A Study to Reach the Proper Measurement of the White to White Diameter Using both the Caliper and IOL Master for ICL Suitable Size

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ABSTRACT

Purpose: Proper measurement of the white to white diameter is very important using both the caliper and IOL master to reach an accurate size of ICL to prevent over or under size. An undersized ICL (less than 0.125 mm vault) may increase the risk of anterior subcapsular opacification. An oversized ICL (more than 1 mm vault) may push the iris forward and close the angles which could lead to IOP rise and Iris malfunction. Material and Methods: Measuring the white to white diameter of the cornea using both the caliper and IOL master for ICL to reach a relation between both sizes to prevent over or under size of the ICL. Thirty cases of seventeen patients have high myopia not suitable for Lasik are prepared to ICL lens implantation, performing the measuring of the white to white diameter of the cornea using both the caliper and IOL master for ICL lens. Results: IOL master measurement is larger than the caliper measurements so the IOL master measurement need to be reduced by \((-0.34)\) for proper vaulting of the ICL, yet it is more accurate way and reproducible. To prevent shallow anterior chamber and increase IOP, and anterior subcapsular cataract. Conclusion: Measuring the white to white diameter of the cornea using both the caliper and IOL master for ICL is the most accurate way to prevent over or under size of the ICL to minimize complications.

Key words: Proper measurement, caliper and IOL, white diameter

Introduction

For years, the only method of permanent vision correction that didn't involve glasses or contact lenses was corrective laser eye surgery. With the advent of phakic lenses, especially in high myopia phakic lenses offers vision correction that’s sharper, clearer, and has greater depth of focus than traditional corneal refractive surgery (Lovisolo and Reinstein, 2005). Mainly the reason that phakic lenses may produce superior vision quality is evidenced by fewer higher order aberrations (Myron and Duker, 2009).

How we can reduce risk of complications in correction of high myopia

Patients undergoing corneal refractive procedures, such as LASIK and PRK, may be susceptible to side effects associated with corneal surgery including dry eye and thinning of the cornea. The LASIK procedure involves removal of tissue from the cornea, which means some of its complications may be more difficult to correct than the possible complications of phakic lenses. All surgical procedures carry some risk; however, the side effects or complications related phakic lenses, in most cases, can be corrected, the lens can be removed and/or replaced if necessary (Sanders and Vukich, 2003). Then why posterior chamber lens? Because the posterior chamber lens is implanted behind the iris, unlike other phakic IOLs, the lens is invisible to both the patient and any observer. Also its positioning in the eye maintains normal iris function and promotes stability, Moreover may reduce potential complications of continuous endothelial cell loss.

ICL preserves Endothelium

The regenerative zone in the peripheral endothelium near Schwalbe’s line contains a high concentration of endothelial cells. These peripheral cells tend to spread and remodel over time. Long

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term functioning of the endothelium relies on the migration and remodeling of these cells. The ICL is placed behind the iris, therefore the endothelium benefits from a shield function of the iris. Additionally, in contrast to large incision surgery, the small incision of ICL procedure preserves the regenerative cells in the peripheral cornea (Myron and Duker, 2009; Mimouni et al., 1991; Edelhauser et al., 2004). 

**Purpose**

Proper measurement of the white to white diameter is very important using both the caliper and IOL master to reach an ideal size of ICL to prevent over or under size (Myron and Duker, 2009). Ideal sized ICL will provide a vault (central distance between anterior surface of the crystalline lens and posterior surface of the ICL) of 0.250 to 0.750 mm (½ CT to 1 ½ CT). An undersized ICL (less than 0.125 mm vault) may increase the risk of anterior subcapsular opacification (Sun et al., 2012). An oversized ICL (more than 1 mm vault) may push the iris forward and close the angles which could lead to IOP rise and Iris malfunction. Another concern is progressive shallowing of the anterior chamber which normally occurs with advancing age due to the growth of the eye's natural lens. Multiple studies have shown a 12-17 µm/year decrease in the anterior chamber depth with aging (Edelhauser et al., 2004; Sanders, 2008). If a phakic IOL patient is assumed to have a 50-year lifespan, the overall decline in ACD may add up to 0.6-0.85 mm. Long-term data about this effect are not available (Sun et al., 2012; Yan et al., 2010).

**Materials and Methods**

Thirty eyes of seventeen patients at the Giza Memorial Research Institute of ophthalmology have high myopia not suitable for Lasik are prepared to ICL lens implantation in the period of March 2014 till August 2016, performing the measuring of the white to white diameter (horizontal diameter) of the cornea using both the caliper and IOL master for ICL lens, to reach a relation between both measurements. 13 patient underwent in both eyes ICL. And 4 patients underwent ICL in one eyes.
Pre-Operative Planning

Proper preoperative screening to select best candidates is important in the inclusion criteria. Myopic between the ages of 21-40 years. Degree of myopia from -9.0 up to -20.0. No previous corneal refractive surgery. ACD greater than 3.0 mm (excluding CT!). Stable refraction (<0.5D change in 12 months).
Exclusion criteria

No ocular pathology (ocular hypertension, glaucoma, any lens opacity, lid pathology, etc). Corneal ectasia or if any corneal pathology. Corneal endothelial count less than 2500 cells/mm².

To minimize the risk of over-/undersized ICL

Accurate preoperative measurements of the White-to-white distance using a caliper has been proven to be a simple but reliable method. Watch the following points: make sure that the caliper is well calibrated. Pre-treat the eye with anaesthetic drops. take the measurement under the microscope or exam lamp. with the patient in the supine position. Be careful with pterygiums, pigmented area around the cornea.

Surgical Technique:

Peribulbar Anesthesia, The implantable staar Visian Implantable Contact Lens™ (ICL) V4B is then gently folded and injected into the anterior chamber through a 3.0mm, temporal, clear corneal incision. The ICL is then carefully positioned. Following implantation, the lens rests behind the iris surface, by placing its four haptics under the iris and the optic is vaulted over the crystalline natural lens of the eye. Peripheral iridectomy is done at the end of the operation using vitrectomy probe.

Measurements of the White-to-white

We use Zeiss IOL Master 500 to measure the white to white to validate caliper measurement. Evaluate discrepancies between measuring devices. There should not be a big difference between both eyes. If there is (e.g. 11.7 OD and 12.3 OS), reconfirm the data. We use the pentacam to evaluate the amount of ICL vaulting after two weeks postoperative.

We use for statistical analysis for the results Pearson's Test of Linear Correlation for Comparison between the "Caliper" vs "IOL master" measurement. And Paired Samples t-test for comparison of the measurement of the "vault " when we compare between the caliper vs the IOL Master"
Results

IOL master measurement is larger than the caliper measurements, so the IOL master measurement need to be reduced for proper vaulting of the ICL, yet it is more accurate way and reproducible, to prevent shallow anterior chamber and increase IOP.

Table 1 shows the characteristics of the examined groups
To compare between the white to white measured by the caliber and the IOL master

<table>
<thead>
<tr>
<th></th>
<th>Caliber WTW</th>
<th>IOL master WTW</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean±SD (mm)</td>
<td>11.107±0.20</td>
<td>11.493±0.29</td>
</tr>
</tbody>
</table>

Table 2 shows the characteristics of the examined groups
To compare between the ICL vault when the white to white measured by the caliber and the IOL master

<table>
<thead>
<tr>
<th></th>
<th>IOL master Vault</th>
<th>caliber vault</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean±SD (mm)</td>
<td>0.79±0.25</td>
<td>0.75±0.23</td>
</tr>
</tbody>
</table>

*significant p value, Paired Samples t-test, N=30
There is significant difference between caliper WTW and IOL master WTW. (P=0.001)

Table 3 shows the results of correlations between the examined parameters

<table>
<thead>
<tr>
<th></th>
<th>Caliper WTW</th>
<th>Caliper vault</th>
<th>IOL master WTW</th>
<th>IOL master Vault</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caliper WTW</td>
<td>r</td>
<td>P value</td>
<td>r</td>
<td>P value</td>
</tr>
<tr>
<td>Caliper WTW</td>
<td>-</td>
<td>-</td>
<td>-0.245</td>
<td>0.192</td>
</tr>
<tr>
<td>Caliper vault</td>
<td>-0.245</td>
<td>0.192</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>IOL master WTW</td>
<td>0.882</td>
<td>&lt;0.001*</td>
<td>-0.24</td>
<td>0.195</td>
</tr>
<tr>
<td>IOL master Vault</td>
<td>-0.21</td>
<td>0.26</td>
<td>0.89</td>
<td>&lt;0.001*</td>
</tr>
</tbody>
</table>

r = Pearson correlation coefficient,  p = probability
*significant p value, Pearson correlation test, N=30

There is significant positive correlation between the caliper WTW and IOL master WTW, Also the caliper vault and IOL master vault. Yet we face very few complications as increase IOP in 3 cases and transient corneal edema for 4 days in five cases all was resolved after treatment for less than one week

ICL and Sizing

The White-to-white value provided by the IOL-MASTER® shows too large values (+0.34mm compared to caliper. A White-to-white measured with the IOL-MASTER® may therefore lead to an oversized ICL. Other white-to-white measurement methods have not been validated yet.
Discussion

The size of the ICL has commonly been done using a formula based on the white-to-white diameter, as recommended by STAAR Surgical, which assumes that there is a correlation between white-to-white and the dimensions of the posterior chamber where the lens is placed. However, numerous studies have now shown that either there is no correlation or only a very weak correlation. (Zaldivar et al., 2000) There’s a lot of scatter, meaning that if you were to predict sulcus diameter by taking white-to-white, 38% of the time you will have an error of more than half a millimeter, which equals one lens size." (Zaldivar et al., 2000)

Undersizing of the ICL is known to cause cataracts, while oversizing causes other complications, like increase intraocular pressure. Shallow vault is also believed to spur cataract formation in some cases (Kodjikian et al., 2002; Sanchez-Galeana et al., 2002)".

The purpose of this study was to compare the vault height predictability of the ICL based on sulcus diameter sizing or white-to-white sizing.”. Other studies using Artemis very high-frequency (VHF) digital ultrasound (ArcScan) to obtain a direct measurement of sulcus diameter show comparable results (Kohnen, 2000)

The size of the ICL was calculated using an algorithm built around the sulcus diameter measurement and other anatomic variables such as anterior chamber depth. The algorithm was developed by Lovisolo and Reinstein, (2005) VHF digital ultrasound was used to measure the vault height achieved using the lens sized by this sulcus-based sizing formula

In order to make a comparison with STAAR Surgical’s conventional white-to-white-based sizing formula, this formula was also used to calculate the lens size that would have been recommended. Investigators then used circle segment trigonometry to calculate the vault height that would have resulted if the white-to-white formula had been used to determine lens size (Brown et al., 1998) which shows similar results to our study that the IOL master measures are more than the white to white measurements by approximately 0.5 mm.

As we had direct measurements of the sulcus diameter and vault height and the size of the lens was known, in the cases where the white-to-white formula would have chosen a different lens size, we could calculate the vault height that would have been achieved if such a lens had been used, assuming that the lens haptics would have been in the same place (Rosen and Gore, 1998).

Significant variations

When used STAAR formula measured by VHF digital ultrasound the mean postoperative vault height was 367 µm. But when the ICL size had been selected based on a direct sulcus diameter measured by white-to-white measurement using a caliper, the mean vault height would have been 163 µm, and this showed comparable results to our study (Brown et al., 1998)

The standard deviation was 163 µm in the population,” It would have been 306 µm had the white-to-white lens sizing formula been used. If we convert that into a 95% confidence interval, we can see clearly that we have 95% confidence of not touching the crystalline lens in the sulcus diameter group, but we would have had a lot of cases of lens touch in the white-to-white STAAR formula group (Rosen and Gore, 1998)

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. Reinstein’s study, one eye (2%) had vault height less than 90 µm and no eyes developed cataracts after 6-year follow-up (Sanders et al., 2002)

If we had used the STAAR formula, vault height would have been less than 90 µm in 36% of eyes,” Reinstein said. “However, cataract formation does not occur in all cases of low vault or where the lens touches the cornea. In the FDA trial cohort, 0.6% of cases developed cataracts that required removal, so if this rate of cataract formation is applied to the results of our study, this translates to a 0.03% chance of cataract needing to be removed when lens sizing is calculated based on sulcus diameter measurements rather than white-to-white (Rosen et al., 1998).

Trials was done to measure white to white diameter using the Topolyzer, it shows most accurate measurement compared to the caliper.
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Eye Cubed’s 40 MHz UBM mode allows you to view anterior structures such as the cornea, iris, ciliary body, crystalline and intraocular lens more clearly than ever before. Whether determining the sulcus-to-sulcus measurement for accurate ICL sizing or the angle for potential angle closure and possible YAG laser iridotomy, Eye Cubed’s 40M Hz UBM mode is the gold-standard in high-resolution ultrasound (Lee et al., 2007; Huang et al., 2015)

Conclusion

- Measuring the white to white diameter of the cornea using both the caliper and IOL master for ICL lens is the most accurate way to prevent over or under size of the ICL to minimize complications.
- Ideal sized ICL will provide a vault (central distance between the crystalline lens and posterior surface of the ICL) of 0.250 to 0.750 mm (½ CT to 1 ½ CT) in the center of the cornea.
- An undersized ICL (less than 0.125 mm vault) may increase the risk of anterior subcapsular opacification. An oversized ICL (more than 1 mm vault) may push the iris forward and close the angles which could lead to IOP rise and Iris malfunction.

References


