

Cataract & Refractive Surgery **TODAY**

June 2014

EXPLORING THE **CATARACT REFRACTIVE** **SUITE**



FEATURING
The VERION Image Guided System

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The Next Evolution in Laser Cataract Refractive Surgery

The VERION Image Guided System creates the possibility for surgeons to realize improved cataract refractive outcomes.

The VERION Image Guided System (Alcon Laboratories, Inc.; Figure 1) is the unique imaging, planning, and surgical guidance component of Alcon's new Cataract Refractive Suite that also includes the LenSx Laser, the CENTURION Vision System, and the LuxOR Operating Microscope. The goal of the VERION Image Guided System is to help surgeons reduce the possibility of human calculation, input, and surgical error throughout the diagnostic, planning, and execution stages of cataract surgery (Figure 2). By automating certain steps of the cataract surgery process, the VERION Image Guided System creates the possibility for improved cataract refractive outcomes and engenders greater confidence in surgeons.

COMPONENTS OF THE SYSTEM

The VERION Reference Unit

The VERION Image Guided System includes the VERION Reference Unit and the VERION Digital Marker, which are both designed to increase the accuracy and efficiency of planning and performing cataract refractive surgery. The VERION Reference Unit is an in-office cataract refractive workstation that allows surgeons and their technicians to target a desired outcome and prepare the patient's complete surgical plan in one setting. This surgical plan follows the surgeon and the patient through each step, as it is digitally transferred throughout the procedure to other key pieces of cataract refractive equipment. The VERION Reference Unit accomplishes this by housing several new proprietary technologies. It captures a high-resolution, digital registration of the eye that the system then uses to map out the center of the undilated pupil, the scleral vessels, the limbus, and the landmarks of the iris. It simultaneously measures keratometry, pupilometry, and other key preoperative measurements.

Next, the surgeon uses the VERION Reference Unit to create the surgical plan via a desktop interface. Using the eye's unique "fingerprint" and diagnostic measurements, which are exported to the VERION System's planning software, the surgeon may choose from several advanced formulas—the Holladay II IOL formula (Holladay



Figure 1. The new VERION Image Guided System comprises the VERION Reference Unit (A), which is used in the practice, and the VERION Digital Marker (B), which is compatible with the LenSx Laser as well as most surgical microscopes.

Consulting, Inc.), the Haigis, and the SRK-T—to perform IOL calculations. He or she may then use the system to generate potential outcomes between various options, such as locating the capsulorhexis on the preoperative pupil or the limbus.

The real planning power with the VERION Image Guided System comes into play with astigmatism management. Using a new comprehensive calculator, the surgeon is able to weigh various methods of astigmatism correction at the ocular surface and the IOL plane. A

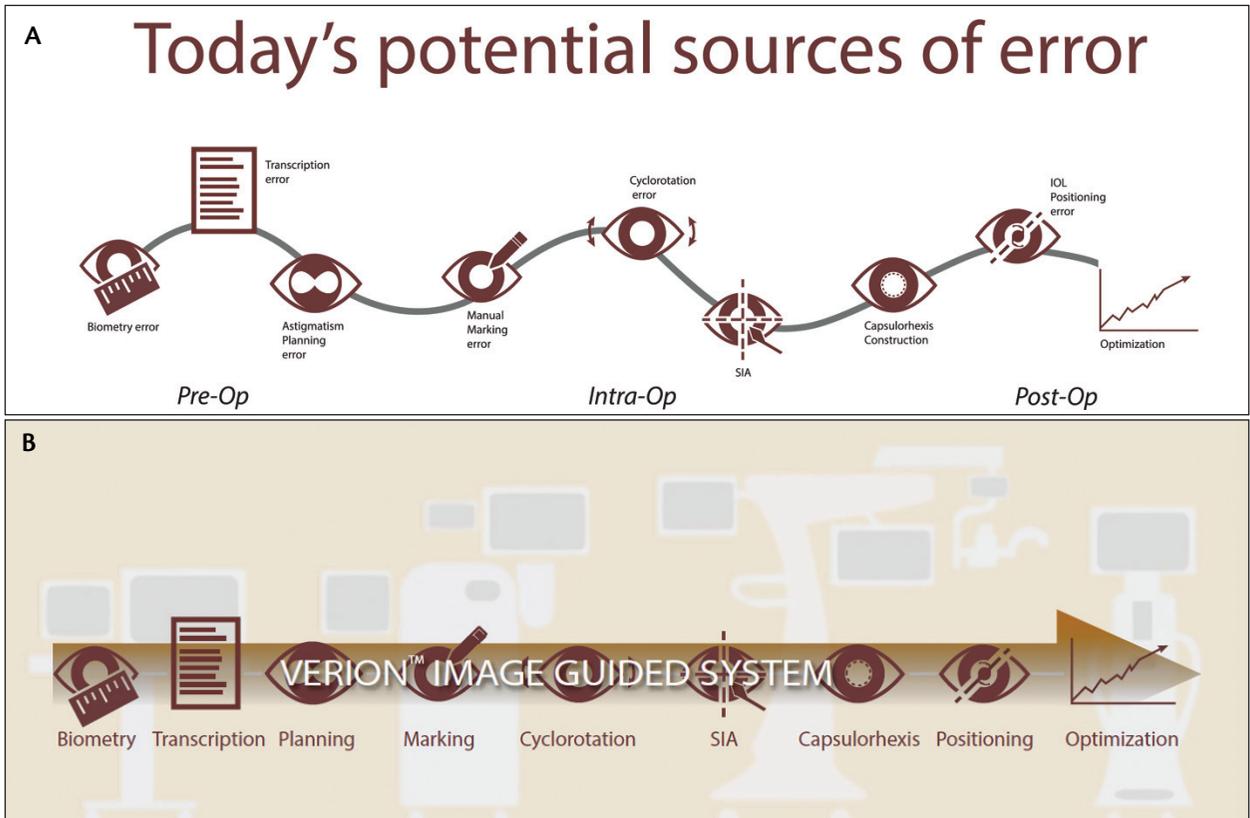


Figure 2. Each component of the traditional manual cataract procedure is subject to human error (A). The VERION Image Guided System is designed to minimize error throughout the process by automating it as much as possible (B).

“slider bar” feature within the interface of the VERION Reference Unit allows the surgeon to seamlessly determine the impact of any blend of correction methods to meet the patient’s targeted outcome.

The VERION Digital Marker

Once all of the preoperative calculations are ready, the surgeon transfers the patient’s data and the surgical plan to any surgical microscope that is compatible with the VERION Image Guided System. The VERION Digital Marker, which interfaces with most microscopes, displays the patient’s eye in real time and overlays outlines of the axes, the capsulorhexis, and arcuate incisions (based on the reference image and surgical plan) to help the surgeon preposition these before commencing surgery. The size, shape, and location of all of these cuts are fully customizable for maximum flexibility within the surgical plan. The astigmatism management feature in the VERION Image Guided System accounts for the diameter and steepness of the cornea, the magnitude of astigmatism, and the patient’s age to calculate precise arcuate incisions.

The VERION Digital Marker also compensates for cyclorotation and registers the eye for the accurate cen-

tering and alignment of multifocal and toric IOLs, thereby eliminating the need for manual corneal marking.

POSTOPERATIVE DATA COLLECTION AND OPTIMIZATION

Surgeons may use the VERION Reference Unit again after surgery for important post-surgical case analysis that will enable them to seamlessly track and refine surgical parameters with their AcrySof IOLs and other key pieces of equipment in the Cataract Refractive Suite by Alcon. For example, the VERION Image Guided System will take postoperative K readings to determine what the surgically induced astigmatism was at the time of surgery, how the surgeon’s A-constants may be better optimized in the case planner, or analyze how their metrics are tracking with the new CENTURION Vision System. Surgeons can use the VERION Image Guided System to plan and perform image-guided surgery with other manufacturer’s IOLs or equipment; however, the system has been designed to complement the technologies within the Cataract Refractive Suite by Alcon as well as the Alcon advanced-technology IOLs. Although personal optimization is widely available in the marketplace, it often requires the manual collection and input of a surgical plan and outcomes data.

The VERION Image Guided System aims to enable more surgeons to take advantage of personal optimization by presenting a streamlined suite of Alcon technologies.

EQUIPMENT FLEXIBILITY

Practices that do not have access to a LenSx Laser for cataract surgery can also benefit from the VERION Image Guided System. It is compatible with most surgical microscopes and offers options for the surgical planning and manual creation of incisions and capsulotomies. Thus, the primary advantage of automated surgical calculations and input are available independently of the Cataract Refractive Suite by Alcon and within reach for most types

of practices. This is particularly valuable for surgeons or practices interested in further developing their advanced-technology IOL segment.

The VERION Image Guided System is the first technology to capitalize on the precision and execution of femto-second lasers for cataract surgery by digitally connecting the LenSx Laser with the advanced calculations of a pre-operative surgical planner. Removing as many human variables as possible from the steps of ocular measurements, IOL calculations, astigmatism planning, data entry, and incisional location and IOL placement should help us take the next step in the constant drive to improve cataract surgery for patients. ■

Raising Our Standard of Care

One-month experience with the new VERION Image Guided System.

BY MICHAEL P. JONES, MD

My partners and I at Illinois Eye Surgeons in Glen Carbon were interested in becoming involved with the new VERION Image Guided System (Alcon Laboratories, Inc.) because we believed in the concept of removing as many variables from the cataract procedure as possible. Within any process, the more opportunity there is for error, the more errors may accumulate to ultimately impact the final outcome. Although the LenSx Laser (Alcon Laboratories, Inc.) has successfully minimized human input variables within the cataract surgical procedure, the preoperative calculation and planning steps still present many opportunities to introduce error when performed manually. Thus, the VERION Image Guided System seemed to us to be the next logical step to help improve the accuracy and efficiency of the entire cataract procedure. As physicians who stringently track our surgical data and postoperative outcomes, we wanted to see how an advanced diagnostic and surgical planning technology might further raise our standard of care.

FIRST IMPRESSIONS

Ours is one of the first practices to receive the VERION Image Guided System, which we have had for approximately 1 month at the time of this writing. The early results of this technology have met our expectations for amazing performance. The VERION Image Guided System is designed to offer a complete package of imaging, planning,

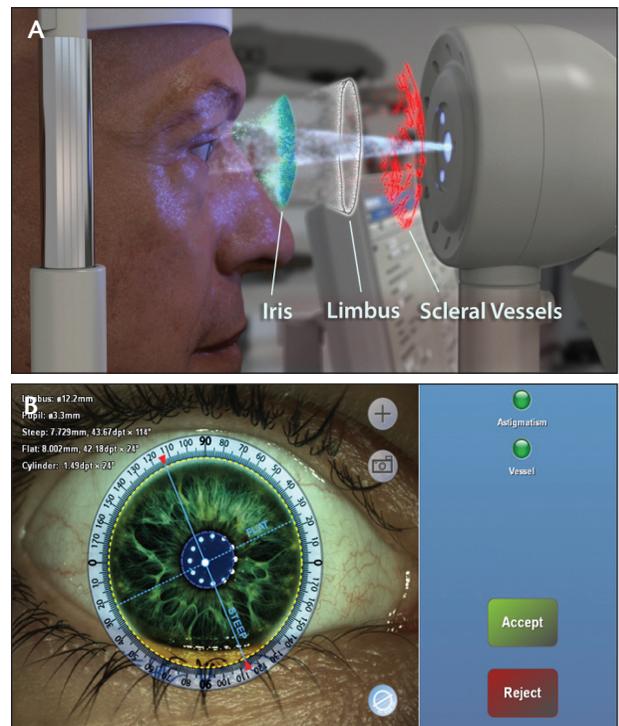


Figure 3. The VERION Reference Unit captures a high resolution “fingerprint” of the patient’s eye by registering iris features, limbus, and scleral vessel patterns (A), while simultaneously capturing key diagnostic variables (B) to construct a customized surgical plan.

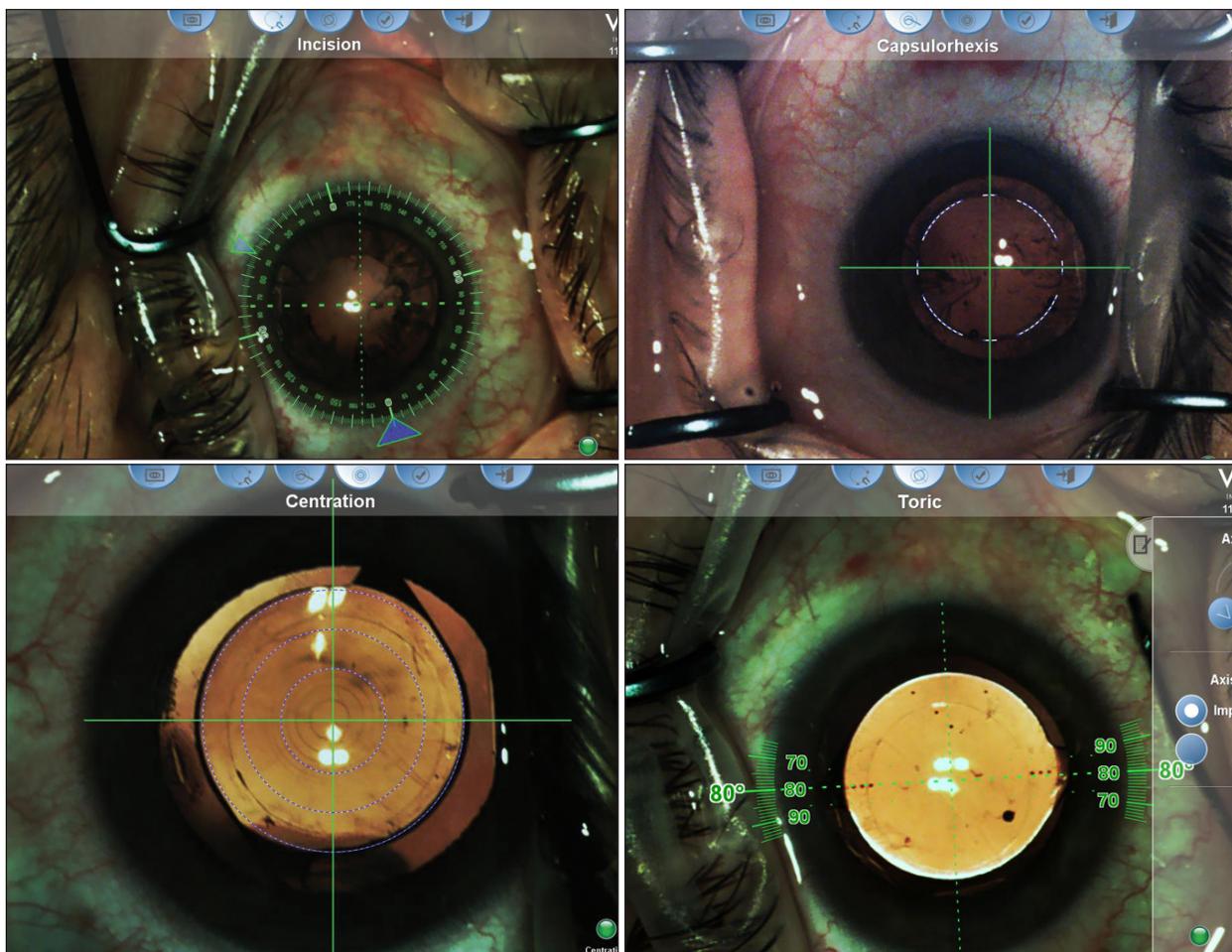


Figure 4. The VERION Digital Marker allows for communication of the surgical plan to key pieces of cataract refractive equipment in the OR. The marker recognizes the patient's eye and plan and tracks with live movement, bringing each step of the plan directly into the surgeon's oculars as well as being visible on the Digital Marker monitor.

and surgical guidance technologies as a standalone tool. Although it is designed to complement the Cataract Refractive Suite by Alcon, practices do not need to have the LenSx Laser, the CENTURION Vision System, or the LuxOR ophthalmic microscope in order to benefit from the VERION System's technology.

The utility of the VERION Image Guided System begins in the practice with the VERION Reference Unit, which a technician uses to capture a high-resolution diagnostic reference image of the patient's eyes (Figure 3). During this step, it calculates the pupillometry, keratometry, and anatomical landmarks such as the scleral vessels, the limbus, and features of the iris—all the necessary preoperative information. The VERION Reference Unit also records the location and amount of preoperative corneal astigmatism so that the VERION Digital Marker may account for cyclorotation once the patient is lying down for the surgical procedure.

This step of data capture and surgical calculations with the VERION Reference Unit takes mere minutes in

a technician's schedule. Our staff has experienced a very short learning curve with this system, because its user interface is so intuitive to navigate.

AUTOMATED CALCULATIONS

The next step is for me or one of our other surgeons to review the patient's data and create a surgical plan that is customized to the eye's biometric and other measurements (Figure 4). Here again, the VERION Image Guided System provides several advanced-formula calculations for selecting the lens power, including the Holladay II (Holladay Consulting, Inc.), the Haigis, and the SRK-T formulas. I no longer have to perform these calculations manually using third-party software or another diagnostic device. Reassuringly, I find that the biometric readings from the VERION Image Guided System corresponded well with those from the Lenstar LS900 biometer (Haag-Streit; distributed in the US by Alcon Laboratories, Inc.).

Next, we calculate the size and location of the primary, secondary, and any arcuate incisions. For this purpose, the VERION Reference Unit includes a new astigmatism planning tool developed with Jack T. Holladay, MD, which brings together components of popular existing arcuate incision planning tools by Douglas Koch, MD; Eric Donnenfeld, MD; and Louis “Skip” Nichamin, MD. This astigmatism planning tool is the most comprehensive and convenient calculation tool currently on the market; it accounts for the magnitude of astigmatism, the cornea’s steepness, the patient’s age (because older patients tend to have more cross-linking in their collagen), the diameter of the cornea, and the depth, diameter, and location of the AK incisions all converted into a simple-to-use continuous function. With all these parameters, the software can calculate the arc length of arcuate incisions in single degrees, and it takes into account any desired amount of intraocular correction I want to balance with my AcrySof Toric IOLs.

Once this comprehensive surgical plan is in place, I save the patient’s data to a USB stick and bring it with me to the LenSx Laser in the OR on the day of the patient’s surgery. The LenSx Laser’s software has been upgraded to work with the VERION Digital Marker (which works with other operating microscopes as well), which reads the patient’s reference image from the VERION Reference Unit and aligns it with the real-time image of the patient’s eye underneath the microscope.

Then, the VERION System helps me determine the location of the capsulotomy and lens placement. One of the system’s features that I especially like is the ability to completely customize the capsulorhexis. Not only can I adjust its size and shape as necessary, but I can choose its location, whether on the visual axis, the limbus, or—my personal preference—on the preoperative pupil. Once I have chosen the placement of the capsulotomy and locked it into the laser, the system overlays an outline of the cut onto the real-time image of the eye, so all I have to do is follow the marks to make the cut with the LenSx Laser.

Also, having the reference image of the preoperative pupil becomes especially helpful in eyes in which iris hooks or a Malyugin ring (MicroSurgical Technology) are necessary, such as those with small pupils or Intraoperative Floppy Iris Syndrome. It is easy to lose the landmarks in these eyes, and the reference image from the VERION Reference Unit solves this problem.

Last but not least, the VERION Digital Marker helps me to implant and position the IOL for optimal visual performance. All of the calculations of the patient’s eye have been transferred from the VERION Reference Unit to the LenSx Laser, and the real-time overlay feature shows me exactly where the incisions will be made. I did not realize how valuable this tool would be until I started using

“All of these features of the VERION Image Guided System have helped to make the cataract procedure easier.”

—Michael P. Jones, MD

it—now I consider the VERION Image Guided System an essential tool for helping me precisely position IOLs, especially toric and multifocal lenses.

To recap: once I bring a cataract patient into the OR, the VERION Image Guided System helps my staff and me to save significant time and stress and helps me minimize the risk of data entry error at the laser. We no longer have to enter the patient’s data, configure the laser, or mark the patient’s cornea. The registration process takes seconds. All of the incisions are pre-placed for me, even if I need to create them manually. And, selecting and implanting an IOL is now fully guided by advanced mathematical and imaging technologies. All of these features of the VERION Image Guided System have helped to make the cataract procedure easier. I simply use the system’s comprehensive case planning system in my practice, and then I take that plan to the operating microscope to execute it—from the incisions, to the capsulorhexis, to markerless IOL alignment. Thus, the VERION Image Guided System has revolutionized my cataract surgery.

TRACKING OUTCOMES FOR SURGICAL REFINEMENT

There is one final component of the new VERION Image Guided System, which I refer to as “closing the loop,” that I think will be invaluable to surgeons in the pursuit of ever-higher standards of care. VERION allows me to capture patients’ postoperative data and compare them to the preoperative surgical plan that I executed. This feature of data capture and analysis enables me to optimize my personal surgical A-constant.

Surgeons may benefit from performing this scan on all cataract patients around the 1-month postoperative visit for the purpose of capturing the postoperative data and better measuring every facet of surgery. For example, we could learn how a chosen arcuate incision affected the postoperative astigmatism; the effect of a customized A-constant; and the size and shape of the capsulorhexis compared with the effective lens position—every possible variable in surgery. With the VERION Image Guided System automatically capturing, storing, and analyzing these data, there will be no excuse for surgeons to skip this important step. In the future, I hope surgeons will be able to share and combine their data to produce some valuable clinical contributions. ■

operating microscopes (so it is not necessary to have the entire Cataract Refractive Suite in order to use the VERION Image Guided System). The VERION Digital Marker displays a high-resolution image of the patient's eye under the LenSx Laser's SoftFit Patient Interface, and it overlays the predetermined steep and flat axes, the incisions, and the capsulotomy from the VERION Digital Marker over this image (Figure 6). I can adjust the incisions as I see fit before I activate the laser, which gives me full decision-making control over the procedure.

PRECISE GUIDANCE FOR INCISIONS AND IOL POSITIONING

For the lens implantation part of the surgery, I simply transfer the USB drive from the LenSx Laser to the VERION Digital Marker of the operating microscope. Here again, the VERION Digital Marker registers and tracks the eye in real time, and it compensates for cyclorotation. The interface then overlays guidelines to show the location of the visual and pupillary axes, and the alignment of the steep and flat meridians so that I do not need to mark the cornea. These alignment features are incredibly helpful in surgery. Previously, I had limited capability to track the eye's axis once the patient reclined under the laser and their eye cyclorotated. The real-time tracking function and the visual guidelines for the axes are valuable tools for myriad surgical steps, such as placing LRIs and surgical incisions, positioning and aligning toric IOLs, and centering multifocal IOLs.

If my surgical plan includes a toric IOL, the VERION Digital Marker displays a pop-up screen that shows the exact location of the eye's axes. It even overlays a green

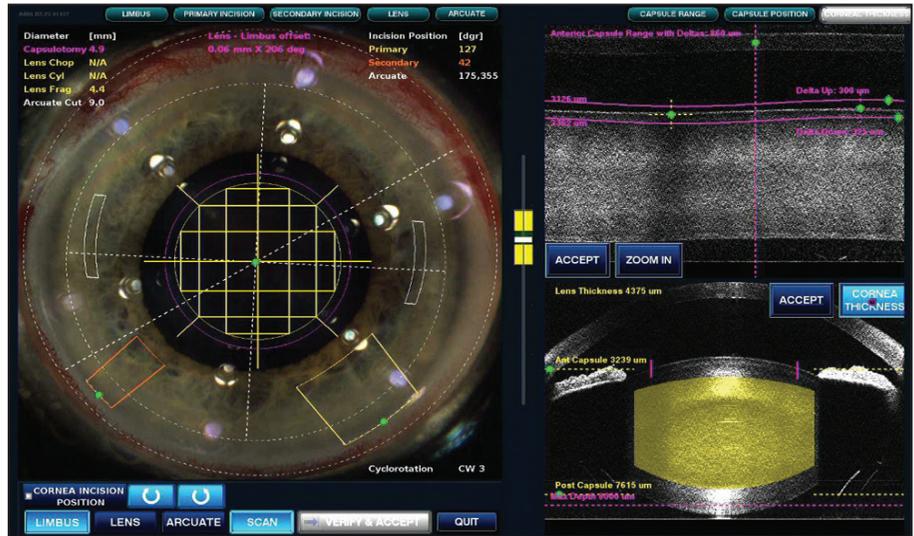


Figure 6. The VERION Digital Marker on the LenSx Laser allows the predetermined surgical plan to automatically align to the patient's eye at the laser, finding precise placement for all incisions, arcuates, and the capsulorhexis, removing the need for manual ink marking before LenSx treatments.

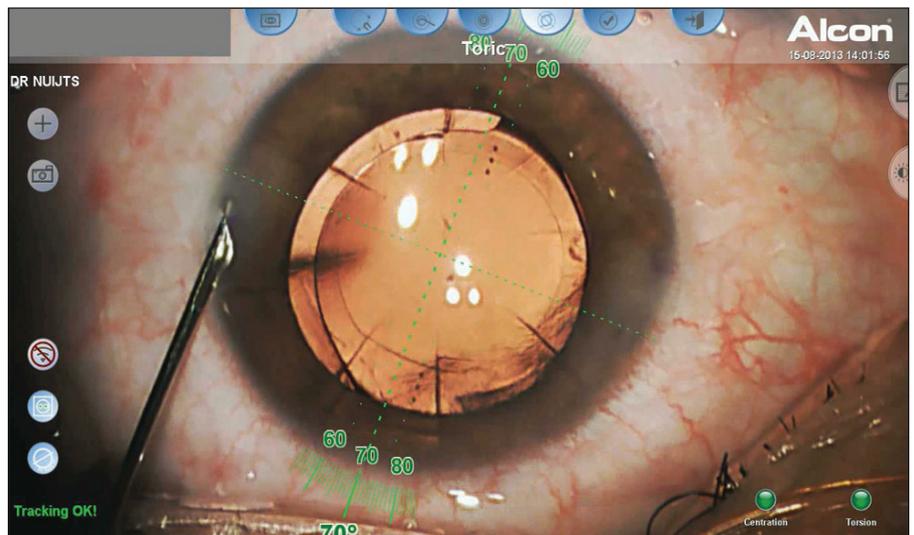


Figure 7. Using the VERION Digital Marker to position an AcrySof Toric IOL to the predetermined orientation. Manual ink marking is no longer required as the system provides live tracking and overlay of all procedural steps through the surgical microscope.

line across the image of the eye to help me align the toric lens precisely; I no longer need to mark the eye to determine the alignment (Figure 7). For my multifocal implants, the software has a crosshairs centration feature that ensures the IOL is centered precisely based upon my preferred alignment option. These functions I find especially helpful, because they ensure the optimal placement of the lens. For these guidance steps, such as centration of the capsulorhexis and IOL, I can choose whether to center on the preoperative pupillary axis, the limbal

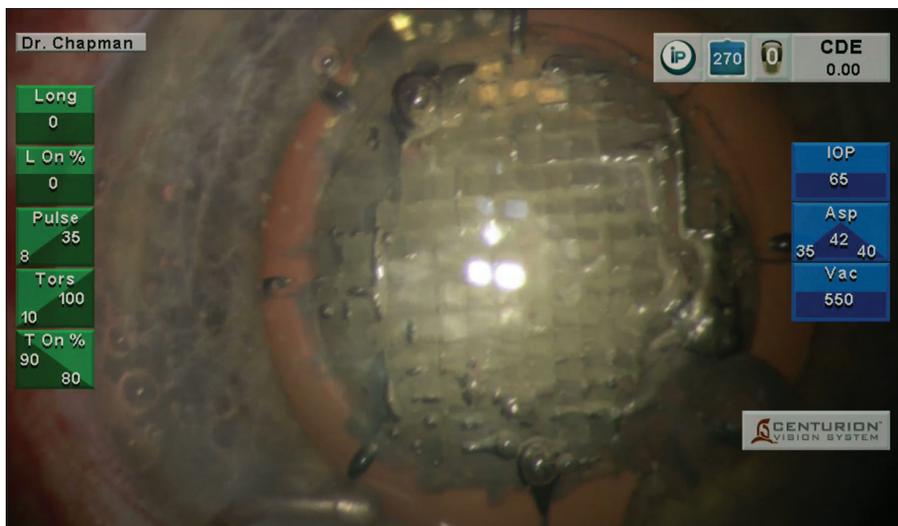


Figure 8. The LenSx Laser communicates with the VERION Image Guided System to import the preoperative surgical plan precisely where it is needed to the docked eye.

“I can choose whether to center on the preoperative pupillary axis, the limbal center, or the visual axis, which helps me customize each step to meet the individual patient’s needs.”

—Jack Chapman, MD

center, or the visual axis, which helps me customize each step to meet the individual patient’s needs.

POSTOPERATIVE UTILITY

In terms of patients’ follow-up, the VERION Image Guided System is useful for tracking postoperative outcomes by refining my personal surgical parameters; it helps to make taking postoperative measurements exceedingly simple. At the conclusion of a case, I save the data from the IOL’s final position onto the USB drive and transfer them to the VERION Reference Unit so that they are saved with the rest of the patient’s data. When

the patient returns for his or her follow-up, my technicians measure their eyes again with the VERION Reference Unit, and it will automatically perform the calculations and customize the A-constants for my IOLs, as well as track my surgically induced astigmatism. I expect this tracking and analytical function of the system to be tremendously helpful in optimizing my surgical parameters to achieve even better outcomes. It will be exciting to realize the benefits of this information over time.

STAFF IMPRESSIONS

Our staff took to the VERION Image Guided System immediately. They have found it very easy and intuitive to use, and they love how much time the device helps save them, both in the preoperative workup and in pre-surgical preparations.

CONCLUSIONS

I have been waiting for a device like this for a long time. Calculating the correct IOL power and positioning used to be a lot of work, and then my staff and I would spend extra time verifying all the measurements to ensure they were as accurate as possible. The procedure for traditional manual cataract surgery has many steps that involve human calculation and data entry, where there is the potential to make an error. The VERION Image Guided System can help reduce the time factor and the potential for human error from each step to better streamline the process and thereby help improve efficiencies for us and our patients. It also helps us to achieve the refractive outcomes that we desire for our patients. Plus, the benefit of having a system to more readily refine our surgical parameters is invaluable to our practice. With all of these advantages, I think the VERION Image Guided System is going to be a game-changer for cataract refractive surgery. ■

Important Product Information for the 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 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 elliptical 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 uninterrupted. 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.

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.

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