

Comparison of Sirius Corneal Topographer and Digital Callipers to Determine Corneal White-To-White Diameter in Phakic Intraocular Lens Implantation

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Abstract: *Precise measurement of the white-to-white diameter is important for the selection of an ideal sized phakic intraocular lens. Purpose: The purpose of this study was to compare the white-to-white measured using Sirius corneal topographer with that of white-to-white measured manually using digital callipers. Method: A prospective observational study conducted in a refractive eye care centre from November, 2016 to April, 2017. Forty eyes of twenty patients were included in the study. The corneal white to white diameter was measured using both digital callipers and Sirius corneal topographer. Statistical analysis was performed using SPSSv20.0. Result: The mean corneal diameter with the Sirius corneal topographer and the digital callipers was 12.18 mm and 11.91 mm respectively. Based on comparison done by paired t-test, corneal diameter measurements using digital callipers were 0.27 mm smaller than the measurements obtained using Sirius topography device. Conclusion: The white-to-white measurement using digital callipers is lesser in comparison to the measurement using the Sirius corneal topographer. The sizing of the phakic IOL was acceptable when the measurements using digital callipers were taken, providing an optimal vault. Measuring the white-to-white diameter of the cornea using the calliper is a reliable method and prevents over or under sizing of the phakic IOL.*

Keywords: corneal white to white diameter; Sirius; digital callipers; phakic IOL

1. Introduction

Obtaining precise and consistent readings of anterior segment parameters is a key step in achieving satisfactory outcomes in refractive anterior segment surgeries.^[1]

The white-to-white (WTW) corneal diameter is the horizontal distance between the margins of the limbus. With the advent of phakic intraocular lenses (pIOL), it is important to get precise measurements of the WTW diameter because the choice of an ideal sized phakic IOL depends on the WTW diameter. Sizing of pIOL would establish the efficacy of the lens.^[2]

Vault is the distance between centre of posterior surface of the phakic IOL and the anterior surface of the crystalline lens. Ideal sized phakic IOL will provide a vault of 250 to 750 μm ($\frac{1}{2}$ corneal thickness to $1\frac{1}{2}$ corneal thickness).^[3] An undersized phakic IOL (leading to a smaller vault; less than 0.125 mm vault) may increase the risk of anterior subcapsular opacification.^[4] An oversized ICL (leading to a larger vault; more than 1 mm vault) may push the iris forward and close the angle of anterior chamber which could lead to IOP rise and Iris malfunction.

There are numerous methods for measurement of corneal WTW diameter. These methods can be divided into two groups: manual (callipers and slit-lamp scales) and automated devices (IOLMaster, ultrasonic biomicroscopy, IOLMaster,

Orbiscan II, magnetic resonance imaging (MRI), Sirius corneal topographer and optical coherence tomography (OCT).^[5-8]

The purpose of this study was to compare the automated WTW measurement obtained using Sirius imaging device with that of manual digital callipers based measurement of WTW.

The Sirius corneal topography device (Costruzione Strumenti Oftalmici, Florence, Italy) is an anterior segment analysis system which combines Scheimpflug camera and Placido disc technology. This device provides the recordings for thickness of the cornea, anterior chamber depth (ACD), angle of the anterior chamber (iridocorneal angle), thickness of the crystalline lens, keratometry, White-to-white diameter, pupillometry, anterior and posterior corneal topography and corneal wavefront analysis.^[9]

2. Materials and Methods

Forty eyes of twenty patients not suitable for corneal refractive surgery were selected for phakic IOL implantation.

The corneal white to white diameter (horizontal diameter) was measured using both digital callipers and Sirius corneal topographer. Written Informed consent was obtained from each patient. The study followed the tenets of the Declaration of Helsinki.

Pre-Operative Planning: Proper preoperative screening to select ideal candidates for phakic IOL is important in the inclusion criteria.

Prerequisites for Phakic Intraocular Lenses

General criteria should be followed for good predictability and safety. These include:

Ametropia not appropriate for corneal refractive surgery, no previous corneal refractive surgery, anterior chamber depth (ACD) greater than 3.0 mm, Iridocorneal angle >30 degrees, Stable refraction (<0.5D change in 12 months), clear crystalline lens.

Exclusion criteria:

Ocular pathology (Corneal ectasia or if any corneal pathology, ocular hypertension, glaucoma, any lens opacity, lid pathology, etc); Corneal endothelial count less than 2500 cells /mm²; Systemic diseases such as diabetes mellitus, connective tissue disease, autoimmune disease, etc., classically associated with poor postoperative healing.

Before surgery, a detailed ophthalmologic examination was performed. This included refraction (both manifest and cycloplegic refractions), keratometry, slit lamp evaluation, intraocular pressure measurement using Goldmann applanation tonometry, fundus evaluation, corneal topography, pachymetry.

To minimize the risk of oversized or undersized phakic IOL accurate preoperative measurements of the White-to-white distance using a calliper has been proven to be a simple but reliable method.

A well calibrated digital calliper was used. Topical anesthetic drops were instilled. With the patient in supine position under the microscope, white-to-white diameter was measured using the digital calliper. Additional care had to be taken with pterygia, pigmented area around the cornea. In the current study, all WTW recordings were measured by the same examiner and three recordings were taken for each eye and average obtained.

Each patient was guided to a seat in front of the Sirius corneal topographer. The patients chin was placed on the chinrest and the forehead touched to the forehead strap. Patients were asked to fixate on a fixation target. Before each measurement patients were asked to blink their eyes completely such that an optically smooth tear film spreads over the entire cornea and keep the eye open during image acquisition. Measurements were obtained according to the guidelines by the manufacturer. Only high quality measurements were included in the subsequent analysis. Scans had to show the "OK" signal, meaning that Placido and Scheimpflug acquisition was above the required quality specification for coverage and centration.

Calculations:

Lens companies provide software for the calculation of a correct lens after entering patient measurements. To choose

an ideal lens, provider can use a nomogram which is typically provided by the lens manufacturers. Binkhorst nomogram is used to calculate the pIOL power. This requires refraction in patient's spectacle plane, corneal power, and anterior chamber depth. To calculate the ideal size of posterior chamber phakic IOL measurement of the angle-to-angle distance is required. Eventually, patient measurements are entered into the software. The software uses formulae which are specific to the lens manufacturer and a phakic IOL power that is ideally within 0.5-1.0 D of emmetropia is provided.^[10]

Several methods are available to obtain the parameters needed to calculate the IOL power. Refraction can be performed by manifest refraction or autorefraction. Anterior chamber depth, which is the distance between corneal endothelium and the anterior surface of the crystalline lens, is calculated by the corneal topographer. The effective lens position (ELP) in posterior chamber phakic IOLs is calculated by subtracting the distance between the phakic IOL and the crystalline lens from the anterior chamber depth.^[11] White-to-white (WTW) distance can be measured with a corneal topographer or callipers to assess the angle-to-angle distance. Keratometry or topography is used to calculate the corneal curvature.^[11,12]

In our study, we used the white to white measurements obtained using digital callipers to calculate the appropriate size of the lens.

Surgical Technique:

The STAAR Visian Implantable Contact Lens™ (ICL) V4B ICL is the most commonly implanted posterior chamber phakic intraocular lens for correction of myopia ranging from -3.0 D to -23.0 D.^[13] It is a rectangular single-block made of collamer and available in 4 diameters (12.1 mm; 12.6 mm; 13.2 mm; 13.7 mm), with the variable optical zone depending on the optical power (4.65 to 5.8 mm for negative lenses and 5.5 mm for positive lenses).

Following peribulbar anesthesia or topical anesthesia, a temporal clear corneal incision of about 3.0 mm is made and the Staar Visian Implantable Contact Lens™ (ICL) is then gently folded and injected into the anterior chamber through the clear corneal incision. Once delivered into the anterior chamber, four footplates of the lens are tucked into the sulcus. The amount of vault between the lens optic and the crystalline lens depends on the lens size.

The patients were followed up on day 1, one week, one month, three months and six months postoperatively. All the patients underwent detailed evaluation on followup visits. This included refraction, slit-lamp examination, IOP measurement using Goldmann's applanation tonometer and fundus evaluation.

Vault Assessment:

The separation between the centre of the posterior chamber phakic IOL and the anterior lens surface is called the vault. Vault was assessed using optical coherence tomography (OCT) (Visante, Carl Zeiss Meditec AG). The separation was measured perpendicular to the lens apex or at the narrowest

space between the 2 surfaces.

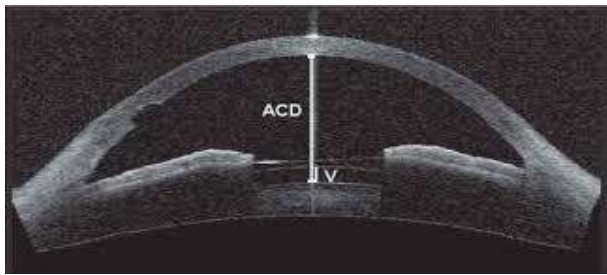


Image: Vault assessment using OCT

The measurement of vault was performed during the follow up visit 3 months postoperatively.

All the measurements of vault were done under similar lighting conditions. To avoid the influence of accommodation in changing the position of anterior surface of the crystalline lens, measures were taken after cycloplegia. All measures were obtained by the same technician and mean value of vault for each eye calculated.^[14]

Statistical analyses were performed using SPSS software (version 20; SPSS Inc., Chicago, IL, USA). *P* value < 0.05 were considered statistically significant. Comparisons between the Sirius and digital callipers measurements of WTW diameter were conducted using paired *t*-tests. Bland-Altman plots to assess the degree of agreement between the two methods was performed. The Bland and Altman plot shows “the differences in the measurement of one specific parameter between the compared methods plotted against the average of the mean results obtained with both methods”.^[15] Descriptive analyses were performed to determine mean, range and standard deviation.

3. Results

In the present study, 40 eyes of 20 patients were analysed. Age was ranging from 20 years to 47 years with a mean of 28.85 and standard deviation of 6.121. The total numbers of female patients were 26(65%) and male patients were 14(35%). The corneal thickness ranged from 467µm to 582 µm (mean=505µm; SD =22.506). The corneal curvature at the apex ranged from 43.56 D to 48.99 D (mean=46.08 D; SD = 1.519). The central vault ranged from 272 µm to 414 µm (mean= 340.85 µm; SD= 40.043). The mean preoperative IOP was 13.55 mm of Hg (SD=1.96) and the mean IOP at follow up visit three months postoperatively was 13.38 mm of Hg (SD=1.82).

	Minimum	Maximum	Mean	Std. Deviation
AGE	20	47	28.85	6.121
WTW(SIRIUS) in mm	11.23	13.19	12.1787	.52045
WTW(H) (CALLIPERS) in mm	11.24	13.00	11.9108	.45954
WTW(V) (CALLIPERS) in mm	11.20	12.95	11.8390	.46683
CCT(in microns)	467	582	505.50	22.506

CURVATURE (in dioptres)	43.56	48.99	46.0800	1.51912
VAULT(in microns)	272	414	340.85	40.043

Table 1

WTW (SIRIUS)-White-to-white diameter using Sirius corneal topographer, WTW (H)-Horizontal White-to-white diameter using digital callipers, WTW (V)- Vertical White-to-white diameter using digital callipers, CCT- Central corneal thickness

The mean corneal WTW measured using Sirius corneal topographer and the digital callipers were 12.18 mm and 11.91 mm respectively. Corneal WTW measured using Sirius corneal topographer and the digital callipers ranged from 11.23 to 13.19 mm and 11.24 to 13.0 mm respectively. Standard deviation from the mean was 0.52 mm for Sirius and 0.46 mm for the digital callipers. Variance was 0.271 mm and 0.211 mm for the Sirius and the digital callipers respectively. The resulting normal range (mean ± 2 standard deviations) was 11.14 to 13.22 mm for the Sirius and from 10.99 to 12.83 mm for the digital callipers. Histograms of measurement frequencies obtained from Sirius and callipers are plotted in Figures 2 and 3, respectively.

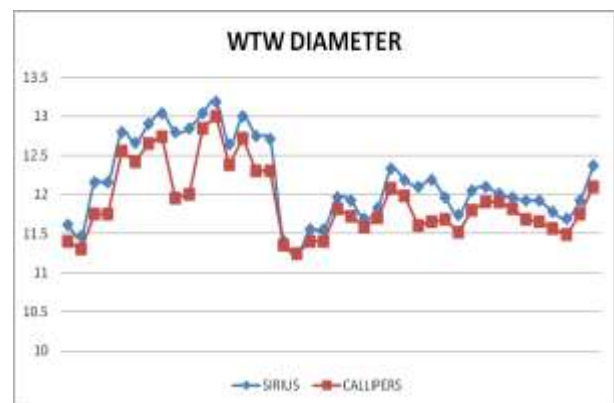


Figure 1

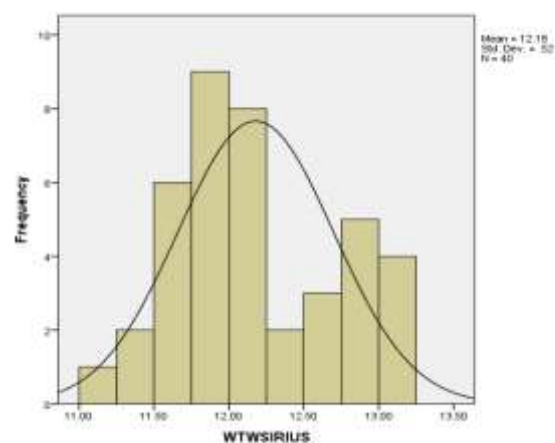


Figure 2

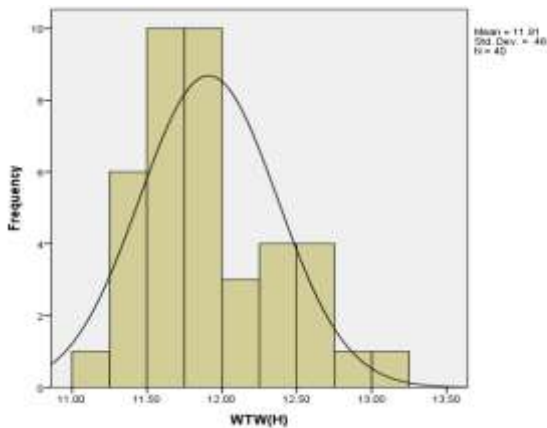


Figure 3

Based on paired t-test comparison, measurements taken with callipers were an average of 0.27 mm smaller than measurements taken by Sirius ($p < 0.001$). Bland Altman analysis showed a mean difference of 0.26 mm and limits of agreement of -0.077 to +0.613 mm between WTW measured with Sirius and digital callipers (Figure 4). Bland Altman plots showed that the measurements were comparable.

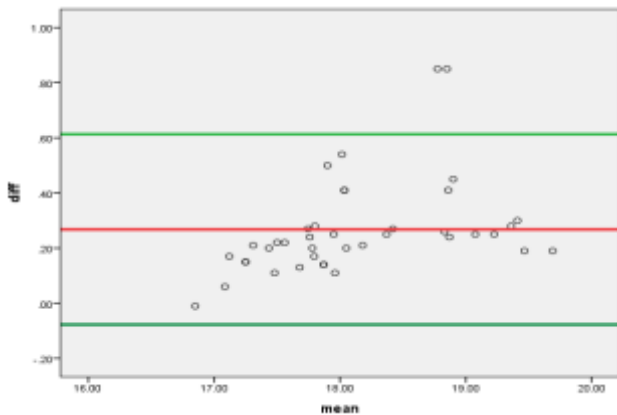


Figure 4

There was a statistically significant correlation between Sirius and digital callipers measurements (Spearman $r = 0.938$, $P = 0.01$). The linear regression analysis then revealed a reasonable model with a good predictability ($R = 0.402$).

4. Discussion

Accurate and precise determination of the anterior ocular segment is fundamental to many clinical and research applications in ophthalmology. The Sirius device is both noncontact and easy to use and showed good repeatability of the anterior segment measurements.^[16]

Although recent studies have shown that the WTW cannot accurately predict the real sulcus-to-sulcus distance,^[17] it remains an important biometric parameter for phakic IOL diameter calculation.^[14]

In our study, we found that this measurement was 12.18 mm using the Sirius and 11.91 mm by the digital callipers. The digital callipers reading was about 0.26 mm lesser compared to the Sirius readings. This disparity was statistically significant and may have clinical implications. Relying on

Sirius measurements may lead to an oversizing of phakic IOLs. Thus, these devices should not be considered interchangeable for WTW assessments in clinical practice. Although we do not yet know the exact reason for the differences in the values obtained by these two imaging devices, we speculate that fundamental methods for acquiring and analyzing images were responsible to the disparity.

Undersizing of the ICL is known to cause cataracts, while oversizing causes other complications, like increase in the intraocular pressure.^[18,19]

In the U.S. Food and Drug Administration trial for the Visian ICL, investigators found that a lens vault of more than 90 μm was required to prevent cataract formation.^[20]

All the calculations for selecting the size of pIOL were done using the WTW measurements obtained on the digital callipers. After the surgery, patients were followed up for a period of six months. Patients were monitored for development of complications. All the cases had an optimal sized vault.

All the cases had satisfactory results and none of them developed any complications related to oversizing or undersizing of the lens.

5. Conclusion

Measuring the corneal white-to-white diameter is an important part of preoperative workup in case of posterior chamber phakic intraocular lens implantation.

The readings of WTW measurement using digital callipers are lesser in comparison to the measurements using the Sirius corneal topographer. The sizing of the phakic IOL was acceptable when the WTW measurements using digital callipers were taken, providing an optimal vault. Measuring the white to white diameter of the cornea using the calliper is a reliable method and prevents over or under sizing of the pIOL.

This study has few weaknesses: small sample size; difficulties which are inherent in measuring the corneal diameter in the operating room. While it is generally accepted that the widest corneal diameter is at 180°, to identify the horizontal meridian by inspection alone is sometimes difficult.

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