



LENSAR

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Customized Femtosecond Laser Assisted Cataract Surgery for the Next Generation

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Next generation intraocular lenses for cataract and lens-based refractive surgery require increasingly customized and precise surgical procedures to ensure their safety, accuracy and performance. For example, capsulotomy size, shape and location have a significant impact on the outcomes of multifocal and extended depth of focus IOLs,¹ and corneal incision size, structure and location affect surgically induced astigmatism.² In addition, the use of excessive intraocular energy for lens extraction has implications for the speed and stability of postoperative recovery.³ In the near future, the emergence of accommodative IOLs will place further demands on the requirements for customized surgery. To address these increasing requirements for customization and precision, the LENSAR Laser System delivers state of the art femtosecond laser assisted cataract surgery (FLACS) with advanced imaging and guidance, allowing superior outcomes and truly customized surgery to match patients' expectations for high quality vision at all distances.

Next Generation Intraocular Lenses

The robust capabilities of the LENSAR laser are acutely aligned to the attributes of next generation IOLs, making it a valuable asset in achieving optimal results on a routine and predictable basis. For example, consider the surgical requirements for implantation of the Light Adjustable Lens (LAL, RxSight, Aliso Viejo, CA). The LAL allows postoperative adjustment of refractive power with ultraviolet (UV) light in order to obtain exceptionally precise correction and superior uncorrected visual acuity.⁴ However, because the LAL is a silicone IOL, it is more likely to engender anterior capsule opacification⁵ and phimosis^{6,7} that may impede treatment by blocking UV irradiation. For example, Hayashi et al reported a 12% reduction in the anterior capsule opening area with silicone IOLs during the time when UV treatments are performed. Fortunately, "use of a larger capsulorhexis can minimize this potential problem."⁸ At the same time, however, it remains critical to achieve 360° overlap of the anterior capsule around the edges of the IOL in order to minimize the potential for posterior capsular opacification.⁹ These competing demands for both a larger capsulotomy and complete overlap of the IOL optic demand precision beyond the routine reach of even the most accomplished manual capsulorhexis surgeon. In this challenging situation, the accuracy and customizability of capsulorhexis construction relative to size, position and shape with the LENSAR laser make it a natural fit for surgery with the Light Adjustable Lens.

The LENSAR laser is similarly beneficial for multifocal IOLs. The recently FDA-approved AcrySof IQ PanOptix Trifocal IOL (Alcon, Ft. Worth, TX) can provide freedom from glasses to over 80% of patients; however, as with other multifocal IOLs, low contrast acuity is reduced, especially at intermediate and near distances.¹⁰ In order to achieve optimal results and high levels of patient satisfaction with multifocal IOLs, rapid visual recovery is critical and requires both a clear cornea and pristine macula postoperatively. Because optimization of laser phacofragmentation patterns reduces both endothelial cell loss and inflammation,¹¹ the LENSAR laser makes these results achievable by automatically selecting the fragmentation pattern based on the characteristics of the lens and minimizing both

"For exciting new intraocular lenses on the horizon, the LENSAR laser will be a natural technology pairing in order to attain the highest levels of patient satisfaction."

laser and ultrasound energy requirements for lens extraction. In addition, IOL power calculation and achievement of spectacle independence with multifocal IOLs are enhanced by achievement of consistent effective lens position. Femtosecond laser capsulotomy results in a more stable refractive result and less IOL tilt and decentration than manual capsulorhexis.¹² LENSAR also allows centration of the capsulotomy on either the pupil center or the Anatomical Lenticular Axis™ of the lens, facilitating optimization of refractive outcomes.

For exciting new intraocular lenses on the horizon, the LENSAR laser will be a natural technology pairing in order to attain the highest levels of patient satisfaction. One such lens is the Juvene Curvature Changing Fluid-Optic Intraocular Lens (LensGen, Irvine, Ca), which will offer a continuous range of vision but also require an ability to fine-tune the correction of astigmatism in order to maximize outcomes, as well as precise capsulotomy construction to ensure effective lens position. LENSAR laser arcuate incisions provide the means to reduce smaller amounts of residual refractive astigmatism to negligible levels. Toric IOLs such as the enVista (Bausch & Lomb, Rochester, NY) can accurately correct moderate and higher degrees of astigmatism, particularly when aligned with LENSAR IntelliAxis Refractive Capsulorhexis (IntelliAxis) steep capsular marks capsular marks. Iris registration and image-guided toric IOL alignment minimize the risk of residual refractive astigmatism, which increases by 3.5% for each degree of rotational error.¹³ Because toric IOLs are only available in distinct powers, arcuate incisions can help to fill the gap between good and great results. The precision and reproducibility of LENSAR laser arcuate incisions, based on iris registration, image guidance and automated implementation of customized surgical nomograms, have advanced the effectiveness of astigmatism correction with the femtosecond laser.

LENSAR's innovations encompass the entire field of femtosecond laser surgery, from imaging and guidance to customized capsulotomy construction, astigmatism management and phacofragmentation, leading to improved refractive outcomes. While these innovations are becoming increasingly critical to the safety and performance of next generation IOLs, their benefits also accrue to implantation of today's standard lenses. The goal remains increased safety and optimal results for all patients.

LENSAR® Laser System

Adaptability, accuracy, and predictability for every IOL

Precise capsulorhexis creation

► Consistent and improved ELP

- Accurate positioning and precise sizing
- Customizable to adapt to any IOL
- Reduced IOL tilt and decentration vs. manual capsulorhexis
- Centration on the pupil center or optical axis

Customized fragmentation patterns

► Faster visual recovery

- Cataract Density Imaging (CDI) uniquely identifies nuclear morphology & density and adapts fragmentation pattern according to category
- Reduced CDE minimizes potential for inflammation and endothelial cell loss

Superior imaging

► Outcomes optimization

- Combines Scheimpflug imaging, ray tracing, and Augmented Reality™
- Creates a 3-D model that identifies the cornea and lens
- Adapts treatment based on lens tilt detection and curvature correction in all axes
- Captures accurate biometric measurements regardless of nuclear density

IntelliAxis Refractive Capsulorhexis®

► Precise toric IOL alignment

- Leverages wireless integration of pre-op data and iris registration to precisely identify the steep axis
- Guides precise toric IOL alignment with unique capsular marks
- Eliminates parallax experienced with corneal markings

Arcuate incision planning

► Reduced residual astigmatism for all IOL types

- Automatically adapts incision parameters based on the surgeon's nomogram and SIA
- Seamlessly connects with pre-op diagnostics
- Iris registration allows for precise incision placement

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Extended Depth of Focus IOLs

- Arcuate incisions reduce or eliminate residual astigmatism to increase spectacle independence and patient satisfaction



Toric IOLs

- IntelliAxis Refractive Capsulorhexis eliminates parallax and guides precise IOL alignment on the steep axis for superior outcomes
- Iris registration and precise IOL alignment minimize the risk of residual refractive astigmatism, which increases by 3.5% for each degree of rotational error



Presbyopic IOLs [Presbyopic Toric IOLs/EDOF/Accommodating IOL/LAL]

- Optimizes capsulotomy size maintaining 360° overlap to prevent PCO
- Results in more stable refractive result and less IOL tilt and decentration vs. manual capsulorhexis
- Adaptive fragmentation patterns based on density reduce endothelial cell loss and inflammation, resulting in clear cornea and pristine macula



Light Adjustable Lenses

- Optimizes capsulotomy size to be as large as possible to maximize area for UV adjustment while maintaining 360° overlap to prevent PCO

Augmented Reality

LENSAR's surgical innovations begin with imaging. The LENSAR laser system incorporates Augmented Reality through advanced Scheimpflug imaging, ray tracing and 3D confocal structured illumination (3D-CSI) to construct a three-dimensional model of the anterior segment of the eye including the cornea and lens (Figure 1). LENSAR's 3D Augmented Reality software consolidates 16 individual high resolution Scheimpflug images from 8 angular positions to identify not only the major interfaces (anterior and posterior corneal surface and anterior and posterior lens capsule) but also reveal details of the location and density of the lens nucleus and the boundaries between endonucleus, epinucleus and cortex (Figure 2), thus allowing automated grading of cataract density and customization of phacofragmentation.

Augmented Reality structured scanning illumination utilizes super luminescent diode (SLD) technology, which adjusts the scan rate for each structure to brighten fine features such as the posterior capsule and prevent saturation of highly reflective features such as the anterior cornea. The resulting uniform brightness from anterior cornea to posterior lens capsule ensures accurate image processing and improves the reliability of automated surface detection. Benefits include accurate lens tilt and curvature correction in all axes, and accurate biometric measurements regardless of the nuclear density of the cataract.

Scheimpflug imaging is different from optical coherence tomography (OCT) systems used by other femtosecond lasers in that the object plane, lenticular plane and image plane are all parallel (with OCT the 3 planes intersect in a straight line). In comparison to OCT, Scheimpflug provides enhanced depth of field and allows more precise laser focalization.¹⁴ Additionally, the rotating Augmented Reality camera scans and displays structures of the anterior segment from 8 angular positions, producing 16 images for 3D reconstruction. In contrast, OCT-based systems display images from only two angles, one sagittal and one transverse.¹⁵ As a result, the LENSAR laser system generates a seamless, in-focus, high definition 3D image without photo stitching.

Because of LENSAR's precise imaging of the posterior lens capsule, surgeons may safely program laser shot applications to within 500 μm of the posterior capsule. Similarly, high-resolution imaging of the pupil allows capsulotomy construction within 250 μm of the pupil margin. Lens tilt is analyzed during 3D reconstruction as the Augmented Reality software reconstructs the anterior and posterior lens curvatures in relation to the Anatomical Lenticular Axis™ of the lens. Identification of lens tilt is critical because it permits the surgeon to center the anterior capsulotomy symmetrically over the Anatomical Lenticular Axis™ or pupil center, avoid incomplete capsulotomies, and prevent damage to the posterior capsule. Because the pupil-centered capsulotomy is automatically tilted to match the lens tilt, a complete capsulotomy is ensured. In addition, precise imaging of the anterior capsule reduces laser application in the lens cortex by narrowing the linear extent of laser shots along the

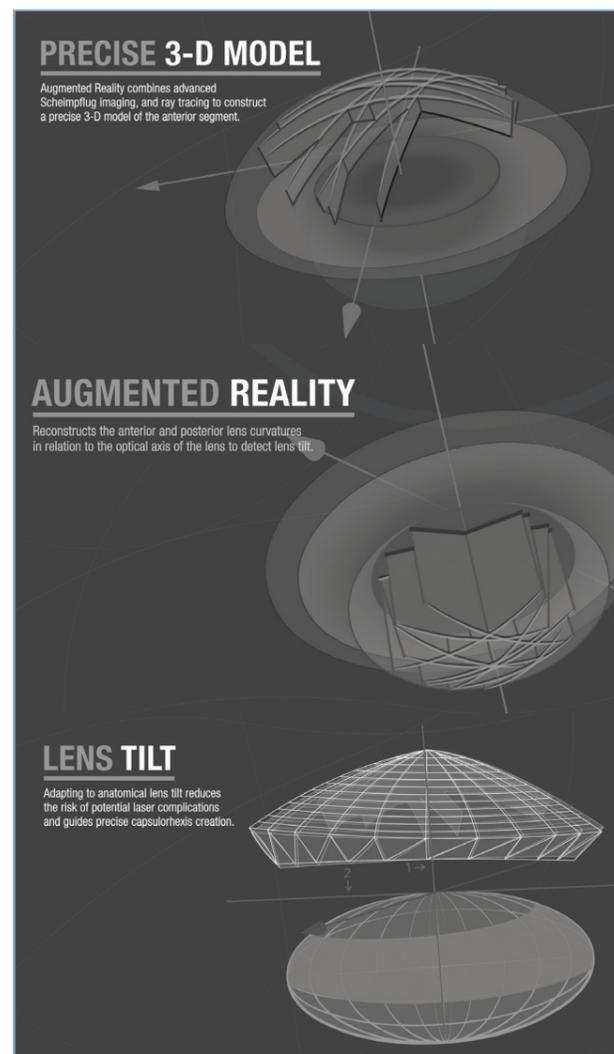


Figure 1. The LENSAR laser system incorporates Augmented Reality through advanced Scheimpflug imaging, ray tracing and 3D confocal structured illumination (3D-CSI) to construct a three-dimensional model of the anterior segment of the eye including the cornea and lens, allowing compensation for lens tilt and precise capsulorhexis construction.

z-axis that are required to insure a complete capsulotomy. In this way, hydrodissection is facilitated and cortical clean up is simplified. Fragmentation patterns are likewise adjusted for lens tilt to prevent damage to the posterior capsule. These unique capabilities of LENSAR's advanced imaging technology maximize both safety and effectiveness and allow customization of the capsulotomy, phacofragmentation and corneal incision construction.

Only the LENSAR femtosecond laser automatically detects and categorizes lens density and using high resolution, high-definition Augmented Reality imaging to accurately locate the nucleus, epinucleus and cortex, and automatically assign the optimal phacofragmentation pattern. Benefits include enhanced operating efficiency and improved rapidity and stability of postoperative visual rehabilitation.

CATARACT DENSITY IMAGING

Reveals the details of the cataract and allows for automated categorizing of cataract density and adaptive fragmentation pattern selection.

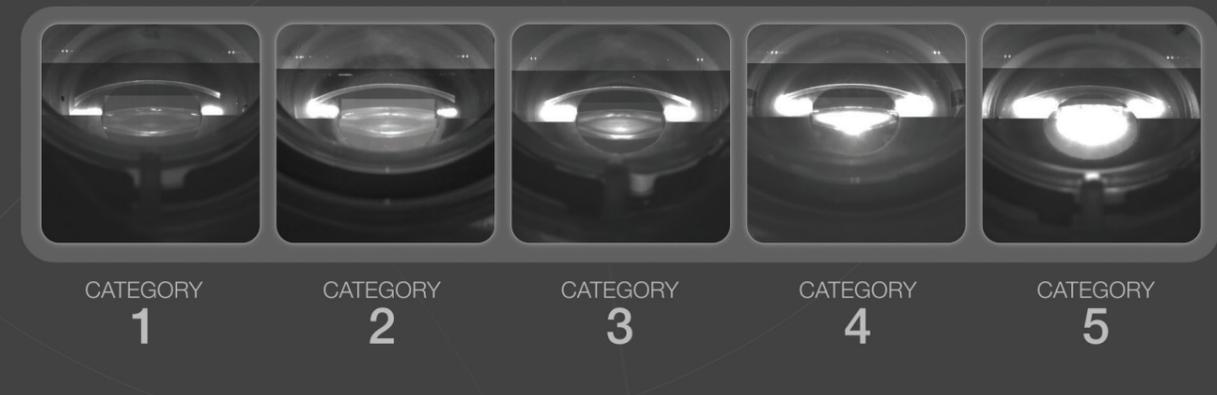


Figure 2. LENSAR's 3D Augmented Reality software consolidates 16 individual high resolution Scheimpflug images from 8 angular positions to not only identify the major interfaces (anterior and posterior corneal surface and anterior and posterior lens capsule) but also reveal details of the location and density of the lens nucleus and the boundaries between endonucleus, epinucleus and cortex, thus facilitating automated cataract density grading and customized phacofragmentation.

Customized Capsulotomy

Every step of lens extraction is facilitated by a perfectly circular, correctly sized capsulotomy. In the long term, stable IOL positioning and elimination of posterior capsular opacification depend on a continuous circular capsulotomy customized to the intraocular lens.¹⁶ Customized capsulotomy also impacts the effective lens position (ELP), thus reducing error from IOL power calculations.¹⁷ The LENSAR laser system significantly improves the accuracy and repeatability of capsulotomy construction and the predictability and stability of postoperative refraction.¹⁸

Because LENSAR Augmented Reality accurately measures lens tilt with respect to the coronal plane it not only avoids incomplete cuts but also enables precise capsulotomy dimensions and improves the predictability of effective lens position (ELP), resulting in improved refractive outcomes. Biometric data is acquired by the LENSAR laser and measured in x-y-z space to detect lens tilt and guide laser spot application, thus not only minimizing incomplete buttons and capsular tags but also reducing the risk of damage to the posterior capsule during phacofragmentation.¹⁹ A reduced treatment zone is available when the posterior capsule is not detectable, such as with exceptionally dense, white or brunescient nuclei.

In an ex-vivo porcine eye study, Packer et al showed that the LENSAR laser capsulotomy demonstrates a significantly higher break force and greater extensibility than a manual capsulorhexis.¹⁶ Data also suggested that larger-sized capsulotomies (>5.0 mm) are more resistant to tearing. With the ability to construct precisely sized capsulotomies, the LENSAR laser allows the surgeon total

flexibility to customize the capsulotomy location and diameter. For example, centration on the Anatomical Lenticular Axis™ of the lens simultaneously allows complete 360 degree overlap of the IOL optic edge while maintaining a large capsulotomy diameter. Furthermore, because the LENSAR laser can safely operate to within 250 μm of the pupil margin, smaller pupil sizes pose no obstacle.

In a clinical study of refractive outcomes, Edwards et al measured the effect of the LENSAR customized capsulotomy on the achievement of targeted postoperative refractive spherical equivalent and compared it to a theoretical model.²⁰ At 6 months postoperative, comparing 249 eyes with LENSAR laser capsulotomy to 123 eyes with manual capsulorhexis, the authors showed that laser capsulotomy produced an incremental but significant reduction in the deviation from the intended postoperative refractive outcome. A total of 11.6% of the laser treated eyes were within 0.12 D of target compared with just 4.1% in the manual group; 78.8% and 52.8% were within 0.50 D for laser treated and manual eyes, respectively. These authors further showed that the theoretical improvement of 0.17 D is closely related to the achieved reduction of 0.18 D in absolute deviation from target manifest refraction spherical equivalent. The authors suggested that in order to achieve further improvements in the accuracy of postoperative refraction more emphasis must be placed on other sources of error such as biometry, choice of calculation formula and IOL power interval.

The customized capsulotomy thus provides a mechanically stable and physically robust opening for lens extraction while also improving postoperative refractive outcomes through consistent construction and precise laser focalization.

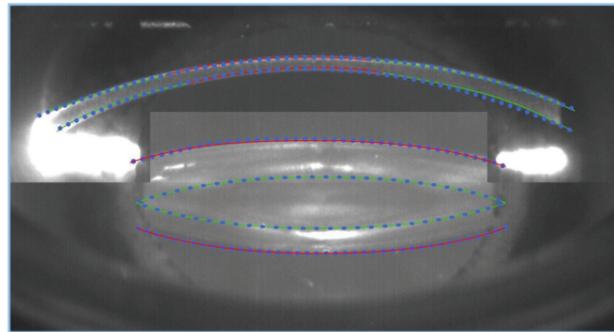


Figure 3. Based on surgeon preference, the LENSAR laser system automatically recommends or assigns the fragmentation pattern best suited to the specific morphology and density of the cataract to minimize both femtosecond and ultrasound energy and optimize lens extraction.

Customized Phacoemulsification

Reduction of intraocular energy utilization for lens extraction improves the speed and stability of postoperative visual rehabilitation. Femtosecond laser assisted phacoemulsification reduces the ultrasound energy necessary to emulsify a cataract, and the reduction is correlated with the nuclear density of the cataract density, i.e., the denser the cataract, the greater the benefit.²¹ Because intraocular energy expenditure from ultrasound may result in inflammation, macular edema and corneal endothelial cell loss, LENSAR has developed automated cataract density grading and optimized laser phacoemulsification to further reduce and eliminate the requirement for ultrasound phacoemulsification.²²

Customization of phacoemulsification to optimize energy utilization depends on accurate laser focalization within the lens.²³ LENSAR achieves precise focalization through high resolution Augmented Reality 3D reconstruction of the cornea, iris and lens. Only LENSAR is capable of automated selection of fragmentation parameters through detailed imaging, image processing and computerized delineation of the nucleus, epinucleus, and cortex, allowing more efficient phacoemulsification.

In addition to delineation of the nucleus, epinucleus and cortex, Augmented Reality software grades nuclear density in a method similar to that utilized by the Pentacam Scheimpflug camera (Oculus, Arlington, WA).²⁴ Scheimpflug cataract density imaging provides rapid, objective and reproducible grading of nuclear density.²⁵ The LENSAR laser system automatically assigns the cataract one of five categories:

- Category 1: low density, no nucleus
- Category 2: low density, nucleus present
- Category 3: high density, nucleus present
- Category 4: high density, unable to image nucleus separately
- Category 5: high density, unable to image nucleus separately and imaging the lens posterior is not possible.

“The concept of total energy optimization, including both femtosecond laser and ultrasound energy, represents a key to maximizing the outcomes of lens extraction.”

The LENSAR laser system then recommends or automatically assigns, based on surgeon preference, a specific fragmentation pattern designed to optimize lens extraction and minimize total energy expenditure, including both femtosecond laser and ultrasound energy, based on the morphology and density of the cataract identified by the imaging system (Figure 3). As demonstrated by Nichamin et al, the phacoemulsification pattern assigned by the LENSAR laser system represents the most efficient method for lens extraction irrespective of nuclear density.²⁶

The concept of total energy optimization, including both femtosecond laser and ultrasound energy, represents a key to maximizing the outcomes of lens extraction. Automatic cataract density grading, restriction of phaco fragmentation to the nucleus and utilization of lens density pattern customization allow effective management of laser energy. Reducing femtosecond laser energy minimizes gas production and can decrease the risk of intraoperative complications because laser energy is correlated with bubble formation and release of free radicals that trigger pupillary constriction.²⁷

Compared with standard phacoemulsification, femtosecond laser assisted cataract surgery reduces the amount of ultrasound energy up to 100% with grade 1 cataracts, greater than 60% with grade 2 cataracts, and more than 40% with grade 3 and 4 cataracts.²⁸ Customized phacoemulsification with the LENSAR Laser System reduces the requirements for ultrasound energy even further. In a retrospective study, Visco compared the amount of cumulative dissipated energy (CDE) used in customized versus standard femtosecond laser assisted cataract surgery.²⁹ The author reported a 10.4% reduction in mean CDE with customized versus standard phacoemulsification, from 4.44 ± 3.06 to 3.98 ± 2.94 . Weinstock compared the efficiency of customized versus standard laser phacoemulsification stratified by grade of cataract.³⁰ Mean time efficiency for customized versus standard fragmentation patterns for nuclear grades 1, 2, 3, and 4 were 10.33 versus 33.67 ($p=0.001$), 13.67 versus 26.00 ($p=0.004$), 22.67 versus 23.67 (0.588) and 8.00 versus 17.00 ($p=0.403$), respectively. The author concluded that cataract density imaging with automatic fragmentation patterns facilitated optimization of laser energy expenditure and reduced

both laser and phaco time. Reduction in ultrasound energy with customized laser phacoemulsification may postoperative inflammation and lower the risk of corneal endothelial cell loss and macular edema.

Customized Corneal Incisions

LENSAR Augmented Reality incorporates unique, corneal imaging and real-time refinement for precise laser focalization. LENSAR's Localized Imaging compensates for corneal movement which may be induced by gas formation secondary to capsulotomy and phacoemulsification, as well as corneal movement that may occur in response to the construction of each corneal incision. During corneal incision construction, LENSAR Augmented Reality re-images the cornea at the specific location of the clear corneal or arcuate incision in real time just prior to incision construction. The actual position of the cornea in real time is then automatically compared to the corneal position from the initial imaging. Data are collected at multiple points along the length of the incision. This re-imaging process allows computation of the precise points for delivery of each laser pulse, resulting in a perfectly positioned corneal incision despite corneal sag, tilt or movement. The process is repeated for each corneal incision and results in uniform depth across the entire arc length. Localized Imaging and its superior accuracy are unique features of the LENSAR system.

The construction of corneal arcuate incisions represents one of the primary methods for management of astigmatism at the time of cataract or refractive lens surgery (the other primary method, toric IOL implantation, is discussed further below). The LENSAR femtosecond laser system improves the precision and accuracy of arcuate incision construction via Streamline digital wireless connectivity. The LENSAR laser connects seamlessly with preoperative diagnostic corneal instrumentation, eliminating significant sources of error in astigmatism correction. In addition, the automated use of pre-programmed, surgeon-defined nomograms based on data transmitted from preoperative corneal measurements allows increased efficiency and reduction of errors.

LENSAR laser acquisition of preoperative corneal topography or total corneal astigmatic data including the posterior corneal surface in combination with high definition infrared digital images of iris features represents the fundamental platform for construction of image-guided laser arcuate incisions with iris registration for correction of cyclorotation. LENSAR Streamline features open architecture capable of transmission of preoperative data from any one of several commercially available linked instruments, including the Cassini Corneal Shape Analyzer (Cassini Technologies, The Hague, Netherlands), OPD Scan (Nidek, Aichi, Japan), Aladdin Topographer (Topcon, Oakland, New Jersey), and Pentacam HR or Pentacam AXL (Oculus, Arlington, WA). Automated selection and matching of iris features from the preoperative, undilated iris to the intraoperative, dilated iris accomplishes accurate registration.³¹ Streamline then automatically

compensates for cyclorotation after the patient is docked to the laser. An advantage of Streamline iris registration over other methods of image registration is that it is not dependent on conjunctival vascular detail that may become obliterated by the vasoconstrictive effects of topical dilating agents.

LENSAR's Arcuate Incision Planning software automatically provides incision parameters, including radius, arc length and depth, based on the surgeon's preferred nomogram and surgically induced astigmatism (SIA), while retaining the capability for manual entry or adjustment if indicated. In addition, Arcuate Incision Planning provides a graphical user interface (GUI) to demonstrate SIA and calculated residual astigmatism. This nomogram-based planning tool optimizes arcuate incision construction by allowing modifications based on patient age and up to three additional parameters, such as corneal white-to-white, corneal pachymetry and keratometry. The GUI facilitates incision planning, including arc length, radius and incision depth, with options for Fixed Depth (250-900 μ), Fixed Residual Depth (0-300 μ) and Percentage Thickness (10-100%). Against the Rule and With the Rule surgeon tables allow for entry of multiple data points for arcuate incision length based on astigmatic power preferences.

Multiple authors have reported clinical outcomes with LENSAR Streamline arcuate incisions.^{32, 33, 34} Jackson reported on 52 eyes of 31 patients with astigmatism from 0.40 to 2.75 D. Following LENSAR customized arcuate incisions there was a significant reduction in mean absolute refractive astigmatism from 1.3 D to 0.30 D ($p < 0.001$). Solomon reported 100% (31/31) of eyes achieved postoperative refractive astigmatism ≤ 0.50 D, while 90.3% of eyes were within 1.00 D and 83.9% of eyes within 0.50 D of spherical equivalent target refraction. Visco reported on 279 eyes of 203 patients with baseline corneal astigmatism from 0.50 D to 1.91 D. Mean baseline corneal astigmatism measured 0.92 ± 0.33 D; postoperatively,

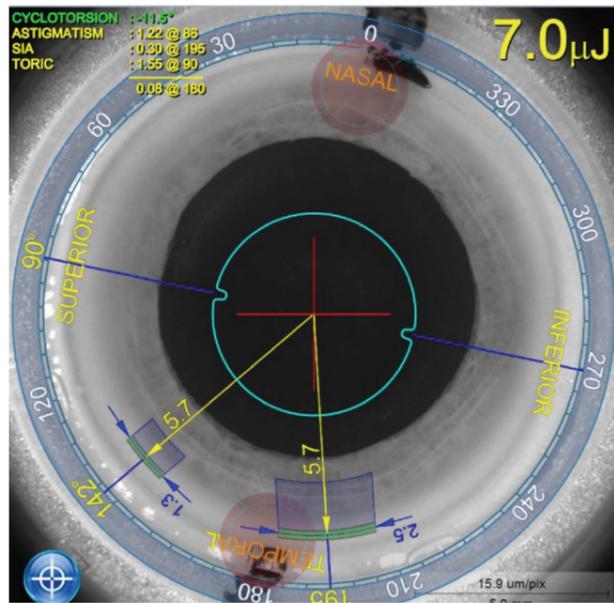


Figure 4. Schematic diagram of the structure of the LENSAR IntelliAxis Refractive Capsulorhexis. The predicted residual astigmatism is calculated based on correction of cyclotorsion achieved through iris registration, preoperative keratometric astigmatism, incision-related surgically induced astigmatism and correct alignment of the toric IOL.

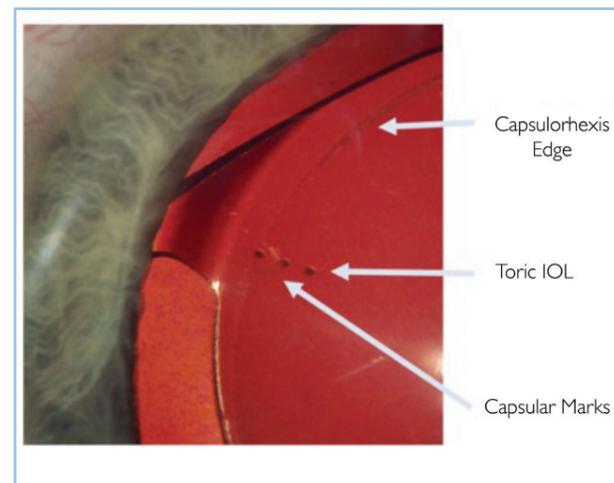


Figure 5. Intraoperative view of a toric IOL aligned with the capsular mark.

mean refractive astigmatism measured 0.09 ± 0.21 D. At the final visit, 94.6% eyes had ≤ 0.50 D and 99.3% eyes had ≤ 0.75 D residual refractive astigmatism. Lee et al evaluated 43 eyes of 26 patients with baseline corneal astigmatism from 0.50 to 2.0 D undergoing multifocal IOL implantation.³⁵ Mean preoperative keratometric astigmatism of 0.68 ± 0.36 D was reduced to 0.07 ± 0.17 D, and 97.7% (42/43) of eyes achieved postoperative refractive astigmatism ≤ 0.50 D.

A recent publication in *The Journal of Cataract and Refractive Surgery* adds further evidence of superior astigmatism correction with LENSAR femtosecond laser customized arcuate incisions.³⁶

Visco et al provided a retrospective analysis of 189 eyes of 143 patients with baseline corneal astigmatism ranging from 0.50 to 2.0 D. At 3 months postoperative, refractive astigmatism was reduced significantly to 0.14 ± 0.23 D compared to preoperative corneal astigmatism of 0.92 ± 0.34 D ($p < 0.001$). 95.8% (181/189) of eyes demonstrated postoperative refractive astigmatism ≤ 0.50 D. Mean uncorrected distance visual acuity was $\log\text{MAR } 0.09 \pm 0.16$; 90% (170/189) of eyes had postoperative uncorrected distance visual acuity of 20/30 or better. Results demonstrated stability at 12 months postoperatively. The authors noted that improved stability relative to manual incisions may be explained because femtosecond laser beveled arcuate keratotomies allow the anterior cornea to slide forward in relation to the posterior cornea and the realigned stroma heals without wound gaping or formation of an epithelial plug. In the absence of an epithelial plug, femtosecond laser-assisted arcuate keratotomies oriented perpendicular to the coronal plane are expected to be associated with a reduced risk for regression of astigmatism.

These clinical data support the improved outcomes available with iris registration and image-guided LENSAR femtosecond laser customized arcuate incisions. However, for those eyes with higher degrees of astigmatism not amenable to correction by arcuate incisions alone, toric IOLs offer a successful alternative. Historically, ink has been used to mark the cornea to provide landmarks for toric IOL alignment; however, ink-based manual marking methods remain prone to errors due to smudging or dissolution of ink, excessively broad or imprecise marks due to Bell's phenomenon or the cyclotorsion effect, and uncorrected parallax.³⁷ The LENSAR laser with Streamline includes IntelliAxis-C, a method of marking the cornea with small but visible intrastromal incisions which provide landmarks for toric IOL alignment. Visco presented results using IntelliAxis-C in 73 eyes with mean preoperative corneal astigmatism of 2.23 ± 0.19 D (range, 1.15 to 4.5 D).³⁸ At one month postoperative, 93.2% of eyes achieved ≤ 0.50 D and 76.7% of eyes achieved ≤ 0.25 D residual refractive astigmatism. Mean residual refractive astigmatism was 0.19 ± 0.38 D. These results compare favourably with other studies of toric IOL implantation.³⁹

Refractive Capsulorhexis

Irrespective of demonstrated clinical success, toric IOL alignment with IntelliAxis-C corneal marks can occasionally encounter difficulty due to compromise of the ocular surface or viewing parallax during surgery. To overcome these limitations, LENSAR developed IntelliAxis Refractive Capsulorhexis, an innovative approach to marking the steep axis by adding two small protuberances on the edge of the capsulotomy 180° apart. These marks provide toric IOL alignment landmarks at the plane of the IOL, thus avoiding parallax.

A schematic diagram of the structure of the LENSAR IntelliAxis Refractive Capsulorhexis steep capsular marks is provided in Figure 4, and the intraoperative appearance of the capsular marks is shown in Figure 5. Teuma et al verified the biomechanical strength of IntelliAxis-L capsulotomies

Author	n	Mean Baseline K, D	Postoperative Manifest Refractive Cylinder, D	Residual Refractive Astigmatism = 0.00 D	Residual Refractive Astigmatism ≤ 0.25 D	Residual Refractive Astigmatism ≤ 0.50 D
Visco ⁴¹	60	2.11	0.15	56%		98%
McKee ⁴²	21	1.54	0.32			81%
Visco et al ⁴³	31	2.06	0.11	71%	84%	100%
Stephenson ⁴⁴	54	1.01	0.11			95%
Solomon ⁴⁵	12	1.59	0.25			88%
O'Neill et al ⁴⁶	18	1.85	0.24			
Lee et al ⁴⁷	28	1.64	0.09			

Table 1. Outcomes reported in studies of IntelliAxis Refractive Capsulorhexis toric IOL alignment.

with capsular marks in an ex-vivo porcine eye study.⁴⁰ The mean break force for standard capsulotomy, capsulotomy with capsular marks with orthogonal load and capsulotomy with capsular marks with in-line load were 180.57 ± 22 mN, 178.04 ± 20 mN and 181.05 ± 15 mN, respectively. There was no statistically significant difference in capsular rim strength between the standard capsulotomy and the capsulotomy with capsular marks with tensile force vectors oriented orthogonally ($p=1.000$) or in-line ($p=1.000$). The mean extensibility at the point of rupture for standard capsulotomy, capsulotomy with capsular marks with orthogonal load and with in-line load were 6.47 ± 0.33 mm, 6.49 ± 0.45 mm and 6.30 ± 0.47 mm, respectively. Again, there was no statistically significant difference in capsular rim extensibility between the standard capsulotomy and the capsulotomy with capsular marks for tensile force vectors, oriented orthogonally ($p=1.000$) or in-line ($p=0.960$) (Figure 3). The results of this study demonstrated that capsulotomies with capsular marks are equivalent in tensile strength and extensibility to standard laser capsulotomies.

Multiple authors have reported clinical outcomes with IntelliAxis (IntelliAxis Refractive Capsulorhexis) toric IOL alignment (Table 1). These studies demonstrate that residual refractive astigmatism ≤ 0.5 D can be routinely achieved from 81% to 100% of eyes.

Iris registration and image-guided femtosecond laser capsular marks eliminate sources of error inherent in older methods. In addition, capsular marks remain visible for postoperative repositioning of toric IOLs if needed.⁴⁸ IntelliAxis customized capsular marks for toric IOL alignment provide improved outcomes.

“IntelliAxis Refractive Capsulorhexis guides LASIK-like outcomes.”

Ergonomics and Workflow Efficiency

The design of the LENSAR Laser System permits maximum flexibility and comfortable operation. The laser's relatively small footprint and integrated mobility allow for positioning of a surgical microscope and phacoemulsification system, so transfer of the patient can be avoided. The LENSAR patient interface features a low-pressure suction ring that 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. The low-pressure liquid interface avoids corneal striae which can distort anterior segment imaging and result in capsular tags and bridges. These features allow easy adoption and utilization of all of the technological advances of the LENSAR laser.

Many features of the LENSAR laser system are designed to increase operating efficiency while also improving outcomes. For example, automated, customized phacofragmentation

patterns are generated to optimize both laser and ultrasound energy utilization and help drive efficiency during lens extraction, reducing total case time. In addition, wireless transmission of preoperative diagnostic data from multiple commercially available devices via LENSAR Streamline allows automated iris registration and image guided correction of astigmatism, creating significant workflow efficiencies while eliminating any potential for transcription error and providing superior refractive outcomes compared to manual marking methods. Digital image guided marking with IntelliAxis Refractive Capsulorhexis also avoids the additional procedure time inherent in intraoperative aberrometry and can demonstrate superior outcomes.⁴⁹ Personalized, automated nomograms for arcuate incision construction also increase efficiency and reduce error by eliminating unnecessary and repetitive planning steps. These integrated features in the LENSAR laser system drive superior outcomes that improve refractive outcomes, reduce the need for enhancement procedures and increase patient satisfaction.

State-of-the-Art Surgery

LENSAR delivers state of the art surgery with advanced imaging, iris registration and automated guidance, providing superior outcomes and allowing truly customized surgery that creates a platform for ongoing innovations. LENSAR provides the optimal tools for customized and precise surgical procedures that are required to ensure the safety, accuracy and performance of next generation intraocular lenses for cataract and lens-based refractive surgery.

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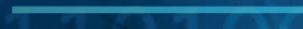
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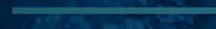
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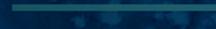
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