### Title:

## Scleral Topography analysed by Optical Coherence Tomography

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#### ABSTRACT

**Purpose:** A detailed evaluation of the corneo-scleral-profile (CSP) is of particular relevance in soft and scleral lenses fitting. The aim of this study was to use optical coherence tomography (OCT) to analyse the profile of the limbal sclera and to evaluate the relationship between central corneal radii, corneal eccentricity and scleral radii.

**Methods:** Using OCT (Optos OCT/SLO; Dunfermline, Scotland, UK) the limbal scleral radii (SR) of 30 subjects (11M, 19F; mean age 23.8 ±2.0SD years) were measured in eight meridians 45° apart. Central corneal radii (CR) and corneal eccentricity (CE) were evaluated using the Oculus Keratograph 4 (Oculus, Wetzlar, Germany). Differences between SR in the meridians and the associations between SR and corneal topography were assessed.

**Results:** Median SR measured along  $45^{\circ}$  (58.0; interquartile range, 46.8-84.8mm) was significantly (p<0.001) flatter than along 0° (30.7; 24.5-44.3mm), 135° (28.4; 24.9-30.9mm), 180° (23.40; 21.3-25.4mm), 225° (25.8; 22.4-32.4mm), 270° (28.8; 25.3-33.1mm), 315° (30.0; 25.0-36.9mm), and 90° (37.1; 29.1-43.4mm). In addition, the nasal SR along 0° were significant flatter than the temporal SR along 180° (p<0.001). Central corneal radius in the flat meridian (7.83±0.26mm) and in the steep meridian (7.65±0.26mm) did not correlate with SR (p=0.186 to 0.998). There was no statistically significant correlation between corneal eccentricity and scleral radii in each meridian (p=0.422).

**Conclusions:** With the OCT device used in this study it was possible to measure scleral radii in eight different meridians. Scleral radii are independent of corneal topography and may provide additional data useful in fitting soft and scleral contact lenses.

**Key words:** Scleral radius, optical coherence tomography, cornea radius, corneal eccentricity, corneo-scleral topography.

1 The selection of the back-surface design of rigid contact lenses was traditionally 2 based on the topography of the central cornea measured by a keratometer. More 3 advanced procedures such as placido-based corneal topography and Scheimpflug 4 tomography allow a more detailed description of the anterior shape of the central, 5 para-central and peripheral cornea. While the topography of the cornea is essential in 6 selecting and predicting the fit of a rigid contact lens [1-3], a weak or no correlation 7 was found between corneal topography and soft contact lens fit [4, 5]. Furthermore, 8 modern rigid scleral contact lenses have gained renewed interest during the last 9 decade and becoming more widely used [6, 7]. Therefore, a precise analysis of the 10 topography of the limbal sclera and the cornea-scleral transition zone is of increasing 11 interest in the fitting process of rigid scleral contact lenses [8, 9], and seems to be a 12 more reliable method to predict the fitting of a soft contact lens [4, 10-12].

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14 Formerly, the topography of the limbal and anterior scleral shape only could be 15 analyzed by the use of an invasive imprint technique [13, 14], where a mould is made 16 of the anterior surface and then used as a positive cast to produce a scleral lens [6], 17 or by grading the limbal profiles termed "Corneo-Scleral-Profile (CSP)" at the slit-18 lamp [15-18]. The CSP is the profile-line that is formed by the shape of the cornea, 19 the sulcus and the sclera. It was first mentioned by Gaggioni and Meier [16], who 20 classified the profile in five different shapes. In clinical practice the CSP can be 21 evaluated by the help of a slit-lamp or a magnifier. However, Bokern et al. [17] 22 reported a low accuracy and repeatability of this subjective grading method.

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The Eye Surface Profiler (ESP) is a newly developed cornea and sclera topographer that can measure up to 20 mm width of the anterior surface of the eye. The technology is based on Fourier transform profilometry which involves projecting and

imaging placido discs from two oblique angles onto the cornea consecutively, integrating the results; a prototype of the instrument was first developed by Jongsma et al. [19]. To achieve good results with the ESP it needs to be considered that the instillation of fluorescein is required and that the alignment procedure differs from placido-based systems [20]. However, in a recently published study it was shown that the ESP can be used to calculate the scleral radius with high precision [9].

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34 Optical coherence tomography (OCT) provides non-invasive high-resolution images 35 of most ocular tissues. While the initial focus was on imaging the posterior segment 36 of the eve, there are now a number of commercial instruments on the market which 37 in addition allow imaging and measurements on the anterior segment of the eye [21-23]. Beside the measurement of the corneal topography from limbus to limbus [22], 38 39 OCT has already been applied to describe the radii of the sclera [11, 12, 24]. 40 However, in previous studies the description of the scleral shape was limited to two 41 or four quadrants. Furthermore, it remains unknown whether the topography of the 42 scleral is related to the topography of the cornea.

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Consequently, the aims of this study were to analyse the profile of the limbal region
sclera over 8 meridians of the ocular surface and to evaluate any relationship
between central corneal radii, corneal eccentricity and scleral radii.

#### 48 MATERIALS AND METHODS

#### 49 Subjects

50 Thirty healthy subjects (mean age 23.8  $\pm$  2.0 (SD) years, male = 11, female = 19) 51 were recruited from the students of the Höhere Fachschule für Augenoptik Köln 52 (Cologne School of Optometry), Cologne, Germany.

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54 Subjects were excluded if they had a current or previous condition known to affect the conjunctiva or the sclera such as pterygium and pinguecula; had a history of 55 56 previous ocular surgery, including refractive or strabismus surgery, eyelid surgery, or 57 corneal surgery; had any previous ocular trauma, were diabetic, were taking 58 medication known to affect the ocular surface or sclera, and/or had worn rigid contact 59 lenses or soft contact lenses during the preceding 24 hours prior to the study. The study was approved by the Research Ethics Committee and all subjects gave written 60 61 informed consent before participating in the study. The procedures were conducted 62 in accordance with the requirements of the Declaration of Helsinki (1983) and patient data were used only in anonymized form. 63

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#### 65 Instruments

The images of the sclera were obtained using an Optos OCT/SLO<sup>™</sup> (Optos plc, Dunfermline, Scotland, UK) (Figure 1). This instrument combines spectral domain OCT imaging (SD-OCT) with a confocal scanning laser ophthalmoscope (SLO) in one instrument. The add-on lens was placed in front of the optics to focus the system on the anterior segment of the eye. To enable the measurement of the scleral radii in different orientations, a black board with white fixation crosses in 0° (nasal), 45° (superonasal), 90° (superior), 135° (superotemporal), 180° (temporal), 225° (inferotemporal), 270° (inferior) and in 315° (inferonasal) was designed and fixed to the instrument (Figure 1). Since the measurement in the different orientation is dependent upon the subject initial alignment, head and chin rest were adjusted while the patient was fixating the central target of the instrument. Central alignment was controlled before each peripheral measurement.

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Central corneal radii for the flat ( $r_{c/fl}$ ) and steep ( $r_{c/st}$ ) meridian as well as corneal eccentricity for the nasal ( $e_{nas}$ ), temporal ( $e_{temp}$ ), inferior ( $e_{inf}$ ) and superior ( $e_{sup}$ ) direction were measured using a topograph (Keratograph 4; Oculus Optikgeräte GmbH, Wetzlar, Germany).

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#### 84 Sample calibration

85 To ensure that on-screen images of the OCT represented curvature of known dimensions, the outer surface of three optical precision glass beads (radius 20, 22 86 87 and 28 mm; Hilgenberg GmbH, Malsfeld, Germany) were used as a model for the sclera. The outer diameters of the glass capillaries were confirmed by use of a gauge. 88 89 Three OCT scans were taken for each glass bead. The OCT images were than 90 exported to ImageJ software (http://imagej.nih.gov/ij/) and a circle was fitted to the 91 confirmed radius of the glass beads. A regression line was then calculated to form a 92 calibration curve, which was used to correct the OCT measurements of the sclera. 93 The OCT measurements of the glass beads were compared at two different sessions 94 at the same time of day. Repeated measurements between day 1 and day 2 were not 95 significantly different (paired t-test; p=0.447). The 95% confidence intervals around 96 differences indicate good repeatability (95% CI: -1.69 to +1.46mm) of the method in 97 vitro.

#### 99 **Procedures**

100 OCT images and topograph measurements were taken during one study visit in a 101 randomized order. One operator collected data from the right eye only.

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103 For the recording the OCT images, subjects were asked to look at the fixation targets 104 along 0, 45, 90, 135, 180, 225, 270 and 315 degrees, in a randomized order. The 105 SLO image of the OCT was used to find the correct position for a line scan (Figure 2). 106 To set up and to check the correct position of the sclera to be measured and to 107 ensure a constant alignment of the OCT, a millimetre grid was attached on the 108 computer screen. The OCT scan axis was moved forwards and backwards until the 109 apex of the sclera was in congruence with a marked horizontal line on the screen, 110 and it was moved left and right until the scleral spur was in congruence with a vertical 111 line on the screen (Figure 3). The OCT images were saved as JPEGs, for 112 subsequent analysis with ImageJ 1.46 software (http://rsbweb.nih.gov/ij). In ImageJ 113 the three-point circle fit technique was applied to calculate the radius of the sclera at 114 the different locations (Figure 4). The mean of three consecutive measurements of 115 the scleral-radii in the different meridians was recorded. Repeated measurements of 116 11 subjects between day 1 and day 2 were not significantly different (Wilcoxon 117 signed-rank test; p=0.501). The 95% confidence intervals around differences indicate 118 good repeatability (95% CI: -0.43 to +1.57mm) of the method in vivo.

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Topography measurements of the central corneal radii and corneal eccentricity were obtained while the subject was looking straight ahead with the left eye occluded. The mean of three consecutive measurements of central radii and corneal was calculated.

#### 125 Statistical methods

Data were tested for normality using the Shapiro-Wilk test. As scleral radii were not normally distributed differences between the scleral radii in the different sectors were analysed by Friedman Test followed by Bonferroni correction. Correlation between central corneal radii and scleral radii as well as between corneal eccentricity and scleral radii were analysed using the Spearman's Rank correlation coefficient. The data were analysed using SigmaPlot 12 (Systat Software Inc., Chicago, USA).

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#### 134 **RESULTS**

The mean values ± standard deviations, the median and the minimum and maximum
values of central corneal radii and corneal eccentricity, are summarised in Table 1.

138 The median superonasal (45°) scleral radius (58.0; interguartile range, 46.8-84.8mm) 139 was significantly (p<0.001) flatter than the radii measured nasal (30.7; 24.5-44.3mm), 140 superotemporal (28.4; 24.9-30.9mm), temporal (23.40; 21.3-25.4mm), inferotemporal 141 (25.8; 22.4-32.4mm), inferior (28.8; 25.3-33.1mm), inferonasal (30.0; 25.0-36.9mm), 142 and superior (37.1; 29.1-43.4mm) (Figure 5 and 6). Scleral radius measured 143 superiorly was significantly flatter than the radii measured temporal (p=0.015). Nasal 144 scleral radius was significantly flatter than temporal radius (p<0.001). There was no 145 statistically significant difference between the scleral radii measured in the other 146 directions (p>0.05).

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There was no statically significant correlation between central corneal radii and scleral radii (p = 0.186 to 0.998) and no significant correlation between the mean corneal eccentricity and the mean scleral radius (p = 0.422).

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### 152 **DISCUSSION**

This study reports the use of a spectral domain OCT combined with a confocal scanning laser ophthalmoscope to evaluate the radius and therefore the profile of the limbal sclera in eight meridians. Using this instrument, differences between scleral radii at the different locations were found, with the flattest scleral radius in the superonasal and the steepest radius in the temporal limbal region.

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159 Hall et al. [11, 12] used a time-domain anterior segment optical coherence 160 tomographer in 204 subjects to measure the scleral radius in four quadrants. They 161 found scleral radii to be nasal 35.5±39.4 mm, temporal 22.4±12.7mm, superior 162 29.3±17.4mm and inferior 33.5±29.6mm, which is in good agreement with the results 163 of this study. Furthermore, like in this study the reported scleral curvature was 164 steepest in the temporal sclera. Likewise, Choi et al. [25] also using time-domain 165 OCT reported that the mean radius of nasal anterior scleral curvature was 166 significantly greater than that of temporal anterior scleral curvature (the only two 167 meridians assessed). However, the reported radii for nasal anterior scleral 168 (13.33±1.12mm) and temporal anterior scleral (12.32±0.77mm) were much steeper 169 than the results of this study and the two studies presented by Hall et al. [11, 12]. 170 This might be explained by the fact that Choi and colleagues calculated the axial 171 (sagittal) radius of the sclera while in the studies of Hall et al. [11, 12] and in this 172 study the tangential scleral radius was assessed. As the tangential radius requires no 173 assumption concerning the location of the optic axis, the tangential radius gives a 174 truer picture of off-axis irregularities than the sagittal radius [26-28]; hence the 175 tangential radius seems to be more useful then the sagittal measurement in the

detection of topographic abnormalities and surface shape changes, as in accurateGP base curve selection [28-32].

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179 Nevertheless, manufacturers of both soft and scleral contact lenses and clinicians 180 are widely used to working with axial or sagittal radii. In corneal topography the 181 sagittal radius can be calculated from a given tangential radius if additional 182 information like the central corneal radius, the fixation angle and the distance from 183 corneal apex is given [33]. The measuring of the tangential scleral radius with OCT is 184 based on a single peripheral cross section. To derive an axial scleral radius from a 185 given tangential scleral radius several assumptions and a manual assembly of 186 different OCT images into one single circular image are required [25]. Applying this 187 technique the scleral is assumed to be rotationally symmetric and therefore the 188 results of scleral shape might be spherically biased [25, 34].

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190 Applying Scheimpflug photography for the measurement of scleral curvature, Tiffany 191 et al. [35] reported scleral radii from 13.3 to 14.3 mm for the temporal scleral close to 192 the limbus, wherein the exact measuring location was not described. Jesus et al. [9] used the newly developed ESP to measure the scleral radius of the naso-temporal 193 194 area and reported values of 11.2±0.3 mm. To differentiate the scleral topography 195 from the cornea topography a circular band between 5 and 6.5 mm from corneal 196 apex was removed from the analysis in their study. In contrast in this study, the 197 radius was measured in a 3 mm zone starting from scleral spur and might include 198 parts of the limbal region. Therefore, it is likely that different parts of the sclera were 199 analysed which might explain the differences in measured radii.

200

201 In this study scleral radii additionally were measured in the oblique meridians, 202 indicating the flattest radii was along 45° (superonasal), albeit a huge range was 203 found (Table 1) (Figure 6 and 7). Kasahara at al. [36] determined the differences in 204 scleral shape between the superonasal and superotemporal guadrants using a swept 205 source OCT. They showed that the scleral curvature in the superonasal quadrant 206 (34.3±12.6mm) was significantly flatter than that in the superotemporal guadrant 207 (18.3±3.6mm), which is in concordance the findings of this study. While they were 208 measuring over a radius of 5 mm, in the present study about 3 mm radius were 209 analysed which might explain the smaller values they reported.

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Using an anterior segment time-domain OCT, the Pacific University studies measured the limbal and scleral angles in reference to the horizontal plane [6]. They found the smallest angles in the superonasal region of the sclera and the largest angle in the temporal region, which seems to correspond with the flattest radii for the superonasal and the steepest radii for the temporal region measured in this study.

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217 Interestingly, in a recently published study by Ebneter et al. [37] mean scleral 218 thickness was also found to significantly different between guadrants. Applying a 219 spectral domain OCT, they investigated the sclera scleral thickness in the 220 inferonasal, inferotemporal, superotemporal, and superonasal guadrant, 2 mm from 221 the scleral spur. The sclera was found to be thinnest in the superonasal region where 222 in this study the flattest scleral radius was found. So it might be hypothesized that 223 variations in scleral thickness influences the curvature of the scleral in the limbal 224 region. Scleral thickness seems to increase with age and was found to be variable in 225 a 2.5 mm zone form scleral spur [37, 38]. Furthermore, it was shown that scleral radii 226 negatively correlate with age [12]. From this it might be postulate that a thick limbal

sclera results in steeper scleral radii, while a thin sclera result in flatter scleral radii.
Therefore, it is likely that age related changes as well as variations in scleral
thickness influence scleral radii resulting in a non-spherical shape of the limbal
scleral region as it was found in this study.

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232 From the literature it is known that central keratometry is a poor predictor of soft 233 contact lens fit and the addition of videokeratoscopy at best slightly improved the 234 prediction, while topography of the limbal region sclera seems to be a more reliable 235 method to predict the fitting of soft contact lenses [4, 5, 11]. This seems to be 236 consistent with the findings of this study since the topography of the cornea was not 237 related to the topography of the limbal region scleral. Moreover, the topographer 238 used in this study was not able to describe the corneal shape from limbus to limbus, 239 although an 8 mm diameter area could be achieved.

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Applying the OCT technique to measure scleral radii has some limitations. For the 241 242 measurement of scleral radii in different orientations it is required that the patient had 243 to fixate several paracentral target. While fixating, the tonus of the ocular muscles 244 may have had an influence on the scleral profile. However, this also reflects the 245 dynamic eye movements a contact lens wearer will make while wearing their lenses. 246 Furthermore, this method is dependent on a correct and repeatable alignment of the 247 system as well as on the manual fitting of a circle in external software. Therefore, the 248 operator dependency of the OCT measurement of scleral radii needs to be 249 addressed in further studies.

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In summary, with the spectral domain OCT used in this study it was possible to measure scleral radii along eight different meridians. Scleral radii were found to be independent of corneal topography and may provide additional data useful in fitting soft and scleral contact lenses.

- **Conflict of interest**
- 257 None

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Figure 1. Optos spectral domain OCT/SLO™ (Optos plc, Dunfermline, Scotland, UK)
with a custom made black board and white fixation crosses in the eight different
meridians.

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Figure 2. Image of the confocal scanning laser ophthalmoscope (SLO) (left) and OCT image (right) of a line scan in an oblique position.

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Figure 3. Millimetre grid attached on the computer screen to check the correct position of the sclera to be measured and to ensure a constant alignment of the OCT. Apex of the sclera in congruence with a marked horizontal line (arrow 1) and scleral spur in congruence with a vertical line on the screen (arrow 2).

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Figure 4. ImageJ 1.46 software (http://rsbweb.nih.gov/ij) for curve fitting and analysis
of scleral radius on OCT image.

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Figure 5. Median values of scleral radii in the eight meridians. Red colour is marking
 the steepest while blue colour is marking the flattest meridian found in this study.

Figure 6. Box plot showing the scleral radii in the different meridians. (Upper
horizontal line of box, 75th percentile; lower horizontal line of box, 25th percentile;
horizontal bar within box, median; upper horizontal bar outside box, 95th percentile;
lower horizontal bar outside box, 5th percentile. Circles represent outliers.)

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- 404 Figure 7. Examples of OCT images taken from a steep (upper image) and a flat405 (lower image) scleral radius.

- 408 Tables

Table 1. Mean values ± standard deviations, the median and the minimum and
maximum values of scleral radii (measured on OCT Images), central corneal radii
and corneal eccentricity (measured with topography).

## Table 1

	Mean ± SD	Median	Range
Scleral radius [mm]			
Nasal (0°)	35.29 <b>±</b> 17.68	30.73	18.52 – 110.11
Superonasal (45°)	74.57 <b>±</b> 45.97	58.00	24.88 – 237.18
Superior (90°)	45.00 <b>±</b> 31.99	37.11	17.55 – 181.78
Superotemporal (135°)	29.41 <b>±</b> 7.70	28.36	21.75 – 60.76
Temporal (180°)	24.40 <b>±</b> 4.86	23.36	17.34 – 36.21
Inferotemporal (225°)	27.17 <b>±</b> 5.90	25.76	19.29 – 42.91
Inferior (270°)	31.42 <b>±</b> 13.44	28.75	20.44 – 95.90
Inferonasal (315°)	36.46 <b>±</b> 34.64	29.96	16.70 – 213.76
	37.97 ± 12.77	32.75	
Central corneal radius [mm]			
Flat meridian	7.83 <b>±</b> 0.26	7.75	7.38 – 8.45
Steep meridian	7.65 <b>±</b> 0.26	7.57	7.26 – 8.29
	7.74 ± 0.26	7.66	
Corneal eccentricity			
Nasal	0.60 <b>±</b> 0.18	0.62	-0.09 - 0.86
Superior	0.46 <b>±</b> 0.18	0.51	-0.19 – 0.79
Temporal	0.47 <b>±</b> 0.08	0.46	0.29 – 0.67
Inferior	0.42 <b>±</b> 0.27	0.46	-0.49 - 0.92
	0.49 ± 0.12	0.49	





















Meridian

