

## WaveLight Refractive Suite: A game changer

by George O. Waring IV, MD

### *Offering a new generation of patients an advanced form of LASIK*

**A**s the economy begins to improve, consumers are showing renewed interest in refractive surgery procedures. LASIK vol-

umes have increased, particularly in the target population of Generation Y or Millennials. These are patients who value a “no nonsense” approach. They want facts, they want speed, and they want results.

The WaveLight\* Refractive Suite (Alcon, Fort Worth, Texas) is particularly well suited to address these patients’ requirements—it pairs the

fastest commercially available excimer laser in the U.S., the EX500, with the fastest commercially available femtosecond laser, the FS200.

### **EX500: Recovery times**

The WaveLight EX500 Laser has a repetition rate of 500 Hz, which

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George O. Waring IV, MD

**“The WaveLight EX500 Laser delivers not only a great patient experience, but a surgeon’s ‘wow factor.’”**

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The WaveLight EX500 Laser is part of an overall refractive suite that includes both the excimer and a femtosecond laser.

Source: George O. Waring, IV, MD

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The WaveLight EX500 Laser provides 25 cm under the microscope.

Source: George O. Waring, IV, MD

translates to approximately 1.4 seconds per diopter.† This high repetition rate reduces the amount of time for flap and stromal bed dehydration, and in theory, should result in quicker recovery times. We observe a similar quick recovery rate with intraocular surgery with proper technique and less manipulation of the eye. In my practice, we have observed the speed of recovery using this laser, and patients have even commented on their quick recovery.

The WaveLight EX500 Laser delivers not only a great patient experience, but a surgeon's "wow factor." When I look at these patients immediately postop under the slit lamp, I am often seeing results I'd expect to see clinically at one week postop. There is minimal edema, swelling, inflammation, dryness—the eyes look pristine.

### Dealing with "extremes"

My advice to surgeons using a new laser is to start conservatively until there's a good sense of how the laser performs using their own techniques and under the conditions of the operating room environment. In my experience, developing a surgeon-specific nomogram usually takes a few hundred cases. Because I had some experience with this laser outside the U.S., I felt comfortable performing cases in the refractive extremes for myopia, hyperopia, and astigmatism my first day of surgery. I have treated anywhere between +5.00 D to -10.00 D of spherical correction, and up to 6.00 D of cylinder, gaining a line of best corrected visual acuity in the majority of these extreme cases. My preliminary outcomes data has been quite encouraging, with my correlation

coefficients (programmed target versus my achieved outcome) to be 0.96 and 0.97 for spherical equivalent and cylinder treatments, respectively.

### Overall advances

The WaveLight EX500 Laser also features a 1050 Hz, multidimensional eye tracker synchronized at 500 Hz, which follows the eye's movements for precision and safety. This tracker features a 2 millisecond latency time and can track all pupil sizes, from 1.5 mm to 8 mm. The tracker self-regulates, meaning it will slow the laser down as needed.

The laser has a large working distance, with 25 cm under the microscope allowing for comfortable surgery and easy handoff of instruments from your technician.

Other features I've found particularly useful: a heads-up display that allows the surgeon to look through the microscope and have all the necessary information available. The system provides real-time feedback on how well tracked the patient is and the progress of the ablation. The online pachymetry allows surgeons to have immediate access to residual stromal bed depths. All of this information in addition to patient identifiers and laterality are digitally viewed through the oculars during surgery. The system comes standard with the IBRA, an intuitive treatment guidance program that provides real-time data analysis to the surgeon while building the surgical nomogram.

The other half of the refractive suite includes the WaveLight FS200 femtosecond laser, which, at 200 kHz, is the fastest femtosecond laser in the U.S. That particular femtosecond laser can create flaps in approximately 6 seconds† with full customization capabilities.

### Patient response

The advantages of this technology aren't just noticeable to surgeons; patients are really responding to it. Our Generation Y or Millennials are responding to the speed that this laser offers. Patients have told me it took less time for me to correct their sight with the WaveLight EX500 Laser than it did for them to put in their contact lenses. This type of phraseology is powerful for word-of-mouth advertising and has helped boost our refractive volume.

The WaveLight Refractive Suite is, in my mind, the most advanced technology available today because of its speed and its noticeable effect on patient outcomes. It is an advanced form of LASIK and can be a valuable tool for any surgeon looking to expand his or her refractive practice.

*\*Trademarks are the property of Alcon, a Novartis company.*

*†Based on typical treatment parameters; Alcon data on file.*

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# Precision, ease-of-use, reliability: Why I use the WaveLight FS200

by Thomas Clinch, MD

**R**efractive surgeons have the envy of most other subspecialties—our outcomes are precise, our patients are thrilled, our complication rates are minute ... but still we do not rest on our laurels. The WaveLight FS200 (Alcon, Fort Worth, Texas) combines the fastest femtosecond laser on the market (200 Hz) with consistently reproducible results. With this laser, I've been able to create flaps in approximately 6 seconds.\* I've had patients tell me the time they were under the WaveLight FS200 laser was less than the time it took them to put in their contact lenses in the morning. The faster we're treating patients, the less likely it is there will be patient movement, and therefore, we have much more precise flaps and fewer imperfections.

While we haven't conducted an approved clinical trial comparing lasers, anecdotally we have conducted small interoffice comparisons among our refractive surgeons. In our experience, none of us has been off by more than 5 microns.

## Unique capabilities

While all femtosecond lasers use an interface, and they are supposed to be calibrated to a specific thickness, that has not always been the case. What I have found advantageous on the FS200 over other lasers is its ability to optically measure the thickness of each interface to ensure that when the LASIK flap is cut, it's precisely at the depth the surgeon needs. As refractive surgeons, we know how critical that can be when treating patients with thinner corneas or higher levels of refractive error.

Earlier versions of femtosecond lasers would have issues shrinking the flap size when the eye was not perfectly planar. So, for example, if I planned on an 8.5 mm diameter flap but the patient moved his/her eye before I achieved good suction, the flap might only be 8 mm, or 7.9 mm. That, in turn, meant that I did not have a large enough diameter to fit the entire ablation. With the FS200, though, once I've applanated the eye, I'm always able to get the diameters I need. In my hands, I've found spherical myopic patients are best treated at 8.2 to 8.5 mm flaps, myopic astigmatas are best treated at

9 mm flaps, and hyperopes are best treated at 9.2 mm flaps.

This laser optimizes both spot size and line spacing to achieve those consistent results.

No laser system will be able to applanate every patient. While rare, there will be that unusual patient with an odd orbital configuration or an inability to remain still. I found it's not uncommon to have patients squeeze their eyes or move their eyes around. With older femtosecond lasers, I was never confident my desired flap size would be achieved—

until now. With the FS200, the unique suction ring design integrated adjustable features that have been shown to minimize ocular distortion and intraocular pressure spikes, and automate vacuum control.<sup>1</sup> For the latter, vacuum control is provided via a computer instead of the typical syringe.

## Opaque bubble layers

All femtosecond lasers create opaque bubble layers (OBL) to some degree

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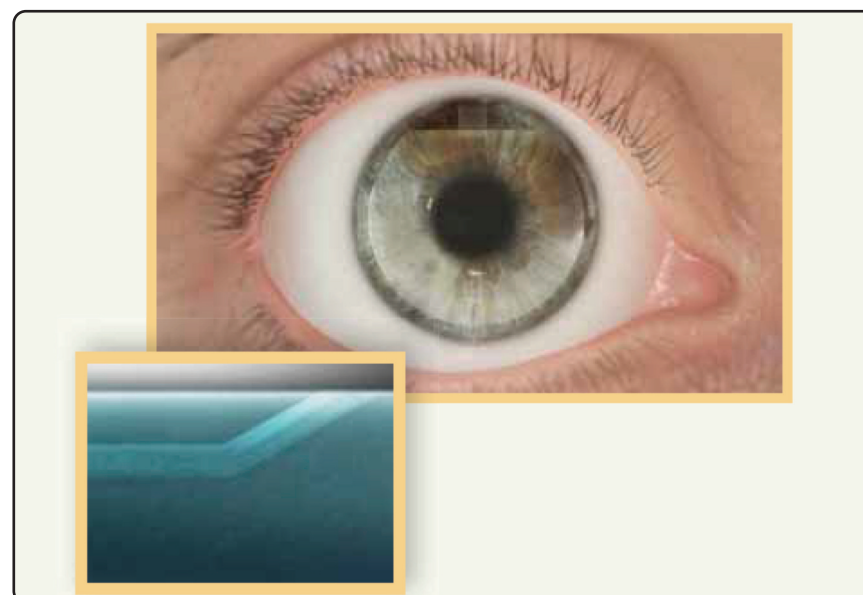


Thomas Clinch, MD



A flap bed and edge, each at 100x magnification

Source: Alcon



The laser-cut channel helps eliminate opaque bubble layers (OBLs).

Source: Alcon

*“What I have found advantageous on the FS200 over other lasers is its ability to optically measure the thickness of each interface to ensure that when the LASIK flap is cut, it's precisely at the depth the surgeon needs.”*

## Seeing is believing

by Michael Jones, MD

### *Improved red reflex and depth of focus with the LuxOR microscope\**

**I**n a cataract surgery center, the microscope is often the last piece of equipment we think about updating. It's easy to be complacent in this regard—the microscope isn't necessarily a dramatic or high profile instrument. We don't let our patients know we have the "latest, greatest" microscope like we would our lasers or premium lens offerings, probably because we don't give our microscopes the attention they deserve ourselves.

This complacency certainly affected my center; before we invested in the LuxOR microscope (Alcon, Fort Worth, Texas), we had been using a 30-year-old microscope. Yet we had updated our phaco units about six times and never thought twice about the importance of the microscope.

It wasn't until we tried the LuxOR that we truly understood what we had been missing. For me, it was the equivalent of transitioning from a TV built in the 1990s to a 1080 plasma screen, high-definition TV. The superior visualization of the LuxOR system, the stability of the

red reflex, and its superior depth of focus truly set this microscope apart, and it has increased the efficiency of our practice.

### Red reflex technology

The LuxOR microscope features Illumin-I technology, a patented three-beam collimated light configuration that generates bright, homogenous light over a larger surface area than other microscopes. This visibility is not contingent on pupil size, centration, lens tilt, or eye movement.

During capsulotomy, cataract surgeons are dependent upon red reflex for visibility, and in cases of very dense cataract, visibility becomes crucial. Our inability to see a red reflex in those difficult eyes is why we have special dyes for use in cataract surgery. But the LuxOR microscope produces a red reflex zone that is six times broader than that of other microscopes, which provides a much more stable red reflex during the entire case.

Because of those two features, we're able to save surgical time as well; it was not uncommon for us to lose red reflex if the patient's eye moved too far one way or the other. We would then need to spend time repositioning the patient's head or

moving the microscope to get the red reflex right back in the center. But the wider zone of red reflex offered by the LuxOR means we're never repositioning the patient. I didn't realize how much time I spent on this seemingly menial aspect of surgery until I realized I wasn't spending time on it any longer.

We have a large number of patients on tamsulosin in our practice, so the brightness of the LuxOR is particularly helpful with these small pupils.

### Depth of focus

Depth of focus is another surgical aspect that, in older microscopes, is at the mercy of patient movement. We found ourselves continually zooming in or out even with the smallest of patient movements. Most microscopes have an extremely narrow focus, limiting the surgeon to concentrate on just the part of the eye that's being operated on at the time. So when we need to move from the cornea to the anterior capsule, it's another adjustment, a few seconds here and there that add time to the surgery. The LuxOR has a superior depth of focus, however, and I've yet to change focus at any point during the surgery. The superior visualization with the LuxOR microscope allows me to see all layers of the eye without zooming in or out.

Precision continued from page 3

when they pulse the energy into the cornea. Each pulse creates small bubbles inside the eye that coalesce to cleave the tissue, but leave gas trapped in the flap. Surgeons need to create a channel that allows the gas to egress from under the flap into the periphery. The way this laser docks creates very symmetric pressure on the eye. The FS200 allows us to modify our treatments to ensure we get that channel so we're sure the gas escapes into the periphery.

### Pearls for use

For refractive surgeons who are considering upgrading to the FS200, here are some "real use" advantages.

This laser allows you to use both the operating microscope and the monitor. I appreciate the ability to

align the microscope with the treatment and then move to the monitor to align the patient's eye. Being able to go back and forth makes it easier for me to evaluate the applanation on the corneal surface.

The precision of the flap cuts has allowed me to immediately move to a reverse side cut, with a beveled outside edge. Once you move the flap back, this type of cut helps the flap to settle into position better and may allow patients to heal faster.

Far and away, the most unique feature of this laser is its precision—treatment-to-treatment variability is minimal. The laser head is extremely robust so we very rarely change our treatment parameters. This laser makes our lives relatively boring—but when it comes to creating fem-

tosecond laser flaps, being "boring" is the highest compliment I can pay.

When we're evaluating patients, we tell them we're using the best equipment in the world. With the FS200, I know I can back that statement up.

*\*Based on typical treatment parameters; Alcon data on file.*

### Reference

1. Mrochen M, Wüllner C, Krause J, Klafke M, Donitzky C, Seiler T. Technical Aspect of the Wavelight FS200 Femtosecond Laser. *J Refract Surg.* 2010;26:S833-S840.

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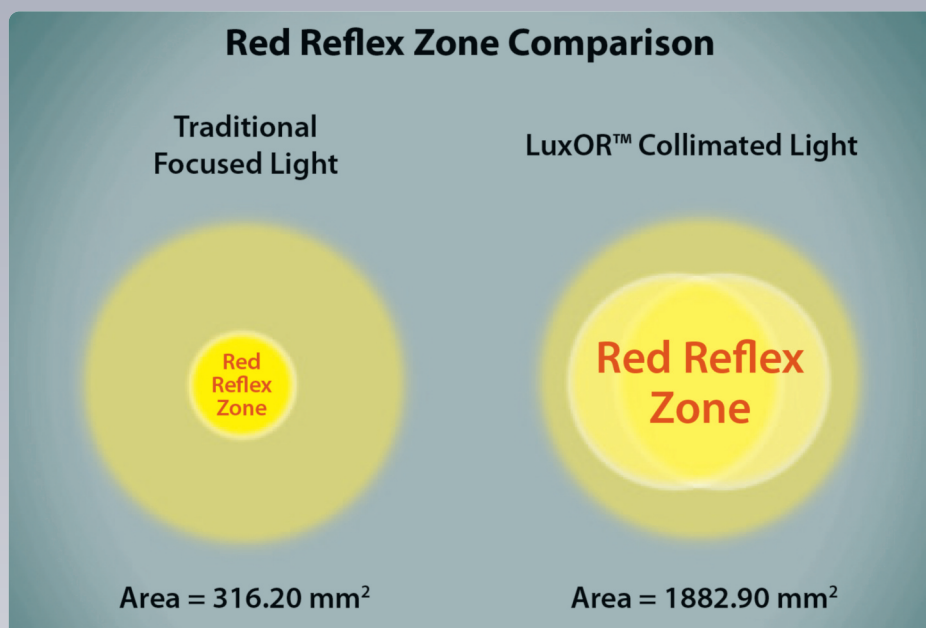


Michael Jones, MD

**“For me, it was a no-brainer: The ‘wow’ factor of this microscope and the superior visualization made other microscopes we demoed pale in comparison.”**

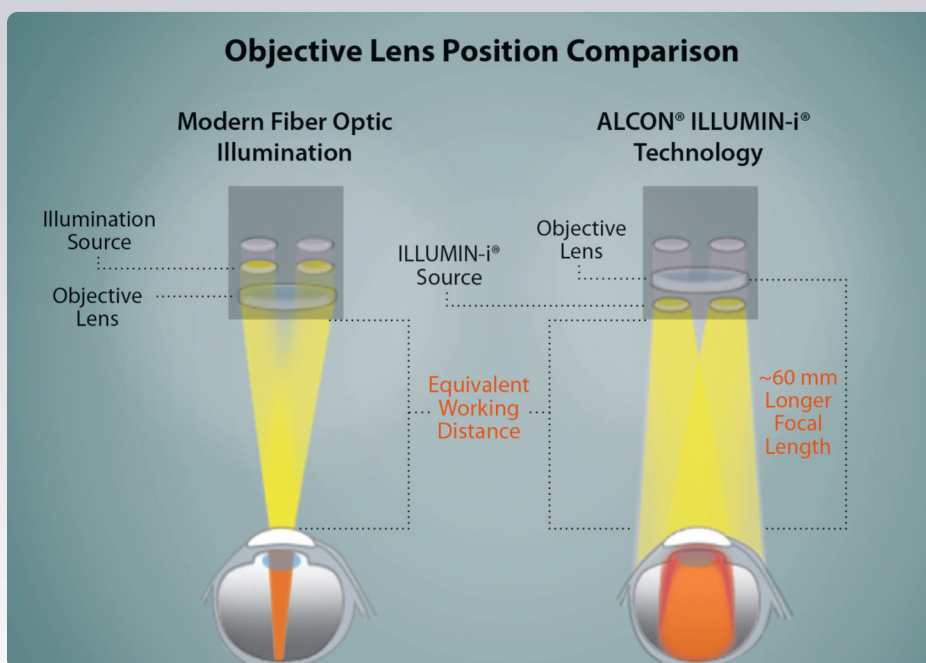


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The LuxOR microscope delivers 6x greater red reflex zone.

Source: Alcon



ILLUMIN-i technology delivers a focal length approximately 60 mm longer than traditional microscopes, regardless of working distance.

Source: Alcon

### Logistical benefits

Our center boasts more than 12 surgeons, each of whom has his or her own surgical approaches and preferences. A unique feature of this particular microscope is its ability to preprogram each surgeon's settings, down to the amount of zoom preferred. A simple push of the button

automatically allows the microscope to go from Dr. A to Dr. B.

Aside from the performance of the microscope itself, I've found a hidden benefit in its wireless foot pedal. The majority of microscopes have a wired foot pedal that is not only cumbersome and inconvenient, but often unreliable. (Full disclosure

here—the wire on our old microscope's foot pedal broke and that was what led us to evaluate purchasing a new microscope in the first place. I've wondered if we'd still be using that old, outdated technology had it not been for my rolling over the cord for the umpteenth time.) I've found the LuxOR wireless foot

pedal to be extremely responsive with minimal to no lag time.

### Surgical learning curve

As with any new technology, there is a learning curve. We've found that for some of our most experienced surgeons, the brightness of the microscope was daunting at first and provided "too much information," one surgeon used to say. Minutiae he had overlooked in the past was now incredibly visible and obvious, and for the surgeon, a bit overwhelming. This same surgeon noted he could see floaters in the vitreous for the first time because of how bright the microscope is.

To hasten the learning curve, the proprietary AMP feature allows a surgeon to adjust the amount of red reflex in view, allowing a surgeon to bring the microscope up to its full potential on his or her own timetable. In the case of our one surgeon, the learning curve was no more than 10 to 15 cases before he was using the LuxOR in full illumination for all parts of the surgery. I believe this microscope has the ability to prolong a career as well—because we can now see tiny defects in the capsule, we're able to prevent what might be a surgical disaster.

### A "no-brainer"

When we decided to invest in a new microscope, we evaluated several other microscopes on the market. For me, it was a no-brainer: The "wow" factor of this microscope and the superior visualization made other microscopes we demoed pale in comparison. There is no doubt surgeons will have much better views with the LuxOR than with their older microscopes and other current models on the market. The stability of the red reflex and increased depth of focus have made us more efficient. In the long run, being more efficient means you'll do more cases and grow your practice.

The superior visibility of this microscope has changed the way we do cataract surgery; it's made our surgeries faster, more efficient, and more effective.

### \*Directions For Use

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## Enhanced comfort, improved patient flow

by Barbara Bowers, MD

### *Incorporating the LenSx Laser and the SoftFit Patient Interface upgrade*

**Y**ou can't sell something to a patient that you don't believe in yourself—especially when you're asking a patient to pay out of pocket. I can confidently say that of all the femtosecond lasers that I have used or evaluated, the LenSx Laser (Alcon, Fort Worth, Texas) is the easiest to use. My advice to surgeons who are not yet using a femtosecond laser for their advanced technology lens patients is to do your homework and determine how to integrate it into your workflow and your center, but do not let pricing become the motivator. In my practice, I determined the price of the laser could be offset by the additional fees I charge patients for advanced technology lens implantation. For my business model, that was preferable to negotiating with a surgery center for time and use of the laser and the OR.

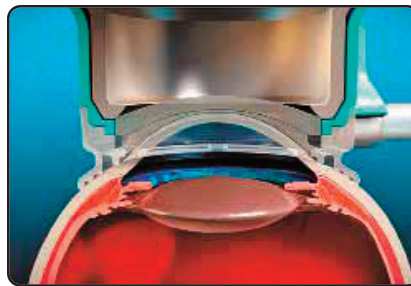
#### **Managing patient flow**

There is some initial adjustment in figuring out your patient flow with the femtosecond laser. Having a staff member solely dedicated to running this part of the surgery will help smooth the flow and may even save time down the road. At our center, the patient is marked and under the laser even before I walk in. Of my cataract surgery patients, about half opt for the upgrade packages that include the LenSx Laser, so it's a simple matter of every other patient is a LenSx Laser patient. Because of how smoothly our laser suite functions, I've been able to limit the additional time the laser portion takes to about 20-30 minutes daily. For the financial rewards that are associated with this technology, I think the investment is worthwhile.

One tip that's worked for me: I started scheduling "right eye femtosecond days" and "left eye femtosecond days." It took a little while to get accustomed to the new flow, but it cut down on my needing to be directed to a particular room.

#### **Educating staff, talking with patients**

Even after you're comfortable with



**Dubbed the SoftFit Patient Interface, there's now a soft, curved contact lens that allows for the natural curvature of the cornea to conform to a soft contact lens insert.** Source: Alcon

the laser, the staff and the patients are going to make the investment a successful one. Getting office staff to be enthusiastic about the technology is essential—energize your staff about the laser and about advanced technology lenses.

Once the staff is comfortable discussing the advanced technology lenses, discussing a premium laser technology is simply a matter of telling the patient there's an option for bladeless cataract surgery as well. Patients already believe laser technology makes any surgery better and more precise, so I've found that part of the discussion is actually rather easy.

#### **SoftFit Interface: Improved comfort**

Patients rarely complained about any discomfort during the procedure, but a new interface on the LenSx Laser is making patient comfort a priority. Dubbed the SoftFit Patient Interface (Alcon), there's now a soft, curved contact lens that allows for the natural curvature of the cornea to conform to a soft contact lens insert. It is designed to reduce corneal folds and corneal distortion to create a pristine, free-floating capsulotomy, and improve lens fragmentation while reducing energy use.

There are also advantages to the image-guided OCT because the SoftFit Patient Interface reduces distortions to the cornea, allowing for a better view and delivery of the laser. Alcon has conducted an IRB study that demonstrated that the reduced corneal distortion with the SoftFit Patient Interface is largely responsible for the more pristine, full-thickness cut of the capsulotomy in nearly every case.<sup>1</sup>

I have also found that procedures using the SoftFit Patient Interface fragment dense nuclei better, which allows me to use less

ultrasound energy for lens fragmentation. In my hands, I've noticed significantly less cell and flare in the anterior chamber as well as less corneal edema postoperatively, and this has led to my femtosecond cataract patients seeing better, faster.

Before using the LenSx SoftFit Patient Interface upgrade, my LenSx Laser treatments took about 50-55 seconds, but the procedure time has been almost cut in half, to about 30 seconds in my hands.

#### **A laser refractive cataract procedure**

When you introduce an innovative technology like the LenSx Laser, your entire procedure is bound to change, and surgeons must be prepared for this. I have found I now have a surgeon factor/A constant for LenSx Laser patients and one for traditional cataract patients. Another aspect leading to a new procedure is that with femtosecond-created arcuates, there is no universal suggested nomogram to perform the architecture of the arcuate incision. With the LenSx Laser we have a more predictable effective lens position because the capsulotomy is so perfect.<sup>2</sup>

#### **A worthwhile investment**

Overall, I would say that I've adopted and integrated this technology quite easily, and it's made my cataract practice more efficient and effective. For patients, the laser surgery makes intuitive sense, and its non-invasiveness and comfort makes for a fast, easy surgery and recovery. As this technology continues to evolve and offer upgrades, it will provide even better ease of use and patient comfort. I encourage surgeons considering this equipment to talk to other surgeons who have successfully incorporated the LenSx Laser into their practices. Once surgeons work out the logistics and the learning curve, this technology will offer a distinct value to the surgeon, the practice, and the patients.

#### **References**

1. Multicenter prospective clinical study (n=197 eyes); Alcon data on file.
2. Cionni, R. "Comparison of Effective Lens Position and Refractive Outcome: Femtosecond Laser vs. Manual Capsulotomy." Presented at the 2011 American Academy of Ophthalmology Refractive Sub-Specialty Day.

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Barbara Bowers, MD

**“With the LenSx Laser we have a more predictable effective lens position because the capsulotomy is so perfect.”**



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# Important safety information

## WaveLight Excimer Laser Systems

This information pertains to all WaveLight Excimer Laser Systems, including the WaveLight ALLEGRETTO WAVE, the ALLEGRETTO WAVE Eye-Q, and the WaveLight EX500.

**Caution:** Federal (U.S.) law restricts the WaveLight Excimer Laser Systems to sale by or on the order of a physician. Only practitioners who are experienced in the medical management and surgical treatment of the cornea, who have been trained in laser refractive surgery (including laser calibration and operation) should use a WaveLight Excimer Laser System.

**Indications:** FDA has approved the WaveLight Excimer Laser for use in laser-assisted in situ keratomileusis (LASIK) treatments for:

- the reduction or elimination of myopia of up to -12.0 DS and up to 6.0 D of astigmatism at the spectacle plane;
- the reduction or elimination of hyperopia up to +6.0 DS with and without astigmatic refractive errors up to 5.0 D at the spectacle plane, with a maximum manifest refraction spherical equivalent of +6.0 D;
- the reduction or elimination of naturally occurring mixed astigmatism of up to 6.0 D at the spectacle plane; and
- the wavefront-guided reduction or elimination of myopia of up to -7.0 DS and up to 3.0 D of astigmatism at the spectacle plane.

The WaveLight Excimer Laser Systems are only indicated for use in patients who are 18 years of age or older (21 years of age or older for mixed astigmatism) with documentation of a stable manifest refraction defined as  $\leq 0.50$  D of preoperative spherical equivalent shift over one year prior to surgery, exclusive of changes due to unmasking latent hyperopia.

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

- are pregnant or nursing;
- have a diagnosed collagen vascular, autoimmune or immunodeficiency disease;
- have been diagnosed with keratoconus or if there are any clinical pictures suggestive of keratoconus; or
- are taking isotretinoin (Accutane\*) and/or amiodarone hydrochloride (Cordarone\*).

**Warnings:** The WaveLight Excimer Laser Systems are not recommended for use with patients who have:

- systemic diseases likely to affect wound healing, such as connective tissue disease, insulin dependent diabetes, severe atopic disease or an immunocompromised status;
- a history of Herpes simplex or Herpes zoster keratitis;
- significant dry eye that is unresponsive to treatment;
- severe allergies; or
- an unreliable preoperative wavefront examination that precludes wavefront-guided treatment.

The wavefront-guided LASIK procedure requires accurate and reliable data from the wavefront examination. Every step of every wavefront measurement that may be used as the basis for a wavefront-guided LASIK procedure must be validated by the user. Inaccurate or unreliable data from the wavefront examination will lead to an inaccurate treatment.

**Precautions:** The safety and effectiveness of the WaveLight Excimer Laser Systems have not been established for patients with:

- progressive myopia, hyperopia, astigmatism and/or mixed astigmatism, ocular disease, previous corneal or intraocular surgery, or trauma in the ablation zone;
- corneal abnormalities including, but not limited to, scars, irregular astigmatism and corneal warpage;
- residual corneal thickness after ablation of less than 250 microns due to the increased risk for corneal ectasia;
- pupil size below 7.0 mm after mydriatics where applied for wavefront-guided ablation planning;
- history of glaucoma or ocular hypertension of  $>23$  mm Hg;
- taking the medication sumatriptan succinate (Imitrex\*);
- corneal, lens and/or vitreous opacities including, but not limited to cataract;
- iris problems including, but not limited to, coloboma and previous iris surgery compromising proper eye tracking; or
- taking medications likely to affect wound healing including (but not limited to) antimetabolites.

In addition, safety and effectiveness of the WaveLight Excimer Laser Systems have not been established for:

- treatments with an optical zone  $<6.0$  mm or  $>6.5$  mm in diameter, or an ablation zone  $>9.0$  mm in diameter; or
- wavefront-guided treatment targets different from emmetropia (plano) in which the wavefront calculated defocus (spherical term) has been adjusted.

In the WaveLight Excimer Laser System clinical studies, there were few subjects with cylinder amounts  $>4$  D and  $\leq 6$  D. Not all complications, adverse events, and levels of effectiveness may have been determined for this population.

Pupil sizes should be evaluated under mesopic illumination conditions. Effects of treatment on vision under poor illumination cannot be predicted prior to surgery.

## Adverse events and complications

**Myopia:** In the myopia clinical study, 0.2% (2/876) of the eyes had a lost, misplaced, or misaligned flap reported at the 1 month examination.

The following complications were reported 6 months after LASIK: 0.9% (7/818) had ghosting or double images in the operative eye; 0.1% (1/818) of the eyes had a corneal epithelial defect.

**Hyperopia:** In the hyperopia clinical study, 0.4% (1/276) of the eyes had a retinal detachment or retinal vascular accident reported at the 3 month examination.

The following complications were reported 6 months after LASIK: 0.8% (2/262) of the eyes had a corneal epithelial defect and 0.8% (2/262) had any epithelium in the interface.

**Mixed astigmatism:** In the mixed astigmatism clinical study, two adverse events were reported. The first event involved a patient who postoperatively was subject to blunt trauma to the treatment eye 6 days after surgery. The patient was found to have an intact globe with no rupture, inflammation or any dislodgement of the flap. UCVA was decreased due to this event. The second event involved the treatment of an incorrect axis of astigmatism. The axis was treated at 60 degrees instead of 160 degrees.

The following complications were reported 6 months after LASIK: 1.8% (2/111) of the eyes had ghosting or double images in the operative eye.

**Wavefront-guided myopia:** No adverse events occurred during the postoperative period of the wavefront-guided LASIK procedures. In the Control Cohort (traditional LASIK treatment) one subject undergoing traditional LASIK had the axis of astigmatism programmed as 115 degrees instead of the actual 155 degree axis. This led to cylinder in the left eye.

The following complications were reported 6 months after wavefront-guided LASIK in the Study Cohort: 1.2% (2/166) of the eyes had a corneal epithelial defect; 1.2% (2/166) had foreign body sensation; and 0.6% (1/166) had pain. No complications were reported in the Control Cohort.

## Clinical data

**Myopia:** The myopia clinical study included 901 eyes treated, of which 813 of 866 eligible eyes were followed for 12 months. Accountability at 3 months was 93.8%, at 6 months was 91.9%, and at 12 months was 93.9%. Of the 844 eyes eligible for the uncorrected visual acuity (UCVA) analysis of effectiveness at the 3-month stability time point, 98.0% were corrected to 20/40 or better, and 84.4% were corrected to 20/20 or better. Subjects who responded to a patient satisfaction questionnaire before and after LASIK reported the following visual symptoms at a "moderate" or "severe" level at least 1% higher at 3 months post-treatment than at baseline: visual fluctuations (28.6% vs. 12.8% at baseline).

Long-term risks of LASIK for myopia with and without astigmatism have not been studied beyond 12 months.

**Hyperopia:** The hyperopia clinical study included 290 eyes treated, of which 100 of 290 eligible eyes were followed for 12 months. Accountability at 3 months was 95.2%, at 6 months was 93.9%, and at 12 months was 69.9%. Of the 212 eyes eligible for the UCVA analysis of effectiveness at the 6-month stability time point, 95.3% were corrected to 20/40 or better, and 67.5% were corrected to 20/20 or better. Subjects who responded to a patient satisfaction questionnaire before and after LASIK reported the following visual symptoms at "much worse" at 6 months post-treatment: halos (6.4%); visual fluctuations (6.1%); light sensitivity (4.9%); night driving glare (4.2%); and glare from bright lights (3.0%).

Long-term risks of LASIK for hyperopia with and without astigmatism have not been studied beyond 12 months.

**Mixed astigmatism:** The mixed astigmatism clinical study included 162 eyes treated, of which 111 were eligible to be followed for 6 months. Accountability at 1 month was 99.4%, at 3 months was 96.0%, and at 6 months was 100.0%. Of the 142 eyes eligible for the UCVA analysis of effectiveness at the 3-month stability time point, 95.8% achieved acuity of 20/40 or better, and 67.6% achieved acuity of 20/20 or better. Subjects who responded to a patient satisfaction questionnaire before and after LASIK reported the following visual symptoms at a "moderate" 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. 32.1% at baseline); and halos (42.3% vs. 37.0% at baseline).

Long term risks of LASIK for mixed astigmatism have not been studied beyond 6 months.

**Wavefront-guided myopia:** The wavefront-guided myopia clinical study included 374 eyes treated; 188 with wavefront-guided LASIK (Study Cohort) and 186 with Wavefront Optimized LASIK (Control Cohort). 178 of the Study Cohort and 180 of the Control Cohort were eligible to be followed at 6 months. In the Study Cohort, accountability at 1 month was 96.8%, at 3 months was 96.8%, and at 6 months was 93.3%. In the Control Cohort, accountability at 1 month was 94.6%, at 3 months was 94.6%, and at 6 months was 92.2%.

Of the 180 eyes in the Study Cohort that were eligible for the UCVA analysis of effectiveness at the 6-month stability time point, 99.4% were corrected to 20/40 or better, and 93.4% were corrected to 20/20 or better. Of the 176 eyes in the Control Cohort eligible for the UCVA analysis of effectiveness at the 6-month stability time point, 99.4% were corrected to 20/40 or better, and 92.8% were corrected to 20/20.

In the Study Cohort, subjects who responded to a patient satisfaction questionnaire before and after LASIK reported the following visual symptoms at a "moderate" or "severe" level at least 1% higher at 3 months post-treatment than at baseline: light sensitivity (47.8% vs. 37.2% at baseline) and visual fluctuations (20.0% vs. 13.8% at baseline). In the Control Cohort, the following visual symptoms were reported at a "moderate" or "severe" level at least 1% higher at 3 months post-treatment than at baseline: halos (45.4% vs. 36.6% at baseline) and visual fluctuations (21.9% vs. 18.3% at baseline).

Long-term risks of wavefront-guided 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 receive a copy of the relevant Patient Information Booklet, and must be informed of the alternatives for correcting their vision, including (but not limited to) eyeglasses, contact lenses, photorefractive keratotomy, and other refractive surgeries.

**Attention:** Please refer to a current WaveLight Excimer Laser System Procedure Manual for a complete listing of the indications, complications, warnings, precautions, and side effects.

\*Trademarks are property of their respective owners.

# Important safety information

## The WaveLight FS200 Laser System

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

As with any surgical procedure, there are risks associated with the use of the WaveLight FS200 Femtosecond Laser System. Before treating patients with this device, you should carefully review the Procedure Manual, complete the Physician WaveLight System Certification Course, and discuss the risks associated with this procedure and questions about the procedure with your patients.

**Indications:** The WaveLight FS200 Laser System is indicated for use in the creation of a corneal flap in patients undergoing LASIK surgery or other surgery or treatment requiring initial lamellar resection of the cornea; in patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments; in the creation of a lamellar cut/resection of the cornea for lamellar keratoplasty; and in the creation of a penetrating cut/incision for penetrating keratoplasty and for corneal harvesting.

The WaveLight FS200 delivery system is used in conjunction with a sterile disposable Patient Interface, consisting of pre-sterilized suction ring assemblies and pre-sterilized applanation cones, intended for single use.

The WaveLight FS200 Laser System should only be operated by, or under the direct supervision of, a trained physician with certification in laser safety and in the use of the WaveLight FS200 Laser.

**Contraindications:** LASIK treatments are contraindicated in: Pregnant or nursing women; patients with a diagnosed collagen vascular, autoimmune or immunodeficiency disease; and patients who are taking one or both of the following medications: isotretinoin (Accutane<sup>1</sup>), amiodarone hydrochloride (Cordarone<sup>2</sup>).

**Flap contraindications:** Lamellar resection for the creation of a corneal flap using the WaveLight FS200 laser is contraindicated if any of the following conditions exist. Potential contraindications are not limited to those included in this list: corneal edema; corneal lesions; hypotony; glaucoma; existing corneal implant; and keratoconus.

**Keratoplasty contraindications:** Penetrating cut/incision (for penetrating keratoplasty) is contraindicated in: any corneal opacity adequately dense to obscure visualization of the iris; descemetocoele with impending corneal rupture; previous corneal incisions that might provide a potential space into which the gas produced by the procedure can escape; and corneal thickness requirements that are beyond the range of the System.

**Other considerations:** The following conditions should also be considered: severe corneal thinning; subjects with pre-existing glaucoma; a history of steroid responsive rise in intraocular pressure; preoperative intraocular pressure greater than 21 mm Hg in the operative eye; subjects with more than 1000 µm corneal thickness at the 9 mm peripheral zone; active intraocular inflammation; and active ocular infection.

**Complications:** Possible complications which may result from flap cutting include (potential complications are not limited to those included in this list): corneal edema; corneal pain; epithelial ingrowth; epithelial infection; flap decentration; incomplete flap creation; flap tearing or incomplete lift-off; free cap; photophobia; corneal inflammation, such as diffuse lamellar keratitis (DLK), corneal infiltrates and iritis; thin or thick flaps; flap striae; and corneal ectasia (secondary keratoconus).

**Warnings:** Any treatment with the WaveLight FS200 is not recommended in patients who have: systemic diseases likely to affect wound healing, such as connective tissue disease, insulin dependent diabetes, severe atopic disease or an immunocompromised status; a history of Herpes simplex or Herpes zoster keratitis; significant dry eye that is unresponsive to treatment; severe allergies; and a history of glaucoma or ocular hypertension.

We recommend discussing the following potential complications of this device with your patients:

**Transient Light Sensitivity Syndrome (TLSS):** Transient Light Sensitivity Syndrome is characterized by symptoms of mild to severe light sensitivity that manifests between two and six weeks postoperatively. Patients experience no decrease in uncorrected or best spectacle-corrected visual acuity. The incidence of this sensitivity was observed in approximately 1% of patients who undergo flap creation with a femtosecond laser.<sup>3</sup> Patients respond to the use of hourly topical steroids such as Pred Forte (Allergan), and most report improvement within one week of treatment.

**Peripheral Light Spectrum (PLS):** Peripheral Light Spectrum is a temporary phenomenon whereby patients report the perception of a spoke-like spectrum of light in the periphery of their vision. PLS has no clinical examination findings and no effect on visual acuity; however the potential diffractive effects may be bothersome to some patients. Reported in only a small amount of cases, the onset of symptoms occurs during the immediate postoperative period, and typically resolves within three months but may be slightly persistent in rare cases. The visual impact of PLS is clinically inconsequential for the vast majority of patients.

1. Accutane is a registered trademark of Hoffmann-La Roche Inc.

2. Cordarone is a registered trademark of Sanofi.

3. FDA Database Research Results Feb. 05, 2009.

## LenSx Laser

### Caution

United States Federal Law restricts this device to sale and use by or on the order of a physician or licensed eyecare 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.
- Patients 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 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 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.