White Paper

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Using ORA SYSTEM® Technology with AnalyzOR™ Technology to Optimize Refractive Cataract Outcomes: Normal to Complex Cases, Simultaneous Innovations

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Key Takeaways:

- ORA SYSTEM® Technology empowers the surgeon to achieve predictable[9] post-operative refractive outcomes which are unique to each patient's visual needs.
- ORA SYSTEM® Technology complements pre-operative measurements and IOL calculations by providing a means to validate these data in real-time through aphakic measurements at the time of cataract surgery AND verifying the correct IOL power (sphere and cylinder) that needs to be implanted in each eye.
- With AnalyzOR™ Technology, each surgeon is capable of continuously optimizing IOL-specific lens constants that may lead to progressively more accurate outcomes.

Introduction

Evolving Cataract Surgery Goals

Cataract surgery has evolved from just the removal of an opacified natural lens to one which can provide the patient with a high level of spectacle independence as the main goal of the procedure. Goals of cataract surgery evolved from safety, to efficiency, to achieving excellent refractive surgery outcomes in parallel with, and perhaps due to, developments in surgical instrumentation. These developments include better microscopes that aid surgeons' visualization for safer surgeries, better phaco instrumentation that allows surgeons to emulsify cataract lenses more efficiently, and high-technology biometers and sophisticated intraocular lens calculation formulas that allow surgeons to determine the correct IOL powers to implant, leading to better refractive targeting.

Presently, patients who require cataract extraction are more knowledgeable about the current trends in Ophthalmology and have greater expectations from a once-in a lifetime procedure like cataract surgery than their predecessors. Most commonly, patients aspire for less dependence on spectacles and the freedom to engage in activities which fit their desired lifestyle.

The desire to see clearly without glasses is not new. Contact lenses have been available since the late 1800s. Contact lenses provide patients reprieve from wearing glasses, but technological developments were still needed to better fill the need for spectacle independence. In the late 1990s, Laser refractive surgery was developed. In the years that followed, the number of patients undergoing keratorefractive procedures grew reaching a peak in 1999 and 2000.[1]

More technological breakthroughs in Ophthalmology were achieved in the 2000s. Additionally, many of the patients with errors of refraction who sought spectacle independence and had Radial Keratotomies (RK) in the '80s and LASIK in the '90s started developing cataracts during this time. These post-keratorefractive patients still desired spectacle-independence after cataract removal. With ample resources to pay extra to achieve their visual goals, these patients expect , if not demand, precision and near perfect visual outcomes after cataract surgery.[2] Consequently, surgeons had to be cognizant of these patients' expectations. From a technical perspective, surgeons also had to be aware of the special care needed in calculating the IOL power for post-LASIK/PRK eyes in order to achieve the desired refractive outcomes.

Doctor-Patient Relationship, the Keystone of Medical Care

The relationship between the doctor and patient is a constant in medicine. Although patients are more involved in their health and wellness decisions, they still consent to their surgeries with the utmost trust that their surgeons will perform the procedure safely and efficiently while delivering the desired outcomes.

The intraocular lens (IOL) is the only device that remains in the eye after cataract surgery. Accordingly, the importance of implanting the IOL with the correct power (i.e. sphere and/or cylinder) in its precise position (i.e. axis in some cases) is essential to the success of the procedure and to the preservation of the trust inherent to the doctor-patient relationship.[3]

Thus, the surgeon would be remiss not to use all available means to ensure that the implanted IOL is the correct one. This is especially important for post-LASIK eyes in which pre-op measurements may be unreliable and no IOL calculation formula has demonstrated that it can consistently and accurately predict IOL power.[4]

The refractive power, which is the product of the corneal power (keratometry), the dioptric power of the lens, and the overall length of the eyeball, is difficult to calculate when the true corneal power has been altered, such as in eyes that have been previously reshaped through laser ablation or radial keratotomy. Consequently, after refractive surgery, the assumption that the effective refractive index of the cornea based on the resultant power of the anterior and posterior corneal curvatures is no longer valid.[5] Given that the cornea contributes 66% of the eye's refractive power[6], even though the most advanced biometer and the latest generation IOL calculation formulas are used to pre-operatively determine the IOL power. The lens power that is derived is an estimate which can only be validated during or after surgery.

ORA SYSTEM® is a technological innovation that allows surgeons to confirm the IOL power that was meticulously calculated pre-operatively. ORA SYSTEM® Technology stands for **O**ptiwave® **R**efractive **A**nalysis SYSTEM and is composed of the ORA SYSTEM® Technology intraoperative wavefront aberrometer and the cloud-based AnalyzOR™ Technology database

"ORA SYSTEM® Technology empowers the surgeon to HELP ensure that the IOL implanted is the one that will achieve the refractive outcomes which are unique to each patient's visual needs.[5]"

Figure 1: ORA SYSTEM® Technology intraoperative wavefront aberrometer and the cloud-based AnalyzOR™ Technology database.

Advanced Cataract Surgery: Measure Twice, Cut (i.e. Implant) Once

The ORA SYSTEM® Technology intraoperative wavefront aberrometer obtains real-time ocular measurements after the removal of the natural lens during cataract surgery by means of a Talbot Moiré aberrometry system that produces a wavefront that is analyzed to derive sphere, cylinder and axis[7] through a proprietary process. Together with measurements and calculations completed pre-operatively, ORA SYSTEM® Technology calculates the IOL power using a modified vergence formula and then recommends the IOL sphere and cylinder power to be implanted in the eye to achieve the lowest residual refractive error.

The ORA SYSTEM® Technology's intraoperative aberrometer is used in the operating room when the eye is aphakic. This gives the surgeon an opportunity to confirm the IOL calculations (or estimations) done pre-operatively and to verify the correct IOL power to be implanted during the surgery rather than relying on subjective patient feedback months later. In this manner, the IOL power, that was at best an estimate prior to surgery due to factors that are beyond the surgeons' control, such as the contribution of the posterior surface of the cornea, dense/opaque cataracts, and physical limitations preventing proper patient positioning during the measurement process, is validated in real-time during cataract surgery as the one that will most likely achieve the visual goals for the patient. [8]

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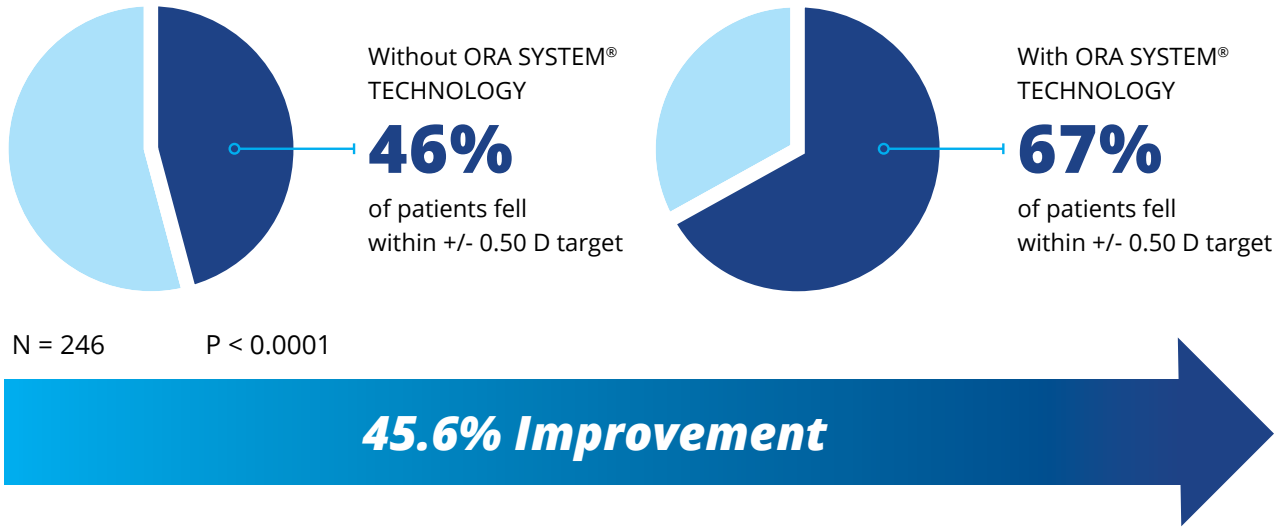

Figure 2: ORA SYSTEM® Technology in myopic patients. N = 246, P < 0.0001

In a study with 215 post-myopic LASIK eyes, 67% of eyes that underwent cataract surgery with intraoperative ocular measurements using ORA SYSTEM® Technology achieved a post-op refraction within 0.50 D of target compared to 46% in the group in which the power of the IOLs implanted were based only on pre-operative calculations alone. Additional use of intraoperative aberrometry showed a 45.6% improvement in the percentage of post-op refractive outcomes within 0.50 D of target.[9]

It can be argued that additional measurements in the operating room entail additional steps which may add to total surgical cost and time. However, the additional investment in cost and time is marginal and with respect to the efficiency gained in consistently achieving predictable cataract-refractive results.[10]

Potential for Progressively Better Outcomes

Possible sources of error in pre-operative IOL power calculation may be related to several factors such as estimation of postoperative IOL position or effective lens position (ELP), post-operative refraction determination, and pre-operative axial length. Of the three mentioned, ELP contributes 35% of errors while the two others contribute 27% and 17%, respectively. Thus, improvement in post-op refractive outcomes is directly related to the refinement in the ability to predict ELP.[11]

Through AnalyzOR™ Technology, the cloud-based component of the ORA SYSTEM® Technology, a surgeon's post-operative refractive outcomes are used to further optimize IOL-specific constants and the regression coefficient to deliver more predictable outcomes. AnalyzOR™ Technology enables post-op data to be entered by surgical or co-management sites to track outcomes and to further optimize lens constants beyond the IOL-manufacturer's recommended lens constant (i.e. estimate of the best Effective Lens Position regardless of other variables unique to a surgeon or an eye). Depending on how diligent surgeons are in entering their post-op data, ORA SYSTEM® Technology can use either of two optimized lens constants to verify IOL power intra-operatively. These lens constants are: Global Lens Optimization Constant and Personalized Surgeon Factor which in turn is the lens constants used in the ORA SYSTEM® Technology formula.

Post-op Data Needed in AnalyzOR™ Technology

Visual Acuity - Distance and Near*

- UCVA
- BCVA

Manifest Refraction

- Sphere
- Cylinder
- Axis

Keratometry*

- Steep K
- Flat K
- Steep axis

** Optional data*

Global Lens Optimization Constant:

For a new IOL to be globally optimized in ORA SYSTEM® Technology, the following criteria are required: at least 100 surgeries with post-op data of ≥10 days from surgery date, from at least 3 surgeons with ≥15 surgeries each with none of the surgeons having more that 50% of all the cases. Only cases which are at least 10 days post-op, with a BCVA of 20/40 or better, post-op BCVA ≥ post-op UCVA, and an absolute ORA SYSTEM® Technology predicted error less than 2.75D will be included in the analysis for optimization.

Furthermore, per lens model which meet the criteria above, Regression Coefficients are optimized for six types of surgical groups: No Post Refractive Surgery, Post Myopic LASIK Surgery with Axial Length ≤ 26, Post Myopic LASIK Surgery with Axial Length > 26, Post Hyperopic LASIK Surgery, Post RK with 4 cuts, and Post RK with 8 cuts.

Using a Linear Regression Formula (specifically, RANSAC, which assigns regression coeffients based on anatomical features) that takes into consideration Axial Length, Average K, White-to-White, Spherical Equivalent, Regression Coefficients customized for lens model, and post-keratorefractive status of the eye, a Global Lens Optimization Constant is derived, which is then re-calculated and updated in AnalyzOR™ Technology every three months.

Once established, the Global Lens Optimization Constant is applied to the calculations which the system performs after the aphakic measurements are taken with the intraoperative aberrometer. This means that each surgeon, who uses ORA SYSTEM® Technology in cases in which the lens constant for a particular IOL has already been optimized through AnalyzOR™ Technology, benefits by receiving IOL power calculations derived using an improved lens constant, which better represents Effective Lens Position (ELP) compared to just using the IOL-manufacturer's lens constant. That is, the calculation for the IOL power becomes more accurate and leads to more predictable post-operative outcomes.

- Set of regression coefficients for non optimized lenses
- Manufacturers' lens constant

- ≥ 100 surgeries (≥ 10-day post-op) per lens
- ≥ 3 surgeons within ≥ 15 surgeries (≥ 1-month post-op) per surgeon
- No surgeon with > 50% of surgeries

- Surgeon-specific lens constant
- Surgeon has at least 30 surgeries for a given lens

Figure 3: Lens Optimization

Personalized Surgeon Factor: If a surgeon continues to have post-op refractive outcomes entered into AnalyzOR™ Technology, the lens constant can be further optimized based on surgeon-specific data rather than based on data from the ORA SYSTEM® Technology user collective. This is called the **Personalized Surgeon Factor**. It requires the surgeons to enter valid refractive outcome data from at least thirty (30) cases for every IOL family on which lens constant optimization is desired into the AnalyzOR™ Technology. As every surgeon consistently enters post-op results, their individual outcomes data are included when the Global Lens Optimization Constant is updated. In the larger picture, these efforts lead to further optimization of both the Global Lens Constant and Personalized Surgeon Factor and ultimately better post-op refractive outcomes for patients.

Since the AnalyzOR™ Technology is unique to the ORA SYSTEM® Technology, continuous intraocular lens constant optimizations can efficiently happen with ORA SYSTEM® Technology. This feature from AnalyzOR™ Technology provides an additional advantage to surgeons who use the ORA SYSTEM® Technology compared to those who only rely on advanced technology biometers and newer theoretical IOL calculation formulas.

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Furthermore, AnalyzOR™ Technology allows co-managing Optometrists to have an active role in the management of their cataract patients. With the ORA SYSTEM® Technology, Ophthalmologists can invite partner Optometrists to add post-op data of patients for whom they are providing the post-op care, which in turn will help their partner Ophthalmologists further optimize their personalized lens constants.

The Goal of Modern Cataract Surgery

Cataract surgery has undergone remarkable technological advancements in recent years. This has elevated visual outcomes to be the primary goal. Excellent visual outcomes equate to patients' satisfaction and their renewed capacity to have the lifestyles they desire.

Cataract surgery is a once-in-a-lifetime procedure for every patient. Although there are many, high-tech devices used during planning and during the surgery, the only device that remains in the patient's eye is the intraocular lens. Additionally, the implanted IOL ultimately determines the post-operative vision and the lifestyle of the patient. Therefore, it is essential to practice meticulous care when choosing the type and the power of the intraocular lens.

In a period of rapid technological innovation, numerous methods and devices exist to enable surgeons to calculate the correct dioptric power of the IOL in order to deliver the best visual outcomes for each patient's needs. Advanced technology biometers and modern theoretical IOL calculation formulas provide excellent estimates of the required IOL power to achieve the best possible outcomes. ORA SYSTEM® Technology is designed to compliment these advances in preoperative technology by providing additional information at the time of cataract surgery. It can be particularly helpful for complex eyes such as those with a history of laser refractive procedures, it is imperative that the IOLs implanted have the appropriate power, in both sphere and cylinder, that will deliver the intended visual outcomes anticipated by patients. Moreover, in parallel with developing technologies, the predictability and accuracy of refractive outcomes could and should advance progressively, as well.

With the ORA SYSTEM® Technology, the continuous improvement of outcomes can be achieved along with real-time verification and validation of the IOL power that would lead to successful outcomes for patients.

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Important Product Information

ORA SYSTEM® WITH VERIFEYE®+ TECHNOLOGY

INTENDED USE:

The ORA SYSTEM® Technology is designed to be used during ophthalmic surgery. Wavefront data is obtained, analyzed, and presented to the user via a cart mounted LCD touchscreen, within a period that does not impede the surgical procedure

The ORA SYSTEM* Technology is intended for use in the measurement and analysis of the refractive power of the eye (i.e. sphere, cylinder, and axis measurements).

The safety and effectiveness of using the data from the ORA SYSTEM® Technology have not been established for determining treatments involving higher order aberrations of the eye such as coma and spherical aberrations.

U.S. Federal law restricts this device to sale by or on the order of a physician or ophthalmologist.

CAUTIONS:

It will be difficult to obtain accurate, consistent, and reliable measurements if any of the following conditions or situations exists:

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.

Patient's 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 limit or prohibit measurement process. Image quality indicator will indicate when this is an issue.

Patients having received retro or peribulbar block, or any other treatment that impairs their ability to visualize the fixation light.

Utilization of Iris hooks during an ORA SYSTEM® Technology image capture will yield inaccurate measurements.

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