# <u>Title:</u>

# Corneo-scleral-topography Measured with Fourier-based Profilometry and Scheimpflug Imaging

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#### Introduction

Scleral lenses entirely rest on the sclera, with a complete bridging of the cornea. Consequently, corneal topography does not seem to be helpful in their fitting process and corneal asymmetry has been shown to be a poor predictor for the need to fit a scleral contact lens with toricity.<sup>1-4</sup>

Formerly, the topography of limbal and anterior scleral shape only could be analysed by using imprint techniques or by grading the limbal profiles termed the "Corneo-Scleral-Profile" at the slit-lamp.<sup>5-7</sup> However, these methods are either invasive or have shown poor repeatability.<sup>6-8</sup> Newer non-invasive measuring techniques such as optical coherence tomography or fourier-based profilometry imaging can make a valuable contribution in the understanding of corneo-scleral-topography and support the fitting process of scleral lenses.<sup>3, 9-16</sup> Sagittal height (depth) data, determined by those techniques, are particularly useful for initial scleral lens selection.<sup>17, 18</sup>

The Eye Surface Profiler (Eagle Eye, Houten, The Netherlands) is a newly developed corneal and scleral topographer, capable of measuring the sagittal height for a chord length up to 20 mm diameter of the anterior ocular surface using fourier-based profilometry.<sup>10</sup> The Eye Surface Profiler, which is based on the principle of the Maastricht shape topographer (1998), has been validated and used in several studies.<sup>9-11, 19-25</sup>

More recently a new corneo-scleral-profile software module for the Pentacam (Oculus, Wetzlar, Germany) was introduced to the market. The corneo-scleral-profile module uses Scheimpflug imaging to measure the sagittal height up to an 18 mm chord length of the anterior ocular surface. First attempts to measure scleral

curvature by Scheimpflug photography were described by Tiffany et al. in 2004.<sup>26</sup> However, up to now no commercially available Scheimpflug instrument for scleral topography was on the market.

Consequently, the aim of this study was to investigate the agreement and repeatability of fourier-based profilometry and Scheimpflug imaging in the measurement of sagittal height, and toricity of the corneo-scleral region.

#### Material and methods

#### Participants

Thirty-eight participants with a mean age of  $25.4 \pm 3.2$  (SD) years (22 females) were recruited from the students of the Cologne School of Optometry (Höhere Fachschule für Augenoptik Köln), Cologne, Germany. Mean spherical equivalent (SE) of the participants was  $-0.9 \pm 1.3$  D. All participants that were invited to take part in the study received a subject information sheet explaining the study, prior to giving signed consent. Participants were excluded if they were pregnant or breastfeeding; had a history of previous ocular surgery, including refractive surgery, eyelid surgery, or corneal surgery; had any previous ocular trauma, were diabetic, had worn contact lenses less than two weeks prior to this study or had worn any kind scleral lenses before. All procedures obtained a favourable ethical opinion and governance approval of the Aston University Human Ethics Committee and were conducted in accordance with the requirements of the Declaration of Helsinki.

#### Procedures

Minimal and maximal sagittal height as well as the maximum possible measurement zone diameter were analysed using the Eye Surface Profiler (Eagle Eye, Houten, The Netherlands) and the corneo-scleral-profile module of the Pentacam (Oculus, Wetzlar, Germany). The difference between the sagittal heights in the perpendicular meridians (maximal sagittal height - minimal sagittal height) was recently defined as scleral toricity.<sup>16</sup> However, previous reports have shown that especially in subjects with corneal ectasias, highest and lowest sagittal height values are not necessarily located 90 degrees apart.<sup>27</sup> As a consequence, we used the difference between the maximal and minimal sagittal heights given from both devices as toricity values. JO and J45, which are Jackson cross-cylinder values, were used for the analysis of toricity through power vector analysis.<sup>28</sup> The orientation (axis) of the flattest meridian (minimal sagittal height) was categorized into six groups: with-the-rule 0° to 30°, withthe-rule150° to 180°, against-the-rule 60° to 90°, against-the-rule 90° to 120°, oblique 30° to 60° and obligue 120° to 150°. Measurements were performed between 9 and 12 AM by one examiner in a randomized order of the instruments on two consecutive days. To avoid any influence of remaining fluorescein on the eye, there was a washout time of at least 10 minutes between the measurements with different instruments. Only the right eyes of the participants were measured. Participants were asked to fixate on a central target and their upper lid was gently raised by the examiner to avoid pressure on the bulbus.

The Eye Surface Profiler is a topographer based on the principle of Fourier domain profilometry and covers an area of up to 20mm in diameter. Therefore, the entire cornea, limbus and parts of the scleral can be imaged and the corneo-scleral topography analysed with this system.<sup>10, 11</sup> The Eye Surface Profiler consists of two blue-light fringe projectors and a centrally positioned camera equipped with a yellow

filter (Figure 1).<sup>11</sup> To achieve good results with The Eye Surface Profiler it needs to be considered that the instillation of fluorescein is required.<sup>10</sup> In contrast the corneoscleral-profile module of the Pentacam uses Scheimpflug images without fluorescein to detect the edges of the cornea, the limbus and the sclera (Figure 2). One central and four peripheral Scheimpflug scans (nasal, temporal, superior and inferior) are necessary to create the total corneo-scleral-profile report with 25 meridians (Figure 4).

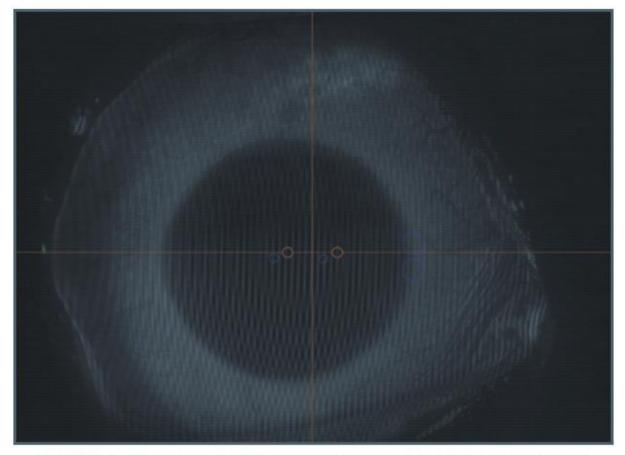


FIGURE 1. Projection of grids on cornea and sclera in Fourier domain profilometry using the Eye Surface Profiler (Eagle Eye).

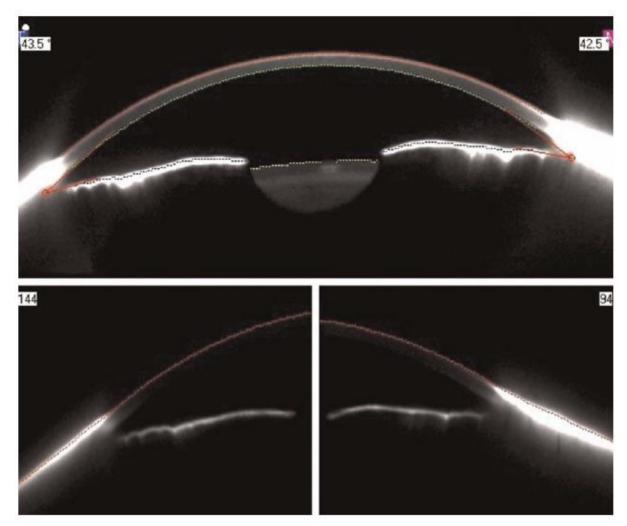


FIGURE 2. Scheimpflug image with edge detection in the corneoscleral region using the Pentacam (Oculus).

The minimum and maximum sagittal height, the axis and the maximum measurable chord length given by the software of both instruments were used for analysis (Figure 3 and 4). Agreement between two instruments was analysed using an equal chord length, which was given by the lower maximum measurable chord length of the two instruments. Repeatability of the single instrument was analysed using the maximal measurable chord length of the respective instrument.

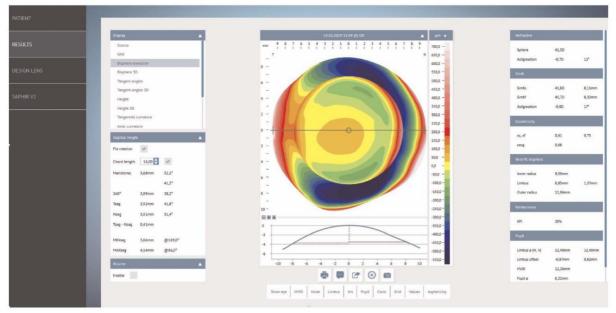


FIGURE 3. Screenshot of the Eye Surface Profiler (Eagle Eye) showing a color-coded map of the corneoscleral elevation (middle), different corneal parameters (right side), and the values for minimal and maximal sagittal height for a given chord length (left side).

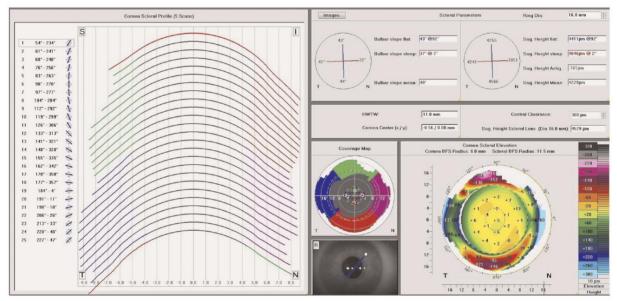


FIGURE 4. Screenshot of the corneoscleral profile module of Pentacam (Oculus) showing corneoscleral profile scans in 25 directions (left side), a color-coded map of the corneoscleral elevation (right side bottom), and the values for minimal and maximal sagittal height for a given chord length (right side top).

## Statistical analyses

Data were tested for normality using the Shapiro-Wilk test. As the data was normally distributed, correlations between the instruments were analysed using the Pearson coefficient. Differences between sessions and instruments were analysed using Bland-Altman and paired-t-tests. *P* values of less than .05 were deemed statistically

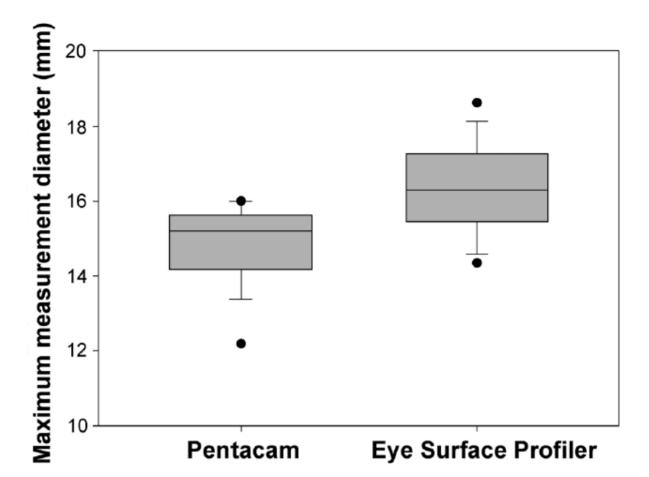
significant. The data were analysed using SigmaPlot 12 (Systat Software Inc., Chicago, USA).

# Results

The mean values  $\pm$  standard deviations measured with both instruments are summarised in Table 1. Maximum possible measurement zone diameter with the Eye Surface Profiler (16.4  $\pm$  1.3mm) was significantly greater than with Pentacam (14.8  $\pm$  1.1mm) (*P* < .001) (Figure 5).

**Table 1:** Descriptive data for means ( $\pm$  standard deviation) of minimal, maximal sagittal height, toricity, vector J0 and vector J 45 and horizontal white-to-white corneal diameter measured with the two instruments (chord length 14.8  $\pm$  1.1 mm).

	Pentacam Corneo- Scleral-Profile	Eye Surface Profiler	P-value
	module		
Minimal sagittal height (µm)	3609 ± 408	3266 ± 392	< .001
Maximal sagittal height (µm)	3716 ± 442	3436 ± 416	< .001
Mean sagittal height (µm)	3663 ± 423	3351 ± 401	< .001
Toricity (µm)	107 ± 87	170 ± 105	< .001
Power vector J0 (µm)	0 ± 62	28 ± 83	= .004
Power vector J45 (µm)	-17 ± 26	-5 ± 49	= .152
Corneal diameter (mm)	11.9 ± 0.36	12.3 ± 0.35	< .001

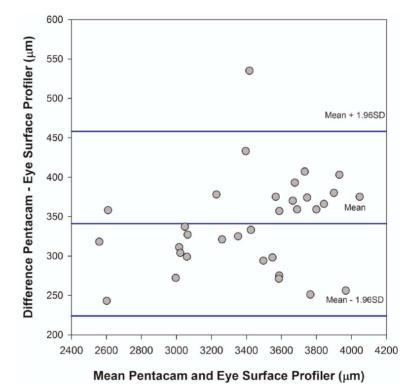


**FIGURE 5.** Box plot showing difference in maximum measurable complete zone (diameter) measured with Pentacam (Oculus) and Eye Surface Profiler (Eagle Eye) (n = 38). The boxes show the median and the 25th and 75th percentiles. The whiskers show the 5th and 95th percentiles. Black dots represent the outliers.

Minimal sagittal height ( $3266 \pm 392 \mu m$ ) and maximal sagittal height ( $3436 \pm 416 \mu m$ ) measured with the Eye Surface Profiler and minimal sagittal height ( $3609 \pm 408 \mu m$ ) and maximal sagittal height ( $3716 \pm 442 \mu m$ ) measured with the Pentacam were significantly very high correlated (r = 0.989 and r = 0.988; *P* < .001), while toricity measured with the Eye Surface Profiler ( $170 \pm 105 \mu m$ ) and Pentacam ( $107 \pm 87 \mu m$ ) was moderately correlated (r = 0.562; *P* < .001).

For an equal chord length (14.8  $\pm$  1.1 mm) the measurement with Pentacam was significantly greater for minimal sagittal height (344 µm; CI 322 to 364; *P* < .001)

(Figure 6), significantly greater for maximal sagittal height (280 µm; Cl 256 to 305; *P* < .001) (Figure 7), but significantly smaller for toricity (-63 µm; Cl -95 to -31; *P* < .001) (Figure 8). Power vector analysis showed that J0 calculated from Pentacam data were significantly smaller (-28 µm; Cl -49 to -8; *P* = .004) (Figure 9) than Eye Surface Profiler values, while there was no significant difference for J45 (-12 µm; Cl -28 to 5; *P* = .152) (Figure 10). The orientation (axis) of scleral toricity defined by the flattest meridian (minimal sagittal height) is summarized in Table 2.



**FIGURE 6.** Bland-Atman plot showing the difference between minimal sagittal height ( $Min_{sag}$ ) measured with Pentacam (Oculus) and Eye Surface Profiler (Eagle Eye) (n = 38). Middle line shows the mean difference, and upper and lower lines are the 95% limits of agreement.

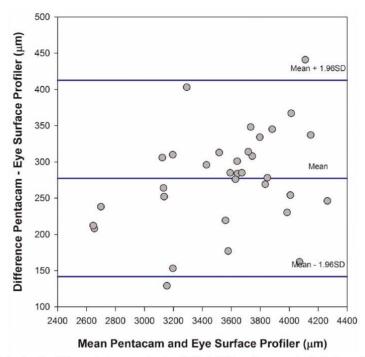
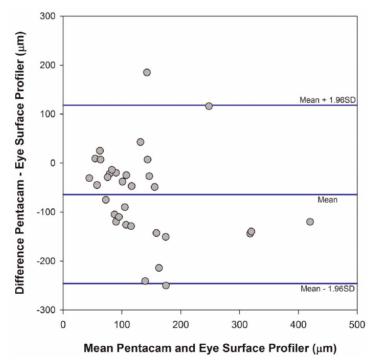
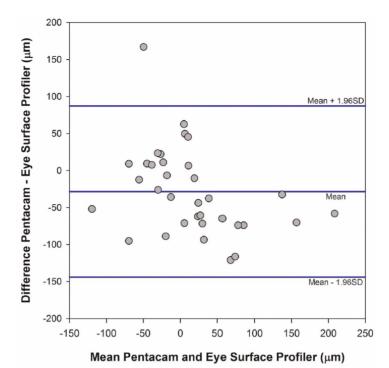


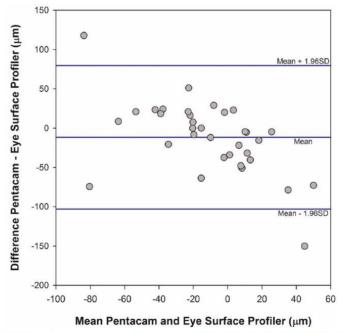
FIGURE 7. Bland-Atman plot showing the difference between maximal sagittal height (Max<sub>sag</sub>) measured with Pentacam (Oculus) and Eye Surface Profiler (Eagle Eye) (n = 38). Middle line shows the mean difference, and upper and lower lines are the 95% limits of agreement.



**FIGURE 8.** Bland-Atman plot showing the difference between toricity ( $Max_{sag} - Min_{sag}$ ) measured with Pentacam (Oculus) and Eye Surface Profiler (Eagle Eye) (n = 38). Middle line shows the mean difference, and upper and lower lines are the 95% limits of agreement.



**FIGURE 9.** Bland-Atman plot showing the difference between power vector  $J_0$  calculated from Pentacam (Oculus) and Eye Surface Profiler (Eagle Eye) (n = 38). Middle line shows the mean difference, and upper and lower lines are the 95% limits of agreement.



**FIGURE 10.** Bland-Atman plot showing the difference between power vector  $J_{45}$  calculated from Pentacam (Oculus) and Eye Surface Profiler (Eagle Eye) (n = 38). Middle line shows the mean difference, and upper and lower lines are the 95% limits of agreement.

# Table 2: Scleral toricity classified by orientation (axis of minimal sagittal height) for a

chord length of chord length  $14.8 \pm 1.1$  mm.

Scleral Toricity		Pentacam		Eye Surface Profiler
Orientation (axis)		corneo-scleral-		Toricity
		profile Toricity		
	Subjects	Mean±SD (µm)	Subjects	Mean±SD (µm)

With-the-rule	13	111 ± 106	20	177 ± 127
0°-30°	5	60 ± 33	6	163 ± 134
150°-180°	8	144 ± 124	14	183 ± 129
Against-the rule	14	115 ± 80	4	118 ± 59
60°-90°	3	134 ± 100	4	118 ± 59
90-120°	11	110 ± 75	0	
Oblique	7	81 ± 75	10	177 ± 64
30°-60°	1	51	1	180
120°-150°	6	86 ± 81	9	177 ± 86

Repeated measurements of mean sagittal height from session 1 and session 2 were not significantly different for Pentacam and Eye Surface Profiler (paired-t-test: P =.737 and P = .636, respectively). The 95% CIs around the differences indicated good repeatability for Pentacam (mean difference -0.9 µm; 95% CI: -6.7 to 4.8) and Eye Surface Profiler (4.6 µm; -22.4 to 31.6).

#### Discussion

This prospective study reports on the use of Scheimpflug imaging and fourier profilometry to measure sagittal height and toricity of the anterior corneo-scleral-region in individuals with healthy eyes. The measurements of mean sagittal height of the Pentacam ( $3663 \pm 423 \mu m$ ) for an average chord length of 14.8 ±1.1mm are in good agreement with previously reported optical coherence tomography measurements of 3670 to 3760 µm for a chord length of 15 mm.<sup>16, 29-31</sup> In contrast the Eye Surface Profiler measurements ( $3351 \pm 401 \mu m$ ) were smaller and in agreement with previously reported optical coherence tomography measurement of sagittal height on optical coherence tomography images requires manual image analysis, the two devices used in this study automatically measure sagittal height in multiple medians.

Sagittal height based fitting of scleral lenses has been found to be an effective method of determining the appropriate lens/cornea relationship.<sup>18, 34</sup> Central apical reservoir thickness and centration of a scleral lens seems to be influenced by variations in sagittal height.<sup>16, 35</sup> The apical reservoir thickness of scleral lens vary between 50 and 400 µm, depending on the fitting philosophy and are influenced by settling time.<sup>12, 34, 36, 37</sup> Thus, the reported difference in sagittal height measurement of the two devices of 280 µm (minimal sagittal height) and 344 µm (maximal sagittal height) can be assumed to be clinically relevant in initial selection of a scleral lens. It can be hypothesis that the differences in sagittal height measurements are due to the diversity of the imaging techniques used. While optical coherence tomography and Scheimpflug imaging are both tomography techniques that uses sections through the three-dimensional object (cornea and scleral) to calculate the sagittal height, the Fourier transform profilometry uses a fringe projection technique to extrapolate the height data.

Scleral toricity has been defined as the greatest difference in scleral sagittal height between two perpendicular meridians.<sup>16</sup> The asymmetry and toricity of the sclera is less pronounced near the limbus, increasing with greater distance (chord length).<sup>1, 15, 16, 19</sup> Furthermore, subjects with corneal ectasia seem to have a different scleral shape compared to those with normal corneal profiles, largely presenting as a quadrant specific effect along the same axis.<sup>27, 38</sup> A limitation of this study is that corneo-scleral shape was analysed in a group with regular corneas. Therefore, the findings of scleral toricity cannot be translated to irregular corneas where scleral shape seems to be more asymmetric than toric.<sup>27, 38</sup>

Over a 15 mm chord length Ritzman et al.<sup>16</sup> reported average toricity values of 198 ± 47  $\mu$ m in normal eyes measured with optical coherence tomography, while Kowaslski et al.<sup>35</sup> reported values of 150 ± 77  $\mu$ m in normal eyes using fourier-based profilometry. This seems to be in agreement with the fourier-based profilometry values of 170 ±105  $\mu$ m in ths study. However, toricity values of the Scheimpflug imaging systems (107 ±87  $\mu$ m) were found to be lower.

It was suggested that a sclera (15 mm chord length) with less than 100 µm of toricity may be fit with a spherical scleral lens, while with increasing lens diameter and scleral toricity ( $\geq 200 \ \mu$ m), special haptic lens designs are required.<sup>15-17</sup> Thus, a difference in toricity measurement between devices might influence the decision as to whether a spheric or toric scleral lens is required. In addition, further analysis of sagittal heights in different quadrant might help in the decision as to whether a toric or quadrant-specific approach will improve the outcome of contact lens selection.

A previous study has reported on the repeatability of sagittal height measurements using the sMap3D corneo-scleral topographer, a topographer similar to the Eye Surface Profiler used in this study.<sup>39</sup> For a group of 25 scleral patients, repeated sagittal height measurements for a chord length of 16 mm showed a mean difference of 14  $\mu$ m, while a difference of -0.9  $\mu$ m (Pentacam) and 4.6  $\mu$ m (Eye Surface Profiler) was found in this study.<sup>39</sup> However, as well as the instruments being comparable for the average of a group of patients, for the data derived to be useful in making clinical decisions for an individual, the intra-session repeatability 95% confidence interval must be small. While this was the case for the Pentacam at 6  $\mu$ m, this was not the case for the Eye Surface Profiler at 27  $\mu$ m. It is unlikely that this can be attributed to

the difference in the chord length that was analysed, which might explain differences in the mean.

In summary a detailed analysis of the topography of the limbal sclera and the corneal-sclera transition zone with modern devices such as Scheimpflug imaging and fourier profilometry is of increasing interest for the scleral lens fitting process. Furthermore, sagittal height data of the corneo-scleral region also seems to be a promising tool in the fitting of soft contact lenses.<sup>31, 40</sup>

## Conclusions

Although both instruments deliver useful data especially for the fitting of scleral and soft contact lenses, the sagittal height and the toricity measurements cannot be considered as interchangeable.

Conflict of interest None

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