

Cataract & Refractive Surgery TODAY

November/December 2013

THE NEXT EVOLUTION
IN CATARACT SURGERY

THE CATARACT REFRACTIVE SUITE



Bringing a new level of
control to every step of
the cataract procedure.

Introducing the Cataract Refractive Suite

As cataract patients set higher expectations for surgical outcomes, they are fueling a demand for advanced surgical technologies that enable cataract surgeons to meet those expectations. Concurrently, the economic climate in healthcare is initiating a paradigm shift in the future of reimbursements.

Innovation plays a major role in advancing the quality of healthcare. Clinicians who are able to minimize surgical errors and inefficiencies and simplify surgical planning and execution could have a greater return on their technological investments by shortening the timeframe of surgery while simultaneously optimizing refractive outcomes.

Therefore, the challenge for every cataract and refractive surgeon is to reject the status quo and pursue new technological innovations. The Cataract Refractive Suite by Alcon Laboratories, Inc., is an innovative surgical platform that offers advanced diagnostic planning and executive capabilities. Each component of the suite is designed to ideally reduce the number of human-dependent variables in cataract surgery, thereby making the procedure more reproducible and accurate, leading to better refractive outcomes.

The Cataract Refractive Suite comprises the VERION Image Guided System, the LenSx Laser, the CENTURION Vision System, and the new LuxOR Ophthalmic Microscope. In this supplement, accomplished surgeons share their individual experiences with the Cataract Refractive Suite of products and explain the benefits of investing in an innovative platform of advanced cataract technology.

—By Stephen G. Slade, MD

Contributors



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Contents

- 3 **DESIGNED TO ACHIEVE A HIGH LEVEL OF ACCURACY IN CATARACT SURGERY**
BY JACK T. HOLLADAY, MD

- 6 **LEADING PLATFORM CONTINUES TO INNOVATE**
BY STEPHEN G. SLADE, MD

- 8 **SETTING A NEW STANDARD FOR PHACOEMULSIFICATION**
BY LAWRENCE WOODARD, MD

- 10 **PROCEDURE-ENHANCING INTEGRATION**
BY MICHAEL P. JONES, MD

Designed to Achieve a High Level of Accuracy in Cataract Surgery

The new VERION Image Guided System.

BY JACK T. HOLLADAY, MD

Recent data show that only 55% of cataract surgery outcomes targeting emmetropia attain the goal of ± 0.50 D, as there are inherent limitations in the way cataract surgery is performed today.¹ In addition, 60% of cataract patients have more than 0.50 D of astigmatism.² Ultimately, this means that those patients need to be treated for their astigmatism in order for ophthalmic surgeons to get the best visual outcomes.

SOURCES OF REFRACTIVE ERROR

There are many opportunities for refractive error to occur. In fact, refractive errors can accumulate over every phase of cataract surgery, as well as through a surgeon's individual techniques.

Biometric Measurement

Biometric measurements impact IOL calculations and surgical planning. There is a potential for error to be introduced in manual data entry transcription and when accounting for cyclorotation. Utilizing a standardized measurement method and automated data capture and transfer can prevent potential errors.

IOL Calculations

IOL calculations impact the selection of the IOL power. Errors may occur with customized formulas for individual patients and when surgeons fail to accurately account for variations in surgically induced astigmatism. Integrated calculation technology that accounts for surgically induced astigmatism and automatic IOL selection based on individual parameters can help minimize surgical errors.

Marking the Eye

Marking the eye impacts the toric IOL alignment and astigmatism correction. Risks for error occur when the

manual placement of marks are imprecise, and marking size alone can skew alignment and potentially impact refractive outcomes. This can be addressed with toric image-guidance overlays and patient eye tracking technology.

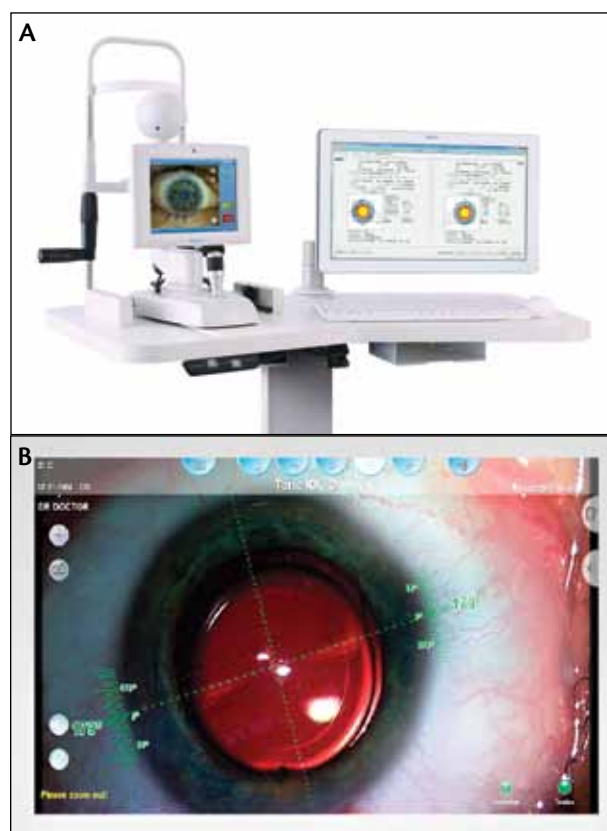


Figure 1. The new VERION Image Guided System comprises the VERION Reference Unit (A), which is used in the practice, and the VERION Digital Marker (B), which is compatible with the LenSx Laser as well as most surgical microscopes.

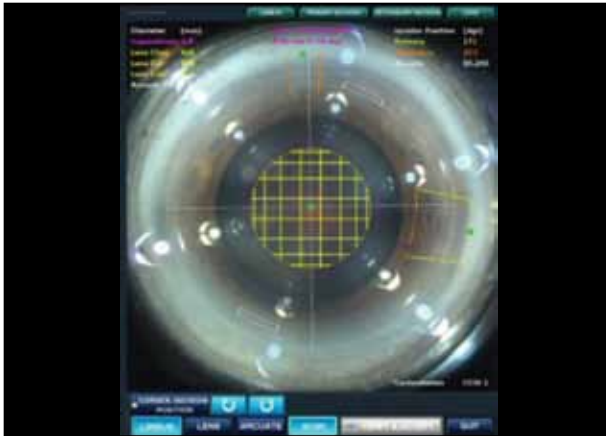


Figure 2. The VERION Image Guided System's high-resolution reference image of the patient's eye autodetects scleral vessels, the limbus, iris, and features of the pupil. This image and the landmark data become the basis for the surgical plan and are used throughout the cataract procedure by the LenSx Laser, LuxOR Ophthalmic Microscope, and CENTURION Vision System.

Surgical Incisions

Surgical incisions can impact surgically induced astigmatism and effective lens placement. Errors can occur with centration and effective lens placement, as they are highly dependent on the precision of the capsulorhexis. Errors can also occur from cyclorotation during surgery. Solutions include precise, image-guided incisions, automated surgical overlays, and auto-adjustments for cyclorotation.

IOL Positioning

IOL positioning impacts centration, effective lens placement, and astigmatism correction. This can occur when manual positioning in the bag is imprecise. Manual eye markings can be a poor guide, and every degree that the marks are off axis equates to a 3.33% loss in effective toricity. Utilizing image-guided surgical overlays and automated patient-moving tracking can avoid these errors.

The Surgeon's Parameters

A surgeon's parameters, such as surgically induced astigmatism, A-constants, nomograms, or incisional planning, can also cause refractive errors. Errors occur when the surgeon has inconsistencies, lacks personalized surgical data, and attempts to account for individual surgical technique. This can be solved with real-time surgical data that are optimized for the surgeon.

Fortunately, the VERION Image Guided System (Alcon Laboratories, Inc.) is designed to minimize the chances for errors that can occur with traditional cataract surgery and breeds confidence in surgeons, as each surgical step can affect the next. The VERION Image Guided System's

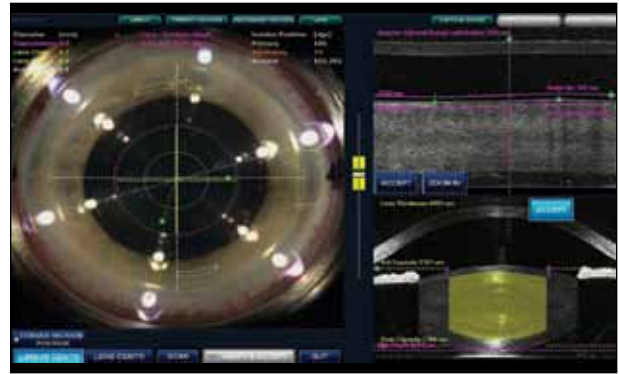


Figure 3. Using the reference image and data from the VERION Reference Unit, the VERION Digital Marker on the LenSx Laser automatically prepositions the capsulotomy and all incisions based on the surgeon's predetermined surgical plan.

solution for imaging, planning, and guiding is designed to control many of these variables.

IMAGING, PLANNING, AND GUIDING

Imaging

The VERION Reference Unit (Figure 1A) allows surgeons to create a blueprint of the best possible procedure for each patient. Its desktop interface measures keratometry, pupillometry, and other key preoperative parameters (Figure 1B). It captures a high-resolution, diagnostic reference image of the patient's eye, and it autodetects scleral vessels, the limbus, pupil, and iris features (Figure 2).

The VERION Image Guided System accounts for cyclorotation. When the patient lies down, even slight rotations of his or her eye do not make a difference, because the system captured the image at the time the diagnostic measurements were taken, and it will automatically register that image with the view under the microscope (Figure 3). The VERION Reference Unit provides a reference point that

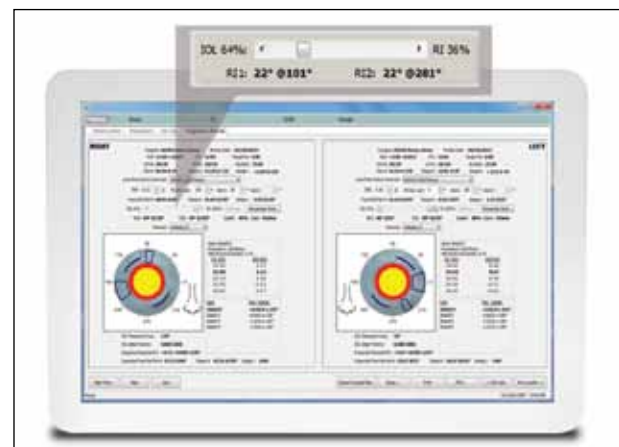


Figure 4. The VERION Reference Unit can interpret K readings and adjusts for pre- and postoperative astigmatism in the surgical planning stage.

allows the surgeon to know exactly where the astigmatism is relative to the patient's eye so that he or she can adjust for any rotation that occurs at the time of surgery.

Planning

Following the operation, a postoperative K reading is taken to determine what the surgically induced astigmatism was at the time of the surgery. The VERION Reference Unit takes that reading using the initial image and feeds it back into the system to create what is called a *closed loop* (Figure 4).

The VERION Digital Marker can be used with the LenSx Laser as well as with most surgical microscopes to target greater accuracy and efficiency during surgical planning and execution.

Guidance

With the VERION Reference Unit, surgeons can quickly and efficiently determine the best surgical plan for their patients. The unit provides access to multiple advanced-formula IOL calculations, including lens and power selection, and it allows surgeons to plan customized incisional and implantation axes for each patient.

To optimize the incision and IOL alignment, the VERION Digital Marker of the LenSx Laser displays the patient's information and images from the VERION Reference Unit. The tracking overlay shows the incisions and the IOL alignment in real time, automatically accounting for cyclorotation, eliminating the need for manual toric eye markings, automatically registering the patient for accurate centering and alignment of multifocal and toric IOLs, and preserving data to help optimize cataract procedures over time (Figure 5).

PERSONALIZED PARAMETERS FOR CALCULATION

Exclusively for the VERION Image Guided System, I developed an algorithm that incorporated the best parts of existing manual nomograms devised by Eric Donnenfeld, MD; Douglas Koch, MD; and Louis D. "Skip" Nichamin, MD. The Holladay algorithm uses the magnitude of astigmatism, the steepness of the cornea, the age of the patient, the diameter of the cornea, and the depth, diameter, and location of the AK incision to calculate arcuate incisions. Collecting all of these necessary parameters into one algorithm was not possible prior to the introduction of the VERION Image Guided System. The system then calculates the arc length in degrees based upon all of these parameters down to the nearest 1° of arc length.

Obviously, a patient's preoperative K readings, the amount of surgically induced astigmatism, and the length and location of the incisions are important, but the age of the patient also helps determine the arcuate incision. The older a patient is, the more cross-linking he or she may



Figure 5. During the IOL's implantation, the intraocular display of the VERION Digital Marker shows the lens' alignment so that the surgeon does not need to mark the eye. It also accounts for cyclorotation in real time.

have, and the more significant the effect will be with the same incision.

The steepness of the cornea also factors into the calculations for the length and location of arcuate incisions. A 12-mm LRI made near the limbus will produce a much smaller effect on corneal astigmatism than an 8-mm AK incision created nearer to the pupil. Also, a horizontal or vertical orientation of the incision makes a difference. Because the lid moves vertically, incisions made in the vertical meridian tend to flatten the cornea more than those made in the horizontal meridian. These parameters, which predict outcomes, are usually referred to as *prediction error* in IOL calculations—the difference between what the actual postoperative refraction is and what the surgeon is targeting.

The VERION Image Guided System has the additional feature of being able to indicate where arcuate incisions should be made. It would be difficult for surgeons to manually achieve the same depth, make incisions accurately to within a degree, or at the correct location, without having an image of the eye and its landmarks as a frame of reference.

A NEW LEVEL OF ACCURACY

The VERION Image Guided System is the first system to combine two modalities of cataract surgery that can be done with a laser and an IOL consultant. Using the LenSx Laser, surgeons will be able to better predict the effective lens position, and the VERION Image Guided System will help eliminate many surgical variables that they cannot tighten manually. ■

1. Behndig A, Montan P, Stenevi U, et al. Aiming for emmetropia after cataract surgery: Swedish National Cataract Register study. *J Cataract Refract Surg*. 2012;38(7):1181-1186.
2. Hoffer KJ. Biometry of 7,500 cataractous eyes. *Am J Ophthalmol*. 1980;90(3):360-368.

Leading Platform Continues to Innovate

The LenSx Laser.

BY STEPHEN G. SLADE, MD

The LenSx Laser (Alcon Laboratories, Inc.) (Figure 1) was designed from inception to be a fast and precise platform. Alcon is now the world's largest manufacturer of femtosecond lasers for cataract surgery, and the LenSx Laser is the market's leading platform, with more than 2,200 surgeons having performed over 150,000 procedures in 64 countries. The LenSx Laser is gaining recognition, as it is designed to build on a solid technological foundation that enables the rapid advancement of software and hardware to ensure continued workstation innovation. This article describes the LenSx Laser's latest upgrades and how they are assisting me in my practice.

SOLID TECHNOLOGICAL FOUNDATION

The LenSx Laser features a new Optimized Variable Numerical Aperture, a patented technology that delivers maximum depth of focus at each surgical plane of the anatomy. As a result, I am able to achieve precise and reproducible cuts in the lens, capsule, and cornea.

Utilizing the SoftFit Patient Interface (PI) allows me to reduce or eliminate corneal folds or compressions for optimal laser performance. The SoftFit PI incorporates a soft contact lens feature that reduces eye movement and delivers consistent placement of corneal incisions because it secures the eye, not the head.

The LenSx Laser also features advanced high-definition optical coherence tomography (OCT) imaging technology, which provides three-dimensional visualization of the entire anterior segment during docking, planning, and throughout the laser procedure. A single 360° scan coincides with the capsulotomy pattern's location to verify all the data points. This gives me all of the necessary anatomical data in an efficient manner. The data points are represented in a 360° unfolded image for the capsulotomy and in a line scan representing all the data points. This OCT technology is proprietary to Alcon Laboratories, Inc., which means the company can continuously evolve and update it.



Figure 1. The LenSx Laser with interface screens showing the VERION Digital Marker software.

RAPID ADVANCEMENTS ENSURE CONTINUED INNOVATION

The LenSx femtosecond laser's engine is manufactured in Alcon's state-of-the-art facility in Aliso Viejo, California. Alcon has the resources to rapidly advance the technology and procedure, which has been proven through its previous hardware and software upgrades.

The LenSx Laser's new software is designed to allow (1) an additional lens fragmentation pattern, (2) advanced automation that includes prepositioning of incisions and the capsulotomy, and (3) use of the VERION Digital Marker (Alcon Laboratories, Inc.), which has an advanced registration feature that automatically recognizes the limbus and generates real-time tracking overlays for automated placement of preplanned primary, secondary, and arcuate incisions (Figure 2). It also prepositions the capsulotomy on the center of the pupil. (See Dr. Holladay's article on pg. 3 for more detailed information about the VERION Image Guided System).

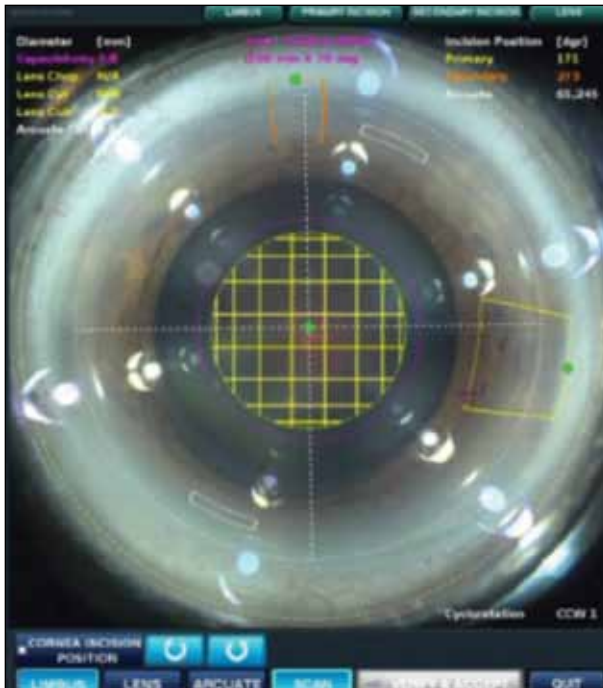


Figure 2. A recent software upgrade on the LenSx Laser includes advanced prepositioning of the capsulotomy and incisions (primary, secondary, and arcuate).

To fragment the nucleus, I am able to use a matrix-like pattern to divide the nucleus into a grid based on my preferred size or dimension (Figure 3). Surgically, the matrix pattern has been a very versatile, effective treatment for me. Previously, I was dividing the nucleus into quadrants or into six slices. The matrix places a grid across the central lens, and I can fragment the lens however I choose. In other words, I am not limited by the quadrants, and this leads to faster phaco times and reduced phaco power.

THE POTENTIAL TO IMPROVE SURGICAL EFFICIENCY

Surprisingly, none of the upgrades requires me to significantly change my technique. They actually cut down on my surgical time because so much of the nucleus is already fragmented, and the autofocus and autocentration functions reduce our staff time and suction time in the OR. There are four timeframes that are significant during laser cataract surgery: total time to get patients on and off the laser, total suction time, total phaco time, and total time inside the eye. Suction time is when the

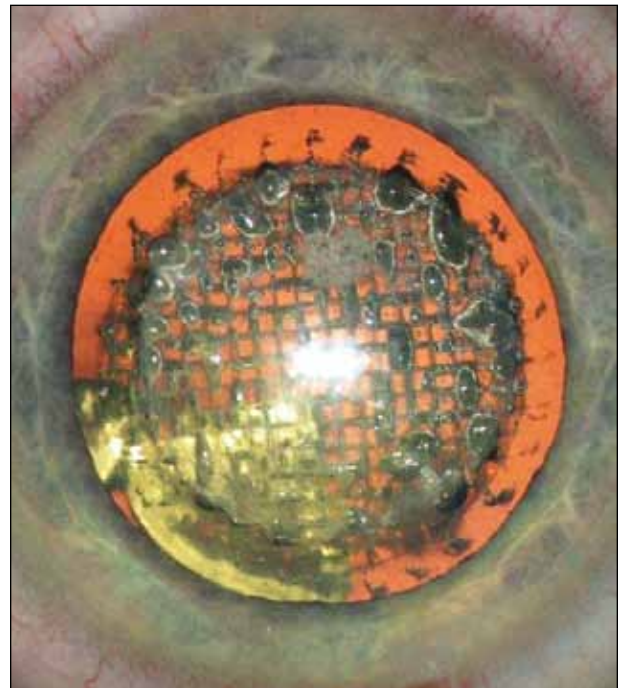


Figure 3. The LenSx Laser's latest software adds a matrix fragmentation pattern that allows surgeons additional treatment options.

eye is at risk, so minimizing the suction time is beneficial to the patient and the doctor. Once I am in the OR, the total phaco time and time inside the eye are important for clear corneas and excellent vision in the immediate postoperative period. I am enjoying using short bursts of phaco energy to remove large amounts of nucleus and reducing the total fluid, time, and manipulation inside the eye.

CONCLUSION

In short, the LenSx Laser offers improved efficiency with precise procedures from start to finish. It is critical for surgeons who are thinking about purchasing femto-second technology to choose a platform that is designed to enable rapid advancement and innovation in order to help maintain the long-term investment value. If we look back at the first 3 years that laser cataract surgery has been in existence, it has made huge strides. Before the LenSx Laser, cataract surgery was performed with all metal instruments and an analog system. Now, its high-technology approach has and will continue to revolutionize cataract surgery. ■

Setting a New Standard for Phacoemulsification

The CENTURION Vision System.

BY LAWRENCE WOODARD, MD

My experience with the CENTURION Vision System with Active Fluidics (Alcon Laboratories, Inc.) (Figure 1) has been game changing. The CENTURION Vision System is designed to maximize chamber stability by allowing the surgeon to target a preferred IOP setting throughout the cataract procedure. Surgeons will now be able to maintain a more consistent IOP throughout all phases of the procedure, as compared to gravity-based phaco systems. As a very satisfied user of Alcon's INFINITI Vision System, I was skeptical that a new phaco system could raise the bar, but the CENTURION Vision System did.

ACTIVE FLUIDICS TECHNOLOGY

When using the CENTURION Vision System with Active Fluidics Technology, I am able to easily set parameters that the system's software will utilize to maintain my target IOP. My target IOP, irrigation factor, and IOP ramp are customized to my technique and choice of phaco tip and sleeve. The system constantly monitors dynamic changes in flow rate, irrigation pressure, and vacuum pressure, and it compensates accordingly to maintain that target IOP.

The improved chamber stability I have experienced with the CENTURION Vision System gives me the confidence to use higher parameter settings for vacuum, aspiration, and IOP than I normally do with a gravity-based fluidics system (Figure 2). The Active Fluidics technology provides greater followability and vacuum capacity. However, when I choose to do so, I can also use lower parameters (IOP, aspiration flow rate, and vacuum) than I typically do with gravity fluidics, and I can still maintain excellent chamber stability throughout the cataract removal procedure. If I combine either the high-parameter or low-parameter settings of OZil IP (Alcon Laboratories, Inc.) with the high-efficiency INTREPID Balanced Tip and sleeve (Figure 3), I achieve increased torsional efficacy and low ultrasound energy through the eye. In my experience, the combination of the CENTURION Vision System with Active Fluidics and



Figure 1. The new CENTURION Vision System.

the INTREPID Balanced Tip is one of the most efficient cataract emulsification technologies available today, enabling the use of smaller incisions and designed to minimize thermal transfer while improving ultrasound cutting efficiency. The ability to target my personally selected IOP and have the system work to maintain that throughout the procedure is a great benefit of the Active Fluidics Technology.

Having a more stable anterior chamber prevents the pressure in the eye from fluctuating, which can minimize the chance of complications occurring. A stable chamber also helps to lower the amount of intraocular inflammation that develops during the procedure.

THE AUTOSERT IOL INJECTOR

Innovation in new technology allows me to focus more on the patient's outcome during surgery. Another innovation integrated into the CENTURION Vision System is the AutoSert IOL Injector handpiece (Alcon



Figure 2. The CENTURION Vision System's intuitive graphic user interface allows surgeons to select a target IOP for the cataract removal procedure.

Laboratories, Inc.) (Figure 4). My experience with the AutoSert IOL Injector handpiece has been that it provides greater control during IOL delivery and allows for less manipulation of the cartridge in the incision. The handpiece delivers the IOL into the eye at a smoother rate than the manual approach of turning the plunger on the injector to deliver the IOL through a micro-incision. By controlling the IOL's injection with the CENTURION footswitch, the AutoSert IOL Injector handpiece also allows me to avoid fatigue in my hands when I have a large number of cases in one day.

SURGICAL EFFICIENCY

There is little down time between my cataract surgery cases. Therefore, it is critical to have a phaco machine that facilitates efficient room turnover. The patient's experience in my clinic begins with a standard examination that includes optical biometry with the Lenstar LS 900 optical biometer (Haag-Streit), corneal topography, corneal pachymetry, and an OCT scan. On the day of surgery, there is usually no additional testing necessary. On a typical day, I perform cataract surgery on quite a few patients. I run two ORs, so when I am performing surgery in one room, the nurses and technicians are preparing the patient in the other room. My technicians prefer the usability of the CENTURION Vision System because of the Active Fluidics Technology, which does not require an extensive setup with many parts. The balanced salt solution (BSS; Alcon Laboratories, Inc.) is in a plastic bag that inserts into the machine, so there is no longer a glass bottle with connected tubing hanging on a pole. At the end of the day, the technician does not need to disassemble anything. Now, the technician only has to reset the CENTURION Vision System.



Figure 3. The innovative design of the INTREPID Balanced Tip maximizes efficiency at the cutting edge with minimal thermal transfer.



Figure 4. The INTREPID AutoSert IOL Injector frees the surgeon's second hand to stabilize the eye during IOL injection.

During the phaco procedure, I am able to navigate through the user interface of the CENTURION Vision System without any challenges. It is ergonomic and user friendly. I can toggle through each step in the procedure with the CENTURION Vision System's wireless foot pedal. When I am aspirating the nucleus during phaco-emulsification, I have a setting to adjust the vacuum levels before, during, and after I occlude the tip with the nucleus. It allows me to control the fluidics in the eye much better. Post-occlusion surge is something that we want to minimize at all costs. The Active Fluidics software works together with the CENTURION Vision System's low-compliance FMS to reduce post-occlusion surge versus my experience with gravity-based fluidic systems. Therefore, I am able to focus more on fragment removal and less on managing anterior chamber fluctuations.

CONCLUSION

Most cataract surgeons today use phaco machines with gravity-based fluidics, but with Active Fluidics Technology on the CENTURION Vision System, surgeons will quickly see improved chamber stability, a more consistent IOP during the entire procedure, and the ability to confidently access higher fluidic parameters to increase efficiency.

The various components of the Cataract Refractive Suite by Alcon allow the full complement of surgical instruments that utilize the surgical plan throughout the procedure. The CENTURION Vision System is an integral part of my suite today. ■

Lenstar is a registered trademark of Haag-Streit.

Procedure-Enhancing Integration

The new LuxOR LX3 Ophthalmic Microscope.

BY MICHAEL P. JONES, MD

When surgeons think about upgrading equipment in their surgery center, the microscope is often the last piece of equipment they consider. In fact, at my high-technology surgery center, we used microscopes that were 25 years old before upgrading to the LuxOR LX3 Ophthalmic Microscope (Alcon Laboratories, Inc.) (Figure 1). The transition to the LuxOR Ophthalmic Microscope was similar to that of upgrading from a standard television set to a high-definition TV. We thought we were seeing just fine, but we didn't know what we were missing until we used the LuxOR Ophthalmic Microscope's state-of-the-art technology. The LuxOR Ophthalmic Microscope combines comprehensive, consistent visualization with user-friendly functionality.

BENEFITS OF THE LUXOR OPHTHALMIC MICROSCOPE TECHNOLOGY

Superior Red Reflex¹

What I like most about the LuxOR Ophthalmic Microscope is its superior red reflex stability. It provides consistent visualization during all intraoperative phases of surgery. Because of the proprietary placement of the objective lens above the light source (data on file, Alcon Laboratories, Inc.), the LuxOR Ophthalmic Microscope uses collimated, nonfocused light to provide a red reflex zone that is six times larger than focused-light microscopes (Figure 2). This red reflex zone allows me to maintain a consistently stable, high-quality red reflex regardless of the patient's pupil size, centration, lens tilt, or eye movement.

The incredible red reflex and increased depth of focus produced by the LuxOR Ophthalmic Microscope means I spend less time moving the scope during surgery. I do not have to waste time repositioning the patient's eye or moving the microscope, because the red reflex zone—which is essential to performing a proper procedure—is so large. The LuxOR Ophthalmic Microscope's high-definition illumination makes my cases easier, and the



Figure 1. The LuxOR LX3 Ophthalmic Microscope with VERION Digital Marker (Alcon Laboratories, Inc.).

quality of illumination allows me to use less light, which is more tolerable for my patients.

Greater Depth of Focus¹

While the proprietary placement of the objective lens above the light source provides a large red reflex zone that is essential to performing a proper procedure, it also increases the focal length of the microscope by 60 mm, without changing my working distance (Figure 3). The increased focal length provides me a greater depth of focus during surgery for an exceptional quality of visualization, including unprecedented detail recognition and contrast in every phase of cataract surgery. I find that with the increased depth of focus, I use the microscope's foot pedal less, which allows me to be more efficient.

Surgeon-Friendly Interface

As a surgeon, having easy access to the user interface saves time. The LuxOR Ophthalmic Microscope delivers a unique, at-a-glance microscope feedback to the surgeon via the LIBERO-XY Communication System

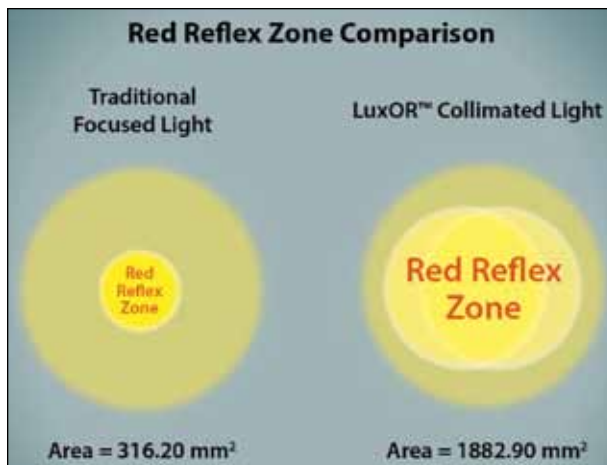


Figure 2. The red reflex zone of the LuxOR Ophthalmic Microscope is 6 times larger than that of focused-light microscopes, which increases the stability of the red reflex.

(Alcon Laboratories, Inc.). It has a full-color touch screen and wireless foot control, which allow me to customize preferred settings for quick, efficient setup. The LuxOR Ophthalmic Microscope incorporates a variable red reflex intensity knob that when fully engaged removes the reflective mirror that creates the red reflex. This versatile feature, called AMP, is great for cases in which a red reflex is not needed, such as corneal and retinal work. Surgeons can also choose to add optional upgrades, including Q-VUE 3D Assistant Visualization, which features a 180° swivel, and an independent magnification changer, a 3D stereo assistant scope that does not take light from the surgeon's optical pathway, and a traditional assistant scope and additional video capabilities.

Heads Up Display

The LuxOR Ophthalmic Microscope's Heads Up Display (HUD) is one of the most innovative features I have ever seen. HUD works with the VERION Image Guided System (Alcon Laboratories, Inc.) (Figure 4), which is part of Alcon's Cataract Refractive Suite. The patient's ocular data are measured in the clinic, including scleral vessels and visual axis. These data are kept on a portable thumb drive that can communicate with all parts of Alcon's Cataract Refractive Suite, including the LuxOR Ophthalmic Microscope. The HUD enables image-guided overlays of the patient's eye directly into the optic. This overlay includes the capsulorhexis' size, visual axis, and toric markings. I now have the same precision for lens placement that I have in my diagnostic and surgical equipment, and it is conveniently available through my optics. The LuxOR Ophthalmic Microscope, together with the VERION Image Guided System, gives the surgeon confidence in lens centration and correct alignment.

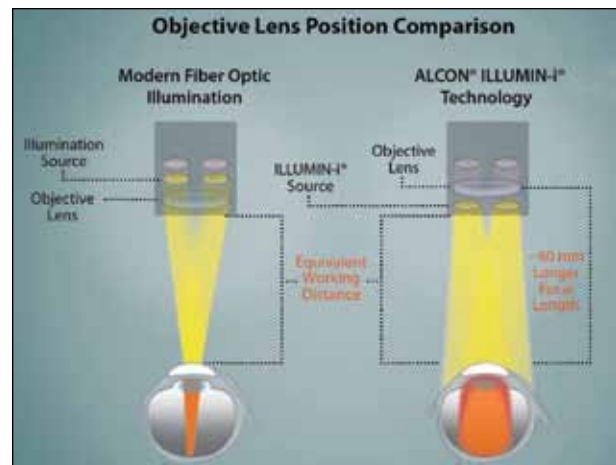


Figure 3. Placing the objective lens above the light source increases the LuxOR Ophthalmic Microscope's focal length by 60 mm without changing the surgeon's working distance. This helps increase depth of focus for the surgeon.



Figure 4. The LuxOR with Q-VUE Ophthalmic Microscope's optical head with VERION Digital Marker.

CONCLUSION

My surgery center treats a very high volume of patients, so my partners and I are always examining ways in which we can make our services more efficient. We found that one way in which we could be more efficient is by spending less time manipulating the eye or moving the microscope around to see the surgery, and we have been successful in that pursuit by upgrading our microscopes to the LuxOR Ophthalmic Microscope. Switching from a standard microscope to the LuxOR Ophthalmic Microscope has been a true asset to our practice. ■

1. Data on file, Alcon Laboratories, Inc; Fort Worth, TX.

Important Safety Information for LenSx laser

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 appplanation of the cornea or transmission of laser light at 1030 nm wavelength

Descemetocle 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 appplanation 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.

CENTURION® Vision System Important Safety Information

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

As part of a properly maintained surgical environment, it is recommended that a backup IOL Injector be made available in the event the AutoSert® IOL Injector Handpiece does not perform as expected.

Indication: The CENTURION® Vision system is indicated for emulsification, separation, irrigation, and aspiration of cataracts, residual cortical material and lens epithelial cells, vitreous aspiration and cutting associated with anterior vitrectomy, bipolar coagulation, and intraocular lens injection. The AutoSert® IOL Injector Handpiece is intended to deliver qualified AcrySof® intraocular lenses into the eye following cataract removal.

The AutoSert® IOL Injector Handpiece achieves the functionality of injection of intraocular lenses. The AutoSert® IOL Injector Handpiece is indicated for use with the AcrySof® lenses SN60WF, SN6AD1, SN6AT3 through SN6AT9, as well as approved AcrySof® lenses that are specifically indicated for use with this inserter, as indicated in the approved labeling of those lenses.

Warnings: Appropriate use of CENTURION® Vision System parameters and accessories is important for successful procedures. Use of low vacuum limits, low flow rates, low bottle heights, high power settings, extended power usage, power usage during occlusion conditions (beeping tones), failure to sufficiently aspirate viscoelastic prior to using power, excessively tight incisions, and combinations of the above actions may result in significant temperature increases at incision site and inside the eye, and lead to severe thermal eye tissue damage.

Good clinical practice dictates the testing for adequate irrigation and aspiration flow prior to entering the eye. Ensure that tubings are not occluded or pinched during any phase of operation.

The consumables used in conjunction with ALCON® instrument products constitute a complete surgical system. Use of consumables and handpieces other than those manufactured by Alcon may affect system performance and create potential hazards.

AEs/Complications: Inadvertent actuation of Prime or Tune while a handpiece is in the eye can create a hazardous condition that may result in patient injury. During any ultrasonic procedure, metal particles may result from inadvertent touching of the ultrasonic tip with a second instrument. Another potential source of metal particles resulting from any ultrasonic handpiece may be the result of ultrasonic energy causing micro abrasion of the ultrasonic tip.

ATTENTION: Refer to the Directions for Use and Operator's Manual for a complete listing of indications, warnings, cautions and notes.

Important Safety 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 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.

Cataract & Refractive Surgery
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