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Intraoperative Biometry *versus* Conventional Methods for Predicting Intraocular Lens Power: A Closer Look at Patients Undergoing Toric Lens Implantation for Astigmatic Correction

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Abstract

Purpose: To compare intraoperative refractive biometry to conventional methods for intraocular lens (IOL) power calculation in patients receiving toric IOLs.

Setting: The New York Eye and Ear Infirmary of Mt. Sinai.

Design: Retrospective Case Series.

Methods: Separate cohorts of patients undergoing primary cataract extraction with toric IOL implantation were analyzed. In 52 patients, Optivue Refractive Analysis (ORA) was used to guide IOL power determination and axis adjustment. In a separate cohort of 52 patients, conventional methods were used to determine the astigmatic axis and calculate the IOL power. Prediction error (Actual spherical equivalent (SE)-Predicted SE) and median absolute error (MAE) were calculated in each group. The percentage of eyes within ± 0.50 diopters (D) and ± 1.00 D of the refractive target along with the residual cylinder and deviation from intended axis were compared.

Results: The 52 patients in the ORA cohort achieved statistically significant better postoperative MAE than those in the conventional group (MAE 0.34 ± 0.29 (conventional) vs. 0.25 ± 0.22 (ORA), $p=0.05$). When ORA were used, patients were more likely to fall within 0.5D of the targeted refraction (87% vs. 79%). Residual astigmatism was less than 1D in 87% of the ORA group compared to 69% of the conventional group. In the ORA group, 29% of eyes ended up within 10 degrees of the intended axis compared to 12% of eyes in the conventional group.

Conclusions: The current study shows that intraoperative biometry significantly improves refractive target outcomes

for patients undergoing toric IOL implantation in comparison to conventional methodology.

Introduction

Traditional intraocular lens (IOL) power calculation methods rely on mathematical assumptions which render them inherently inaccurate, particularly in eyes that fall outside of the "normal" bell curve such as post-laser vision correction (LVC) or in eyes with extreme hyperopia or myopia. This is due to multiple factors, including the inability of manual keratometers to accurately measure the anterior corneal curvature, the use of incorrect refractive indices to calculate corneal power, and the inaccurate prediction of effective lens position [1,2].

The traditional lens calculation formulas require an estimation of the position of the IOL in the eye. This factor is known as the effective lens position (ELP). IOL formulas differ in the way they calculate ELP. Most of the modern day formulae are based upon the theoretical equation designed by Fedorov and its modifications [3,4]. Conventional methods of intraocular lens (IOL) power calculation are based on preoperative biometry using keratometry (K), axial length (AL), and, in some formulas, additional measurements such as anterior chamber depth. While newer third and fourth-generation formulas, and improvements in biometric technology have increased the accuracy of IOL power prediction, only about 70% of eyes fall within ± 0.5 diopters (D) of the targeted refraction after cataract surgery [2]. In patients with preexisting astigmatism, toric lens implantation with conventional calculations have been shown to improve uncorrected visual acuity and provided greater spectacle independence than lenses that did not correct astigmatism [5,6].

Intraoperative aberrometry may be advantageous for patients undergoing toric intraocular lens implantation for astigmatic

correction. Not only does the ORA allow the surgeon to confirm or revise the IOL power selection that was based on preoperative biometry calculations, but it also allows for intraoperative axis adjustment. In addition, it can help eliminate potential sources of errors such as posterior corneal astigmatism, surgically induced astigmatism, and tilting or head misalignment either with preoperative testing or perioperative axis marking. In a previous study by our group at the New York Eye and Ear Infirmary, A we analyzed 529 eyes undergoing uncomplicated cataract surgery. The toric subgroup was found to have a statistically significant difference in MAE in postoperative refractive outcomes when using ORA *versus* conventional methods ($p=0.005$). However, in all of these patients, ORA were used intraoperatively. Therefore, there was no control group of toric IOL patients to compare to, who used conventional methods only.

In the current study, we analyzed the refractive target outcomes using an intraoperative aberrometer (Optiwave Refractive Analysis [ORA] System WaveTec Vision, Inc, Aliso Viejo, CA) and compared it to a control group cohort using conventional preoperative methods in whom the ORA was not utilized.

Methods

This series compared two separate cohorts of patients undergoing primary cataract extraction with toric IOL implantation. The group undergoing conventional preoperative calculations underwent surgery from 2010 through 2012, and the group undergoing ORA intra-operatively underwent surgery from 2013 through 2014. All patients who underwent primary phacoemulsification and IOL implantation for cataract without additional visually significant ocular comorbidities were queried from our office medical records and the ORA surgical outcomes database. An Acrysof® toric IOL (Alcon, Ft worth, Tx) was used in all cases. (Table 1) Chart reviews were conducted to document preoperative demographic data and biometric measurements. Exclusion criteria were as follows: A preoperative diagnosis of irregular astigmatism, keratoconus, previous corneal laser vision correction, prior intraocular surgery, and other ocular disease that might prevent a best-corrected vision. Postoperatively, we excluded patients with a best-corrected visual acuity of worse than 20/30 three weeks after surgery. Patients who developed cystoid macular edema were also excluded. Our study involved two experienced cataract surgeons at one institution. The study protocol was approved by the Investigational Review Board at our institution.

Preoperatively, the axial length (AL) and keratometric values (K) were obtained using partial coherence optical biometry (IOL Master, Carl Zeiss Meditec, Jena, Germany). K values were also obtained manually and through corneal topography (Pentacam, Oculus, Dutenhofen, Germany). If the measurements were inconsistent, they were repeated. The IOL predictive formulas used in the IOL Master (i.e. Holladay, Haigis, or SRK-T) were chosen by the surgeon based on preoperative patient data. For each study eye, the surgeon used his/her best judgment to choose atoric IOL based on the patient's targeted postoperative refraction. For toric IOL axis placement, all patients underwent

pre-operative corneal topography using Pentacam which uses Scheimpflug technology. Calculation of power of the implanted IOL was determined using: 1. The HicSoaPro™ software for toric IOL calculations (IOLMaster®), and/or 2. The online toric calculator from Alcon (<http://www.acrysoftoriccalculator.com/>), The Baylor Nomogram, which considers the effect of posterior corneal astigmatism [7]. The K value from the IOL Master was plugged into the formulas. The surgeon compared the lens recommendations from the HicSoaPro software and the online toric manufacturer's calculator to choose a lens power and astigmatic correction based on their best judgment.

To determine the proper axis at which the toric lens should be aligned, the astigmatic axis was measured manually as well as from the corneal topography and IOLMaster®. The keratometry and axis were used from the two devices that showed the most consistent results. If none of the three were consistent, the measurements were repeated until some consensus could be reached. The ORA's Wavetec vision website (<https://home.wavetecvision.com/>) was used to remotely enter the patient data, including which keratometric method was used, the magnitude of the flat and steep K as well as the axis, white-to-white measurement and the axial length. The target refraction was entered as well as data about the IOL to be implanted, including manufacturer, model, power, and formula used to determine the lens power, and predicted refractive outcome.

Prior to entering the operating room with the patient in a seated position, the surgeon used a marking pen to delineate the horizontal axis using a Stephens Bubble Level Toric Axis Marker (Stephens Instruments, Lexington Kentucky). In the operating room, the conventional group underwent routine phacoemulsification through a temporal clear corneal incision. Prior to implanting the IOL, viscoelastic was used to fill the capsular bag. A Henderson toric axis IOL marker (Katena instruments, Denville NJ) was used to mark the axis of astigmatism at the predetermined axis determined from the preoperative calculations. The IOL was implanted and aligned to the correct axis marked on the cornea. Care was taken during viscoelastic removal to prevent rotation of the toric IOL after placement.

In the ORA toric subgroup, after the cataract was removed, the capsular bag and anterior chamber were filled with viscoelastic. The intraocular pressure was measured using an applanation tonometer in order to ensure that the eye was pressurized to at least 30 mmHg, as per the manufacturer's recommendations. As with the conventional methods, a Henderson toric axis IOL marker was used to mark the axis of astigmatism at the predetermined calculated astigmatic axis. The ORA was then used to determine the aphakic refractive state of the eye, and the ORA's calculation of the predicted postoperative refraction was used to either confirm or adjust the toric IOL power prior to implantation. The toric IOL was then implanted into the eye, and was aligned with the previously calculated marked toric axis. The ORA was then utilized for real-time axis adjustment. The lens was rotated according to the ORA's recommendations. The measurement was repeated until

there was no residual astigmatism measured and confirmed with the ORA platform. The predicted postoperative refraction for the implanted IOL was recorded and was imported to the database. The predicted refractive refraction from the IOL Master printout for the actual implanted IOL was also recorded.

Postoperatively, best-corrected visual acuity and the spherical equivalent were calculated from a refraction performed by an experienced optometrist or ophthalmologist during an office visit at a minimum of three weeks after surgery. The prediction error for the implanted IOL power was calculated as the difference between the postoperative outcome and the predicted refraction from the IOL Master for the lens that was implanted or the predicted refraction from the ORA for the lens

that was implanted. Median absolute errors (MAE) were derived for all refractive outcomes.

Results

A total of 104 patients were included in the series. There were 52 eyes in the conventional calculations subgroup and 52 eyes in the ORA subgroup (Table 1). Patients in the ORA cohort achieved a statistically significant lower MAE than those in the conventional subgroup (0.34 ± 0.29 (conventional) vs. 0.25 ± 0.22 (ORA), ($p=0.05$). Of the ORA group, 45/52(87%) of eyes were within 0.5D of the targeted refraction, compared to 41/52 (79%) in the conventional group ($p=0.437$) (Table 2).

Table 1: Patient & Operative Characteristics of Study Eyes.

Characteristic	Conventional Group (N=52)	ORA Group (N=52)
	Mean \pm SD or %	Mean \pm SD or %
Male	56%	46%
Age at time of surgery (years)	66 \pm 9	67 \pm 8
Preoperative astigmatism	2.23 \pm 1.38 (min 0.76D, max 9.4D)	2.19 \pm 0.88 (min 0.82D, max 4D)
Average K (IOL Master)	44.20 \pm 1.68	44.01 \pm 1.99
Axial Length (mm)	25.23 \pm 1.96	24.62 \pm 1.71
Implanted IOL Power (D)	16 \pm 5	17 \pm 5
Implanted IOL Type	100%	100%
Alcon toric		
D=Diopter, IOL=Intraocular lens, K=Keratometry		

Table 2: Refractive Outcomes.

	Conventional Group (N=52)	ORA Group (N=52)	P value*
MAE, D	0.34 \pm 0.29	0.25 \pm 0.22	
% within \pm 0.50D	79	87	0.437
Residual Astigmatism			
0D	18/52 (35%)	14/52 (27%)	0.524
<0.5D	28/52 (54%)	34/52 (65%)	0.318
<1D	36/52 (69%)	45/52 (87%)	0.059
MAE=Mean Absolute Error, D=Diopter, *Chi square			

With the help of the ORA, surgeons were able to reduce astigmatism to less than 1D in 45/52 (87%) of patients compared to only 36/52 (69%) of patients who underwent conventional planning without ORA, which almost reached statistical significance ($p=0.059$). Of the ORA group, 14/52 (27%) had no postoperative residual astigmatism vs. 18/52 (35%) of the conventional group. Of the remaining patients with residual astigmatism postoperatively, 15/52 (29%) of the ORA group refracted to an axis within 10 degrees of the intended axis at

which the IOL was aligned in the operating room, compared to 6/52 (12%) of the conventional patients ($p=0.133$).

Discussion

Preoperative astigmatism 1.5D or greater is present in 20% of all patients undergoing operation for age-related cataracts [8]. It is well known that residual postoperative astigmatism is an important cause for the inability to obtain emmetropia after cataract surgery. Residual postoperative astigmatism is an important reason for spectacle use even in patients with a spherical equivalent refraction \pm 0.5 D [9]. Correcting residual astigmatism results in improved visual acuity at all contrast levels at both distance and near [10].

Refractive astigmatism can be corrected by three main methods: implanting a toric IOL, changing the corneal curvature through laser vision correction (LVC), or through limbal relaxing incision(s) [11]. Generally, relaxing incisions may correct up to 3D of astigmatism, LVC may correct up to 6D of astigmatism, and toric IOLs can correct up to 8D of astigmatism [12]. Despite the weakness inherent in correcting astigmatism with manual incisions, the advent of the femtosecond-laser created corneal incisions has raised the possibility that arcuate incisions created with the femtosecond laser may be more accurate not only in

depth but length than those incisions created manually and might attain the accuracy seen with toric IOLs.

Nevertheless, toric IOL's have significant advantages including the ability to achieve correction of higher amounts of astigmatism, minimally traumatic surgeries, improved accuracy (less likely to regress with healing), and the ability to readjust the axis or exchange the alignment post-operatively. You cannot easily undo corneal incisions, whether made manually or made with the femtosecond laser. It has also been our group's experience that LRI's for astigmatism greater than 1.5D has less satisfactory long-term results and stability.

One potential downfall of toric implants is the postoperative rotation of the implant within the capsular bag. A rotation of greater than 30 degrees off the intended axis could potentially reduce the power of the IOL to the point of eliminating its correcting effect [13]. These cases may require surgical repositioning of the IOL and increase the risk for an untoward complications including rupture of the capsule.

In addition, patients who are paying out-of-pocket for a premium toric IOL, typically have higher expectations for postoperative results. In these patients, accurate determination of the amount of astigmatism and its axis is paramount. It is important preoperatively to determine the amount of refractive, lenticular and corneal astigmatism. As the patient is undergoing cataract surgery, the lenticular astigmatism should not be factored into preoperative calculations. As the corneal incision may induce astigmatism, surgeons must consider this in their calculation of how much astigmatism needs to be corrected, and the axis of their wound. The manufacturer's toric calculators take this into account and recommend a final cylindrical power and axis of IOL orientation.

While conventional methods of IOL calculation are accurate in the majority of eyes, their accuracy is reduced in eyes that deviate from the "normal", such as eyes with high astigmatic error [5,6,14]. This is in part due to preoperative factors such as the inability to accurately measure the amount or axis of astigmatism, as well as operative factors such as correct alignment of the IOL. Traditionally, surgeons choose the alignment of a toric IOL based on preoperative topography and biometry calculations. The ability to use ORA to guide IOL alignment and adjust the power of the lens has intuitive benefits. Our study identified a statistically significant difference in predictive accuracy when using the ORA compared with conventional methods for patients received a toric implant. Hatch et al. looked specifically at toric IOL patients, and analyzed residual astigmatism using ORA *versus* conventional methods. Their study demonstrated that cataract extraction with toric IOL placement aided by intraoperative aberrometry (37 eyes) was 2.4 times more likely to have less than 0.50D of residual astigmatism after surgery compared to standard methods (27 eyes) [15]. One advantage of the ORA in these patients is that the technology is the first to allow for the adjustment of both power and axis of the implanted IOL in the perioperative setting. It allows for real time analysis of astigmatism, which is subject to errors due to induced astigmatism from corneal incision as well as torsion of the eye when the patient is in the supine position. The ORA avoids some of the errors in preoperative

measurements and allows us to resolve disagreements between preoperative tests. Traditional biometry only measures anterior corneal astigmatism. By measuring the aphakic refraction of the whole eye, the ORA may also factor in the posterior corneal astigmatism that is not identified by conventional measurements, potentially leading to better outcomes [16].

Our study identified a statistically significant difference in the predictive accuracy when using the ORA compared with conventional methods for the patients who required a toric IOL. It is possible that in addition to the anterior corneal astigmatism, these eyes have significant posterior astigmatism that is not identified by conventional measurements. ORA's wave front technology incorporates the contributions of the posterior cornea into the IOL calculation, which could potentially lead to better outcomes and explain the advantage of ORA in these patients. Additionally, the ORA helps guide the surgeon with alignment of the IOL based on axis of astigmatism while in the operating room. The surgeon is able to take into account intraoperative variables that may affect astigmatism such as the cataract incision and torsion of the globe that occurs when the patient is in the supine position. Traditional toric implant alignment is dependent on preoperative topography and the determination of the "best guess" for the astigmatic axis. The ORA allows for real-time power and axis adjustment and may contribute to better outcomes in these patients, not only in its ability to modify the power of the toric IOL, but also in the ability to modify the axis of astigmatism.

Conclusion

This study demonstrated a number of potential advantages of intraoperative methodology for IOL power calculation. The aphakic refraction is an optical measurement obtained using wavefront technology. It allows us to use the optics of the eye instead of relying on estimations of corneal power. We believe that intraoperative aberrometry is a promising technology that will allow for more reliable, predictable, and accurate surgical decisions. Based on the findings of this study, intraoperative refractive biometry may be a helpful adjuvant in obtaining target refractions in patients undergoing cataract surgery, particularly those requiring astigmatic correction. Only the absolute error was significantly improved in these patients using ORA. The other variables tested, such as proximity to the targeted axis, were also improved in the ORA subgroup, but they did not achieve statistical significance. A larger study may help elucidate if these variables are significantly different.

What Was Known

Prior to undergoing cataract surgery, all patients must undergo calculations to determine which lens power to use. While these calculations have proven to be extremely accurate, newer technology allows surgeons to repeat and confirm these calculations intraoperatively.

What This Paper Adds

Intraoperative aberrometry leads to more accurate refractive target outcomes if used in lieu of or in conjunction with traditional lens calculations in patients undergoing toric lens implantation for astigmatic correction?

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