ENHANCING CATARACT REFRACTIVE SURGERY EVERY STEP OF THE WAY
INNOVATIONS IN RECENT TECHNOLOGY continue to advance cataract refractive surgery. However, these developments often exist in silos—raising the bar on a singular tool or device within the surgical procedure but largely overlooking the process itself.

Consider the dichotomy in a world with femtosecond lasers: We have technology capable of firing down to micron-level accuracy yet “guided” by a preoperative ink mark manually placed on the patient’s eye.

Today’s surgical course is filled with limiting factors inherent in the status quo, which cataract surgeons must account for in their pursuit of targeted refractive outcomes. “Our tools and devices in cataract refractive surgery have clearly entered the 21st century, yet are still built upon a 20th-century process,” according to Robin R. Vann, MD, assistant professor of ophthalmology and chief of Comprehensive Ophthalmology, Duke University Eye Center, Durham, North Carolina.

“Because there are multiple entry points for variation along the way, the sum total of that has equaled outcomes that aren’t as accurate as we would like,” said Michael P. Jones, MD, who practices with Quantum Vision Centers in St. Louis, and is assistant professor at St. Louis University Eye Institute.1 “When mapping out the cataract refractive process, steps inherent to the status quo are prone to variability and limit the surgeon’s and patient’s potential to reach a targeted outcome.”

The VERION™ Image Guided System—which is composed of the VERION™ Reference Unit and VERION™ Digital Marker—automates many of the steps in the cataract refractive procedure and reduces the potential for human error.

Read on as our experts share their insights into how the VERION™ Image Guided System targets and addresses these sources of refractive error and enhances accuracy and efficiency during cataract refractive surgery (Fig. 1).

Precise Imaging
In a cataract refractive procedure, limiting factors arise long before the first incision is made, beginning with diagnostic measurements.

“Busy clinicians often review only the summary of measurements provided by their staff before surgery and...
don’t always recognize the wide range of values within that summary,” Dr. Vann said.

When performing preoperative measurements, staff often use optical biometers or ultrasound A-scanners with third-generation formulas incorporated into the machines to calculate intraocular lens (IOL) powers. However, they are not as accurate as more modern formulas, according to Dr. Vann.

Furthermore, when cataract refractive surgery is performed according to the status quo, surgeons often enter patient biometry data into multiple isolated calculation sources to complete a surgical plan, none of which cross-calculate with one another.

The VERION™ Reference Unit captures key diagnostics from the ocular surface, such as keratometry, pupilometry, white-to-white horizontal distance, eccentricity of the visual axis, and other data, while simultaneously registering the unique “fingerprint” of each eye. This high-resolution digital registration tracks critical landmarks for image-guided surgery from the patient’s scleral vessel patterns, limbus, and iris features.

Imaging and diagnostic information from the scan is automatically imported into the VERION™ Image Guided System Reference Unit Surgical Planning Module. For the intraocular depth measurements, such as axial length, anterior chamber depth, and lens thickness, the information obtained from an A-scan or an optical biometer then is added to the comprehensive case planner as well. These landmarks enable tracking throughout the procedure and allow communication and guidance of the preoperative surgical blueprint when the surgeon is at the LenSx® Laser and surgical microscope.

If a surgeon uses the Lenstar® biometer, the VERION™ Image Guided System can directly import the patient file and metrics via a USB stick, reducing the potential for transcription error. Additionally, the use of the Lenstar® for optical biometry allows the surgeon to take into account an actual measure of true lens thickness. This is a key variable required in newer-generation formulas, such as the Holladay II.

**Accurate Planning**

VERION™ Reference Unit streamlines surgical preparation. “The VERION™ Reference Unit really becomes like an IOL planning assistant,” said Dr. Jones. The technology contains the most common IOL formulas, allowing
the surgeon to compare differences between them, he explained.

The system enables detailed customization. “For example, it measures the corneal astigmatism, and then it helps you estimate what effects your incisions are going to have—your main cataract incisions and secondary cataract incisions,” said Stephen Slade, MD, in private practice with Slade and Baker Vision, Houston, Texas. “It gives you that information so that you get the total picture. Otherwise you’re calculating your astigmatic incisions, but you’re not calculating the effect that the other incisions on the eye will have.”

Surgeons can control how much astigmatism they would like to correct with a cut with relaxing incisions and how much they would like to correct with an AcrySof® Toric IOL. For instance, the surgeon can control 75% of the astigmatism with the toric implant and the remainder with an arcuate cut or limbal relaxing incision. “You can absolutely do that because there’s a slider bar that allows you to pick that during the planning phase,” Dr. Jones said (Fig. 2).

“What I like about the VERION™ Reference Unit is that it allows me to plan this patient’s surgical outcome before I’ve even cut on their eye,” Dr. Jones said. “Before I get down into the operating room, I’m sitting down at this unit, I’m entering all the data in, and it’s allowing me to create a plan that’s customizable to that patient’s needs based on his or her measurements.”

When the patient leaves the clinic, his or her preoperative measurements and reference image are transferred with a USB stick to the LenSx® Laser or surgical microscope. “It’s very easy to have all your data right there on a stick that’s easily portable to many different locations,” Dr. Jones said. Furthermore, he added, it’s a major time saver because the staff will not need to spend time manually entering patient data.

### Comprehensive Guidance

The VERION™ Digital Marker, which guides the procedure, superimposes the patient’s information and customized plan on the digital image of the eye. It provides real-time overlays for incisions, capsulorrhexis construction, centration for multifocal IOL positioning, and a toric alignment guide. “There are four different overlays that are on the heads-up display that you can toggle through with a foot switch,” Dr. Slade said (Fig. 3).

The system eliminates the need for manual eye marking, otherwise necessary for femtosecond laser arcuate incisions and toric IOLs, and accounts for cyclorotation. “The LenSx® Laser takes an image of the patient as they
are lying down for the procedure and then it matches that picture using landmarks on the sclera and on the iris to the reference image,” Dr. Slade said. “The problem with manual marking is that the marks themselves are often several degrees wide (Fig. 4). You’re asking the patient to look while there’s a pen coming at them. In comparison, the VERION™ Image Guided System superimposes the axis of alignment to a single degree as determined by your pre-op plan.”

“With manual marking, sometimes the marks are off center or a little higher or lower than we want them to be,” Dr. Vann said. “Unfortunately, it only takes 30 degrees off from where you are, where you intend to treat, to totally negate any treatment effect when it comes to astigmatism. So for every degree you’re off, you lose 3% of your treatment effect.”

The VERION™ Image Guided System also helps surgeons analyze and optimize surgically induced astigmatism, providing clear guidelines on incision placement. “You turn on the heads-up display and it shows you exactly where they’re supposed to be calculated, laid out as marked,” Dr. Slade said.

The system learns from the surgeon’s results over time to help optimize personalized surgically induced astigmatism values for incision size and location on each case. The comprehensive astigmatism management calculator then takes this value into consideration with other variables (such as toric IOLs and relaxing incisions), offering a total case view of all astigmatic impact.

The VERION™ Image Guided System works with the LenSx® Laser, but surgeons without access to the laser will appreciate the significant planning and guidance features this technology brings to manual cataract surgery.

The surgeon can customize an exact capsulorrhexis plan for each case. In addition to entering the desired capsulorrhexis size into the system, the surgeon can use the image-guided system to view the precise anatomical placement he or she prefers.”

“If you have not used the LenSx® Laser on the patient and you have to manually cut the capsulorrhexis, it will allow you to center that capsulorrhexis on any point, either the visual axis, preop pupil, or limbal center,” Dr. Jones said.

The VERION™ Image Guided System also assists surgeons in centering multifocal IOLs.
The VERION™ Image Guided System gives you three different options to choose from on where you want to center it,” Dr. Jones said. “You can center it on the patient’s visual axis that was measured in the clinic on the VERION™ Reference Unit. You can now also center that lens on the patient’s pre-op undilated pupil, or you can also center it on the limbal center.”

After implanting the ReSTOR® IOL, Dr. Jones turns on the patient’s preoperative undilated pupil marker. “I’m centering my ReSTOR® lens on that patient’s preop undilated pupil because that’s where the patient lives,” he said. “And this lens is pupil dependent. Instead of centering it on just a visual axis from a light reflex from the patient looking at the scope, I’m actually now centering the multifocal lens on the patient’s undilated preop pupil, and it has made a world of difference (Fig. 5).

Dr. Jones explained that the VERION™ Image Guided System is also a necessity in positioning toric IOLs. “I can’t even imagine trying to put a toric lens in now with some sort of hand mark that I’ve made on the patient’s cornea,” he said. The system provides a real-time display of the patient’s steep axis of astigmatism that will move as the patient’s eye moves during surgery and allows him to perfectly position the toric implant based on his preoperative plan, he explained. “I especially think the power for this is in placing toric lenses,” he said (Fig. 6).

Figure 4. Image shows a typical ink mark compared with the toric alignment overlay from the VERION™ Digital Marker. This ink mark covers up to 10 degrees. Courtesy of Michael P. Jones, MD.

Figure 5. Surgeons implanting RESTOR® IOLs can choose from a number of centration options with the VERION™ Image Guided System. Courtesy of Michael P. Jones, MD.
Dr. Slade also has found the VERION™ Image Guided System useful in patients with eccentrically dilated pupils where the pupil is centered 1-2 mm away from the true optical center. “Since we’re operating on the patients with their pupils dilated, you have no idea where the pupil is going to be when it comes down,” he said. The VERION™ reference image demonstrates the location of the undilated pupil.

**Optimizing Future Outcomes**

After surgery, a clinician can choose to use the VERION™ Reference Unit to store the results of the surgery to help optimize personal A-constants and surgically induced astigmatism. “It will start to develop a better nomogram for you as far as personalized surgeon A-constants and surgically induced astigmatism,” Dr. Jones said. “Some surgeons do this tracking manually, but the ability to track patient outcomes on this machine after surgery, and then have it re-calculate those personally optimized values for you is priceless.”

“I think because it’s not only using the modern formulas, but it’s also taking your personal outcomes and then using that to further fine-tune your personal constants, it’s going to be able to continue to improve your accuracy with time,” Dr. Vann said.

**Pivotal Change**

The VERION™ Image Guided System empowers cataract refractive surgeons in a number of ways.

“For the last eight years I have been focusing on improving my cataract surgery outcomes and working very hard at doing so,” Dr. Vann said. He explained that this has been a labor-intensive and meticulous process. “Now somebody can buy the VERION™ Image Guided System and replicate this sort of work, all automatically with very little effort,” he said.

“It allows me to sit down and formulate a plan ahead of time so that I know exactly what I need to do when I walk into the operating room,” Dr. Jones said. “And for me that’s not just very empowering, it actually makes my OR day much easier because I’m not having to worry about formulating some of these plans on the fly. It gives me a nice printout of what I need to do, and all of that is transferred with a USB stick into either the LenSx® Laser or onto the microscope. I don’t have to manually type anything in. It has simplified my whole process.”

“I think it is a pivotal change in how we’re going to be able to take care of patients,” Dr. Vann said. “It’s going to finally give surgeons the tools that they’ve needed all along. By presenting a platform to minimize all the potential errors that occur in cataract surgery outcomes, the
DR. JONES OBSERVED the value of the VERION™ Image Guided System in particular when he compared toric IOL results in a patient who received one implant before he had the technology and the other after he began using it.

According to standard procedure, for the first IOL Dr. Jones marked the patient’s cornea with an ink pen as she sat upright. During surgery, however, some of the ink washed off and the markings expanded.

“When I measured her postoperatively, the toric placement ended up being off by about 15 degrees. It’s not much, and the patient’s vision wasn’t too bad uncorrected. She’s happy with it, but it wasn’t exactly where I wanted it,” he said.

For the fellow eye, Dr. Jones used the VERION™ Reference Unit to take preoperative measurements and opted to correct the patient’s astigmatism with the IOL and a relaxing incision. “During surgery, I was able to see that live image of her steep axis of astigmatism and put that toric lens implant exactly where it needed to be,” he said (Figure below).

A toric IOL is positioned with the VERION™ Image Guided System. Courtesy of Michael P. Jones, MD.
VERION™ Image Guided System can give a surgeon all the tools to improve outcomes today and into the future.”

Dr. Vann also appreciates the comprehensive character of the suite. “It guides you from beginning to end, from when you measure the eye to how you’re going to keep maintaining those outcomes postoperatively,” he said.

Despite advances in toric and multifocal IOLs, they are still implanted in a small minority of cataract patients who could benefit from them, Dr. Slade said. He believes some clinicians may be uncertain about implanting the lenses. “What this does, at least for us, is it gives us more confidence in doing Advanced Technology IOL procedures,” he said. “I’m more confident about the success of my procedures with this system.”

**Reference**


**Disclosures** Dr. Jones is a consultant, speaker, and clinical investigator for Alcon; Dr. Slade is a consultant for Alcon, B&L, and Glaukos; Dr. Vann is a consultant for Alcon.

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**Guidance in Floppy Iris Syndrome**

**DR. JONES FOUND** the VERION™ Image Guided System to be especially helpful in a patient taking an alpha blocker who had floppy iris syndrome.

The patient had an extremely small pupil that did not dilate well. Because he had floppy iris syndrome, Dr. Jones used a Malyugin ring. “Any time you put that Malyugin ring in, it will manually dilate the pupil, but all of a sudden you’ve started to lose your landmarks,” he said. “You don’t understand where that patient’s center of vision is because the pupil is manually stretched open.”

After dilating the pupil with the Malyugin ring, he turned on the VERION™ Image Guided System. “It instantly told me where the center of his visual axis was, where the center of his undilated preop pupil was,” he said (Figure above).

The VERION™ system allowed him to choose the size of the capsulorrhexis and perfectly center it. “That is not something we could have done before the VERION™ Image Guided System,” he said.
**VERION™ Reference Unit and VERION™ Digital Marker — Important Product Information**

**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 order to determine the radii and corneal curvature of steep and flat axes, limbal position and diameter, pupil position and diameter, and corneal reflex position. In addition, the VERION™ Reference Unit provides pre-operative surgical planning functions that utilize the reference image and pre-operative measurements to assist with planning cataract surgical procedures, including the number and location of incisions and the appropriate intraocular lens using existing formulas. The VERION™ Reference Unit also supports the export of the high-resolution 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, the planned capsulorhexis position and radius, IOL positioning, and implantation axis 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.

- Only trained personnel familiar with the process of IOL power calculation and astigmatism correction planning should use the VERION™ Reference Unit.
- Poor quality or inadequate biometer measurements will affect the accuracy of surgical plans prepared with the VERION™ Reference Unit.
- The following contraindications 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.

- Only use the provided medical power supplies and data communication cable. The 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.
- Only use a VERION™ USB stick to transfer data. The VERION™ USB stick should only be connected to the VERION™ Reference Unit, the VERION™ Digital Marker, and other compatible devices. Do not disconnect the VERION™ USB stick from the VERION™ Reference Unit during shutdown of the system.
- 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.

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**AcrySof® IQ Toric 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 suggest, 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, physicians should provide prospective patients with a copy of the Patient Information Brochure available from Alcon for this product informing them of possible risks and benefits associated with the AcrySof® IQ Toric Cylinder Power 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.
AcrySof® IQ ReSTOR® 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 ReSTOR® Posterior Chamber Intraocular Lens (IOL) is intended for primary implantation for the visual correction of aphakia secondary to removal of a cataractous lens in adult patients with and without presbyopia, who desire near, intermediate and distance vision with increased spectacle independence. The lens is intended to be placed in the capsular bag.

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. Physicians should target emmetropia, and ensure that IOL centration is achieved. Care should be taken to remove viscoelastic from the eye at the close of surgery.

Some patients may experience visual disturbances and/or discomfort due to multifocality, especially under dim light conditions. Clinical studies with the AcrySof® ReSTOR® lens indicated that posterior capsule opacification (PCO), when present, developed earlier into clinically significant PCO. Prior to surgery, physicians should provide prospective patients with a copy of the Patient Information Brochure available from Alcon for this product informing them of possible risks and benefits associated with the AcrySof® IQ ReSTOR® 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.

LenSx® Laser — Important Product Information

Caution: United States Federal Law restricts this device to sale and use by or on the order of a physician or licensed eye care practitioner.

Indication: The LenSx® Laser is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, phacofragmentation, and the creation of single plane and multi-plane arc cuts/incisions in the cornea, each of which may be performed either individually or consecutively during the same procedure.

Restrictions:
• Patients must be able to lie flat and motionless in a supine position.
• Patient must be able to understand and give an informed consent.
• Patients must be able to tolerate local or topical anesthesia.
• Patients with elevated IOP should use topical steroids only under close medical supervision.

Contraindications:
• Corneal disease that precludes applanation of the cornea or transmission of laser light at 1030 nm wavelength
• Descemetocoele with impending corneal rupture
• Presence of blood or other material in the anterior chamber
• Poorly dilating pupil, such that the iris is not peripheral to the intended diameter for the capsulotomy

• Conditions which would cause inadequate clearance between the intended capsulotomy depth and the endothelium (applicable to capsulotomy only)
• Previous corneal incisions that might provide a potential space into which the gas produced by the procedure can escape
• Corneal thickness requirements that are beyond the range of the system
• Corneal opacity that would interfere with the laser beam
• Hypotony or the presence of a corneal implant
• Residual, recurrent, active ocular or eyelid disease, including any corneal abnormality (for example, recurrent corneal erosion, severe basement membrane disease)
• History of lens or zonular instability
• Any contraindication to cataract or keratoplasty
• This device is not intended for use in pediatric surgery.

Warnings: The LenSx® Laser System should only be operated by a physician trained in its use.

The LenSx® Laser delivery system employs one sterile disposable LenSx® Laser Patient Interface consisting of an applanation lens and suction ring. The Patient Interface is intended for single use only. The disposables used in conjunction with ALCON® instrument products constitute a complete surgical system. Use of disposables other than those manufactured by Alcon may affect system performance and create potential hazards.

The physician should base patient selection criteria on professional experience, published literature, and educational courses. Adult patients should be scheduled to undergo cataract extraction.

Precautions:
• Do not use cell phones or pagers of any kind in the same room as the LenSx® Laser.
• Discard used Patient Interfaces as medical waste.

AES/Complications:
• Capsulotomy, phacofragmentation, or cut or incision decentration
• Incomplete or interrupted capsulotomy, fragmentation, or corneal incision procedure
• Capsular tear
• Corneal abrasion or defect
• Pain
• Infection
• Bleeding
• Damage to intraocular structures
• Anterior chamber fluid leakage, anterior chamber collapse
• Elevated pressure to the eye

Attention: Refer to the LenSx® Laser Operator’s Manual for a complete listing of indications, warnings and precautions.
Visit ImagePlanGuide.com for more information on the VERION™ Image Guided System.

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