September 25, 2017

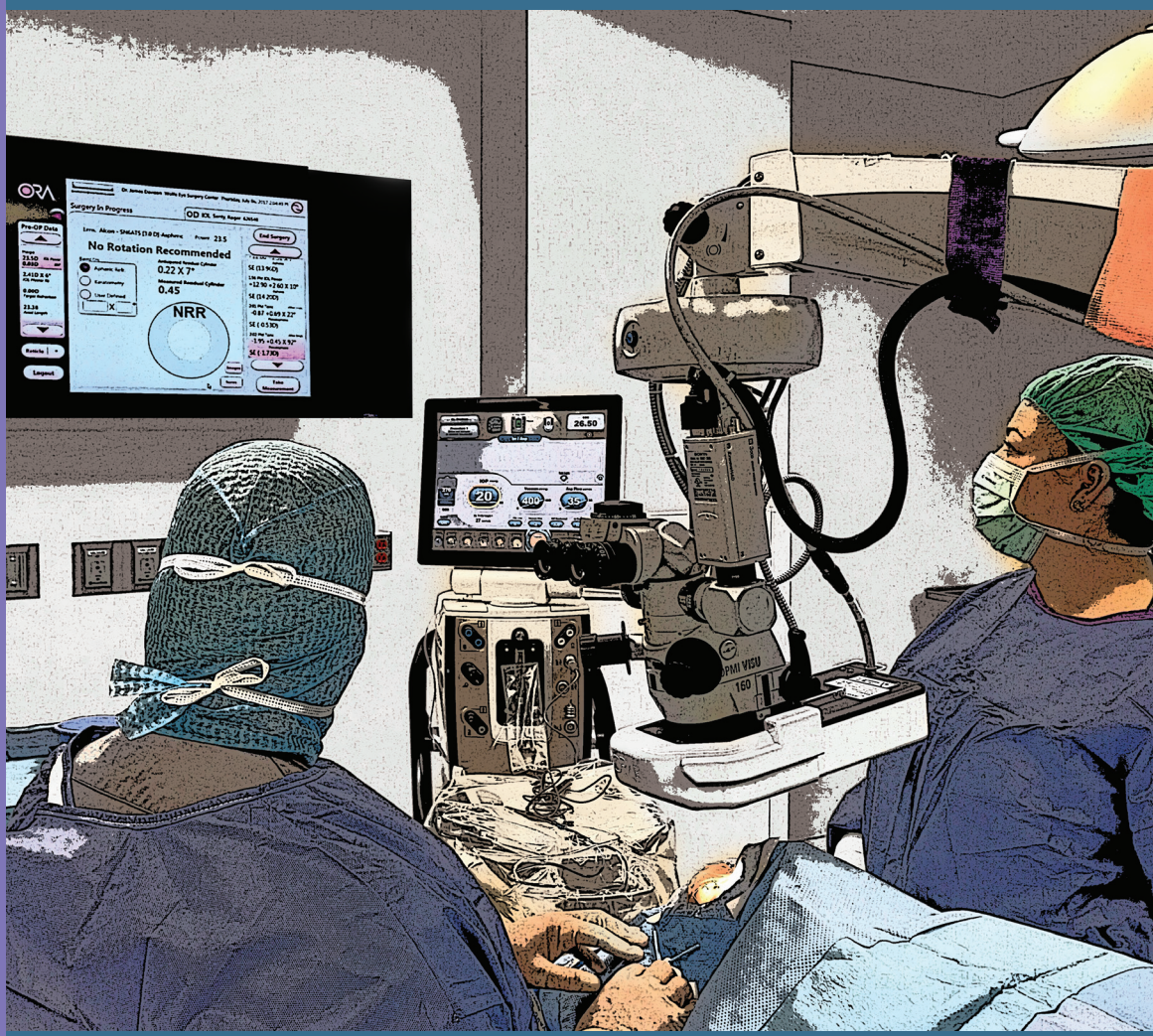
Supplement to

OCULAR SURGERY NEWS®

SPOTLIGHT

Dynamic Process of Intraoperative Aberrometry

for the Performance-Driven Surgeon



This *Ocular Surgery News* spotlight supplement is produced by SLACK Incorporated and sponsored by Alcon Laboratories, Inc.

INTRODUCTION

The ORA SYSTEM® (Alcon Laboratories, Inc.) uses intraoperative wavefront aberrometry that provides real-time data during cataract surgery which helps enable surgeons achieve improved outcomes.[1] This tool allows surgeons to gather aphakic refractive measurements to help determine the correct IOL sphere power for monofocal and multifocal IOLs, as well as cylinder power for toric IOLs. It also obtains pseudophakic measurements to aid the surgeon in proper alignment of toric IOL axes. With the ORA SYSTEM, surgeons can see real-time axis alignment, and they are able to adjust IOL positioning during the surgery and confirm its correct placement within the eye, evolving cataract surgery into a dynamic surgical process.

In the spring of 2017, Alcon Laboratories, Inc., conducted a survey of ORA SYSTEM users to evaluate how use of the ORA SYSTEM impacts surgeons' rates of refractive surprises and enhancements, as well as its potential impact to a practice and value for cataract surgeons. In this supplement, key opinion leaders review the survey results and relate their experiences using the ORA SYSTEM and its effect on their practice and patient expectations.

I thank the faculty members for their participation and Alcon Laboratories, Inc., for sponsoring this OCULAR SURGERY NEWS spotlight supplement. For more information on this topic, visit Healio.com/Ophthalmology/Education-Lab.

Richard L. Lindstrom, MD
Chief Medical Editor
Ocular Surgery News

1. 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(6):817-825.

The ORA SYSTEM Surgeon Survey 2017[1,†]

James A. Davison, MD, FACS

It is important for the ophthalmic industry and surgeons to work together to develop and integrate technology that creates improved outcomes for patients. With that in mind, Alcon Laboratories, Inc., conducted a survey to understand the effectiveness, economic impact and overall value the ORA SYSTEM provides for cataract surgeons. Ophthalmologists were recruited by email to participate in an online survey of users, and eligibility was restricted to surgeons who had used the ORA SYSTEM in the last 12 months.

The data and graphs discussed in this supplement came from the ORA SYSTEM Surgeon Survey 2017. Of the 150 collected survey responses, 70% of surgeons had been using the ORA SYSTEM for more than 1 year.[1] The survey asked surgeons about using the ORA SYSTEM to adjust sphere, cylinder power and confirm cylinder axis alignment in real time during surgery. Many of the surgeons reported using the ORA SYSTEM helped them to reduce refractive surprises.[1] As a result of more accurate IOL selection and alignment, surgeons found that postoperative refractive enhancement rates were reduced.[1]

1. Alcon Laboratories, Inc., data on file. March 2017.

† Graphs in this supplement do not represent the entirety of the survey results. Only selected questions and answers.

***The physicians featured in this supplement are paid consultants for Alcon Laboratories, Inc.**

Intraoperative aberrometry: A dynamic process to help improve outcomes

Q&A with James A. Davison, MD, FACS

NUMBER OF YEARS IN PRACTICE	37
WORK SETTING	10 main offices and 10 family vision centers 22 ophthalmologists (including 11 anterior segment surgeons in glaucoma, cornea, external diseases and cataract/refractive) 20 optometrists Surgeries performed in 30 hospitals 4 ASCs 17,000 cataract surgeries/year 190,000 patient visits/year Self: 25 to 30 surgeries/day
NUMBER OF YEARS USING THE ORA SYSTEM	1.5
PREOPERATIVE AND INTRAOPERATIVE DIAGNOSTIC TOOLS	ORA SYSTEM (Alcon) IOLMaster (Zeiss) Pentacam (Oculus)
PERCENT OF SURGERIES IN WHICH THE ORA SYSTEM IS USED	90% toric 100% refractive and multifocal IOLs
PERCENT OF SURGERIES IN WHICH THE ORA SYSTEM RECOMMENDS A CHANGE	40% for sphere change 40% for T power change 80% for axis rotation
ADOPTION RATE OF ADVANCED-TECHNOLOGY IOLS	Multifocal: 3% pre-ORA; 4% post-ORA Toric: 12% pre-ORA; 17% post-ORA
ENHANCEMENT RATE	2% pre-ORA <1% post-ORA
ASTIGMATISM MANAGEMENT	We screen all patients for anterior and total corneal refractive power astigmatism.

Most surgeons reported a learning curve of less than 30 cases with the ORA SYSTEM.[1] When did your office acquire the ORA SYSTEM, and what was your learning curve with it?

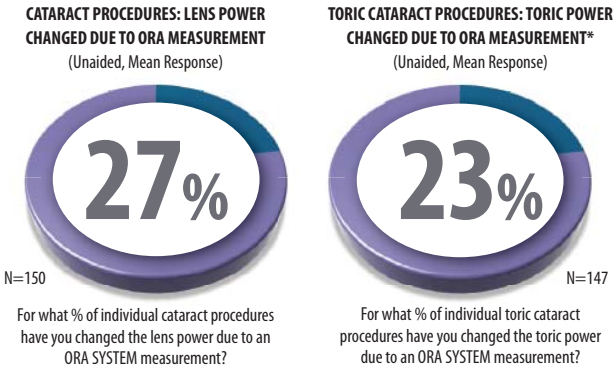
James A. Davison, MD, FACS: Our office acquired the ORA SYSTEM in early 2016. We waited until the current version with VerifEye® Technology had been in commercial use for a while. The process of incorporating this technology is unlike that of, for example, switching to a different kind of scalpel. With this technology, surgeons must introduce a new kind of thinking during the surgery. I found that it did not take long to learn how to operate the ORA SYSTEM itself, but it did take time to master the dynamic way of thinking about what the technology is telling us about our IOL calculations and how to integrate that into each individual, real-time surgical situation. Surgeons must continue to analyze and judge the given data of each case and consider their previous experience to determine what is ideal for each patient.

The survey reported that a change in IOL power was recommended 27% of the time, and a toric power change was recommended 23% of the time based on the intraoperative measurements provided by the ORA SYSTEM (Figure 1).[1] How does the recommendation of the ORA SYSTEM impact IOL selection during cataract surgery?

Davison: Before the development of intraoperative aberrometry, surgeons performed cataract

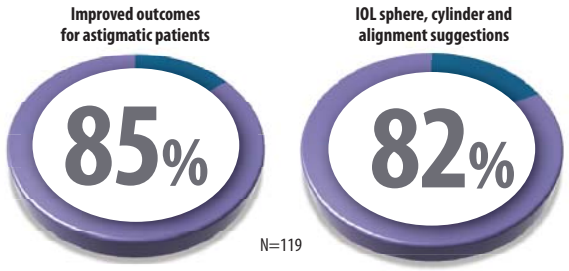
Please see page 15 for Important Product Information about the ORA SYSTEM, Verion Imaging Guided System and AcrySof IQ toric IOL.

Figure 1. ORA SYSTEM SURGEONS SEE THE VALUE IN ORA: POWER CHANGES DUE TO ORA SYSTEM †



† Surgeons who utilized ORA 12 months or less stated that they used ORA in 30% of their IOL procedures.
* Among those who have used the ORA SYSTEM with a toric cataract procedure.
Source: Alcon Laboratories, Inc.

Figure 2. REDUCED ENHANCEMENTS WITH THE ORA SYSTEM †



† Percent of surgeons who selected these options in response to the question "Which of the following do you consider a benefit of ORA for you?" This is from a subgroup of surgeons (79%) who responded "strongly agree" or "somewhat agree" that the ORA SYSTEM has reduced their enhancement rate.
Source: Alcon Laboratories, Inc.

WHAT MY COLLEAGUE SAYS

"The ORA SYSTEM guides surgeons to make better decisions intraoperatively and provides the measurements surgeons need for improved outcomes."

— NEEL R. DESAI, MD

surgery with a fixed surgical plan based solely on preoperative measurements; however, with the ORA SYSTEM, surgeons now have a chance to obtain aphakic and pseudophakic measurements during surgery.[2] The system is a valuable addition to the surgeon's armamentarium, evolving cataract surgery into a more dynamic intellectual process. Surgeons must think about the predictive data the system is showing them intraoperatively and confirm if their preoperative measurements are accurate or if IOL specifications or alignment should be adjusted to improved the chances for achieving desired refractive targets.

As we all know, choosing the correct lens power is necessary for any IOL to work optimally. The aphakic measurements provided by the ORA SYSTEM maximize the chance of selecting the most accurate power.[2] Additionally, with astigmatism-correcting IOLs, the ORA SYSTEM not only aids surgeons in predicting the best IOL power, but also helps to guide IOL positioning to optimally treat astigmatism.

The survey results show improved outcomes for patients. What is the role of the ORA SYSTEM in that improvement?

Davison: Selecting the correct IOL improves patient outcomes and, in my hands, the ORA SYSTEM helps me improve the ratio of satisfied to dissatisfied patients. The survey indicates that, of those surgeons reporting reduced enhancements with the ORA SYSTEM, 85% stated that the ORA SYSTEM improved astigmatic outcomes for patients, and 82% of surgeons reported that patients benefited from the ORA SYSTEM's IOL sphere, cylinder and alignment suggestions (Figure 2).[1]

These results are consistent with current research on the value of intraoperative aberrometry with toric IOL implantation. In a study conducted by Woodcock and colleagues, the researchers found a significant difference between eyes that had residual astigmatism of 0.5 D or less when intraoperative aberrometry was used (89.2%) compared with eyes in the control group that underwent standard preoperative biometry and calculations with a toric calculator (76.6%) 1 month postoperatively.[2] These findings show that intraoperative aberrometry provides surgeons with an opportunity for validation or modification of their IOL calculations and axis orientation and, therefore, provides the opportunity to improve the ratio of good vs. marginal outcomes for their patients. It is all about that ratio.

According to the survey, more than 50% of surgeons ranked correcting astigmatism to 0.5 D or less as "very" or "extremely" important.[1] How important is the use of the ORA SYSTEM in managing patients with astigmatism?

Davison: The survey results show that 88% of surgeons found the ORA SYSTEM to be a valuable tool during toric IOL implantation.[1] This value is appreciated at two junctures during surgery. First, the aphakic intraoperative measurements of the ORA SYSTEM either confirm the pre-selected cylinder power or suggest a different IOL,

allowing the surgeon to consider the individual circumstances of the case and then select the optimal IOL power. Second, in the pseudophakic mode, it guides the surgeon during the rotational adjustment of the IOL on the table. Once the ideal placement of the toric IOL has been reached, the screen will display "NRR," which means "No Rotation Recommended" so the surgeon then knows that optimal alignment of the IOL has been achieved.

What does the NRR reading confirm for you?

Davison: The NRR reading confirms that the toric IOL is aligned which can help achieve the best vision astigmatism management and the best vision for the patient. Marking the eye manually and then using only preoperative corneal measurements is not as accurate as also using the intraoperative aberrometer, which provides real-time feedback on exactly where the lens should be aligned. This is the final and best chance to accurately locate the axis and obtain perfect orientation, and this is one of the values of the ORA SYSTEM. Seeing the "NRR" on the screen is a great feeling for everyone in the room because the surgeon and his or her team know the alignment is right on the money, and they know that they have done a good job for the patient.

How has the ORA SYSTEM impacted your practice as a performance-driven surgeon?

Davison: The ORA SYSTEM is another tool in the cataract surgical toolbox, which helps surgeons refine results and improve expectations and performance. Using postoperative analysis, we know that our patients have achieved better outcomes since we began using the ORA SYSTEM. Because of that, we feel that the system is worth the additional required surgical time and effort.

Before adopting the ORA SYSTEM, I would have to explain to some patients why their results were less than expected — an unpleasant conversation that I experience much less often now. I would even have to refund money or perform an enhancement with LASIK at a discounted rate in some instances. To improve the ratio of satisfied to dissatisfied patients, the surgeon must deliver better results. It is all about the ratio, and the ratio is improved with this additional technology.

Our goal is to do the best we can and use all the tools that are available to deliver the best results possible. For us, the motivation is not about pushing IOL sales; it is about getting the right match for each patient, and I can better achieve that with the ORA SYSTEM.

MY AHA MOMENT

We realized the ORA SYSTEM was an invaluable tool after treating a female patient who presented with substantial cataracts, abnormally deep anterior chambers, moderate astigmatism, substantial epimacular membranes and a desire for continued monovision. During her cataract surgery on her distance eye, the ORA SYSTEM confirmed sphere and cylinder power but gave me a 15-degree difference in the orientation of the toric IOL. I followed its suggestion, and she ended up with 0.18 D of cylinder postoperatively. That was a great result and we knew the ORA SYSTEM had assisted us with obtaining that outcome for her. *— James A. Davison, MD, FACS*

Dr. Davison and staff donning "NRR" caps.

Source: Davison JA

James A. Davison, MD, FACS, *is senior surgeon at the Wolfe Eye Clinic in Marshalltown and West Des Moines, Iowa. Dr. Davison is a paid consultant for Alcon Laboratories, Inc.*

Please see page 15 for Important Product Information about the ORA SYSTEM, Verion Imaging Guided System and AcrySof IQ toric IOL.

Managing astigmatism and reducing refractive surprises

Q&A with Kevin J. Everett, MD

NUMBER OF YEARS IN PRACTICE	20
WORK SETTING	8 offices 30 ophthalmologists (including 14 cataract surgeons) 4,000 cataract surgeries/year across health system Self: 800 cataract surgeries/year
NUMBER OF YEARS USING THE ORA SYSTEM	4.5
PREOPERATIVE AND INTRAOPERATIVE DIAGNOSTIC TOOLS	ORA SYSTEM (Alcon) TMS-4N topographer (Tomey) Lenstar (Haag-Streit) Verion Image Guided System (Alcon) Pentacam (Oculus)
PERCENT OF SURGERIES IN WHICH THE ORA SYSTEM IS USED	45%
PERCENT OF SURGERIES IN WHICH THE ORA SYSTEM RECOMMENDS A CHANGE	25% for sphere change 65% for T power change
ADOPTION RATE OF ADVANCED-TECHNOLOGY IOLS	25% pre-ORA 40% post-ORA
ENHANCEMENT RATE	5% pre-ORA 2% post-ORA
ASTIGMATISM MANAGEMENT	We screen all patients for astigmatism.

In the survey, many surgeons felt the ORA SYSTEM significantly reduced the rate of refractive surprises.[1] How has the ORA SYSTEM impacted your rate of refractive surprises?

Kevin J. Everett, MD: In the survey, 62% of surgeons saw a reduction in refractive surprises due to toric alignment or misalignment exceeding 10°; 53% of surgeons saw a reduction of refractive surprises because the ORA SYSTEM allowed them to make an unplanned adjustment in astigmatism correction with manual limbal relaxing incisions; and 48% of surgeons saw a reduction in refractive surprises because they were changing the IOL power by 1 D or more based on the data generated by the ORA SYSTEM (Figure 3).[1]

According to the survey, most surgeons reported reduced enhancement rates. The survey reported an average decrease from 9% to around 3% for enhancements such as excimer laser, toric rotation and lens exchange.[1] Has the ORA SYSTEM impacted your enhancement rate?

Everett: Yes, the ORA SYSTEM has reduced my enhancement rate from approximately 5% to approximately 2%. With the power changes based on the ORA SYSTEM data, theoretically, I can prevent refractive surprises. I perform only a handful of enhancements per year anymore, and that reduction directly correlates with the optimization of results from using the ORA SYSTEM.

The survey shows the most often used AnalyzOR report is the Outcomes Analysis. How has tracking your results using AnalyzOR impacted the rate at which you change IOL power?

Everett: AnalyzOR, a feature of the ORA SYSTEM, collects and analyzes postoperative data for optimization and reporting, and it undergoes regular software updates that optimize the system's surgical variables and algorithms. When using AnalyzOR, surgeons can compare their data to the global data in the system. In addition, as surgeons input their personal outcomes, the system becomes customized to each surgeon. As their optimization increases, surgeons can compare themselves to their own outcomes as well, creating personalized A-constants and sets.

I use AnalyzOR to track and optimize my surgical results. My technician enters patient data into the AnalyzOR 1 month postoperatively for all cases in

which I use the ORA SYSTEM. I can then refer to the data from those cases to see the percentage of patients who hit their refractive goals. As data accumulates, the system becomes increasingly customized to me. In my earlier years with the ORA SYSTEM, I changed the IOL power approximately 50% of the time. Today, however, because my A-constants and sets are optimized with AnalyzOR, I now change IOL power approximately 20% of the time with non-toric IOLs.

How does tracking your surgical results help you achieve better outcomes for your patients?

Everett: Using AnalyzOR to track my results has increased my confidence in the selected IOL. The recommended power changes have improved outcomes for my patients, and this is reflected in my decreased rates of refractive surprises and enhancements. Many surgeons overlook AnalyzOR, but the ability to track surgical outcomes and to optimize IOL selection is a critical element of this technology. AnalyzOR is a powerful tool, and it allows the surgeon to deliver what was promised to the patient.

Of survey respondents, 88% of surgeons found the ORA SYSTEM to be a valuable tool for implanting toric IOLs (Figure 4).[1] How important is it to consider astigmatism management?

Everett: Astigmatism management is as crucial to cataract surgery outcomes as the air we breathe is to life itself, and the key behind correct refractive outcomes is astigmatism management. Ninety percent of the time I spend with patients who have significant astigmatism involves monitoring and controlling their cylinder outcome. It is not enough to say spherical equivalent is –0.5 D, as that could mean that a patient's sphere is –1.0 D and the astigmatism is +1.0 D, which is not a great outcome. So, I screen all patients for cylinder, and I begin a serious discussion with my patients about astigmatism management at 0.25 D at 180° on the axis and at 0.75 D at 90° on the axis because I know that the ORA SYSTEM will find at least some degree of astigmatism on almost every patient.[3]

For me, the ORA SYSTEM provides either confirmation that the plan I created for a patient is the correct plan, or its information allows me to adjust my preoperative plan during surgery for a better outcome. Without the ORA SYSTEM, a surgeon is only going halfway to where they could go for a patient undergoing refractive cataract surgery.

In your opinion, what is the value of the aphakic measurement for the surgeon?

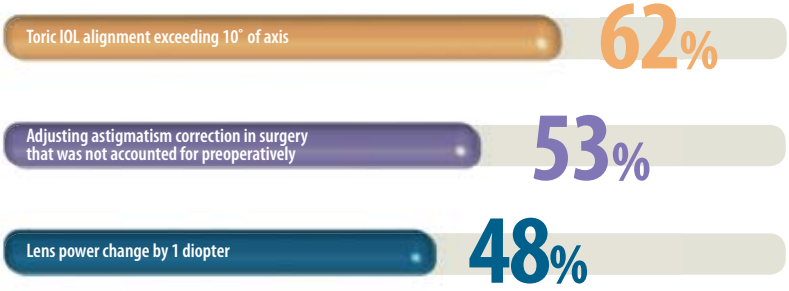
Everett: The aphakic measurement is one of the purest measurements a surgeon can obtain. Some have claimed this measurement can be inaccurate because of factors such as the interference of viscoelastic or because the aphakic state is not a natural environment. However, if the surgeon pays attention to the details, ensuring that the patient has a clear cornea, a clear capsule and proper pressure in the eye, and that the patient is focusing correctly, then the aphakic measurement becomes an accurate and powerful measurement.

According to the survey, surgeons felt comfortable using the ORA SYSTEM after an average of 30 cases.[1] How would you describe the learning curve associated with the ORA SYSTEM?

Everett: In my opinion, the learning curve associated with the ORA SYSTEM has more than one level.

Figure 3. REFRACTIVE SURPRISES PREVENTED BY THE ORA SYSTEM

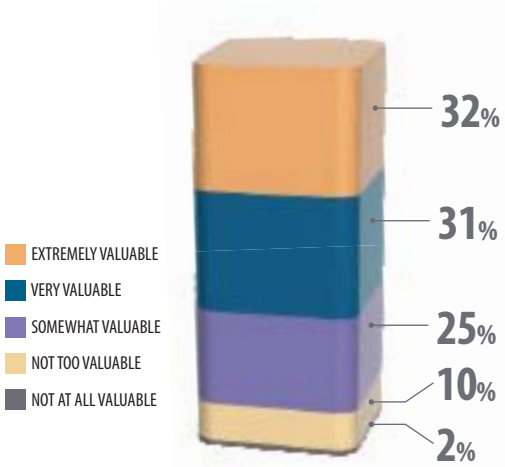
Surgeons responded "frequently" or "sometimes" to the question:
"How often, if ever, has the use of ORA technology prevented each of the following refractive surprises for your procedures?"*



* Possible answer choices were "never," "rarely," "sometimes" or "frequently." N=150
Source: Alcon Laboratories, Inc.

Figure 4. MAJORITY OF SURGEONS SURVEYED RELIED ON THE ORA SYSTEM WHEN IMPLANTING TORIC IOLS

VALUE OF ORA SYSTEM INTRAOPERATIVE ABERROMETER WHILE IMPLANTING
(Aided, Single Response)



Source: Alcon Laboratories, Inc.

88%
VIEW ORA SYSTEM AS A VALUABLE TOOL FOR IMPLANTING TORIC IOLS
88% of responses were "extremely valuable," "very valuable" or "somewhat valuable."
N=150

Please see page 15 for Important Product Information about the ORA SYSTEM, Verion Imaging Guided System and AcrySof IQ toric IOL.

MY AHA MOMENT

I realized the value of the ORA SYSTEM after treating a patient with severe myopia of –11.0 D. This patient was adamant about not wearing glasses for distance vision after surgery. I had planned to implant a +9.5 D monofocal IOL, but during surgery, the ORA SYSTEM recommended I use a +11.0 D AcrySof IQ T4 toric IOL (Alcon Laboratories, Inc.). I repeated the ORA SYSTEM measurement 10 times because I could not believe what I was seeing. However, having used the ORA SYSTEM for quite a while by then, I knew that once I had several consistent readings, I could trust it. So I placed the +11.0 D toric IOL, and the patient ended up with 20/20 uncorrected distance vision. If I had not made the adjustment, this patient would have required glasses full time and would have been very dissatisfied. This case impressed me because it was an extreme example in which I had to change both the power and type of the IOL in a very demanding patient, saving the two of us from many frustrating appointments together. Over the years, the ORA SYSTEM has made similar recommendations that have surprised me, and it continues to be correct just about every time.

— Kevin J. Everett, MD

WHAT MY COLLEAGUE SAYS

"If a surgeon is performing cataract surgery, the technology of the ORA SYSTEM should be available."

— JAMES A. DAVISON, MD, FACS

First, surgeons must master the basics of operating the actual machine, including how to position the patient. After learning the basics, the surgeon then needs to understand the nuances of the technology to determine whether a reading is good or not, and to ensure the cornea is clear and the capsule is clean. I feel this level of comfort with the ORA SYSTEM may be achieved after approximately 50 to 75 cases.

Has the ORA SYSTEM impacted your surgical flow and length of time?

Everett: I adopted both femtosecond laser-assisted cataract surgery and the ORA SYSTEM at the same time, so that was a major change in surgical flow. In my experience, the ORA SYSTEM adds 1 to 2 minutes to a monofocal or a laser case with monofocal case, and it adds a few additional minutes to a toric case. Some surgeons may feel the ORA SYSTEM is not worth the additional surgical time, but I disagree because when patients are paying for ideal outcomes, surgeons should provide premium service. To claim that using the ORA SYSTEM is not worth the additional few minutes in the OR for a patient who paid out of pocket for improved refractive outcomes is unacceptable to me.

In the survey, 74% of surgeons reported "predictable outcomes" as a benefit of using the ORA SYSTEM.[1] Why is it important for surgeons to develop trust in the ORA SYSTEM?

Everett: Knowing when to trust the ORA SYSTEM is key. With experience, surgeons will get to the point where trust of the system becomes intuitive. That ability to be completely locked in and trusting of the ORA SYSTEM is rewarding because surgeons can be confident they are delivering the outcomes they promised to patients.

In this survey, surgeons identified multiple benefits of using the ORA SYSTEM, such as improved outcomes for astigmatic patients, informed refractive decision making and alignment suggestions for improved outcomes.[1] In your opinion, what is the true value of the ORA SYSTEM?

Everett: The ORA SYSTEM is a valuable tool for any cataract surgeon. To me, the time needed to learn the technology, as well as the extra time needed to use it during the procedure, is well worth the improved outcomes I can provide for patients. I believe the survey data supports this, as a high percentage of surgeons find that the ORA SYSTEM is a valuable tool that increases their confidence, which in turn, makes a positive difference for patients.[1] I am not interested in solely increasing my volume. For me, the true value of the ORA SYSTEM is that it enables me to stay focused on taking my time and ensuring the surgery is performed correctly, which to me, defines being a performance-driven surgeon.

Kevin J. Everett, MD, *is the medical director at Henry Ford OptimEyes Lakeside in Sterling Heights, Michigan, clinical assistant professor at Wayne State University School of Medicine in Detroit, and the official team ophthalmologist for the Detroit Lions. Dr. Everett is a paid consultant for Alcon Laboratories, Inc.*

The ORA SYSTEM is a valuable tool to cataract surgeons and their patients

Q&A with Neel R. Desai, MD

NUMBER OF YEARS IN PRACTICE	10
WORK SETTING	7 offices 30 ophthalmologists and optometrists 2 primary cataract surgeons 8 partners Physician-owned ASC 5,000 cataract surgeries/year between 2 surgeons 8,000 cataract surgeries/year in the ASC
NUMBER OF YEARS USING THE ORA SYSTEM	9
PREOPERATIVE AND INTRAOPERATIVE DIAGNOSTIC TOOLS	ORA SYSTEM (Alcon) Cassini (i-Optics) Lenstar (Hagg-Streit) IOLMaster (Zeiss) Galilei (Ziemer) Orbscan (Bausch+Lomb) OPD2 (Nidek) Manual keratometry
PERCENT OF SURGERIES IN WHICH THE ORA SYSTEM IS USED	80%
PERCENT OF SURGERIES IN WHICH THE ORA SYSTEM RECOMMENDS A CHANGE	20% for sphere change 45% for T power change
ADOPTION RATE OF ADVANCED-TECHNOLOGY IOLS	30% pre-ORA 40% post-ORA
ENHANCEMENT RATE	5% pre-ORA 3% post-ORA
ASTIGMATISM MANAGEMENT	We screen for low cylinder, with 0.5 D or more being significant.

The majority of respondents to the survey had been using the ORA SYSTEM for 12 months or longer.[1] How long have you been using the system?

Neel R. Desai, MD: My experience with intraoperative aberrometry goes back to the early days before a commercial product was available, and I was involved in beta testing the original Wavetec Vision Systems units for intraoperative aberrometers. This testing saw the first viable commercial product, the ORange intraoperative wavefront aberrometer from WaveTec Vision Systems, and although the early technology was not perfect, it was clear the technology would be a game-changer in terms of achieving better outcomes for patients. Later, this product became the ORA SYSTEM when it was acquired by Alcon Laboratories, Inc.

This ORA SYSTEM has advanced the technology of intraoperative aberrometry to a new level of utility and accuracy. My colleagues and I have had significant experience with the ORA SYSTEM, performing approximately 8,000 intraoperative aberrometry cases. Through this experience, we have a solid sense of the beneficial impact the ORA SYSTEM has on patient experience and outcomes.

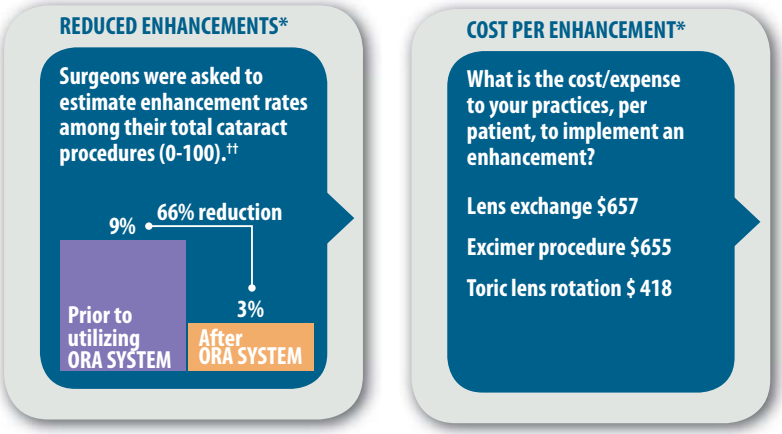
The survey showed that 88% of surgeons stated the ORA SYSTEM, as a tool, is "somewhat valuable" to "extremely valuable" when implanting toric IOLs.[1] What value does the ORA SYSTEM bring to your surgical suite?

Desai: As the only practice in the world that offers three different femtosecond laser platforms, my colleagues and I show that we embrace and believe in technology. Yet, of all the technologies to which I have access, the most critical to me and my outcomes is

Please see page 15 for Important Product Information about the ORA SYSTEM, Verion Imaging Guided System and AcrySof IQ toric IOL.

Figure 5. ECONOMIC IMPLICATION OF USING THE ORA SYSTEM†

When using the ORA SYSTEM, surgeons reported a 66% reduction in enhancements.*



BASED ON THE AVERAGE VALUES REPORTED IN THE SURVEY, A PRACTICE PERFORMING 1,000 PROCEDURES A YEAR COULD SAVE OVER $30K ON ENHANCEMENTS.

* Enhancements were defined as excimer procedure, toric rotation or lens exchange.
† Unaided, mean response. Calculated based on surgeon responses to survey N=150.
†† Unaided, mean response. Excluding those who disagree that the ORA SYSTEM has reduced rate of enhancement.
Source: Alcon Laboratories, Inc.

the ORA SYSTEM. For cases in which I cannot rely on preoperative data because they are inconsistent or misleading, I rely heavily on the ORA SYSTEM to guide a great outcome and allow me to make better decisions intraoperatively for the patient. The one tool I would not want to do without is the ORA SYSTEM because it provides the most power for me in terms of intraoperative decision-making.

In this survey, surgeons reported a 66% decrease in their enhancement rates, from an average of 9% to 3% (Figure 5).[1] What are some of the benefits of a reduction in enhancement rates?

Desai: I saw a reduction in my personal enhancement rates to less than 3%, including post-refractive cases. This reduction is beneficial to both the patient and the practice as performing fewer enhancements affects patient cost, as well as calculable costs for the practice. The survey reported the average cost for an enhancement ranges between $400 and $700.[1] That is a significant cost for surgeons to absorb, and they also absorb various intangible costs in terms of time and dollars.

Surgeons should consider the impact of having 66% fewer patients in need of an enhancement because of a refractive surprise. Even if the surgeon performs an enhancement, and the patient achieves a great outcome and is happy, that patient may have already shared a negative review of the initial experience with friends and family. Decreasing enhancement rates by 66% could reduce the potential for poor reviews.

Do you think there has been a positive economic impact from using the ORA SYSTEM?

Desai: With fewer enhancements to perform, surgeons have more time to perform additional cataract procedures and, therefore, may increase their overall volume. For example, in the survey, surgeons estimated that it takes an average of 10 to 15 minutes to perform a refractive procedure, such as a laser enhancement or a photorefractive keratectomy; it was also estimated to take an average of 25 minutes to perform an IOL exchange because of a refractive surprise. As a result, the time spent performing these enhancements translates to additional cost for the surgeon.

Surgeons should consider the intangible or incalculable costs of performing enhancements. In the 25 minutes it takes to exchange an IOL, I could perform five cataract procedures, and that only considers the actual IOL replacement surgical time. That time estimate does not include the two or three additional office visits that require significant chair time — perhaps 10 minutes per visit — to get the dissatisfied patient to the point where he or she trusts the surgeon again to perform the enhancement. So, one enhancement could potentially add up to a full hour of additional time per patient, and in that hour, I could have performed 12 to 15 additional cataract cases. So, the opportunity cost of the additional enhancements, which can be reduced with the ORA SYSTEM, is substantial.

According to the survey, many surgeons track their postoperative results using AnalyzOR. What is the value of AnalyzOR for tracking outcomes?

Desai: AnalyzOR — a feature of the ORA SYSTEM — is the hidden gem. Early in my experience with intraoperative aberrometry, I would change my lens power from the preoperatively predicted power by more than 0.5 D about 60% of the time, based on recommendations from the ORA SYSTEM. However, because we enter data from all our intraoperative aberrometry cases into the AnalyzOR, that rate has now decreased to about 20%, which speaks to the power of the AnalyzOR data.

WHAT MY COLLEAGUE SAYS

"The economic impact of needing to do enhancements is small compared to the reputational impact."

— JOHN A. HOVANESIAN, MD, FACS

AnalyzOR provides reports that are useful in optimizing our surgeons' factors. As a result, we have optimized our own surgeons' A-constants and customized surgeons' factors based on AnalyzOR data. So, not only have refractive surprises and enhancement rates decreased, but the number of cases in which the ORA SYSTEM disagrees with our preoperative calculations has also decreased.

The bottom line is if surgeons do not take intraoperative measurements, then they do not know the full picture of the surgical case. Surgeons assume they have excellent refractive outcomes, and probably estimate they reach within 0.5 D of intended refractive target 90% of the time. However, American Society of Cataract and Refractive Surgery data show that the rate is closer to 65% for the average surgeon.[4] Therefore, I recommend surgeons take the opportunity to use the AnalyzOR data to optimize their personal constants and improve outcomes.

According to the survey, surgeons who use the ORA SYSTEM have experienced reduced enhancements and better patient outcomes. What impact does the ORA SYSTEM have on surgeons' confidence?

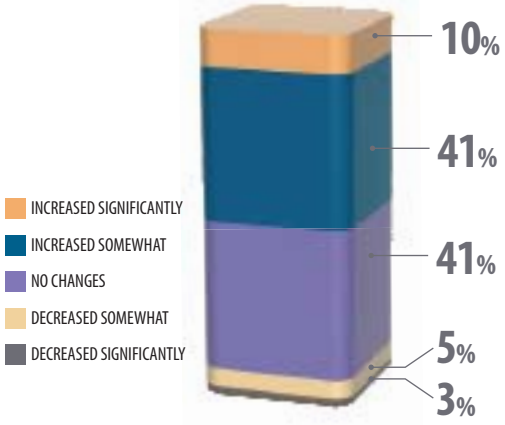
Desai: In the survey, 92% of surgeons stated that their utilization of the system increased or stayed the same over the prior 3 to 6 months (Figure 6).[1] This suggests that, as surgeons grow more comfortable with the ORA SYSTEM and experience the improved outcomes, they use it more frequently.

Increased surgeon confidence can translate to all aspects of treating patients, from discussing refractive cataract surgery options with the patient to performing the surgery itself. With increased confidence, surgeons change how they present options to patients and patients perceive their surgeons' confidence. The surgeon can engage in a more patient-centric, outcome-driven way, which makes for a more efficient conversation and likely impacts the patient's experience and that is what matters most to the patient.

What is the role of the ORA SYSTEM in a performance-driven cataract surgeon's surgical suite?

Desai: In this era of refractive cataract surgery, surgeons must be performance-driven and outcome-driven, or they fail to serve their patients. The ORA SYSTEM is a useful tool that improves patient outcomes by reducing refractive surprises and the need for enhancements, which increases surgeons' overall confidence when performing surgery and counseling patients. I have used intraoperative aberrometry and the ORA SYSTEM since their inception, and if I had to choose only one tool from my surgical suite for cataract surgery and refractive cataract surgery, then I would pick the ORA SYSTEM.

Figure 6. SURGEONS INCREASE THEIR USE OF THE ORA SYSTEM OVER TIME AS THEY GAIN MORE EXPERIENCE†‡



92%

OF THE SURGEONS SURVEYED STATED THEIR ORA SYSTEM UTILIZATION HAS INCREASED OR STAYED THE SAME OVER THE LAST 3-6 MONTHS.

N=144

† Among those who have been utilizing ORA SYSTEM for 4+ months.
‡ Surgeons who utilized ORA 12 months or less stated that they used ORA in 30% of their IOL procedures.
Source: Alcon Laboratories, Inc.

MY AHA MOMENT

The moment I realized the value of the ORA SYSTEM was during a live cataract surgery demonstration I performed for 50 surgeons in training with a world-class faculty in the audience. During the demonstration, the ORA SYSTEM reported that I was going to have a 3-D hyperopic refractive surprise based on my preoperatively selected IOL. Everyone wondered whether I should trust the ORA SYSTEM. I decided to trust the recommendation and exchange the premium IOL for another one. The next day, that patient had 20/20 vision. The ORA SYSTEM gave me the opportunity to select a better IOL for that patient, and it was a teachable moment for everyone. — *Neel R. Desai, MD*

Neel R. Desai, MD, *is an ophthalmologist at The Eye Institute of West Florida in Tampa Bay. Dr. Desai is a paid consultant for Alcon Laboratories, Inc.*

Please see page 15 for Important Product Information about the ORA SYSTEM, Verion Imaging Guided System and AcrySof IQ toric IOL.

Enhancing the premium cataract practice with advanced-technology IOLs and staff support

Q&A with John A. Hovanesian, MD, FACS

NUMBER OF YEARS IN PRACTICE	18
WORK SETTING	3 offices 12 surgeons 4 cataract surgeons 3,300 cataract surgeries/year
NUMBER OF YEARS USING THE ORA SYSTEM	3
PREOPERATIVE AND INTRAOPERATIVE DIAGNOSTIC TOOLS	ORA SYSTEM (Alcon) IOLMaster (Zeiss) Pentacam (Oculus) iTrace (Tracey Technologies) Cirrus OCT (Zeiss)
PERCENT OF SURGERIES IN WHICH THE ORA SYSTEM IS USED	95%
PERCENT OF PATIENTS IN WHICH THE ORA SYSTEM RECOMMENDS A CHANGE	50% for sphere change 40% for T power change
ADOPTION RATE OF ADVANCED-TECHNOLOGY IOLS	80% both pre- and post-ORA
ENHANCEMENT RATE	10% pre-ORA 4% post-ORA
ASTIGMATISM MANAGEMENT	We screen all patients for astigmatism.

According to the survey, a majority of surgeons said IOL sphere, cylinder and alignment suggestions were a benefit of the ORA SYSTEM.[1] How does intraoperative aberrometry assist surgeons in improving patient outcomes?

John A. Hovanesian, MD, FACS: Many preoperative tools are available to surgeons today, but none of them claim they reduce enhancement rates by 66%.[1] Surgeons are accustomed to continuing with what works for them, and for years, only preoperative diagnostics were available. However, today's cataract surgery patients expect LASIK-like outcomes, and although surgeons strive to achieve that with refractive cataract surgery, they can get a lot closer with the ORA SYSTEM, which has reached a level of refinement in which surgeons can rely on the additional measurements.

The ORA SYSTEM is the most widely used intraoperative aberrometry system in the U.S., and I use it with almost every cataract surgery patient. My colleagues and I took a long time to decide to adopt the ORA SYSTEM because we did not realize it provided such a significant opportunity to improve our results. The ORA SYSTEM is in its own class because it captures the aphakic measurement during surgery to verify the measurements of the eye. Surgeons should use every tool available to minimize the risk for missing the refractive target, and if surgeons can reduce their enhancement rates in half with the ORA SYSTEM, then I would say that is a valuable tool.

In the survey, more than half of the surgeons reported that the ORA SYSTEM increased their use of advanced-technology IOLs.[1] With regard to these IOLs, how has your adoption rate been impacted as a result of the ORA SYSTEM?

Hovanesian: Surgeons reported a 66% increase in adoption of both toric IOLs and presbyopia-correcting

Please see page 15 for Important Product Information about the ORA SYSTEM, Verion Imaging Guided System and AcrySof IQ toric IOL.

IOLs (Figure 7).[1] Increased adoption of advanced-technology IOLs means more patients achieve better vision. It also means surgeons perform the same surgery but with greater precision, giving patients greater visual freedom.

In my office, we have a 90% adoption rate for premium cataract surgery, which is higher than most places in the country. I would attribute that to two things. First, we work hard for the best outcome for each patient. Second, we spend time educating patients so that if they are a candidate for advanced-technology IOLs, we can ensure they understand the technology and why we are choosing a particular IOL for them.

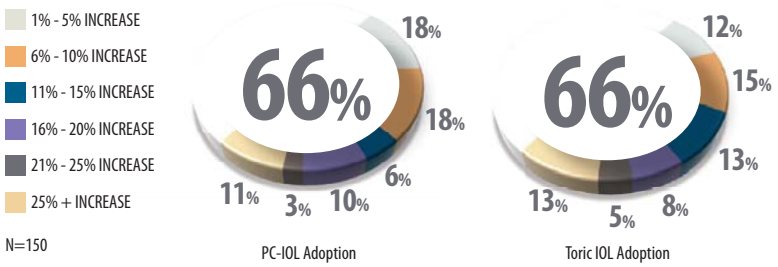
In the past 2 years, the conversation about premium IOLs has become easier with patients, and I think it is partly because our past patients are happy with their results and are promoting the idea of these IOLs to their friends and family. I spend time talking to my patients about the IOLs we will use, and many patients want surgeons to use whatever tools we need to provide the results they want. I discuss the cost of advanced-technology IOLs with patients because they need to understand the expense. I help patients separate the financial decision from the personal one, and that drives our adoption rate. The ORA SYSTEM is part of almost every surgical package we offer. Surgeons who are implanting advanced-technology IOLs and not using the ORA SYSTEM are missing a great opportunity.

Has your confidence and trust in IOL selection increased with the ORA SYSTEM?

Hovanesian: The ORA SYSTEM increased my confidence in power selection significantly. AnalyzOR encompasses a global database, which optimizes the recommendation for an IOL based on collected experience of other surgeons using the same IOL, and the ORA SYSTEM often affirms the chosen IOL. Sometimes I must change the IOL power by 0.5 D, but it is rare that I need to change the IOL by more than 0.5 D.

Before my colleagues and I incorporated the ORA SYSTEM into practice, we performed enhancements in about 10% of patients, but now that rate is reduced by more than half, to almost 4%. About one-third of the time, a technician must retrieve an IOL that was not brought into the operating room because the ORA SYSTEM's recommendation was a significantly different diopter power than what was anticipated. Typically, that happens more often with toric IOLs because they have two dimensions that can change, sphere and cylinder power. Once a surgeon learns to trust the ORA SYSTEM and changes such as these, the surgeon will understand that he or she can make small adjustments and achieve better outcomes for the patient.

Figure 7. MAJORITY OF ORA SYSTEM SURGEONS STATE THAT ORA INCREASED THEIR UTILIZATION OF ADVANCED-TECHNOLOGY IOLS†‡



† Among those who have been utilizing ORA SYSTEM for 4+ months.
‡ In a majority (66%) feel ORA SYSTEM has increased the adoption rate of ATIOLs N=150
Source: Alcon Laboratories, Inc.

MY AHA MOMENT

I realized a few months after my training on the ORA SYSTEM that not only was I achieving more accurate results with it, but the tool was driving my premium cataract practice. An increasing number of patients were eagerly choosing premium IOLs because they had heard more positive reviews from friends and neighbors about their visual results. It was with this increase in my premium practice that I realized the value of the ORA SYSTEM.

— John A. Hovanesian, MD, FACS

According to the survey, 73% of staff have a positive view of the ORA SYSTEM (Figure 8, page 14).[1] How did you integrate the ORA SYSTEM into your practice and work to gain staff acceptance?

Hovanesian: Gaining staff acceptance takes coordination, effort and commitment from everyone. I have found that one of the biggest barriers to surgeons is the change of routine that the ORA SYSTEM requires; however, it is a worthwhile change. In training, my colleagues and I started by introducing the ORA SYSTEM to the staff and explaining how it will

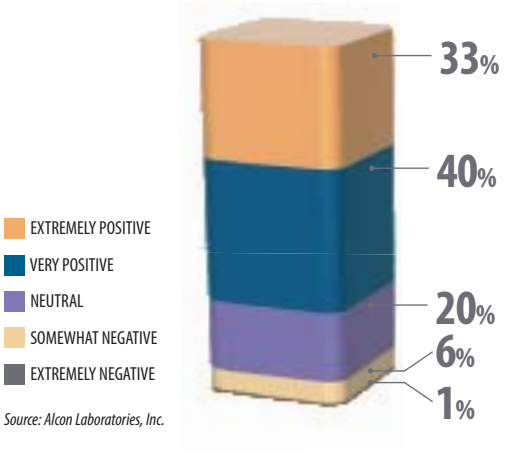
WHAT MY COLLEAGUE SAYS

"We have had the ORA SYSTEM for 4 ½ years now, and we have never looked back. It has been a home run for our staff, patients and practice."

— KEVIN J. EVERETT, MD

Figure 8. SURGEONS REPORT THEIR STAFF OPINION

(Aided, Single Response)



Source: Alcon Laboratories, Inc.

73%

ORA SYSTEM SURGEONS STATED THAT THEIR STAFF HAVE A FAVORABLE OPINION OF THE ORA SYSTEM IN THEIR CLINIC.

N=150

improve our results. We explained the roles everyone would have. For example, we discussed how the counselors were going to input the data before and after surgery and how the operating room staff would work with the system, including setting it up on the microscope and collaborating on where to place the ORA SYSTEM.

How does the ORA SYSTEM help to raise the standard of outcomes for a performance-driven surgeon?

Hovanesian: Being performance-driven means that surgeons view themselves as servants to their patients, and that they put the ability to give patients the best outcomes above their own egos or benefits. Part of being a good, ethical surgeon is choosing the proper tools and techniques for our patients. A surgeon's motivation in learning about and recommending a technology, and in improving results going forward, are all driven by the desire to get it right for the patient. Using the ORA SYSTEM is a way for surgeons to double-check they are doing the best job they can for patients, and it helps them create a higher standard of outcomes.

John A. Hovanesian, MD, FACS, *is a specialist in cataract and corneal surgery at Harvard Eye Associates in Laguna Hills, California, a faculty member at the University of California, Los Angeles Jules Stein Eye Institute, and cataract surgery section editor of* Ocular Surgery News. *Dr. Hovanesian is a paid consultant for Alcon Laboratories, Inc.*

PEARLS FOR USING THE ORA SYSTEM

James A. Davison, MD, FACS: Surgeons must keep in mind that the ORA SYSTEM is just one tool to be used in a dynamic surgical, measurement and calculation process. Although it takes some time to learn how to appreciate all the ORA SYSTEM has to offer, surgeons will soon learn how to trust their own judgment when using this tool to provide better outcomes for patients. This improves the number of satisfied patients a surgeon sees every day.

Kevin J. Everett, MD: If surgeons make the commitment to use the ORA SYSTEM, then they must also make the commitment to learn and understand how the technology works. This is the only way for surgeons to know when they are getting good vs. inaccurate readings. Without question, the ORA SYSTEM is a powerful and proven technology. If the surgeon makes the effort to understand it completely, he or she, as well as their patients, will be rewarded with significantly improved refractive outcomes.

Neel R. Desai, MD: If surgeons do not measure intraoperatively, then they do not have the full surgical picture. The ORA SYSTEM provides the opportunity to measure and confirm the IOL power and alignment in the operating room before concluding surgery; therefore, the surgeon can be confident in a good outcome. As a result, the surgeon can continue to strive for never-ending improvement, while working to achieve better goals with the technologies that are available.

John A. Hovanesian, MD, FACS: To make changing the IOLs efficient, the nurses plan to have three or more IOLs for each patient in the room. As we prepare for surgery, we choose an IOL based on our preoperative measurements and bring in that IOL, as well as the IOL for both sphere and cylinder power that is one level up and one level down from the preoperatively selected IOL. This way, we have all the likely options in the room so staff do not need to run down the hall to find another IOL during surgery. Having multiple IOLs available is a little more work for the staff, but it saves time during that critical operating room experience.

ORA SYSTEM®
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 sale by, or on the order of, a physician.

INTENDED USE: The ORA SYSTEM® uses wavefront aberrometry data in the measurement and analysis of the refractive power of the eye (i.e. sphere, cylinder, and axis measurements) to support cataract surgical procedures.

CONTRAINDICATIONS: There are no known contraindications for this device.

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

- 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® 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.
- The ORA SYSTEM® 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.

VERION® Image Guided System
Important Product Information
VERION® Reference Unit and VERION® Digital Marker

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

INTENDED USES: The VERION® Reference Unit is a preoperative measurement device that captures and utilizes a high-resolution reference image of a patient's eye. In addition, the VERION® Reference Unit provides pre-operative surgical planning functions to assist the surgeon with planning cataract surgical procedures. The VERION® Reference Unit also supports the export of the reference image, preoperative measurement data, and surgical plans for use with the VERION® Digital Marker and other compatible devices through the use of a USB memory stick. The VERION® Digital Marker links to compatible surgical microscopes to display concurrently the reference and microscope images, allowing the surgeon to account for lateral and rotational eye movements. In addition, details from the VERION® Reference Unit surgical plan can be overlaid on a computer screen or the physician's microscope view.

CONTRAINDICATIONS: The following conditions may affect the accuracy of surgical plans prepared with the VERION® Reference Unit: a pseudophakic eye, eye fixation problems, a non-intact cornea, or an irregular cornea. In addition, patients should refrain from wearing contact lenses during the reference measurement as this may interfere with the accuracy of the measurements. The following conditions may affect the proper functioning of the VERION® Digital Marker: changes in a patient's eye between pre-operative measurement and surgery, an irregular elliptic limbus (e.g., due to eye fixation during surgery, and bleeding or bloated conjunctiva due to anesthesia). In addition, the use of eye drops that constrict sclera vessels before or during surgery should be avoided.

WARNINGS: Only properly trained personnel should operate the VERION® Reference Unit and VERION® Digital Marker. Use only the provided medical power supplies and data communication cable. Power supplies for the VERION® Reference Unit and the VERION® Digital Marker must be uninterruptible. Do not use these devices in combination with an extension cord. Do not cover any of the component devices while turned on. The VERION® Reference Unit uses infrared light. Unless necessary, medical personnel and patients should avoid direct eye exposure to the emitted or reflected beam.

PRECAUTIONS: To ensure the accuracy of VERION® Reference Unit measurements, device calibration and the reference measurement should be conducted in dimmed ambient light conditions. Only use the VERION® Digital Marker in conjunction with compatible surgical microscopes.

ATTENTION: Refer to the user manuals for the VERION® Reference Unit and the VERION® Digital Marker for a complete description of proper use and maintenance of these devices, as well as a complete list of contraindications, warnings and precautions.

AcrySof® IQ Toric Astigmatism Intraocular Lenses
Important Product Information

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

INDICATIONS: The AcrySof® IQ Toric posterior chamber intraocular lenses are intended for primary implantation in the capsular bag of the eye for visual correction of aphakia and pre-existing corneal astigmatism secondary to removal of a cataractous lens in adult patients with or without presbyopia, who desire improved uncorrected distance vision, reduction of residual refractive cylinder and increased spectacle independence for distance vision.

WARNING/PRECAUTION: Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting a lens in a patient with any of the conditions described in the Directions for Use labeling. Toric IOLs should not be implanted if the posterior capsule is ruptured, if the zonules are damaged, or if a primary posterior capsulotomy is planned. Rotation can reduce astigmatic correction; if necessary lens repositioning should occur as early as possible prior to lens encapsulation. All viscoelastics should be removed from both the anterior and posterior sides of the lens; residual viscoelastics may allow the lens to rotate.

Optical theory suggests that, high astigmatic patients (i.e. > 2.5 D) may experience spatial distortions. Possible toric IOL related factors may include residual cylindrical error or axis misalignments. Prior to surgery, for products for which a Patient Information Brochures (PIB) is available, physicians should provide prospective patients with a copy of the Patient Information Brochure informing them of possible risks and benefits associated with the AcrySof® IQ Toric Astimatism IOLs.

Studies have shown that color vision discrimination is not adversely affected in individuals with the AcrySof® Natural IOL and normal color vision. The effect on vision of the AcrySof® Natural IOL in subjects with hereditary color vision defects and acquired color vision defects secondary to ocular disease (e.g., glaucoma, diabetic retinopathy, chronic uveitis, and other retinal or optic nerve diseases) has not been studied. Do not resterilize; do not store over 45° C; use only sterile irrigating solutions such as BSS® or BSS PLUS® Sterile Intraocular Irrigating Solutions.

ATTENTION: Reference the Directions for Use labeling for a complete listing of indications, warnings and precautions.

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1. Alcon Laboratories, Inc., data on file. March 2017.
2. 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(6):817-825.
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4. Global Trends in Ophthalmology and the American Society of Cataract and Refractive Surgery. ASCRS Clinical Survey 2015. Fairfax, VA: Global Trends in Ophthalmology; 2015.

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This *Ocular Surgery News* spotlight supplement is produced by SLACK Incorporated and sponsored by Alcon Laboratories, Inc.

8/17 US-ORA-17-E-2133