Innovations in cataract and refractive surgery

Updates to the LenSx Laser and WaveLight Refractive Suite improving the user experience

Featuring:
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The physicians are consultants for Alcon and received compensation for their contributions to this supplement.
Innovations in cataract and refractive surgery

LenSx Laser and WaveLight Refractive Suite continue to evolve

by Michael Gordon, MD

At this meeting, you have the opportunity to see new software and hardware developments across the Alcon (Fort Worth, Texas) laser portfolio. This article will highlight some of the innovations from Alcon in refractive and femtosecond laser-assisted cataract surgery (FLACS). The LenSx Laser (Alcon) elevates precision and efficiency in cataract refractive surgery and provides a precise and predictable approach to cataract surgery. It has been used in more cataract surgeries worldwide than any other femtosecond laser. In fact, its evolving technology has been used in more than 1 million cataract refractive procedures in the United States alone. Alcon continues to maintain its market leadership despite competitive platform entry. LenSx Laser procedures have grown 8–10% during the past 2 years as more surgeons acquire the technology (Alcon data on file). FLACS now accounts for nearly 12% of all cataract procedures, and that penetration continues to improve quarter after quarter (Market Scope Q4-17).

The LenSx Laser offers these benefits: enhanced procedure automation; precise and customizable incision architecture; pristine capsulotomy; versatile fragmentation patterns; a simple and effective one-piece patient interface; and innovative, high definition OCT technology for precise incisions.

The LenSx Laser was the first femtosecond laser for laser-assisted cataract surgery. With the software upgrade launching at this meeting, you will see a variety of enhancements. First and foremost, the new graphic user interface (GUI) has been enhanced for further efficiency (Figure 1), and the flow is more intuitive. Many of the buttons and steps have been simplified based on surgeon feedback. Alcon also enhanced the laser’s incision-making capability. Surgeons now have the ability to see an enhanced visualization of the angle for improved incision placement. As you can see in Figure 2, they added a limbal reference line in yellow to assist in the planning process. For secondary (side port) incisions, the angle range options have been widened as well. The LenSx Laser already had the ability to do a LASIK flap. In this software launch, a side cut-only function has been added for increased refractive capabilities. For the cataract surgeon who may need additional cornea capabilities but does not have enough volume to support acquiring a femtosecond laser like the FS200 to be paired with an excimer laser, Alcon added the FS200 pocket and tunnel functions to the LenSx Laser. Having the flexibility to serve the corneal inlay market for presbyopia and tunnels for corneal rings is a welcome addition that delivers on Alcon’s promise to continuously develop the platform into a complete anterior segment/corneal workstation.

The WaveLight EX500 excimer laser (Alcon) also includes new software features like the LenSx Laser. The new software on this platform will improve surgeon and technician ease of use as well. This improved GUI will provide better visibility under low light conditions due to the improved contrast for dark or fairly lit surgery rooms and enhanced typeface and font size. This same look and feel will be consistent across the WaveLight EX500, FS200 and WaveNet Planning Station (Figure 3). The new software is clearly arranged and designed for improved workflow and clearly identifies eye selection with a synchronized color scheme.

The WaveLight Refractive Suite includes new ergonomic enhancements designed to enhance surgeon comfort and convenience for the new platforms being manufactured. The keyboard is now illuminated for better visibility in dark surgery rooms. For controlled activation, the emergency stop switch has been integrated and recessed into the laser housing. Furthermore, the control panels have been improved and divided into surgeon and assistant areas, which increases comfort for the surgeon and staff. During installation of a new unit, surgeons will have the option of customizing the heads-up display (HUD) for their dominant eye.

Similarly, the WaveLight FS200 femtosecond laser is at the cutting edge of refractive technology. It integrates many new functions for fast, effective, and reliable femtosecond laser treatments. The combination of an optimized repetition rate at 200 kHz; a special scanning algorithm; and customizable energy and spacing parameters make the WaveLight FS200 femtosecond laser the fastest flap creation laser platform in the United States. CONTOURA Vision, introduced by Alcon in 2016, will also be featured. I have relied on this technology as well to deliver superior results in my practice. CONTOURA Vision has added a benefit to patient outcomes in those where we obtain good WaveLight Topolyzer VARIO images and fall within the approval range. As demonstrated in the FDA trial and since, rates of UCVA better than 20/20, better contrast, and improved visual symptoms make this a valuable addition to what we can offer our patients.

Alcon is offering additional color options for the WaveLight Refractive Suite that may fit your office surroundings better, and the LenSx Laser exterior color is now harmonized with the rest of the Alcon Cataract Refractive Suite. Both of these new options are available for viewing at the Alcon booth.

In this supplement, Terry Kim, MD, will highlight the LenSx Laser’s ability to shine in difficult cases, Cathleen McCabe, MD, will discuss the corneal capabilities, and Mark Lobanoff, MD, will discuss best practices for integrating CONTOURA Vision into your practice.

It’s an exciting time in ophthalmology, as the refractive and cataract worlds become one.

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Please refer to pages 7 and 8 for Important Product Information about the Alcon products described in this supplement.
LensX Laser technology for routine and complex cataract cases

by Terry Kim, MD

As a cornea specialist and cataract surgeon at an academic institution, it has been exciting to have the latest technology in cataract surgery at our disposal. The LensX Laser (Alcon, Fort Worth, Texas) is one example of this technology that has proven to be a safe and effective option that we offer to our cataract patients.

A high percentage of my patients now choose the LensX Laser for their cataract surgery, which is an elective decision that comes with an out-of-pocket cost, and that percentage continues to grow. The LensX Laser offers higher precision and minimizes some of the safety concerns seen with manual procedures, and patients easily understand the advantages of laser technology in cataract surgery with minimal chair time and explanation. As a result, they have been receptive and motivated to proceed with femtosecond laser-assisted cataract surgery (FLACS).

Capsulotomy in routine and complex cases

The LensX Laser complements my cataract procedure well from numerous standpoints. For example, more than 99% of the time, I achieve a complete capsulotomy. It’s invaluable in routine cases, where it helps to ensure the position of the intraocular lens and this is extremely relevant to advanced technology lenses. The LensX Laser ensures that I have a consistently sized, shaped, and centered capsulotomy, with predictable overlap of the anterior capsule over the IOL optic edge, which contributes to optimal IOL centration and stability long term.

It is also helpful in complex cases, such as mature white cataracts. In my experience, these cases are unpredictable when the capsulotomy is performed manually. Despite the use of an ophthalmic viscoelastic device and trypan blue staining, intracapsular pressure frequently leads to extension of the anterior capsule opening and the well-described Argentinian flag sign, which increases the risk for intraoperative complications, including posterior capsular extension, vitreous loss, posterior lens dislocation into the retina, and complex IOL management. For these scenarios in particular, it is advantageous to have the capsulotomy performed in a closed anterior chamber setting to minimize these complications and ensure a successful anatomic and visual outcome (Figure 1a and b).

Lens fragmentation

Another underappreciated and overlooked benefit of FLACS with the LensX Laser is the lens fragmentation portion of the procedure. I see a lot of dense cataracts in my practice, and I have a specific lens fragmentation pattern for these cases that makes the phacoemulsification portion of the procedure more predictable and controlled. I am a chop surgeon, and before using the LensX Laser, I was using a horizontal chopper that required passing the chopper underneath the anterior capsule and around the lens equator while immobilizing the lens with my phaco handpiece. Many surgeons are not comfortable with this maneuver. Now, thanks to the FLACS lens fragmentation pattern, I am performing my horizontal chop procedure in the central nucleus with the phaco handpiece to immobilize the lens and a Nichamin-style chopper to perform a quick horizontal chop without having to pass the chopping instrument blindly under the anterior capsule. Others may opt to do a vertical chop here, but the same principle applies, whereby the need for passing a second instrument peripherally and/or blindly is eliminated, and instead the second chopping instrument is kept in the middle of the nucleus where it is clearly visible and undoubtedly safer. This approach also helps with the extremely dense lens that is typically accompanied by a leathery posterior plate that makes it difficult to completely fracture no matter what technique is being used. By employing these lens fragmentation patterns, where I use three radial lines in a spoke pattern to fragment the dense lens into six pie-shaped pieces (Figure 2), I can use my chopping maneuver to then fracture the dense nucleus (even those with leathery posterior plates) along these fragmentation planes completely in a predictable manner, which reduces the use of ultrasound energy and phaco time as well as the overall struggle of managing the flexible posterior lens fibers.

Incisions

Another area where the LenSx Laser makes a difference is with arcuate incisions. When targeting a specific visual outcome in cataract surgery, whenever possible I target emmetropia and plan to address any and all factors that could impact my planned correction target. This includes evaluating preop astigmatism, SIA, and the potential for residual astigmatism that may hamper full refractive correction. We have all been performing limbal relaxing and astigmatic keratotomy incisions manually as part of cataract surgery for a long time, and their utilization has certainly increased with the arrival of presbyopia-correcting IOLs in an effort to help manage residual astigmatism that can impact the visual outcomes with multifocal IOLs. Anything we can do to improve the accuracy and predictability when creating these incisions is welcome, and I think that arcuate incisions performed with the femtosecond laser offer a higher level of precision than even I can achieve using an AK knife. We know from the high definition OCT image of the cornea that we can program the architecture of these incisions more accurately in terms of their depth, optical zone, and angle of incidence. Most of us typically do not use a pachymeter to...
Intraoperative planning with the LenSx Laser

by Cathleen McCabe, MD

I'm excited about the fact that the newest upgrade will provide the ability to create tunnels in the cornea and create pockets. As we expand the indications for corneal procedures, it will help our patients with other refractive procedures, other therapeutic treatments for complex corneal disease, and presbyopia correction in the future. One of the strengths of this platform is the adaptability and the ability to continue to present new treatment options in the future that will allow us to help our patients.

Figure 1. Thick lens

Kim:
CONTOURA Vision provides a unique, truly customized LASIK procedure

by Mark Lobanoff, MD

are unique, and every cornea is slightly different. Here, the ridges narrow and flare out at different points (blue arrows). These small topographic imperfections create astigmatism that is mildly irregular and asymmetric.

In the bottom axial power maps, the yellow shows where the light is being focused more intensely and the light green a little less so. The topography is driving a mildly asymmetric astigmatism (red arrows). A pure perfect astigmatism pattern looks like a bowtie. In a perfect cornea, they would be equal in direction, shape, and magnitude. The images are not perfect bowties. There is asymmetry that is created by the slight imperfections in the corneas’ astigmatism.

Figure 2 shows the ablation profile that a traditional LASIK or a Wavefront Optimized laser would use to treat astigmatism. It ablates in a perfect rectangular shape.

There is a standardized amount of tissue removal in the purple zone all the way across the ridge that is generating minus cylinder astigmatism. This ablation profile is assuming that the astigmatism is perfect, linear, and symmetrical. If this perfect rectangular grid pattern is placed on the corneas in Figure 1, most of the ridge will be removed. But some parts of the ridge, where the yellow tapers down, don’t need that full correction. The traditional laser pattern would be overcorrecting those areas. Areas where the astigmatism flares out and becomes broader and

Figure 2. Thin lens changer. It used to be anxiety pro-

For me, the LenSx Laser is critical in complicated cataracts. With white cataracts, it is a game changer. It used to be anxiety pro-

Figure 2. Thin lens changer. It used to be anxiety pro-

free floating capsulotomy, and the rest of the case goes safely and smoothly. Dense cataracts, especially in patients who have endothelial dystrophy or Fuchs’ dystrophy, are another instance where the LenSx Laser plays a huge role in softening the nucleus and allowing for less phaco power. The LenSx Laser also allows for a quicker nucleus disassembly so that there is less fluid going through the eye. That makes a huge difference in the health of the endothelium and the speed of recovery after surgery.

Since we first purchased the LenSx Laser in 2012, I have been interested in a complete refractive treatment of the eye and managing astigmatism that could interfere with the patient’s postop visual outcome. While the advent of toric lenses helped us make great strides to correct astigmatism at the time of cataract surgery, arcuate incisions have remained in my tool kit to address residual astigmatism that would impact a complete refractive correction. However, using a blade (manual) to cut an arcuate during cataract surgery can be unpredictable. The availability of LenSx to create precise and reproducible arcuate incisions has allowed me to confidently manage even low amounts of astigmatism as well as take one less manual step in performing cataract surgery. I think any amount of astigmatism correction is within my reach with laser or toric lenses or a combination. This has caused us to focus on our outcomes and target zero residual astigmatism in our patients.

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Figure 1. Topographies of two different corneas

continued on page 6

continued from page 4

Figure 1. Topographies of two different corneas

Figure 2. Ablation profile that a traditional LASIK or Wavefront Optimized laser would use to treat astigmatism

Source: Cathleen McCabe, MD

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more intense need more treatment. This traditional classic pattern would undertreat those areas.

Although traditional and Wavefront Optimized LASIK do a good job treating astigmatism, these are examples of how it could be better. CONTOURA Vision is superior to these options because it takes 22,000 different measurements of each cornea’s topography, determines where that patient’s corneal astigmatism flares or tapers, and corrects it perfectly for that pattern. Every cornea is treated uniquely. It is not a cookie-cutter approach like we have had in the past. This is one reason why patients see better and have better optical quality with CONTOURA Vision than with traditional LASIK.

Case study
A 32-year-old woman underwent LASIK on her left eye. Preoperatively, with her glasses, she could see 20/20. Her manifest refraction was −3.75 −0.50 × 55 correcting to 20/15. This was good vision, but CONTOURA Vision allows surgeons to take patients’ vision beyond what is possible with glasses or contacts, both in quantity (Snellen acuity) and in quality. On the first day after CONTOURA Vision LASIK surgery, this eye could see 20/15 without any glasses or contacts, a full line beyond preop best corrected visual acuity. Three months later, this patient was 20/15+1, and her manifest refraction was perfect at plano sphere. Here’s how it was done.

The ablation profile in Figure 3 shows the small unique topographical abnormalities on this cornea that CONTOURA Vision corrected. This is in addition to the customized myopic and astigmatic correction that was applied. The three purple areas are where CONTOURA Vision added more laser treatment and removed more tissue. This is the step that has never been done before, and this is how we take LASIK surgery to the next level. Traditional LASIK and Wavefront Optimized LASIK don’t treat these abnormalities, and these abnormalities have an effect on the way light is focused. They affect quality of vision.

WaveLight Topolyzer VARIO, the topolyzer that Alcon has provided to use with CONTOURA Vision, allows for some advanced monitoring and analysis of each cornea. Surgeons can compare the preoperative and postoperative exams to see the changes that were made to the cornea. The top right image in Figure 4 is the patient’s postoperative topography that was performed about 3 months after LASIK surgery. The bottom right is the preoperative exam. The blue image is the difference between the two. This map highlights what CONTOURA Vision has done for this patient.

Examining the preoperative map, the green arrow is pointing out a small but critical butterfly-shaped abnormality directly in the center of the visual axis. Looking at the difference map, in the center of the patient’s pupil is the butterfly wing pattern of tissue removal that underwent a small unique treatment. This would not have been done in traditional or Wavefront Optimized LASIK. Notice also the unique ablation at the 5:00 position (red arrow) just outside the pupil (denoted by the white and black circle). Here, CONTOURA Vision recognized that the cornea needed less treatment than in other areas. When the laser makes the cornea perfect on its anterior surface and corrects all of these small topographic abnormalities, the optics are improved, and the eye is able to focus better than it was before.

Higher order aberrations
The Zywave wavefront analysis charts in Figure 5 show the patient’s ocular higher order aberrations before and after surgery. The preoperative higher order aberrations are on the left. The gray bars represent averages for the United States’ population, and the tan and blue represent the abnormalities present in this patient. Some of the significant higher order aberrations that affect vision quality are trefoil, quatrefoil, and secondary astigmatism. At night, these three cause distortion and create glare, starbursting, and halo effects. When these are present, it changes the quality of the image that the patient sees.

Before surgery (on the left), the patient had a fair amount of trefoil (red arrow). The map on the right shows that this has been dramatically reduced because CONTOURA Vision treated all of the small corneal abnormalities that created the trefoil.

Shown in Figure 6 are the pre- and postoperative point spread function (PSF) maps for the eye. The goal is for all of the blue to be in the
white circle (denoting the foveola of the macula), where the very best vision is. On the left, there are faint stray areas of blue wisps extending outside of this white circle, which causes a starburst effect in the patient’s nighttime vision. After surgery, on the right, the blue is contained almost completely within the white circle, which is why the patient sees better at night than she did before surgery. At 6 and 12 months out, this map will improve even further.

The maps in Figure 7 show the total eye’s higher order aberrations present. Preoperatively, on the left side, the blue arrow is pointing to an area of yellow that is extending beyond the 4-mm circle. That same area on the right side (postoperatively) shows that the blue has been drawn out beyond that 4-mm circle. Treatment with CONTOURA Vision has pulled the higher order aberrations away from the center of the pupil, and because the pupillary zone is so critical for good vision, pulling that outward improves vision as well. Look carefully again at the preoperative map. The center of best focus is the smallest, darkest blue circle “bullseye,” and it is displaced ever so inferiorly to the center of the crosshairs, denoting the central visual axis. Examining the postoperative map, this “bullseye” is now perfectly centered on the crosshairs. This is a powerful image because it shows that CONTOURA Vision is able to align the optical correction perfectly.

Some reports indicate that Fourier analysis is even more accurate at examining corneas than Zernike or higher order aberrations. In Figure 8 on the left is a map of the patient 3 months after surgery showing spherical equivalence. We want this image to be perfectly symmetrical and centered, and it is perfect after this CONTOURA Vision treatment. The map on the right denotes irregularities in the corneal topography with regard to shape. If irregularities were present, they would be in different colors. This is a perfect cornea with no irregularities.

Figure 9 is a beautiful postoperative cornea. This is powerful technology. Surgeons are now able to make patients’ corneas topographically better than we ever have before. Additionally, we can achieve postoperative vision that is better than patients had preoperatively with glasses or contact lenses. However, these optimal results require work. We must make sure that our staff understands and embraces the technology, and we must obtain good images from our technicians. These are the keys to a great result with CONTOURA Vision.

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**LenSx Laser important product information**

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

**Indication**
The LenSx Laser is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, phaco fragmentation, 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.

**Contraindications**
**Cataract Surgery Contraindications**
- Corneal disease that precludes applanation 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 that 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, glaucoma* 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.

*Glaucoma is not a contraindication when these procedures are performed using the LenSx Laser SoftFit Patient Interface Accessory

**Corneal Flap Contraindications**
- Corneal lesions
- Corneal edema
- Hypotony
- Glaucoma
- Existing corneal implant
- Keratoconus
- 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 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 instruments 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.

**Complications**
**Cataract Surgery AEs/Complications**
- Capsulotomy, phaco fragmentation, or cut or incision decentration
- Incomplete or interrupted capsulotomy, fragmentation, or corneal incision procedure
- Capsular tear
- Epithelial defect
- Epithelial in-growth
- Keratoconus

**Corneal Flap AEs/Complications**
- Corneal edema
- Corneal pain
- Infection
- Flap decenteration
- Incomplete flap creation
- Flap tearing or incomplete lift-off
- Free cap

**Attention**
Refer to the LenSx Laser Operator’s Manual for a complete listing of indications, warnings and precautions.
The Wavefront-guided LASIK procedure requires accurate and reliable data from the wavefront examination. Every step of every wavefront measurement that may be used in the calculation of the wavefront-guided LASIK procedure must be validated by the user. Inaccurate or unreliable data from the wavefront examination will lead to an inaccurate treatment.

Topography-guided LASIK requires preoperative topography-guided LASIK examination. Preoperative topography may affect the accuracy of the wavefront analysis and may result in poor vision after topography-guided LASIK.

Precautions: The safety and effectiveness of the WaveLight Excimer Laser System are not established for:
- use in patients who...

Contraindications: The WaveLight Excimer Laser Systems are contraindicated for use with patients who:
- ...

Warnings: The WaveLight Excimer Laser Systems are not recommended for use with patients who:
- ...

Information: This information pertains to all WaveLight Excimer Laser Systems, including the WaveLight ALLEGRO Topolyzer and topography-guided LASIK treatment. Poor quality topography maps may affect the accuracy of the wavefront-guided LASIK treatment. Preoperative topography examination may be required to provide a more accurate wavefront examination.

Topography-Guided Myopia: There were six adverse events reported in the topography-guided myopia clinical study. Four of the eyes experienced transient or temporary decreases in vision prior to the final follow-up visit. Subject 4 suffered from decreased vision in the treated eye, followed by trauma due to a razor blade. Subject 1 experienced retinal detachment, which was concluded to be unrelated to the surgical procedure.

Clinical Data

Myopia: The myopia clinical study included 290 eyes treated, of which 81 eyes were eligible for follow-up. Accountability at 3 months was 93.8%, 6 months was 99.1%, and 12 months was 93.9%. Of the 782 eyes that were eligible for the UCVA analysis of effectiveness at the 6-month stability time point, 98.3% were corrected to 20/20 or better, and 87.7% were corrected to 20/20 or better. Subjects who responded to a patient satisfaction questionnaire before and after LASIK reported the following visual symptoms: marked or severe level at least 1% higher at 3 months post-treatment than at baseline: sensitivity to light (52.9% vs. 43.3% at baseline); visual fluctuations (43.0% vs. 37.0% at baseline); and halos (42.3% vs. 37.0% at baseline).

Long-term risks of LASIK for myopia with and without astigmatism have not been studied beyond 6 months.

Information for Patients: Prior to undergoing LASIK surgery with a WaveLight Excimer Laser System, prospective patients must:
- ...

Attention: Please refer to the current WaveLight Excimer Laser System Procedure Manual for a complete listing of the indications, contraindications, and precautions.