Original Article

Confounding sizing in posterior chamber phakic lens selection due to white-to-white measurement bias

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Purpose: To assess the agreement in the white-to-white (WTW) measurement with two different devices, the reproducibility and the probability of confusing sizing (PCS) in selecting a different implantable collamer lens (ICL). **Study Design:** Retrospective observational case series. **Methods:** Images of 192 eyes were captured with both devices. The WTW was measured automatically (OA) and manually (OM) with the Orbscan and Keratograph (KA and KM) by one examiner who repeated a total of four measures. A second examiner conducted a single manual measure for each device over the same image. The ICL sizing was computed for each measure of WTW and the PCS was calculated as the percentage of cases for which the confronted or repeated measure resulted in a different size of the ICL. The critical WTWs with highest PCS were identified. **Results:** KM overestimated the WTW versus OM in 0.13 ± 0.18 mm ($P < 0.001$) but not in the automated method comparison, 0.01 ± 0.19 mm ($P = 0.58$). Inter-examiner reproducibility (R) was higher with OM than with KM, and the intra-examiner R decreased with the average of two measures in both cases. The PCS was higher with the increase of mean differences, the limits of agreement (LoAs), and R. WTWs from 11.1 to 11.2 mm, 11.6 to 11.7 mm, and 12.3 to 12.4 mm resulted in higher PCS. **Conclusion:** The mean difference is not enough to apply conversions between devices and the LoAs and R should be considered. Special attention should be taken for WTWs with higher PCS.

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The implantation of posterior chamber phakic intraocular lenses (pIOLs) has become a widely used surgical method for the correction of refractive errors.[1] The implantable collamer lens (ICL, STAAR Surgical, Monrovia, CA, USA) is one specific type of pIOL that was approved in 2005 by the United States Food and Drug Administration (FDA) and that has demonstrated to be safe and effective for the correction of myopia, hyperopia, and astigmatism.[2] Long-term studies with this modality of pIOL have reported an increased risk for lens opacities and the possible need of phacoemulsification cataract surgery up to 10 years after ICL implantation.[3] The risk of developing cataract with ICL has been correlated with its vaulting,[3] defined as the distance between the posterior surface of the pIOL and the anterior surface of the crystalline lens. Schmidinger *et al*.[4] reported that vault height decreases with time around 20–28 µm per year. For this reason, these authors recommended an early postoperative vaulting of approximately 430 µm or 550 µm[3] to maintain an adequate vault at the long term (>10 years).[4]

The selection of the correct sizing of the ICL is fundamental to achieve a postoperative vault close to that recommended.[2] The standard method proposed by the manufacturer for ICL sizing is based on the use of the white-to-white (WTW) corneal diameter and anterior chamber depth (ACD).[5] However, WTW varies depending on the instrument used, manual or automated, and the reliability is different among systems.[6] Therefore, an inter-device conversion is required to better comply with the manufacturer's nomogram requirements.[7]

The main aim of this study was to assess the level of agreement in the WTW measurement between the Orbscan IIz (Bausch and Lomb Inc, Rochester, New York, USA) and Keratograph 5M (Oculus Optikgeräte GmbH, Wetzlar, Germany) systems. Inter-examiner and intra-examiner reproducibility were also evaluated depending on the number of measures taken and averaged. Finally, the probability of selecting a different ICL sizing due to WTW bias was also computed for providing useful clinical recommendations.

Methods

Subjects

This retrospective observational study included patients who attended the Qvision, Vithas Virgen del Mar Hospital,

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Spain, for a complete ocular and visual examination to assess if they were possible candidates for any refractive surgery procedure. Therefore, those patients were later implanted with an ICL were not considered an inclusion criteria and we included in the sample all the patients without any ocular disease (e.g., pterygium) as well as history of previous surgery that could difficult the measure of the WTW. Exclusion criteria were any active ocular and/or systemic disease and a history of previous ocular surgery. Specifically, the data of a total of 192 right eyes of 192 subjects (110 females, 82 males; 31 ± 7 years old) captured with the Orbscan IIz and Keratograph 5M during the preoperative visit were retrieved from our historical database. The research was conducted in accordance with the principles laid down in the Declaration of Helsinki, and local ethics committee approval was obtained.

Description of devices

The Orbscan IIz system is an anterior segment analyzer based on slit scanning technology that measures, among other biometrical parameters, the WTW and ACD. As the Orbscan system was the first commercial corneal topographer providing a measure of ACD, it has been used as a reference to compare with other instruments and to obtain a correction of WTW before computing the ICL sizing.[7] Two measuring methods are available with this system, an automated method (OA) for measuring the WTW from limbus to limbus across the entire cornea and a manual method (OM) based on a caliper included in the Eyemetrics tool of the software (version 3.14 [Bausch & Lomb-Orbtek, Inc]). Fig. 1 (left) shows how WTW is measured with the OM method by means of drawing a line along the 5 point-reflection seen on a gray-scale image from limbus to limbus.

The Keratograph 5M is an advanced placido-based corneal topographer used in the preoperative screening of refractive surgery.[8] The particular difference with other topographers based on the same technology is that incorporates additional imaging modalities designed to non-invasively measure some tear film properties.[9] Furthermore, this system also includes an automatic (KA) and manual (KM) mode of measurement of WTW. Fig. 1 (right) shows how WTW is evaluated with the KM method in a similar way than the described previously with the OM, but in this case, over a color picture of the anterior ocular surface and drawing the line from limbus to limbus along a central red point that represents the normal vertex.[10]

Computing ICL sizing using the WTW

The nomogram included in the FDA report [sizing A in Table 1] was taken as a starting point to develop a Matlab function (version R2013a, The Mathworks, Inc.) to compute the ICL sizing for each one of the measures included in the analyses and considering the ACD measured with the Orbscan system.[5] Prior to use this function, the agreement between the FDA nomogram and the results obtained with the current Online Calculator of Sizing (OCOS)[11] was evaluated considering that OCOS is currently used for ICL sizing in clinical practice. For the validation of our function, the recommended sizing of the last 133 right eyes (133 subjects) computed with the OCOS was retrieved from our historic database of ICL implants with ACD ≥ 3 mm. The sizing A nomogram matched with the OCOS recommended sizing in 126 of the 133 analyzed cases (94.7%). Therefore, a re-adjustment of the nomogram [sizing B in Table 1] was performed for achieving 100% of agreement with the OCOS retrieved data.

Agreement and reproducibility

An image, as shown in Fig. 1, was captured for each subject with the Orbscan and Keratograph systems by the same clinician in a random order during the preoperative visit. An automated WTW measure was obtained with both the Orbscan (OA) and Keratograph (KA) systems in order to compute the inter-device agreement in the automated mode. Two trained examiners (examiners 1 and 2) conducted a manual measure over the same subject picture (OM and KM). The agreement between devices of the manual measure was calculated considering the measure taken by the examiner 1 with each device.

The examiner 1 also measured over the same image obtained with both devices, the WTW in three additional days (a total of four measures spaced 2 weeks) in a random order for avoiding remembering the measures taken in the previous days. The intra-examiner reproducibility was evaluated in two different modes: directly for the comparison between one measure at Days 1 and 3 (intra-examiner A) and for the comparison of the mean of two measures obtained from Days 1 and 3 versus 2 and 4 (intra-examiner B). The inter-examiner reproducibility for the

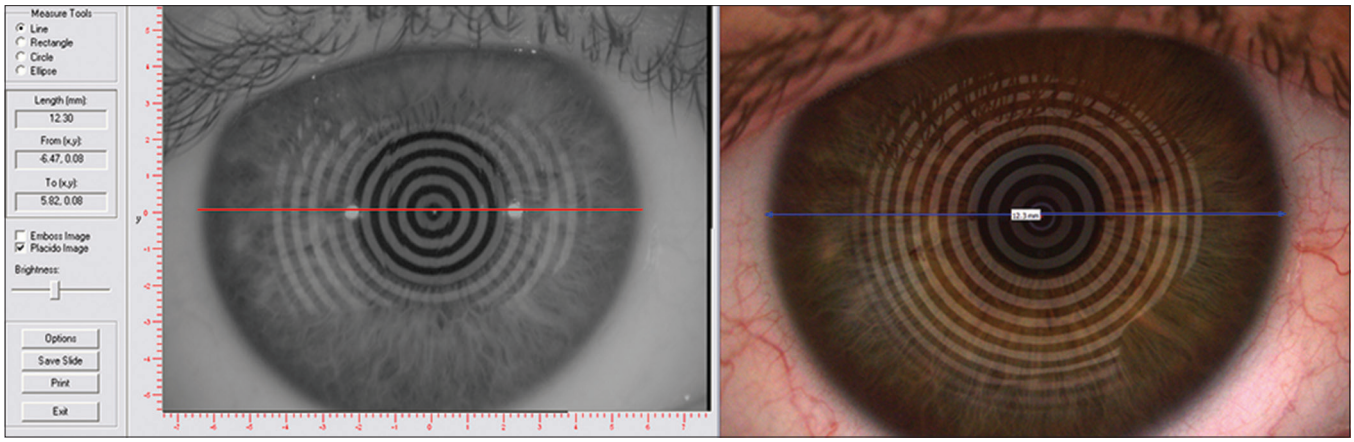

Figure 1: Image captures used for measuring the horizontal white-to-white with the Keratograph 5M (right) and Orbscan IIz (left) systems

manual measure obtained with each device was computed by means of the measure taken by examiners 1 and 2 at Day 1.

Probability of confounding ICL sizing

The probability of confusing sizing (PCS) was computed for those measured eyes with ACD ≥ 3 mm. This probability refers to the possibility of selecting a different sizing of the ICL due to the measurement bias of WTW. The ACD criterion was accomplished in 128 of the 192 eyes measured. The PCS was calculated comparing the ICL sizing obtained for each comparison performed and counting the number of cases for which the sizing was different. As example, for the inter-examiner reproducibility experiment, the ICL sizing was calculated for each examiner and the number of cases for which the examiners obtained a different sizing was divided by the total number of cases (n = 128). The mean of the two WTWs leading to a confounding sizing was computed with the aim of defining the distribution of WTWs with higher probability of different ICL sizing due to measurement bias.

Statistical analysis

The distribution of differences in the agreement and reproducibility experiments followed a normal distribution with the presence of some outliers. The outliers were not removed from the sample to remark these particular cases that are outside the limits of agreement (LoAs) and that are critical for computing the PCS. The agreement between manual and automated methods for measuring WTW with the Orbscan and Keratograph systems was represented by the mean differences with their corresponding LoAs (1.96 × standard deviation).[12] The reproducibility (S_R) was calculated with one-way analysis of variance (ANOVA) and the reproducibility limit (R) was equal to $1.96\sqrt{2}\,x\,S_R$.[13] The sample size used was considered enough to achieve 10% of confidence in the estimate as it has been previously reported.[13] The statistical analyses were performed using the SigmaPlot™ software (version 12, Systat Software, Inc.), Matlab, and IBM SPSS 20.0 for Windows (SPSS, Chicago, IL).

Results

Table 2 shows the results of the agreement analyses for manual and automated methods. The inter-device agreement showed an overestimation of the mean WTW using KM compared to OM (0.13 ± 0.18 mm, P < 0.001). This overestimation was reduced using the automated method (KA–OA), resulting in no significant mean differences between devices (0.01 ± 0.19 mm, P = 0.58). Furthermore, despite LoAs were slightly higher for the automated method (0.38 mm) compared to the manual (0.35 mm), the PCS associated to the agreement between automated methods was the lowest of all agreement analyses (14.8%). The Orbscan system showed higher mean differences (−0.09 ± 0.20 mm, P < 0.001) between the manual and automated methods (OM–OA) in comparison to the Keratograph (KM–KA) (0.03 ± 0.19 mm, P = 0.06), but with lower PCS associated [see PCS in Table 2].

Table 3 shows the results for the intra-examiner and inter-examiner reproducibility analyses. Mean differences were very similar for intra-examiner A and intra-examiner B analyses with both devices, but R was reduced when the mean from Day 1 and 3 was compared with the mean of Day 2 and 4 (intra-examiner B analysis). The reduction of the R after averaging the measures of 2 days led to a reduction of PCS from 18.8 to 11.7% using the

Table 1: Summary of the nomogram described in the FDA report (sizing A) and the re-adjusted (sizing B)

White-to-white (mm)	ACD (mm)	Sizing A (mm)	Sizing B (mm)
10.7-11.0	All	12.1	12.1
11.1	≤3.5	12.1	12.1
11.1	>3.5	12.6	12.6
11.2-11.4	All	12.6	12.6
11.5-11.6	≤3.5	12.6	12.6
11.5-11.6	>3.5	13.2	13.2
11.7-12.1	All	13.2	13.2
12.2	≤3.5	13.2	13.2
12.2	>3.5	13.7	13.2
12.3	≤3.5	13.7	13.2
12.3	>3.5	13.7	13.7
12.4-12.9	All	13.7	13.7

Table 2: Agreement between devices and measuring methods. Probability of selecting a different ICL sizing on each of the confronted measures

	MD±SD	*P*-value[a]	LoAs (mm)	PCS, *n* (%)
Manual				
KM-OM	0.13±0.18	<0.001	0.35	25 (19.5)
Auto				
KA-OA	0.01±0.19	0.58	0.38	19 (14.8)
Manual–auto				
KM-KA	0.03±0.19	0.06	0.37	31 (24.2)
OM-OA	−0.09±0.20	<0.001	0.39	21 (16.4)
OM-KA	−0.10±0.20	<0.001	0.39	28 (21.9)
KM-OA	0.03±0.21	0.03	0.41	24 (18.8)

[a]Paired *t*-test. MD=mean differences, SD=standard deviation, LoAs=limits of agreement, PCS=probability of confounding sizing, KA=automated measure with the Keratograph, OA=automated measure with the Orbscan, KM=manual measure with the Keratograph, OM=manual measure with the Orbscan, ICL=implantable collamer lens

Table 3: Reproducibility results for the Orbscan and Keratograph and probability of selecting a different ICL sizing on each of the confronted measures

	MD±SD	*P*-value[a]	S_R (mm)	R (mm)	PCS (%)
Orbscan					
Intra-examiner A	0.01±0.14	0.19	0.10	0.26	24 (18.8)
Intra-examiner B	0.01±0.10	0.17	0.07	0.19	15 (11.7)
Inter-examiner	−0.05±0.22	0.001	0.16	0.43	32 (25.0)
Keratograph					
Intra-examiner A	<0.01±0.13	0.51	0.09	0.26	14 (10.9)
Intra-examiner B	<0.01±0.07	0.69	0.05	0.14	8 (6.3)
Inter-examiner	0.04±0.14	<0.001	0.10	0.29	17 (13.2)

[a]Paired t-test= S_R reproducibility, S_R=reproducibility limit, PCS=probability of confounding sizing, MD=mean differences, SD=standard deviation, Intra-examiner A=reproducibility from one measure taken in two different days, Intra-examiner B=reproducibility from the average of measures taken in Days 1 and 3 versus the average of Days 2 and 4, ICL=implantable collamer lens

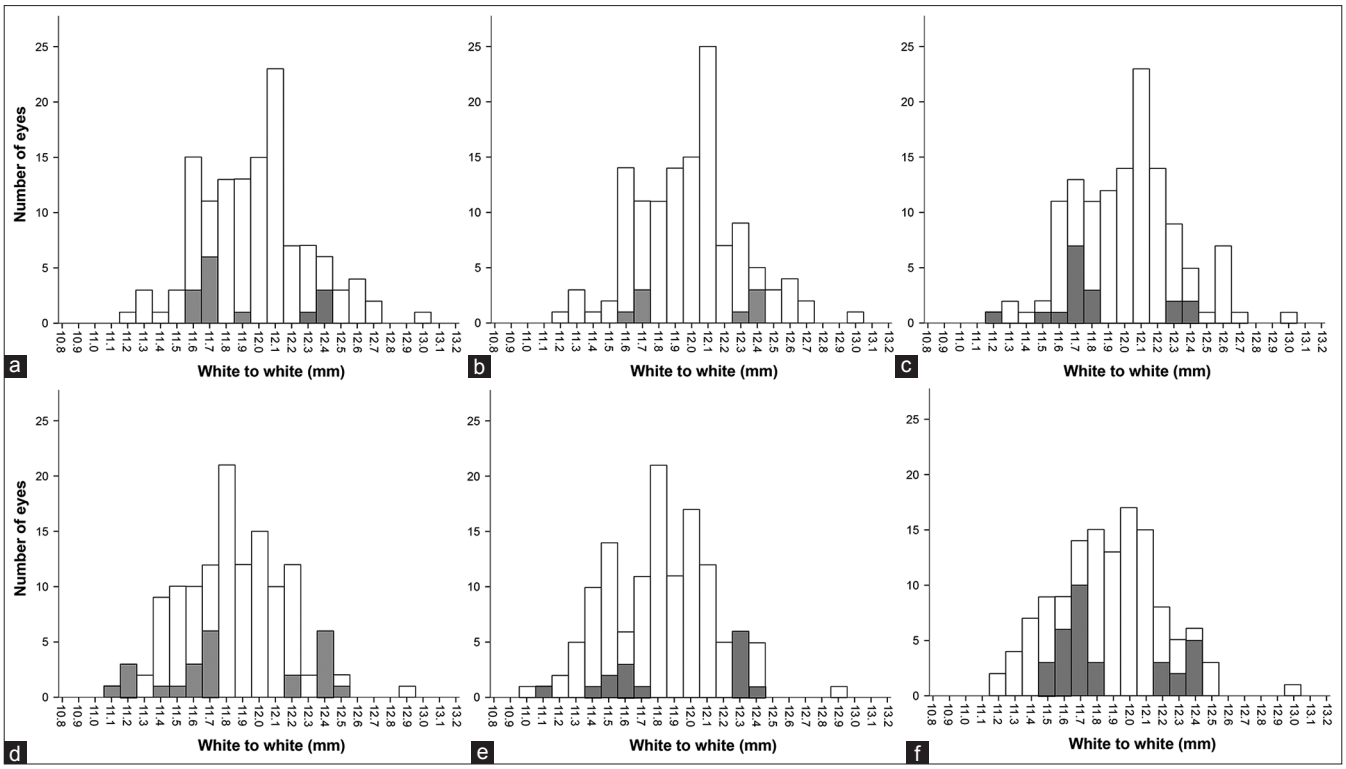

Figure 2: Total number of eyes for each particular white-to-white from 128 eyes with anterior chamber depth ≥ 3 mm (white bars) and the cases for which the two compared measures resulted in different implantable collamer lens sizings (gray bars). Obtained with the Keratograph intra-examiner A (a); intra-examiner B (b); inter-examinerer (c); and the Orbscan intra-examiner A (d); intra-examiner B (e); inter-examiner (f)

OM and from 10.9 to 6.3% using the KM. The inter-examiner reproducibility resulted in an important increment of *R* with the Orbscan system (0.43 mm), yielding the highest PCS from all the comparisons performed [see PCS in Table 3]. In fact, the mean differences of WTWs measured one time by two different examiners (inter-examiner) were statistically significant with both devices, although the *R* was lower with the Keratograph system.

Fig. 2 shows the distribution of all WTWs included in the reproducibility analyses. White bars describe the frequency of the mean of the compared measures, rounded to the first decimal, and the gray bars represent the number of cases for which the sizing was confounded for each mean of WTW. Top row of Fig. 2 shows the distributions obtained for the Keratograph reproducibility experiments for intra-examiner A [Fig. 2a], intra-examiner B [Fig. 2b], and inter-examiner [Fig. 2c]. The bottom row represents the same results for the Orbscan system: intra-examiner A [Fig. 2d], intra-examiner B [Fig. 2e], and inter-examiner [Fig. 2f]. The distributions for which the sizing was confused (gray bars) were similar in all experiments and characterized by a two peak-valley distribution, one centered approximately on 11.6–11.7 mm and the second one centered approximately on 12.3–12.4 mm for both devices. Furthermore, a third peak appeared only in the Orbscan between 11.1 and 11.2 mm due to the lower number of eyes around these values of WTW.

The standard deviations from the means of the Days 1 and 3 (intra-examiner A) were computed for all cases in which the ICL sizing was confounded [gray bars in Fig. 2]. The maximum tolerated standard deviation for not confounding the sizing of the ICL in those WTWs with higher PCS was 0.07 mm and this tolerance was increased by adding 0.07 mm for each 0.1 mm more of WTW around the peaks of maximum confusion as shown in Table 4.

Discussion

The precise measure of WTW is of great importance to compute the ICL sizing leading to a vault inside the recommended range of values. The standard method for computing the ICL sizing is the OCOS of STAAR.[11] We found that the OCOS algorithm has some small discrepancies compared to the STAAR sizing nomogram included in the FDA report as 94.7% of cases matched the results retrieved from our historical database of ICL implants.[5] Therefore, we performed a re-adjustment of this nomogram to obtain an agreement of 100% between the FDA nomogram and our historical data based on the use of the OCOS. It should be considered that our re-adjusted nomogram may not necessarily be implemented by the OCOS.

Several studies have reported the use of WTW and manufacturer recommendations to compute the ICL sizing.[14-18] These studies usually use the Orbscan system to measure the WTW, but not reporting the number of measures[14–17] or if measures had been masked in case of being manual.[18] In the current study, we have detected the critical WTWs for which the bias due to a manual measure can lead to a selection of a different ICL sizing depending on the measurement system, the number of masked measures taken, or the clinician (examiner) who conducts the manual measure.

Venkataraman *et al.*[19] found that automated Orbscan measurements underestimated the WTW length when compared

to those provided by the Eyemetrics tool by an average of 0.19 mm. Our results are not consistent with their observation. Indeed, we found that the automated measurement provided by the Orbscan system only overestimates that obtained with the Eyemetrics tool by an average of 0.09 mm. Furthermore, we found that the automated measures of the Orbscan and Keratograph systems were completely interchangeable, with no significant mean differences among them and additionally with the lowest PCS of all the agreement analyses. Mean differences between the Orbscan and Keratograph automated WTW measures were lower than those reported with when the Orbscan system was compared with other devices, such as the iTrace,[20] IOL Master,[21] Galilei,[22] EyeSys,[22] and Pentacam.[23]

Our results suggest that the Eyemetrics tool is less accurate for measuring WTW, possibly due to more significant difficulty to detect the gray transition between the cornea and sclera. In fact, the Eyemetrics tool showed a poorer reproducibility compared to the manual measure with the Keratograph system, either in intra-examiner or inter-examiner analyses. This can be one of the reasons explaining the discrepancy between our results and those reported by Venkataraman *et al*.[19] Furthermore, it is important to note that our reproducibility data are only applicable to the Orbscan IIz and Eyemetrics (version 3.14) and current versions might offer different reproducibility results.

Guber *et al*.[3] defined the conversions required to calculate the ICL sizing if the automated Orbscan approach was not used. In our series, we demonstrated that although the mean difference between devices measuring WTW is close to zero, such as happened with OA and KA, there is a risk of obtaining a different ICL sizing due to the width of LoAs (PCS of 14.8% associated to the agreement OA vs. KA). The PCS depends not only on the mean differences between devices but also on the LoAs and *R* of the agreement and reproducibility analyses, respectively. Therefore, it is important to consider both analyses before deciding changing the method of measuring WTW, and not only the mean difference between methods. This tendency of higher PCS as the mean difference and *R* increases can be clearly seen in Table 3. However, this trend is not so evident in Table 2 for mean differences and LoAs.

Besides all analyses previously described, we identified the WTWs with greater risk associated of leading to a confounding ICL sizing due to a bias in the measurement obtained with the manual method (11.1–11.2 mm, 11.6–11.7 mm, and 12.3–12.4 mm). According to the results of this study, the following recommendations to reduce the risk of different ICL sizing selection due to manual measure bias have been defined:

1. Take a frontal eye picture to compute the sizing.
2. Take two masked horizontal manual measures with the caliper rounded to the first decimal.
3. Compute the mean and standard deviation from both measures.
4. Locate the range in which your mean is included in Table 4. If the standard deviation is equal or less than the described in the table (rounded to the second decimal), consider the mean as the final WTW. If this is not the case, continue to the point five.
5. If the standard deviation is greater than that shown in Table 4, the clinician can use different approaches for increasing the number of averaged measures up to reduce the levels of standard deviation below the described in Table 4. For instance, to capture more than one image, increase the number of masked measures, average the measures with the obtained by other clinician, and so on.

Table 4: Maximum tolerated standard deviation from the mean of two masked manual measures for which the sizing can be confused if the mean is inside of a specific range of WTW

White-to-white range (mm)	Maximum tolerated SD (mm)
<12.9	0.28
10.9–10.99	0.21
11.0–11.09	0.14
11.1–11.19	0.07
11.2–11.29	0.14
11.3–11.39	0.21
11.4–11.49	0.21
11.5–11.59	0.14
11.6–11.69	0.07
11.7–11.79	0.14
11.8–11.89	0.21
11.9–11.99	0.28
12.0–12.09	0.28
12.1–12.19	0.21
12.2–12.29	0.14
12.3–12.39	0.07
12.4–12.49	0.14
12.5–12.59	0.21
>12.6	0.28

To follow our recommendations does not mean that the vault is going to be inside the recommended range after surgery. The vault depends on multiple variables such as WTW, ACD, age, refractive error,[24,25] pupil diameter,[26] and the presence of ciliary sulcus microcysts.[27] Consequently, the vault cannot be quantitatively predicted despite some regression models that have been proposed with some of these variables.[28] This means that our recommendations allow the clinician to minimize one of the sources of variability, the variations in the selection of the ICL size depending on the accuracy of WTW measurement.

Conclusion

In conclusion, the automated measures of WTW obtained with the Orbscan and Keratograph systems can be considered as interchangeable, whereas some special considerations should be taken into account when the manual measure is used, such as the number of masked measures averaged. For WTWs from 11.1 to 11.2 mm, 11.6 to 11.7 mm, and 12.3 to 12.4 mm, the probability of selecting different ICL sizing depending on the method used to measure the WTW is higher and the number of average measures should be increased up to obtain a standard deviation below our recommendations. Finally, mean differences, LoAs, and *R* are highly important to improve the precision of ICL sizing computing.

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Conflicts of interest

There are no conflicts of interest.

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