

Phakic intraocular lens: Getting the right size

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Phakic intraocular lenses (IOL) are a boon for patients who want spectacle independence but are unable to get refractive correction through laser platforms due to high refractive error or certain corneal contraindications. Phakic IOL's (PIOL) have their own set of complications and challenges, the most important being getting the sizing right. This paper attempts to solve the problem of accurate sizing of PIOL's. Parameters needed for calculating the ideal size of PIOL's have been studied in a step by step manner using all possible tools depending upon the availability and preference of the surgeon. The pros and cons of using a particular tool for measurements have been highlighted along with illustrative case examples to help surgeons who are starting PIOL implantation surgery.

Key words: Algorithmic approach, Phakic IOL, preferred practice patterns

Phakic Intraocular lenses (PIOL) are one of the must have tools in the armamentarium of any refractive surgeon today. Studies show that it can be used to correct Myopia,^[1] Hyperopia^[2] and Astigmatism.^[3,4] Today its scope has been extended to stable keratoconus.^[5] However the most common use is in the treatment of Myopia. High myopia is prevalent today in 163 million people; which accounts for 2.7% of the world population.^[6]

Phakic intraocular lenses are a well-established alternative in patients who are not fit for corneal refractive surgery. Initially, Phakic IOL were associated with a variety of complications which have reduced significantly over a period of time.^[7] The main problem that remains is determining the accurate size of the phakic IOL to be implanted. The postoperative vault of the PIOL is defined as the distance between the posterior surface of the PIOL and the anterior surface of the crystalline lens. The ideal vault postoperatively is between 200 to 800 microns and acts as a marker for accurate preoperative sizing.^[8] Various parameters need to be taken into account for sizing, such as the pre-operative measurements of White to White (WTW), Anterior Chamber Depth (ACD), Sulcus to Sulcus (STS) measurements. It is the variation in the sizing of the lens due to the dilemma upon which parameter is better suited for calculating the lens size that can lead to complications.^[9] Secondly, sizing is limited

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by the already available standard sizes of PIOL's. Inaccurate sizing leads to postoperative surprises in the PIOL vault. A larger PIOL will be compressed within the sulcus to sulcus and hence lead to a high vault and an anterior bulging of the PIOL producing pigment dispersion syndrome, endothelial cell damage or raised Intra ocular pressure that can lead to an angle closure attack.^[10-12] A smaller sized PIOL may lead to a low vault with anterior lens touch and cataract formation or postoperative rotation of the PIOL which can lead to postoperative refractive errors especially in toric PIOL's.^[12]

In this article we will try to elucidate how to utilize and interpret different parameters to accurately determine the size of the Phakic IOL to be implanted. Planning a PIOL surgery requires a multi-faceted approach and accuracy is of utmost importance during planning in order to achieve desirable results.

Types of Phakic Intra Ocular Lenses

The Implantable Collamer Lens, VISIAN ICL (STAAR Surgical Co) is FDA approved Posterior chamber PIOL. It is made from biocompatible material named Collamer, comprising of a hydrophilic porcine collagen (<0.1%) hydroxyethyl methacrylate copolymer with an ultraviolet-absorbing chromophore. There is a plate-haptic design along with a central convex/concave optical zone and incorporates a forward vault to minimize contact of the ICL with the central anterior capsule of crystalline lens. The placement of the lens was designed such that it is

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placed in the posterior chamber, behind the iris with the haptic zone resting on the ciliary sulcus.^[13] The range of correction for the ICL is from +10D to -20D with cylindrical correction upto 6D and it is available in 4 sizes 12.1, 12.6, 13.2 and 13.7 mm. Other PIOL's produced in India include implantable phakic contact lens (IPCL; Care Group, Vadodara, India) with a range of correction of +15D to -30D with cylindrical power upto 10D. It is available in sizes with incremental increase of 0.25 mm from 11 to 14 mm. The other Phakic IOL's that are available in the Indian market are Refractive implantable lens (RIL; Appasamy associates, Chennai, India) and Eyecryl phakic IOL (Biotech Vision Care, Ahmedabad, India).

WTW vs STS

Conventionally, the manufacturers have advocated lens sizing by measuring white-to-white (WTW) by either manual or automated technique and using the measurements of the anterior chamber depth to decide whether PIOL is a suitable option.^[13] Although it is also proposed that directly measuring the sulcus-to-sulcus (STS) and using it for PIOL sizing diameter would be advantageous, as placement of the lens is in the ciliary sulcus. However, analysis of several studies have shown no significant correlation between assessment of WTW and diameter of STS.^[14-18] A previous study while comparing WTW and STS diameter showed that there was high standard deviation (SD) in the mean difference between them.^[19] Hence selection of a suitable parameter for accurate PIOL sizing is imperative to achieve exemplary outcomes.

WTW Measurement

Reliability amongst various machines that are used to measure WTW by either automated or manual methods varies significantly. Repeatability in manual measurements is significantly low as compared to automated values.^[20] Manual calipers that have been traditionally used, usually have increments of 0.2 mm, where as digital calipers provide a reading at increments of 0.1 mm. Also, wide inter examiner variability in the values has been obtained leading to inaccurate readings,^[21] therefore it is recommended that a single person should be designated for obtaining the readings.

The Orbscan Ilz, a slit scanning method is considered a reference for comparison with various devices and to use a correction of WTW prior to PIOL sizing.^[22] There are two options available in this device for calculation of the WTW- the automated mode (OA) and a manual mode (OM) which basically uses callipers from the Eyemetrics tool. OM method using Eyemetrics toolbox was found inferior to the OA mode. The possible reason for the same was difficult visualization of the transition grey zone from cornea to sclera.^[23] The contrast of the image obtained can be adjusted for better identification of the grey zone. The accuracy of automated limbus recognition in the OA mode by the computer software depends on the quality of the anterior segment images. With the Orbscan topographer, this is composed of a series of slit lamp images.^[24] Repeating the scan 3 times and taking the average of the 3 readings is essential to ascertain accuracy.

Keratograph,^[25] a Placido based topographer is another device that enables the calculation WTW values by using both manual and automated modes. The automated WTW measurements obtained from Keratograph and Orbscan showed no significant difference and thus their values could be used interchangeably.^[23] However significant differences were revealed while comparing WTW values obtained from Orbscan with other devices like Pentacam^[26] and IOL Master.^[27]

ATA Measurement

Recently, ATA (Angle to angle) measurements have been used to predict the ideal PIOL size using swept source OCT.^[28] A new study that used the anterior segment optical coherence tomography (AS-OCT) machine to measure ATA and WTW values suggested that reproducibility with ATA values was higher in contrast to measurements obtained from WTW. ATA distance was obtained automatically by marking a line between iris roots on the two opposite sides. They also found good correlation between ATA values, PIOL size and post-operative vault.^[21]

STS Measurement

The ciliary sulcus is defined as a circumferential depression which is bounded anteriorly by the posterior surface of iris and posteriorly by the anterior surface of ciliary processes.^[29] The horizontal sulcus to sulcus (STS) diameter measurement has been advocated as being better for posterior chamber phakic intraocular lens (PIOL) calculations as the haptic footplates are located on the ciliary sulcus.^[15] Ultrasound bio-microscopy (UBM) allows for direct measurement of the horizontal STS diameter^[22] [Fig. 1].

Other machines that have been used to measure the STS include Artemis 1 (very high-frequency (VHF) digital ultrasound arc-scanner),^[14] Vumax II (wide-scanning-field ultrasound bio-microscopy)^[30] and HiScan.^[7]

UBM measures the STS by first capturing an image of the posterior chamber including the ciliary sulcus. It then uses this captured image to determine the ends of the sulcus and allows for the STS diameter to be measured.^[30] In a study by Dougherty *et al.* UBM was used to measure STS preoperatively and the vault postoperatively. Multiple regression analysis was done to derive a UBM based nomogram for PIOL sizing.^[31]

All measurement techniques, be it the WTW, STS or the ATA are fraught with their inherent limitations which may be machine dependent or associated with inter or intra-observer variations. However in vast majority of cases with fairly reliable values, post op measured vaults falling in a safe range of 250-750 microns remain uneventful over periods of time. Hence accurately obtained WTW or STS values may be consistently used for precise PIOL sizing.

Algorithm for PIOL

We are yet to reach a consensus for finalising an ideal algorithm for a perfect PIOL sizing and calculation protocol. In today's era there is a huge diversity in the way we carry out our practices, and hence having one single protocol to follow becomes very difficult. It is also of utmost importance to plan a safe surgery in view of patient safety and medicolegal concerns. We propose a preferred practice pattern which will be based on the setup that one has and will allow us to make the best use of the devices that we have in our practice.

An ideal work up would include measurement of each and every parameter so that we may get the maximum accuracy achievable. A comprehensive assessment of the anatomical structure and physiological function of the eye is carried out. Listed here are the various tools and methods that are needed for PIOL work up and the reasoning behind their use [Fig. 2 and Table 1].

Refraction

One of the major causes of visual impairment worldwide is uncorrected refractive error which has a significant impact

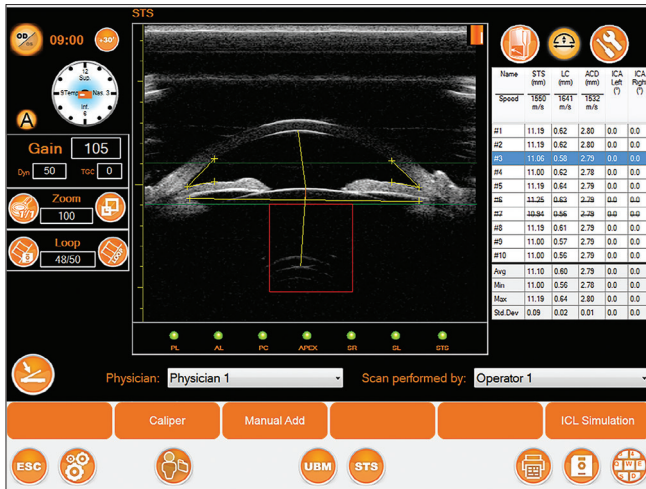


Figure 1: Horizontal STS Diameter measurement on the UBM

on the quality of life. Aiming to improve the patient’s uncorrected visual acuity (UCVA) is imperative for improved visual function and visual comfort. With the advancement of technology, a wide range of options are easily available for refractive error correction.^[32] The target is to impart the quality and quantity of vision that meets the patient’s functional needs while minimizing complications. The refractive state of each eye should be evaluated separately and accurately which includes manifest as well as cycloplegic refraction. The visual acuity with the power of current correction is noted for distance and near (if required) 35.^[33] In cooperative patients, subjective refinement of refraction using a phoropter or trial lens set is preferred. The reproducibility of subjective refraction has been found to be within 0.50 D for spherical equivalent, spherical power, and cylindrical power.^[34,35] Optimization of the reproducibility and accuracy of manifest refraction is important for a satisfactory outcome post refractive surgery.^[36] Cycloplegic refraction is necessary to suspend accommodation. Any unnoticed considerable residual accommodation may lead to suboptimal results.^[37] Visual acuity determination and refraction require particular attention as the power of the lens to be implanted is based on the manifest refraction. In keratoconus patients, a stable refraction for 6 months in patients who haven’t undergone surgery for 2 years must be ensured. For patients who have undergone cross-linking procedure, phakic IOL can be considered only after stable refraction has been attained for three consecutive visits over 1 year.^[38]

Optical biometry

Biometry helps in the determination of the various anatomical parameters of the eye like axial length, anterior chamber depth (ACD) etc. The derived data is then used to calculate the power of PIOL for implantation. It also helps in the identification of any abnormality in the anatomical structure of the eye to improve accuracy of power calculation. A-scan Biometry scan can be repeated and the axial length can be compared and co-related with the degree of refractive error in case patient is suffering from progressive myopia. In addition to this doing an optical biometry also gives us a white to white measurement which can be co-related with the manual measurement or the measurement done on another machine for verification of the value achieved.

Corneal topography

Corneal topography plays a crucial role in the planning of any refractive surgery. Measurements like corneal toricity,^[39] type

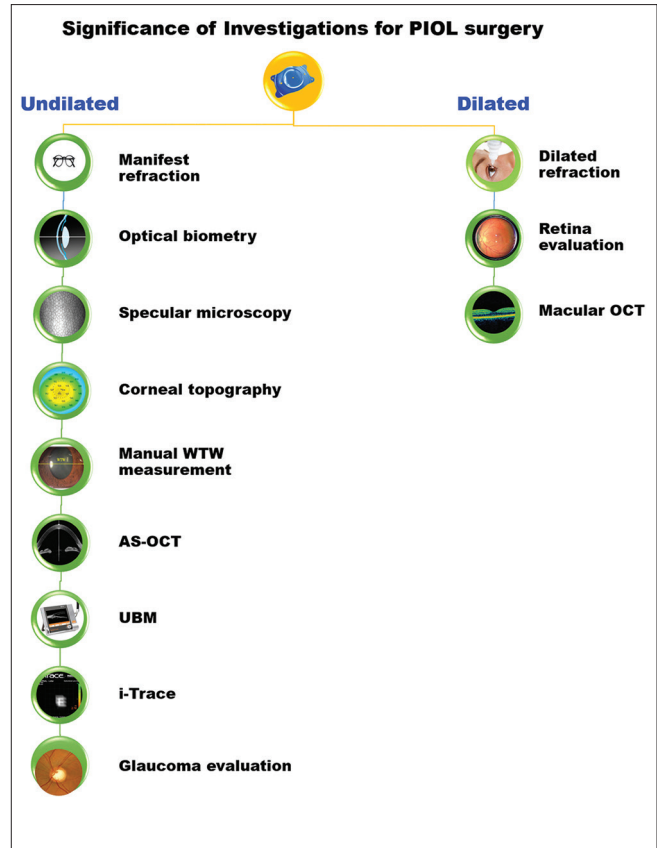


Figure 2: Investigations for Phakic IOL Surgery

of astigmatism (with the rule or against the rule), Keratometry readings, ACD and WTW derived from the topographers help us in the planning of the PIOL and acts as a screening tool enabling us to detect cases with suspicious corneas and identifying the candidates not suitable for surgery. In our clinical practice we acquire three consecutive topography scans and the average WTW value attained is then used for the PIOL calculation. In keratoconus patients, stability must be ensured before considering for phakic IOL implantation which is indicated by a stable topography scans between 2 visits and no surgery for 2 years. For patients who have undergone cross-linking procedure, phakic IOL can be considered only after the comparative topography scans are stable for 1 year. Additional criteria include a centralized cone, clear central cornea and keratometric values ≤ 52.00 D for optimum results in keratoconic eyes.^[38]

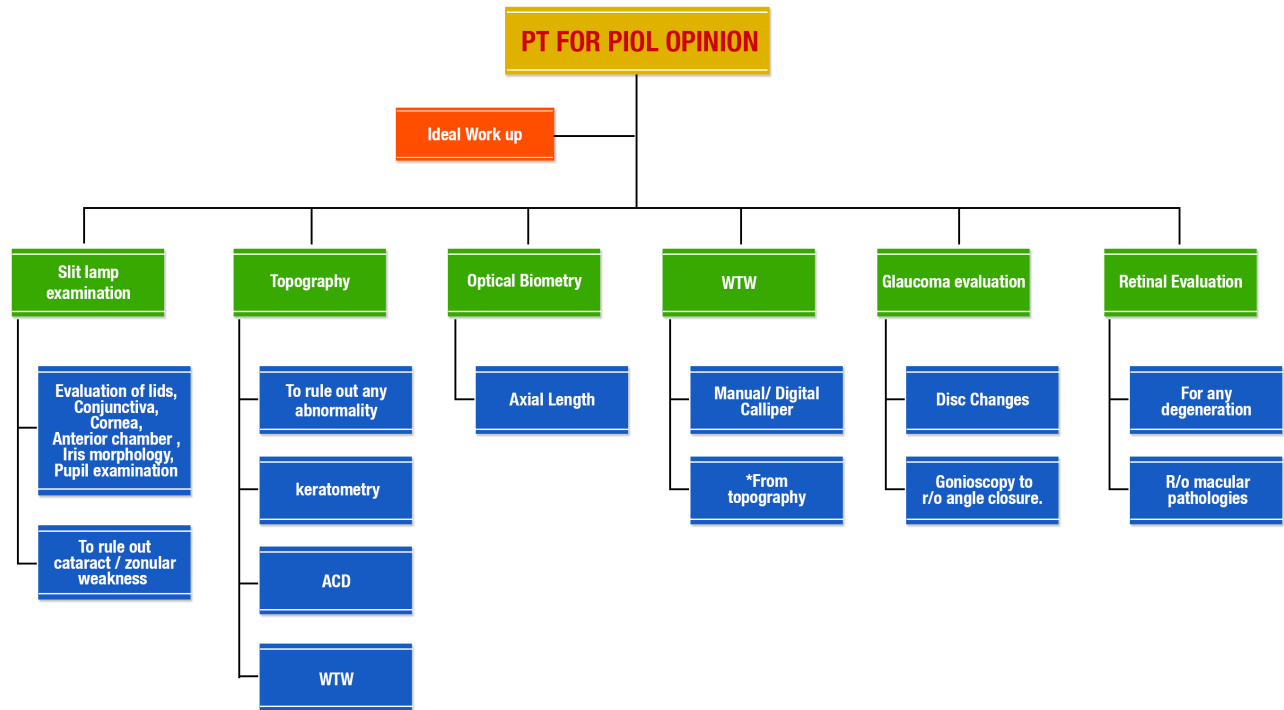
Specular microscopy

Specular microscopy is an important non-invasive prognostic test which aids in identifying any potential endothelial dysfunction or cell loss and excluding such patients from undergoing any refractive surgery. Post-operatively, serial scans are advisable at each visit to document any endothelial cell loss after PIOL surgery and to address the pathology before permanent corneal oedema sets in.^[40] Many studies have shown decrease in endothelial cell density over time post PIOL surgery,^[41] making it very important for us to assess the endothelial cell count prior to planning PIOL implantation.

Manual WTW measurement

WTW can be determined using various methods such as manual and automated.^[24] Measuring the WTW distance manually

Table 1: Ideal pre-operative phakic IOL work up



*It would be ideal to measure manual(Vernier/digital caliper) WTW and to do a topography for all patients undergoing Phakic IOL Surgery

using a digital or vernier’s calliper, gauges, scales etc., has been shown to be less accurate than automated measurement because of defocus or head movements. Also, there is dependency on the examiner and greater variability in the results. Automated devices, on the other hand are more reliable and yield more reproducible and accurate results. Objective measurements are thus proven to be superior as compared to subjective measurements.^[20] Manual measurement remains the method of choice in case automated devices are unavailable or are not able to measure the WTW distance as they need good quality images of the anterior segment for accurate limbus recognition.^[24] Study conducted by Chen TH *et al.* has showed that the WTW measurements obtained by automated devices are smaller than callipers.^[42] However, Naguib MA and co-workers have revealed that the most accurate way to measure WTW is by using both automated and manual methods.^[43] We recommend cross-checking the automated values (three values) manually using a digital callipers for verification and to avoid visually significant complications post- surgery.

AS-OCT

AS-OCT provides rapid, non-invasive structural imaging of the anterior segment of the eye. AS-OCT facilitates the analysis of corneal shape and angle of anterior chamber. It measures parameters like Angle to Angle (ATA) diameter, Anterior chamber width (ACW), Lens vault (LV), Crystalline lens rise (CLR) which can help in the proper planning of PIOL in terms of sizing and placement of the lens in order to achieve an ideal vault size between the desirable range of 250-750µD. Post-operatively AS-OCT helps in the assessment of vault size.^[28]

UBM

UBM scan is performed to determine the Sulcus to Sulcus distance (STS) which can aid in assessing the predicted vault. The value of STS distance measured by UBM is considered to be more sensitive as compared to other machines. The IPCL calculator takes into account the STS distance to provide an accurate estimation of the size of PIOL. It enables us in diagnosing iridociliary cysts and discerning their morphology before surgery.^[44]

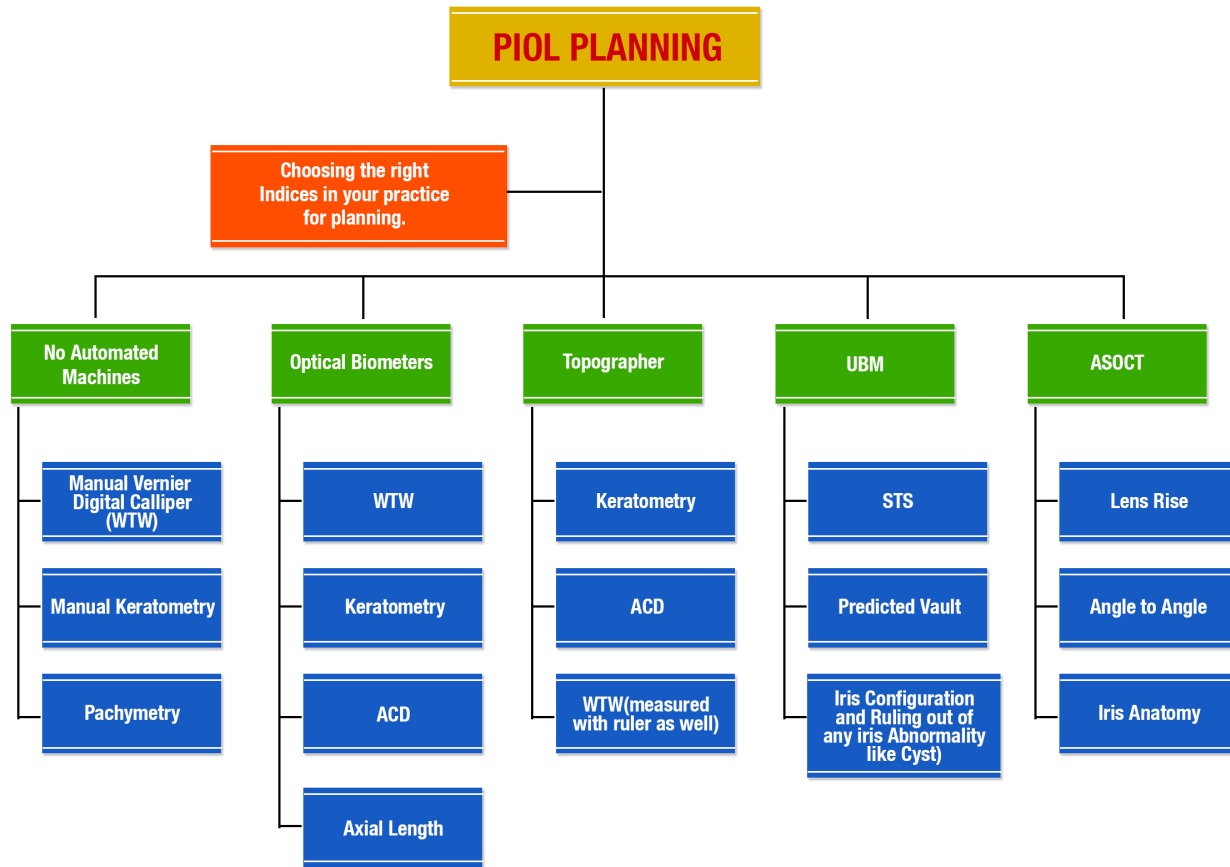
Aberrometry

The iTrace enables the measurement of visual quality and visual function using the principle of optical ray tracing. It provides a unique analysis which subtracts corneal aberrations from total aberrations and thus gives internal aberrations separately. PIOL surgery also induces higher order aberrations (primarily negative spherical aberrations) but less than those induced by laser vision correction. These aberrations can be attributed to corneal incisions and the optical properties of the PIOL. Along with the measurement of these aberrations post-surgery, itrace measures Dysfunctional lens index (DLI) which is of pivotal importance in the presbyopic age group. It measures the performance of the lens objectively while taking into account the pupil size, contrast sensitivity and internal HOAs.^[45] The presence of DLI should be ruled out pre-operatively and in the presbyopic age group.

Glaucoma evaluation

Many studies have reported the complication of raised IOP post PIOL implantation.^[46] Raised IOP can be attributed to

Table 2: Summary of choosing the right indices from different tools in your practice for planning Phakic IOL Surgery



*It would be ideal to measure manual(Vernier/digital caliper) WTW and to do a topography for all patients undergoing Phakic IOL Surgery

Calculate For ICL Toric ICL

Patient ID 123456

Patient Name ABC

Operative Eye OD OS

DOB 1995.1.1

Gender M F

BVD 12

Sphere -8.50

Cylinder -1.25

Axis 90

Power Degrees

K1 45.3 @ 77

K2 46.9 @ 167

ACD 3.16

CT 0.506

WTW 11.6

CL Sphere 0

Any previous intervention? No Yes

Please select a lens from the list below

Sel Sph	Sel Cyldr	Exp Sphere	Exp Cylinder	Exp Axis	Exp Seq
-11.50	+1.0	+00.43	+00.26	176	+00.56
-11.00	+1.0	+00.04	+00.26	176	+00.17
-10.50	+1.0	-00.35	+00.25	177	-00.22
-10.00	+1.0	-00.74	+00.25	177	-00.62
-09.50	+1.0	-01.14	+00.25	177	-01.02

Lens Selected Toric Myopic 12.6mm -10.50/+1.0/X180

DIFFERENT LENGTH REQUESTED

Cylinder Power

+0.5 +1

+1.5 +2

+2.5 +3

+3.5 +4

+4.5 +5

+5.5 +6

Figure 3: STAAR ICL calculation form showing various parameters required for calculating lens size and power

Sel Sph	Sel Cyldr	Exp Sphere	Exp Cylinder	Exp Axis	Exp Seq
-10.00	+3.0	+00.61	+00.25	178	+00.74
-09.50	+3.0	+00.22	+00.25	178	+00.35
-09.00	+3.0	-00.16	+00.25	178	-00.04
-08.50	+3.0	-00.56	+00.24	178	-00.43
-08.00	+3.0	-00.95	+00.24	178	-00.83

Lens Selected Toric ICM 13.2mm -09.00/+3.0/X178

DIFFERENT LENGTH REQUESTED

12.1

12.6

13.2

13.7

Cylinder Power

+0.5 +1

+1.5 +2

+2.5 +3

+3.5 +4

+4.5 +5

+5.5 +6

Figure 4: Option of selecting Size of lens and cylinder for STAAR ICL

White to White(mm)	ACD (mm)	Recommended ICL length
<10.5	All	Not recommended
10.5-10.6	<=3.5	Not recommended
10.5-10.6	>3.5	12.1
10.7-11.0	All	12.1
11.1	<=3.5	12.1
11.1	>3.5	12.6
11.2-11.4	All	12.6
11.5-11.6	<=3.5	12.6
11.5-11.6	>3.5	13.2
11.7-12.1	All	13.2
12.2	<=3.5	13.2
12.2	>3.5	13.7
12.3-12.9	All	13.7
>=13	All	Not recommended

Figure 5: FDA Recommended diameter of ICL according to WTW and ACD measurements for STAAR ICL

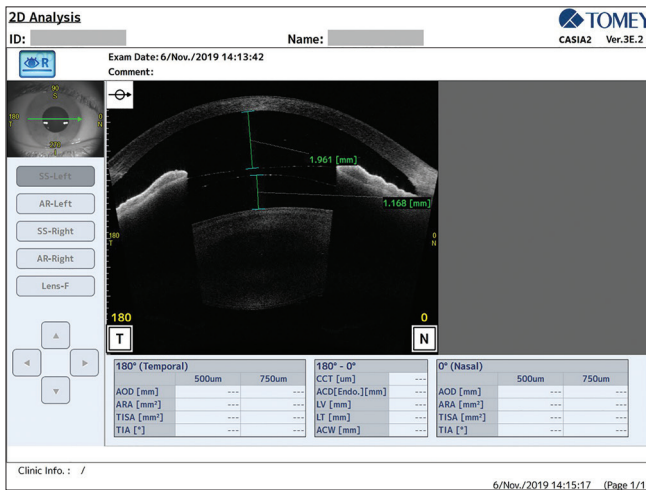


Figure 7: ASOCT scan of a 26 years old female patient showing high vault (1.168 mm) post phakic IOL surgery

retained visco-elastics, steroid response, pupillary block, malignant glaucoma or pre-existing juvenile open angle glaucoma. A thorough evaluation of the angles by gonioscopy is a must to rule out primary angle closure glaucoma before planning to go ahead with PIOL implantation.^[46] The issue of pupillary block post-surgery has been largely addressed by the introduction of a central opening in the optic of the PIOL which allows for the drainage of the aqueous. Myopes are known for high incidence of glaucoma,^[47] so a thorough disc evaluation and documentation before surgery is recommended.

Retina evaluation

A thorough retina evaluation to look for macular as well as peripheral pathologies is a must. Indirect ophthalmoscopy to carry out a thorough evaluation any peripheral degenerations in all quadrants is mandatory and doing a barrage laser before taking up for PIOL surgery is recommended in case lattice degeneration is present.

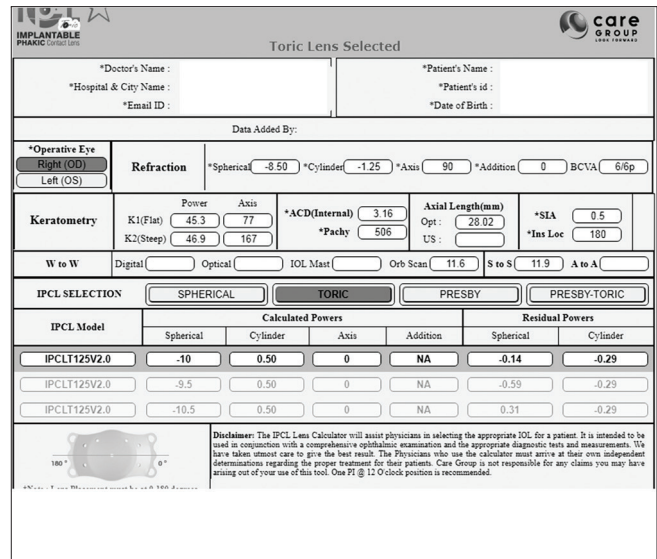


Figure 6: CARE group IPCL calculation form showing various parameters required for calculating lens size and power

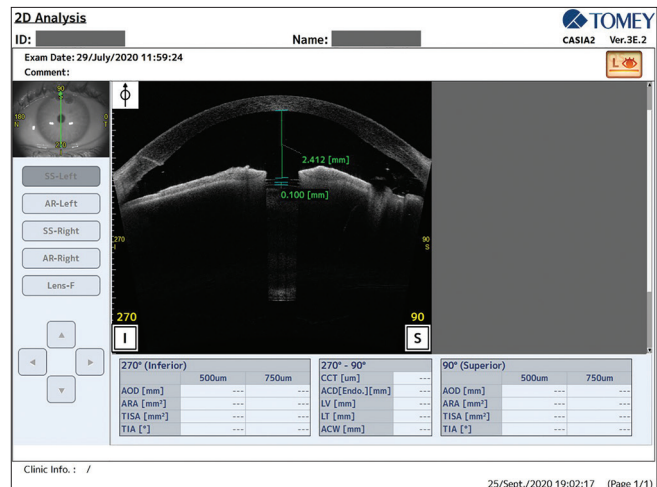


Figure 8: ASOCT scan of a 24 years old male patient showing low vault (0.100 mm) post phakic IOL surgery

Macular OCT

Macular OCT is a valuable imaging tool to screen the macula for any pathologies which could be easily missed with a slit lamp examination like myopic macular retinoschisis, macular hole etc., and can have a detrimental effect on the post-operative visual recovery of the patient.^[48] Macular OCT is thus advisable for all patients who have been planned for PIOL surgery pre-operatively and on serial follow up visits.

How to use the Tools present in your clinic optimally for Phakic IOL Planning.

Ideal work-up of a patient would be as mentioned in Table 1. We have enlisted an approach to calculating the perfect size of the PIOL using tools available in your practice in Table 2.

Cases

Case 1: STAAR ICL calculation form showing various parameters required for calculating ICL size and power. The parameters required to fill are patient's identification details,

refraction, K1 (flat meridian with axis) K2 (steep meridian with axis), ACD (distance taken from corneal endothelium), Corneal thickness entered in decimal upto 3 points, WTW distance in mm, Contact lens sphere and whether any previous intervention has been done. Once we have selected the power, there is an option for changing the size and cylinder of the ICL, if need be [Figs. 3 and 4].

PIOL sizing is determined by ACD and horizontal white-to-white measurements. For eyes with ACD more than 3.5 mm, addition of 1.6 mm to the white-to-white measurement is required upto maximum length of 13.7 mm. Eyes exhibiting ACD equal to or less than 3.5 mm, PIOL size is measured by addition of 1.1 mm to the horizontal white-to-white measurement. PIOL sizes were rounded up for ACD more than 3.5 mm and rounded down if ACD is less than or equal to 3.5 mm. between lens diameters available [Fig. 5].^[49]

Case 2: CARE group IPCL calculation form showing various parameters required for calculating IPCL power and size. The parameters required to fill are patient identification details, refraction, K1 (flat meridian with axis) K2 (steep meridian with axis), ACD (distance taken from corneal endothelium), corneal thickness, axial length optical/ultrasound, surgically induced astigmatism, incision location, WTW measurement which can be entered from manual/digital calliper/optical biometer/topographer, Sulcus to sulcus reading is optional [Fig. 6].

Case 3: ASOCT scan of a 26 year old Female patient depicting various anterior segment structures and parameters like vault size and the anterior chamber depth after ICL surgery. The ASOCT scan of a patient is showing a high vault of 1.168 microns and low ACD. The vault size after surgery must be within the desired range of 250-750 microns. High vault (as shown in Fig. 7 can occur due to oversized phakic IOL, multiple or large ciliary body cysts)^[50] predisposes the patient to angle closure glaucoma caused by the forward displacement of iris and endothelial cell loss. Choosing the appropriate sized phakic IOL is of paramount importance for a good outcome. Rotation of the IOL in case of ciliary body cyst and IOL exchange are two options to achieve an appropriate vault size.^[50]

Case 4: ASOCT scan of a 24 years old male patient after ICL surgery [Fig. 8] showing less vault (100 microns) value than the acceptable limit. Low vault or a decrease in vault size over time (which may occur due to age-related increased lens thickness, accommodative movement of the pupil, low ACD) can increase the propensity of constant or intermittent crystalline lens-phakic IOL touch leading to anterior subcapsular opacities.^[51] Low vault is also associated with higher chances of rotation of Toric PIOL from its original placed axis resulting in induction of refractive error and loss of Uncorrected distance visual acuity. Selection of a larger phakic IOL in patients with relatively less ACD or small WTW measurement may help to achieve better results.^[50] Close follow up is required to monitor the vault size in such patients and phakic IOL exchange can be considered as a viable option to optimize the vault size.

Key Points

- WTW distance is the most important parameter to determine the sizing of PIOL.
- WTW can be measured manually as well as by automated machines. It would be ideal to add manual W-W measurements along with Automated measurements.
- STS is measured by the UBM and is a time consuming and invasive procedure.

- PIOL sizing is directly related to the post-operative vault size.

Conclusion

There is no one correct way of determining the ideal size of PIOL, however it is recommended to follow a step by step approach to decipher the size of PIOL to be implanted in order to avoid unforeseen complications which are associated with the incorrect sizing of the PIOL. We have attempted to summarize all facets needed to reach a consensus and recommend everyone to follow the pattern best suited for their practice.

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Conflicts of interest

There are no conflicts of interest.

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