Cataract & Refractive Surgery

November/December 2013

The LenSx Laser:

First Femtosecond Laser Continues to Lead



The leader in laser refractive cataract surgery continues to deliver practical innovations and refractive predictability.

The LenSx Laser Continues its Legacy of Innovation as Part of the Cataract Refractive Suite by Alcon



I have been fortunate to witness and work with all the major changes that have occurred in cataract surgery over the past 4 decades; from intracapsular cataract surgery in a hospitalized setting, to small-incision extracapsular

surgery with IOLs in an ASC with regional anesthesia, to phacoemulsification with a 2.2-mm incision under topical anesthesia. All these improvements allowed us surgeons to advance from giving our patients the best *corrected* visual acuity to a stage where we could attain the best *uncorrected* acuities.

The recent advent of femtosecond laser cataract surgery is a major step in allowing us to reach this goal of best uncorrected acuity more consistently. It does this by providing a higher level of automation and customization than we have ever seen before. This fall, Alcon Laboratories, Inc., is introducing the Cataract Refractive Suite—a suite of advanced-technology surgical tools consisting of the VERION Image Guided System, an enhanced LenSx Laser, an improved LuxOR LX3 with Q-Vue Ophthalmic Microscope, and the new CENTURION Vision System. The overarching goal of this Cataract Refractive Suite is to provide surgeons the most advanced technologies in cataract surgery to help improve refractive outcomes for our patients. Each of the elements of this suite is designed to advance cataract

surgery, from the planning process through positioning of the IOL.

—Satish Modi, MD

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Advanced Cataract Technology

An overview of the advancements to the LenSx Laser and Alcon's new surgical platform.

BY MICHAEL P. JONES, MD

he LenSx Laser (Alcon Laboratories, Inc.) is designed to be a fully upgradable platform (Figure 1) that simplifies the most challenging steps of cataract surgery. At the time of this writing, my partners and I at Illinois Eye Surgeons have been using the latest version of the LenSx Laser. Although we were happy with the performance of the LenSx Laser before the upgrade, we have since seen a dramatic increase in our surgical efficiency, improved patient outcomes, and an ease of operation for all of our surgeons, whether they are experienced LenSx Laser users or not. The new software upgrade delivers on Alcon's promise of continual innovation and technological improvement—both for the LenSx Laser on its own, and also as part of a new, digitally integrated system for laser cataract surgery called the Cataract Refractive Suite (Alcon Laboratories, Inc.). This article provides an overview of the latest improvements to the LenSx Laser as well as two other components of the Cataract Refractive Suite: the VERION Image Guided System and the CENTURION Vision System.

LENSX LASER: ENGINEERED FOR ADVANCEMENT

The latest software on the LenSx Laser improves the prepositioning of the capsulotomy and incisions (primary, secondary, and arcuate) and allows the LenSx Laser to be used with the VERION Image Guided System. We now have even more fragmentation patterns to choose from, based on the density of the cataract or the eye's pathology. The newest advanced fragmentation pattern will turn the cataractous lens into a matrix of cubes (Figure 2) that are very easy to extract. This new pattern will allow us to break up the nucleus almost as much as we want to, which may reduce the amount of phaco energy needed to extract the fragments in the OR.

THE VERION IMAGE GUIDED SYSTEM

The new VERION Image Guided System is an all-in-one imaging, surgical planning, and surgical guidance system



Figure 1. The LenSx Laser with new software and the VERION Digital Marker Screen (middle screen).

that is compatible with the LenSx Laser and the LuxOR Ophthalmic Microscope (Alcon Laboratories, Inc.), although it may also be used with other operating microscopes and in manual cataract surgery. The VERION Image Guided System changes the surgical process by enabling clinical staff to take preoperative ocular measurements in the office before the day of surgery. It can also incorporate data from an optical biometer if the staff chooses to perform these measurements as well. Then, the VERION Image Guided System shares all of this preoperative data with its planning software, which the surgeon uses to create a tailored surgical plan for each patient (Figure 3).

The VERION Image Guided System also contains IOL calculation software that lets the surgeon choose from a number of popular algorithms for calculating the desired lens power—both with and without astigmatism. This function of the VERION Image Guided System should significantly increase the accuracy of my team's astigmatism correction, because it takes the guesswork out of these calculations. We have not had specific nomograms for treating preoperative astigmatism prior to this technology, and it has given my team and me a new level of confidence in our surgical plans. (See Dr. Solomon's article on pg. 5 for more details on the VERION Image Guided System.)

My team and I can usually dock a power in the extra patient to the LenSx Laser, make the incisions, capsulorhexis, and lens fragmentation, then roll the patient into the OR and prepare him or her for cataract extraction in a few minutes. Because I have already inputted my settings into the VERION Reference Unit's software, once the patient is docked to the LenSx Laser, the typical treatment time is 30 to 60 seconds or less. In our experience, this treatment time has not compromised our results. We have found that all of our capsulotomies are free-floating, which is consistent with the results of the Alcon-sponsored clinical studies.

THE CENTURION VISION SYSTEM

The CENTURION Vision System is the new phaco platform that Alcon has developed to advance phaco technology. It is also compatible with the VERION Image Guided System, the LuxOR Ophthalmic Microscope, and the LenSx Laser through the Cataract Refractive Suite (Alcon Laboratories, Inc.). I have to say, as good as Alcon's INFINITI Vision System was, the CENTURION Vision System is that much better.

The CENTURION Vision System features a new Active Fluidics technology that is not dependent on gravity-based infusion. Active Fluidics technology allows me to completely customize a target IOP during the cataract procedure. Not only does this capability potentially increase patients' comfort, but it is designed to keep the anterior chamber more stable during the procedure, which allows me to operate with higher parameters for vacuum and aspiration. Not only have I seen reductions in my phaco times and fluidic consumption while using the CENTURION Vision System, but the IOP and the anterior chamber remain remarkably stable at all times, which gives me great confidence while I operate. Active Fluidics technology is an innovative approach to fluidics management and a clear improvement over gravity-based systems of the past.

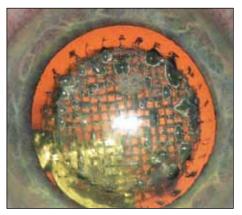


Figure 2. The grid-like fragmentation incorporates a combination of linear and radial incisions to enhance lens removal and increase the efficiency of cataract removal. This pattern is optimized to reduce phaco power in the extraction phase.

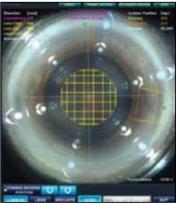


Figure 3. LenSx Laser software includes advanced prepositioning of the capsulotomy and incisions (primary, secondary, and arcuate) and allows for user-selectable fragmentation settings (size and spacing of the grid pattern).

If I am using the CENTURION Vision System in combination with the LenSx Laser, the fluidics of the CENTURION Vision System are so good that I can easily remove a LenSx Laser-fragmented cataract with very little manipulation inside the eye. The nuclear fragments come toward the tip automatically and are emulsified with very little manipulation on my part.

Other features of the CENTURION Vision System include the OZil IP technology; a new INTREPID Balanced Tip with a unique double-bend design to improve the tip's movement at the distal end; a new, more ergonomic foot pedal; and IOL injection capabilities with the new AutoSert handpiece. The AutoSert handpiece frees up my second hand so that I can apply countertraction on the eye to control the implantation through a microincision.

THE END RESULT

The VERION Image Guided System, the LenSx Laser, the LuxOR Ophthalmic Microscope, and the CENTURION Vision System all feature technological advancements that accomplish these main goals: they reduce the human variables in cataract surgery to create a more standardized and repeatable procedure, and they offer surgeons a combination of customized parameters, safety, and speed. Best of all, this system is designed to support future upgrades, so that it can serve surgeons for years to come. I am excited about the Cataract Refractive Suite and proud to be able to offer this level of service to my patients.

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Better Surgical Outcomes Through Imaging, Planning, and Guidance

An overview of the new VERION Image Guided System.

BY KERRY D. SOLOMON, MD

et's face it: we surgeons need to step up our game with refractive cataract surgery. With LASIK, we are getting 95% to 98% of patients within 0.50 D of postoperative astigmatism. Although our spherical outcomes with cataract surgery are slowly improving, most surgeons are within ±0.50 D for the spherical equivalent in only 72% to 78% of patients (based on the database of more than 200,000 implantations maintained by Warren E. Hill, MD, of Mesa, Arizona¹). For the correction of pre-existing astigmatism with a toric IOL, the residual refractive astigmatism for most surgeons is between 0.50 D to 0.75 D. I believe that if we can remove some of the variables from cataract surgery—for example, using blue ink to manually mark the eye—we can improve our cataract outcomes and

better reflect our refractive surgical outcomes.

The new Cataract Refractive Suite by Alcon Laboratories, Inc., provides the automation and customization we have been looking for in cataract surgery. The centerpiece of this integrated platform is the VERION Image Guided System, which is comprised of the VERION Reference Unit and the VERION Digital Marker. The VERION Image Guided System performs imaging, surgical planning, and surgical guidance through each step of laser cataract surgery. This article describes its role within the Cataract Refractive Suite.

THE VERION IMAGE GUIDED SYSTEM Imaging

The best analogy I can use to describe the importance of the VERION Image Guided System in the Cataract



Figure 1. The VERION Reference Unit is designed to perform all of a patient's preoperative workup in the office.

Refractive Suite by Alcon is customized wavefront-guided surgery versus conventional laser vision correction. Just like wavefront-guided technology improved our outcomes in LASIK, I expect the VERION Image Guided System to have a similar effect on cataract surgery.

As part of the preoperative workup, the Reference Unit of the VERION Image Guided System (Figure 1) captures a high-resolution, digitally referenced image of each patient's eye, including the scleral vessels, the limbus, and the landmarks of the iris (Figure 2). It determines the center of the undilated pupil in the office. Next, this digital "fingerprint" of the eye, with all of the measurement data, is exported to the VERION Image Guided System's planning software so

that the surgeon can create a customized surgical plan for both eyes of the patient.

Surgical Planning

The second function of the VERION Image Guided System is its IOL calculation software (Figure 3), which was developed with the assistance of Jack Holladay, MD, of Bellaire, Texas, and Warren Hill, MD, who are amongst the brightest minds today for surgical planning and IOL calculations. The VERION Image Guided System allows surgeons to use multiple algorithms to perform the lens power calculations, for eyes with and without astigmatism. If the patient has preoperative astigmatism, the surgeon may decide whether to include arcuate incisions or a toric IOL (or a combination of the two) in the treatment plan.



Figure 2. The VERION Reference Unit takes a high-resolution digital image of the eye that includes important landmarks.

The system displays the potential outcomes between various options (ie, longer or deeper arcs) in real time, so we do not have to use a Web site on a separate computer to plan the surgery. Thus, not only does the program save time, but it can be continually fine-tuned as we record information about our surgical parameters, surgically induced astigmatism, etc.

Surgical Guidance

Once we have chosen and saved a treatment plan, we export it to a jump drive that inserts into the LenSx Laser prior to the procedure. The LenSx Laser and the LuxOR Ophthalmic Microscope (also part of the Cataract Refractive Suite) each have an additional screen called the VERION Digital Marker. The VERION Digital Marker on the LenSx Laser uses the reference image (the "fingerprint" of the eye) and the surgical plan to generate a real-time tracking overlay on the laser's interface (Figure 4). This overlay shows us where to place the incisions and the capsulotomy, which we can accept or modify as desired. We can choose to center the capsulotomy on the limbus or the center of the dilated pupil, and soon we will have the ability to center the capsulotomoy on the optical or visual axis. The software even

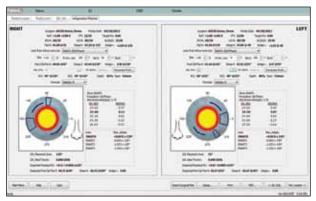


Figure 3. The VERION Reference Unit can interpret K readings and adjusts for pre- and postoperative astigmatism in the surgical planning stage.

provides a capsulorhexis guide for manual procedures. Then, after we dock the eyepiece to the patient's eye, the LenSx Laser will register the eye again, using the ocular surface landmarks provided by the VERION Image Guided System software to auto-align these critical laser steps to the precise location where they have been pre-determined during the case planning stage. This registration and auto-alignment technology removes the need for pre- and intraoperative marking throughout the process, thereby removing the variability traditionally associated with cyclotorsion and marking errors. All we have to do is confirm the image before operating the LenSx Laser.

Once the LenSx Laser has fragmented the cataractous lens, we use the same jump drive to transfer the eye's information to the LuxOR Ophthalmic Microscope. Again, the LuxOR Ophthalmic Microscope will register the eye and auto-align its predetermined plan, automatically compensating for cyclotorsion. There is a centration guide to help us center a multifocal IOL, and a toric alignment guide that automatically shows us where to place a toric IOL so we do not have to mark the eye manually (Figure 5). Surgeons who do not have a LenSx Laser could simply take their VERION Image Guided System jump drive

FEATURES OF THE VERION IMAGE GUIDED SYSTEM

Imaging

Via a desktop interface, the VERION Reference Unit

- Measures keratometry, pupillometry, and other preoperative parameters
- Captures a high-resolution, diagnostic reference image of the patient's eye
- Autodetects scleral vessels, the limbus, and features of the pupil and iris

Planning

- Multiple advanced-formula IOL calculations, including lens and power selection
- Incision and implantation axis planning customized for each patient

Guidance

To help optimize incision and IOL alignment, the VERION Digital Marker displays patient information and images from the VERION Reference Unit:

- Features a tracking overlay that enables surgeons to see all incisions and alignment in real time
- · Automatically accounts for cyclorotation
- Eliminates the need for manual toric eye markings
- Automatically registers the patient for accurate centering and alignment of multifocal and toric IOLs
- Allows documentation of data to help optimize procedures over time



Figure 4. Using the reference image and data from the VERION Reference Unit, the (LenSx Laser) Digital Marker automatically prepositions the capsulotomy and all incisions based on the surgeon's predetermined surgical plan.

straight to their microscope's VERION Digital Marker for guidance of all their surgical plan's steps at the scope.

Intraoperatively, the real-time guidance system is so responsive that as we are implanting a lens, manipulating it with our instruments, the tracker locks onto the limbus and follows the eye in real time so that we can identify with exquisite precision if the multifocal or toric lens is properly aligned.

LEARNING CURVE

So far in my experience with it, I have found the VERION Image Guided System to work seamlessly across all of these platforms. My technicians have had no issues adapting to the system, because it works similarly to the other diagnostic units they use routinely in the office. They tell me that it is faster for them to plan a surgery with the VERION Image Guided System compared to calculating IOL measurements and incision locations via multiple Web sites into which they have to input the data manually. They think the process is quick and very intuitive.

Although ultimately I think having an integrated system for laser cataract surgery is ideal, surgeons do not need a femtosecond laser to benefit from the VERION Image Guided System. They can still use the system to take diagnostic measurements in the office and plan surgeries, and they can still use the jump drive to transfer that information to their operating microscope to execute the surgical plan. The VERION Image Guided System will still show exactly where the visual axis is for placing limbal relaxing incisions or a toric lens. As mentioned previously, the VERION Image Guided System will project a capsulotomy through the LuxOR Ophthalmic Microscope to help surgeons make a manual capsulorhexis. Surgeons can adjust the size and location of this projected shape, so they can decide whether to center it on the dilated pupil, the undilated pupil, the visual axis, or the limbus. In fact, the system now permits the surgeon, when using the manual mode, the option to center the capsulotomy on the visual axis as determined from the preoperative diagnostic measurement with the undilated pupil (this feature will soon

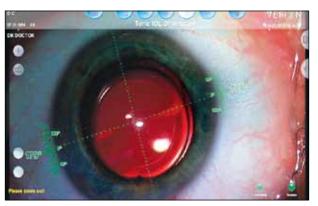


Figure 5. During the IOL's implantation, the intraocular display of the VERION Digital Marker shows the lens' alignment so that the surgeon does not need to mark the eye. It also accounts for cyclorotation in real time.

be available with the femtosecond interface). Thus, the VERION Image Guided System can work independently of the Cataract Refractive Suite for surgeons who do not want to make the full investment.

TOWARD BETTER REFRACTIVE OUTCOMES

I am thrilled to have an integrated system available for cataract surgery. Now, I am able to use the VERION Image Guided System in the diagnostic area of my office, transfer the patient's information to the LenSx Laser, carry the same real-time image over to the LuxOR Ophthalmic Microscope, and extract a cataract and implant an IOL via the CENTURION Vision System (Alcon Laboratories, Inc.), a brand-new phaco system that uses advanced fluidics. It is the combination of these components, however, that I think will help improve not only our safety but our refractive outcomes in much the same way as wavefront aberrometry has been combined with a femtosecond laser.

Although the potential for improved safety with this level of automation is exciting enough, what really matters to our patients when they are paying additional money is their refractive outcomes. They want to be able to see well without glasses—that is the end point. By reducing the number of human variables in the cataract procedure, I am confident that we will be able to achieve this goal for all patients in the near future. The VERION Image Guided System is a great first step in the right direction of LASIK-type outcomes with our refractive cataract patients.

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^{1.} Hill WE. Refractive outcomes in large cohort of laser refractive cataract surgeries. Presented at: American Society of Cataract & Refractive Surgery Cornea Day; 2012; Chicago, IL.

Bringing Value to Both Patients and Practices

ROI with the LenSx Laser.

BY JOHN P. BERDAHL, MD

y partners and I at Vance Thompson Vision in Sioux Falls, South Dakota, decided to invest in laser cataract surgery (or as we call it, ReLACS—refractive laser-assisted cataract surgery) because we were convinced of the technology's potential to improve the safety and repeatability of cataract extraction. However, we also recognized that a technology—especially an elective one—would only succeed if it could provide fair value to patients as well as to practitioners. Since we purchased the LenSx Laser (Alcon Laboratories, Inc.) in 2011 (ours was the fifth system sold), we have been thrilled with its return on investment. This article describes the value the LenSx Laser has brought both our patients and our practice.

BENEFITTING BOTH PATIENT AND PRACTICE

A primary benefit of the LenSx Laser for cataract removal is that it helps reduce the noise in the surgical procedure. The laser standardizes the incisions and the capsulotomy, making the surgery fast and predictable. It also decreases the amount of phaco energy needed to extract the cataract so that the eye is clearer with less inflammation and therefore recovers faster from the surgery.

As physicians, we firmly believe in offering a technology because of the benefits it can offer patients, not for the benefit of our bottom line. Happily, the technology has delivered on both fronts. Personally, I consistently get closer to my refractive targets when I use the LenSx Laser versus performing traditional cataract surgery. With conventional cataract surgery, a little over half of my patients achieved within ±0.50 D of the target. With the LenSx Laser, three quarters of my patients are within ±0.50 D.

Monetarily, the LenSx Laser has performed better than we expected. For our first year of owning the laser, we projected we would need to perform approximately 330 surgeries to break even with our investment. The technology was popular enough that we did more than 1,000 laser cataract surgeries in our first year. Obviously, purchasing the LenSx Laser financially benefitted our practice.

"The decision to choose the Alcon technology was an easy one. We knew that the company would be committed to ongoing technical support and upgrades to the technology."

PUTTING THE FOCUS ON THE PATIENT

When discussing with patients the surgical options we provide, I try to understand the individual's visual needs and goals, as opposed to trying to sell him or her on the benefits of a particular technology. We have found that this strategy of relating the service to them personally is very effective. I have this conversation with patients myself, and it is fairly brief. I ask them how they want to use their eyes after cataract surgery; whether they want to wear glasses all the time, do not want to wear them for distance viewing, or do not want to wear much them at all. If they respond that it would be nice to not have to wear glasses much at all, then I tell them about the costs of the laser cataract surgery package. If the value of the surgery sounds worth it to them, we proceed with ReLACS. If they opt for the standard procedure, they are still happy, because they felt like they were given the choice between all the options.

PATIENT FLOW

The LenSx Laser has fit into our practice surprisingly easily from the perspective of patient flow. We have used it in two locations: previously, our laser was in a hospital setting, and now we have moved it to our new ASC that was built around the ReLACS technology. In the hospital, the LenSx Laser was in a preoperative bay area where we perform the capsulorhexis and cataract sectioning. My staff and I liked the convenience and speed of performing

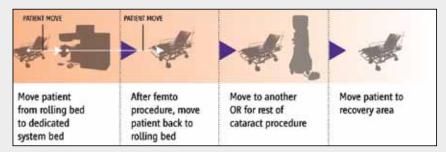
the cataract fragmentation in one room and the extraction and IOL implantation in another.

In our surgery center, we have created a pass-through laser area where we wheel the patient into the laser room on a convertible bed/chair, perform the cataract fragmentation, and then take the patient right into the OR on the same bed to complete the surgery. This can be done very quickly, in about 2 or 3 minutes, thanks to the LenSx Laser's nonfixed patient bed that helps facilitate our efficiency (Figure 1).

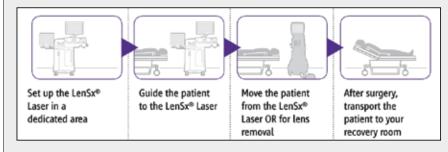
One way in which our patient flow may differ from that of other centers is that we plan our day and have a "traffic cop"—one person who is responsible for making sure where the patients and surgeons are going. Each surgical day is fully planned, and knowing where I am supposed to go next reduces downtime between patients.

FIGURE 1. LENSX LASER PATIENT FLOW

• The LenSx Laser can be placed in a nonsterile preoperative environment to enhance patient scheduling and through-put. This location can offer greater procedural flexibility and ease of patient flow.



Competitive lasers that have a fixed gantry require a dedicated patient bed to make the
adjustments required for docking. This means that the patient must be transferred from
a rolling bed to the dedicated bed for the femto procedure, then transferred again to
the rolling bed so they may be moved into the OR for the completion of the cataract
procedure. This frequent movement may be problematic for patients who are under
anesthesia or lack mobility for another reason.



LASER DEPENDABILITY AND FUTURE POTENTIAL

In the past 2.5 years, we have been very happy with the robustness and dependability of our laser. We have performed 1,800 to 2,000 cases on it.

Although there were not many choices of laser cataract technology when we purchased the LenSx Laser, the decision to choose the Alcon technology was an easy one. We knew that the company would be committed to ongoing technical support and upgrades to the technology. True to form, the LenSx Laser was just updated with a new software system that offers surgeons multiple choices of lens fragmentation patterns and options for treating challenging eyes such as those with loose zonules, pseudoexfoliation, etc. This software upgrade also includes digital integration with a preoperative imaging and planning system that controls for surgical variables, called the VERION Image Guided System, as well as with a new operating microscope, the LuxOR Ophthalmic Microscope. These systems are designed to be compatible with one another in order to reduce human error and to provide an entirely new level of automation and customization for laser cataract surgery.

CONCLUSION

We are glad we made the decision to adopt laser cataract technology early in its development. The technology has been proven effective, and the LenSx Laser delivers for us every time. We know that the user experience is pleasant, too, because our ReLACS service has grown with minimal marketing efforts on our end. We have not done specific direct-to-consumer marketing of the LenSx Laser technology; we have only educated our optometrist referral network about the technology. That strategy has worked well for us, because these providers have seen first hand the value of the technology, and they refer to us because they appreciate that we help their patients understand all the technological options.

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Integrating the LenSx Laser Into Your Practice

Since adopting femtosecond cataract surgery, this practice now performs more premium surgeries than standard procedures.

BY BRET L. FISHER, MD

y clinic first received the LenSx Laser (Alcon Laboratories, Inc.) 2 years ago. Because my colleagues and I were among the early adopters of the femtocataract technology, we learned through trial and error how to most effectively integrate it into our practice. This integration was a worthwhile process, because it gave us the opportunity to review every aspect of our surgical services and make improvements. We focused on making the LenSx Laser's integration a learning experience rather than a hassle, and the exercise benefitted our overall practice significantly. This article describes that process and the impact the LenSx Laser has had on our clinic.

A GROUP EFFORT

We enlisted input from everyone involved in the process—from our physicians, to the nurses, to the technicians, to the anesthesia providers—about where to put the LenSx Laser and how to reengineer the surgical flow and make the surgical center run smoothly (in the state of Florida, the laser has to be in a separate room from the OR). Our anesthesiologists suggested the winning idea: moving our director of nursing into a different office and using her former space as the new preoperative waiting area. Directly adjacent to that room is now the room that houses the LenSx Laser (Figure 1), and right across from that are two ORs—a very efficient triangle for cataract surgery. We also have a postoperative recovery room that used to be the preoperative prep room.

During this process, my partners and I gave ourselves and our staff the chance to learn the new technology slowly, without any time pressure, so everyone could get on board with it and enjoy the experience, the excitement of this wonderful new technology. It was a good decision, because once we integrated it into our routine, our pace picked up to being comparable with standard cataract surgery. It took a couple of months, but our



Figure 1. Dr. Fisher's LenSx Laser has its own room separate from the OR.

integration of the laser seemed to move along smoothly at an expected pace.

SURGICAL FLOW

Scheduling

We divide our patients into two pathways: standard or premium cataract surgery. The standard option includes traditional phacoemulsification surgery with implantation of a standard monofocal lens. Within the premium category, patients can opt for femtosecond fragmentation of the cataract with the LenSx Laser coupled with the implantation of an advanced-technology IOL.

When we first started working with the LenSx Laser, we thought we had a good idea of how to schedule the premium patients versus the standard patients. Our approach has evolved significantly over time, however, as we have learned from the experience and knowledge of other centers and LenSx Laser users. For example, in our early days of using the LenSx Laser, when we had a

smaller percentage of premium patients, we were able to alternate premium patients with standard patients in the same day. Now that the majority of our patients are electing premium services, however, we schedule all the premium patients first in the day and finish their surgeries before beginning to operate on the standard patients. This patient flow works much better because it allows me to focus my attention on one type of service before switching into a different mode with the standard patients.

Patients' preoperative evaluations occur on a separate day and typically last about 2 hours. The surgical day is also about 2 hours per patient; this timing allows room in the schedule to repeat some preoperative tests on the premium patients if needed. Patients are in the laser room for 3 to 5 minutes, and they are in the OR for the remainder of the procedure, about another 5 minutes.

From Waiting Room to Laser Bed

Rather than having patients wait for surgery while lying on a bed, we have them wait in lounge chairs so they are comfortable and relaxed. Most of them receive only oral sedation, although we will administer an IV if someone is particularly anxious.

When it is time for surgery, a member of our staff walks the patient from the lounge chair to the laser's bed, which is in the next room. The patient stays on that bed for the rest of the surgery, until he or she enters the recovery room. Our patients like not having to stand or move from one bed to another between the femtosecond laser phase and the cataract extraction and IOL implantation phase. This arrangement also works well for our surgical flow, because our nurses can keep patients moving from the laser room to the OR, freeing me up to prepare for the next patient.

Because of this mobility, my staff and I love the non-fixed bed that accompanies the LenSx Laser, and our patients report that it is extremely comfortable.

RECENT UPGRADES TO THE LENSX LASER

The LenSx Laser has undergone upgrades this year to make it even more user friendly. Two of these upgrades

WHY CHOOSE THE LENSX LASER: THE BENEFITS OF PARTNERING WITH ALCON

- · Alcon has years of proven technological performance
- · Alcon is an industry leader with superb tech support
- The LenSx Laser has proprietary femtosecond fragmentation patterns and treatment algorithms
- The LenSx Laser is part of Alcon's Cataract Refractive Suite

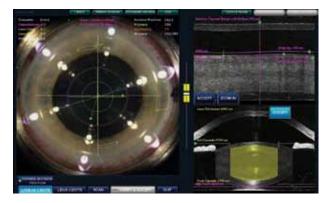


Figure 2. Using the image and data from the VERION Reference Unit, the LenSx Laser pre-positions the capsulotomy and all incisions based on the surgeon's predetermined surgical plan.

that have made a significant difference in my practice are the patient interface—how the LenSx Laser docks to the patient's eye—and a new software interface that gives me a greater range of programmability.

The patient interface has been redesigned to put a very low amount of pressure on the eye in the docking process. I performed my older sister's surgery a couple of weeks ago, and she reported being very comfortable under the laser. I like having the confidence in the LenSx Laser to treat all my friends and family, and no one has had an unpleasant experience. Of course, if there are patients with very deep-set eyes, we warn them that they will feel a little more pressure around the eyepiece. If necessary, we will use a little more sedation in these patients.

My staff and I adapted very quickly to the LenSx Laser's upgrades because of the software's new overlay feature that allows us to preprogram all the laser's operations before we dock it to the patient's eye (Figure 2). In essence, the majority of the planning work is already done, and our job is just to confirm that the laser is set to the parameters of surgery that I identified preoperatively. In this way, the interface saves our patients a lot of time underneath the laser, because I do not have to make surgical decisions while the system is docked to the patient's eye. My technicians and I can then move through the surgical process very rapidly.

To help me operate the LenSx Laser, I appointed one of my technicians as the laser operator. Beyond that, I have not needed additional staff in the surgery center as a result of adopting femtosecond laser cataract surgery.

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LenSx® Laser Important Safety 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 Descemetocele 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 endothe-lium (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.

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 AcrySor® 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 SN6OWF, 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.

VERION™ Reference Unit and VERION™ Digital Marker Important Safety 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 comea, 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 VERIONTM Reference Unit. Poor quality or inadequate biometer measurements will affect the accuracy of surgical plans prepared with the VERIONTM Reference Unit.

The following contraindications may affect the proper functioning of the VERIONIM 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.



