

Cataract Surgery and the LenSx® Femtosecond Laser System—2015 Update

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Abstract

Femtosecond laser-assisted cataract surgery continues to gain popularity as clinicians adopt the technology with the desire to improve the safety and efficacy of cataract surgery. The technology continues to evolve as clinical experience points to improvements to better meet the needs of surgeons and patients. The effect of these system updates, and the increasing body of experience with femtosecond laser systems, has reduced complication rates and seen the technology applied to more challenging cases. This article provides an updated review of the LenSx® femtosecond Laser system, including recent system modifications and the most- recent published literature.

Keywords

Femtosecond laser, cataract surgery, docking, capsulotomy, fragmentation, phacoemulsification, incisions

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Safe and effective cataract surgery is the goal for both patients and surgeons, with increasing demands for accurate refractive outcomes.¹ Femtosecond laser-assisted cataract surgery (FLACS) is arguably the most significant change to cataract surgery since phacoemulsification, the adoption of which is in large part fueled by the desire for more precise and safe surgery with more predictable outcomes. In the past two years, the use of femtosecond laser systems has increased dramatically. An estimated 250,000 surgeries have been performed with these systems.¹ One of the earliest and most-studied laser systems is the LenSx® Laser system (Alcon Laboratories, Inc., Aliso Viejo, California). The purpose of the current review is to update the reader on the most recent innovations of the LenSx® Laser system and the latest studies discussing clinical results.

The LenSx® Laser system uses an optical coherence tomography (OCT) and video imaging to view and plan the treatment steps, which are generally customizable by the surgeon² and tailored to the patient's needs.³ Clinical studies have demonstrated that the incorporation of the laser for lens fragmentation, capsulotomy, and incisions is safe and effective.^{2,4} Results from a large dataset showed that the surgical outcomes of FLACS was comparable to the best standard cataract surgical outcomes.² The accurate positioning of capsulotomies appears to improve intraocular lens (IOL) overlap, which is expected to enhance IOL positioning and minimize IOL calculation errors.² This is of particular importance for eyes with short or long axial lengths where calculating accurate IOL power is

challenging and also for eyes receiving advanced technology IOLs where there are high expectations for precise refractive results.²

LenSx® Femtosecond Laser System Fundamentals

The steps performed with the LenSx® Laser may include capsulotomy and lens fragmentation, as well as corneal and arcuate incisions.² Clinical studies have demonstrated that the level of precision for steps performed by femtosecond laser systems are superior to those performed manually.⁵ The recent updates to the LenSx® Laser system are designed to further improve accuracy and reduce the required phacoemulsification energy.⁶ A key feature of the LenSx® femtosecond Laser system is its Variable Numerical Aperture, which changes the focal characteristics of the laser to correspond with the location of the incision (cornea, lens capsule, or lens).⁶ This improves the overall laser efficiency.

Imaging

Proper targeting of the laser pulses is important in reducing the likelihood of complications.⁶ To help achieve proper targeting, the LenSx® Laser OCT provides clear images of the anterior segment and corneal cross section.⁶ The LenSx® Laser software update links with the VERION™ Image Guided System.⁷ The VERION™ system includes a diagnostic tool, called the VERION™ Reference Unit, which measures preoperative data including keratometry and pupillometry. Most importantly, it captures a high-resolution image of the eye (Measurement Module), which allows

for reference features from the limbus, scleral vessels, and the iris to be used as anatomical landmarks.^{3,7} The reference data are transmitted directly to the VERION™ Digital Marker L attached to the laser system to prevent transcription errors.^{3,7} The VERION™ Digital Marker L allows for cyclorotation adjustments prior to creating the capsulotomy and incision: this allows the axis position to exactly match the intended location for incisions (see *Figure 1*).^{3,7}

Docking

Docking the patient interface has been previously shown to be quick and successful.² The LenSx® Laser system upgrade includes the SoftFit™ Patient Interface, which uses a soft contact lens that more closely matches the corneal curvature and reduces pressure on the eye,^{7,8} improving efficiency and eye centration.⁶ One study found that when the updated interface was used, there were no reported cases of anterior capsule tear or corneal fold and no additional applanation attempts were required.⁹ The SoftFit™ Patient Interface appears to result in lower complications compared with conventional cataract surgery results as well as with the older direct contact interface.⁹ The smaller size is also advantageous in small eyes because canthotomy, along with its associated risks, may be avoided.¹⁰ The docking mechanism does not require a suction ring or cup, elements that are more prone to movement and increased risk for suction loss.¹¹

Shortening the femtosecond laser treatment duration can decrease the likelihood of suction breaks,¹² pupil miosis, and conjunctival redness or hemorrhage.¹³ In a recent short case series, the LenSx® Laser system was shown to have much lower total suction-on time relative to the Catalys* and Victus* femtosecond laser systems.¹¹ This could be attributed to the combination of the LenSx® Laser's high-repetition rate and efficient incision algorithms.⁷

Capsulotomy

Studies demonstrate that the vast majority of laser capsulotomies are complete and free-floating.^{2,14} Laser capsulotomies have been previously shown to be well centered, more regularly shaped, stronger, with a more precise diameter and positioning as well as better circularity than manual capsulotomies.² Recent updates to the LenSx® Laser system allow more flexibility in automated prepositioning of the capsulotomy.⁷ The capsulotomy can be centered over the dilated or undilated pupil, the visual axis, or the center of the limbus.⁷

Fragmentation

Previous lens fragmentation patterns included radial and cylinder patterns of varying diameters.⁷ The newly updated LenSx® Laser software is now capable of creating a grid fragmentation pattern of segments, called the "frag" pattern (see *Figure 2*).⁷ The advancement allows both size and spacing to be customized to meet the specific demands of a given cataract.⁶ Customization is particularly useful for denser cataracts⁶ where a greater degree of fragmentation may significantly reduce phacoemulsification energy and time requirements.⁷ The estimated time to complete a difficult fragmentation using the new pattern is about 40 to 45 seconds.³

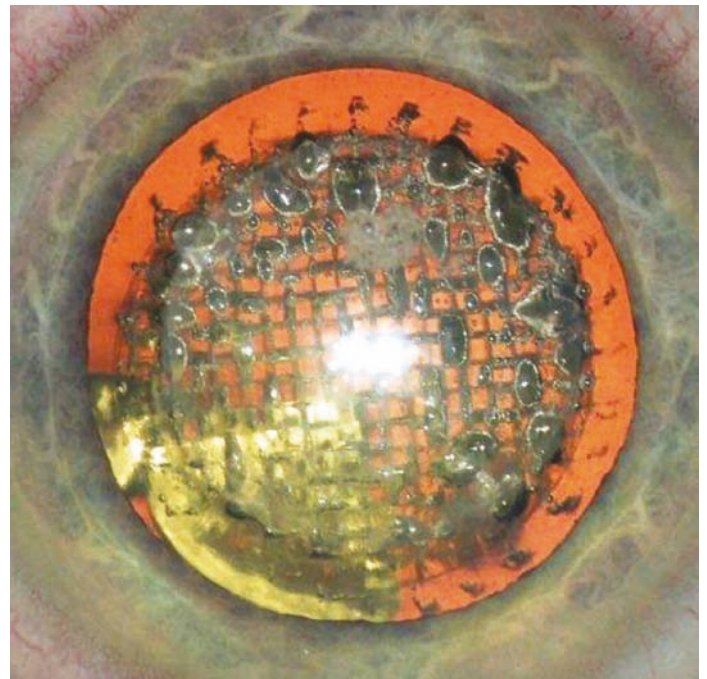
Phacoemulsification

Previous studies have shown that FLACS may decrease phacoemulsification energy, potentially reducing endothelial cell loss and corneal edema

Figure 1: The Verion Digital Marker Compensates for Ocular Cyclotorsion to Allow for Precise Alignment of LenSx® Laser procedures³



Figure 2: The "Frag" Lens Pattern⁶



when compared with conventional cataract surgery.^{15,16} A recent study demonstrated that effective phacoemulsification time and endothelial cell loss were lower in a FLACS-treated group compared with the conventional cataract surgical group: both groups had similar cataract grades and included grade 5 cataracts.¹⁷ Reduced phacoemulsification energy has

the potential to improve visual acuity in the early postoperative period by reducing surgically induced corneal edema.¹⁸

Characteristics of Femtosecond Laser Incisions

Corneal incisions created with femtosecond laser systems have previously been shown to be precise and stable.² FLACS corneal outcomes have also been formerly associated with fewer internal aberrations.² Recently, incisions created by FLACS were shown to be predictable and minimally impact higher order aberrations in the eye.^{19,20} When compared with manual clear corneal incisions (CCIs), FLACS CCIs had reduced endothelial cell loss and edema, as well as better endothelium orientation and wound sealing in the corneal epithelium and endothelium.²⁰ In addition, FLACS CCIs produce more predictable surgically induced astigmatism results when compared with manual CCIs and this was attributed to the laser allowing a more accurate and repeatable incision construction.²⁰ The LenSx[®] Laser allows all incisions to be customized, including location, length, depth, and size.⁶

In one study, laser incisions appear to increase cell death relative to manual incisions but this has not been associated with a significant increase in inflammation.²¹ Another important consideration is that the laser suite is generally not sterile, which means that caution should be observed when moving patients after incisions have been created, to reduce the risk for infection and/or endophthalmitis.^{4,22}

Clinical Results of Challenging Cases

FLACS can be applied in surgically challenging cases.⁴ Recent studies have demonstrated how certain complications can be mitigated and how incorporating FLACS in challenging cases may be useful.

FLACS shows promising results in patients with small pupils and intraoperative floppy iris syndrome (IFIS).⁴ Iris damage from manual manipulation during standard cataract surgery may be decreased when using FLACS.⁴ In a recent case report of a patient with small pupils and IFIS, standard cataract surgery was performed on one eye and FLACS with an iris expander was performed on the other eye.⁴ The laser-treated eye had no complications but the fellow eye had posterior capsule rupture during phacoemulsification.⁴ FLACS may be beneficial in eyes with IFIS because the capsulotomy and lens fragmentation are completed before making any incision, reducing the amount of time, phacoemulsification energy, and manipulation required to perform the cataract surgery once the eye is opened.⁴

FLACS was successfully performed in a patient with nanophthalmos,²³ and in a patient with a shallow anterior chamber.¹⁸ In small eyes and/or eyes with a restricted surgical space, FLACS may provide better surgical results than conventional cataract surgery.^{4,23} Laser technology affords a more stable anterior chamber, reduces manual manipulation, and limits the disruption to surrounding tissue compared with standard cataract surgery.^{4,23} In addition, FLACS offers capsulotomy precision that can be maintained

in the confined space.²³ Complications in small eyes are expected to be low using FLACS due to decreased phacoemulsification time and power, with an associated reduction in endothelial cell loss likely.^{4,23}

Previous studies show that FLACS may be successfully performed in postpenetrating keratoplasty cases.² Recently, it has also been shown that mild corneal scarring, such as with radial keratometry scars, may be overcome by increasing laser energy.⁴ FLACS was also successfully performed in eyes after postrefractive surgery and postpenetrating keratoplasty.⁴ In these cases, the corneas may be very flat or steep with an increased risk for suction breaks or increased IOP; however, no such problems were reported.⁴ Instead, the postoperative spherical equivalent in the postrefractive eyes were comparable to untouched corneas, probably due to improved IOL position.⁴ FLACS was also noted to reduce phacoemulsification time and manual manipulation.⁴ This is advantageous in eyes with conditions such as Fuchs' endothelial dystrophy, where FLACS may lower the likelihood that later corneal surgery will be required.⁴

Intraocular pressure (IOP) is known to increase when docking the patient interface.¹¹ However, the average IOP rise observed with the SoftFit[™] Patient Interface is <17 mmHg, which is considered a nominal risk.^{11,12} An examination of post-trabeculectomy eyes 6 months after FLACS showed that the bleb, IOP, visual fields, and OCT retinal nerve fiber layer findings were stable.⁴ In all reported cases, the docking with the LenSx[®] Laser SoftFit[™] Patient Interface was uneventful without intrableb hemorrhage.⁴ Furthermore, a patient suffering from phacomorphic glaucoma underwent uneventful FLACS using the LenSx[®] femtosecond Laser system.¹⁸ FLACS may also decrease zonular stress in pseudoexfoliation syndromes by improving capsular strength and reducing lens rotation.⁴

Previous studies have suggested improved visual results with FLACS relative to standard cataract surgery in patients undergoing combined vitrectomy and cataract surgery.² A recent study also found that phacovitrectomy cases were completed successfully without complications with better postoperative visual acuity compared with preoperative values.⁴

Conclusion

Recent research presented here builds on earlier results, looking at ways to further improve the safety, applicability, and accuracy of FLACS. Expectations for standard surgery have been established; new articles addressed more challenging cases.

There have been a number of recent changes to the LenSx[®] Laser, with results from these changes now available in the literature. The SoftFit[™] Patient Interface was reported to reduce complications and improve capsulotomy results. The efficiency of the LenSx[®] Laser system has been improved through the introduction of a variety of new fragmentation patterns. Continued clinical evaluation of the FLACS procedure and the LenSx[®] Laser system will drive the continuous improvement of both. ■

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VERION™ Image Guided System – Important Product Information

Caution

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

Intended Uses

The VERION™ Reference Unit is a preoperative measurement device that captures and utilizes a high-resolution reference image of a patient's eye. In addition, the VERION™ Reference Unit provides pre-operative surgical planning functions to assist the surgeon with planning cataract surgical procedures. The VERION™ Reference Unit also supports the export of the 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, details 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. The following conditions may affect the proper functioning of the VERION™ Digital Marker: changes in a patient's eye between pre-operative measurement and surgery, an irregular elliptical limbus (e.g., due to eye fixation during surgery, and bleeding or bloated conjunctiva due to anesthesia). In addition, the use of eye drops that constrict sclera vessels before or during surgery should be avoided.

Warnings

Only properly trained personnel should operate the VERION™ Reference Unit and VERION™ Digital Marker. Use only the provided medical power supplies and data communication cable. 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. 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.