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Rotation asymmetry of the human sclera

Alejandra Consejo, MSc PhD,^{1,2} Clara Llorens-Quintana, MSc,² Maciej M. Bartuzel, MSc,²
D. Robert Iskander, MSc PhD DSc,² and Jos J. Rozema, MSc PhD^{1,3}

¹ *Department of Ophthalmology, Antwerp University Hospital, Edegem, Belgium*

² *Department of Biomedical Engineering, Wroclaw University of Science and Technology, Wroclaw, Poland*

³ *Department of Medicine and Health Sciences, University of Antwerp, Antwerp, Belgium*

ABSTRACT

Purpose: To characterize the mean topographical shape of the human sclera of a normal eye.

Methods: Forty-five participants aged from 19 to 45 years and with no previous ocular surgeries were included in this study. Four three-dimensional (3D) corneo-scleral maps from both eyes were acquired using a corneo-scleral topographer (Eye Surface Profiler). For each 3D map, the sclera (maximum diameter of 16 mm) and cornea were automatically separated at the level of the limbus. The remaining 3D scleral ring was further fit to a quadratic function. The elevation difference between the original and fit data was calculated. For statistical analysis, sclera was separated in eight sectors, nasal, temporal, superior, inferior, supero-nasal, supero-temporal, inferior-nasal and inferior-temporal. In addition, sclera was separated as inner sclera (inner ring of 6-7 mm radius) and outer sclera (external ring of 7-8 mm radius).

Results: Horizontally, the nasal area of the sclera showed less elevation (mean (SD) – 30 (SD, 52) μm (OD)) than the temporal area (mean (SD) 4 (SD, 47) μm (OD)), $p < 0.001$. Vertically, the inferior area of the sclera (mean (SD) 32 (SD, 72) μm (OD)) was slightly less elevated than the superior area (mean (SD) 36 (SD, 84) μm), but this difference was not statistically different ($p=0.40$). Besides, the asymmetry of the sclera was found to increase with radial distance from the corneal apex. No statistically significant difference was found between right and left eye.

Conclusions: Human sclera is rotationally asymmetric and its shape varies considerably between subjects.

KEYWORDS: sclera; ocular surface; topography; scleral lenses

INTRODUCTION

The human sclera is an opaque, tough, fibrous tissue that helps to maintain the eye's shape and protects the inner structures, offering resistance to internal and external forces, and provides an attachment for the extraocular muscle insertions. Even though the sclera covers about five-sixths of the outer surface of the eye and performs several important functions essential for visual integrity, current knowledge about scleral shape beyond the corneo-scleral transition is scarce.

The importance of scleral topography in different surgical applications has been repeatedly acknowledged, such as flap creation in trabeculectomy (Kesahara et al., 2014), penetration and perforations in strabismus surgery (Surachatkumtonekul et al., 2009) or in LASIK surgery, where information about scleral shape could reduce potential complications due to an inappropriate selection of the suction ring (Lavaque et al., 2006). Beyond the operating room, a better knowledge of scleral shape could enhance scleral contact lens design and fitting, since these are entirely borne by the sclera (van der Worp et al., 2014). Nowadays scleral contact lenses are used in a broad spectrum of conditions, such as keratoconus, keratoglobus, pellucid marginal degeneration or post-refractive surgery ectasia. The geometric characteristics of the lens, and consequently the fitting, can influence comfort, quality of vision, and the health of the eye (Shovlin et al., 2013)(Chalmers, 2014).

Analyzing scleral topography in-vivo is not an easy task due to technical limitations that constrain ocular topographical studies to the corneal area. Hence recent studies aimed to describe scleral topography by assessing scleral radius (Hall et al., 2013) (Kasahara et al., 2014) (Choi et al., 2014) (Lee et al., 2016) (Bandlitz et al., 2017). In a recent work, scleral sagittal height up to 15.0 mm chord was evaluated in certain isolated meridians using Optical Coherence Tomography (OCT) (Ritzmann et al., 2018). Although the importance of scleral topography has been recognized, previous works in scleral topography were restricted to few isolated scleral points. To the best of our knowledge no accurate description of the human scleral shape, measured in vivo, as a continuous surface (i.e., not discretely) has been reported. Today, it is possible to overcome the technical limitations that constrained the topographical studies to the corneal region with noncontact commercially available instruments, such as corneo-scleral profilometers that cover the corneo-scleral area far beyond the limbus up to 20 mm chord (Iskander et al., 2016).

The aim of this study was to characterize for the first time the mean topographic shape of the sclera of a normal human eye from complete three-dimensional (3D) corneoscleral maps and determine whether there exist differences between right and left eye of the same participant.

MATERIALS AND METHODS

Forty-five participants (90 eyes) were included in this study. They were adult participants (32 females, 13 males) aged between 19 and 45 years old (mean (SD) 26.6 (SD,5.7) years old). The study was approved by University of Manchester Human Research Ethics Committee and adhered to the tenets of the Declaration of Helsinki. All participants gave written informed consent to participate after the nature and possible consequences of the study were explained. All participants were free of ocular disease, had less than 1.00 D of astigmatism in both eyes and current use of topical ocular medications was specified by the participants as part of a background questionnaire. Participants with moderate or high myopia (≤ -2.00 D) were excluded. Exclusion criteria also included the presence of any corneal, conjunctival or scleral pathology, any history of

ocular surgery, as well as contact lens wear. The refractive state was measured monocularly using a wide-view open window autorefractometer (Shin Nippon SRW-500, Ajinomoto Trading Inc.)

The study was performed in a single visit for each of the participants. Topographical data was obtained using a non-contact corneo-scleral topographer (Eye Surface Profiler (ESP), Eaglet Eye BV, Netherlands), a height profilometer able to measure the corneo-scleral topography several millimeters beyond the limbus. The algorithms used in the ESP achieve similar levels of accuracy for corneal surface heights as Placido disk based videokeratoscopes, with below 10 μm RMS error for the central 8 mm area of a calibrated artificial surface, and below 40 μm for an extended measurement area of 16 mm (Iskander et al., 2016). Anterior eye surface measurements using ESP require instillation of fluorescein with a solution more viscous than saline. 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 moistened with one drop of an eye lubricant (HYLO-Parin, 1mg/ml of sodium hyaluronate). Four measurements were collected from the left eye and right eye of each subject. Participants were instructed to open their eyes wide, but without using force, prior to the ESP measurements to ensure maximal coverage of the corneo-scleral area. Measurements in which the corneo-scleral area was covered by eyelids were excluded. From the four measurements acquired per eye the one with the largest scleral area coverage was included for data analysis. It is important to highlight that right and left eyes were always treated independently from each other and no merging data technique was applied in this work.

Following data acquisition the raw 3D anterior eye height data (X , Y , and Z coordinates) was exported from the ESP for further analysis. For each 3D map, the sclera and cornea were automatically separated at the level of the limbus, assuming a mean limbal diameter of 12 mm based on recent work (Consejo et al., 2017a). The remaining 3D scleral ring (Figure 1a) was further fit to a quadratic function given by (see also Figure 1b).

$$Z_{fit}(X, Y) = aX + bY + c(X^2 + Y^2) + d \quad (1)$$

This four-parameter (a , b , c and d) model was chosen for its simplicity and to account for the bulk of surface shape. By analysing parameters a and b it is possible to estimate how much the sclera is tilted with respect to the cornea in X and Y directions, respectively. Finally, the difference between the raw elevation data and the fit was calculated (Figure 1c). It is worth noting that the reference

Figure 1. An example, corresponding to a left eye, of the methodology followed. (a): original raw scleral data corresponding to a 6-8 mm scleral ring; (b) fitting of the scleral data to a quadratic function; (c): difference between original and fit data, this is (a)-(b). The color scale varies from dark blue (lower elevation values) to dark red (highest elevation values).

level for scleral elevation is the corneal apex. The ESP device incorporates an internal procedure, based on 3-dimensional data, to estimate the position of the corneal apex and to ensure that corneal data is not tilted or rotated (for details, see Consejo et al., 2017b). For statistical analysis, the sclera was first separated into eight sectors: nasal [330,30]°, superior-nasal (30,60)°, superior [60,120]°, superior-temporal (120,150)°, temporal [150,210]°, inferior-temporal (210,240)°, inferior [240,300]°, inferior-nasal (300,330)°, as indicated in Figure 2. In addition, sclera was divided into two annuli, denoted as inner sclera (inner ring of 6 to 7 mm radius, represented as an orange ring in Figure 2) and outer sclera (external ring of 7 to 8 mm radius, represented as a purple ring in Figure 2).

The statistical analysis was performed using SPSS software for Windows version 23.0 (SPSS Inc., Chicago, Illinois, United States). Normality of all data sets was not rejected (Shapiro-Wilk test, $p > 0.05$). Further, t-test was used for comparison between data sets. For all tests the level of significance was set to 0.05.

Figure 2. Schema of the part of the sclera considered for analysis (radius 6-8 mm). Inner sclera (orange ring, 6-7 mm radius) and outer sclera (purple ring, 7-8 mm radius). Sectors for statistical analysis are also indicated. OD denotes 'right eye', while 'OS' denotes 'left eye'.

RESULTS

The human sclera is rotationally asymmetric. Following the sectors in Figure 2 we found that horizontally, the nasal area of the sclera showed less elevation (mean (SD) -30 (SD, 52) μm (OD); mean (SD) -17 (SD, 61) μm (OS)) than the temporal area (mean (SD) 4 (SD, 47) μm (OD); mean (SD) 9 (SD, 37) μm (OS)), which was statistically different (paired t-test, $p < 0.001$ (OS and OD)). Vertically, the inferior area of the sclera (mean (SD) 32 (SD, 72) μm (OD); mean (SD) 15 (SD, 67) μm (OS)) was slightly less elevated than the superior area (mean (SD) 36 (SD, 84) μm (OD); mean (SD) 25 (SD, 65) μm (OS)), however this difference was not statistically different (paired t-test, $p = 0.40$ (OD), $p = 0.84$ (OS)). Table 1 shows the detailed results for all sectors and ring under analysis. The large values in standard deviation suggest substantial inter-subject variation in scleral shape. No statistically significant difference was found between right and left eye, independently of the scleral area considered (for details see Table 1). Similarly, no statistical significant differences were found in scleral elevation between male and female participants in either eye (t-test, $p = 0.50$ (OD), $p = 0.98$ (OS)).

Note that the difference in scleral shape elevation between nasal and temporal sectors (N-T) (mean (SD) -34 (SD, 40) μm (OD); mean (SD) -26 (SD, 55) μm (OS)) was found to be larger in absolute value than the difference in elevation found between superior and inferior sectors (S-I) (mean (SD)

3 (SD, 90) μm (OD); mean (SD) 8 (SD, 70) μm (OS)). This difference was found to be statically different (t-test, $p = 0.001$ (OD), $p = 0.02$ (OS)).

Table 1. Mean scleral elevation change 360 degrees around analyzed in eight different eye sectors, considering scleral rings of different radius, for both eyes of 45 participants.

Scleral ring considered (mm)	Sector	n	Right eye elevation difference (μm)	$\pm\text{SD}$	Left eye elevation difference (μm)	$\pm\text{SD}$	p-value (two-tailed) Right vs. Left eyes
6.0 – 8.0	Nasal [330,30] $^\circ$	45	-30,01	52	-17,02	61	0,14
	Superior nasal (30,60) $^\circ$	45	-4,73	52	-23,21	62	0,06
	Superior [60,120] $^\circ$	45	35,86	84	24,61	65	0,32
	Superior temporal (120,150) $^\circ$	45	19,06	65	31,14	44	0,27
	Temporal [150,210] $^\circ$	45	3,62	47	9,22	37	0,37
	Inferior temporal (210,240) $^\circ$	45	-21,97	56	-23,79	50	0,84
	Inferior [240,300] $^\circ$	45	31,73	72	15,15	67	0,07
	Inferior nasal (300,330) $^\circ$	45	1,99	56	10,25	47	0,33
6.0 – 7.0 (inner ring)	Nasal [330,30] $^\circ$	45	-9,42	43	-5,34	42	0,52
	Superior nasal (30,60) $^\circ$	45	0,43	37	-10,07	56	0,20
	Superior [60,120] $^\circ$	45	26,91	78	17,67	62	0,45
	Superior temporal (120,150) $^\circ$	45	-3,22	44	8,44	28	0,12
	Temporal [150,210] $^\circ$	45	6,16	28	7,94	25	0,64
	Inferior temporal (210,240) $^\circ$	45	-9,96	45	-23,22	43	0,05
	Inferior [240,300] $^\circ$	45	11,93	50	7,68	52	0,58
	Inferior nasal (300,330) $^\circ$	45	-11,39	35	6,18	32	0,05
7.0 – 8.0 (outer ring)	Nasal [330,30] $^\circ$	43	-44,66	71	-12,39	63	0,05
	Superior nasal (30,60) $^\circ$	44	18,61	91	-4,83	93	0,64
	Superior [60,120] $^\circ$	40	54,15	106	41,48	100	0,67
	Superior temporal (120,150) $^\circ$	45	48,85	93	53,28	98	0,23
	Temporal [150,210] $^\circ$	44	-13,20	66	3,62	48	0,13
	Inferior temporal (210,240) $^\circ$	44	-39,59	76	-30,39	101	0,55
	Inferior [240,300] $^\circ$	44	72,00	144	28,13	115	0,06
	Inferior nasal (300,330) $^\circ$	44	25,87	98	26,89	73	0,93

Figure 3 shows an example of the corneo-scleral profile respect to corneal apex of one eye, where this effect is highly noticeable. Data plotted in Figure 3 corresponds to raw data directly acquired from the corneo-scleral profilometer, i.e. without fitting.

The magnitude of scleral asymmetry increases with radial distance from the corneal apex (Table 1). Statistically difference was found between inner and outer scleral ring in all the sectors considered except in supero-nasal sector (paired t-test, $p = 0.13$ (OD), $p = 0.38$ (OS)). Sclera was found to be tilted with respect to the cornea. By independently analyzing parameters a and b from (1) the tilt of the sclera with respect to the cornea was estimated. The horizontal tilt is greater than the vertical one, as Table 2 indicates.

Figure 3. Example of meridians along 0° (orange), 90° (blue), 45° (red) and 135° (green) for the left eye of a 19 years-old female subject. The central grey area corresponds to the corneal surface while white areas correspond to sclera. Dashed blue horizontal lines indicate the elevation change range between superior (S) and inferior (I) parts, while dashed orange horizontal lines indicate the elevation change range between nasal (N) and temporal (T) parts.

Table 2. Estimated scleral tilt with respect to the cornea for different chord lengths.

Chord length	Tilt direction	Right Eye elevation tilt (μm)	± SD	Left eye elevation tilt (μm)	± SD
12.0 mm	X	238	78	231	86
	Y	32	93	52	83
14.0 mm	X	278	91	269	100
	Y	32	93	52	83
16.0 mm	X	317	104	307	115
	Y	42	124	69	111

Further, for all participants, correlations of elevation change were made between right and left eye for every ring under analysis. A significant positive correlation was found in inner ring ($R^2 = 0.41$, $p = 0.04$) and outer ring ($R^2 = 0.74$, $p = 0.003$).

DISCUSSION

To the best of our knowledge this is the first report of topographic corneo-scleral maps to define the mean shape of human anterior sclera. From the 90 ocular topographic maps of 45 participants we described the mean elevation of the human sclera and found that the anterior eye surface beyond the cornea is not rotationally symmetrical. The average elevation for a 6-8 mm scleral ring was higher for the temporal sclera and lower for the nasal sclera, in accordance with previous works (Kasahara et al., 2014) (Choi et al., 2014) (Bandlitz et al., 2017)(Ritzmann et al., 2018). No statistically significant differences were found between right and left eyes. Similarly, no statistically difference was found in scleral shape between male and female participants.

Some previous works aimed to calculate scleral radius in different scleral points as a measure of scleral topography (Hall et al., 2013) (Kasahara et al., 2014) (Choi et al., 2014) (Lee et al., 2016) (Bandlitz et al., 2017). Ritzmann et al. (2018), on the other hand, have recently estimated scleral sagittal height using a manual built-in caliper in OCT images. Our results agree with their analysis. Moreover, in both works high variability in scleral asymmetry was observed between participants. Since there appear to significant intra-individual differences it is important in clinical practice to incorporate an automatic and objective techniques, as the one presented here. Such a technique should consider the entire scleral surface rather than isolated points, as was traditionally done with OCT. The novelty of our contribution is that, contrary to previous works, we used a continuous 3-dimensional topographical map to assess scleral shape rather than several discrete points. The method is also automated and independent of the practitioner's subjective criteria, as opposed to most previous works that used a manual composite of OCT images and/or built-in digital calipers. Automatization not only leads to a higher reliability, but also to an easier and quicker procedure to assess the scleral shape of a particular patient in daily clinical practice.

Scleral asymmetry magnitude was found to increase with radial distance, which we conjecture may be related to the effect of the extra-ocular muscles' anatomy (de Gottrau et al, 1994). It has been suggested that a possible factor influencing scleral shape is the orientation of extraocular rectus muscles insertions (Apt, 1980). Also, that scleral shape might be also influenced by the proximity of two adjacent extraocular muscles. The distance between lateral rectus and inferior rectus is shorter than that between medial rectus and inferior rectus. The close proximity of adjacent muscles may create a flatter contour of the eye, while a greater distance between muscles could contribute to a steeper temporal scleral shape (Ritzmann et al., 2018).

To calculate the elevation change in different scleral sectors we used a quadratic function of X and Y coordinates. This function was chosen because it allows to extract the information on how much the sclera is tilted with respect to the cornea. As indicated in Table 2, the larger the diameter under consideration the more noticeable the effect of misalignment between both surfaces is. It is important to notice that the ESP device uses an internal procedure to present the data with respect to a perfectly aligned cornea (Consejo et al., 2017b), thus if the fitting model is not allowed to freely tilt, the scleral differences between the original data and the fit data would be larger than the results here presented. Similar fitting function such as a sphere or a radial quadratic function, chosen arbitrarily to account for the bulk of surface data, would have been equally acceptable. However, it is important to understand that depending on the model used the final result might vary; the values obtained will likely be consistent with the results here presented, but different in magnitude.

This study has some limitations, however, with regards to the coverage of the corneo-scleral area, which plays a key role in the measuring process and the accurate description of the scleral shape. In all cases analyzed the inner scleral ring (6-7 mm radius) was complete, but this was not always the case for the outer scleral ring (7-8 mm radius). Examples with 15% or larger amount of missing data in the outer ring were not included in the analysis. Even though the methodology presented is equally valid in presence of missing values, one should approach the numerical results of to the outer scleral ring with some caution. Additionally, several, mostly elderly participants experienced difficulties to open their eyes sufficiently for inclusion into our analysis. To overcome this limitation one could restrict the analysis to only the nasal and temporal quadrants, which would lose the scleral profile in superior and/or inferior sectors. Hence, this would lead to a less accurate

description of scleral elevation. Also, the study considers a group of healthy subjects and its results may not necessarily be generalized to eyes with pathological sclera.

Detailed knowledge of the scleral shape might be helpful for refractive surgeons, who usually select the suction ring based on the corneal curvature. However, it has been shown that in myopic eyes the corneal curvature often does not correlate with the anterior scleral curvature (Barraquer, 1972). In case the radius of the suction ring does not match the shape of the sclera, the vacuum generated might cause a substantial deformation of the globe wall that could induce secondary vitreoretinal complications (Lavaque et al., 2005). For this reason it has been recommended to evaluate the shape of the sclera before surgery as key information to assess whether a patient is an optimal LASIK candidate (Lavaque et al., 2005). Furthermore, better knowledge of scleral shape could be of use in many other surgical procedures such as in trabeculectomy (Condon et al., 2014), non-penetrating deep sclerectomy and strabismus surgery by reducing the incidence, risk factors and sequelae depending on the position of scleral perforation (Surachatkumtonekul et al., 2009). It could also be of use in scleral reinforcement surgery, transscleral cyclophotocoagulation or scleral surgery of intraocular tumors surgeons. Similarly, gaining knowledge of scleral shape might be helpful for clinicians when applying surgical techniques such as scleral incision in cataract surgery (Tsuneoka et al., 2000), scleral perforations (Vivian et al., 1993), scleral tunnel incisions (Kohnen, 1997) (Vouri & Viitanen, 2001), implantation of silicone rings, laser coagulation or trans-scleral cryotherapy. In addition, scleral contact lenses are gaining popularity over the last decade as an effective form of visual correction in cases of ocular surface disorders, such as keratoconus (Nau et al., 2017). Scleral lenses rest on the sclera. Therefore, the presented methodology would facilitate the manufacture of personalized scleral contact lenses to the geometric characteristics of each individual, with the only use of a non-contact instrument. In addition, as scleral lenses become more popular, governmental regulations start to appear restricting the use of trial lenses (nowadays non-disposable) for safety reasons. Non-contact scleral topographers and the use of new methodologies for describing the shape of the sclera for each individual as the presented here, could be a tremendous advantage when fitting scleral contact lenses.

In conclusion, we used, for the first time, full 3D scleral maps to accurately describe the shape of the human sclera. Human sclera is rotationally asymmetric and its shape is subject-dependent. Nasal area of the sclera is less elevated than the temporal area. Furthermore, for healthy subjects, statistically significant differences in scleral shape between right and left eye were not found. In addition, the asymmetry of the sclera was found to increase with radial distance from the corneal apex.

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