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Comparing sagittal heights calculated using corneal parameters and those measured with profilometry

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ABSTRACT

Purpose: To compare the sagittal height of the anterior eye (OC-SAG) calculated using corneal parameters with the OC-SAG measured by profilometry.

Method: Seventy right eyes of soft contact lens wearers measured with the ESP (Eaglet Eye, The Netherlands) after lens removal were retrospectively analyzed for this study. The OC-SAG of the eyes was calculated using mean k-values, eccentricity and the inner (corneal) radius obtained with the ESP for an 11-mm chord diameter. It was then extrapolated to chord diameters of 14, 14.5 and 15 mm. These values were compared with OC-SAG values obtained with the ESP for the same chord diameters. Additionally, the OC-SAG was calculated through the formula used by a lab that manufactures custom soft lenses (mark'ennovy, Madrid, Spain) and compared again with the values obtained using the ESP.

Results: Differences between calculated OC-SAG obviating the shape factor were 121 ± 44 , 155 ± 105 , 172 ± 117 and $189 \pm 129 \mu\text{m}$ for chord diameters of 11, 14, 14.5 and 15 mm, respectively ($p < 0.001$). When the shape factor was included in the calculation, differences were 28 ± 48 , 62 ± 102 , 79 ± 113 and $96 \pm 123 \mu\text{m}$ ($p < 0.001$). When the inner best fit sphere was used to estimate OC-SAG, differences were 34 ± 11 , 0 ± 72 , 17 ± 86 and 34 ± 99 , respectively, with no significant differences for the 14 and 14.5 mm-chord diameters ($p = 0.99$ and 0.11 , respectively). Correlation coefficients between OC-SAG calculated and measured OC-SAG ranged from 0.53 to 0.90 depending on the chord diameter used. When the mark'ennovy formula was used to calculate the OC-SAG as the lens diameter proposed by the formula, the difference was $-47 \pm 147 \mu\text{m}$ ($p < 0.01$).

Conclusions: Differences between the OC-SAG calculated using corneal parameters and that measured with a profilometer are statistically and clinically significant, especially for large chord diameters. The impact of this on contact lens fitting should be addressed in future studies.

1. Introduction

Calculating the sag of a determined circular arc for a specific chord is straightforward from a mathematical or geometric perspective. Simple trigonometry offers the formula (Eq. (1)):

$$S = r - \sqrt{r^2 - \left(\frac{d}{2}\right)^2} \quad (1)$$

where S is the sag, r is the radius of curvature and d is the chord diameter [1].

In the contact lens field, the sagittal depth (CL-SAG) is a parameter that defines the height of a lens and depends largely on the base curve (BC), the intermediate curves and the lens diameter (TD) [2]. It has long been suggested that a contact lens can be designed by matching the CL-SAG to the sagittal height of the anterior eye (OC-SAG) [3]. To calculate the corneal sag, the above equation becomes more complex since the cornea is not completely spherical and flattens towards the periphery. Therefore, the equation for the conicoid family of curves is more suitable and includes the eccentricity (e) as a variable to estimate how the peripheral cornea flattens (Eq. (2)) [4].

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$$S = \frac{r - \sqrt{r^2 - \left(\frac{d}{2}\right)^2}}{p} \quad (2)$$

where S is sag, r is the radius of curvature, d is the chord diameter and p (the shape factor) = $1 - e^2$.

OC-SAG was utilized in early soft contact lens fitting and has become more relevant with the advent of modern scleral contact lenses [2,5] and has also recently re-emerged in soft lens fitting [6]. Thus, although this fitting approach has been proposed for contact lenses in general, it is more commonly embraced for larger contact lenses, such as soft and sclerals that land beyond the cornea. Consequently, the OC-SAG has to be calculated for chord diameters larger than the cornea.

When calculating the OC-SAG for chord diameters larger than the cornea, at least two more variables are involved: the scleral radius and the corneo-scleral junction (CSJ) angle [3,7]. The eccentricity of the sclera will also play a role; however, it has been suggested that using tangent angles is a better way to define the transition from the cornea to the sclera [8,9]. Some specific technologies such as optical coherence tomography (OCT), scleral topography or profilometry, obtaining a mould of the anterior eye and or more complex imaging techniques are needed to measure these scleral parameters. Unfortunately, they are not yet as widespread as corneal topography, and only a small group of ECPs who fit contact lenses are equipped with these technologies. Since 77% of the CSJ angles are within 5 and 180 degrees [10], one approach to determining the OC-SAG beyond the cornea involves calculating the OC-SAG at a chord of 11 mm and extrapolating this value by adding 200 μm for every 0.5 mm of chord beyond 11 mm [11]. This assumes that the scleral surface is tangential to the corneal slope and that a linear increase is acceptable. The approach does not regard eyes whose CSJ angle is not between 5 and 180 degrees, nor count whether the variation in OC-SAG for each one of these 5 degrees is significant or not. A second approach proposes calculating the slope at the corneal periphery and extrapolating, assuming that this same slope goes on to the sclera [12]. This latest strategy considers the inter-individual variability of the peripheral corneal slope [12], but assumes that the scleral surface follows this same corneal slope. Nevertheless, it does not consider the intrasubject variability within the 360 degrees of the corneo-scleral profile, which can be significant [13,14]. It is still unclear how this intra-individual scleral asymmetry could affect the OC-SAG calculation.

The aim of the current study was to compare, in a sample of healthy eyes, different methodologies to calculate the sagittal height from corneal parameters with the direct measurements obtained with a profilometer of the ocular sagittal height in order to define the level of agreement between these approaches.

2. Methods

2.1. Patients

Seventy right eyes of seventy Caucasians soft contact lens wearers (23 males and 47 females) from a single center were analyzed retrospectively. Ages ranged from 18 to 59 years and only one eye was selected to avoid potential bias introduced by the inter-eye correlations. Inclusion criteria were any healthy right eye of soft contact lens wearers who who attended their regular follow-ups. Any amount of myopia, hyperopia and astigmatism was included, as well as any scleral shape (symmetric or asymmetric). Patient with any previous ocular surface surgery, corneal ectasia, or any form of corneal irregularity were excluded. Patients suffering from any systemic condition that could affect the physiology of the eye, those being treated with any medication that could affect the ocular tissues, and those wearing rigid gas-permeable contact lenses were also excluded. The study methods adhered to the tenets of the Declaration of Helsinki and were approved by the ethics committee for medical research of the Health Department of Alicante (General Hospital, Alicante, Spain) (CEIm 2021-105,

ISABIAL 2021-0224).

2.2. Ocular examination

All eyes included were measured with the Eye Surface Profiler-ESP (Eaglet Eye, The Netherlands) after lens removal during the patients' regular follow-up visit to check their contact lens fitting. Once the lenses were removed, fluorescein was applied. A single drop of Blink single dose artificial tears (Johnson & Johnson Vision, Santa Ana, CA, California) was used to moisten a fluorescein strip and then the inferior, superior and temporal bulbar conjunctiva were gently stained in that order. After that, the patient was placed to take the measurement. The ESP is a scleral topographer that maps the cornea and a large portion of the sclera up to 20-mm chord [15]. Three measurements were taken for every eye and the best map in terms of coverage and quality index was selected.

Some parameters that were directly obtained with the ESP software (Research Edition Version 5.1.11) were recorded and used in this study:

- Flat and steep keratometric (K) values: used to calculate the mean corneal radius (r). Mean variation coefficient (CV) of 1.07 and an Intraclass Correlation Coefficient (ICC) of 0.99 have been reported in previous studies for the mean corneal radius obtained with the ESP [16].
- Flat and steep meridian eccentricity: the mean eccentricity (e) was calculated using both meridians. To date, there are no reports of reliability and reproducibility for the eccentricity obtained with the ESP.
- Horizontal and vertical visible iris diameter to obtain the mean corneal diameter (d). There are no reports of reliability and reproducibility of the corneal diameter obtained with the ESP. However, the limbal diameter determined by the intersection of the inner and outer best-fit spheres has a CV of 2.60 and ICC of 0.441 [16].
- Inner (corneal) radius, which for this device is a best fit sphere over a 12 mm area (iBFS). This corneal parameter has a CV of 1.48 and ICC of 0.884 [16].
- OC-SAG measured with the ESP (OC-SAG ESP) at 11, 14, 14.5 and 15 mm chord diameters. The reliability and reproducibility of this parameter has been studied for 11, 12 and 13 mm chord diameters [16]. Within the corneal diameter (11 mm chord), the OC-SAG measured with the ESP has a CV of 1.20 and ICC 0.905. Beyond the cornea (13 mm chord), the CV was 1.51 and the ICC was 0.896 [16].

The OC-SAG was calculated from corneal parameters obtained with the ESP in different ways:

- OC-SAG calculated without eccentricity (OC-SAG CWe). Equation (1) was used to obtain the OC-SAG at an 11 mm chord using the mean corneal radius obtained from keratometry values provided by the ESP. Then, 200 μm were added for each 0.5 mm of chord diameter to obtain the OC-SAG CWe at 14, 14.5 and 15 mm chord diameters.
- OC-SAG calculated with eccentricity (OC-SAG Ce). Equation (2), which includes the eccentricity, was used to calculate the OC-SAG at an 11 mm chord using the mean corneal radius. Again, a linear increase of 200 μm was applied for each 0.5 mm chord to obtain the OC-SAG Ce at 14, 14.5 and 15 mm chord diameters.
- OC-SAG calculated with the iBFS (OC-SAG CiBFS). Equation (1) was used to obtain the OC-SAG at an 11 mm chord using the inner corneal radius and the same linear extrapolation was used to calculate the OC-SAG CiBFS at 14, 14.5 and 15 mm chord diameters.
- OC-SAG calculated with the formula of the custom soft lens manufacturer mark'envoy, (Madrid, Spain) (OC-SAG CME). The formula calculates the sag of an asphere over 10 mm using the sim k and e values [12]. The peripheral OC-SAG is calculated via a tangent angle

extended from the previously calculated sphere at the total diameter proposed [12]. It is calculated in several steps:

1. OC-SAG is calculated at 10 and 9.9 mm chord diameters using Equation (2).
2. The tangent angle (α) is calculated through the difference between OC-SAG at 10 and 9.9 mm chords.

$$\alpha = \arctg \frac{OCSAG@10 \text{ mm} - OCSAG@9.9 \text{ mm}}{0.05}$$

1. The lens diameter (OAD) is selected to calculate the OC-SAG at the same chord as the lens diameter. The recommended OAD is the horizontal visible iris diameter (HVID) plus 3 mm, but the limbal diameter showed a lower reliability than the mean corneal radius, with an ICC of 0.44 [16]. Since Montani found that the ESP overestimated the required OAD by 0.30 ± 0.35 mm [17], the OAD was calculated as the HVID plus 2.5 mm instead of 3 mm. Based on these results, the OAD was calculated as HVID plus 2.5 mm instead of HVID plus 3 mm.

$$OAD = HVID + 2.5 \text{ mm}$$

2. The tangent angle (α) is used to calculate the OC-SAG from a 10 mm chord to a chord equal to the OAD selected and it is expressed by "y"

$$y = \tan \alpha \times z$$

$$\text{where } z = \frac{OAD-10}{2}$$

3. Then the OC-SAG for the same chord diameter as the OAD is determined by adding "y" to OC-SAG at 10 mm.

$$OCSAG@OAD = OCSAG@10 \text{ mm} + y$$

All these calculations were compared to the values measured with the ESP (OC-SAG MESP). The OC-SAG difference was used to analyze if higher values corresponded with greater differences between calculated and measured values of OC-SAG.

2.3. Statistical analysis

The statistical analysis was performed using Excel (Microsoft, WA, US). First, all data samples were confirmed to be normally distributed by means of the Kolmogorov-Smirnov test and then parametric statistics were used. Mean and SD values were obtained for calculated OC-SAG values (CWe, Ce, CiBFS and CME) and for measured values (OC-SAG MESP). Differences between pairs of values were analyzed using the paired Student's *t* test. All statistical tests were 2 tailed, and P values <0.05 were considered statistically significant. Additionally, Pearson coefficients were calculated to assess the level of correlation between calculated and measured values at the different chord diameters. A Bland-Altman analysis was performed to test the agreement between calculated and measured values. The limits of agreement (LoA) were defined as the mean \pm 1.96 SD of the differences and the range of agreement of the distance between both limits. The range of agreement was analyzed in terms of clinical significance for contact lens fitting.

3. Results

The results of the comparative analysis of the calculated and measured sagittal height values are displayed in Table 1. OC-SAG CWe

Table 1

Results of the comparative analysis of the sagittal height measured with the profilometer ESP (OC-SAG MESP) and the following estimations for different chord diameters: OC-SAG calculated without eccentricity (OC-SAG CWe), OC-SAG calculated with eccentricity (OC-SAG Ce), OC-SAG calculated with the iBFS, and OC-SAG calculated with the formula of the custom soft lenses manufacturer Mark'Ennovy, (Madrid, Spain) (OC-SAG CME).

OC-SAG Method	Chord diameter (mm)	Mean (μm)	Mean differences calculated vs measured (μm)	Correlation coefficients	LoA (μm)	p-value
Measured with the ESP (MESP)	11	2103 \pm 77				
	14	3269 \pm 129				
	14,5	3452 \pm 140				
	15	3635 \pm 150				
	CL diameter	3384 \pm 36				
Calculated without eccentricity (CWe)	11	2224 \pm 99	121 \pm 44	0.90	86	<0.001
	14	3424 \pm 99	155 \pm 105	0.60	206	<0.001
	14,5	3624 \pm 99	172 \pm 117	0.56	229	<0.001
	15	3824 \pm 99	189 \pm 128	0.52	253	<0.001
Calculated with eccentricity (Ce)	11	2131 \pm 102	28 \pm 48	0.89	94	<0.001
	14	3331 \pm 102	62 \pm 102	0.63	200	<0.001
	14,5	3531 \pm 102	79 \pm 113	0.60	221	<0.001
	15	3731 \pm 102	96 \pm 123	0.57	241	<0.001
Calculated with the best fit sphere (CiBFS)	11	2068 \pm 74	-34 \pm 11	0.99	22	<0.001
	14	3268 \pm 74	0 \pm 72	0.88	141	0.49
	14,5	3468 \pm 74	17 \pm 86	0.86	169	0.05
	15	3668 \pm 74	34 \pm 99	0.81	194	<0.01
Calculated with the Mark'Ennovy formula (CME)	CL diameter	3337 \pm 184	-47 \pm 137	0.81	269	p < 0.01

values were significantly higher than OC-SAG MESP with differences of 121 ± 44 , 155 ± 105 , 172 ± 117 and $189 \pm 129 \mu\text{m}$ for chord diameters of 11, 14, 14.5 and 15 mm, respectively (all $p < 0.001$). When eccentricity was included in the calculation, the differences between OC-SAG Ce and OC-SAG MESP decreased to 28 ± 48 , 62 ± 102 , 79 ± 113 and $96 \pm 123 \mu\text{m}$ for the same chords, but were still were significantly different (all $p < 0.001$). The use of iBFS to calculate the OC-SAG resulted in an OC-SAG CiBFS lower than OC-SAG MESP at the 11-mm chord diameter ($-34 \pm 11 \mu\text{m}$, $p < 0.001$). Differences beyond the CSJ angle at 14, 14.5- and 15-mm chord diameters were 0 ± 72 , 17 ± 86 and $34 \pm 99 \mu\text{m}$, with no statistically significant differences for the 14 and 14.5-mm chords ($p = 0.99$ and $p = 0.11$, respectively). The OC-SAG CME underestimated the OC-SAG by $-47 \pm 137 \mu\text{m}$ ($p < 0.01$) compared to the OC-SAG MESP for the same chord diameter as the proposed lens diameter (Table 1).

Correlation coefficients between OC-SAG CWe/OC-SAG Ce and OC-SAG MESP values were high at the 11-mm chord diameter (0.90), but dropped to below 0.63 for chord diameters beyond the cornea. The correlation between OC-SAG CiBFS and the OC-SAG MESP decreased with increasing chord diameters, but remained above 0.80, as did the correlation with OC-SAG CME at the proposed lens diameter (Table 1).

Bland-Altman analysis offered a range of agreement between values calculated with the different methods and measured values below $100 \mu\text{m}$ at the 11-mm chord diameter. For larger chord diameters, the range of agreement was between a minimum of $141 \mu\text{m}$ with the OC-SAG CiBFS at 14-mm chord and a maximum value of $269 \mu\text{m}$ with the OC-SAG CME (Table 1). Bland-Altman plots for OC-SAG CWe, Ce and CiBFS at 11, 14, 14.5 and 15 mm and CME at the proposed lens diameter, showed a clear tendency of higher dispersion for those OC-SAG values far away from the mean (Figs. 1–4). CWe values at 11 mm overestimated the OC-SAG MESP and showed greater differences for larger OC-SAGs and smaller differences for lower OC-SAGs (Fig. 1). For Ce values at 11 mm, a pattern of over-estimation for larger OC-SAGs and under-estimation for lower OC-SAGs was observed (Fig. 2). This same pattern was inverted for chord diameters beyond the cornea (14, 14.5 and 15 mm) for CiBFS values, where an over-estimation was seen in

lower OC-SAGs and an under-estimation was the pattern in higher OC-SAGs (Fig. 3).

4. Discussion

This study compared the OC-SAG values calculated with different methods and measured OC-SAG values. Corneal parameters such as the mean corneal radius, eccentricity and iBFS obtained with the ESP were used to calculate the OC-SAG at a corneal chord diameter of 11 mm. This value was extrapolated to chord diameters beyond the cornea (14, 14.5 and 15 mm), assuming a linear transition between the cornea and the sclera.

The OC-SAG calculated using the corneal radius without eccentricity was found to be significantly higher than that measured OC-SAG ($p < 0.001$). When eccentricity was introduced in the calculation, the calculated values were still significantly higher than those measured ($p < 0.001$), but the differences decreased. This could be expected as it is well known that the eccentricity plays a role in defining the corneal shape [3,4]. Significant over-estimation in calculated values compared to measured values was also reported by Michaud et al [18]. The smallest differences were found when the iBFS was used to calculate the OC-SAG, and no statistically significant differences were observed for the 14 and 14.5-mm chord diameters ($p = 0.49$ and $p = 0.05$ respectively). Nevertheless, the iBFS provided by the ESP cannot be considered as interchangeable with the best fit sphere provided by other devices [19]. Besides the differences between methods, a pattern of higher differences with larger chord diameters were observed with the three methods used to calculate the OC-SAG, which suggests that the larger the chord diameter the less accurate the calculation. Several factors may contribute to this, including the significant flattening of the conjunctival-scleral area, the impact of CSJ, and the increase in irregularity of the sclera increasing chord diameter [8,13].

Corneal parameters obtained with the ESP were also used to calculate the OC-SAG by using the formula proposed by a custom soft contact lens manufacturer. This formula intends to avoid the inter-individual variability in the peripheral cornea by calculating the corneal slope at

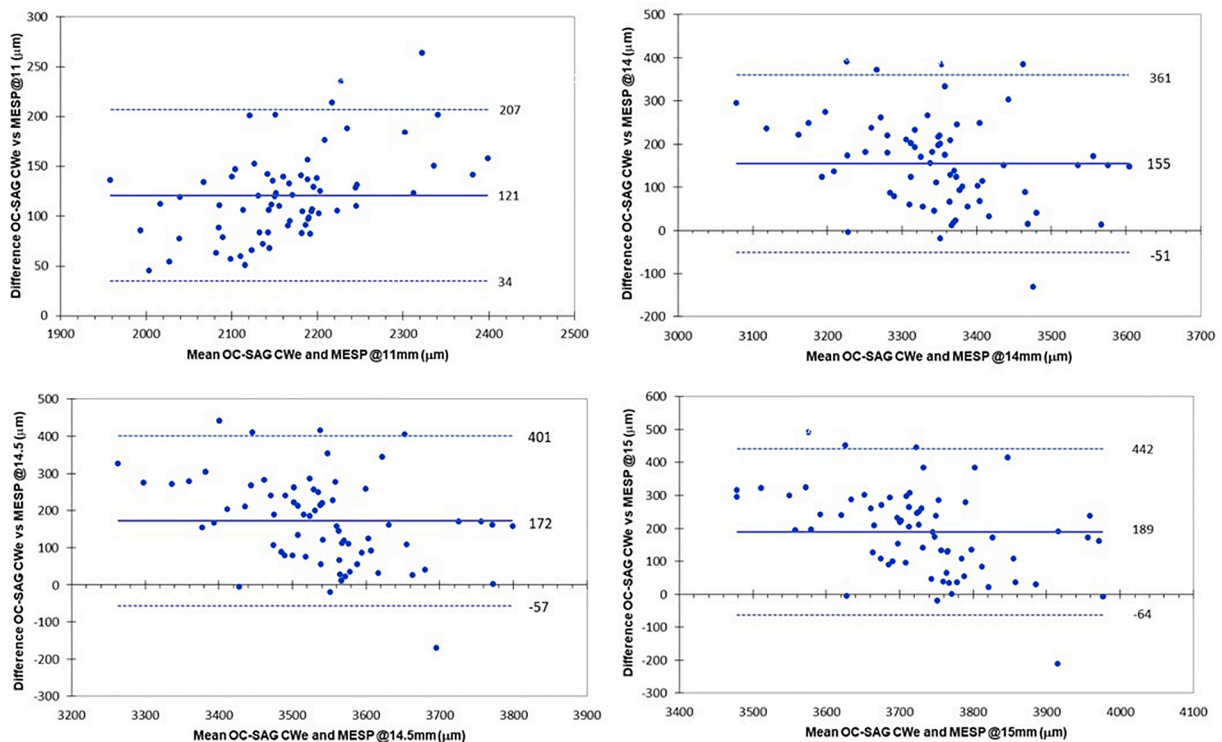


Fig. 1. Bland-Altman plots for calculated values without eccentricity (OC-SAG CWe) and measured values (MESP).

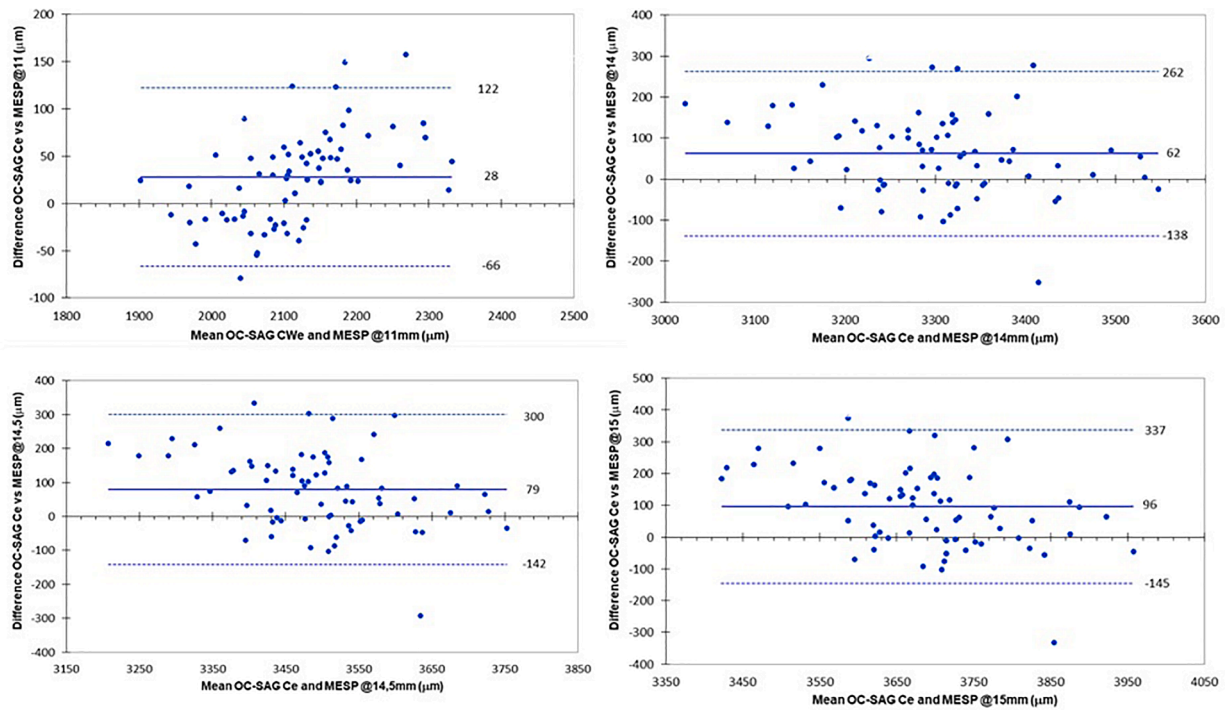


Fig. 2. Bland-Altman plots for calculated values with eccentricity (OC-SAG Ce) and measured values (MESP).

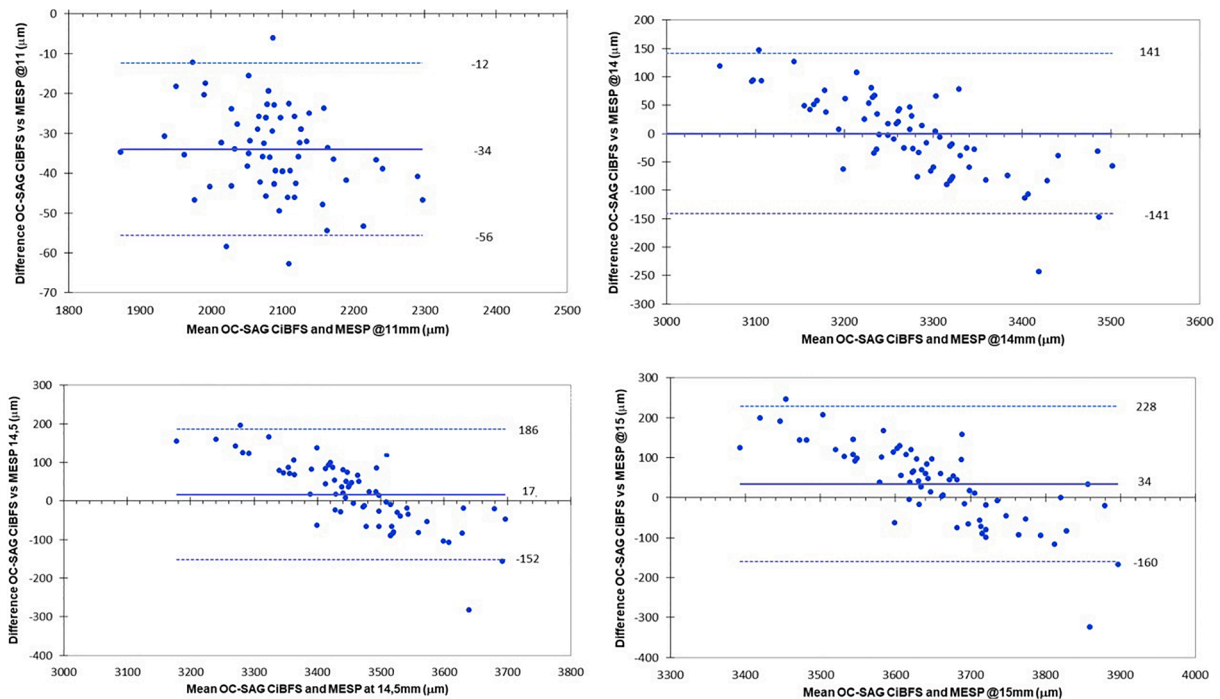


Fig. 3. Bland-Altman plots for calculated values with the inner best fit sphere (OC-SAG CIBFS) and measured values (MESP).

a 10-mm chord, but again assuming a linear transition between the cornea and the sclera. Once more, statistically significant differences were found ($p < 0.01$), although this time the measured values were higher than those calculated for a chord equal to the proposed lens diameter ($p < 0.01$).

In terms of clinical significance, the δ -sag parameter has recently been used to define the difference or relationship between CL-SAG and OC-SAG with custom soft contact lenses [20]. While there is limited information about the ideal δ -sag when custom soft lenses are fitted,

Michaud et al [21] reported optimal fit and comfort with $+200 \mu\text{m}$ and Montani suggested $+350 \mu\text{m}$ [17]. Nevertheless, the soft lens fitting is also dependent on many other factors such as the material and design [22]. In contrast, there is greater consensus on the fitting of SL. Instead of using δ -sag, the tear reservoir (TR) thickness is the term usually chosen to describe the relationship between the CL-SAG and the OC-SAG when fitting scleral lenses. The optimal TR thickness is strongly related to the corneal oxygen requirements since it conforms a space filled by a fluid that is a barrier for the oxygen flux to the cornea. It is one of the

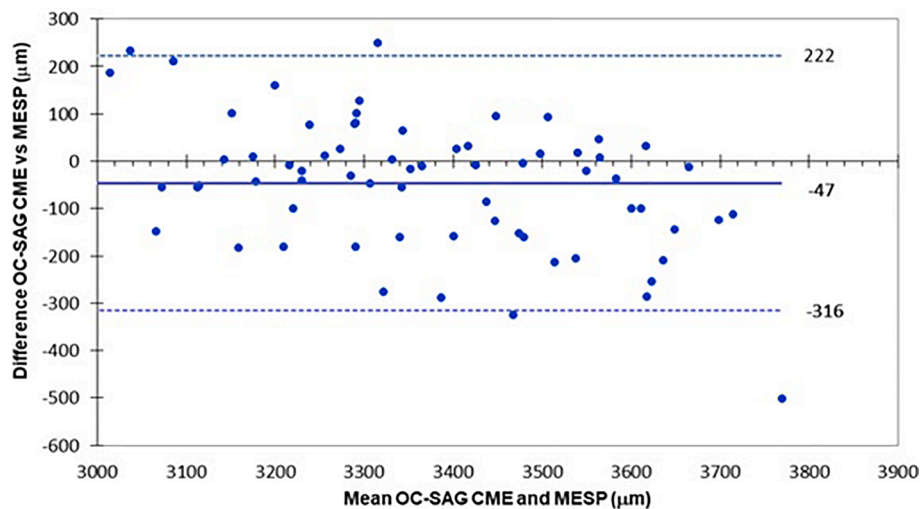


Fig. 4. Bland-Altman plots for calculated values with the mark'envovy formula (OC-SAG CME) and measured values (MESP).

variables involved in the amount of oxygen that reaches the cornea with sclerals, together with the material Dk and lens thickness. A TR with a thickness of 300–350 μm is accepted on insertion, as it is assumed that it will settle down to around 200 μm after a few hours [5,23,24]. These values would meet the theoretical corneal oxygen requirements, depending on the other two variables, and would minimize the likelihood of corneal bearing with scleral lenses [25,26]. This range of agreement (141–253 μm) is approximately half to two-thirds the proposed target OC-SAG/CL-SAG difference values for soft (200–350 μm) and SL (300–350 μm) and therefore the calculated and measured sagittal values would not be interchangeable when fitting large diameter contact lenses.

Another critical point is the analysis of the role of the CSJ junction on the OC-SAG value. Since the level of agreement and correlation coefficients substantially decrease with increasing chord diameter beyond the cornea, the CSJ likely plays a significant role. This suggests that the predictive capability of corneal parameters decreases when the chord diameter increases. Moreover, some Bland-Altman plots showed a pattern at 11 mm chord and the opposite for chord diameters beyond the cornea. Last, Pearson correlation coefficients also dropped significantly far away from the cornea. These last two findings lead to the assumption that the CSJ may play a significant role in the measurement of OC-SAG beyond the cornea, which cannot be predicted by corneal parameters or by the peripheral corneal slope.

A potential limitation of this study is that corneal parameters were measured with the ESP. This is a device that was initially conceived to map the sclera and measure sagittal height rather than corneal curvature, however, more recent versions of the software have improved the repeatability of corneal curvature measurements [16]. Furthermore, the results of this study showed not only statistically significant differences between calculated and measured values, but also clinically significant differences between the sagittal values at chord diameters within and beyond the cornea. Nevertheless, a comparison between values calculated with a corneal topographer and values measured with the ESP would supplement this study. The retrospective design of the present study as well as the fact that the maps were obtained after lens removal are also limitations that could be addressed by a prospective study. Alonso-Caneiro et al reported some tissue compression measured with OCT after short-periods of soft lens wear [27], which could impact measurements at 14–15 mm depending on the soft lens worn and duration of lens wear that day. Additionally only normal eyes were examined, hence the results cannot be applied to diseased or ectatic eyes, although the observed differences would likely be similar or worse in such eyes [13].

In conclusion, differences between measurements of ocular sagittal height with a profilometer and estimations of it from corneal parameters are statistically and clinically different, especially for increasing chord diameters. ECPs should consider this clinically significant difference when fitting large diameter lenses. Custom soft lenses designed with sagittal values derived from corneal parameters may not provide an optimal fit due to these observed differences. The ECP should examine the fit of the lens on eye and modify parameters to optimize lens centration and movement. When fitting sclerals, the trial lens selection might be affected by this same gap and therefore CL-SAG modifications may be expected. Nevertheless, future studies should investigate the impact that these differences may have on the success of contact lens fitting.

Disclosure

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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