The LENSAR® Laser System–fs 3D for Femtosecond Cataract Surgery

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Abstract

The LENSAR® Laser System's ergonomic design permits flexible functionality in any operating environment. Its low-pressure liquid interface eliminates corneal compression and facilitates accurate and complete capsulotomy construction. The Augmented Reality™ imaging system utilizes a variable super luminescent diode for scanning structured illumination to provide high-contrast, high-definition targets, which guide the laser. Real-time imaging adjustments compensate for minute degrees of tissue displacement, permitting unrivalled precision in corneal incision architecture. Precise laser spot application allows fragmentation of all grades of cataract, without the need for unnecessarily large safety margins. Iris registration compensates for cyclotorsion in the construction of arcuate incisions by aligning preoperative corneal biometry to intraoperative imaging. The ability to define the cataract grade intraoperatively facilitates efficient phacofragmentation by permitting surgeon-specified preset patterns for the full range of nuclear densities. The LENSAR Laser System represents the state of the art in femtosecond cataract surgery.

Keywords

Femtosecond laser, cataract, capsulotomy, corneal incision, arcuate incision, iris registration, phacoemulsification, intraocular lens, ultrasound, phacofragmentation

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Since the introduction of ultrasound phacoemulsification in 1967, cataract surgery has become the most commonly performed outpatient operation in the US. While phacoemulsification has shown to be safe and effective, application of ultrasound power within the eye does carry some risk for ocular injury, such as endothelial cell loss. In addition, the manual method of creating the anterior capsulotomy, which is performed using the continuous curvilinear capsulorhexis (CCC), cannot ensure that the capsulotomy is consistently centered or circular,[1–3] thereby affecting the effective lens position (ELP). This is especially significant for multifocal, accommodating and toric intraocular lenses (IOLs) with more complex optical designs.

Recently, there has been increasing interest in the use of femtosecond lasers as an adjunct to ultrasound phacoemulsification in cataract surgery. Clinical studies have demonstrated incremental improvements with femtosecond laser-assisted cataract surgery compared with standard ultrasound.[4] Femtosecond lasers deliver ultrashort pulses of infrared energy so that collateral tissue damage is avoided. They cut tissue by photodisruption, that is, vaporization of targeted tissue, generation of cavitation bubbles, and creation of cleavage planes within tissue.[5] As transparent tissues do not absorb the lasers' infrared wavelengths, photodisruption can be focused precisely at a given depth within the anterior segment of the eye.

Four femtosecond laser systems have been cleared by the US Food and Drug Administration (FDA) for capsulotomy, phacofragmentation, and construction of corneal incisions in the context of cataract surgery: LenSx® (Alcon, Fort Worth, Texas), Catalys® (Abbott Medical Optics, Santa Ana, California), LENSAR® (LENSAR, Orlando, Florida), and Victus® (Bausch & Lomb, Rochester, New York). This article discusses the technological specifications and clinical applications of the LENSAR Laser System.

Specifications and Performance

The LENSAR Laser System was designed from the beginning to meet the strictest standards of accuracy and precision specifically for refractive cataract surgery. Optimal docking, imaging, and guidance set the stage for accurate laser shot placement and effective cutting, making the LENSAR Laser System the perfect preparation for phaco aspiration, IOL implantation, and wound sealing. The intrinsic qualities of LENSAR's optical laser, coupled with its novel, patented proprietary imaging technology and user-friendly patient interface, provide predictable and reproducible results, including free-floating anterior capsulotomies, ultrasound-sparing phacofragmentation patterns, easily opened clear corneal incisions (CCIs), and precise arcuate cuts. The outstanding safety and effectiveness of these advanced algorithms drive enhanced outcomes and improved

Figure 1: The Unique Design of the LENSAR Laser System-fs 3D (LLS-fs 3D) Prioritizes Flexibility and Ergonomics with a Mobile Platform that Functions Comfortably in a Variety of Settings

satisfaction for all IOL patients. In addition, the capability for integration of preoperative imaging and intraoperative guidance through iris registration allows increased efficiency and accuracy of arcuate incisions. Finally, the intraoperative ability to define the cataract nuclear density facilitates optimal phacofragmentation.

The unique utility and superior efficiency of the LENSAR Laser System-fs 3D (LLS-fs 3D) Augmented Reality™ result from these major innovations:

- Ergonomic profile and flexible system footprint that function efficiently in any operating environment.
- Patient-friendly, low-pressure liquid interface that allows for comfort, stable fixation, and ease of use.
- Augmented Reality structured scanning illumination and high-resolution imaging that provides automated surface detection, including accurate tilt and curvature correction in all axes. Structured scanning illumination adjusts the intensity of illumination for each specific structure so that dim features appear brighter and bright features do not saturate. Structured scanning results in uniform image brightness from anterior cornea to posterior lens capsule ensuring robust image processing that improves the accuracy and reliability of automated surface detection.
- Proprietary intraoperative imaging of the cornea that insures accuracy is maintained while each incision is performed. This imaging process takes place just prior to construction of each corneal incision, allowing adjustment of incision location and depth in order to compensate for any movement that necessarily occurs as a result of capsulotomy, fragmentation, or previous corneal incision construction.
- Precise laser delivery and placement that allows accurately structured multiplane corneal incisions, safe free-floating capsulotomies to within 250 μm of the pupil margin and safe phacofragmentation to within 500 μm of the posterior capsule.
- Planned addition of wireless data transmission of preoperative iris image capture and corneal biometry with pending addition of intraoperative iris registration that corrects for cyclotorsion in astigmatism treatment planning.
- Intraoperative cataract analysis that facilitates selection of phacofragmentation pattern for optimal reduction of energy.

Ergonomics

The LLS-fs 3D was designed for maximum flexibility with cataract surgeons in mind. The laser may be installed within a preoperative treatment room, holding area, or operating room (see *Figure 1*). It has a small footprint and is fully mobile. The laser can be moved away from the patient's bed to allow for positioning of a surgical microscope and ultrasound phacoemulsification system, so the patient does not have to be transferred to another operating bed or moved to a separate room. It works with any rolling bed or rolling chair in the office, ambulatory surgery center, or hospital outpatient environment. The patient bed can be positioned in line with the laser or perpendicular to the laser to allow for maximum utilization of the existing space.

The femtosecond procedure is surgeon controlled from a joystick and fully visualized on a dedicated surgeon's monitor. The docking head is on an extending arm that is electronically deployed to a neutral position, ready to receive the patient. Placement of the patient interface device (PID) proceeds smoothly and comfortably. After the PID is applied, the laser head is docked to the interface via the patient interface arm, using a joystick. Fine calibration permits smooth, delicate docking. The docking head itself is under patented servo control and maintains a low pre-determined force on the eye, minimizing any impact on ocular tissues or intraocular pressure (IOP). Three screens provide viewing capability for the surgeon, circulating nurse and technician. The surgeon may sit in a superior or temporal position, and perform the entire procedure solo or with an assistant. Once imaging of the anterior segment and femtosecond laser treatment are complete, suction is automatically released and the docking head is retracted to an out-of-the-way neutral position. To allow greater working distance, the docking head can be programmed to automatically move back even further to allow additional unrestricted access to the patient.

The intuitive user interface on the monitor allows the surgeon to customize the treatment beyond default software parameters. Capsulotomy size can be programmed according to the IOL manufacturer's recommended specifications or the surgeon's preference. The width of the fragmentation pattern can be extended or reduced within the pupil diameter subject only to programmed safety margins. The depth of the pattern can be increased to fragment the posterior nuclear plate. Laser energy and spot density can be pre-programmed or adjusted based on the intraoperative ability to define cataract grading to insure effective phacofragmentation in both soft and dense cataracts.

Pattern Selection

In addition to the standard phacofragmentation patterns, the LLS-fs 3D provides full customization options for femtosecond laser treatment. This customization is available via the selection of a surgery profile. This profile can be completely customized by accessing the LENSAR pattern designer feature. The capsulotomy, phacofragmentation pattern, and incisions can be customized for each individual patient or the optimized LENSAR patterns may be utilized. Fragmentation options include both cylindrical and cubic patterns, and adding one to four chops can provide additional phacofragmentation. More parameters can be accessed to provide complete control of the size and spacing of the selected pattern.

Docking and Coupling

The LLS-fs 3D patient interface incorporates a low-pressure suction ring that comfortably immobilizes the eye. Once the suction ring is applied and filled with saline, the laser is docked to the interface using a servo controlled docking head and patient interface arm that limits the amount of pressure applied to the eye. Similar to the principle of gold-standard immersion ultrasound for axial length measurement, the low-pressure liquid interface avoids the creation of corneal striae that distort anterior segment imaging. Crisp, clear images of the anterior and posterior cornea and crystalline lens are thus obtained without any disturbing artifacts. Live pupil-tracking video demonstrates the stability of the LENSAR patient interface. During the entire procedure, the eye moves less than 70 microns and only ±15 microns during the critical laser surgery phase.[6]

To insure maximum accuracy, the LENSAR system employs several methods of real-time correction of ocular movement. At the initiation of Augmented Reality imaging, the LENSAR system measures and stores the pupil position. Then, prior to the initiation of laser firing, the pupil position is again measured. Any relative shift in eye position is instantaneously corrected. The LENSAR system has the ability to correct up to 250 μm of detected movement. If the patient interface is improperly docked (i.e., in rare cases of >250 μm of eye movement), safety software prompts the surgeon to re-dock the patient.

For further system accuracy, real-time adjustment for relative eye movement continues during construction of the corneal incisions. Immediately prior to the laser beginning a corneal incision, the Augmented Reality system re-images the cornea at multiple locations along the target area for that incision. The corneal treatment pattern is then instantaneously adjusted to fit the real-time corneal position and curvature. This process compensates for any corneal movement induced by gas expansion during capsulotomy and lens fragmentation, as well as for the corneal sag intentionally induced by corneal arcuate relaxing incisions. The re-imaging process is repeated for every corneal incision. The result is uniform depth across the entire arc length of the corneal incision, a feature unique to the LENSAR system.

Imaging—Augmented Reality

The LLS-fs 3D incorporates proprietary Augmented Reality imaging and anterior segment biometry built around the innovative technology of scanning structured illumination. Augmented Reality utilizes super luminescent diode (SLD) technology that scans at a variable rate depending on the target structure. This methodology insures optimum contrast for structures with a high degree of light scatter, such as the cornea, as well as for those structures with little light scatter, such as the posterior lens capsule.

The Augmented Reality (structured illumination) software minimizes image background noise, permitting high-definition imaging and accurate biometric measurements regardless of nuclear density of the cataract. Enhanced depth of field is attained through angular displacement of the imaging lens and sensor, which allows crisp focus of the entire image. These innovations allow capture of a focused image from the anterior cornea to the posterior lens capsule despite dense or even opaque media.

The rotating Augmented Reality camera scans and displays the structures of the anterior segment from up to five angles, unlike optical coherence tomography (OCT)-based systems that display only two angles: one sagittal and one transverse. The LENSAR System thus provides high-definition imaging of the anterior chamber and lens during the treatment planning process.

Figure 2: Augmented Reality Performs Two Scans from Each of Five Viewing Aspects to Produce 10 Images for 3D Reconstruction. Position 1 is Shown Here.

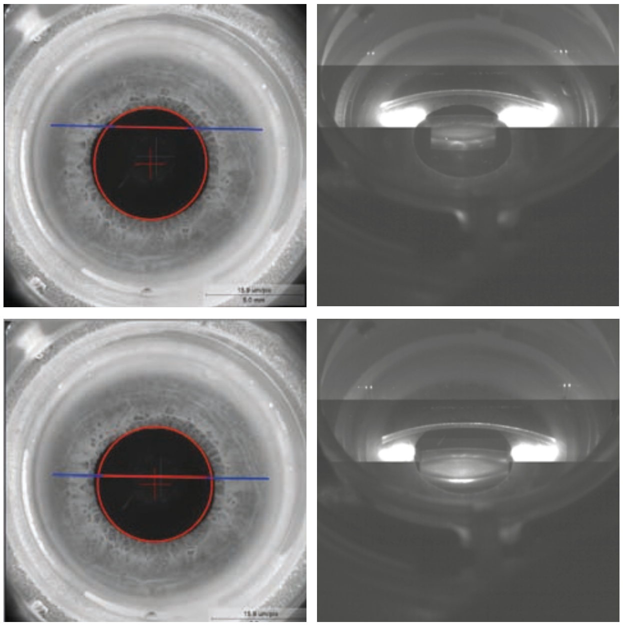


Figure 3: Automated Surface Detection of the Corneal and Lenticular Surfaces

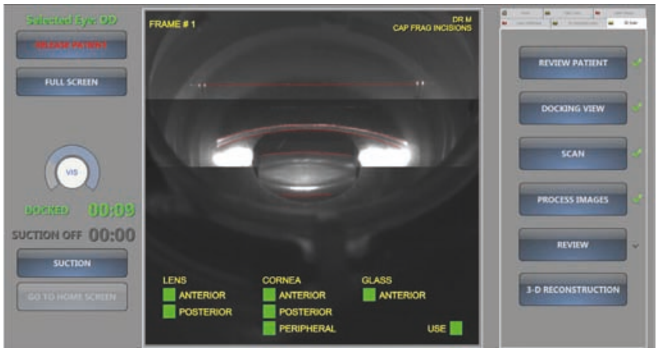
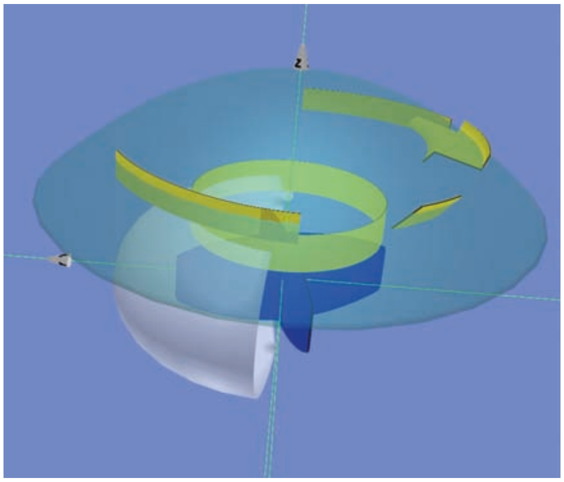


Figure 2 displays the off-center scanning capability of the Augmented Reality camera. Detailed imaging of the posterior lens capsule allows the surgeon to program safe and precise laser shot applications to within 500 μm of the posterior capsule. The high-resolution imaging of the pupil allows safe capsulotomy construction within 250 μm of the pupil margin. Augmented Reality performs two scans from each of the five viewing angles to produce up to 10 images for 3D reconstruction. The 3D-Augmented Reality imaging software identifies major interfaces including anterior and posterior corneal surfaces and anterior and posterior lens capsules (see *Figure 3*). Using optical ray tracing techniques, software collates the multiple acquired images and measurements to generate an exact 3D reconstructed model of the anterior segment (see *Figure 4*).

Lens tilt is determined during the 3D reconstruction process as the Augmented Reality software analyzes the anterior and posterior curvatures of the lens capsule in relation to the optical axis. Identifying lens tilt is important because it allows the surgeon to center the anterior

Figure 4: The 3D Reconstruction Displays the Clear Corneal Incision, Corneal Relaxing Incisions, Paracentesis, Anterior Capsulotomy, and Lens Fragmentation Pattern



capsulotomy symmetrically over the optical axis or pupil center, avoid incomplete capsulotomies, and prevent damage to the posterior capsule. The pupil-centered capsulotomy is tilted to match the lens tilt, ensuring a complete capsulotomy. Fragmentation patterns are likewise adjusted for lens tilt to prevent damage to the posterior capsule.

Capsulotomy

Creating the capsulorhexis is often acknowledged as the most important step in a cataract procedure. A properly constructed capsulorhexis provides the foundation for stable IOL positioning. A perfectly circular and properly sized capsulorhexis allows the capsular bag to envelop the optic, reducing the incidence of posterior capsular opacification, and providing a more predictable ELP. The capsular opening created requires mechanical strength sufficient to assure the integrity of the capsule during lens extraction and IOL implantation.

A laser anterior capsulotomy provides all the benefits of a capsulorhexis, but with more accurate centration, size, and circular symmetry. These characteristics are difficult to achieve with the manually created CCC. The LENSAR laser allows the user to select whether the capsular opening will be centered on the pupil or on the optical axis of the lens, based on precise, automatic measurements of the eye by the 3D-Augmented Reality biometric system, something no surgeon can achieve manually.

The accuracy, circularity, and repeatability of the laser capsulotomy allow an often-overlooked degree of flexibility in choice of capsulotomy diameter, which can help assure the capsular edge integrity. As part of FDA pre-clinical trials validating the performance of the LENSAR Laser System, LENSAR conducted tests in *ex vivo* porcine lenses, comparing the strength and extensibility of anterior laser capsulotomy to that of manual capsulorhexis. As part of the testing, the effect of capsulotomy diameter on extensibility and break force was investigated. The data for these parameters for the laser capsulotomies demonstrated consistently higher break forces and maximum extensions than those constructed manually. Of note, the larger diameter (>5.0 mm) capsulotomies exhibited greater resistance to tearing. The precision, accuracy, and circularity of laser anterior capsulotomies allow a capsulotomy of precise diameter to ensure the capsular edge completely overlaps the implanted IOL. The accuracy of the LENSAR Laser System in particular facilitates construction of these capsulotomies because it only requires a safety margin of 250 μm clearance from the pupil margin. These factors contribute to ensuring the integrity of the anterior capsule edge during cataract removal and IOL placement.

Fragmentation

While the use of ultrasound phacoemulsification has made the cataract operation relatively safe, application of ultrasound power within the eye does carry the risk for ocular injury. Using rabbit eyes, Murano et al. studied the effect of ultrasound oscillations in the anterior chamber. The authors observed oxidative stress and cellular necrosis after ultrasound, and concluded that corneal endothelial cell damage was caused by free radicals associated with ultrasound oscillation within the anterior chamber.[7] Similarly, Shin et al., showed that increasing ultrasound time and energy had a direct relationship to endothelial cell injury.[8]

With consideration to a reduction in ultrasound energy and instrumentation, femtosecond laser cataract surgery has shown improved safety and decreased complications. This is achieved through the focus of light energy on very small focal spots over very brief periods of time. This process, photodisruption, results in plasma formation and the propagation of acoustic waves within the lenticular mass. These sound waves incise and soften the cataractous material facilitating gentle phaco aspiration with minimal need for ultrasound power.

The LLS-fs 3D Augmented Reality system's laser engine and delivery optics have been uniquely designed to fragment nuclei across a wide range of Lens Opacities Classification System (LOCS) III grades, including deeply brunescent and white cataracts. Femtosecond cataract surgery utilizes low levels of laser energy to fragment the lens nucleus. Laboratory data demonstrate that the femtosecond laser photo disruption process generates significantly lower levels of acoustic waves and mechanical forces compared with that of traditional ultrasound phacoemulsification. This fact, combined with the reduction in effective (ultrasound) phaco time (EPT) and cumulative dissipated energy (CDE) that result from laser fragmentation, offers a clinically relevant reduction in the risk for endothelial cell damage.

A clinical study comparing the efficacy of laser fragmentation to conventional phacoemulsification utilizing the Alcon Infiniti platform with the Ozil Intrepid hand piece demonstrated a reduction in CDE of 79.3 %, 66.3 %, and 55.6 % for LOCS III Grade 2, 3, and 4 cataract nuclei.[9] These early data proved the efficacy of femtosecond laser phacofragmentation for ultrasound reduction.

With worldwide use of the system, the need for a variety of programmable lens fragmentation patterns was identified to facilitate surgeons' drive towards zero utilization of ultrasound energy. The LLS-fs 3D Augmented Reality proprietary LensDoctor software incorporates a variety of customizable lens fragmentation patterns. The choice of treatment algorithm will depend on surgeon technique, nuclear density, and patient anatomy. These parameters will in turn likely influence surgical efficiency and the amount of ultrasound energy needed for nuclear extraction.

Utilization of femtosecond cataract surgery will reduce the need for ultrasound energy to varying degrees dependent on the pattern that is utilized. This reduction of energy may be particularly helpful in patients with high risk for corneal decompensation, such as patients with dense cataracts, compromised corneal endothelium, shallow anterior chambers, glaucoma, or prior corneal transplant.

The pending addition of the Fragmentation Pattern Selection menu with LENSAR Augmented Reality imaging allows increased efficiency in selection of fragmentation patterns by locating the endonucleus boundary and analyzing nuclear density (see *Figure 5*). The high-resolution, high-definition Augmented Reality imaging system permits accurate grading of nuclear opalescence compared with grading performed by certified users of the LOCS III.[10] Mapping cataract density to preset, surgeon-specified fragmentation patterns, while permitting the physician the latitude to alter settings for unusual cases, allows tailoring of the fragmentation for each case to reduce total suction time and ultrasound phaco time while increasing operating efficiency.

Corneal Incisions

Manual keratome constructed CCI have become a commonly adopted approach for cataract surgery since their introduction in 1992.[11] While simple and effective, it has been suggested that the CCI is associated with an increased risk for postoperative endophthalmitis.[12] According to the American Academy of Ophthalmology, "It has been proposed that the increased infection rates correspond to the increased use of CCIs for cataract surgery, because improperly constructed CCIs are more prone to postoperative instability, leakage, and a potential influx of microbes than are sclerocorneal incisions."[13] A recent study utilizing anterior segment OCT showed that a majority of eyes had internally gaping corneal wounds and detachment of Descemet's membrane after CCI.[14] It is hypothesized that these defective wounds can increase the risk for postoperative endophthalmitis.

The utilization of femtosecond lasers for the creation of corneal incisions has been well documented. Femtosecond laser CCIs introduce accuracy and structured architecture to the clear corneal surgical wound. This structured architecture allows for greater postoperative wound sealing and a reduced impact on postoperative anterior corneal topography compared with manual CCIs. Laser incisions allow for a more square architecture, which has proved resistant to leakage.[15]

The greater uniformity of laser incisions from case to case implies greater predictability in surgically induced astigmatism. Although surgically induced astigmatism resulting from manual CCIs is generally less than one diopter, surgeons typically find a standard deviation as large or larger than their means. The standardization of laser incisions can help to reduce this variation and make astigmatic outcomes more predictable.

The accuracy of the femtosecond laser CCIs hinges upon the proper delivery of the intended pulse pattern. However, a femtosecond cataract platform must be able to deliver the capsulotomy and fragmentation as well as corneal incisions all within a single docking instance. A fluid interface is crucial for optimal capsulotomy and fragmentation delivery, but conversely does not possess the hold of high-vacuum corneal applanation patient interfaces typically utilized in laser-assisted *in situ* keratomileusis (LASIK) flap creation.

Figure 5: The Automated Cataract Grading Process Virtually Partitions the Lens to Analyze Nuclear and Epinuclear Density

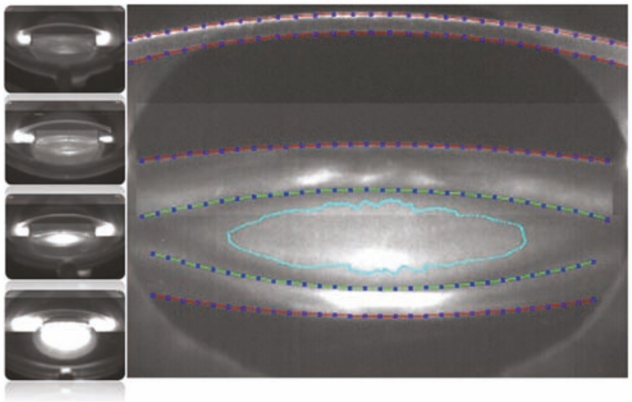
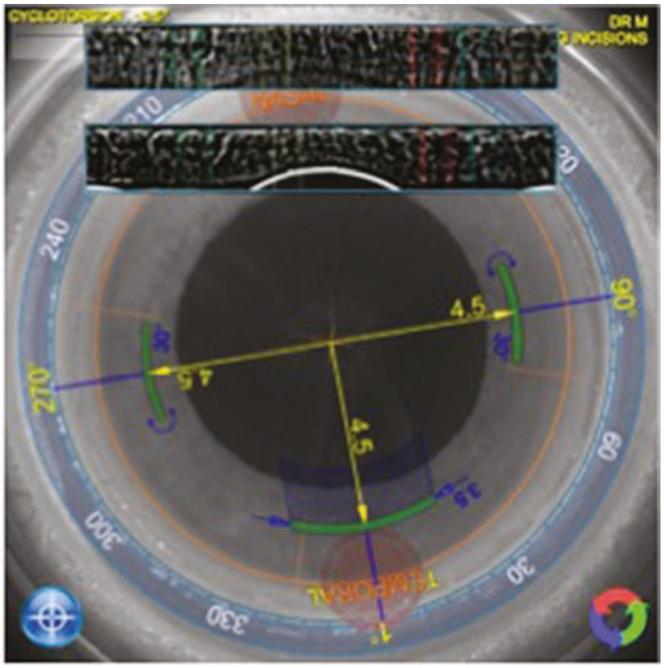


Figure 6: Iris Registration



Iris registration matches features of the preoperative and intraoperative images to compensate for cyclotorsion and accurately place arcuate incisions, thus eliminating the need to mark the eye.

The LLS-fs 3D Augmented Reality utilizes a unique real-time corneal imaging and adjustment technique named 'Localized Imaging' to compensate for the corneal movement that may be induced by the gas formation secondary to capsulotomy and phacofragmentation. During the corneal incision phase of laser surgery, the LLS-fs 3D Augmented Reality re-images the cornea at the specific location of the intended corneal or arcuate incision. The real corneal position at this point in the surgery is compared with the corneal position at the beginning of the procedure. Since the cornea moves in response to the effects of every corneal incision, this information is gathered at multiple points along the length of the incision and allows the LensDoctor software to compute the exact points to deliver each laser pulse in order to have a perfectly positioned corneal incision despite corneal sag, tilt, or movement. This process is performed for each corneal incision and results in uniform depth across the entire arc length of the corneal incision. This feature and its resultant accuracy are unique to the LENSAR system.

Iris Registration and Arcuate Incisions

The pending addition of the iris registration feature to the LLS-fs 3D utilizes preoperative imaging and corneal biometry supplied by automated keratometry or topography. Wireless transmission of data from diagnostics to laser increases efficiency and removes potential sources of error from transcription or translation. The preoperative image is immediately compared with the LENSAR Augmented Reality intraoperative image, matching iris features from the undilated, preoperative iris to the same features located in the dilated, intraoperative iris in order to compensate for natural recumbent cyclotorsion. In the example shown in *Figure 6*, iris registration detected a 9.5° clockwise rotation that was corrected during the incision-planning phase of the procedure.

Clinical Experience in Laser-assisted Cataract Surgery

Short Procedure Time and Low Intraocular Pressure Elevation

In a recent commercial use clinical series, the data on IOP elevation and procedure duration were tracked. Procedure time was short, from 1 minute 16 seconds to 2 minutes 50 seconds, and the low-pressure suction ring immobilized the eye with only moderate IOP rise. More recent commercial use experience has demonstrated average total docking times of 1.5 minutes, with the laser active time also reduced to as low as 8 to 12 seconds.

Reduced Endothelial Cell Loss

In a series of 433 cases, the percent reduction in cell count was 0.4 ± 11.3 for the laser cases and 2.6 ± 9.6 for the standard ultrasound phaco cases. This difference was clinically significant at the 90 % level.[16]

Free-floating Capsulotomies

The industry-standard perfect capsulotomy depends on position, size, and 'free-floating' or complete pattern with no or insignificant capsular /cortical tags. In one study, 95.9 % of capsulotomies were free floating or complete; whereas nearly 100 % of capsulotomies showed no or only insignificant tags.[7]

The LENSAR Laser System

The attributes of ideal femtosecond laser cataract surgery include a perfect capsulotomy, round, centered, flawless; a fragmented nucleus chopped and ready for aspiration without ultrasound; and pristine corneal incisions, predictable, accurate, precise. Today, an increasing percentage of surgeons are using femtosecond laser technology, which may be said to be still in its infancy; however, femtosecond lasers for cataract surgery represent the most significant innovation in our field since the introduction of ultrasound over 40 years ago.

Femtosecond surgery has demonstrated reduced endothelial cell loss, reduced corneal edema, and reduced macular edema compared with ultrasound phacoemulsification. We have seen evidence of reduced postoperative mean refractive spherical equivalent absolute error, reduced IOL tilt, and reduced postoperative astigmatism.

Surgeons using the LENSAR Laser System have demonstrated these clinical improvements in the outcome measures of cataract surgery. These improvements are made possible by several main innovations:

- The convenient, ergonomic design permits flexible functionality, in the operating room or laser room.
- The low-pressure liquid patient interface eliminates corneal compression and allows precise imaging and laser delivery.
- The Augmented Reality imaging system utilizing variable SLD and scanning structured illumination provides high-contrast, high-definition targets to guide the laser.
- Real-time targeting adjustments compensate for minute degrees of tissue displacement, permitting unrivalled precision in corneal incision architecture.
- Precise laser spot application allows fragmentation of all grades of cataract, without the need for unnecessarily large safety margins.

Premium surgery demands premium technology. They work hand-in-hand to create great visual outcomes and satisfied patients. ■

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