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Comparison of IOL Power Calculated by Preoperative Biometry versus Intraoperative Wavefront Aberrometry in Thai Cataract Patients.

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Abstract

Background: To find agreement between the calculated intraocular lens (IOL) power from using the SRK/T based preoperative biometry and the intraoperative wavefront aberrometry (ORA®) in Thai cataract patients, and to compare the accuracy of each method with the postoperative refraction results.

Methods: Eyes that underwent cataract surgery with monofocal or multifocal IOL implantation were enrolled in this prospective study. All eye biometry was measured preoperatively and the ORA intraoperatively. The SRK/T suggested IOL from the preoperative biometry was chosen in all cases. The suggested power and the estimated refraction (EST) from both devices were collected. Bland Altman analysis was used to find the agreement between them. The predicted EST of implanted IOL from both devices were compared with the one-month postoperative SE.

Results: The study comprised 97 eyes (79 patients). Of these, 38 eyes (39.2%) had the same suggested IOL power, 36 eyes (37.1%) were within ±0.5D, 20 eyes (20.6%) were within ±1.0D and 3 eyes were beyond ±1.0D. Bland-Altman analysis found the mean difference between IOL power calculated from both devices was 0.39 with LoA of -0.54 to 1.31. The correlation was 98.50% (95%CI 98%- 99.10%). In the same suggested IOL power group, the median difference of EST by preoperative biometry and ORA compared with one-month postoperative SE were -0.08 (95%CI: -0.08, 1.11), and -0.14 (95%CI: -0.88, 1.2), respectively.

Conclusions:The ORA and preoperative biometry results were in concordance with each other. The result of preoperative biometry was more accurate than ORA in this study.

Trial Registration: The thai clinical trial registration

number: TCTR20171005001

Registration Date: October 3rd, 2017

First Enrollment: November 10th, 2017

Background

Cataract is the leading cause of reversible blindness worldwide. The World Health Organization(WHO) has estimated that in 2020, 32 million cataract operations will be performed.[1] People now are expecting more precise and predictable results from cataract surgery. With advanced technologies and surgical techniques, outcome of cataract surgery was expected as a refractive surgery.[2] Therefore, routine preoperative biometry (Axial length, keratometry, etc.) plays an important role in enabling the accuracy of IOL power calculation which essential in good refractive outcome.[3]

Ultrasound biometry (A-scan) has been used to measure the ocular axial length (AL) which requires a technician's skill.[3] We found that the AL measurement was shorter in contact or applanation ultrasound

compared with non-contact or immersion ultrasound in prior studies.[2,4,5] Since 2000, optical biometry has become the new standard for measuring the axial length and other ocular parameters. The latest generation IOLmaster®700 (Carl Zeiss Meditec AG, Germany), which is a Swept source OCT with B-scan biometry-based device[6], is now one of the standards for pre-operative biometry. Various studies show that the IOLmaster®700 results are more precise and repeatable than ultrasound biometry.[7-10]

Even though the IOL power can be calculated in eyes with abnormal axial length, prior to keratorefractive surgery and toric intraocular lens implantation there are still challenges as they are prone to have prediction error.[11] Therefore, another method is needed which can give us the precise ocular biometry especially intraoperatively after lens removal. The optiwave refraction analysis (ORA system® with VerifEye™ Alcon Laboratories, Inc., Tx, USA) is the latest technology using wave-front aberrometry refraction intraoperatively in phakic, aphakic or pseudophakic stages which promise to be more accurate for IOL selection and positioning compared to standard methods.[12-14] It gives the intraoperative IOL calculation power and the postoperative refraction at the end of surgery. This seems to satisfy the expectations of the patients.

This study was designed to find the agreement between the calculated intraocular lens (IOL) power by using the SRK/T based preoperative biometry (IOL master®700) and the intraoperative wave-front aberrometry (ORA system® with VerifEye™ 2017 Alcon Laboratories, Inc., Tx, USA) in Thai cataract patients. We also compared the estimated postoperative refraction results from each device at one month to determine their accuracy.

Methods

Ninety-seven eyes from 79 patients that underwent cataract surgery at the King Chulalongkorn Memorial Hospital performed by a single surgeon (KB) with monofocal or multifocal IOL implantation were enrolled in this prospective nonrandomized study. The Institutional Review Board (IRB) of the Faculty of Medicine, Chulalongkorn University, has approved the study.

Inclusion criteria were scheduled cataract patients over 18 years who underwent cataract surgery by phacoemulsification and femtosecond laser assisted phacoemulsification with non-toric monofocal and multifocal IOL implantation within the bag. All cases were planned to have an estimated refraction close to plano (0 diopter). Exclusion criteria were patients who have limitation of using the IOL Master®700 (Densely opacities media/mature cataract), conditions that was not suitable for using intraoperative aberrometry (corneal scar, small pupil size less than 5.0 mm., macular and retinal abnormality, inability to fix intraoperative aberrometry aiming beam, etc), previous refractive surgery history, intraoperative complications (ruptured posterior capsule, dropped nucleus, etc).

Once the written informed consent was obtained, each eye was completely examined by slit lamp and auto kerato-refractometer (Auto Kerato-refractometer KR-800; Topcon Co, Tokyo, Japan) under standard preoperative assessment. During the first visit each preoperative biometry was measured with the IOL

Master®700 before any ocular contacts such as mydriatric and other topical drugs instillation. In this study the SRK/T suggested IOL power and the estimated postoperative refraction that targeting emmetropia from the preoperative biometry was chosen in all cases and represented as the IOL master 700 calculated or chosen power.

On the operating day each eye was routinely prepared with topical antibiotic (0.5%Moxifloxacin eye drop 1 drop every 15 minutes for 1hour preoperatively), mydriatric drug (1% Tropicamide eye drop 1 drop every 15 minutes for 1hour preoperatively). All surgeries were performed under topical anesthesia (0.5% Tetracaine eye drop 1 drop every 10 minutes for half an hour preoperatively). Each eye was also prepared with the same technique by draping with Opsite™ (Smith & Nephew, Hull, UK) and using the Lieberman adjustable temporal speculum size (E40-100 adult size; PMS, Germany) in order not to apply excessive pressure to the eye. Phacoemulsification was performed with temporal clear corneal incision (2.75 mm wound size) technique. The incision site was approximately aligned at 180˚. The 2 side-port were opened by using 1mm. slit knife at 90 and 225 degree respectively. The circular capsulorrhexis size aiming 5.5 mm was created by no.27 needle tip in all cases under Provisc® (Provisc® ; Alcon, Tx, USA). The standard phacoemulsification with vertical chopped technique was used in all cases.

In the Femtosecond laser assisted cataract surgery (FLACS) group, the treatment was performed with the LenSx laser (Alcon Laboratories, Fort Worth, TX, USA). Each eye was prepped as Phacoemulsification group. After completely docking of the laser-patient interface, spectral domain optical coherence tomography imaging of the anterior segment was performed. Images of the intraocular structures were automatically identified. The surgeon carefully confirmed each step of the procedure with the safety margins. After that, the laser treatment was started with creating a 5.50 mm capsulotomy and lens fragmentation (pattern: 2 concentric cylinders and 8 segment cuts) without corneal incision. After femtosecond laser precut was completed, phacoemulsification was performed using the Centurion Vision System (Alcon Laboratories). The main incisions and side-port were opened with a blade as conventional phacoemulsification. The cohesive ophthalmic viscosurgical device (OVD) (Provisc, Alcon Laboratories) was injected into the anterior chamber to protect the endothelium. The anterior capsule was removed with Utrata forceps (Katena Products, Denville, NJ) and was followed by sterilized balance salt solution (BSS) hydrodissection. The surgery was then completed After the lens nucleus and cortex were removed, we inflated Provisc® to maintain the ocular volume. During the ORA measurement, the Provisc® was used as the ophthalmic viscoelastic device (OVD) of choice for maintaining normotensive level of eye pressure during the measurement in all cases. The IOP checked with a Barraquer tonometer was not to exceed 20 mmHg before start measured with the ORA. The ORA was measured once in the aphakic stage to derive the suggested IOL power and estimated postoperative refraction in all cases and represented as the ORA suggested IOL power. All eyes were implanted with preoperative chosen foldable monofocal IOL and multifocal IOL power suggested by IOL Master®700 in the bag due to the ethical considerations. Wounds ware closed with corneal stromal hydration. All patients had standard routine postoperative follow up.

The suggested IOL power and the estimated refraction (EST) from both devices were collected. We also collected the postoperative auto refraction (Auto Kerato-Refractometer KR-800; Topcon Co, Tokyo, Japan)

results at approximately 1day, and 1 month for determining the accuracy of both devices. The UCVA and BCVA of the eyes at each visit were collected.

Bland Altman analysis was used to find the agreement between them. Subgroup analysis in eyes with the same IOL power reading from both devices were analyzed. The predicted estimated refraction of implanted IOL power from both devices were compared with the one-month postoperative Spherical equivalent from auto-keratorefractometer.

Results

This study comprised 79 subjects with 97 eyes of which 65 eyes received a monofocal IOL (ALCONSA60WF, HOYAIMICS250, HOYAIMICS251 or ACRYSOFMA60AC) and 32 eyes received a multifocal diffractive IOL (ATLISATRI839). All eyes met the inclusion criteria and completed the follow-up as set in the protocol. The characteristics of population are shown in Table1.

Table 1 Demographics of the study population

Characteristics	N	%
Gender		
Male	21	26.6
Female	58	73.4
Total	79	
Age (year)	67.3 ± 6	
Eye		
OD	45	46.4
OS	52	53.6
Total	97	
Axial length (mm)	23.60 ± 1.23	
IOL		
Monofocal	65	67.0
Multifocal	32	33.0
Type of Surgery		
Phacoemulsification	87	89.7
Femtosecondlaser-assisted phacoemulsification	10	10.3
Total	97	

Of these, the A constant of each varied as 118.7 for ALCONSA60WF, 118.4 for HOYAIMICS250/251and ACRYSOFMA60AC for monofocal IOL group. The A constant of ATLISATRI839MP was 118.3.

We found that 38 eyes (39.2%) had the same suggested IOL power from the IOL master and the ORA whereas 36 eyes (37.1%) were within ±0.5D, 20 eyes (20.6%) were within ±1.0D and 3 eyes were beyond ±1.0D, consecutively as shown in Table 2.

Table 2. Differences of IOL power between preoperative biometry (IOL Master^{Ò}) or chosen power and Intraoperative aberrometry (ORA^{Ò})

Difference of IOL power from both devices	Eyes(N=97)	%
Chosen IOL=Suggested IOL power	38	39.2
within ±0.5D	74	76.3
within ±1.0D	94	96.9
> ±1.0D	3	3.1

The IOL powers calculated from IOL master and the ORA were used in the analysis. The Bland-Altman analysis found the mean difference between IOL power calculated from both devices was 0.39 with LoA of -0.54 to 1.31. The correlation was 98.50% (95%CI 98%- 99.10%) as shown in Fig 1.

Figure 1 Bland-Altman analysis shows the difference between the IOL power derived from both devices is plotted against the mean for the two devices. The dotted lines represent the 95% limits of agreement.

Since we wanted to know the kind of calculation that gives us the closest to refractive target (plano). Since this was the first project using the ORA in the country and due to ethics considerations the IOL master calculated power was the chosen as the IOL implanted in this study. We analysed only the same suggested IOL power group and found that the median difference of estimated refraction by preoperative optical biometry (IOL master®700) and intraoperative wavefront aberrometry (ORA system® with VerifEye™) compared with one-month postoperative spherical equivalent by auto refraction were -0.08 (95%CI: -0.08, 1.11), and -0.14 (95%CI: -0.88, 1.2) respectively with statistical significance. A total of 75 eyes (77%) achieved a visual acuity of 20/20.

Discussion

As the advance in cataract surgery technology is moving forward. We have entered an era of precise and predictable outcome of the cataract surgery.[15] Both preoperative biometry and IOL calculation are important factors for cataract surgery.[16] The new generation of formulas are being used for reaching the refractive target, but they also have some limitations especially in the post keratorefractive eyes and abnormal axial length. The non-contact optical biometry has been routinely used worldwide due to its precision. Because not only the monofocal IOL is the IOL of choice for the patients, but also multifocal and Toric IOL that need to be considered. Intraoperative wave-front aberrometry (ORA system® with VerifEye™) is a new technology that provides more accuracy and is promising for IOL power calculation especially in toric IOL implantation and post-refractive surgery patient.[13-17] It might also help the cataract surgeons work with confidence.

In our study the subjects were implanted with non-toric IOL, and most of them had normal axial length eyes (within 22mm. - 25mm).[18] There were 38 eyes (39.2%) that had the same suggested IOL power whereas 74 eyes (76.3%) were within ±0.5D. From the Bland-Altman analysis the correlation between both devices was 98.50%. We also found that the ORA result is inconcordance with IOL master®700 which is the current gold standard for modern optical biometry devices.[19] Comparing with Zhang *et al*, they found that 46.9% (107 from 228 eyes) had same recommended IOL power from ORA and IOL master 300 or IOL master 500.[14] And the ORA postoperative refractive outcomes were comparable to conventional biometry for monofocal IOL selection.[14] Another previous study was from Davison J. A. *et al*, a retrospective review in uncomplicated cataract surgery with no previous ocular surgery found that 46% had same recommend IOL power from IOLmaster700 and ORA, though this percentage was lower in the multifocal IOL group.[20] Fisher *et al* [21], reported 39% of 44 post-lasik eyes that had the same suggested IOL power from the IOL master and the ORA. The limited number of subjects could have made our results lower than the others. And we also included the monofocal and multifocal IOL in the same group.

In 38 eyes which both the ORA and IOL master calculated the same IOL power were analysed. The estimated refraction (EST) of those were different in the same reading group. We found that the median differences of EST by preoperative biometry and ORA compared with one-month postoperative SE were -0.08 (95%CI: -0.08, 1.11), and -0.14 (95%CI: -0.88, 1.2) respectively. The IOL master calculated power (the chosen power) gave the closer estimate refraction compare to autorefraction at 1 month post-operative than the ORA . Cionni *et al* found that the ORA mean absolute prediction error was lower than the preoperative calculation, 0.30 D ± 0.26 (SD) versus 0.36 ± 0.32 D (p <0.0001). And the absolute median prediction error was lower than the preoperative calculation, 0.24 D versus 0.29 D (p< 0.0001).[22]

In our study, however, there were 77 % of the subjects who achieved visual acuity of 20/20. Although it was statistically significant with the median difference of were -0.08 and -0.14 respectively. But it may not be clinical significant due to the availability of IOL power in the market increments step is 0.5D.

In our study, we had a limited the number of subjects especially the post-keratorefractive and Toric cases were not recruited. So we need further studies to determine the accuracy of both devices in these groups. We also had the heterogeneity of the study population i.e. more than one eye from each patient was used, so some of the data is paired, the difference in IOL type (multifocal and 4 monofocal IOL) and the difference kind of phacoemulsification (Femtosecond assisted and conventional phacoemulsification).

The factors that might affect the ORA results varied such as the eye lid speculum pressure that was applied to the eye during the ORA refraction, the ocular surface, type of viscoelastic, type of IOLs manufactured and surgeon experienced. Even though we used the Provisc OVDs and measured with the Barraquae tonometer but we could only estimate that the pressure was around 20mmHg. We could not have a precise IOP at 20 mmHg while measuring. The clarity of the cornea and the pupil size were the factors that affected the IOL power calculation by the ORA. We noticed that dry and cloudy cornea, the constricted pupil less than 4.50 mm could not complete the measurement. The type of IOLs with different design, materials and A constant might also have had an effect on the calculated IOL power derived from

the ORA while we use their EST refraction to compare with the IOL master. We also found that the ORA could only be used with some IOL brands. So it needs numerous databases from multiple brands of IOL to be accumulated in their Analyzor™ (Alcon Laboratories, Inc., Tx, USA) software. That means each surgeon can continuously optimizing IOL-specific lens constants that lead to progressively more accurate outcomes. In our study 10% of eyes were performed with FLACS eventhough only laser assisted capsulorhexis and lens fragmentation and it should be the other factor that affected. And to avoid the learning period factor, in our study the surgeon had experienced of using the ORA in more than 20 cases before the study started. The surgeon could do it with in 30 sec average for the whole measurement.

ORA itself can not only calculates the IOL power intraoperatively but it can also be used for refraction intraoperatively in supine position at the end of surgery. It might help us find the estimated refraction at the end of the surgery. However, this feature will need to be evaluated in terms of accuracy and precision.

Conclusions

The intraoperative aberrometry (ORA system® with VerifEye™) and preoperative optical biometry (IOLmaster®700) results were in concordance with each other. Although the result of preoperative biometry was more accurate than that of ORA in this study. ORA seems to be helpful in reassuring the IOL power trend for the surgeon in difficult and complicated cases.

Abbreviations

- Intraocular lens (IOL)
- Intraoperative wave-front aberrometry (ORA)
- Estimated Refractio (EST)
- Spherical equivalet (SE)
- Axial length (AL)
- Femtosecond laser assisted cataract surgery (FLACS)
- Ophthalmic viscosurgical device (OVD)

Declarations

Ethics approval and consent to participate: IRB 694/59 from Faculty of

Medicine, Chulalongkorn University, Bagkok, Thailand.

Consent for publication

We had our consent for each subject that can be requested to see the copy at any stage.

Availability of data and material

The datasets generated and/or analysed during the current study are not publicly available due to the government of Thailand policy but are only available from the corresponding author on reasonable request.

Competing interests:

There are no financial disclosure in this study.

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Authors' contributions:

Coceptual design, Critical revision of Manuscript, Securing funding, Admin, technical or material support, Supervision, Final Approval and Correspondig author : BK (Bharkbhum Khambhiphant, MD)

Data acquisition, Data Analysis/Interpretation, Drafting manuscript, Statistical analysis : TS (Thanyaporn Sribenjapanon, MD)

All authors have read and approved the manuscript

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Not Applicable

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Figures

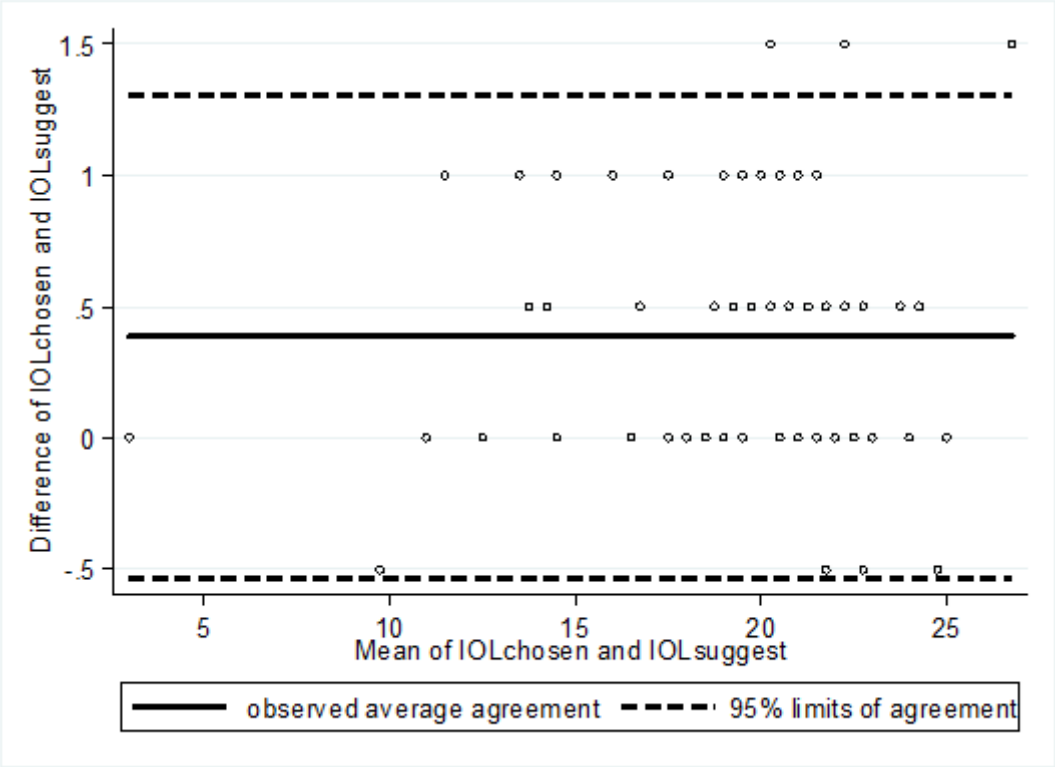

Figure 1

Bland-Altman analysis shows the difference between the IOL power derived from both devices is plotted against the mean for the two devices. The dotted lines represent the 95% limits of agreement.