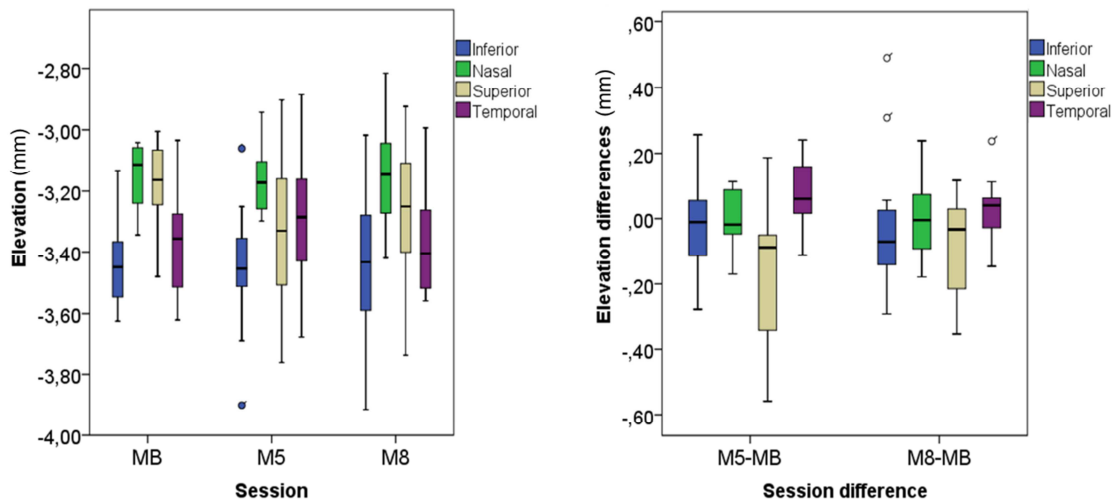
133 The observed increment in limbal radius was reversed 3 hours after contact lens removal for 42%  
 134 of the participants (5 out of 12). It was assumed that limbal radius comes back to its original size  
 135 when it is within the range of  $\pm 20 \mu\text{m}$  from the baseline measurement. That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



139  
 140 **Figure 1.** The boxplot illustrates the changes in limbal radius for 12 subjects who participated in the experiment,  
 141 within the three sessions: before contact lens wear (MB), immediately after contact lens removal (M5) and 3 hours  
 142 after contact lens removal (M8). Blue color corresponds to the eye which wore a miniscleral contact lens, while  
 143 green color corresponds to the fellow eye. Asterisks denote statistically significant difference between sessions. For  
 144 details see text.

145 Miniscleral lens wear did not result in significant corneal flattening. The group change over a  
 146 11.0 mm corneal diameter was  $-3 \pm 17 \mu\text{m}$  immediately after lens removal ( $p=1.000$ ), which  
 147 coincides with the results obtained for the fellow eye between M5 and MB,  $-4 \pm 11 \mu\text{m}$   
 148 ( $p=0.153$ ). Contrarily, miniscleral lens wear resulted in significant scleral flattening. The group

149 change over the scleral region under analysis (13.0-16.0 mm diameter) amounted to  $-122 \pm 90$   
 150  $\mu\text{m}$  ( $p=0.003$ ), which did not completely regress to baseline values 3 hours after lens removal,  
 151  $-94 \pm 108 \mu\text{m}$  ( $p=0.045$ ). Differences within scleral sectors were also found (Figure 2). Within  
 152 sessions two-way ANOVA test revealed differences between inferior and nasal ( $p < 0.001$ ),  
 153 inferior and superior ( $p=0.021$ ) and nasal and temporal ( $p=0.001$ ) sectors.



154  
 155 **Figure 2.** Left: Scleral elevation within sectors for each session. Right: Difference respect to baseline in scleral  
 156 elevation within sectors. Sessions: Before contact lens wear (MB), immediately after contact lens removal (M5) and  
 157 3 hours after contact lens removal (M8).

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

161 Statistical power post-hoc estimation was made. The analysis was conducted for 80% power at  
 162 the 5% alpha level. For a sample size of 12 subjects, differences in limbal radius of  $60 \mu\text{m}$  and  
 163 differences in scleral flattening of  $40 \mu\text{m}$  could be differentiated.

164



165 **DISCUSSION**

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

172 Limbal radius increment after minislcleral contact lens wear amounted, on average, to  $146 \pm 80$   
173  $\mu\text{m}$ . This value is slightly larger than that obtained when following the same protocol using  
174 silicone hydrogel soft contact lenses,  $130 \pm 74 \mu\text{m}$ . [Consejo CL, 2017]. The observed increment  
175 in limbal radius was reversed 3 hours after contact lens removal for 42% participants when  
176 wearing minislcleral contact lenses, and 68 % participants when wearing soft contact lenses. This  
177 result is in accordance with the previously reported observation that the more the limbal radius  
178 increments, the longer it takes for the effect to be reversed [Consejo CL, 2017].

179 The magnitude of corneal flattening as a consequence of minislcleral contact lens wear, which  
180 amounted, on average, to  $-3 \pm 17 \mu\text{m}$  was smaller than that previously reported by Vincent and  
181 colleagues which amounted, on average, to  $-30 \pm 20 \mu\text{m}$  [Vincent, 2014], who found statistical  
182 significant differences in corneal shape following minislcleral lens wear. They analysed corneal  
183 flattening by means of corneal axial curvature using scheimpflug imaging, while in this work we  
184 examined height elevation maps using profilometry. This methodological differences could  
185 justify the differences found. In addition, in their work they took into account the diurnal  
186 fluctuations in all corneal parameters measured. However, we did not find a statistical significant  
187 difference between the control eye and the eye in which the lens was worn. Our findings are in

188 accordance with a more recent work, also by Vicent and colleagues [[Vicent, 2016](#)], in which  
189 posterior corneal curvature was reported to remain stable following 8 hours of miniscleral contact  
190 lens wear.

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

201 Scleral flattening as a consequence of miniscleral lens wear was not uniformly distributed  $360^\circ$   
202 around. Statistical significant differences in scleral flattening were found among sectors, being  
203 the superior sector the most affected by miniscleral lens wear (Figure 2). Scleral toricity [[Consejo](#)  
204 [EVER, 2017](#)][[Ritzmann, 2017](#)][[Bandlitz, 2017](#)] may result in an uneven distribution of the load  
205 for a spherical lens design, like the ones used on this experiment, which might consequently  
206 contribute to uneven compression across quadrants. Orientation of extraocular rectus muscle  
207 insertions, eye lid forces and lid position have been designated as potential factors influencing  
208 scleral shape [[Ritzmann, 2017](#)]. Likely, these factors would also influence the effect of wearing  
209 miniscleral contact lenses. In a recent work on limbal shape differences in radial distance among  
210 quadrants were found, being the superior semimeridian the shortest.[[Consejo JCRS, 2017](#)] This

211 difference was justified by the effect of the eyelid pressure on this area. We conjecture that,  
212 precisely due to the eye lid forces and position, [Read, 2006][Read, 2007] the greatest changes in  
213 scleral shape as a consequence of miniscleral contact lens wear was observed in the superior  
214 sector.

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

229 Note that the results presented need to be put in perspective by considering the instrument's  
230 measurement noise. The ESP corneo-scleral topographer used for data acquisition has been  
231 demonstrated to provide an RMS error of  $< 10 \mu\text{m}$  for the central 8 mm area of a calibrated  
232 artificial surface and  $< 40 \mu\text{m}$  for an extended measurement area of 16 mm.[Iskander, 2016] Our

233 analysis was performed for an area with a diameter of 0 – 16 mm. It is worth noting that the  
234 internal measurement error of the device is minor in comparison to the values reported.

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

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

252 In the present study, limbal radius increment was found for all, except for two, participants. For  
253 those two subjects the limbal radius increment of 20  $\mu\text{m}$  was at the resolution limit of the  
254 instrument. In addition, those two participants were the only ones that did not experience a  
255 significant scleral flattening as a consequence of miniscleral contact lens wear. These results

256 remark the importance of lens-subject biocompatibility. It is important to notice that in some of  
257 the studied cases more than 0.6 mm increment in limbal diameter or 300 µm scleral flattening  
258 were found and these changes were unavailable to the examiner using a slit lamp.

259

## 260 **CONCLUSION**

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

265

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