Intraoperative Aberrometry with the ORA™ System

Clinical Science Compendium

Summary of peer-reviewed clinical research

Medical Affairs North America

Alcon

INTRODUCTION

At Alcon, our surgical medical device products, such as the ORA™ System for intraocular lens (IOL) power calculation, are designed, manufactured and marketed with a body of science developed through rigorous bench research and clinical studies. As the body of knowledge behind Alcon's products grows, so does the challenge of making our customers aware of its depth. Our medical affairs organization is thus focused on both high-quality data generation and its communication to the clinical community.

High-quality scientific publications are essential to convey the clinical community's knowledge and experience with new technology. This clinical science compendium provides a consolidated view of peer-reviewed publications for intraoperative aberrometry using the ORA™ System, which allows surgeons to evaluate refractive findings, refine IOL power, cylinder power, and IOL alignment in real time to provide optimal refractive outcomes in cataract surgery.

In addition to exploring this compendium, we encourage you to visit Alcon's Medical Affairs website—AlconScience.com—to learn more about how medical science matters to us. Beyond scientific publications relating to Alcon's portfolio, you will find more information on independent medical educational grants, teaching facility equipment placement, and areas of interest for investigator-initiated trials.

METHODOLOGY

The 22 articles summarized in this compendium were identified using the PubMed and Google Scholar databases incorporating the search terms "Optiwave Refractive Analysis," "ORA," "intraoperative aberrometry," and "intraoperative refractive biometry." Articles were included when they were published between January 1, 2010 and November 1, 2019 and contained research relevant to the ORA™ System for guidance and verification during cataract refractive surgery. Only manuscripts published in peer-reviewed journals and available in English were included in this compendium.

Table of Contents

Table of Contents / Continued

Comparison of IOL Power Calculation Methods and Intraoperative Wavefront Aberrometer in Eyes after Refractive Surgery

Canto et al. *J Refract Surg.* 2013;29:484-489

OVERVIEW

STUDY DESIGN

Retrospective study to compare preoperative methods for calculating IOL power versus the ORange intraoperative wavefront aberrometer (IA) in eyes with a history of refractive surgery (LASIK, photorefractive keratectomy [PRK], radial keratectomy [RK])

STUDY SETTING(S)

Data from a single clinic, United States

PATIENTS

Forty-six (46) eyes of 33 patients

SURGICAL METHODOLOGY

Cataract surgery with IOL implantation; IOL power predicted using ORange for IA or preoperative methods (SRK-T formula from the IOLMaster; average central keratometry [Avg K] from corneal topography; American Society of Cataract and Refractive Surgery [ASCRS] web site)

IOL TYPE(S)

Alcon SN60WF, Advanced Medical Optics ZA9003, Alcon SN6AT (in patients who had previously undergone myopic treatment); Bausch & Lomb Crystalens AT52AO

KEY ENDPOINT(S)

Spherical equivalent; formula accuracy defined as the difference between IOL power that would have achieved emmetropia and the calculated IOL power for emmetropia of each formula

ANALYSIS AND CONCLUSIONS

IA with ORange was more accurate than the preoperative methods studied for predicting IOL power within ±0.5 and ±1.0 D of emmetropia, but myopic and hyperopic shifts occurred.

No method was able to achieve a prediction to within ±0.5 D of emmetropia more than 50% of the time.

STUDY RESULTS

PREDICTIVE ACCURACY FOR ALL EYES

- Considering all eyes, IA with ORange predicted IOL power within ±0.50 and ±1.0 D of emmetropia more frequently than the other three methods
- In 37% of cases, ORange predicted IOL power to within ±0.50 D of emmetropia, compared to 30% for IOLMaster keratometry, 26% for Avg K, and 17% for ASCRS web site (**Table 1**)
- The two methods with the best arithmetic mean prediction errors were the ORange and ASCRS estimations

PREDICTIVE ACCURACY FOR EYES BASED ON HISTORY OF REFRACTIVE SURGERY

- In eyes after myopic treatment, ORange, IOLMaster, Avg K, and ASCRS web site predicted within ±0.50 D of emmetropia in 39%, 27%, 24%, and 18%, respectively, and within ±1.0 D in 60%, 39%, 39%, and 51%, respectively (**Table 2**)
- In eyes after RK, the ORange, IOLMaster, and Avg K methods frequently estimated a lens power that would have resulted in a hyperopic refraction (>0.5 D) in 57%, 43%, and 57% of the cases, respectively (**Table 2**)
- This is in contrast to the ASCRS method, which would have predicted a myopic result in 57% of cases, but never predicted a hyperopic refraction (**Table 2**)

Table 1. Formula accuracy for all eyes.

Accuracy	IOLMaster Keratometry	ORange	Avg K Estimation	ASCRS Estimation
> -1.0 off	3 (7%)	5 (11%)	7 (15%)	14 (30%)
-1.0 to -0.51	1 (2%)	6 (13%)	2 (4%)	7 (15%)
-0.5 to +0.5	14 (30%)	17 (37%)	12 (26%)	8 (17%)
+0.51 to +1.0	5 (11%)	4 (9%)	4 (9%)	9 (20%)
> +1.0 off	23 (50%)	14 (30%)	21 (46%)	8 (17%)

Avg K, average keratometry; ASCRS, American Society of Cataract and Refractive Surgery; IOL, intraocular lens; PRK, photorefractive keratectomy. All values shown as n (%).

Table 2. Formula accuracy based on refractive history of the eyes.

Accuracy	IOLMaster Keratometry	ORange	Avg K Estimation	ASCRS Estimation
Post-myopic LASIK and PRK				
> -1.0 off	0 (0%)	3 (9%)	3 (9%)	9 (27%)
-1.0 to -0.51	0 (0%)	5 (15%)	1 (3%)	3 (9%)
-0.5 to +0.5	9 (27%)	13 (39%)	8 (24%)	6 (18%)
+0.51 to +1.0	4 (12%)	2 (6%)	4 (12%)	8 (24%)
> +1.0 off	20 (61%)	10 (30%)	17 (52%)	7 (21%)
Post-myopic LASIK and PRK				
> -1.0 off	1 (14%)	2 (29%)	2 (29%)	4 (57%)
-1.0 to -0.51	0 (0%)	0 (0%)	0 (0%)	2 (29%)
-0.5 to +0.5	3 (43%)	1 (14%)	1 (14%)	1 (14%)
+0.51 to +1.0	0 (0%)	0 (0%)	0 (0%)	0 (0%)
> +1.0 off	3 (43%)	4 (57%)	4 (57%)	0 (0%)

Avg K, average keratometry; ASCRS, American Society of Cataract and Refractive Surgery; IOL, intraocular lens; PRK, photorefractive keratectomy. All values shown as n (%).

Utilizing Intraoperative Aberrometry and Digital Eye Tracking to Develop a Novel Nomogram for Manual Astigmatic Keratotomy to Effectively Decrease Mild Astigmatism During Cataract Surgery

Monofocal IOL Implantation

ORA vs. Conventional Preoperative Biometry

Chen et al. ***Taiwan J Ophthalmol.*** **2019;9:27-32**

OVERVIEW

STUDY DESIGN

Single-surgeon comparative study with retrospective data collection to develop a novel nomogram for manual astigmatic keratotomy (MAK) with assistance of the ORA™ System and digital eye tracking (VERION) in mild astigmatic correction enhancement

STUDY SETTING(S)

Single site, United States

PATIENTS

Control group with 60 consecutive cases without refinement using intraoperative aberrometry (IA; ORA™ System) and VERION, 60 consecutive cases with refinement using the ORA™ System and VERION

SURGICAL METHODOLOGY

MAK performed before phacoemulsification during cataract surgery according to the surgeon's own nomogram; ORA™ System utilized after phacoemulsification and IOL implantation

IOL TYPE(S)

Not specified

KEY ENDPOINT(S)

Visual acuity and refractive outcomes at 3 months; development of novel nomogram

ANALYSIS AND CONCLUSIONS

The use of IA (ORA™ System) and VERION for mild astigmatism correction with MAK during cataract surgery produced statistically significant better outcomes than cases without the assistance of these technologies.

Calculating the added correction after ORA™ System/VERION enabled the authors to develop a novel nomogram for surgeons who do not have access to these technologies; a future prospective, controlled study is needed to validate the efficacy of this nomogram.

STUDY RESULTS

REFRACTIVE OUTCOMES AND VISUAL ACUITY

- Three-month postoperative refractions with Alpins vector analysis showed that the group using ORA™ System/VERION had a better correction index (CI) of 0.62 compared to control CI of 0.41 (**Table 1**)
- There was also less magnitude of error (ME) of 0.37 in the ORA™ System / VERION group compared to control ME of 0.51 (**Table 1**)
- The proportion of postoperative patients with cylinder <0.5 D was 87% in the ORA™ System/VERION group vs 70% ($P<0.05$) in the control group without utilizing ORA™ System/VERION (**Table 1**); this improvement of undercorrection by CI was used to formulate a new nomogram
- Better than 20/25 best-corrected vision was achieved more frequently in the ORA™ System/VERION group compared to non-ORA™ System/VERION group (**Figure 1**)

NOVEL NOMOGRAM

- A new nomogram developed from cases using ORA™ System/VERION (**Table 2**) tested favorably compared to the former nomogram with respect to statistical difference for cylinder correction
- Improvement of CI from 0.41 to 0.62 suggests this novel nomogram is superior to the previous version and can be applied to practices even without the use of the ORA™ System and VERION
- No intraoperative or postoperative complications occurred in this patient population, including perforation and infection

Table 1. Alpins vector analysis comparison.

	IA (ORA™ System/VERION) (n=60)	No ORA™ System/VERION (n=60)
Mean TIA	1.1±0.1	1.1±0.1
Mean SIA	0.72+0.1	0.57±0.1
Mean CI	0.62±0.1	0.41±0.1
Mean ME	0.37±0.1	0.51±0.1
Postoperative cylinder <0.50 D (%)	87	70; P<0.05

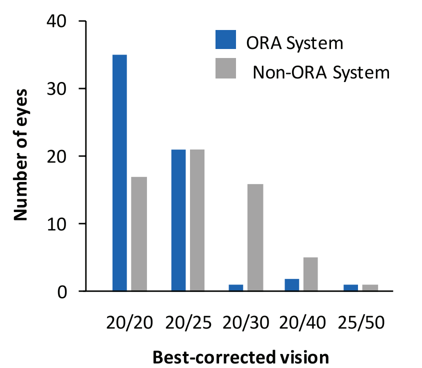
IA, intraoperative aberrometry; TIA, target-induced astigmatism (preoperative cylinder); SIA, surgical-induced astigmatism (surgically corrected cylinder); CI, correction index; ME, magnitude of error (remaining postoperative cylinder).

Table 2. New nomogram.

	1.00-1.25 D	0.50-0.75 D
ATR 58 eyes	5°±2.5° ×1 at 9 mm, former was 40°	35°±2.5° ×1 at 9 mm, former was 30°
WTR 2 eyes	15°×2 at 9 mm, former was the same	25°±2.5° ×1 at 9 mm, former was 20°

*ATR has only one incision due to cataract surgery main wound made temporally. ATR desire slight overcorrection will add 2.5° and WTR desire slight undercorrection due to WTR is more favorable for better vision will minus 2.5°. That is why the correction is different between WTR and ATR. *Age <60 add 5° for both group. ATR, against the rule; WT, with the rule.*

Figure 1. Comparison for best-corrected postoperative vision between groups with and without intraoperative aberrometry (IA; ORA™ System).



A Large Retrospective Database Analysis Comparing Outcomes of Intraoperative Aberrometry with Conventional Preoperative Planning

Monofocal IOL Implantation

Multifocal IOL Implantation

Toric IOL Implantation

ORA vs. Conventional Preoperative Biometry

Cionni et al. *J Cataract Refract Surg.* 2018;44;1230-1235†

OVERVIEW

STUDY DESIGN

Retrospective, using de-identified data from a surgical database

STUDY SETTING(S)

Procedures performed by 209 surgeons across 122 U.S. surgical centers

PATIENTS

24,375 patients with no history of refractive surgery who received IOL implantation in at least one eye (32,189 eyes total)

SURGICAL METHODOLOGY

Interoperative aberrometry (IA) using the ORA™ System and pre-operative biometry were performed for all cases

IOL TYPE(S)

Alcon Acrysof® IQ IOLs (monofocal, multifocal, toric) (**Table 1**)

KEY ENDPOINT(S)

IOL power prediction error with IA vs. preoperative calculation; percentage of cases with prediction error ≤0.50D

ANALYSIS AND CONCLUSIONS

IA using the ORA™ System outperforms preoperative calculation, reducing predictive error and improving spherical equivalent outcomes, in eyes with no history of refractive surgery.

Because the database comprised real-world data from a variety of surgical centers, the preoperative formulas used by surgeons were not standardized or necessarily optimized. This could be viewed as a study limitation (Runde, 2019), but it also provides evidence for the benefits of IA (ORA™ System) vs. preoperative calculations used in real-world practice (Cionni, 2019).

†Financial support for this article was provided by Alcon, Inc.

STUDY RESULTS

PRIMARY OUTCOMES

- When examining all 32,189 IOL implants, mean and median absolute prediction error were significantly lower with IA (ORA™ System) vs. preoperative calculation (P<0.001; **Table 2**)
- This was also observed for the subset of eyes in which the power of the implanted IOL differed from the preoperatively calculated IOL power (P<0.0001)
- Absolute prediction error ≤0.50 D was achieved significantly more frequently with IA (ORA™ System) (81.9% vs. 75.9% of eyes, P<0.0001 for all IOLs [**Figure 1**]; 81.3% vs. 68.8%, P<0.0001 for the subset of eyes in which the power of the implanted IOL differed from the preoperatively calculated IOL power [**Figure 2**])

SECONDARY OUTCOMES

- Mean and median absolute prediction errors for non-toric and toric IOLs were consistent with the full data set (**Table 2**)
- For non-toric IOLs, absolute prediction error with IA (ORA™ System) was ≤0.50D in 82.4% of eyes (vs. 76.8% with preoperative calculation)
- For toric IOLs, absolute prediction error with IA (ORA™ System) was ≤0.50D in 80.8% of eyes (vs. 74.3% with preoperative calculation)
- In 8,850 (26.7%) of eyes overall, the IOL power recommended by IA (ORA™ System) differed from the preoperatively planned IOL, and the surgeon implanted the IA-recommended IOL power

Table 1. Baseline patient characteristics and frequency of IOL models implanted

Patients and Implanted IOLs	n (%)
Sex (N=24,375 patients)	
Male Female	14,235 (58.4) 10,140 (14.6)
IOL type (N=32,189 eyes)	
Non-toric Acrysof® IQ (monofocal) Acrysof® IQ Restor (multifocal) Toric (Acrysof® IQ Toric)	21,429 (66.6) 15,548 (48.3) 5,881 (18.3) 10,760 (33.4)

Table 2. Absolute prediction error, IA vs preoperative calculation. Adapted from Cionni et al. *J Cataract Refract Surg.* 2018;44; 1230-1235.

		IA (ORA™ System)	Preoperative calculation	P-value
All eyes (N=32,189)	Mean (SD)	0.30 (0.26)	0.36 (0.32)	<0.0001
	Median	0.24	0.29	<0.0001
Eyes implanted with non-toric IOL (N=21,429)	Mean (SD)	0.30 (0.26)	0.35 (0.31)	-
	Median	0.24	0.28	-
Eyes implanted with toric IOL (N=10,760)	Mean (SD)	0.31 (0.27)	0.37 (0.34)	-
	Median	0.25	0.30	-
Eyes in which implanted IOL power ≠ preoperatively calculated IOL power (N=12,779)	Mean (SD)	0.31 (0.27)	0.42 (0.37)	<0.0001
	Median	0.25	0.34	<0.0001

SD, standard deviation

Figure 1. Percentage of cases in which the absolute prediction error was ≤0.50 D.

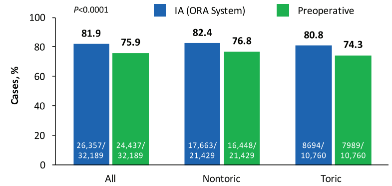
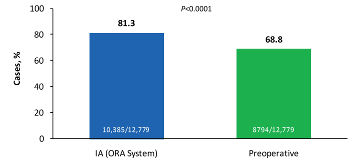


Figure 2. Percentage of cases in which the absolute preoperative prediction error was ≤0.50 D in cases in which the power of the preoperative IOL and the power of the IOL implanted did not agree.



Preoperative Measurement vs Intraoperative Aberrometry for the Selection of IOL Sphere Power in Normal Eyes

Davison et al. *Clinical Ophthalmology*. 2017;11:923-929

OVERVIEW

STUDY DESIGN
Retrospective chart review to objectively assess the value of intraoperative aberrometry (IA) using the ORA™ System in determining the IOL sphere power in eyes with no previous ocular surgery

STUDY SETTING(S)
Data from single clinic, United States

PATIENTS
One hundred sixty (160) eyes of 112 patients

SURGICAL METHODOLOGY
Uncomplicated cataract surgery where standard preoperative measurements and IA using ORA™ were performed

IOL TYPE(S)
Multifocal, toric and aspheric single-vision non-toric (i.e., monofocal) Alcon IOLs

KEY ENDPOINT(S)
Calculated IOL sphere powers and postoperative refractions (actual and theoretical)

ANALYSIS AND CONCLUSIONS

There is no significant improvement in clinical outcomes in eyes with no previous ocular surgery when calculating IOL sphere power using IA with the ORA™ System compared to standard preoperative planning methods.

An exception to this conclusion may be in the rare case where the two methods show a sphere calculation difference of 1.5 D or more, but more data are required to corroborate this observation.

STUDY RESULTS

POWER DIFFERENCES

- **Table 1** shows the difference between the calculated sphere power for IA (ORA™ System) relative to preoperative calculation by IOL type
  - IOL power calculation results from IA with the ORA™ System and the preoperative calculation were similar in nearly half of cases (47%, 73/155)
  - For toric and multifocal IOLs, there was statistically significant bias toward lower-powered lenses with IA with the ORA™ System (P<0.01)
- There were only three instances in which preoperative and IA (ORA™ System) calculations differed by 1.5 D; in all instances an adjustment of the preoperative lens power by 0.5 D toward the IA calculation showed a positive effect

Table 1. Difference in suggested lens power with IA (ORA™ System) vs. preoperative calculation by IOL type.

IOL type	Eyes	IA (ORA™) suggests lower by:			No change	IA (ORA™) suggests higher by:	
		1.5D	1.0D	0.5D		0.5D	1.0D
Aspheric non-toric	9		1		5	2	1
Toric	124	1	4	38	66	14	1
Multifocal	22	2	9	8	2	1	
All lenses	155	3	14	46	73	17	2

ERROR DIFFERENCES AND SURGEON CHOICES

- Actual postoperative refractive errors were not statistically significantly different when categorized by measurement method
- Calculated errors by measurement method showed no statistically significant differences in expected outcomes
- In 35% (22/63) of cases in which IOL power differed by at least 0.5 D between IA with the ORA™ System and preoperative calculation, the surgeon chose (for non-specific reasons) the non-optimal method (**Table 2**)
- In 56% (35/63) of these cases, the IA (ORA™ System) result was a better option, and in 44% (28/63) of cases, the preoperative calculation was better; this was not statistically significantly different from random expectation (50/50, P=0.53) (**Table 2**)

Table 2. Surgeon choice of IOL power formula and "best" IOL power when IA (ORA™ System) and preoperative calculations differed by 0.5 D. Adapted from Davison et al. *Clinical Ophthalmology*. 2017;11:923-929.

Surgeon used	Eyes	Best IOL calculation	
		Preoperative	IA (ORA™)
Preoperative	36	21	15
IA (ORA™)	27	7	20
All	63	28 (44%)	35 (56%)

Clinical Outcomes with Distance-Dominant Multifocal and Monofocal IOLs in Post-Lasik Cataract Surgery Planned Using an Intraoperative Aberrometer

Fisher et a l. *Clin Exp Ophthalmol.* 2018;46:630-636*

Monofocal IOL Implantation

Multifocal IOL Implantation

ORA vs. Conventional Preoperative Biometry

IOL Implantation in Post-Refractive Eyes

OVERVIEW

STUDY DESIGN
Retrospective chart review to determine whether intraoperative aberrometry (IA) using the ORA™ System improved clinical outcomes following post-LASIK cataract surgery

STUDY SETTING(S)
Data from one surgeon at a single surgical center, United States

PATIENTS
Forty-four (44) eyes of 31 patients

SURGICAL METHODOLOGY
Uncomplicated cataract surgery in post-LASIK eyes, with IOL power determined using preoperative calculation and IA (ORA™ System)

IOL TYPE(S)
AcrySof® ReSTOR® +2.5D distance dominant multifocal or AcrySof® monofocal IOL (SN60WF lens)

KEY ENDPOINT(S)
Uncorrected distance visual acuity and the percentage of eyes with a spherical equivalent refraction within 0.5D of the intended correction (available in the range of interest [3 months, 70–140 days])

ANALYSIS AND CONCLUSIONS

There was no apparent clinical benefit to the use of IA with the ORA™ System in the post- LASIK eyes evaluated in this study, although a positive trend was evident; larger prospective studies are needed to determine patient-specific value of IA in these cases.

In patients with a history of LASIK, a distant-dominant multifocal IOL was likely to provide improved intermediate and near visual acuity while maintaining the same distance visual acuity and refraction when compared with a monofocal IOL.

Supported by an investigator-initiated study grant from Alcon Research Ltd.

STUDY RESULTS

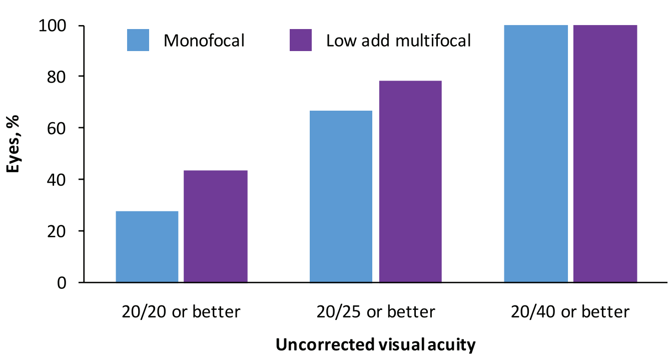
VISUAL ACUITY AND REFRACTION

- There was no statistically significant difference in the percentage of eyes with uncorrected distance visual acuity of 20/25 or better between IOL groups (P=0.41) (**Figure 1**)
- The distant-dominant multifocal IOL provided patients with slightly better intermediate than near vision
- The percentage of eyes with a refraction within 0.50 D of intended was statistically significantly higher in the multifocal group (chi-square test, P=0.03)

POWER CALCULATIONS

- In 39% of cases (14/44), the preoperative and IA (ORA™ System) power calculations suggested the same IOL power
- In cases where the preoperative and IA (ORA™ System) calculations were not equal, a chi-square test showed that the IA results were not significantly more likely to be 'best" (24/10 vs. 18/18, P = 0.08), but the low P-value suggested a trend in that direction (**Table 1**)
- When IOL power calculations were repeated using the Barrett TrueK formula, no statistically significant differences in prediction error were observed between IA (ORA™ System) and this formula (−0.11 ± 0.48 vs. −0.21 ± 0.61, P=0.25)

Figure 1. Postoperative uncorrected visual acuity.



The monofocal group includes only those eyes where the refractive target was plano (n = 18, as three eyes had a monovision target in the monofocal group).

Table 1. Difference in suggested lens power by IOL model.

Lens Power Difference	n	IA (ORA™ System)	Equal	Preop
		'Better' calculation (closer to postop)		
IA > 1.00 D higher	2	2		
IA 1.00 D higher	5	3		2
IA 0.50 D higher	15	12	1	2
Equal	17	7	7	3
IA 0.50 D lower	4		2	2
IA 1.00 D lower	1			1
All eyes	44	24	10	10

IA, intraoperative aberrometry (ORA™ System).

Comparison of Intraoperative Aberrometry, OCT-Based IOL Formula, Haigis-L, and Masket Formulae for IOL Power Calculation after Laser Vision Correction

Fram et al. *Ophthalmology*. 2015;122:1096-1101

OVERVIEW

STUDY DESIGN

Retrospective consecutive case series to intraoperative aberrometry (IA) using the ORA™ System , OCT-based IOL formula, Haigis-L, and Masket formulae for IOL power calculation

STUDY SETTING(S)

Data from 2 surgeons, United States

PATIENTS

Twenty (20) eyes of 20 patients with historical data for laser vision correction, 39 eyes of 29 patients for whom historical data was not available

SURGICAL METHODOLOGY

Cataract surgery in patients with a history of LASIK or photorefractive keratectomy; IOL power estimated with Haigis-L formula, Masket regression formula, IA (ORA™ System), Optovue RTVue® Fourier-domain OCT-based IOL formula

IOL TYPE(S)

Monofocal Alcon IOLs

KEY ENDPOINT(S)

Median absolute error (MedAE), mean absolute error (MAE), and % of eyes within ±0.25, ±0.50, ±0.75, and ±1.00 D of refractive prediction error

ANALYSIS AND CONCLUSIONS

Newer technologies (IA [ORA™ System] and Fourier-domain OCT-based formula [Optovue RTVue®]) to estimate IOL power calculations in eyes after laser vision correction showed promising results when compared with established methods.

The findings of improved benefit with IA and Fourier-domain OCT-based IOL formula are particularly meaningful in patients for whom prior data are not available.

STUDY RESULTS

PATIENTS WITHOUT HISTORICAL DATA

- Patients without historical data (n=39 eyes) were compared using Haigis-L, IA (ORA™ System), and Optovue
- In the group without historical data (**Figure 1**):
  - 49% of eyes were within ±0.25 D, 69%-74% were within ±0.50 D, 87%-97% were within ±0.75 D, and 92%-97% were within ±1.00 D of targeted refractive IOL power prediction error
  - The MedAE was 0.26 D for Haigis-L, 0.29 D for IA (ORA™ System), and 0.28 D for Optovue
  - The MAE was 0.37 D for Haigis-L, 0.34 D for IA (ORA™ System), and 0.39 D for Optovue
  - There was no statistically significant difference among the methods

PATIENTS WITHOUT HISTORICAL DATA

- Patients with historical data (n=20 eyes) were compared using Masket regression formula, Haigis-L, IA (ORA™ System), and Optovue
- In the groups with historical data (**Figure 2**):
  - 35%-70% of eyes were within ±0.25 D, 60%-85% were within ±0.50 D, 80%-95% were within ±0.75 D, and 90%-95% were within ±1.00 D of targeted refractive IOL power prediction error
  - The MedAE was 0.21 D for the Masket regression formula, 0.22 D for the Haigis-L formula, 0.25 D for IA (ORA™ System), and 0.39 for Optovue
  - The MAE was 0.28 D for the Masket regression formula, 0.31 D for the Haigis-L formula, 0.37 D for IA (ORA™ System), and 0.44 D for Optovue
  - There was no statistically significant difference among the methods

Figure 1. Percentage of eyes within certain refractive IOL power prediction errors (eyes without historical data (n=39)).

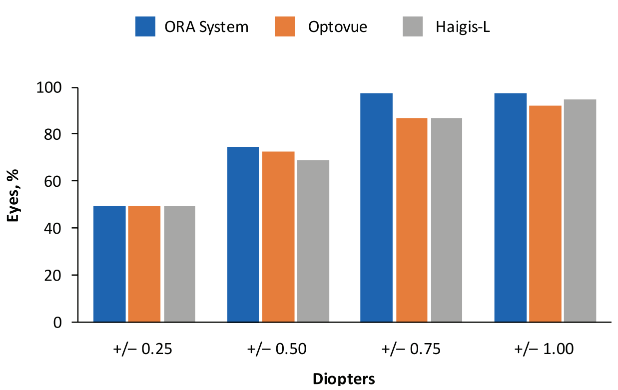
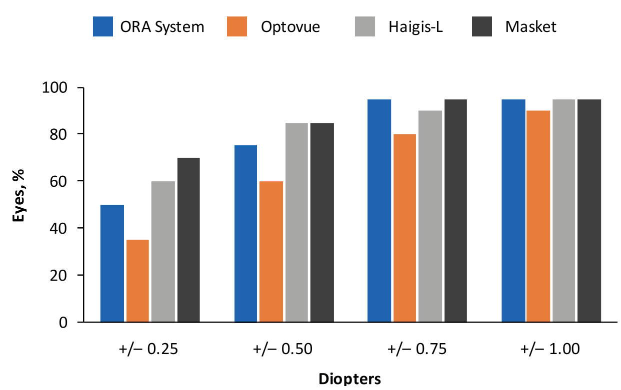


Figure 2. Percentage of eyes within certain refractive IOL power prediction errors (eyes with historical data (n=20)).



IOL Power Selection and Positioning with and Without Intraoperative Aberrometry

Hatch et al. *J Refract Surg.* 2015:31:237-242

Toric IOL Implantation

ORA vs. Conventional Preoperative Biometry

OVERVIEW

STUDY DESIGN
Non-randomized retrospective comparative trial to determine the value of intraoperative aberrometry (IA) using the ORA™ System in cases of toric IOL implantation and positioning

STUDY SETTING(S)
Data from 2 surgeons in a private practice, United States

PATIENTS
Thirty-seven (37) eyes in IA (ORA™ System) group, 27 eyes in toric calculator group

SURGICAL METHODOLOGY
Cataract surgery with toric IOL implantation, where standard preoperative measurements (toric calculations) and IA using ORA™ were performed

IOL TYPE(S)
AcrySof® IQ Toric IOL and TECNIS® Toric IOL

KEY ENDPOINT(S)
Mean postoperative residual refractive astigmatism (RRA), manifest cylinder reduction, percentage reduction in astigmatism, uncorrected distance visual acuity (UDVA)

ANALYSIS AND CONCLUSIONS

Patients undergoing cataract extraction with toric IOL placement aided by IA using the ORA™ System were 2.4 times more likely to have less than 0.50 D of RRA compared to standard methods.

Larger, prospective, randomized studies are warranted to further validate and refine the use of IA (ORA™ System).

STUDY RESULTS

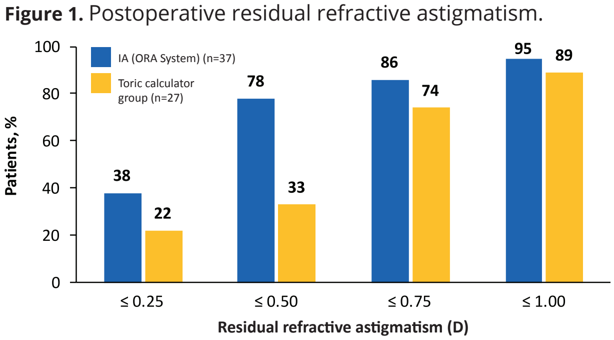
PRIMARY OUTCOME (RRA)

- Mean postoperative period for analysis was 58 days for IA (ORA™ System) group and 60 days for the toric calculation group
- Mean RRA measured at follow-up after surgery was 0.46 ± 0.42 and 0.68 ± 0.34 D in the IA (ORA™ System) and toric calculator groups, respectively (P=0.0153) (**Figure 1**)
- RRA of ≤0.25 D, ≤0.50 D, ≤0.75 D, and ≤1.00 D was seen 38%, 78%, 86%, and 95% of the time, respectively, in the IA (ORA™ System) group, and 22%, 33%, 74%, and 89% of the time in the toric calculator group (**Figure 1**)
- These data show that the chance of a patient being in a lower postoperative RRA range increased when IA with the ORA™ System was used (P=0.0130)

SECONDARY OUTCOMES

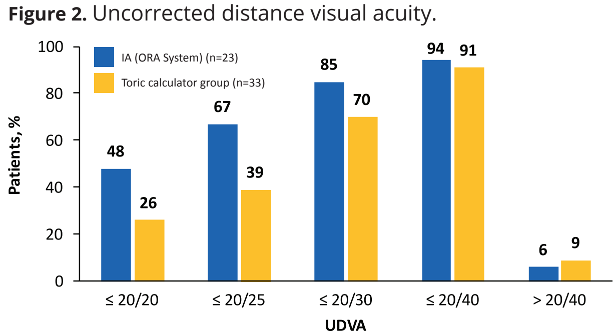
- IA with the ORA™ System yielded superior results in mean manifest cylinder reduction (P=0.0330), and manifest cylinder percentage change (P=0.0023)
- Percentage cylinder reduction was classified into quartiles, showing superior results for IA (ORA™ System) (P= 0.0128)
- A 75% and 57% reduction in cylinder was noted between preoperative keratometric astigmatism and postoperative RRA in the IA (ORA™ System) and toric calculator groups, respectively (P=0.0027)
- Differences in percent of eyes achieving UDVA ≤20/25 and ≤20/30 were statistically significant in favor of IA (ORA™ System) (P=0.0398 and P=0.0307, respectively) (**Figure 2**)

Figure 1. Postoperative residual refractive astigmatism.



	Mean	Standard Deviation	p-value
IA (ORA System)	0.46 D	+/- 0.42 D	***0.153 statistically significant***
Preoperative	0.68 D	+/- 0.34 D	

Figure 2. Uncorrected distance visual acuity.



	Mean	Standard Deviation	min	max
IA (ORA System)	0.11 D	+/- 0.17 D	-0.12	0.70
Toric calculator group	0.16 D	+/- 0.14 D	-0.12	0.40

Intraoperative Aberrometry Versus Preoperative Biometry for IOL Power Selection in Axial Myopia

Hill et al. *J Cataract Refract Surg.* 2017;43:505-510

- Monofocal IOL Implantation
- Multifocal IOL Implantation
- Toric IOL Implantation
- ORA vs. Conventional Preoperative Biometry

OVERVIEW

STUDY DESIGN
Retrospective consecutive case series to compare the accuracy of IA (ORA™ System) and the Hill-radial basis function (RBF) formula with other formulas based on preoperative biometry in predicting residual refractive error

STUDY SETTING(S)
Data from one private practice, United States

PATIENTS
Fifty-one (51) eyes of 37 patients

SURGICAL METHODOLOGY
Cataract surgery in eyes with axial myopia (axial length [AL] >25 mm), with IOL implantation where standard preoperative measurements, IA (ORA™) and Hill RBF formula were used

IOL TYPE(S)
Multifocal, toric and monofocal TECNIS® IOLs

KEY ENDPOINT(S)
Ability to predict residual refractive error, proportion of patients with hyperopic outcomes

ANALYSIS AND CONCLUSIONS

IA with the ORA™ System was better than all formulas based on preoperative biometry and as effective as the AL-optimized Holladay 1 formula in predicting residual refractive error and reducing hyperopic outcomes.

The data also suggest that patients with axial myopia might benefit from the use of IA.

STUDY RESULTS

MEAN NUMERICAL ERRORS

- The mean numerical errors (MNE) ± standard error associated with using the SRK/T, Holladay 1, AL-optimized Holladay 1, Holladay 2, Barrett Universal II, and Hill-RBF formulas and IA (ORA™ System) were 0.20 ± 0.06 diopters (D), 0.33 ± 0.06 D, -0.02 ± 0.06 D, 0.24 ± 0.06 D, 0.19 ± 0.06 D, 0.22 ± 0.06 D, and 0.056 ± 0.06 D
  - MNE differed significantly between the 7 groups (P<0.001)
- **Table 1** shows the pairwise comparisons between the groups with respect to MNE
  - IA (ORA™ System) produced significantly lower MNE than all other groups except AL-optimized Holladay 1
  - AL-optimized Holladay 1 produced significantly lower MNE than IA (ORA™ System)

OTHER FINDINGS

- The proportion of patients within ±0.5 D of the predicted error was 74.5%, 62.8%, 82.4%, 79.1%, 73.9%, 76.7%, and 80.4% for SRK/T, Holladay 1, AL-optimized Holladay 1, Holladay 2, Barrett Universal II, and Hill-RBF formulas and IA (ORA™ System) groups, respectively (P=0.09)
  - There was a statistically significant difference between AL-optimized Holladay 1 and IA (ORA™ System)
- The groups differed significantly with respect to hyperopic outcomes (P<0.007), occurring in 70.6%, 76.5%, 49.0%, 74.4%, 76.1%, 74.4%, and 45.1% of eyes in the SRK/T, Holladay 1, AL-optimized Holladay 1, Holladay 2, Barrett Universal II, and Hill-RBF formulas and IA (ORA™ System) groups, respectively
  - The difference was not statistically significant between AL-optimized Holladay 1 and IA (ORA™ System)

Table 1. P-values for pairwise comparisons of mean numerical errors between IOL calculation methods.
Table adapted from Hill et al. *J Cataract Refract Surg*. 2017;43:505-510.

Method	IA (ORA™ System)	SRK/T	Holladay 1	AL-optimized Holladay 1	Holladay 2	Barrett Universal II	Hill-RBF
IA (ORA™ System)	-	-	-	-	-	-	-
SRK/T	P<0.001*	-	-	-	-	-	-
Holladay 1	P<0.001*	P<0.001*	-	-	-	-	-
AL-optimized Holladay 1	P=0.033*	P<0.001*	P<0.001*	-	-	-	-
Holladay 2	P<0.001*	P=0.33	P=0.018*	P<0.001*	-	-	-
Barrett Universal II	P<0.001*	P=0.79	P<0.001*	P<0.001*	P=0.22	-	-
Hill-RBF	P<0.001*	P=0.94	P=0.001*	P<0.001*	P=0.38	P=0.74	-

**Statistically significant*

Intraoperative Refractive Biometry for Predicting IOL Power Calculation after Prior Myopic Refractive Surgery

Ianchulev et al. *Ophthalmology*. 2014;121:56-60

OVERVIEW

STUDY DESIGN
Retrospective consecutive case series to evaluate intraoperative aberrometry (IA) using the ORA™ System for IOL power calculation

STUDY SETTING(S)
Data from 66 surgeons, United States

PATIENTS
Two hundred forty-six (246) eyes of 215 patients

SURGICAL METHODOLOGY
Cataract surgery after prior myopic LASIK or photorefractive keratectomy, where standard preoperative measurements and IA using ORA™ were performed

IOL TYPE(S)
Not specified

KEY ENDPOINT(S)
Median absolute error of prediction and percentage of eyes within ±0.50 diopters D and ±1.00 D of refractive prediction error

ANALYSIS AND CONCLUSIONS

The IOL power estimation in challenging eyes with prior LASIK/photorefractive keratectomy was most accurately predicted by IA (ORA™ System) compared with conventional practices such as use of Haigis L and Shammas formulas.

These favorable results were obtained with many surgeons and a wide variance in ocular axial lengths; the data show that IA (ORA™ System) can provide benefits as an adjunct to traditional preoperative biometry in all eyes undergoing cataract surgery.

STUDY RESULTS

ABSOLUTE ERROR OF PREDICTION

- Results were calculated between 30 and 90 days after cataract surgery (average of 39 days for entire cohort)
- In 246 eyes (215 first eyes and 31 second eyes), IA using the ORA™ System achieved the greatest predictive accuracy, with a median absolute error of 0.35 D (95% confidence interval, 0.35-0.43 D; P<0.0001) and mean absolute error of 0.42 D (**Table 1**)
- All other methods demonstrated at least a 45% higher error than IA (ORA™ System), which in the case of surgeon best choice was 70% higher at 0.60 D (95% confidence interval, 0.58-0.73 D)

REFRACTIVE PREDICTION ERROR

- With IA (ORA™ System), 67% of eyes were within ±0.5 D, 85% were within ±0.75 D, and 94% were within ±1.0 D of the predicted outcome (**Table 1**)
- This was significantly more accurate than the other preoperative methods: prediction with IA (ORA™ System) almost 45% more accurate than the surgeon best choice (46% within ±0.5 D) and 34% more than the Shammas method, which came in second (50% within 0.5 D)
- These outcomes were consistent across all endpoints for 0.75 D and 1.0 D postoperative refractive thresholds

Table 1. Refractive outcomes in all eyes (N=246).

Refractive Outcomes	IA (ORA™ System)	Conventional Preoperative Methodology (Surgeon Best Choice)	Haigis L Method	Shammas Method
MedAE, D (95% CI)	0.35* (0.35-0.43)	0.60 (0.58-0.73)	0.53 (0.52-0.65)	0.51 (0.50-0.60)
MAE ± SD (D)	0.42±0.39†	0.71±0.56	0.65±0.58	0.59±0.52
% within ±0.50 D	67†	46	48	50
% within ±0.75 D	85†	63	66	72
% within ±1.00 D	94†	76	80	87

CI, confidence interval; D, diopters; MAE, mean absolute error; MedAE, median absolute error; SD, standard deviation.
**P<0.0001 for IA versus Surgeon Best Choice, IA versus Haigis L, and IA versus Shammas (2-sided binomial proportion test).*
†P<0.0001 for IA versus Surgeon Best Choice, IA versus Haigis L, and IA versus Shammas (repeated measures analysis of variance).

Influence of Ophthalmic Viscosurgical Devices on Intraoperative Aberrometry

Masket et al. ***J Cataract Refract Surg.*** **2016;42:990-994**

OVERVIEW

STUDY DESIGN
Prospective interventional case series to assess whether an ophthalmic viscosurgical device (OVD) in the anterior chamber influences intraoperative aberrometry (IA) using the ORA™ System and the suggested IOL power

STUDY SETTING(S)
Data from one surgical center, United States

PATIENTS
One hundred twenty (120) eyes

SURGICAL METHODOLOGY
Cataract surgery followed by placement of balanced salt solutions (BSS) followed by OVDs in the anterior chamber, along with IA using ORA™

IOL TYPE(S)
Single-piece acrylic (AcrySof®) IOLs

KEY ENDPOINT(S)
Mean absolute error (MAE) compared with extrapolated refraction (clinical manifest refraction performed 3 weeks after surgery)

ANALYSIS AND CONCLUSIONS

The IOL power determination was lower with OVD filling the chamber; a strong correlation between differences in the index of refraction between BSS and specific OVDs appeared to be causal.

Surgeons should be aware of the influence of OVDs on the accuracy of IA using the ORA™ System because specific agents may alter the optical results and suggested IOL power.

STUDY RESULTS

IOL POWER AND MEAN ABSOLUTE ERROR

- The OVD agents tested were Discovisc, Provisc, Healon, Healon GV, Amvisc and Amvisc Plus
- Aberrometry readings taken with BSS varied from those taken when the anterior chamber was filled with OVD (**Table 1**)
- The results for Discovisc and Amvisc Plus suggested an IOL power approximately 0.50 D lower than readings taken with BSS, while the difference for the other agents was less than 0.25 D
- In addition, the MAE outcomes were lower with BSS than with OVD, with the exception of Amvisc, for which the results were identical
- The differences were statistically significant with Discovisc (P<0.001) and Amvisc Plus (P<0.026)

PREDICTED APHAKIC POWER ERROR

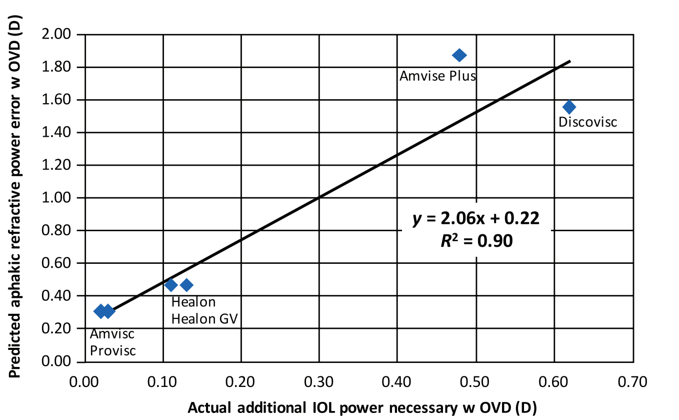
- **Figure 1** shows the predicted aphakic power error in diopters on the y-axis and the actual additional IOL power necessary on the x-axis
- The R^2 of 90% suggests a strong correlation between aphakic power error and the index of refraction of the OVD
- Explanations for the remaining 10% of the data include variation in anterior chamber volume, mix of OVD and BSS, and that the higher index of refraction of the OVDs could alter the wavefront estimation of axial length

Table 1. Summary of outcomes data for all OVDs.

Accuracy	Intraocular Lens		Mean Absolute Error		P-value
OVD	**BSS**	**OVD**	**BSS**	**OVD**	
Provisc	19.94	19.92	0.33±0.31	0.37±0.33	NS
Discovisc	19.64	19.02	0.47±0.42	0.88±0.49	<0.001
Healon	19.54	19.43	0.40±0.31	0.48±0.32	NS
Healon GV	18.21	18.08	0.45±0.36	0.53±0.44	NS
Amvisc	19.33	19.30	0.31±0.30	0.31±0.31	NS
Amvisc Plus	19.68	19.20	0.29±0.28	0.50±0.36	<0.026

BSS, balanced salt solution; NS, not statistically significant; OVD, ophthalmic viscosurgical device

Figure 1. Correlation between predicted power error (based on index of refraction disparity between balanced salt solution (BSS) and ophthalmic viscosurgical device (OVD)) and actual aphakic power error.



Effect of Intraoperative Aberrometry on the Rate of Postoperative Enhancement: Retrospective Study

Packer M. *J Cataract Refract Surg.* 2010; 36:747-755

OVERVIEW

STUDY DESIGN
Retrospective, case-control chart review to assess whether the use of IA (ORA™ System) reduces the frequency of postoperative laser enhancements compared with cases in which aberrometry was not used

STUDY SETTING(S)
Data from 1 surgeon in a private surgical center and private practice, United States

PATIENTS
Sixty-seven (67) eyes of 48 patients

SURGICAL METHODOLOGY
Correction of preexisting corneal astigmatism by limbal relaxing incisions (LRIs) at the time of cataract surgery or refractive lens exchange, along with IA using ORA™

IOL TYPE(S)
Monofocal, multifocal and accommodating IOLs

KEY ENDPOINT(S)
Odds ratio of subsequent excimer laser enhancement

ANALYSIS AND CONCLUSIONS

The use of IA (ORA™ System) to measure and enhance the effect of LRIs reduced the odds of needing subsequent excimer laser enhancement by more than 5-fold.

Although the effect was not statistically significant (P=0.12), it appears to represent a trend; further research, particularly a prospective randomized study, is indicated to validate the significance of the effect of IA using the ORA™ System.

STUDY RESULTS

EXCIMER LASER ENHANCEMENT

- Mean postoperative follow-up was 3 months in the IA (ORA™ System) group, 6 months in the control group
- Overall, laser enhancements were performed in 7 eyes of 5 patients, for a rate of 10.4% (**Table 1**)
  - The excimer laser enhancement rate was 3.3% (1 patient) in the IA (ORA™ System) group and 16.2% (6 patients) in the control group
  - The 1 patient in the IA (ORA™ System) group had a monofocal IOL and no intraoperative LRI enhancement; after photorefractive keratectomy, uncorrected distance visual acuity improved from 20/25 to 20/20
  - The odds ratio of a laser enhancement without IA (ORA™ System) was 5.71 (P=0.21); this was not statistically significant

OTHER FINDINGS

- During the study, the only significant alteration in procedure or technique was the introduction of IA (ORA™ System)
- In 2 eyes having enhancement, the myopic spherical equivalent played a role in the overall refractive error; in the other 5 eyes, the cylindrical component alone resulted in the patients' decision to have an enhancement
- A residual manifest refractive cylinder of 1.00 D appeared to be a watershed in the decision to have a postoperative enhancement procedure
- Thus, reducing postoperative refractive cylinder to 0.75 D or less may be an effective strategy to avoid postoperative enhancement procedures

Table 1. Summary of outcomes data for all OVDs.

Group and patient	Preop ΔK	MR before enhancement	Eye	UDVA	IOL Model/Power (D)
Control					
1	2.32 @ 148	−2.00 +2.50 x 180	L	20/70	Z9002, 22.0; monofocal
2	1.63 @ 88	−0.25 +1.00 x 90	R	20/30	NXG1, 13.5; multifocal
2	2.05 @ 86	−0.25 +1.25 x 90	L	20/30	SN6AD3, 14.0; multifocal
3	2.13 @ 115	−1.75 +1.25 x 43	R	20/40	AT50SE, 18.0; accommodating
3	1.32 @ 67	−1.25 +1.75 x 106	L	20/40	AT50SE, 19.0; accommodating
4	0.76 @ 67	−0.50 +1.00 x 90	L	20/50	AT52SE, 16.0; accommodating
IA (ORA™ System)					
5	2.61 @ 78	−1.25 +1.25 x 75	L	20/25	ZCBOO, 27.0; monofocal

ΔK, delta keratometry value; MR, manifest refraction; UDVA, uncorrected distance visual acuity

Toric IOL Implantation

ORA vs. Conventional Preoperative Biometry

Factors Associated with Clinical Outcomes

Factors Associated with Residual Astigmatism after Toric IOL Implantation Reported in an Online Toric IOL Back-calculator

Potvin et al. *J Refract Surg.* 2018;34:366-371*

OVERVIEW

STUDY DESIGN
Retrospective data review to evaluate factors associated with residual astigmatism after toric IOL implantation based on data from an online toric IOL back-calculator

STUDY SETTING(S)
Data from an online toric IOL back-calculator including preoperative toric planning information and postoperative lens orientation and refractive results

PATIENTS
Total of 3,159 validated records; 566 included data allowing calculation of surgically induced astigmatism

SURGICAL METHODOLOGY
Toric IOL implantation, along with a femtosecond laser system, intraoperative aberrometry (IA) with the ORA™ System, and an image guidance system

IOL TYPE(S)
Toric IOLs

KEY ENDPOINT(S)
Factor associated with residual refractive astigmatism, such as preoperative/ postoperative keratometry and IA (ORA™ System)

ANALYSIS AND CONCLUSIONS

Higher levels of residual refractive astigmatism when present after cataract surgery were most associated with large measured differences in preoperative to postoperative keratometry.

To a lesser degree, the use of IA (ORA™ System) was associated with lower levels of residual refractive astigmatism.

**Supported by an investigator-initiated study grant from Alcon Research Ltd.*

STUDY RESULTS

ASSOCIATIONS WITH RESIDUAL ASTIGMATISM

- Higher measured surgically induced astigmatism (calculated as the vector difference between the preoperative and postoperative keratometry) was most associated with higher levels of reported residual astigmatism
- There were no differences in the residual refractive astigmatism values associated with use or non-use of a femtosecond laser system (95% CI of the odds ratio related to rotation or a new IOL spans 1.0) (**Table 1**)
- The use of IA (ORA™ System) was associated with significantly lower refractive cylinder values (approximately 0.20 D, P<0.01); the odds ratio indicates a 29% higher likelihood of needing a new IOL rather than being able to successfully rotate the current IOL (**Table 1**)

USE OF A TORIC BACK-CALCULATOR

- Use of the toric back-calculator suggested a significant decrease in the mean refractive astigmatism could be obtained through IOL reorientation, with an observed mean of 1.85 ± 1.02 D input by surgeons and an expected mean after reorientation of 0.75 ± 0.66 D (P<0.01)
- Almost three-quarters (72%, 2283 of 3159) of cases had initial residual refractive astigmatism between 0.50 and 2.00 D
- In 1416 cases (44.8%), the expected residual refractive astigmatism after lens reorientation was less than 0.50 D
- The mean percentage reduction in refractive astigmatism expected was 56% ± 31% (range: 0% to 100%)

Table 1. Categorization of clinical data with identified technologies.

Technology	No, %	Current	Expected	Rotation sufficient	New IOL suggested	Rotation vs. new IOL OR (95% CI)
		Mean Residual Refractive Astigmatism				
Femtosecond laser system Used Not used P-value	448 (15%) 2603 (85%)	1.83 ± 1.04 1.86 ± 1.02 0.69	0.74 ± 0.67 0.75 ± 0.65 0.82	205 1170	243 1433	1.03 (0.84 to 1.26)
IA (ORA™ System) Used Not used P-value	537 (17%) 2614 (83%)	1.72 ± 0.88 1.88 ± 1.05 <0.01	0.64 ± 0.53 0.77 ± 0.68 <0.01	269 1142	268 1472	1.29 (1.07 to 1.56)
Image guidance system Used Not used P-value	566 (23%) 1931 (77%)	1.76 ± 0.94 1.90 ± 1.06 <0.01	0.67 ± 0.55 0.76 ± 0.68 <0.01	273 864	293 1067	1.15 (0.95 to 1.39)

CI, confidence interval; IOL, intraocular lens; OR, odds ratio.

Toric Outcomes: Computer-Assisted Registration Versus Intraoperative Aberrometry

Toric IOL Implantation

ORA vs. Intraoperative Computer-Assisted Registration

Solomon et al. *J Cataract Refract Surg.* 2017;43:498-504*

OVERVIEW

STUDY DESIGN
Prospective randomized case series to compare refractive outcomes of intraoperative computer-assisted registration and intraoperative aberrometry (IA) using the ORA™ System for the reduction of cylinder during toric IOL placement

STUDY SETTING(S)
Data from a single clinic, United States

PATIENTS
One hundred four (104) eyes of 52 patients (**Table 1**)

SURGICAL METHODOLOGY
Toric IOL implantation after phacoemulsification where intraoperative computer-assisted registration was performed in one group and IA (ORA™ System) in a separate group (contralateral eye)

IOL TYPE(S)
TECNIS® Toric IOLs (models ZCT150, ZCT225, ZCT300, ZCT400)

KEY ENDPOINT(S)
Mean postoperative remaining refractive astigmatism, compared with the predicted amount of cylindrical correction with the IOL

ANALYSIS AND CONCLUSIONS

Computer-assisted registration resulted in less remaining refractive astigmatism with toric IOL guidance than IA (ORA™ System); however, mean absolute predictabilities were statistically indistinguishable.

The delivery of reproducible reduction of astigmatism is achieved when computer-assisted registration and IA (ORA™ System) are incorporated individually; the microscope might serve as a future hub for the two technologies to provide continuous monitoring and deliver vital biometrics during refractive cataract procedures.

**Supported by an investigator-initiated study grant from Alcon Research Ltd.*

STUDY RESULTS

REMAINING REFRACTIVE ASTIGMATISM

- Patients were examined 1 week and between 4 weeks and 6 weeks postoperatively
- The mean postoperative remaining refractive astigmatism was -0.29 ± 0.22 D and -0.46 ± 0.25D with intraoperative computer-assisted registration and IA (ORA™ System), respectively; analysis by t-test showed better results with intraoperative computer-assisted registration (P=0.00039)
- **Figure 1** shows the cumulative distribution of the remaining refractive astigmatism at the final postoperative evaluation
  - In the computer-assisted registration group, more than 25% of the cases had no postoperative astigmatism, compared with 8% of cases in the IA (ORA™ System) group
  - Overall, 92.2% of cases in the computer-assisted registration group had remaining refractive astigmatism of 0.50 D or less, compared with 76.5% in the IA (ORA™ System) group

OTHER OUTCOMES

- The correction index was 1.03 with intraoperative computer-assisted registration and 0.95 with IA (ORA™ System)
- A difference vector of 0.1 @ 87 degrees (0.31 D arithmetic mean) was calculated in the intraoperative computer-assisted registration group and 0.0 @ 82 degrees (0.44 D arithmetic mean) in the IA (ORA™ System) group
- The median absolute error in predicting cylindrical correction by IOL was similar for both guidance systems: 0.35 D in the intraoperative computer-assisted registration group and 0.39 D in the IA (ORA™ System) group, irrespective of the axis (P=0.91)

Figure 1. Distribution of postoperative magnitude of refractive cylinder.

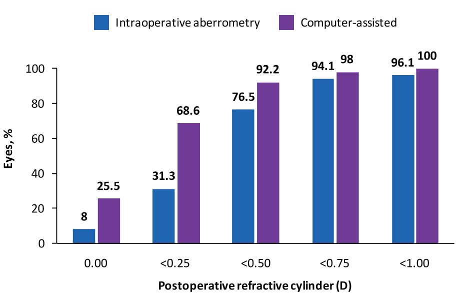


Table 1. Patient demographics.

Parameter	Number	Parameter	Number	Parameter	Number	Parameter	Number
Age (y) Mean ± SD Median Range	 70.4 ± 9.8 69.7 43.6, 85.4	Age group, n (%) <60 y 60-69 y 70-79 y >80 y	 7 (13.4) 21 (40.4) 14 (26.9) 10 (19.2)	Sex, n (%) Female Male	 33 (63.5) 19 (36.5)	Race, n (%) White Black Asian Other	 36 (69.2) 12 (23.1) 2 (3.8) 2 (3.8)

Correcting Astigmatism at the Time of Cataract Surgery: Toric IOLs and Corneal Relaxing Incisions Planned with an Image-Guidance System and Intraoperative Aberrometer Versus Manual Planning and Surgery

Solomon et al. *J Cataract Refract Surg*. 2019;45:569-575*

OVERVIEW

STUDY DESIGN
Prospective case series to compare the outcomes of the combination of an image-guided system and intraoperative aberrometer IA (ORA™ System) with the surgeon's standard of care for correcting astigmatism using toric IOLs or corneal incisions

STUDY SETTING(S)
Single site, United States

PATIENTS
Thirty-eight (38) eyes implanted with toric IOLs, 40 eyes received corneal astigmatic incisions

SURGICAL METHODOLOGY
Uncomplicated bilateral cataract surgery, including combined use of an image-guided system and IA (ORA™ System) or surgeon's standard of care in the absence of these technologies

IOL TYPE(S)
AcrySof® IQ Toric IOLs

KEY ENDPOINT(S)
Residual refractive astigmatism at 3 months, spherical equivalent (SE) refraction, uncorrected and corrected distance visual acuities (UDVA and CDVA) at 1 month and 3 months

ANALYSIS AND CONCLUSIONS

The combined use of an image-guided system and IA (ORA™ System) did not significantly improve outcomes compared with the surgeon's standard of care.

Based on keratometry, there was good agreement in corneal astigmatism measurements between the image-guided system and the optical biometer.

**Supported by an investigator-initiated study grant from Alcon Research Ltd.*

STUDY RESULTS

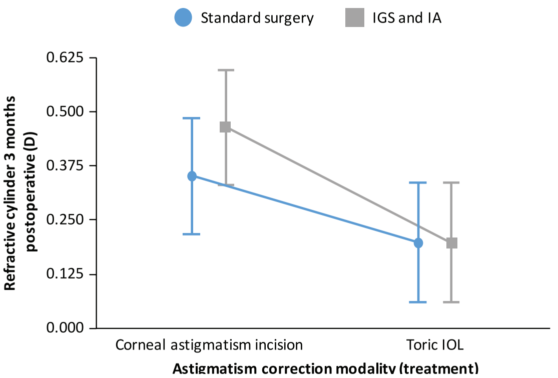
RESIDUAL REFRACTIVE ASTIGMATISM

- There was a statistically significant difference in the mean residual cylinder by treatment, with toric IOLs resulting in almost 0.25 D less cylinder than corneal astigmatic incisions on average (0.20 ± 0.19 [SD] versus 0.41 ± 0.37; P<0.01) (**Figure 1**)
- There was no statistically significant difference between surgical methods (P=0.41) and no significant interaction between surgical method and treatment (P=0.41) (**Figure 1**)
- With respect to cumulative residual cylinder, 100% of toric cases and 75% to 85% of the corneal astigmatic incision cases were within ±0.50 D (**Figure 2**)

OTHER OUTCOMES

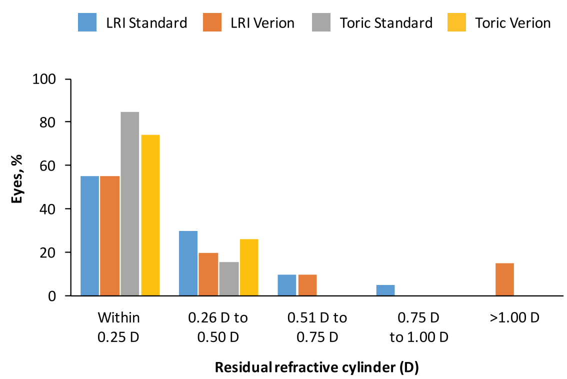
- There was no statistically significant difference in the mean SE refraction between surgical methods (P=0.51) or treatments (P=0.48) and no interaction between surgical method and treatment (P=0.31)
- There was no statistically significant difference in the UDVA between treatments or surgical methods or over time, and no interactions between these factors (all P>0.06)
- For the CDVA, there was no statistically significant difference between methods or treatments; there was a statistically significant difference over time (P=0.04), but the difference was less than 1 letter and considered clinically irrelevant

Figure 1. Mean residual refractive cylinder at 3 months post-surgery by surgical method and treatment.



IGS and IA, image-guided system and intraoperative aberrometry.

Figure 2. Cumulative residual cylinder at 3 months postoperatively by surgical method and treatment.



LRI, limbal relaxing incision.

Evaluating the Relative Value of Intraoperative Aberrometry Versus Current Formulas for Toric IOL Sphere, Cylinder, and Orientation Planning

Solomon et al. *J Cataract Refract Surg.* 2019;45:1430-1435

OVERVIEW

STUDY DESIGN

Retrospective data review of previous clinical trials to assess IOL outcomes and compare actual results to those expected from preoperative calculations and intraoperative aberrometry (IA) using the ORA™ System in normal eyes

STUDY SETTING(S)

Single center, United States

PATIENTS

One hundred thirty-two (132) eyes of 68 patients

SURGICAL METHODOLOGY

Cataract surgery with IOL implantation, where standard preoperative measurements and IA (ORA™ System) were performed in normal eyes

IOL TYPE(S)

Toric IOLs: SN6ATx (Alcon Laboratories, Inc.) or Tecnis Symfony (Johnson & Johnson Surgical Vision, Inc.)

KEY ENDPOINT(S)

Spherical equivalent refractive error and residual cylinder, proportion of patients with 0.5 D or less of residual refractive astigmatism 3 months postoperatively

ANALYSIS AND CONCLUSIONS

The use of current-generation formulas for sphere power and toric IOL planning can produce clinical outcomes with toric IOLs that are as good or better than those achieved with IA using the ORA™ System.

Such outcomes can be achieved through appropriate management of ocular surface disease, the use of modern IOL calculation formulas, and precise orientation of toric IOLs with digital alignment technology.

STUDY RESULTS

SPHERICAL EQUIVALENT

- The mean expected spherical equivalent refractive error was not statistically significantly different between the preoperative calculation group and the IA (ORA™ System) group (P=0.44) 3 months postoperatively (**Table 1**)
- However, the percentages of eyes with expected spherical equivalent refractions within ±0.25 D and ±0.50 D of the target were higher for the preoperative calculation group than the IA (ORA™ System) group (P=0.02 and P=0.05, respectively) (**Table 1**)
  - Overall, 87% of eyes in the preoperative calculation group were within ±0.50 D of the intended spherical equivalent
- Calculated IOL sphere power was the same for 90 (68%) of 132 eyes; of the 42 remaining eyes, 5 had a 1.0 D or higher difference between the preoperative and IA (ORA™ System) calculation, and in all 5 eyes, the expected spherical equivalent refractive error was lower for the preoperative IOL

RESIDUAL CYLINDER

- The expected residual refractive cylinder was calculated for the actual (already known), the preoperative, and the IA (ORA™ System) IOL cylinder power and axis determinations
- The mean expected residual refractive astigmatism was significantly lower for preoperative calculations than for IA (ORA™ System) (P<0.001) (**Table 2**)
- Overall, the percentage of eyes expected to have 0.50 D or less of residual astigmatism was 57.8% for IA (ORA™ System) group vs 94.7% for the actual group and 94.0% for the preoperative calculation group (P<0.001) (**Table 2**)

Table 1. Actual and expected spherical equivalent refractive error (132 eyes) 3 months postoperatively.

Calculation	Sphere Error, D		Difference from Target, n (%)	
	Mean ± SD	Range	Within ±0.25 D	Within ±0.50 D
Actual	0.18 ± 0.31	−0.75, 0.75	89 (67.4)	115 (87.1)
Preoperative	0.18 ± 0.32	−0.75, 0.75	87 (65.9)	115 (87.1)
IA (ORA™ System)	0.20 ± 0.39	−1.09, 0.94	68 (51.5)	103 (78)

IA, intraoperative aberrometry

Table 2. Actual and expected residual cylinder (132 eyes) 3 months postoperatively.

Calculation	Residual Cylinder, D		Difference from Zero, n (%)		
	Mean ± SD	Range	Within ±0.25 D	Within ±0.50 D	Within ±0.50 D
Actual	0.22 ± 0.22	0.00, 0.75	94 (71.2)	125 (94.7)	130 (98.5)
Preoperative	0.24 ± 0.24	0.00, 1.00	90 (68.2)	124 (94.0)	126 (95.4)
IA (ORA™ System)	0.67 ± 0.51	0.00, 2.75	39 (29.6)	76 (57.8)	101 (76.5)

IA, intraoperative aberrometry

Evaluation of Variables Affecting Intraoperative Aberrometry

Stringham et al. ***J Cataract Refract Surg.*** **2012;38:470-474**

IOL Implantation

Factors Associated with Clinical Outcomes

OVERVIEW

STUDY DESIGN

Comparative case series to understand variable refractive changes that occur during routine cataract surgery that could affect the accuracy and effectiveness of intraoperative aberrometry (IA) with ORange as it relates to the postoperative refractive state

STUDY SETTING(S)

Single center, United States

PATIENTS

Five (5) patients without cataract in phase 1, 10 patients with cataract in phase 2

SURGICAL METHODOLOGY

Phase 1: Induction of cylinder and axis by 2 eyelid speculums (open wire and closed wire). Phase 2: Cataract surgery with IOL implantation, where standard preoperative measurements and IA using ORange were performed

IOL TYPE(S)

Not specified

KEY ENDPOINT(S)

Topography measurements; refractive changes in cylinder, axis, and spherical equivalent within 1 hour and 1 week after surgery

ANALYSIS AND CONCLUSIONS

This study demonstrated that cataract surgery induced changes in cylinder, its axis, and spherical equivalent within 1 hour of cataract surgery compared with 1 week after surgery.

These results call into question the clinical applicability and accuracy of IA using ORange in predicting the long-term stable sphere and cylinder (both amount and axis) after cataract surgery.

STUDY RESULTS

DATA IN PATIENTS WITHOUT CATARACT

- In phase 1 of the study, 45 topography measurements of 5 participants without cataract were taken with each speculum (closed wire and open wire)
- The presence of a speculum induced erratic changes in cylinder and a statistically significant difference in axis when comparing open-wire speculum and the closed-wire speculum (both P<0.0001) (**Figure 1**)
- Cylinder and axis changes were common, very variable, and commonly clinically significant (i.e., >1.0 D and >30 degrees, respectively), with or without variable lid squeezing

DATA IN PATIENTS WITH CATARACT

- In phase 2 of the study, which evaluated 10 patients, there was a significant change in the spherical equivalent within 1 hour of cataract surgery compared with 1 week after surgery (P=0.039) (**Figure 2**)
- Six of the 10 patients had increased cylinder immediately after surgery, 1 patient had no change, and 3 patients had more cylinder at the 1-week follow-up (P=0.007)
- Eight of the 10 patients had a shift in axis, and the shift was very erratic (P=0.04)
- Clinically important shifts in sphere, cylinder, and axis also were common and unpredictable

Figure 1. Cylinder measurements before speculum placement and with closed-wire and open-wire speculums in participants without cataracts. Error bars represent SD.

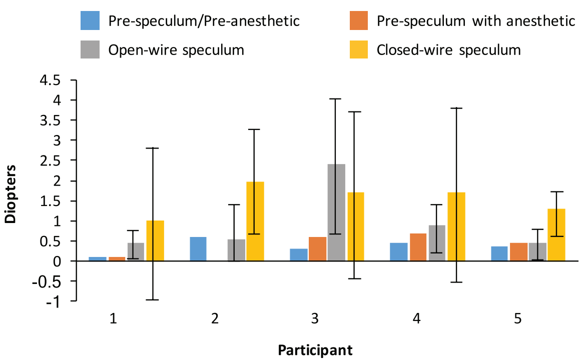
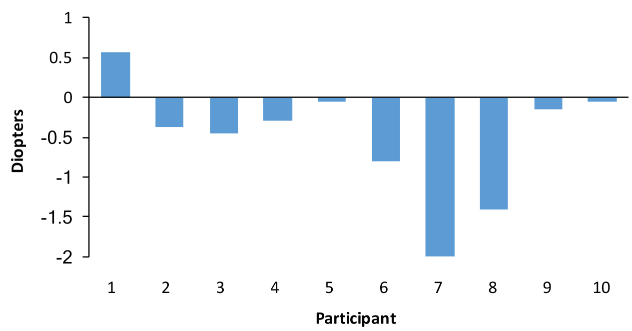


Figure 2. Change in spherical equivalent immediately after cataract surgery compared with 1 week after surgery (P=0.039). Measurements from participants 1 to 4 are from intraoperative aberrometry (IA) with ORange. Measurements from participants 5 to 10 are from manual refraction.



Intraoperative Aberrometry Versus Preoperative Biometry for Intraocular Lens Power Selection in Short Eyes

Sudhakar et al. ***J Cataract Refract Surg.*** **2019;45:719-724**

Monofocal IOL Implantation

Multifocal IOL Implantation

Toric IOL Implantation

ORA vs. Conventional Preoperative Biometry

OVERVIEW

STUDY DESIGN
Retrospective consecutive case series to compare the accuracy of preoperative biometry-based formulas to intraoperative aberrometry (IA) using the ORA™ System, with respect to predicting refractive outcomes after cataract surgery in short eyes

STUDY SETTING(S)
One private ambulatory surgery center, United States

PATIENTS
Fifty-one (51) eyes of 38 patients

SURGICAL METHODOLOGY
Cataract surgery with IOL implantation in short eyes, where standard preoperative measurements and IA (ORA™ System) were performed

IOL TYPE(S)
Monofocal, multifocal, and toric IOLs

KEY ENDPOINT(S)
Difference between predicted and actual postoperative spherical equivalent (SE) (numerical error), and proportion of eyes within ±0.5 D and ±1.0 D of their target SE refraction

ANALYSIS AND CONCLUSIONS

IA using the ORA™ System was equivalent to the best tested preoperative biometry-based methods of IOL power prediction in short eyes.

When IA (ORA™ System) disagreed with the preoperative prediction by more than 0.5 D, the ability of IA to suggest a more emmetropic outcome was no better than chance.

STUDY RESULTS

NON-OPTIMIZED EYES

- Without optimizing the formulas for the study population (i.e., not using lens constants and surgeon factors that were specifically optimized for short eyes), the mean numerical errors (MNEs) associated with Hoffer Q, Holladay 2, Haigis, Barrett Universal II, Hill-RBF, and IA (ORA™ System) were −0.08 (95% confidence interval [CI], −0.30 to 0.13), −0.14 (95% CI, −0.35 to 0.07), +0.26 (95% CI, 0.05 to 0.47), +0.11 (95% CI, −0.10 to 0.32), +0.07 (95% CI, −0.14 to 0.28), and +0.00 (95% CI, −0.21 to 0.21), respectively (P<0.001) (**Table 1**)
- The proportion of eyes within ±0.5 diopter (D) of the predicted SE with Hoffer Q, Holladay 2, Haigis, Barrett Universal II, Hill-RBF, and IA (ORA™ System) were 49.0%, 43.1%, 52.9%, 52.9%, 60.8%, and 58.8%, respectively (P=0.06) (**Table 1**)
- A Bonferroni analysis showed that Hoffer Q, Holladay 2, and IA (ORA™ System) had the lowest MNEs and were not significantly different from one another; there was no statistically significant difference with regard to the proportion of eyes within ±0.5 D and ±1.0 D of the target SE

OPTIMIZED EYES

- Optimizing for the study population (in those patients receiving one of the monofocal IOLs) changed the performance of many of the formulas with regard to the proportion of eyes within ±0.5 D and ±1.0 D of the target SE; however, these differences were small and not significant
- IA using the ORA™ System remained one of the best performing methods, but its performance was not statistically different from the other methods
- When a formula and IA predictions differed by 0.5 D or more, IA's ability to recommend a more emmetropic outcome was no better than chance (50%)
- For example, when there were disagreements greater than 0.5 D, the Barrett Universal II would have outperformed IA 13.7% of the time, and IA would have outperformed Barrett Universal II 13.6% of the time

Table 1. Comparison of the 6 calculation methods before optimizing for the study population.

Parameter	MNE (95% CI)	MedNE	MAE	Within ±0.5 D (%)	Within ±1.0 D (%)
Hoffer Q	−0.08 (−0.30, 0.13)	−0.09	0.54	49.0	86.3
Holladay 2	−0.14 (−0.35, 0.07)	−0.09	0.53	43.1	88.2
Haigis	+0.26 (0.05, 0.47)*	+0.19	0.60	52.9	80.4
Barrett Universal II	+0.11 (−0.10, 0.32)	+0.17	0.51	52.9	86.3
Hill-RBF	+0.07 (−0.14, 0.28)	+0.11	0.49	60.8	90.2
IA (ORA™ System)	+0.00 (−0.21, 0.21)	−0.02	0.48	58.8	88.2
P value	P<0.001	P<0.001	0.47	0.06	0.31

**Statistically significant*
CI, confidence interval; IA, intraoperative aberrometry; MAE, mean absolute error; MedNE, median numerical error; MNE, mean numerical error

Intraoperative Biometry Versus Conventional Methods for Predicting IOL Power: A Closer Look at Patients Undergoing Toric Lens Implantation for Astigmatic Correction

Waisbren et al. *J Eye Cataract Surg.* 3:27

OVERVIEW

STUDY DESIGN

Retrospective case series to compare intraoperative refractive biometry to conventional methods for intraocular lens (IOL) power calculation in patients receiving toric IOLs

STUDY SETTING(S)

Data from 2 surgeons in one center, United States

PATIENTS

Total of 104 patients: 52 eyes in the conventional calculations group and 52 eyes in the IA (ORA™ System) group (**Table 1**)

SURGICAL METHODOLOGY

Cataract surgery with toric IOL implantation, where standard preoperative measurements and IA using ORA™ were performed

IOL TYPE(S)

AcrySof® Toric IOLs

KEY ENDPOINT(S)

Prediction error (actual spherical equivalent (SE)-predicted SE) and median absolute error (MAE); percentage of eyes within ± 0.50 D and ± 1.00 D of the refractive target, residual cylinder and deviation from intended axis; calculations for refractive outcomes were performed at a minimum of 3 weeks after surgery

ANALYSIS AND CONCLUSIONS

Absolute error was significantly improved in patients using IA (ORA™ System); other variables tested, such as proximity to the targeted axis, were also improved but did not achieve statistical significance.

Based on the findings of this study, IA using the ORA™ System may be a helpful adjuvant in obtaining target refractions in patients undergoing cataract surgery, particularly those requiring astigmatic correction.

STUDY RESULTS

REFRACTIVE OUTCOMES

- Patients in the IA (ORA™ System) cohort achieved a statistically significant lower MAE (0.25 ± 0.22) than those in the conventional calculations cohort (0.34 ± 0.29) (P=0.05) (**Table 2**)
- In the IA (ORA™ System) group, 45/52 (87%) of eyes were within 0.5 D of the targeted refraction, compared to 41/52 (79%) in the conventional preoperative calculation group (P=0.437)
- With the help of IA using the ORA™ System, surgeons were able to reduce astigmatism to <1 D in 45/52 (87%) of patients compared to only 36/52 (69%) of patients who underwent conventional planning (P=0.059)
- In the IA (ORA™ System) 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 IA 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)

Table 1. Patient and operative characteristics of study eyes.

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

D, diopter; IOL, intraocular lens; K, keratometry

Table 2. Refractive outcomes at a minimum of 3 weeks after surgery.

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

*D, diopter; MAE, mean absolute error; *Chi square*

Intraoperative Aberrometry Versus Standard Preoperative Biometry and a Toric IOL Calculator for Bilateral Toric IOL Implantation with a Femtosecond Laser: One-Month Results

Toric IOL Implantation

ORA vs. Conventional Preoperative Biometry

Woodcock et al. ***J Cataract Refract Surg.*** **2016;42:817-825***

OVERVIEW

STUDY DESIGN
Prospective cohort study to compare astigmatic outcomes in patients having toric IOL implantation with intraoperative aberrometry (IA, ORA™ System) measurements in 1 eye and standard power calculation in the contralateral eye

STUDY SETTING(S)
Twelve (12) sites, United States

PATIENTS
Two hundred forty-eight (248) eyes of 124 patients

SURGICAL METHODOLOGY
Cataract surgery with toric IOL implantation, where standard preoperative measurements (including toric calculator with inked axis marking) and IA using ORA™ were performed

IOL TYPE(S)
AcrySof® IQ Toric IOLs

KEY ENDPOINT(S)
Proportion of eyes with postoperative refractive astigmatism of 0.50 D or less at 1 month (primary endpoint), or of 0.25 D, 0.75 D, and 1.00 D or less (secondary endpoints); proportion of eyes having manifest refraction spherical equivalent (MRSE) absolute prediction errors of 0.25 D, 0.50 D, 0.75 D, and 1.00 D or less

ANALYSIS AND CONCLUSIONS

Compared with standard methods, the use of IA (ORA™ System) increased the proportion of eyes with postoperative refractive astigmatism of 0.50 D or less and reduced the mean postoperative refractive astigmatism at 1 month.

The number of patients falling outside the intended astigmatic target was reduced by more than half in the IA (ORA™ System) cohort when compared with the group in which the toric calculator was used.

**Dr. Breen is an employee of Alcon Laboratories, Inc.*

STUDY RESULTS

REFRACTIVE ASTIGMATISM

- The percentage of eyes with astigmatism of 0.50 D or less at 1 month was higher in the IA (ORA™ System) group than in the standard group (89.2% versus 76.6%) (P=0.006) (**Figure 1**)
- The number of patients (14 [53.8%]) falling outside the intended astigmatic target (<0.50 D) was lower in the IA (ORA™ System) group than in the standard group
- The proportions of eyes with postoperative refractive astigmatism of 0.25 D or less, 0.75 D or less, and 1.00 D or less were also higher in the IA (ORA™ System) group (**Figure 1**)
- Similarly, mean postoperative astigmatism was lower in the IA (ORA™ System) group than in the standard group (0.29 ± 0.28 D versus 0.36 ± 0.35 D; P=0.041)

MANIFEST REFRACTION SPHERICAL EQUIVALENT

- The mean absolute value of the prediction error was slightly lower in the IA (ORA™ System) group than in the standard group (0.25 ± 0.19 D versus 0.27 ± 0.21 D; P=0.23)
- The percentages of eyes with an absolute value of the prediction error within specified threshold levels (≤0.25 D, ≤0.50 D, ≤0.75 D, and ≤1.00 D) relative to the predicted postoperative SE were slightly higher in the IA (ORA™ System) group than in the standard group (**Figure 2**)
- None of these differences was statistically significant

Figure 1. Percentages of eyes with postoperative refractive astigmatism of 0.25 D or less, 0.50 D or less, 0.75 D or less, and 1.00 D or less at 1 month (n=222 eyes).

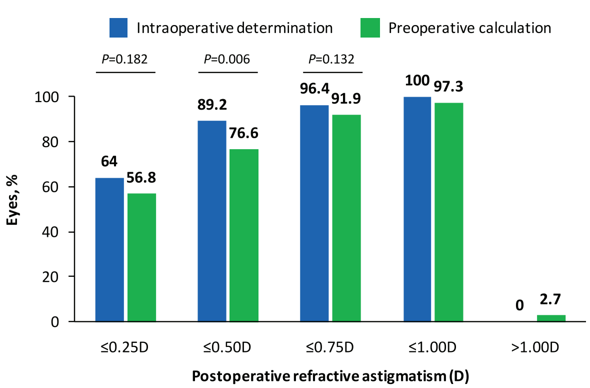
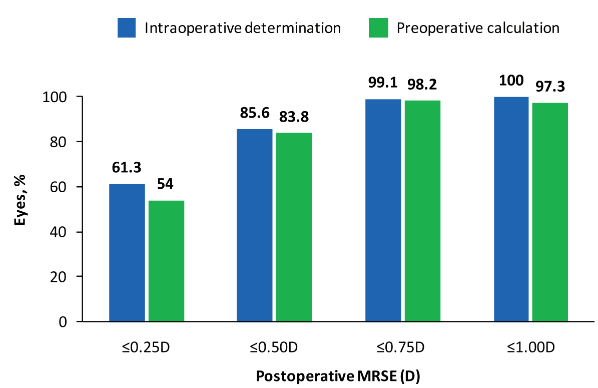


Figure 2. Mean absolute value of the prediction error and proportion of eyes with postoperative manifest refraction spherical equivalent (MRSE) at specified threshold levels (n=222 eyes).



Intraoperative Wavefront Aberrometry for Toric Intraocular Lens Placement in Eyes With a History of Refractive Surgery

Yesilirmak et al. *J Refract Surg.* 2016;32:69-70

Toric IOL Implantation

ORA vs. Conventional Preoperative Biometry

IOL Implantation in Post-Refractive Eyes

OVERVIEW

STUDY DESIGN
Retrospective case review to assess the accuracy of intraoperative aberrometry (IA) using the ORA™ System for toric IOL power selection in eyes with a history of refractive surgery and significant residual astigmatism following refractive surgery

STUDY SETTING(S)
Not specified

PATIENTS
Fifteen (15) eyes; 12 eyes had a history of myopic LASIK and 3 of hyperopic LASIK

SURGICAL METHODOLOGY
Cataract surgery after prior myopic or hyperopic LASIK, where standard preoperative measurements (IOLMaster and the American Society of Cataract and Refractive Surgery [ACSRS] calculator) or IA using ORA™ were performed

IOL TYPE(S)
Toric IOLs

KEY ENDPOINT(S)
Corrected distance visual acuity and manifest refraction 1 month after surgery

ANALYSIS AND CONCLUSIONS

Overall, 80% of eyes with IA (ORA™ System) achieved a spherical equivalent of 0.75 D or less, whereas only 53% of eyes would have achieved this if the calculated preoperative lens per IOLMaster had been implanted instead.

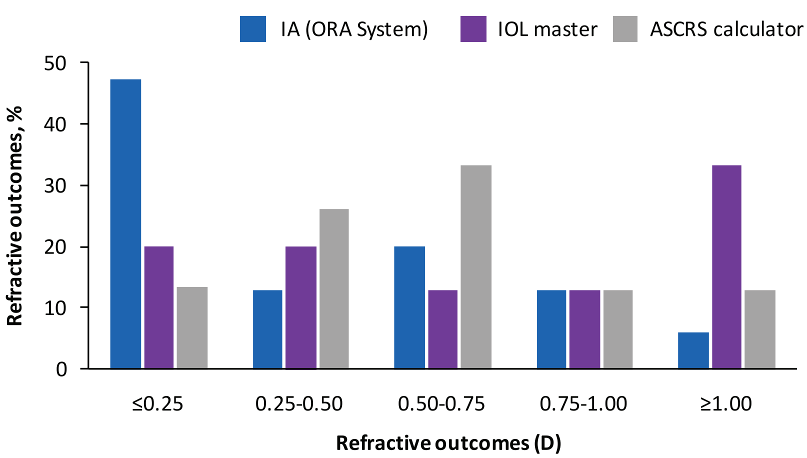
This study is the first to report the successful use of IA (ORA™ System) in eyes undergoing toric IOL implantation after refractive surgery; results are limited by the retrospective design of the study and the small number of patients.

STUDY RESULTS

REFRACTIVE OUTCOMES

- Mean residual astigmatic prediction using IA (ORA™ System) was 0.64 ± 0.61 D and the mean postoperative manifest astigmatism was 0.74 ± 0.63 D
- Twenty-seven percent of the eyes had 0.25 D or less of astigmatism postoperatively, 47% had 0.50 D or less, 60% had 0.75 D or less, and 73% had 1.00 D or less
- Mean IA (ORA™ System) prediction error was 0.43 ± 0.33 D, compared to a mean prediction error of 0.77 ± 0.56 D for the calculated preoperative lens choice using the IOLMaster (P=0.03) and 0.61 ± 0.34 D using the online ASCRS calculator (P=0.08)
- As seen in **Figure 1**, 80% of the treated eyes ended up with a spherical equivalent of 0.75 D or less, whereas only 53% of them would have achieved this if the calculated preoperative lens per IOLMaster had been implanted instead

Figure 1. Refractive outcomes with IA (ORA™ System), IOLMaster, and the American Society of Cataract and Refractive Surgery calculator.



ASCRS, American Society of Cataract and Refractive Surgery; IA, intraoperative aberrometry.

Refractive Outcomes of Intraoperative Wavefront Aberrometry Versus Optical Biometry Alone for IOL Power Calculation

Zhang et al. *Indian J Ophthalmol.* 2017;65:813-817

Monofocal IOL Implantation

ORA vs. Conventional Preoperative Biometry

OVERVIEW

STUDY DESIGN
Nonrandomized, consecutive retrospective study to compare the outcomes of IA using the ORA™ System versus optical biometry alone for IOL power calculation in eyes undergoing cataract surgery

STUDY SETTING(S)
Data from 1 surgical center, United States

PATIENTS
Two hundred ninety-five (295) eyes

SURGICAL METHODOLOGY
Cataract surgery with monofocal IOL implantation, where standard preoperative measurements (including IOLMaster) and IA using the ORA™ System were performed

IOL TYPE(S)
Monofocal IOLs

KEY ENDPOINT(S)
Accuracy of monofocal IOL power prediction and postoperative manifest refraction at 1 month

ANALYSIS AND CONCLUSIONS

Absolute error was significantly reduced in eyes where IA (ORA™ System) and IOLMaster recommended the same IOL power based on preoperative target refraction compared with IOL selection based on IA (ORA™ System) or IOLMaster alone.

Overall, IA using the ORA™ System provided postoperative refractive results comparable to conventional biometry for monofocal IOL selection.

STUDY RESULTS

PATIENT GROUPS

- *Pre-ORA™ group:* 61 eyes (20.7%) had cataract surgery with IOLMaster measurements, but without IA using the ORA™ System
- *BOTH group:* 107 eyes (36.3%) had the same IOL power recommendation from IOLMaster and IA (ORA™ System)
- *ORA™ group:* For 95 eyes (32.2%), the final IOL power implanted was chosen from ORA recommendations rather than IOLMaster
- *IOLMaster group:* For 26 eyes (8.8%), the final IOL power implanted was based on surgeon's best choice from IOLMaster measurements rather than ORA™

PREDICTION ERRORS

- **Table 1** shows the prediction errors of the postoperative manifest refraction spherical equivalent compared to the IOLMaster's target refraction spherical equivalent
  - There was a statistically significant difference between the 4 groups in absolute error (P=0.0049) but not in real error (P=0.57)
  - *Post hoc* comparisons demonstrated that the absolute error in the BOTH group was significantly smaller than in the ORA™ (P=0.002) and pre-ORA™ (P=0.0037) groups, but not than in the IOLMaster group (P=0.35); there was no significant difference between ORA™, IOLMaster and pre-ORA™ groups (all P>0.25)
  - Percentage of eyes within an error range less than ±0.5D of target refraction was 65.3%, 80.4%, 73.1% and 63.9% for ORA™, BOTH, IOLMaster and pre-ORA™ groups, respectively
- **Table 2** shows the distribution of the ORA™'s prediction error for postoperative refraction
  - There was a significant group difference in absolute prediction error (P=0.0053) but not in real prediction error (P=0.91)
  - The absolute prediction error in the BOTH group was significantly less than in the ORA™ group (P=0.004) but not the IOLMaster group (P=0.12), and there was no difference between ORA™ and IOLMaster groups (P=0.75)
  - Percentage of eyes within an error range less than ±0.5D of predicted refraction was 66.3%, 79.4%, and 69.2% for ORA™, BOTH, and IOLMaster groups, respectively

Table 1. Prediction error of IOLMaster target manifest refraction. Adapted from Zhang et al. *Indian J Ophthalmol.* 2017;65:813-817.

Group	n	Real prediction error	Absolute prediction error*	Number (proportion) in error range, %		
Control		Mean ± SD	Mean ± SD	≤ ±0.5	> ±0.5 to ±1	> ±1
ORA	95	−0.007±0.556	0.434±0.345	62 (65.3)	24 (25.3)	9 (9.5)
BOTH	107	−0.05±0.399	0.295±0.272	86 (80.4)	18 (16.8)	3 (2.8)
IOLMaster	26	0.027±0.443	0.359±0.251	19 (73.1)	7 (26.9)	0
pre-ORA	61	−0.155±0.575	0.462±0.37	19 (73.1)	17 (27.9)	5 (8.2)

**BOTH group was significantly smaller than ORA and pre-ORA groups. IOL, intraocular lens; SD, standard deviation.*

Table 2. Prediction error of IA (ORA™ System) predicted manifest refraction. Adapted from Zhang et al. *Indian J Ophthalmol.* 2017;65:813-817.

Group	n	Real prediction error	Absolute prediction error*	Number (proportion) in error range, %		
Control		Mean ± SD	Mean ± SD	≤ ±0.5	> ±0.5 to ±1	> ±1
ORA	95	−0.022±0.561	0.434±0.354	63 (66.3)	26 (27.4)	6 (6.3)
BOTH	107	−0.05±0.403	0.299±0.273	85 (79.4)	20 (18.7)	2 (1.9)
IOLMaster	26	0.027±0.506	0.412±0.283	18 (69.2)	7 (26.9)	1 (3.8)

**BOTH group was significantly smaller than ORA. IOL, intraocular lens; SD, standard deviation.*

Optiwave Refractive Analysis May Not Work Well in Patients with Previous History of Radial Keratotomy

Zhang et al. ***Am J Ophthalmol Case Rep.*** **2018;10:163-164**

Monofocal IOL Implantation

ORA vs. Conventional Preoperative Biometry

IOL Implantation in Post-Refractive Eyes

OVERVIEW

STUDY DESIGN

Case report assessing significant hyperopic outcome (both eyes) following IA (ORA™ System) IOL power recommendation in a cataract patient with history of 8 cut radial keratotomy (RK) in each eye

STUDY SETTING(S)

Data from private practice, United States

PATIENTS

One (1) patient

SURGICAL METHODOLOGY

Cataract surgery along with IA using the ORA™ System

IOL TYPE(S)

Alcon monofocal IOL (SN60AT)

KEY ENDPOINT(S)

Visual acuity, refractive outcomes

ANALYSIS AND CONCLUSIONS

After cataract surgery and IOL power calculations using IA (ORA™ System), a patient with a history of RK showed hyperopic refraction; macular edema did not seem to account for the refraction, and a review of preoperative biometry showed no error in calculations.

Surgeons should be cautious when using IA (ORA™ System) on RK patients, especially in those patients who have more than 6 cuts.

STUDY RESULTS

REFRACTIVE OUTCOMES

- A 57-year-old male with a history of RK presented for cataract surgery (**Table 1**)
- Surgery was performed OS with a 2.4 mm incision aiming −1.50 D; 4 aphakic readings were taken and IA (ORA™ System) recommended +26.00 to +26.50 (aiming −1.43D)
- Right eye surgery was performed about a month later; 4 aphakic readings were taken and IA (ORA™ System) recommended +25.50D for −1.25D, but +26.50 was used
- Two weeks after the second eye surgery, the patient's distance vision OD was 20/25 with +4.50 sphere and OS 20/25 with +3.25 + 1.00 × 151
- At the three months follow up, distance vision was OD 20/30 with +1.75 + 1.50 × 089; OS 20/25 with +0.50 + 0.75 × 055
- If there had been no adjustments of the chosen IOL by 1 D in each eye, the postoperative hyperopia would be worse in each eye
- If preoperative selection of IOL 32 D for OD and 30 D for OS per Barrett True K formula were used, it would theoretically end up close to −1.25 D for OD and −1.50 for OS
- Macular edema did not seem to account for the refraction, and a review of preoperative biometry showed no error in calculations
- *The corneal curvature of patients with a history of RK may be subject to significant change due to swollen corneal cuts and increased IOP from phacoemulsification; thus, the measurement of the corneal curvature, anterior chamber depth and axial length may be incorrect when measured intraoperatively even at intraocular pressure of 21 mmHg as required by IA (ORA™ System) instructions*

Table 1. Patient preoperative examination.

Preoperative examinations	OD	OS
CDVA (Snellen)	20/30	20/30
Manifest Refraction	+7.75 + 0.25 × 151	+6.00 + 0.50 •132
Cornea RK/AK Cuts	8 RK	8 RK and 1 AK
Cataracts	3 + Cortical	3 + Cortical
Dilated Fundus	Mild BDR, otherwise unremarkable	Mild BDR, otherwise unremarkable
IOP (mmHg)	17	17
Corneal Topography	33.22/34.53 @135	34.51/36.76 @058
Refractive Target	−1.25 D	−1.50 D
IOL Power with Barrett True K Formula	+32.00 SN60AT	+30.00 SN60AT

AK, astigmatic keratotomy; BDR, background diabetic retinopathy; CDVA, corrected distance visual acuity; IOL, intraocular lens; IOP, intraocular pressure; RK, radial keratotomy.

References

Canto AP, Chhadva P, Cabot F, Galor A, Yoo SH, Vaddavalli PK, Culbertson WW. **Comparison of IOL Power Calculation Methods and Intraoperative Wavefront Aberrometer in Eyes after Refractive Surgery.** *J Refract Surg.* 2013;29:484-489.

Chen M, Reinsbach M, Wilbanks ND, Chang C, Chao CC. **Utilizing Intraoperative Aberrometry and Digital Eye Tracking to Develop a Novel Nomogram for Manual Astigmatic Keratotomy to Effectively Decrease Mild Astigmatism During Cataract Surgery.** *Taiwan J Ophthalmol.* 2019;9:27-32.

Cionni RJ, Dimalanta R, Breen M, Hamilton C. **A Large Retrospective Database Analysis Comparing Outcomes of Intraoperative Aberrometry with Conventional Preoperative Planning.** *J Cataract Refract Surg.* 2018;44;1230-1235.

Davison JA, Potvin R. **Preoperative Measurement vs Intraoperative Aberrometry for the Selection of IOL Sphere Power in Normal Eyes.** *Clin Ophthalmol.* 2017;11:923-929.

Fisher B, Potvin R. **Clinical Outcomes with Distance-Dominant Multifocal and Monofocal IOLs In Post-Lasik Cataract Surgery Planned Using an Intraoperative Aberrometer.** *Clin Exp Ophthalmol.* 2018;46:630-636.

Fram NR, Masket S, Wang L. **Comparison of Intraoperative Aberrometry, OCT-Based IOL Formula, Haigis-L, and Masket Formulae for IOL Power Calculation after Laser Vision Correction.** *Ophthalmology.* 2015;122:1096-1101.

Hatch KM, Woodcock EC, Talamo JH. **IOL Power Selection and Positioning with and Without Intraoperative Aberrometry.** *J Refract Surg.* 2015:31:237-242.

Hill DC, Sudhakar S, Hill CS, King TS, Scott IU, Ernst BB, Pantanelli SM. **Intraoperative Aberrometry Versus Preoperative Biometry for IOL Power Selection in Axial Myopia.** *J Cataract Refract Surg.* 2017;43:505-510.

Ianchulev T, Hoffer KJ, Yoo SH, Chang DF, Breen M, Padrick T, Tran DB. **Intraoperative Refractive Biometry for Predicting IOL Power Calculation after Prior Myopic Refractive Surgery.** *Ophthalmology.* 2014;121:56-60.

Masket S, Fram NR, Holladay JT. **Influence of Ophthalmic Viscosurgical Devices on Intraoperative Aberrometry**. *J Cataract Refract Surg.* 2016;42:990-994.

Packer M. **Effect of Intraoperative Aberrometry on the Rate of Postoperative Enhancement: Retrospective Study.** *J Cataract Refract Surg.* 2010; 36:747-755.

Potvin R, Kramer BA, Hardten DR, Berdahl JP. **Factors Associated with Residual Astigmatism after Toric IOL Implantation Reported in an Online Toric IOL Back-calculator.** *J Refract Surg.* 2018;34:366-371.

Solomon JD, Ladas J. **Toric Outcomes: Computer-Assisted Registration Versus Intraoperative Aberrometry.** *J Cataract Refract Surg.* 2017;43:498-504.

Solomon KD, Sandoval HP, Potvin R. **Correcting Astigmatism at the Time of Cataract Surgery: Toric IOLs and Corneal Relaxing Incisions Planned with an Image-Guidance System and Intraoperative Aberrometer Versus Manual Planning and Surgery.** *J Cataract Refract Surg.* 2019a;45:569-575.

Solomon KD, Sandoval HP, Potvin R. **Evaluating the Relative Value of Intraoperative Aberrometry Versus Current Formulas for Toric IOL Sphere, Cylinder, and Orientation Planning.** *J Cataract Refract Surg.* 2019b;45:1430-1435.

Stringham J, Pettey J, Olson RJ. **Evaluation of Variables Affecting Intraoperative Aberrometry.** *J Cataract Refract Surg.* 2012;38:470-474.

Sudhakar S, Hill DC, King TS, Scott IU, Mishra G, Ernst BB, Pantanelli SM. **Intraoperative Aberrometry Versus Preoperative Biometry for Intraocular Lens Power Selection in Short Eyes.** *J Cataract Refract Surg.* 2019;45:719-724.

Waisbren E, Ritterband D, Wang L, Trief D, Koplin R, Seedor J. **Intraoperative Biometry versus Conventional Methods for Predicting IOL Power: A Closer Look at Patients Undergoing Toric Lens Implantation for Astigmatic Correction.** *J Eye Cataract Surg.* 3:27.

Woodcock MG, Lehmann R, Cionni RJ, Breen M, Scott MC. **Intraoperative Aberrometry Versus Standard Preoperative Biometry and a Toric IOL Calculator for Bilateral Toric IOL Implantation with a Femtosecond Laser: One-Month Results.** *J Cataract Refract Surg.* 2016;42:817-825.

Yesilirmak N, Palioura S, Culbertson W, Yoo SH, Donaldson K. **Intraoperative Wavefront Aberrometry for Toric Intraocular Lens Placement in Eyes with a History of Refractive Surgery.** *J Refract Surg.* 2016;32:69-70.

Zhang Z, Thomas LW, Leu SY, Carter S, Garg S. **Refractive Outcomes of Intraoperative Wavefront Aberrometry Versus Optical Biometry Alone for IOL Power Calculation.** *Indian J Ophthalmol.* 2017;65:813-817.

Zhang F. **Optiwave Refractive Analysis May Not Work Well in Patients with Previous History of Radial Keratotomy.** *Am J Ophthalmol Case Rep.* 2018;10:163-164.

ORA SYSTEM® Technology Important Product Information

CAUTION: Federal (USA) law restricts this device to the sale by or on the order of a physician.

INDICATIONS: Federal (USA) law restricts this device to the sale by or on the order of a physician.

INTENDED USE: The ORA SYSTEM® technology utilizes wavefront aberrometry data to measure and analyze the refractive power of the eye (i.e. sphere, cylinder, and axis measurements) to support cataract surgical procedures.

WARNINGS AND PRECAUTIONS: The following conditions may make it difficult to obtain accurate readings using the ORA SYSTEM® technology:

- Patients having progressive retinal pathology such as diabetic retinopathy, macular degeneration, or any other pathology that the physician deems would interfere with patient fixation;
- Patients having corneal pathology such as Fuchs', EBMD, keratoconus, advanced pterygium impairing the cornea, or any other pathology that the physician deems would interfere with the measurement process;
- Patients for which the preoperative regimen includes residual viscous substances left on the corneal surface such as lidocaine gel or viscoelastics;
- Visually significant media opacity, such as prominent floaters or asteroid hyalosis, will either limit or prohibit the measurement process; or
- Patients having received retro or peribulbar block or any other treatment that impairs their ability to visualize the fixation light.
- Use of iris hooks during an ORA SYSTEM® technology image capture will yield inaccurate measurements.

In addition:

- Significant central corneal irregularities resulting in higher order aberrations might yield inaccurate refractive measurements.
- Post refractive keratectomy eyes might yield inaccurate refractive measurement.
- The safety and effectiveness of using the data from the ORA SYSTEM® have not been established for determining treatments involving higher order aberrations of the eye such as coma and spherical aberrations.
- ORA SYSTEM® technology is intended for use by qualified health personnel only.
- Improper use of this device may result in exposure to dangerous voltage or hazardous laser-like radiation exposure. DO NOT OPERATE the ORA SYSTEM® in the presence of flammable anesthetics or volatile solvents such as alcohol or benzene, or in locations that present an explosion hazard.

ATTENTION: Refer to the ORA SYSTEM® Operator's Manual for a complete description of proper use and maintenance, as well as a complete list of contraindications, warnings and precautions

Alcon