

## Agreement between the biometric measurements used to calculate the size of the implantable collamer lenses measured with four different technologies

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**Purpose:** To evaluate the agreement between the biometric measurements used to calculate the size of the implantable collamer lenses (ICL) with different technologies: swept-source optical coherence tomography, spectral domain optical coherence tomography, and Scheimpflug tomography. **Methods:** This retrospective observational study included subjects undergoing refractive surgery with posterior chamber phakic IOL implantation to correct their myopia. The anterior chamber depth (ACD) and the horizontal white to white (WTW) or the angle to angle (ATA) distance were measured with the following four devices: the IOLMaster 700 biometer (Carl Zeiss Meditec, Jena, Germany), based on swept-source optical coherence tomography; the Cirrus and Visante optical coherence tomographs (Carl Zeiss Meditec) based on low-coherence interferometry; and the Pentacam rotating Scheimpflug camera (Oculus, Wetzlar, Germany). **Results:** In the horizontal corneal diameter measurements, there were statistically significant differences between Pentacam–IOLMaster 700 pair ( $P < 0.001$ ) and Pentacam–Visante pair ( $P < 0.001$ ). WTW from CIRRUS showed the lowest correlation when paired with Pentacam and IOLMaster 700 ( $R^2 = 0.452$  and  $0.385$  for Visante and  $R^2 = 0.494$  and  $0.426$  for Cirrus). Regarding the linear correlation of the ACD measurements, all pairs of devices were statistically significant and all of them showed a very good correlation index. **Conclusion:** There is a good agreement between the different devices under evaluation for ACD measurements. As for WTW, the values measured with the different devices showed large discrepancies with low correlation levels, especially when comparing the tomographs with the other devices under evaluation.

**Key words:** Anterior Chamber Depth, ICL, phakic lens, white to white

The use of posterior chamber phakic implantable collamer lenses (ICL; STAAR Surgical, Monrovia, CA, USA) has increased in recent years, in parallel with the improvement of the lens design, the availability of a wider dioptric range, and the rapid development of diagnostic methods for preoperative evaluation, which reduce the calculation errors for the lens to be implanted.<sup>[1]</sup>

When implanting such a lens, the main obstacle is to choose the correct lens size (sizing) based on the anatomical data that has been collected preoperatively. The selection of a suitable size is tightly linked with the absence (or, otherwise, the presence) of postoperative problems, both in the short as well as in the long term. According to the study by AlSabaani et al.,<sup>[2]</sup> the main reason for explanting the ICL is implantation of an improperly sized lens.

The nomogram provided by the STAAR laboratory relies on white-to-white (WTW) distance (i.e., corneal diameter) and the anterior chamber depth (ACD) to calculate the final lens size, despite the fact that the location where this lens model is placed is the ciliary sulcus. The algorithm used by the calculator (Online Calculator and Ordering System [OCOS]) is based on the selection of the ICL lens size according to the WTW

and the ACD, so that in some cases, the WTW measurement is the only one used for the selection of size, and in others, the selection also depends on the ACD. The choice of this metric by the laboratory stems from the fact that a sulcus-to-sulcus (STS) measurement requires ultrasonic biomicroscopy (BMU), a technique which is not available in most eye centers due to the device's high price and the complexity that such a measurement entails. In the absence of STS data, the alternative parameters are WTW or angle-to-angle (ATA) distance. Nonetheless, since these variables are not related to the location where the ICL is to be fitted, they can make the chosen size to be inadequate; it is equally problematic to have a lens that is too large or too small.<sup>[3,4]</sup>

It has been shown that the vault decreases between 50 and 70  $\mu\text{m}$  during the first postoperative year and by an additional 10–15  $\mu\text{m}$  in each subsequent year. Bearing in mind that an ICL can remain inside the wearer's eye for an average of 25 years, a minimum of 350  $\mu\text{m}$  of vault is needed in the early postoperative period to ensure that this distance is not compromised by the passing of time.<sup>[5]</sup> Hence, in the preoperative assessment, it is

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crucial to collect accurate data for those biometric parameters that are involved in lens size and power calculations.

Moreover, it is also important to know before surgery whether the ICL will be placed vertically or horizontally since several studies,<sup>[6,7]</sup> as well as our own experience, have shown that the size of the vertical STS distance is greater than the same distance measured along the 0°–180° axis, the vertical implant is often used as a clinical–surgical approach for vault management when the horizontal meridian is excessively high. This is a value that we must keep in mind, since the corneal diameter that all measuring instruments provide refers to the horizontal meridian. The ATA distance can be measured along any meridian, and the same happens for the STS distance.

The purpose of this paper is to evaluate the agreement between the biometric measurements used to calculate the size of the ICL to be implanted, which are essential to perform the calculation. Each calculation method to be compared relies on different biometric parameters: these are WTW distance – which is obtained by means of either swept-source optical coherence tomography (SS-OCT), spectral domain optical coherence tomography or Scheimpflug tomography – and ATA size, which is obtained with segment optical coherence tomography. The ACD values yielded by these four devices were also to be compared.

## Methods

This is a retrospective and observational study.

A total of 42 right eyes from 42 patients were included; they all underwent refractive surgery with posterior chamber phakic Intraocular lens (IOL) implantation to correct their myopia. The study adhered to the tenets of the Declaration of Helsinki and was approved by the local ethics committee.

All measures were taken at the time of preoperative assessment.

Finally, in all cases, the definite size of the ICL lens to be implanted was calculated with the calculator provided by the laboratory, which, in its turn, relies on the WTW and ACD values obtained with SS-OCT.

In the context of the present study, the following devices were used to make the measurements that were subsequently compared:

The IOLMaster 700 biometer (Carl Zeiss Meditec, Jena, Germany) is based on SS-OCT. This IOLMaster 700 device relies on a wavelength of 1055 nm and has a scan depth of 44 mm and a scan width of 6 mm. Its resolution in tissue is 22 μm, and its measurement speed is 2000 A-scans per second. WTW and ACD distances are computed automatically once the device has performed one and six measurements, respectively.

The Cirrus optical coherence tomograph (Carl Zeiss Meditec) uses low-coherence interferometry with a scan of five parallel lines of 840 nm wavelength (4096 A images/line) to produce high-resolution images of the anterior segment. We used Anterior Segment 5-Line Raster scans through five parallel lines of equal length that can be used to view high-resolution images of the anterior chamber angle and cornea. The scan was performed by making a horizontal cut centered on the pupil and measuring manually from scleral spur to scleral spur.

The Pentacam rotating Scheimpflug camera (Oculus, Wetzlar, Germany) imaging system is a rapid, noncontact modality that enables the study of the eye's anterior segment using a blue light-emitting diode and a rotating Scheimpflug camera. Using the Pentacam rotating Scheimpflug camera, the patient was asked to fixate straight ahead on the blue circular fixation target. The rotating camera captured up to 25 slit images of the anterior segment in less than 2 s, whereas the horizontal WTW and the ACD were automatically yielded by the imaging system.

The Visante OCT anterior segment optical coherence tomograph (Carl Zeiss Meditec) uses low-coherence interferometry with a light source wavelength of 1310 nm and a scanning speed of 512 A-scans at 250 ms, resulting in higher speed without signal loss. All patients were instructed to look at a target light. The center of the measurement was aligned with the corneal apex and the scan was performed so as to make the ATA horizontal, that is, from 0° to 180°.

For the Visante OCT and the Cirrus OCT devices – bearing in mind that manual procedures are involved – three measurements were made with each of them, and the average value was computed before undertaking the comparative statistical analysis.

## Statistical Analysis

Statistical data was analyzed using SPSS 22.0 software (IBM Inc., Chicago, IL, USA). Sample size was calculated using Granmo software v7.12 (Institut Municipal d'Investigació Mèdica, Barcelona, Spain) according to the standard deviation observed in a previous pilot study: the software indicated a minimum of 40 observations required for  $\alpha = 0.05$ , risk  $\beta = 0.20$  in bilateral contrast. After normality and equality of variances were assessed (Kolmogorov–Smirnov [K–S] method), parametric tests were performed to assess the bias between instruments. Differences were considered to be statistically significant when the  $P$  value was  $< 0.05$  (i.e., at the 5% level).

These tests were used to achieve the goal of this study: paired Student's  $t$ -test was performed to assess the mean values between pairs of devices, and linear correlation coefficient was used to correlate the measurements from each pair of devices.

Bland–Altman concordance method was used with the 95% of limits of agreement (LoA) in pairs between measurements; intraclass correlation coefficient (ICC) was also studied.

## Results

The mean age of the 42 patients included in the study was  $31.92 \pm 6.83$  years (range: 23–51).

The sizes of ICL implanted in the 42 eyes were the following: 12.1 mm ( $n = 3$ , 7.1%); 12.6 mm ( $n = 10$ , 23.8%); 13.2 mm ( $n = 28$ , 66.7%), and 13.7 mm ( $n = 1$ , 2.4%).

The average vault measured by optical coherence tomography, 1 month after the intervention, was  $0.605 \pm 0.05$  mm (range 0.16–0.91), and the measurement between the endothelium and the anterior face of the ICL was  $2.33 \pm 0.08$  mm (range 1.62–2.88).

Table 1 shows the descriptive statistics. WTW and ATA values were always measured along the horizontal meridian.

ACD was measured as the distance between the corneal endothelium and the crystalline lens' anterior surface.

Table 2 shows the mean value and statistical significance of the difference in horizontal diameter and ACD measurements from each pair of variables. In the horizontal corneal diameter measurements, there were statistically significant differences between Pentacam–IOLMaster 700 pair ( $P < 0.001$ ) and Pentacam–Visante pair ( $P < 0.001$ ). Regarding the differences between devices in the ACD from endothelium measurement, all the differences were statistically significant.

Fig. 1 shows the linear correlation graphs of the horizontal diameter measurements from different devices in pairs. Table 3 shows the Pearson correlation significance for all pairs. In all cases, there was a statistically significant correlation between devices ( $P < 0.001$  in all cases); however, ATA measurement obtained in Visante, which is an anatomical different measure, and WTW from Cirrus showed the lowest correlation when paired with Pentacam and IOLMaster 700 ( $R^2 = 0.452$  and  $0.385$  for Visante and  $R^2 = 0.494$  and  $0.426$  for Cirrus).

Regarding the linear correlation of the ACD measurements, all pairs of devices were statistically significant and all of them showed a very good correlation index. Fig. 2 shows the correlation graphs, and Table 3 shows the correlation and statistical relationship.

When the ICC was analyzed, there were good results overall in the correlation in pairs with the horizontal diameter measurements and a very good correlation between pairs in the ACD measurements. Results are presented in Table 4.

Figs. 3 and 4 show the Bland–Altman graphical representation between the means of each pair of measures versus the difference between devices.

## Discussion

Choosing the optimum ICL size is essential to prevent both short- and long-term post-surgical complications.<sup>[3,8,9]</sup> There are several studies found in the literature about ICL sizing, although none of them aimed to develop an algorithm that would establish a relationship between STS and WTW distances or ATA values, so as to be able to improve the outcomes without being obliged to measure the patient's STS distance.

The measures that are taken to be able to calculate both the power and size of the lens to be implanted are essential

to prevent complications in the medium and long term. Although the ICL is implanted exactly on the sulcus, this (the STS distance) is precisely the parameter that is not measurable at every eye clinic because it requires ultrasonic biometry. Therefore, in our study, we have compared the different metrics that can be measured in a noninvasive manner during a routine consultation at the eye clinic, so as to assess the agreement or discrepancy level between them.

Regarding ACD, in our analysis, it has been observed that there is a very good correlation – greater than 0.95 in all cases – when comparing the ACD values (measured from the endothelium) yielded by the Pentacam, the IOLMaster 700, the posterior-pole Cirrus optical tomograph, and the anterior-pole Visante optical tomograph. When doing a pairwise comparison, the differences were always statistically significant ( $P < 0.001$ ) on comparing the IOLMaster 700 with any of the other devices, but not when comparing these devices among themselves. In any case, all measurements were less than or equal to 0.09 mm. We also calculated the ICC, which exceeded 0.97 in all cases, a figure that reconfirms the excellent agreement across all the measurements. It is important to emphasize that even though the class correlation index (ICC) for ACD is statistically very good, the difference found across different measurements could be clinically significant in those cases where the STAAR calculator proposes a change in size (i.e., ICL diameter); let us remember, for instance, that the STAAR calculator (OCOS) calculates the size of the ICL lens to be implanted based on WTW and ACD values. Therefore, depending on the specific device used to measure the ACD and WTW values to be fed into the calculator, the resulting ICL size could be different and could even entail a larger ICL model, which may cause a post-surgical hypervault.

In line with our outcomes, Sayed's<sup>[10]</sup> study concluded that there was a good agreement between Pentacam and IOLMaster in terms of ACD and K-readings, making them interchangeable in biometry and phakic IOL power calculation, but they were not interchangeable when it comes to WTW line measurement, since small differences could affect the phakic IOL diameter, which, in turn, would have an impact upon lens safety.

Contrary to what was observed for ACD, this excellent agreement across devices does not exist for WTW measurements. The correlation is also close to 0.95 in the Pentacam versus IOLMaster case, but it is considerably lower when comparing these two devices with the two optical coherence tomographs: the correlation values dropping to 0.62 for the IOLMaster 700 versus Visante OCT comparison or to 0.65 in the IOLMaster 700 versus Cirrus OCT case. It is important to point out that both the IOLMaster 700 and the Pentacam platforms do measure WTW distances, while the Visante OCT relies on ATA distance and the Cirrus OCT on scleral-spur-to-scleral-spur distance; this is because of the inherent limitations in these devices to make more direct measurements.

Nakamura *et al.*<sup>[11]</sup> evaluated ICL size accuracy using an anterior segment optical coherence tomography system (CASIA2; Tomey Corp., Nagoya, Japan). For this purpose, a nomogram was developed (the Nakamura (NK) formula), which relied on the ATA, the anterior chamber width (ACW), defined as the distance between the scleral spurs on the nasal and temporal sides, the lens vault, defined as the perpendicular distance between the anterior crystalline lens surface and a horizontal line joining the two scleral spurs,

**Table 1: Statistical demographic data**

	Mean (mm)	SD (mm)	Range (mm)
Pentacam WTW	11.84	0.31	11.00-12.50
IOLMaster 700 WTW	12.05	0.30	11.20-12.60
Cirrus WTW	11.88	0.65	10.08-13.08
Visante ATA	12.10	0.32	11.35-12.65
Pentacam ACD	3.25	0.23	2.84-3.74
IOLMaster 700 ACD	3.19	0.21	2.83-3.59
Cirrus ACD	3.29	0.43	2.42-4.01
Visante ACD	3.28	0.22	2.90-3.74

ACD=anterior chamber depth (from endothelium to anterior lens surface), ATA=angle to angle (horizontal), WTW=white to white (horizontal)

**Table 2: Mean differences between horizontal and anterior chamber depth measurements for each pair of variables**

Variables in pairs	Mean (mm)	SD (mm)	Range (mm)	P
WTW Pentacam-WTW IOLMaster 700	-0.21	0.09	-0.10--0.50	<0.001
WTW Pentacam-WTW Cirrus	-0.10	0.46	-0.88-1.12	0.156
WTW Pentacam-ATA Visante	-0.26	0.26	-0.85-0.18	<0.001
WTW Cirrus-WTW IOLMaster 700	-0.11	0.49	-1.62-0.60	0.146
ATA Visante-WTW IOLMaster 700	0.05	0.27	-0.45-0.65	0.227
ACD Pentacam-ACD IOLMaster 700	0.06	0.06	-0.11-0.15	<0.001
ACD Pentacam-ACD Cirrus	-0.04	0.09	-0.43-0.23	0.003
ACD Pentacam-ACD Visante	-0.03	0.06	-0.23-0.11	0.003
ACD Cirrus-ACD IOLMaster 700	0.09	0.05	-0.14-0.23	<0.001
ACD Visante-ACD IOLMaster 700	0.09	0.05	-0.04-0.21	<0.001

ACD=anterior chamber depth (from endothelium to anterior lens surface), ATA=angle to angle (horizontal), WTW=white to white (horizontal)

**Table 3: Linear correlation and significance for different devices in pairs for the horizontal diameter measurements and anterior chamber depth**

Variables in pairs	Correlation R	R <sup>2</sup>	P
WTW Pentacam-WTW IOLMaster 700	0.950	0.902	<0.001
WTW Pentacam-WTW Cirrus	0.703	0.494	<0.001
WTW Pentacam-ATA Visante	0.673	0.452	<0.001
WTW IOLMaster-WTW Cirrus	0.654	0.426	<0.001
WTW IOLMaster-ATA Visante	0.621	0.385	<0.001
ACD Pentacam-ACD IOLMaster 700	0.965	0.931	<0.001
ACD Pentacam-ACD Cirrus	0.982	0.964	<0.001
ACD Pentacam-ACD Visante	0.958	0.917	<0.001
ACD IOLMaster-ACD Cirrus	0.992	0.984	<0.001
ACD IOLMaster-ACD Visante	0.975	0.952	0.023

ACD=anterior chamber depth (from endothelium to anterior lens surface), ATA=angle to angle (horizontal), WTW=white to white (horizontal)

**Table 4: ICC between pairs of WTW, ATA, and ACD measurements**

	ICC	95% CI (mm)	P
WTW Pentacam-WTW IOLMaster 700	0.973	0.949-0.986	<0.001
WTW Pentacam-WTW Cirrus	0.788	0.605-0.886	<0.001
WTW Pentacam-ATA Visante	0.803	0.627-0.896	<0.001
WTW IOLMaster 700-ATA Visante	0.764	0.652-0.873	<0.001
WTW IOLMaster 700-WTW Cirrus	0.754	0.542-0.868	<0.001
ACD Pentacam-ACD IOLMaster 700	0.980	0.963-0.989	<0.001
ACD Pentacam-ACD Cirrus	0.990	0.981-0.995	<0.001
ACD Pentacam-ACD Visante	0.979	0.960-0.989	<0.001
ACD IOLMaster 700-ACD Visante	0.986	0.975-0.993	<0.001
ACD IOLMaster 700-ACD Cirrus	0.996	0.993-0.998	<0.001

ACD=anterior chamber depth (from endothelium to anterior lens surface), ATA=angle to angle (horizontal), CI=confidence interval, ICC=intraclass coefficient, WTW=white to white (horizontal)

and the crystalline lens rise. Their results showed that the predicted mean absolute error of the vault was significantly lower with the NK formula than with the STAAR nomogram. In Nakamura’s study,<sup>[11]</sup> the mean difference between WTW and ATA amounted to 0.14 mm when measured with the

tomograph. In our study, the mean difference between the ATA measured with the optical coherence tomograph and the WTW measured with Pentacam (which was the method we used to calculate the ICL) was almost twice as large as that found by Nakamura, that is, 0.26 mm; this difference was statistically significant and is of great clinical relevance.

No studies have been found in the literature that compared the Pentacam platform with the Cirrus tomograph or the Visante tomograph; but taking into consideration the inter-device differences found by other authors, including ourselves, especially with regard to WTW, it might be necessary to create a different nomogram for each device if we wanted to rely on measurements that are different from those indicated by the laboratory, so as to avoid undesired post-implantation vaults.

In our study, the size of the lens to be implanted was computed by means of the calculator provided by the laboratory, which relies on the WTW and ACD values provided by the Scheimpflug system. None of our patients experienced either intra- or postoperative complications, the vault being in all cases above 160 µm and below 910 µm. Gonvers *et al.*<sup>[12]</sup> had already evaluated the relationship between a high cataract index and a very low vault with the ICM V3 and ICM V4 models. Other authors subsequently suggested different safety ranges for the vault, so as to prevent secondary cataract from occurring: Schmidinger<sup>[13]</sup> claimed that 230 µm was the minimum vault required, it being 52 µm in the case of patients over 45 years of age, according to Maeng<sup>[14]</sup> or 90 µm according to Gonvers,<sup>[15]</sup> although their recommendation is that the central vault should be no less than 150 µm. A very high vault (>1000 µm) can also lead to problems such as pupillary block and angle closure causing glaucoma,<sup>[16]</sup> although it is also true that the new ICL designs, with their central port, have resulted in lower complication rates.<sup>[16,17]</sup> In a literature review performed by Packer<sup>[17]</sup> in January 2018 that included peer-reviewed publications assessing the V4c Visian ICL with KS Aquaport (Visian intraocular collamer Myopia [VICMO] model), which is the same one as we used in our study, he found a 0.49% incidence of asymptomatic anterior subcapsular opacities and no visually significant cataract resulting from an insufficient vault following VICMO implantation. The incidence of pupillary block, as described in Packer’s analysis,<sup>[17]</sup> amounted to 0.04%. These low complication rates seen with the Aquaport model are very

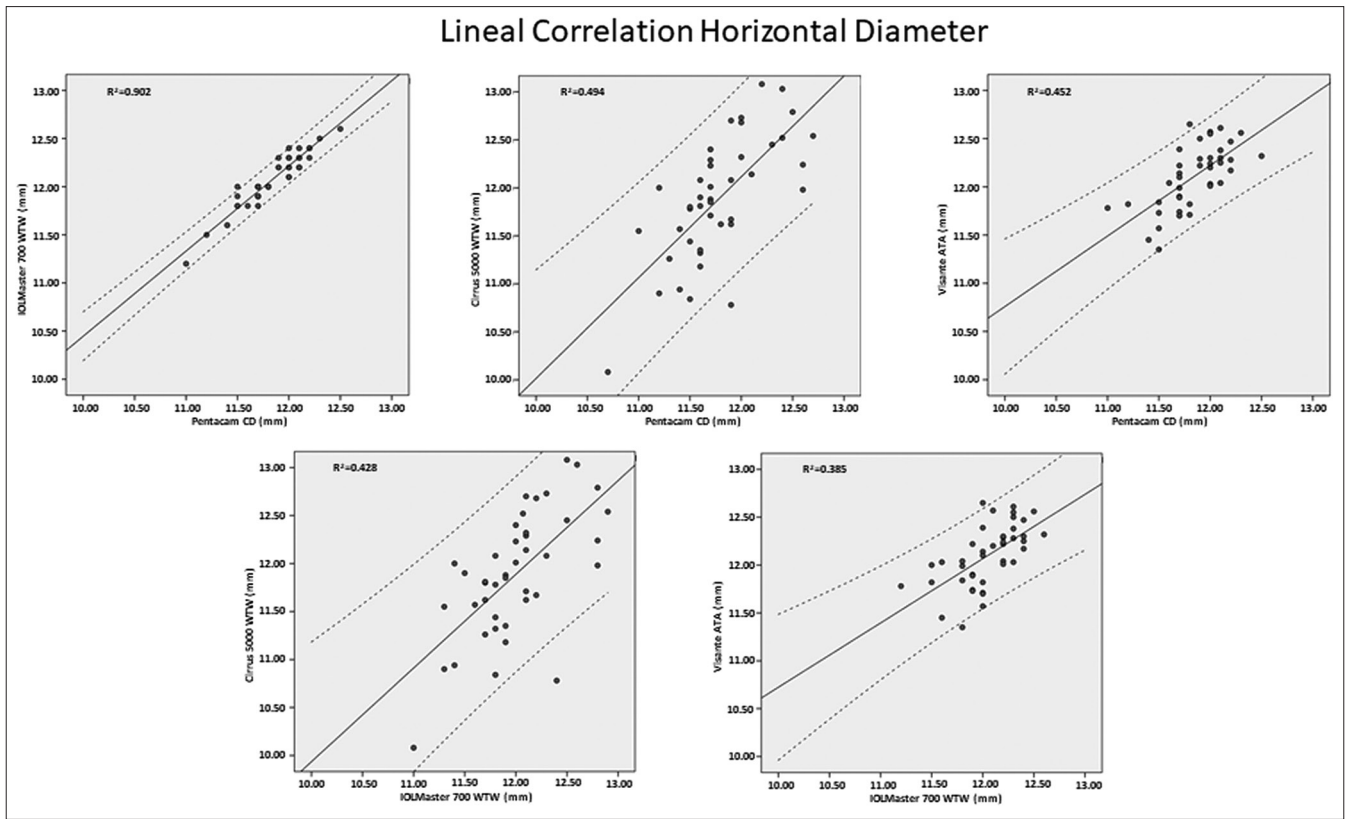


Figure 1: Linear correlation graphs of the horizontal diameter measurements from different devices in pairs

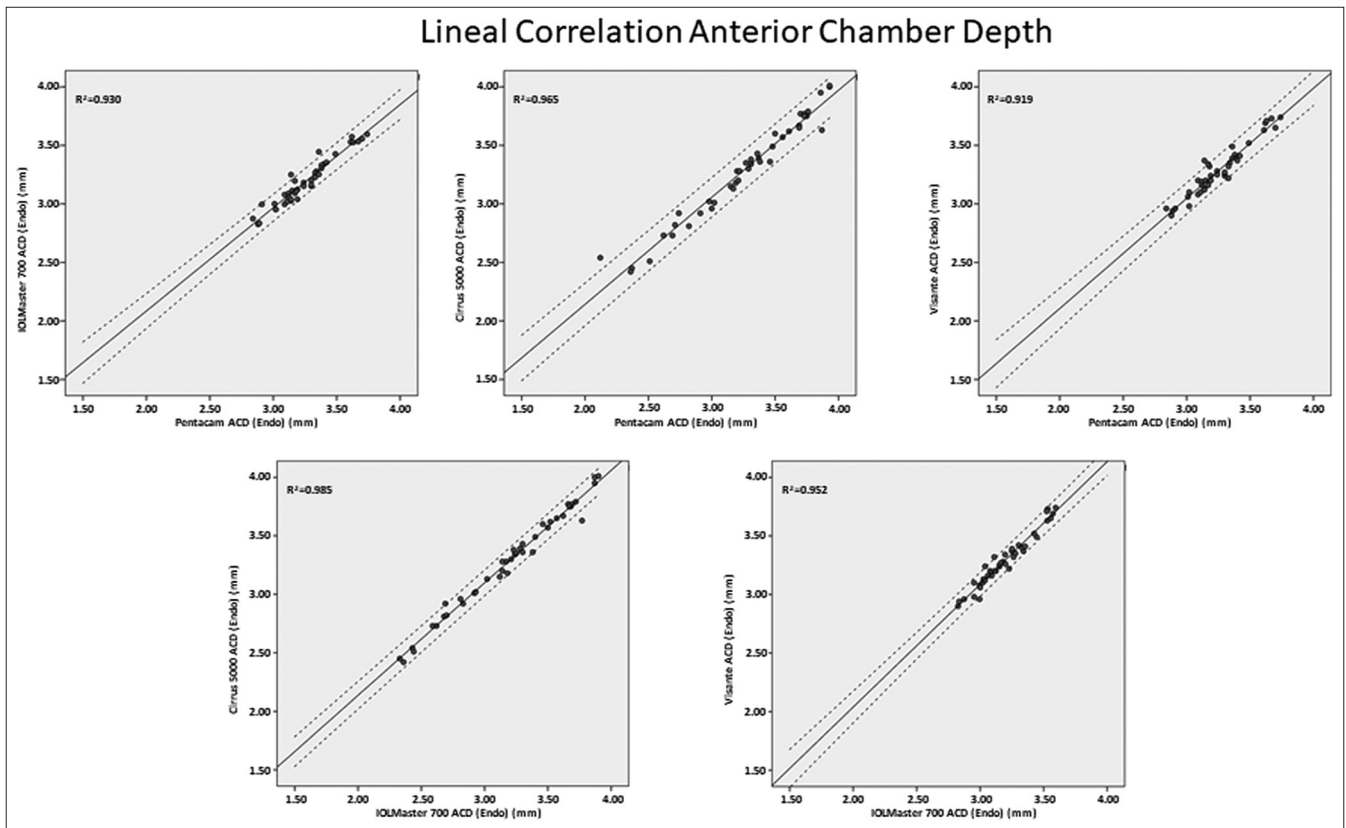


Figure 2: Linear correlation graphs of the anterior chamber depth, from corneal endothelium to anterior capsule of the lens, from different devices in pairs

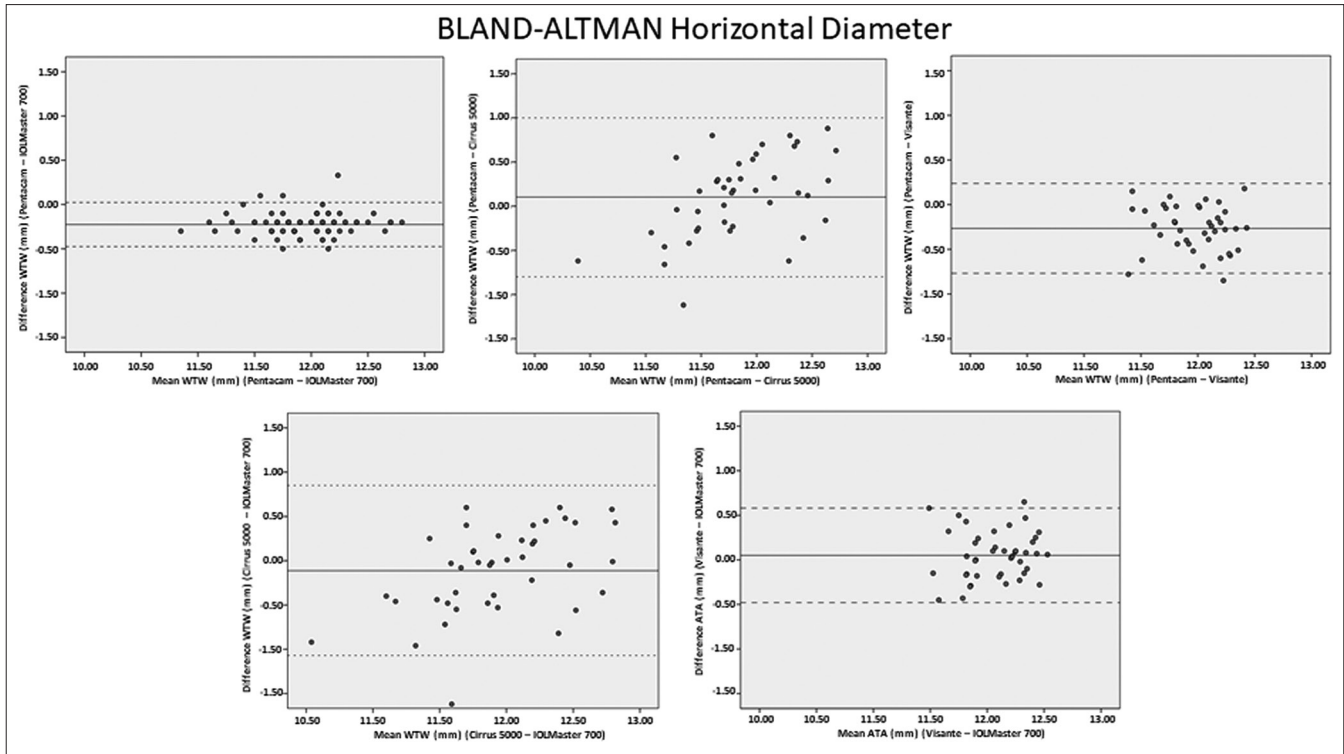


Figure 3: Bland–Altman representation for the horizontal corneal diameter between means of measurements and differences between devices

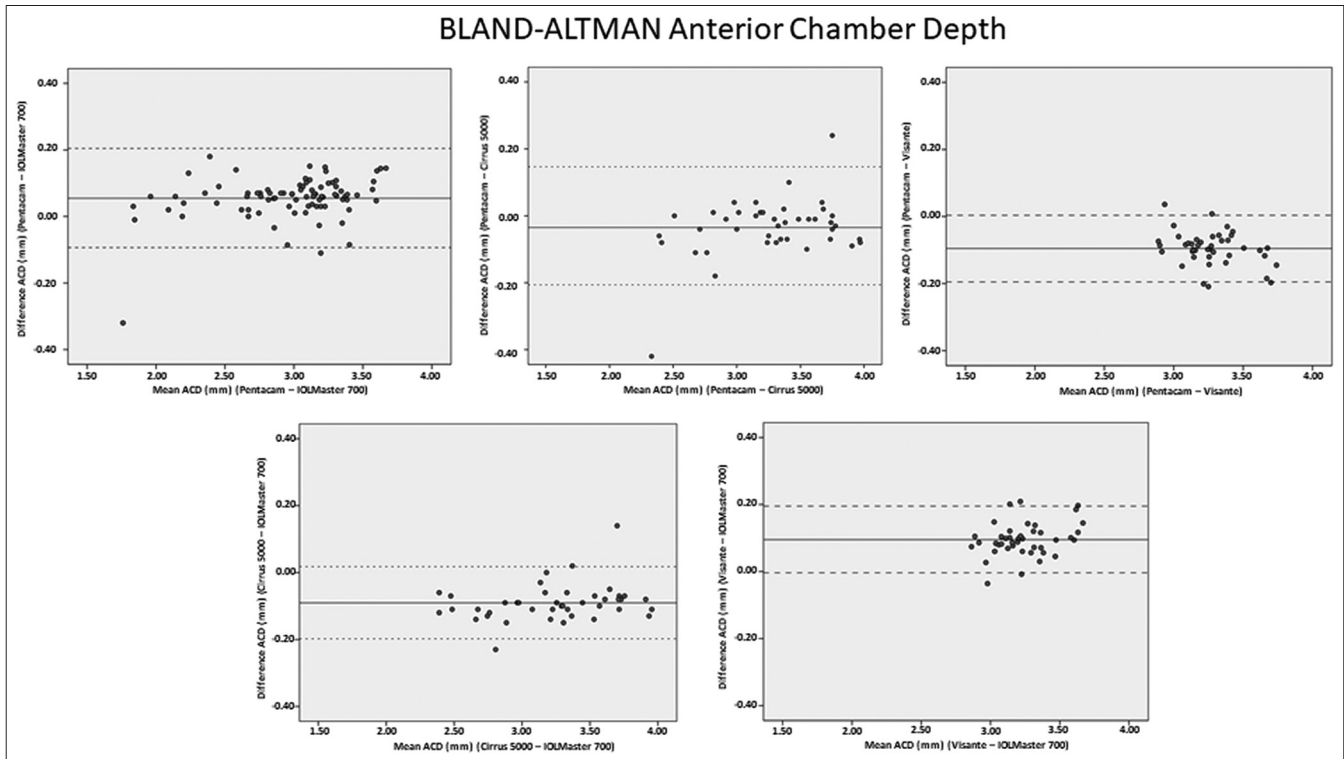


Figure 4: Bland–Altman representation for the anterior chamber depth between means of measurements and differences between devices

similar to those that emerged from our study, although it will be interesting to follow them up in the long term.

It has to be said that our study has certain limitations. One of them is that all measurements were made along the horizontal

meridian, since that is the value automatically provided by some devices such as Pentacam or IOLMaster 700. Werner<sup>[18]</sup> studied WTW distance and anterior chamber and sulcus size in eyes obtained postmortem and also studied the correlation

between these measurements. He found a positive correlation between WTW and the anterior chamber diameter along the 6-h–12-h meridian, but not along the 3-h–9-h meridian. No correlation was found between WTW and sulcus diameter in any of the meridians under study. For this reason, it would be interesting to carry out a study where different devices could be compared along different meridians.

## Conclusion

As overall conclusion, in view of the results found in our study, we can say that for ACD measurements, there is a good agreement between the different devices under evaluation (Pentacam, IOLMaster, Cirrus OCT, and Visante OCT), with the differences in all pairwise comparisons being below 0.1 mm. However, we have to bear in mind that a minor difference in ACD can have great clinical relevance, especially in those borderline cases where it could entail receiving a different ICL size model, among those manufactured by the laboratory. As for WTW, the values measured with the different devices showed large discrepancies with low correlation levels, especially when comparing the tomographs with the other devices under evaluation.

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## Conflicts of interest

There are no conflicts of interest.

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