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THE LENSx FEMTOSECOND LASER

Responsive technology that produces improved surgical outcomes versus manual surgery.

SPONSORED BY ALCON

The LenSx Femtosecond Laser

Responsive technology that produces improved surgical outcomes versus manual surgery.



Roughly 20 years ago, the introduction of the excimer laser forever changed the world of ophthalmology. This new device ushered in the subspecialty of refractive surgery and expanded the mindset of ocular surgeons. A new treatment paradigm arose around the surgical pursuit of perfect uncorrected vision, and this mentality has propagated into the world of cataract surgery over the past decade. Many of us now find ourselves part of a growing movement called refractive cataract surgery, in which advanced biometry, new IOL optic designs, intraoperative measurements, and surgical guidance devices are becoming integral to our surgical skill set.

Perhaps the foundation of this paradigm is the femtosecond laser for cataract surgery. Toward the pursuit of optimal surgical outcomes, this device continues to improve precision and safety for our patients. The initial phases of innovation and early adoption for femtosecond lasers are now giving way to mainstream usage, which is fueling continued refinements to their hardware and software. As well, the body of literature supporting the efficacy of the laser for cataract surgery and documenting its impact on patient safety and better visual outcomes continues to grow.

This monograph, featuring contributions from an outstanding panel of trendsetting and innovative surgeons, delves deeply into the most up-to-date details of femtosecond-assisted laser surgery with the LenSx Laser, and it explores many of the reasons why and how these surgeons use the device to deliver top-tier care to their patients. Regardless of whether you are a seasoned laser refractive surgeon or are just beginning to evaluate the technology, we hope you enjoy the information shared herein and gain some insights to help you in your own quest for surgical perfection.

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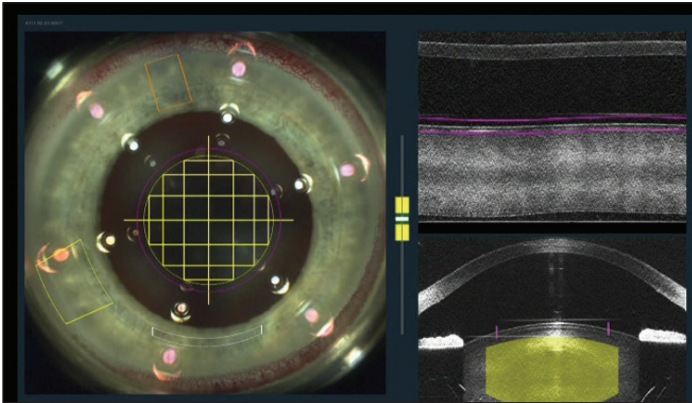


Figure 1. The LenSx Laser's software is designed to optimize precision in making arcuate incisions, the capsulorhexis, and fragmenting cataractous lenses.

Dr. Yeu: We are going to begin our discussion with the nonclinical components of incorporating advanced cataract surgery technology into the practice, and then delve into the clinical advantages. For starters, I want to know which components of the Cataract Refractive Suite (Alcon) do each of you use?

Dr. Goldman: My team and I have access to a LenSx Laser (Alcon) and a VICTUS laser (Bausch + Lomb), and I have access to the INFINITI and CENTURION Vision Systems (Alcon). Previously, I have used the LENSAR laser (LENSAR).

Dr. Goldberg: In the past, I would travel up to Beverly Hills to use the CATALYS (Abbott Medical Optics) and the LenSx systems, and I have gone elsewhere to use a LENSAR laser. We recently began using a LenSx Laser with two CENTURION Vision Systems.

Dr. Majmudar: My team and I have had a LenSx Laser in our surgery center for almost a year and a half, and we recently upgraded to the VERION Image Guided System (Alcon). We have always had the INFINITI Vision System, and now we use the CENTURION Vision System.

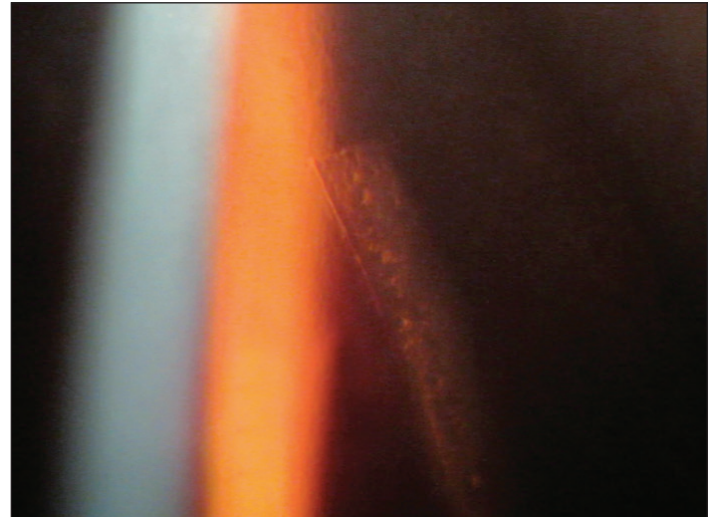


Figure 2. An arcuate incision made with the LenSx Laser, at 3 months.

"I have about a 35% femtosecond laser adoption rate, but I find the adoption of multifocal and accommodative lenses has increased 10% more as well."

—Dr. Goldberg

Dr. Yeu: I moved to Virginia Eye Consultants in Norfolk 2 years ago. The practice administrators had recently incorporated the LenSx Laser, as well as the CENTURION Vision System and VERION Image Guided System. We have extensive experience with the LuxOR Ophthalmic Microscope (Alcon) as well, and the optics on that are, bar none, the best optics on the market for cataract surgery, in my opinion.

EASY PATIENT DISCUSSIONS, MORE PREDICTABLE SURGICAL OUTCOMES

Dr. Yeu: How has the femtosecond laser changed the way you offer cataract surgical options to your patients? Has it increased your adoption rates?

From the Literature

"Comparing refractive predictability, 41.6% of eyes were within ± 0.25 D of target refraction in the laser group compared to 28.1% of eyes in the conventional group." More patients were within 0.50 D of the intended target.

"In this study, we found that the use of an intraocular femtosecond laser resulted in significantly lower IOL power calculation errors as expressed by a smaller MAE [mean absolute error] than in manual capsulorhexis. The more predictable size, shape, and position of a femtosecond laser-created capsulorhexis may contribute to minimized IOL misalignment, decentration, and tilt and therefore results in a smaller variability of the precalculated effective lens position."

Filkorn T, Kovács I, Takács A, et al. Comparison of IOL power calculation and refractive outcome after laser refractive cataract surgery with a femtosecond laser versus conventional phacoemulsification. *J Refract Surg.* 2012;28(8):540-544.

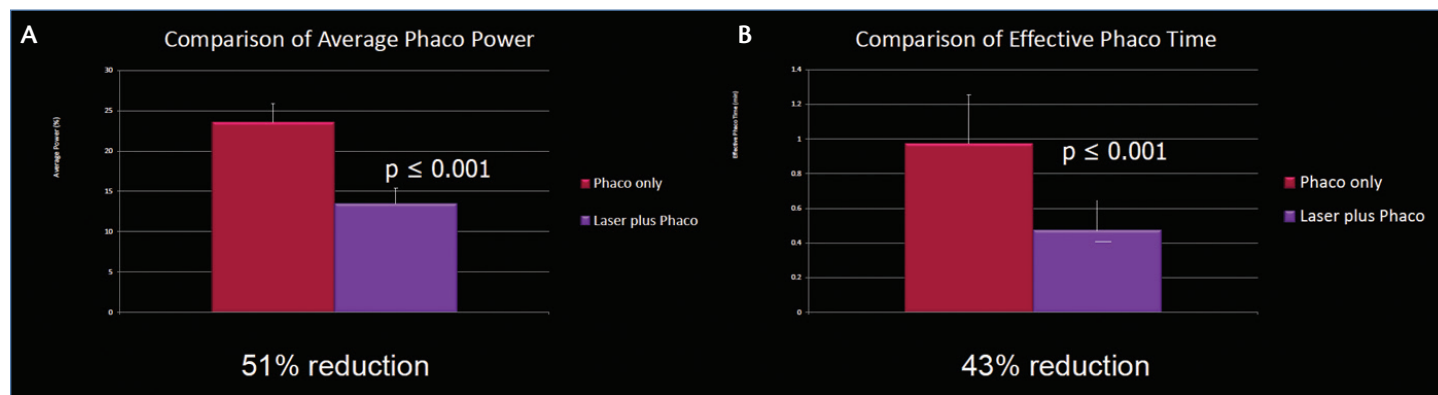


Figure 3. Reduction in phaco power and time with the LenSx Laser. The chop pattern efficiently fragments the lens for removal with reduced phaco power and time (A and B). (Data adapted from: Nagy ZZ, Takacs A, Filkorn T, Sarayba M. Initial clinical evaluation of an intraocular femtosecond laser in cataract surgery. *J Refract Surg.* 2009;25:1053-1060.)

Dr. Goldberg: For cataract surgeons not using advanced technology, I think the most difficult part is talking about money and delivering results. What do you do when you get that unhappy patient? I feel very comfortable talking about the femtosecond laser technology. Now that we have it right at our local surgery center, it is the easiest conversation I have with patients. It is simple to explain, and patients quickly understand the precision afforded by a laser versus a manual technique. It is what I would recommend for my own family.

Dr. Yeu: Has having the femtosecond laser technology changed your adoption rate?

Dr. Goldberg: I have about a 35% femtosecond laser adoption rate, but I find the adoption of multifocal and accommodative lenses has increased 10% more as well.

Dr. Goldman: I find the hardest part about the preoperative conversation is that most of my patients think cataract surgery has always been performed with the laser. So, my technician describes the surgical options to cataract candidates. Once we schedule a patient for cataract surgery, their first visit is to have their measurements taken. The technician then talks with the patient about the surgical technologies and lens options appropriate for him or her, and the patient can follow up with me for further information as needed. This strategy saves a lot of chair time. I feel it is important to make sure patients understand what is involved with their surgery.

Dr. Majmudar: The first question we have to ask ourselves is this: If I think I perform great cataract surgery, why do I need a laser? For me, the answer is that I want to deliver both the best surgical outcomes possible and the most satisfying patient experience.

When my staff and I talk to patients about the benefits of the LenSx Laser, we meet with very little resistance. Everybody likes the idea of greater surgical precision. This is a tool that I think definitely improves surgical outcomes (Figure 1). Yes, cost

is a barrier for some patients. I practice within a range of socioeconomic strata, and I perceive a disparity of adoption rates for premium technologies between different groups. However, within the past 18 months, I have definitely seen an increase in my practice's LenSx Laser adoption rates. At the outset, approximately 10% of my cases elected to have their surgery using the LenSx Laser; currently, 20% to 25% of my patients opt for the laser. The largest segment of my patients who are interested in the laser are the patients who choose to have monofocal lenses with arcuate incisions (Figure 2). In addition, these incisions can be opened postoperatively at the slit lamp in cases where the flattening effect has been less than expected.

Dr. Yeu: Gaining lines of uncorrected vision is ideal, and the ability to help those patients who otherwise would have lived with compromised vision has been rewarding. When I was in an academic setting, my conversion rate was probably 15%, and since joining Virginia Eye Consultants, my adoption rate has increased to 55% in 2014. Our cataract surgery volume has increased 33% from 2 or 3 years ago, and I think some of this is easily attributable to the fact that we are more reliably meeting surgical targets.

THE LENsX LASER DIFFERENCE: PRECISION IN THE ENTIRE ANTERIOR SEGMENT AND SPEED

Dr. Yeu: What specific factors does the LenSx Laser possess that can clinically help to augment the cataract surgery experience? With the SoftFit Patient Interface, what would you say is your rate of complete capsulorhexis, or free-floating capsulorhexis?

Dr. Goldberg: I have not seen an incomplete capsulorhexis with this software and patient interface.

Dr. Goldman: I consistently see complete capsulotomies since the SoftFit PI.

Dr. Yeu: Dr. Majmudar, would you say that the upgrade to

the LenSx Laser has increased your speed? Certainly, among the femtosecond laser systems, I know there is a difference in speed.

Dr. Majmudar: When we discuss speed, we have to look at the surgeon's overall experience, from the time the patient is brought under the LenSx Laser, to the time the phaco procedure is completed. From the standpoint of the speed of the actual phaco procedure, the laser removes the step of having to manually create the capsulorhexis. It also prechops the nucleus, so there is definitely a time savings during phacoemulsification, as these steps are completed already with the laser. Also, there is no question that the femtosecond laser reduces the amount of ultrasonic energy used in the eye to extract the cataract (Figure 3), and that reduction in energy output protects the cornea's health. I see a high number of patients with Fuchs' dystrophy, and I recommend the LenSx Laser for them, because it is safer for the endothelium.¹ The LenSx Laser offers a more efficient procedure that minimizes surgical trauma to the eye.

Dr. Goldman: In terms of safety of the femtosecond laser, I agree with Dr. Majmudar that it is a no-brainer in eyes with dense lenses, particularly those with low endothelial cell counts.

INTEGRATING THE LENsX LASER FOR OPTIMAL EFFICIENCY

Dr. Yeu: Can we offer advice on how to make surgery with the LenSx Laser as efficient and streamlined as possible, so it does not slow down the surgical flow? What is the arrangement for each of you?

Dr. Goldman: I like that the LenSx Laser does not have a fixed bed, so we can roll the patient directly into the OR. That certainly saves some time and is easier for the patient.

Dr. Goldberg: Sometimes, if I have mixed cases between two rooms, I will perform a standard cataract surgery, then a laser cataract surgery, and then another standard cataract surgery while the anesthesiologist moves the laser patient into the next room. It requires a little more finessing with my surgery scheduler.

One other consideration: Paul Ernest, MD, told me that if he is creating arcuate incisions superiorly, he makes them at 9 mm. If he is going to make arcuate incisions temporally, however, he places them at 8 mm, to account for the posterior corneal curvature.

Dr. Yeu: I find it very encouraging that on average, it only takes me about 2 minutes of total surgical time to complete the LenSx Laser procedure, with total laser treatment time under 30 seconds for all incisions, capsulotomy, and lens fragmentation together [*editor's note: information based on timed surgical videos*]. Thus, it can be done in-between cases. Because the LenSx laser requires patients to have a certain level of dilation, if you are working between two rooms, I suggest scheduling the laser patients in between two traditional cases, so you are not waiting for patients to dilate.

"The first question we have to ask ourselves is this: If I think I perform great cataract surgery, why do I need a laser? For me, the answer is that I want to deliver both the best surgical outcomes possible and the most satisfying patient experience."

—Dr. Majmudar

Dr. Majmudar: I schedule a LenSx Laser procedure as my first case of the day. While I am working on that patient, the staff brings a patient who is not having a LenSx Laser procedure into our first OR. I perform that standard surgery second, while the staff takes the LenSx Laser patient into the second OR for cataract removal, and the cycle is repeated. For us, this seems to be the most efficient process for the six surgeons in our center.

THE VERION IMAGE GUIDED SYSTEM

Dr. Yeu: Can anyone share their experience using Alcon's VERION Image Guided System?

Dr. Majmudar: We have begun doing much of our treatment planning on the VERION Image Guided System, which helps us determine what contribution the lens, the wounds, and/or the arcuate incisions will give to the overall corneal power. The VERION Image Guided System has a recent software upgrade that offers much more customization in terms of astigmatism planning. The system also allows us to track our outcomes data, which I believe every surgeon should do. Outcomes-tracking creates a standardized platform from which to base our surgery planning. Until we start tracking our outcomes, we don't know what we don't know.

CENTERED CAPSULORHEXES, MOUNTING EVIDENCE, AND REFRACTIVE OUTCOMES

Dr. Yeu: I agree that the Cataract Refractive Suite can improve surgical outcomes. It can raise our existing skillset another level or two by standardizing the capsulorhexis and providing the lens-fragmentation techniques.

Dr. Goldman: Having spent many years working in academic centers, I am quite comfortable creating a capsulorhexis manually. Yet, ophthalmic residents often are not so comfortable with this maneuver, so the femtosecond laser is certainly an advantage for those surgeons. For veteran surgeons, I think it is also nice to have the automated option.

Dr. Yeu: Does it make a difference in the refractive outcome to have a perfectly round, centered capsulorhexis versus the dynamic differences among manual capsulorhexes? Does the capsulorhexis have to be continuous and linear?

TABLE 1. DISTRIBUTION OF INTRAOCULAR LENS TILT >5° AND DECENTRATION VALUES > 0.4 MM IN EYES THAT UNDERWENT FEMTOSECOND LASER AND MANUAL CONTINUOUS CURVILINEAR CAPSULORHEXIS			
	Laser CCC	Manual CCC	P Value
Horizontal tilt (°)	0/20	1/25	> .05
Vertical tilt (°)	0/20	10/25	.008*
Horizontal decentration (mm)	0/20	6/25	.036*
Vertical decentration (mm)	0/20	1/25	> .05
Total decentration (mm)	0/20	8/25	.017*
*P.05 between groups using chi-square test.			
“Holladay et al [†] calculated the critical amount of decentration to be 0.4 mm and tilt of 5°.”			
Data adapted from: Kránitz K, Miháltz K, Sándor GL, et al. Intraocular lens tilt and decentration measured by Scheimpflug camera following manual or femtosecond laser-created continuous circular capsulotomy. <i>J Refract Surg.</i> 2012;28(4):259-263.			
[†] Holladay JT, Piers PA, Koranyi G, et al. A new intraocular lens design to reduce spherical aberration of pseudophakic eyes. <i>J Refract Surg.</i> 2002;18(6):683-691.			

Dr. Goldberg: The science definitely suggests that it does. A study by Mastropasqua et al¹ published in 2014 examined morphologic and functional outcomes of the cornea between cataract surgery performed with the LenSx Laser versus the traditional manual technique. The authors concluded that eyes treated with the LenSx Laser exhibited less endothelial cell loss, reduced corneal thickness, and better incisional tunnel morphology as measured by endothelial and epithelial gaping.

Dr. Majmudar: As to the architecture of the capsulotomy and whether it makes a difference in outcomes, a few papers have shown there is a difference that a perfectly round capsulorhexis (as opposed to a manual one) improves the centration of the IOL and produces a much more stable refractive result. Michael Knorz, MD, and Zoltan Nagy, MD, in Europe have studied this extensively.² A study published by Filkorn et al³ in 2012 concluded that laser cataract surgery performed with the LenSx Laser produced much higher predictability in the IOL calculation compared to traditional manual surgery. In 2013, Kranitz et al⁴ showed that IOLs implanted in eyes that received a manual capsulorhexis had significantly greater tilt and decentration rates compared to eyes that received a LenSx Laser-created capsulorhexis (Table 1). Nagy et al² published a study of the LenSx Laser versus the manual technique in 2014 that showed better

“Outcomes tracking creates a standardized platform from which to base our surgery planning.”
—Dr. Majmudar

IOL centration with the laser. Moreover, initial data on cataract surgery performed with the LenSx Laser specifically, show only a 0.2% incidence of anterior tears to the capsular bag, compared to rates up to 5.3% in manual cataract surgery.⁵

The VERION Image Guided System enables the surgeon to center the capsulorhexis by three different parameters: the preoperative, undilated pupil, which is what I do most of the time; on the limbus; and on a dilated pupil. No matter how skillfully you can make a manual capsulorhexis, only the femtosecond laser can provide this level of customization.

Dr. Yeu: The Femtosecond Laser-Assisted Cataract Surgery (FLACS) literature review,⁵ published by Lawless et al, showed some very compelling evidence of close to zero IOL decentration or tilt achieved with the LenSx Laser.

Have each of you examined your own surgical outcomes? Compared with traditional cataract surgery, are your outcomes with femtosecond cataract surgery on target? Are they any closer?

Dr. Majmudar: As far as refractive results, I think some other variables may play a role. Using better biometry and even the ORA System (Alcon) may factor into better outcomes.

Dr. Goldman: I think it depends on your entire technology. I have been overwhelmingly impressed with the refractive outcomes produced with the LENSTAR LS 900 (Haag-Streit) and Holladay 2 Consultant formula (Holladay Consulting). My colleagues and I have a very high rate of achieving our refractive targets. I know that there are practices using very old IOLMasters (Carl Zeiss Meditec) with their femtosecond lasers, and I think they are operating at a disadvantage. Their capsulorhexes may be perfect, but because their biometry is not up to the latest technology, their surgery is not optimized.

Dr. Yeu: That is a key pearl of refractive outcomes. The final result is not dependent on any single component, but in the synergy of preoperative planning, good technology, and postoperative management.

Dr. Goldman: I think it is easier to prevent cystoid macular edema than treat it. I also think postoperative treatment has a role in the final result.

Dr. Goldberg: I think it is very appropriate to treat patients with both steroids and NSAIDs. In particular, I think we should pre-treat patients with an NSAID before we use the femtosecond laser.

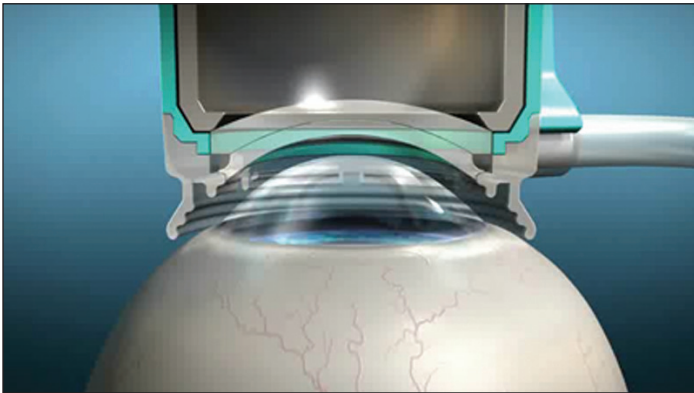


Figure 4. The SoftFit PI (Patient Interface) on the LenSx Laser enables fast and comfortable docking to the patient's eye.

"[Mastropasqua et al] concluded that eyes treated with the LenSx Laser exhibited less endothelial cell loss, reduced corneal thickness, and better incisional tunnel morphology as measured by endothelial and epithelial gaping."

—Dr. Goldberg

Because the intraocular concentrations of certain NSAIDs are so high after 1 drop, I usually instill the drop in the patient's eyes on the day of surgery, in the preoperative area. I know several surgeons who start this medication 1, 2, or 3 days before surgery; I may start it earlier in someone who is at high risk.

TIMING IS KEY

Dr. Yeu: How do each of you time a patient's pupillary dilation between using the LenSx Laser and taking the patient to cataract surgery?

Dr. Goldman: My team pretreats the patient with the NSAID before taking him or her to the LenSx Laser. Once the cornea is applanated, as long as there are no hypertensive issues, we will usually administer a drop of 10% phenylephrine to redilate the pupil before the patient enters the OR. Once in the OR, I like the epi-Shugarcaine technique. I have been using it for years on every patient, and I think it really helps maintain dilation.

FINANCIAL CONSIDERATIONS

Dr. Yeu: What was the thought process of your fellow surgeons and administrators before you purchased the LenSx Laser?

Dr. Majmudar: We had a surgery center with 8 to 10 committed users, and we thought we had an adequate volume of advanced-technology IOL patients. We purchased the LenSx Laser thinking we would break even on the investment in 4 years.

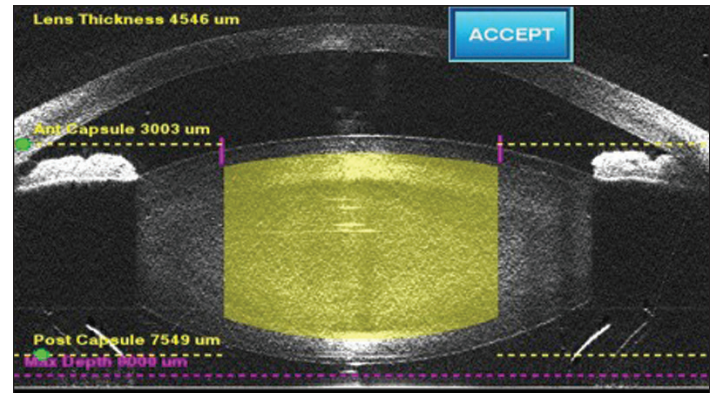


Figure 5. The LenSx Laser is guided by real-time, high-definition OCT imaging that uses circle and line scans to assist viewing.

In fact, it took us just under 12 months to break even. Now, our LenSx Laser volume is 4 times what we expected. With the surgeons working together at the surgery center, we found that it exceeded our expectations, and we are also now attracting other surgeons to our center.

Dr. Goldberg: My center had been doing well with advanced-technology IOLs. Alcon implemented financing of the LenSx Laser that my team and I felt comfortable with. We felt like it was the right decision for us.

Dr. Goldman: Our cataract surgeons who had not previously used a femtosecond laser in refractive surgery adapted very quickly to the LenSx Laser, and all of them now perform a high volume of LenSx Laser surgery. The reality is that the LenSx Laser has a very low learning curve.

VISION CARE PACKAGES: STRAIGHTFORWARD & STREAMLINED

Dr. Yeu: Our practice administrators simplified our offerings by creating a distance vision package versus a distance and near vision package. There are two price points within the distance package: one if we are implanting a toric IOL, and one for femto-created arcuate incisions exclusively.

Dr. Majmudar: My team and I designed two vision care packages. One is the distance package, broken into toric versus monofocal lenses. It includes the implantation of a monofocal lens plus an arcuate incision, use of the LenSx Laser, and surgical planning with the VERION Image Guided System. The patient pays extra to receive a toric IOL, which includes the increased cost of the lens. The second package is to receive a multifocal implant for distance and near vision.

I think these two packages are easy for patients to understand and select from. Previously, we had a laundry list of procedures, and it was getting confusing for our coordinators, as well as our physicians and patients.

Dr. Goldberg: You are right, and I want my practice to even-

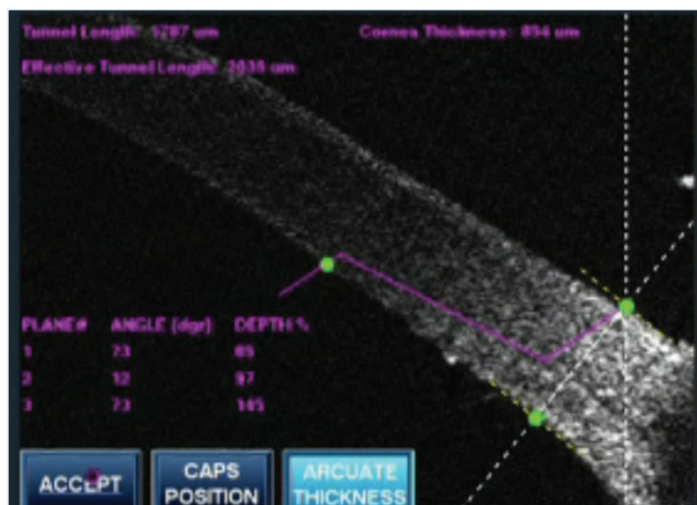


Figure 6. The LenSx Laser creates triplaned (shelved) arcuate incisions.

tually adopt similar packages. Because not all of our providers are using the LenSx Laser yet, we still have to offer a menu of treatment options. I think that once all of our surgeons are on board, we will offer three refractive packages.

Dr. Goldman: From a practical standpoint, I feel more comfortable correcting large amounts of astigmatism with a toric IOL. Most people who are interested in a multifocal lens do not have dense nuclei and may not benefit as much from femto-fragmentation of the lens.

LENsX LASER LEARNING: TIPS & TRICKS

Dr. Yeu: We all have various levels of experience using the femtosecond laser for cataract surgery. What pearls can we offer readers on the learning curve of adopting laser-assisted cataract surgery?

Dr. Goldman: I think the most important thing is to remain calm during the first few cases, and to continually communicate with the patients. In my ASC, patients do not get overly sedated prior to applanation, and they can get anxious without what I call “verbal anesthesia.” I find it so important to continually speak to the patient in a calm voice. It really makes the whole procedure a lot better for the patient.

Dr. Majmudar: I agree that the “verbal anesthesia” is very important, and I think the surgeons who are used to doing femtosecond LASIK surgery are used to talking patients through the procedure. If there are 30 to 60 seconds where nothing is happening, and you are not saying anything, the patient may be tempted to look around.

Dr. Goldberg: I hesitate to liken femtosecond laser cataract surgery to LASIK surgery, because there are some definite differences. I see a huge advantage in using the LenSx Laser to fragment the nucleus. In fact, I no longer use a fluid wave—I usually just use my cannula and spin the lens on the pneumodissection that probably

“Because the intraocular concentrations of certain NSAIDs are so high after 1 drop, I usually instill the drop in the patient’s eyes on the day of surgery, in the preoperative area. I know several surgeons who start this medication 1, 2, or 3 days before surgery; I may start it earlier in someone who is at high risk.”

—Dr. Goldberg

happened from the gas bubble down in the lens. Surgeons will find different approaches that work quickly for them.

Dr. Majmudar: I would suggest that surgeons new to the femtosecond laser first get used to the procedure of docking the laser to the patient’s eye (Figure 4). It is important to understand the architecture of the wound and how the femtosecond laser is making the incision. I use the LenSx Laser’s HD-OCT image to adjust the height of the incision, the depth of the tunnel, and other parameters (Figure 5). The LenSx Laser is designed to offer a high level of customization until the surgeon feels confident in the incision.

I learned a very important pearl about how to hydrate these incisions. They hydrate very differently than what we would use for a metal keratome blade. In manually made incision, we usually enter with a cannula and just hydrate the corners of the incision, and it seals up perfectly. With the laser technique, I found the best approach is to lightly hydrate the roof of the incision using the cannula. You do not have to go very far in; you can remain quite anterior in the incision’s lip, but hydrate the roof of that incision. Doing this, the eye firms up very, very quickly, with no leakage in most cases.

Dr. Yeu: I agree. The laser creates a very nice triplaned or shelved incision (Figure 6) and within that groove, you can hydrate posteriorly toward the sclera, which also seals the entrance very nicely.

Dr. Majmudar: As far as the subsequent steps of surgery, I think the biggest mistake surgeons make in the beginning is assuming that the capsulorhexis is complete. Although it is complete almost 99% of the time, it is best not to assume.

Dr. Goldman: I agree. I sort of pull everything toward the center very slowly, and it works for me.

Dr. Majmudar: I use that technique. I dimple down with the forceps, and this allows me to see everything. I do not remember who originally described this technique, but you pinch down on the lens, and then you can just peel the whole thing off in about 1 second.

“We purchased the LenSx laser thinking we would break even on the investment in 4 years. In fact, it took us just under 12 months to break even.”

—Dr. Majmudar

Dr. Goldberg: We talked so much about what to do in the OR, what pearls do you have on the actual laser?

Dr. Majmudar: Well, the first pearl for operating the laser is: know what the laser is doing. Be aware, be interactive, and adjust things. Resist the temptation to default all your settings. Look at how the OCT is reading. Make sure that when you are setting up the capsulorhexis, that you are setting it at the highest point of the curvature, making sure that the architecture of your wound is exactly so. If it is not, adjust it. That’s what the flexibility is there for.

Dr. Goldberg: Right. Have you found a lot of cyclorotation with the LenSx Laser?

Dr. Majmudar: We use the reference image that we take during the preoperative workup with the VERION Image Guided System and compare it to the image taken at the LenSx Laser at the time of surgery. Except for one case that had 13° or 14° of cyclorotation, for the most part, I see within 1° to 3° of cyclorotation. No matter the amount, the VERION Image Guided System compensates for cyclorotation.

RESPONSIVE PREMIUM-LEVEL SERVICE & SUPPORT

Dr. Yeu: I have to say that I love the level of service and responsiveness we receive from the LenSx Laser support team:

it is unbelievable, fantastic. They are very responsive. Of course, it is quite inconvenient if your LenSx Laser goes down during the day. But I had somebody drive 3 hours to get to my surgery center at 6:00 pm so that the laser would be ready for the next OR day—now that is premium-level service. What do you guys think?

Dr. Majmudar: I will take it one step further. As a company, it is impressive to launch the first femtosecond laser FDA-cleared for cataract surgery. Beyond that, however, it is amazing how responsive Alcon has been, listening to the surgeons and incorporating their ideas into upgrades. The VERION Image Guided System is a great example: Alcon’s team heard our suggestions on how to improve it, and they made numerous changes in a relatively short timeframe. I really appreciate that the company is so responsive.

Dr. Yeu: I agree; it is pretty clear that Alcon listens to users to improve its technology.

Dr. Goldman: Alcon’s service is really exceptional.

Dr. Goldberg: I have worked in the same territory for 10 years. My Alcon surgical rep has been the same person the entire time, whereas other companies have changed reps two or three times. I think this fact speaks not only to service, but to relationship-building and trust. ■

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CENTURION® Vision System Important Product 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 Product Information for the 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 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.

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 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 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:

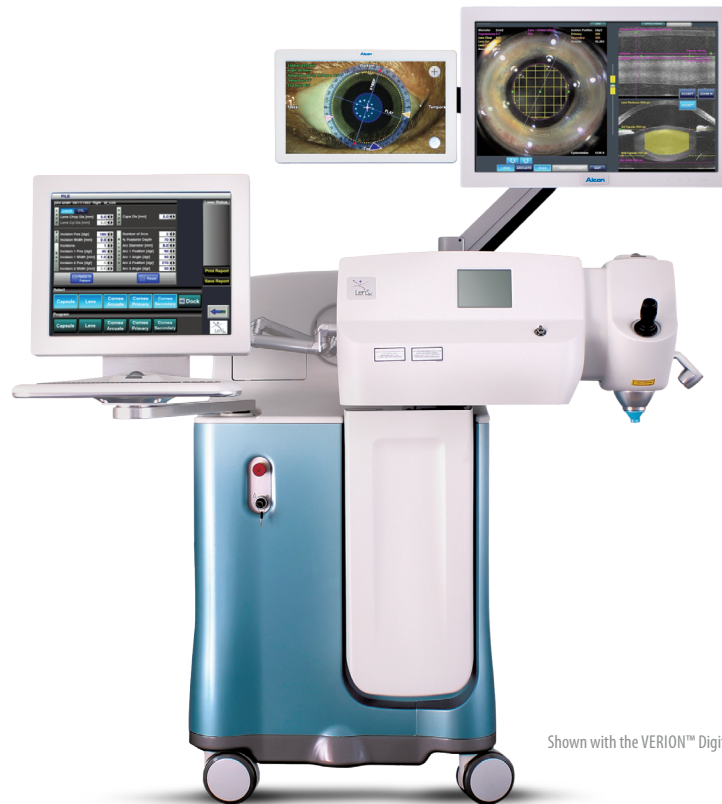
To ensure the accuracy of VERION™ Reference Unit measurements, device calibration and the reference measurement should be conducted in dimmed ambient light conditions. Only use the VERION™ Digital Marker in conjunction with compatible surgical microscopes.

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.



Cornea. Capsule. Lens. One optimized solution.



Shown with the VERION™ Digital Marker

Demand precision across the entire anterior segment.

Part of The Cataract Refractive Suite by Alcon, the LenSx® Laser is designed to optimize performance across the entire anterior segment to deliver:

- Precise primary and secondary corneal incisions, and arcuate incisions
- Complete, reproducible capsulotomies with pristine edges¹
- Versatile fragmentation patterns

1. Alcon data on file.

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Visit LenSxLasers.com, or talk to your local Alcon representative about how the LenSx® Laser can help enhance the precision of cataract surgery with AcrySof® IOLs.


COMPLETE PRECISION

CRST
Cataract & Refractive Surgery Today

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