

## Correcting inter-device bias of horizontal white-to-white and sulcus-to-sulcus measures used for implantable collamer lens sizing

Ivo Guber, MD<sup>1</sup>, Ciara Bergin, PhD<sup>1</sup>, Sylvie Perritaz, Optom<sup>1</sup>, François Majo, MD, PhD<sup>1</sup>

<sup>1</sup> Department of ophthalmology, University of Lausanne, Fondation Asile des aveugles, Jules-Gonin Eye Hospital, Lausanne, Switzerland

**Key words:** ICL; sulcus-to-sulcus; white-to-white; corneal diameter; UBM; Pentacam, HiScan; Biograph; Lenstar; Phakic Lens; vaulting; nomogram; ICL sizing.

**Short title:** Improving implantable collamer lens sizing

### Corresponding author:

François Majo, MD, PhD

Department of ophthalmology, University of Lausanne

Fondation Asile des aveugles, Jules-Gonin Eye Hospital,

Cornea and Refractive Surgery Unit, Anterior Pole.

Avenue de France 15, 1000 Lausanne 7, Vaud, Switzerland

Phone: +41 (0) 21 626 81 11; Fax: +41 (0) 21 626 88 89; E-mail: [fmajo@bluewin.ch](mailto:fmajo@bluewin.ch)

## **ABSTRACT**

**PURPOSE:** To assess the agreement and repeatability of horizontal white-to-white (WTW) and horizontal sulcus-to-sulcus (STS) diameter measurements and use this data in combination with available literature to correct for inter-device bias in pre-operative implantable collamer lens (ICL) size selection.

**DESIGN:** Inter-instrument reliability and bias assessment study.

**METHODS:** A total of 107 eyes from 56 patients assessed for ICL implantation at our institution were included in the study. This was a consecutive series of all patients with suitable available data. The agreement and bias between WTW (measured with the Pentacam and BioGraph devices) and STS (measured with the HiScan device) were estimated.

**RESULTS:** The mean spherical equivalent was  $-8.93D \pm 5.69D$ . The BioGraph measures of WTW were wider than those taken with the Pentacam (bias= 0.26 mm,  $p < 0.01$ ), and both horizontal WTW measures were wider than the horizontal STS measures (bias  $> 0.91$  mm,  $p < 0.01$ ). The repeatability (Sr) of STS measured with the HiScan was 0.39 mm, which was significantly reduced (Sr=0.15 mm) when the average of two measures were used. Agreement between the horizontal WTW measures and horizontal STS estimates when bias was accounted for was  $r=0.54$  with the Pentacam and  $r=0.64$  with the BioGraph.

**CONCLUSIONS:** Large inter-device bias was observed for WTW and STS measures. STS measures demonstrated poor repeatability, but the average of repeated measures significantly improved repeatability. In order to conform to the Federal Drug Administration's accepted guidelines for ICL sizing clinicians should be aware of and account for the inconsistencies between devices.

## INTRODUCTION

The number of refractive surgery cases continuously increases; this is in line with the patients' expectation to achieve a perfect visual outcome, which demands highly accurate pre-operative measures. A primary example of this is the implantable collamer lens (ICL; Staar Surgical, Monrovia, California, USA), which is a posterior chamber type phakic intraocular lens designed to be implanted in the ciliary sulcus. The FDA approved method of ICL size determination is the conventional STAAR sizing nomogram that indicates the size using two ocular parameters: horizontal white-to-white (WTW=distance from limbus to limbus/corneal diameter) and anterior chamber depth (ACD).<sup>1</sup> This method of determining the ICL size relies predominately on the horizontal WTW measurement; which relies on the assumption that there is a correlation between the white-to-white distances and the sulcus iridociliaris.<sup>2,3</sup>

An incorrect ICL-size will result in a suboptimal vaulting (distance between the anterior lens surface and the ICL), which has been associated with number of visually significant postoperative complications.<sup>4-12</sup> Despite efforts to improve predictability of vault following ICL implantation, it remains poor; the reasons for this are multiple.<sup>5,13-23</sup> High-frequency ultrasound biomicroscopy (UBM) with a wide scanning field has enabled direct measurement of horizontal sulcus-to-sulcus (STS) diameter. Poor correspondence ( $r < 0.50$ ) between the horizontal WTW and STS measure has since been reported, however the width of the limits of agreement (LoA) reported between horizontal WTW and STS measures is similar to repeatability limits of STS estimates. UBM devices have relatively low precision in STS estimates (coefficient of variation (CoV): Artemis NA; HiScan 0.9-2.7%<sup>16,24</sup>; VuMax 5%<sup>25</sup>) as compared to horizontal WTW measures of Scheimpflug imaging or partial low-coherence interferometry (CoV: Orbscan 0.7%-1%<sup>24</sup>; Galilei Sirius  $< 0.5\%$ <sup>26,27</sup>; IOLMaster 2%<sup>28</sup>; Lenstar 0.2%<sup>23</sup>). For example, Yokoyama et al. have reported the within subject repeatability ( $S_w$ ) of the Vumax UBM device to be approximately 0.53mm (confidence interval (CI) of repeatability -1.1mm, 1.5mm).<sup>25</sup> Afterwards Biermann et al. reported a “*poor*” level of agreement between the STS as measured with Vumax and horizontal WTW measured with Orbscan and IOLMaster, with a LoA of approximately (-0.7mm,-0.1mm) and (-0.4mm,+0.6mm) respectively (figure 5C pg. 1690), but since the inter-device agreement (between Vumax and Orbscan/IOLMaster) is better than intra-device precision (Vumax with itself), a conclusion of “*poor*” agreement is unsupported.<sup>18</sup> In another article on UBM Artemis device, the CoV for STS measures was estimated as 0.4%, referencing a study on metallic bolt (not an eye), before reporting the “*poor*” agreement between the Artemis UBM and the Orbscan.<sup>2</sup> Considering the higher axial resolution than lateral resolution with UBM devices (50MHz probe: axial resolution 30-40 $\mu$ m and lateral resolution 50-60 $\mu$ m) and since central corneal thickness is a more clearly defined anatomical structure with less to inhibit clear imaging, it is reasonable that repeatability of central corneal thickness would be at least as good as STS. Therefore since the repeatability of the Artemis in central corneal thickness has since been established  $\sim 2\%$ , it seems reasonable to propose the CoV of STS measures would be at least as wide as that of the CCT, which would translate to LoA in STS of  $> \pm 0.25$ mm. This would explain up to 50% of the disagreement observed between STS (Artemis) and horizontal WTW (Orbscan) measures.<sup>2,29</sup> In short, different levels of measurement noise/calibration between measurement devices confound comparison.

The following study examines three index measures, namely the STS diameter determined with ultrasound biomicroscopy (HiScan®), and the horizontal WTW distance measured with two different devices (Pentacam® and BioGraph®). The repeatability of each and the agreement between these index measures was assessed and in a large number of myopic and hyperopic patients undergoing ICL-implantation. The BioGraph and HiScan devices were selected based on the high level of precision accorded to each.<sup>23-25,29-32</sup> Our ultimate aim was to combine these results with those available in the literature and to provide an inter-device conversion table in

order to better comply with the STAAR nomogram for ICL sizing.

## METHODS

This study conformed to the declaration of Helsinki and was approved retrospectively by the cantonal ethic committee of Vaud (Authorization no. 035.0003-48).

### Patients

All patients came with the desire for refractive surgery to a specialized consultation of the unit for cornea and refractive surgery at the Jules-Gonin Eye Hospital, Lausanne.

### Methods

This is inter-instrument reliability and bias assessment using retrospective data, from a review of the ICL database of all consecutive patients, who had undergone pre-operative ICL assessment, between January 2000 and June 2014. In total 210 eyes of 107 patients were reviewed; of which 125 eyes of 65 patients had Pentacam measures available, 124 eyes of 64 patients had BioGraph measures available, and 116 eyes of 59 patients had UBM available, 107 eyes of 56 patients had all three measures available. There were no further inclusion or exclusion criteria applied to the study cohort.

All patients were measured with Pentacam HR and BioGraph as part of preoperative evaluation for refractive surgery. If the patients were considered to be suitable candidates for ICL implantation, a UBM measure of the ciliary sulcus was additionally performed. Prior to the measurement one eyedrop of pilocarpin nitrate 2% (Bausch and Lomb, Surrey, UK) was instilled in order to achieve the best possible alignment of the UBM handpiece with the horizontal and vertical STS. All measurements were carried out by the same experienced optometrist (SP).

#### • Measurements:

**Index test 1)** Pentacam HR® (Oculus; Optikgeräte GmbH, Wetzlar, Germany software version 1.20r02). Corneal tomography measurements in the 25-picture mode, scans were taken in automatic release mode. If the system considered the measurement to be unreliable, the measurement was repeated. Only measurements with a quality factor (Q) “OK”, as displayed by the system, were used for analysis. Testing was conducted with the patient’s natural pupils under mesopic conditions. The horizontal WTW was determined manually on the Scheimpflug image no. 17/25, as it represents the horizontal axis (183 degree; (Figure 1, top panel)). The caliper function available within the device was used to measure the distance from the anterior corneal-scleral transition point from one side to the other (Figure 1, top panel). Two images taken of the same eye from pre-operative follow-up visits were assessed by a single observer to estimate the repeatability of this measure.

**Index test 2)** The ALLEGRO BioGraph (Wavelight AG) /BioGraph LS 900 (Haag Streit AG) is a multifunctional device which is used in preoperative patient evaluation before cataract surgery and other procedures of refractive surgery. It is based on optical low coherence interferometry (OLCI) which captures 16 images in sequence. Along with standard biometry measures this device additionally provides a measurement of pupil diameter and visual axis, and horizontal WTW diameter (Figure 1, center panel).

**Index test 3)** A high-frequency B-scan diagnostic ultrasound biomicroscopy imaging system (Optikon HiScan, Optikon 2000 SpA, Rome, Italy) was employed in the present study. The system can capture the entire anterior segment in a single scan (Figure 1 bottom panel). A probe with a 35 MHz transducer was used for STS measurement. The axial and lateral resolution

is 70  $\mu\text{m}$  in the anterior segment with a penetration of 7-8 mm. The calliper function available within the device was used to measure the distance of the horizontal ciliary sulcus from one side to the other (Figure 1, bottom panel). The repeatability of STS measurements has been previously evaluated, and the coefficient of variation was 2.7%.<sup>26</sup> To reduce measurement error 4-6 UBM images were taken and the average STS measure was reported (0.9% as estimated by Oh et al.<sup>16</sup>). A single, experienced examiner (SP) carried out all UBM measurements.

#### • Statistical analysis

Data were exported and imported into R version 2.15.120 for analysis. Parameters used in analysis were age, spherical equivalence (SE), axial length (AL), intraocular pressure (IOP), anterior chamber depth (ACD), WTW as measured with the Pentacam and the BioGraph and STS as measured with the HiScan. Data were split into three subgroups for 3 parameters for sub-analysis: ACD; shallow <3.2mm, medium 3.2mm-3.4mm and deep >3.4mm as previously reported by Gao et al.<sup>3</sup> AL: moderate<25.0mm, long 25.0-27.0 and very long >27; SE: Hyperopia to moderate myopia up to -6D, high myopia -6 to -10D and very high myopia stronger than -10D. For UBM measures between 4 and 6 measures were taken, and the average of the full set of measures was using in the agreement analysis. As per the British Standards Institute and the International Organization for Standardization, repeatability (Sr) (the within-subject SD for repeated measures with the same observer) was derived using a one-way analysis of variance (ANOVA). For the HiScan device the STS estimate was the outcome and image number (1-6), patient (1-54) and eye (right/left) were covariates. For the Pentacam device, the horizontal WTW estimate was the outcome and image number (1-2), patient (1-48) and eye (right/left) were covariates.

## RESULTS

One-hundred and seven eyes of 56 patients were analyzed. Mean spherical equivalent was  $-8.9\text{D}$  SD  $\pm 5.67\text{D}$ , mean axial length was  $26.67\text{mm}$ , SD  $\pm 2.44\text{mm}$  and mean ACD was  $3.17\text{mm}$ , SD  $\pm 0.25\text{mm}$ . The baseline characteristics of these eyes are given in Table 1. A summary has been given based on spherical equivalence (SE), where those with SE of  $>-6\text{D}$ , those with SE  $-6\text{D}$  to  $-10\text{D}$  and very high myopes ( $<-10\text{D}$ ) are compared. Furthermore, those eyes with astigmatism have been characterized (Table 1). Notably the horizontal WTW measures taken with the BioGraph were significantly wider than those taken with the Pentacam (bias:  $0.26\text{mm}$ ,  $p<0.01$ ) and the STS measures (bias:  $1.17\text{mm}$ ,  $p<0.01$ ), also the horizontal WTW measures taken with the Pentacam were significantly wider than the STS (bias:  $0.91\text{mm}$ ,  $p<0.01$ ). The relationship between horizontal WTW/ACD and horizontal WTW/axial length has been given in Figure 2. Here the horizontal WTW (Pentacam and BioGraph) and STS (UBM) measures were significantly smaller in eyes with shallow ACD ( $<3.2\text{mm}$ ) than in eyes with medium ( $3.2\text{-}3.4\text{mm}$ ) or deep ACD (with the exception of horizontal WTW measures using the Pentacam in eyes with deep and shallow ACD). There were no significant differences observed in the horizontal WTW measures of eyes in terms of axial length, however there were significant differences observed in the STS measures of moderate versus long or very long eyes (Figure 2). Vertical and horizontal STS diameters were highly correlated ( $p<0.001$ ), however vertical STS was significantly larger than horizontal STS by approximately  $0.4\text{mm}$ , 4% of eyes had the inverse.

### Repeatability of ultrasound biomicroscopy measures:

The HiScan UBM measures were less repeatable than expected with a Sr of  $0.39\text{mm}$  between any two images and a 95% CI of  $\pm 0.76$  (shown with dotted horizontal line in Figure 3). Repeatability index improved to Sr of  $0.15\text{mm}$  when the average of two measures was used (solid horizontal line Figure 3); therefore, it is safe to assume that the repeatability is less than  $0.15\text{mm}$  when the average of 4 or more images was used. Similar repeatability was observed between single measures of vertical STS (Sr= $0.26\text{mm}$ ).

### Repeatability of horizontal white to white in Pentacam measures:

Two images with image quality rated as “OK” within the device software were available on 89 eyes of 48 study patients. The manual method for horizontal WTW assessment showed good repeatability, with Sr= $0.13\text{mm}$  and a CoV of 1%.

### Agreement between devices:

The agreement between the devices was examined using Bland Altman plots (Figure 4), limits of agreement and Pearson correlation coefficients. The horizontal WTW measures as taken with the Pentacam and the BioGraph showed good agreement ( $r=0.73$ ) with some systematic bias ( $-0.26\text{mm}$ ) and relatively tight limits of agreement (95% CI  $-0.93$ ,  $+0.41$ ). Comparing the horizontal WTW of the Pentacam with the STS showed moderate agreement ( $r=0.54$ ) with a large systematic bias ( $0.91\text{mm}$ ) with wide limits of agreement (95% CI  $-0.15$ ,  $1.97$ ). Comparing the horizontal WTW of the BioGraph with the STS showed moderate agreement ( $r=0.64$ ) with a larger systematic bias ( $1.17\text{mm}$ ) with wide limits of agreement (95% CI  $+0.26$ ,  $2.07$ ). The agreement between the ACD measures was better between BioGraph and Pentacam than between these two devices and UBM ( $r=0.99$  vs  $r=0.88/0.87$ ).

The relationship between systematic error and noise was examined with respect to SE, ACD and AL, the analysis is given in Table 2 using analysis of variance and accounting for pairs of eyes. On comparing the horizontal WTW measures of the Pentacam and BioGraph we see

that the bias was significantly less in eyes with deep ACD than shallow ( $p=0.02$ ). The agreement was best between horizontal WTW and HCS estimates in eyes with average anterior chamber depth (BioGraph vs UBM Pearson  $r = 0.74$ ).

In Table 3 we provide a device conversion table to be used with the STAAR nomogram (or any replacement ICL sizing methodology) established from results of this study and the available literature (PubMed search with the keywords: corneal diameter, white-to-white, horizontal ciliary sulcus diameter, repeatability, precision, agreement, Pentacam, IOLMaster, Scheimpflug, Topography, UBM, ultrasound biomicroscopy, Orbscan, Vumax, Galilei, Lenstar, Biograph, Artemis, Hiscan).



## DISCUSSION

This study provides information on the inter-device bias with measuring STS and horizontal WTW. This is important as with the current STAAR nomogram for calculation of the ICL size, a larger ICL size is proposed every  $\sim 0.4\text{mm}$  of increasing horizontal WTW distance.<sup>1</sup> Therefore with the observed bias, large errors in sizing are possible due to differences between instruments. For example the LoA between the Pentacam and BioGraph estimates of horizontal WTW (bias of  $-0.26\text{mm}$   $\text{SD}=0.34$ ) observed here, were similar to that previously reported between Lenstar and Scheimpflug device.<sup>30, 32, 33</sup> This equates to the Pentacam indicating an ICL size one increment smaller than that by the BioGraph in approximately 35% of cases. Matters are considerably worse between STS vs horizontal WTW with a very large variance and systematic error (bias of up to  $1.2\text{mm}$ ) between measures, indicating that rarely ( $<10\%$  of cases) would the same ICL size be chosen. In this article the STS estimates were considerably narrower than the horizontal WTW estimates (absolute bias:  $> 0.9\text{mm}$ ). These results agree with some estimates of bias between horizontal WTW and STS estimates previously reported (bias  $-0.9\text{mm}$ ),<sup>19</sup> but are completely contradictory of others (bias:  $0.9\text{mm}$ ; bias:  $0.5\text{mm}$ ; bias:  $0.4\text{mm}$ ).<sup>2, 18, 24</sup> This shows that there is very poor agreement between UBM devices in STS estimates (bias up to  $1.2\text{mm}$ , 3 ICL sizes), highlighting the need for a conversion table between devices.

Table 3 is of particular relevance as several authors have already suggested new nonograms for use with STS estimates.<sup>21, 23, 34, 35</sup> A summary of available literature (to the best of our knowledge, based on a PubMed search) on agreement between horizontal WTW and STS, showed that the Orbscan device was included in the largest proportion of articles, followed by reports including the IOLMaster. Therefore, the conversion table below gives the estimated bias correction necessary when moving from the Orbscan to each of the other devices. To validate this conversion table, a second table summarizing the conversion of IOLMaster to three different devices was included (Table 4). Importantly, Table 4 used non-overlapping literature, using Table 3 and 4 a conversion loop of Orbscan to each of these three different devices, then to IOLMaster was created to demonstrate that the result is compatible with direct conversion (Orbscan to IOLMaster, Table 3). Here it was observed that the difference between the conversion loop and the direct conversion was  $\leq 0.1\text{mm}$ , this indicates that the conversion table performs well. As more literature becomes available it can be compiled within this table to strengthen it. We suggest that the surgeon specify the device used such that the manufacturer may account for the respective systematic bias via this conversion table when calculating the ICL size.

In our study the relationship between horizontal WTW and STS was good, especially in highly myopic eyes ( $r=0.69$ ) or eyes with medium ( $3.2\text{mm}$ - $3.4\text{mm}$ ) ACD ( $r=0.74$ ). A full literature search was completed on PubMed with the keywords as previously described. In this study the correlation between the two horizontal WTW measures was marginally higher than the correlation with STS, comparing the results of these studies; we observed very similar results as reported between horizontal WTW measures with optical low coherence reflectance biometry and scanning slit lamp imaging devices.<sup>24, 30, 36</sup> Several authors have reported poor correlation between horizontal WTW and STS, however some important considerations were observed on reviewing this literature: Fea et al. used magnetic resonance imaging which cannot produce clear images of the posterior chamber structures.<sup>15</sup> Werner et al. measured the horizontal sulcus diameter with digital calipers after dissection of cadaver eyes.<sup>14</sup> Pop et al. used analog ultrasound microscopy to measure STS, where the lateral scan width is insufficient to image sulcus diameters in 1 scan sweep.<sup>13</sup> On the other hand Kawamorita et al. examined the agreement of the HiScan and Orbscan devices, and reported a similar correlation between STS and horizontal WTW as reported here.<sup>24</sup> The repeatability of the UBM in our study was worse than reported in the

literature; however, using the average of several measures significantly reduced the LoA, making these compatible to limits of repeatability reported with Scheimpflug methods.

ACD measures taken with the BioGraph or the Pentacam correlate very well with one another with near perfect agreement, comparatively these measures do not correlate well with the ACD estimate taken with the HiScan. Gao et al. previously reported a difference in the correlation between STS and horizontal WTW in shallow and deep eyes.<sup>3</sup> Caution should be taken when used the ACD measures from the HiScan device.

The correct distance from the anterior capsule of the crystalline lens to the posterior surface of the ICL or vault is an important consideration. In general, an acceptable vault height is between 250  $\mu\text{m}$  and 1000  $\mu\text{m}$ .<sup>5</sup> In the preoperative evaluation of patients potentially suitable for ICL implantation it is very important to highlight those patients who are at high risk of improper sizing of the ICL and consequently incorrect ICL vaulting. Apart from device related measurement error, the limitation of ICL sizes is problematic, currently only 500 $\mu\text{m}$  increments are available and the range of the ideal vaulting is relatively narrow by comparison. Lee et al. have demonstrated that there is a relationship between the achieved vault and difference between the horizontal WTW/STS measures and ICL sizes.<sup>22</sup> If the ICL implant was available in smaller increments this would facilitate the weakening of this relationship as the difference between the horizontal WTW/STS and ICL size choice could be decreased.

In conclusion the relationship between the horizontal ciliary sulcus diameter and white-to-white distance is good especially in eyes with average ACD or high myopia. Care should be taken with the STS estimate for ICL sizing considering the relatively poor repeatability with UBM; however repeatability can be significantly improved when the average of repeated measures is used. Furthermore there is large systemic bias between devices in estimates of horizontal WTW (e.g. BioGraph vs Pentacam) and between estimates of horizontal WTW and STS (e.g. Pentacam vs HiScan) and between estimates of STS (Artemis vs HiScan). The large bias reported here, had been observed at our clinic and until this point was subjectively adjusted for. In this article we have attempted to estimate an appropriate error correction for all currently reported devices with the inclusion of a conversion table to be used in conjugation with the STAAR nomogram for ICL sizing.

## **ACKNOWLEDGMENTS/DISCLOSURE**

- a. Funding/Support: none
- b. Financial Disclosures: "No financial disclosures."
- c. Other Acknowledgments: none

## REFERENCES

1. AG SS. Visian ICL (Implantable Collamer Lens) For Myopia. Visian ICL Product Information, 2005. Available at: [http://www.accessdata.fda.gov/cdrh\\_docs/pdf3/P030016c.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf3/P030016c.pdf). Accessed August 24 2015.
2. Reinstein DZ, Archer TJ, Silverman RH, Rondeau MJ, Coleman DJ. Correlation of anterior chamber angle and ciliary sulcus diameters with white-to-white corneal diameter in high myopes using Artemis VHF digital ultrasound. *J Refract Surg* 2009;25:185-194.
3. Gao J, Liao R-F, Li N. Ciliary sulcus diameters at different anterior chamber depths in highly myopic eyes. *J Cataract Refract Surg* 2013;39:1011-1016.
4. Guber I, Chokri L, Majo F. [Preoperative sizing of the TICL (Toric Implantable Collamer Lens): the largest was too small!]. *Klin Monbl Augenheilkd* 2012;229:457-458.
5. Gonvers M, Bornet C, Othenin-Girard P. Implantable contact lens for moderate to high myopia: relationship of vaulting to cataract formation. *J Cataract Refract Surg* 2003;29:918-924.
6. Trindade F, Pereira F. Cataract formation after posterior chamber phakic intraocular lens implantation. *J Cataract Refract Surg* 1998;24:1661-1663.
7. Fink AM, Gore C, Rosen E. Cataract development after implantation of the Staar collamer posterior chamber phakic lens. *J Cataract Refract Surg* 1999;25:278-282.
8. Chung T-Y, Park SC, Lee MO, Ahn K, Chung E-S. Changes in iridocorneal angle structure and trabecular pigmentation with STAAR implantable collamer lens during 2 years. *J Refract Surg* 2009;25:251-258.
9. Rosen E, Gore C. Staar collamer posterior chamber phakic intraocular lens to correct myopia and hyperopia. *J Cataract Refract Surg* 1998;24:596-606.
10. Khalifa YM, Goldsmith J, Moshirfar M. Bilateral explantation of Visian Implantable Collamer Lenses secondary to bilateral acute angle closure resulting from a non-pupillary block mechanism. *J Refract Surg* 2010;26:991-994.
11. Schmidinger G, Lackner B, Pieh S, Skorpik C. Long-term changes in posterior chamber phakic intraocular collamer lens vaulting in myopic patients. *Ophthalmology* 2010;117:1506-1511.
12. Igarashi A, Shimizu K, Kamiya K. Eight-year follow-up of posterior chamber phakic intraocular lens implantation for moderate to high myopia. *Am J Ophthalmol* 2014;157:532-539.
13. Pop M, Payette Y, Mansour M. Predicting sulcus size using ocular measurements. *J Cataract Refract Surg* 2001;27:1033-1038.
14. Werner L, Izak AM, Pandey SK, Apple DJ, Trivedi RH, Schmidbauer JM. Correlation between different measurements within the eye relative to phakic intraocular lens implantation. *J Cataract Refract Surg* 2004;30:1982-1988.
15. Fea AM, Annetta F, Cirillo S, et al. Magnetic resonance imaging and Orbscan assessment of the anterior chamber. *J Cataract Refract Surg* 2005;31:1713-1718.

16. Oh J, Shin H-H, Kim J-H, Kim H-M, Song J-S. Direct measurement of the ciliary sulcus diameter by 35-Megahertz ultrasound biomicroscopy. *Ophthalmology* 2007;114:1685-1688.
17. Kim K-H, Shin H-H, Kim H-M, Song J-S. Correlation between ciliary sulcus diameter measured by 35 MHz ultrasound biomicroscopy and other ocular measurements. *J Cataract Refract Surg* 2008;34:632-637.
18. Biermann J, Bredow L, Boehringer D, Reinhard T. Evaluation of ciliary sulcus diameter using ultrasound biomicroscopy in emmetropic eyes and myopic eyes. *J Cataract Refract Surg* 2011;37:1686-1693.
19. Petermeier K, Suesskind D, Altpeter E, et al. Sulcus anatomy and diameter in pseudophakic eyes and correlation with biometric data: Evaluation with a 50 MHz ultrasound biomicroscope. *J Cataract Refract Surg* 2012;38:986-991.
20. Choi KH, Chung SE, Chung TY, Chung ES. Ultrasound biomicroscopy for determining Visian implantable contact lens length in phakic IOL implantation. *J Refract Surg* 2007;23:362-367.
21. Kojima T, Yokoyama S, Ito M, et al. Optimization of an implantable collamer lens sizing method using high-frequency ultrasound biomicroscopy. *Am J Ophthalmology* 2012;153:632-637.
22. Lee D-H, Choi S-H, Chung E-S, Chung T-Y. Correlation between preoperative biometry and posterior chamber phakic Visian implantable collamer lens vaulting. *Ophthalmology* 2012;119:272-277.
23. Dougherty PJ, Rivera RP, Schneider D, Lane SS, Brown D, Vukich J. Improving accuracy of phakic intraocular lens sizing using high-frequency ultrasound biomicroscopy. *J Cataract Refract Surg* 2011;37:13-18.
24. Kawamorita T, Uozato H, Kamiya K, Shimizu K. Relationship between ciliary sulcus diameter and anterior chamber diameter and corneal diameter. *J Cataract Refract Surg* 2010;36:617-624.
25. Yokoyama S, Kojima T, Horai R, Ito M, Nakamura T, Ichikawa K. Repeatability of the ciliary sulcus-to-sulcus diameter measurement using wide-scanning-field ultrasound biomicroscopy. *J Cataract Refract Surg* 2011;37:1251-1256.
26. Montalbán R, Piñero DP, Javaloy J, Alió JL. Intrasubject repeatability of corneal morphology measurements obtained with a new Scheimpflug photography-based system. *J Cataract Refract Surg* 2012;38:971-977.
27. Savini G, Carbonelli M, Barboni P, Hoffer KJ. Repeatability of automatic measurements performed by a dual Scheimpflug analyzer in unoperated and post-refractive surgery eyes. *J Cataract Refract Surg* 2011;37:302-309.
28. Huang J, Savini G, Li J, et al. Evaluation of a new optical biometry device for measurements of ocular components and its comparison with IOLMaster. *Br J Ophthalmol* 2014;98:1277-1281.
29. Ogbuehi KC, Osuagwu UL. Repeatability and interobserver reproducibility of Artemis-2 high-frequency ultrasound in determination of human corneal thickness. *Clin Ophthalmol* 2012;6:761.

30. Chen W, McAlinden C, Pesudovs K, et al. Scheimpflug–Placido topographer and optical low-coherence reflectometry biometer: Repeatability and agreement. *J Cataract Refract Surg* 2012;38:1626-1632.
31. Shammas HJ, Hoffer KJ. Repeatability and reproducibility of biometry and keratometry measurements using a noncontact optical low-coherence reflectometer and keratometer. *Am J Ophthalmol* 2012;153:55-61.
32. Zhao J, Chen Z, Zhou Z, Ding L, Zhou X. Evaluation of the repeatability of the Lenstar and comparison with two other non-contact biometric devices in myopes. *Clin Exp Optom* 2013;96:92-99.
33. Chen Y-A, Hirschschall N, Findl O. Evaluation of 2 new optical biometry devices and comparison with the current gold standard biometer. *J Cataract Refract Surg* 2011;37:513-517.
34. Ghoreishi M, Mohammadinia M. Correlation between preoperative sizing of implantable collamer lens (ICL) by white-to-white and sulcus-to-sulcus techniques, and postoperative vault size measured by Scheimpflug imaging. *J Clin Exp Ophthalmol* 2014;5:2.
35. Reinstein DZ, Lovisolo CF, Archer TJ, Gobbe M. Comparison of postoperative vault height predictability using white-to-white or sulcus diameter-based sizing for the Visian implantable collamer lens. *J Refract Surg* 2013;29:30-35.
36. Martin R, Ortiz S, Rio-Cristobal A. White-to-white corneal diameter differences in moderately and highly myopic eyes: Partial coherence interferometry versus scanning-slit topography. *J Cataract Refract Surg* 2013;39:585-589.

## FIGURE LEGENDS

**Figure 1.** (top) Pentacam Scheimpflug image no 17 of 25 at 183° with the anterior corneal scleral transition delineated (center) BioGraph iris photo with limbus border delineated (bottom) HiScan 35MHz ultrasound biomicroscopy (UBM) image with sulcus-to-sulcus (STS) and anterior chamber depth (ACD) marked with the calipers.

**Figure 2.** Boxplots showing the relationship between white to white measures and the anterior chamber depth (ACD; top row) and the axial length (bottom row) with each of the three study instruments (Pentacam column 1, BioGraph column 2, and HiScan ultrasound biomicroscopy (UBM) column 3). Significant differences are denoted with an asterisk on with the respective groups indicated. The heavy horizontal lines bisecting each box denotes the median, the top and bottom of the box the interquartile range, the foot and head of the box the 95% interval and the outliers with a dot above or below the 95% confidence interval.

**Figure 3.** Bland-Altman plot of the repeatability of sulcus-to-sulcus (STS) measures using the HiScan ultrasound biomicroscopy (UBM), open symbols show the agreement between any two STS measures the limits of agreement are given with dotted horizontal lines, details given in legend, closed symbols give the agreement between the average of pairs of measures, the limits of agreement are given with a solid line.

**Figure 4.** Bland-Altman plot of the agreement between devices and horizontal white to white (WTW)/sulcus-to-sulcus (STS) measures (top row) the anterior chamber depth (ACD) measures (bottom row). Bias is denoted with the dashed line and the 95% limits of agreement with the dotted line.

**Table 1.** Baseline characteristics prior to implantable collamer lens implantation of all study patients and for groups of patients with respect to different spherical equivalence or the presence of astigmatism

| Parameter             | Hyperope/<br>moderate<br>myopes<br>(up to -6.0D) | High myopes<br>(-6D to -10D) | Very high<br>myopes<br>(stronger<br>than -10D) | Full<br>group           | Astigmatic<br>eyes ( $\geq 1D$ ) |
|-----------------------|--|------------------------------|--|-------------------------|----------------------------------|
| Number of eyes        | 17   | 40                           | 50   | 107                     | 70                               |
| SE                    | +1.90<br>( $\pm 4.16$ )                          | -8.52<br>( $\pm 1.16$ )      | -12.94<br>( $\pm 5.69$ )                       | -8.93<br>( $\pm 5.69$ ) | -9.53<br>( $\pm 5.33$ )          |
| AL                    | 22.80<br>( $\pm 1.56$ )                          | 26.8<br>( $\pm 0.97$ )       | 27.88<br>( $\pm 2.15$ )                        | 26.67<br>( $\pm 2.44$ ) | 26.87<br>( $\pm 2.46$ )          |
| ACD                   | 3.05<br>( $\pm 0.22$ )                           | 3.26<br>( $\pm 0.26$ )       | 3.14<br>( $\pm 0.23$ )                         | 3.17<br>( $\pm 0.25$ )  | 3.18<br>( $\pm 0.24$ )           |
| IOP                   | 14.6<br>( $\pm 1.9$ )                            | 15.5<br>( $\pm 2.9$ )        | 16.1<br>( $\pm 2.3$ )                          | 15.6<br>( $\pm 2.5$ )   | 15.6<br>( $\pm 2.5$ )            |
| WTW<br>Pentacam       | 11.91<br>( $\pm 0.48$ )                          | 12.00<br>( $\pm 0.53$ )      | 11.73<br>( $\pm 0.47$ )                        | 11.86<br>( $\pm 0.52$ ) | 11.83<br>( $\pm 0.49$ )          |
| WTW<br>BioGraph       | 12.08<br>( $\pm 0.43$ )                          | 12.36<br>( $\pm 0.49$ )      | 11.93<br>( $\pm 0.47$ )                        | 12.12<br>( $\pm 0.51$ ) | 12.07<br>( $\pm 0.48$ )          |
| Horizontal<br>STS UBM | 10.77<br>( $\pm 0.48$ )                          | 11.19<br>( $\pm 0.57$ )      | 10.81<br>( $\pm 0.53$ )                        | 10.95<br>( $\pm 0.56$ ) | 10.93<br>( $\pm 0.61$ )          |
| Vertical STS<br>UBM*  |  |                              |  | 11.31<br>( $\pm 0.48$ ) |                                  |

Data are presented as mean ( $\pm$ standard deviation) unless otherwise noted. Spherical equivalence (SE), axial length (AL), anterior chamber depth (ACD), white-to-white (WTW), sulcus-to-sulcus (STS), intraocular pressure (IOP), diopter (D), ultrasound biomicroscopy (UBM). \* 80% of patients had vertical STS measures.



**Table 2.** Inter-device agreement summary measures of three pairwise comparisons (Pentacam vs. BioGraph, Pentacam vs. HiScan, BioGraph vs. HiScan) of devices used to select lens size prior to implantable collamer lens implantation. Parameters are given for the full group and for three subgroups of patients based on anterior chamber depth

|   |         | Inter-device agreement summary measures |       |      |               |         |         |
|---|---------|---|-------|------|---------------|---------|---------|
| Group                                   |         |   | Bias  | SD   | 95% LoA       | Pearson | p-value |
| WTW (Pentacam)<br>vs. WTW<br>(BioGraph) | Total   |   | -0.26 | 0.34 | (-0.93,0.41)  | 0.743   | <0.001  |
|   | ACD, mm | <3.2                                    | -0.18 | 0.27 | (-0.71,0.35)  | 0.726   | <0.001  |
|   |         | 3.2-3.4                                 | -0.23 | 0.40 | (-1.01,0.55)  | 0.604   | <0.001  |
|   |         | 3.4+                                    | -0.54 | 0.26 | (-1.05,-0.03) | 0.782   | <0.001  |
| WTW (Pentacam)<br>vs. STS (HiScan)      | Total   |   | 0.91  | 0.54 | (-0.15,1.97)  | 0.536   | <0.001  |
|   | ACD, mm | <3.2                                    | 1.07  | 0.47 | (0.15,1.99)   | 0.451   | <0.001  |
|   |         | 3.2-3.4                                 | 0.93  | 0.43 | (0.09,1.77)   | 0.650   | <0.001  |
|   |         | 3.4+                                    | 0.41  | 0.57 | (-0.71,1.53)  | 0.392   | 0.08    |
| WTW (BioGraph)<br>vs. STS (HiScan)      | Total   |   | 1.17  | 0.46 | (0.27,2.07)   | 0.644   | <0.001  |
|   | ACD, mm | <3.2                                    | 1.25  | 0.48 | (0.31,2.19)   | 0.412   | 0.001   |
|   |         | 3.2-3.4                                 | 1.16  | 0.35 | (0.47,1.85)   | 0.737   | <0.001  |
|   |         | 3.4+                                    | 0.95  | 0.51 | (-0.05,1.95)  | 0.574   | 0.008   |

Anterior chamber depth (ACD), white-to-white (WTW), sulcus-to-sulcus (STS), limits of agreement (LoA).

**Table 3.** Conversion table of white-to-white measures by Orbscan to white-to-white/sulcus-to-sulcus measures by other clinical devices used for lens sizing prior to implantable collamer lens implantation

| Device                          | Bias estimates (Reference)   | Sample size                  | Suggested bias correction |
|---------------------------------|--|------------------------------|---------------------------|
| <b>Ultrasound biomicroscopy</b> |  |                              |                           |
| Artemis (50 MHz)                | -0.89 <sup>(2)</sup><br>-0.58 <sup>(35)</sup>  | 50                           | -0.74                     |
| HiScan (35 MHz)                 | -0.39 <sup>(24)</sup><br>-0.71 <sup>(17)</sup><br>-0.42 <sup>(16)</sup>  | 31<br>20<br>28               | -0.48                     |
| Vumax (35 MHz)                  | 0.46 <sup>(18)</sup>   | 37                           | 0.46                      |
| Quantel medical (50 MHz)        | 0.14 <sup>(34)</sup>   | 63                           | 0.14                      |
| Humphrey 840 (50 MHz)           | 0.46 <sup>(13, 36, 37)</sup>   | (100, 10, 72)                | 0.46                      |
| Carl Zeiss 835 (50 MHz)         | 0.40 <sup>(22)</sup>   | 129                          | 0.40                      |
| <b>Scheimpflug image</b>        |  |                              |                           |
| Pentacam                        | 0.43 (Guber)   | 117                          | 0.43                      |
| <b>Iris camera</b>              |  |                              |                           |
| Pentacam                        | 0.1 <sup>(38)</sup>  | 101                          | 0.1                       |
| Galilei                         | 0.34 <sup>(39)</sup>   | 74                           | 0.34                      |
| Eyesys                          | 0.42 <sup>(39)</sup>   | 74                           | 0.42                      |
| Eyemetrics                      | 0.18 <sup>(40)</sup>   | 73                           | 0.18                      |
| IOLMaster                       | 0.50 <sup>(41)</sup><br>0.24 <sup>(36)</sup><br>0.47 <sup>(18)</sup><br>0.22 <sup>(42)</sup><br>0.33 <sup>(43)</sup> | 328<br>100<br>37<br>40<br>52 | 0.41                      |
| Biograph/Lenstar                | 0.48 <sup>(37)</sup><br>0.69 (Guber)   | 72<br>117                    | 0.57                      |
| <b>Manual</b>                   |  |                              |                           |
| Calipers                        | 0.11 <sup>(36)</sup><br>0.01 <sup>(37)</sup>   | 100<br>72                    | 0.07                      |
| Holladay-Godwin gauge           | 0.02 <sup>(36)</sup>   | 100                          | 0.02                      |

**Example:** If a horizontal white-to-white measure of 12.50 mm is observed with the IOLMaster, then to account for the inter-device bias and have better agreement with the official nomogram developed on Orbscan measures, this should be corrected by subtracting 0.41 mm, i.e. 12.09 mm should be used to calculate the implant size. Notably, the bias between Vumax (Vumax to Orbscan 0.46 mm) and HiScan (Orbscan to HiScan 0.48 mm) is 0.94 mm, which corresponds to a difference of 2 implant sizes.

**Table 4.** Conversion table of white-to-white measures by IOLMaster to white-to-white/sulcus-to-sulcus measures by other clinical devices (Vumax, Quantel and BioGraph) used for lens sizing prior to implantable collamer lens implantation

| Device<br>'X'        | Bias<br>estimates                            | Sample<br>size | IOLmaster<br>► 'X' (bias) | Orbscan<br>► 'X'<br>(Table 3) | Orbscan<br>► 'X' ►<br>IOLMaster | Difference:<br>Orbscan ►<br>IOLMaster |
|----------------------|--|----------------|---------------------------|-------------------------------|---------------------------------|---------------------------------------|
| Vumax<br>(35 MHz)    | 0.01 <sup>(18)</sup>                         | 37             | 0.01                      | 0.46                          | 0.45                            | <b>0.04</b>                           |
| Quantel<br>(50 MHz)  | -0.17 <sup>(3)</sup>                         | 111            | -0.17                     | 0.14                          | 0.31                            | <b>0.10</b>                           |
| Biograph/<br>Lenstar | 0.26 <sup>(33)</sup><br>0.07 <sup>(39)</sup> | 336<br>56      | 0.23                      | 0.57                          | 0.34                            | <b>0.07</b>                           |

**Example:** Looking at the bias between IOLMaster and BioGraph devices (line 3, column 3), a correction of 0.23 mm is required, and the bias between the Orbscan and BioGraph devices requires a correction of 0.57 mm. Therefore, to correct for the bias between Orbscan and IOLMaster using this information, a correction of 0.34 mm is required (0.57 mm-0.23 mm). Using the information from Table 3, a direct comparison between Orbscan and IOLMaster indicates a bias of 0.41 mm. The difference between these two corrections is <20%.

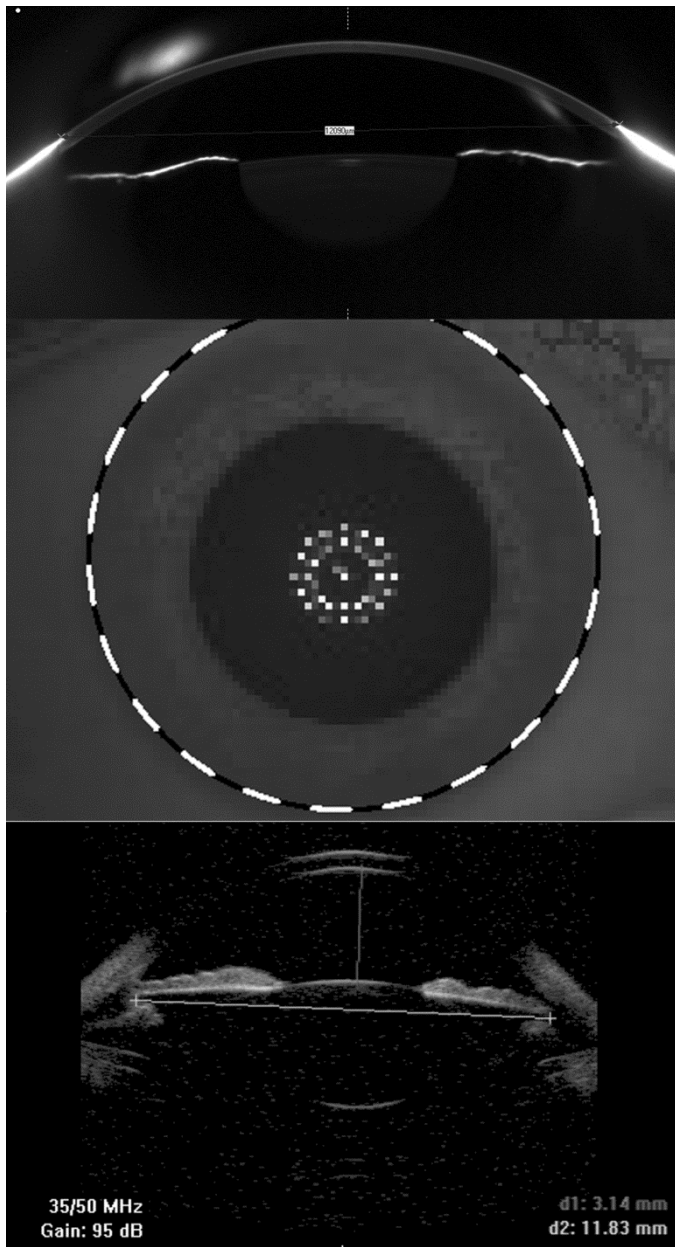


Figure 1