Femtosecond Lasers for Refractive Cataract Surgery

Cataract & Refractive Surgery Today asked three knowledgeable surgeons to discuss the technology that is generating the biggest buzz in the industry.

The LenSx Laser

By Stephen G. Slade MD

During the last week in February 2010, I had the luck and privilege to become the first ophthalmic surgeon to perform cataract surgery using a femtosecond laser in the United States. I was impressed with the improved safety and efficiency of this technology. Since then, I have become increasingly intrigued by the refractive advantages of the LenSx laser (LenSx Lasers Inc., Aliso Viejo, CA). I believe that cataract surgeons will be able to offer patients improved UCVA, owing to both reduced astigmatism and an ability to control induced spherical error. These advantages derive from the laser's ability (1) to benchmark or standardize incisions and the IOL's effective lens position and thus control induced astigmatism and (2) to treat preexisting astigmatism with corneal incisions at the time of surgery.

PROCEDURE AND SAFETY

The LenSx laser is an optical coherence tomography (OCT) image-guided femtosecond laser that currently addresses the first three of the following five major steps of cataract surgery: incisions, including astigmatic; capsulotomy; nuclear fragmentation; cortical removal; and the IOL's insertion. I perform the surgery at our office-based ambulatory surgery center in Houston. The patient is first placed under the femtosecond laser in a clean room, where the incisions, capsulotomy, and nuclear fragmentation are performed. He or she is then taken to the OR for the remainder of the procedure.

The LenSx laser effectively creates precise corneal incisions, and all have been self-sealing postoperatively. Every capsulotomy that I have attempted has been precisely centered and had a diametric accuracy of ±0.25 mm. As already reported, the LenSx laser reduces phaco times and power.[1,2] Because of its ease of use and the "no touch" capsulotomy, I believe the laser also offers specific advantages in terms of safety for difficult cases such as those involving a dislocated lens, weak zonules, pseudoexfoliation, a traumatic cataract, or a white cataract. Anecdotally, both my partner and I independently have felt that the corneas on day 1 are exceptionally clear, perhaps due to less intraocular maneuvering and manipulation of the corneal tissue.

I anticipate a lower complication rate than currently associated with standard cataract surgery. The present

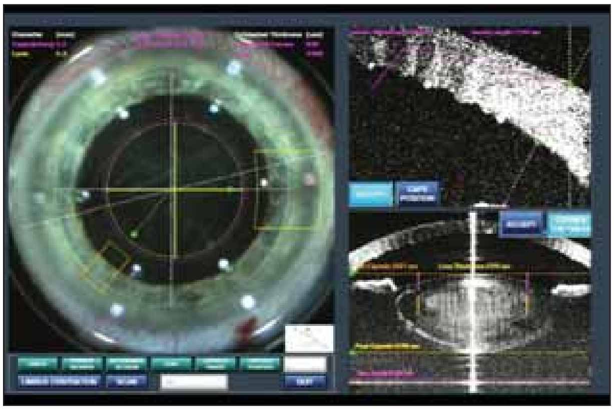

Figure 1. The LenSx laser uses a real-time OCT imaging system to map the eye and place the incisions, capsulotomy, and nuclear cuts. A video image of the surgeon's view is overlaid with "drag and drop" incisions and the capsulotomy's parameters (left). An OCT section of the cornea in which a multiplaned incision is planned and positioned (top right). A section through the anterior segment shows the lens for planning and placement of the nuclear cuts (bottom right).

rate of vitreous loss ranges from 2% to 6% of all cases (personal communication, data from industry). I believe this rate will decrease due to reduced phaco time and the automated capsulorhexis (Figure 1).

PATIENTS' ACCEPTANCE

I found that patients readily appreciate and choose "laser cataract surgery." Then again, many of them already thought that cataract surgery was performed with a laser. How patients perceive a particular procedure is pivotal to its level of acceptance, as I learned with LASIK. That procedure's results were never proven to be significantly better than PRK's, but patients recognized the benefits of quicker recovery and a laser flap rather than one created by a metal microkeratome. I expect a similar trend for femtosecond laser refractive cataract surgery. Although most cataract surgeons are proud of how well they can make an incision with a keratome and open a capsule with a bent needle, patients will perceive the laser's performance of these steps as more precise and safer. I believe their impression will encourage their acceptance of and even requests for femtosecond technology.

REFRACTIVE ADVANTAGES

Femtosecond laser cataract technology may offer several benefits. By providing a benchmark, the technology will allow surgeons to determine the clinical significance of precisely sized and positioned incisions and capsulotomies. The ability of the laser to make precise, reproducible corneal incisions and capsulotomies will permit surgeons to optimize the lens' position, more effectively manage preexisting astigmatism, and possibly even reduce induced astigmatism. Ophthalmologists may also learn that they can improve and quantify the effective lens position of an IOL by controlling the size, centration, and shape of a laser capsulorhexis. It is time that surgeons provide better UCVA to cataract patients. The results from current FDA IOL approval studies pale next to LASIK results (40% at 20/40 compared to 90% with LASIK, data on file with the FDA).

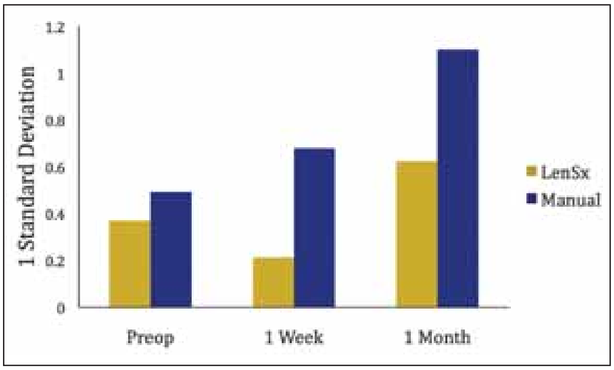

Figure 2. A comparison of the effective lens position between LenSx and manual cases shows reduced variability with the laser.

The LenSx laser has been shown to improve refractive results in three ways. First, it creates a reproducible, precise capsulotomy. Other researchers have demonstrated that the opening of the capsule directly affects the final resting position of the lens. Because manual capsulotomies vary in diameter and centration, the final resting place of the lens varies as the capsule contracts to its final position.[3] This variability of the effective lens position necessitates a variable in IOL calculation formulae, surgeon factor, or A-constant. Nagy showed that a precise, centered capsulotomy produces a more constant effective lens position.[4] I also achieved excellent spherical accuracy with accommodating IOLs in our first 50 consecutive cases[5] (Figure 2).

A second advantage of the LenSx laser is the perfect centration and circularity of the capsulotomy. An irregular capsule will contract asymmetrically, inducing coma and astigmatism as well as other aberrations. Table 1 shows reduced aberrations with laser capsulotomies.

Finally, Nagy demonstrated better centration of the IOL in eyes with a laser versus a manual capsulotomy. This quality will be particularly advantageous for multifocal IOLs.[6]

TABLE 1. COMPARISON OF INDUCED ABERRATIONS AND TILT[a]

	Manual (n = 51)	Femtosecond (n = 48)	*P*
Ocular vertical tilt	0.09 ±0.44	-0.08 ±0.35	> .05
Ocular horizontal tilt	0.1 ±0.49	0.16 ±0.39	> .05
Ocular vertical coma	0.04 ±0.19	-0.02 ±0.16	> .05
Ocular horizontal coma	-0.01 ±0.16	0.02 ±0.14	> .05
Internal vertical tilt	0.27 ±0.57	-0.05 ±0.36	.006
Internal horizontal tilt	0.15 ±0.59	0.16 ±0.63	> .05
Internal vertical coma	0.1 ±0.15	0.003 ±0.11	.006
Internal horizontal coma	0.03 ±0.18	0.06 ±0.11	> .05

[a]*Comparison between matched cohorts, with one group's having a manual capsulotomy and the other a femtosecond laser capsulotomy.*

(Courtesy of Prof. Zoltan Nagy.)

CONCLUSION

My initial experience with laser cataract surgery has been extremely positive. In my years as a refractive and cataract surgeon, I have had the good fortune to be deeply involved with the introduction of a number of new technologies, including LASIK, accommodating IOLs, and the femtosecond laser for creating corneal flaps. Phacoemulsification itself, however, essentially has not changed since the 1980s. I believe that the LenSx laser will enhance the performance of premium IOLs. As a wave of baby boomers approaches cataract surgery, surely this technology is in the right place at the right time.

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The OptiMedica System

By William W. Culbertson, MD

Since 2004, I have witnessed firsthand the evolution of femtosecond laser technology for cataract surgery from a concept to a well-integrated, high-performance system. Of many milestones, one stands out as the time I knew this technology would make a major difference in the lives of cataract patients. During the initial feasibility study for the OptiMedica laser cataract system (not available in the United States; OptiMedica Corporation, Santa Clara, CA) at Centro Laser in Santo Domingo, enrollment was limited to a single eye. A patient named Maria, who had successfully undergone the femtosecond cataract procedure, was so impressed with the results that she returned under a different name to try to sneak back into the trial to have her fellow eye treated.

It is clear to me that increased precision and safety from image-guided femtosecond laser cataract systems will improve the results of both standard and premium cataract surgery. By optimizing IOLs' performance and reducing surgical complications, these systems promise to increase patients' satisfaction by providing emmetropic refractive outcomes that improve their quality of life.

With the OptiMedica laser cataract system, I have successfully and easily performed anterior capsulotomies, fragmented the lens, and created cataract incisions and corneal relaxing incisions. The OptiMedica platform was designed to enable the highest level of surgical precision, surgical control, and patients' safety during cataract surgery. Surgical precision has important implications for safety and performance in refractive cataract surgery, both intraoperatively and long term. Intraoperatively, laser cataract surgery replaces manual methods with repeatable technique, and it incises the eye with architectural and locational control not possible with keratomes, cystotomes, forceps, choppers, and phaco tips. In addition, laser cataract surgery facilitates reproducible positioning of the IOL and thus improves surgeons' ability to accurately calculate the required lens power for each eye treated. More predictable biometry, specifically of effective lens position, will produce more consistent refractive results.

A HIGH-PERFORMANCE SYSTEM TAILORED SPECIFICALLY FOR CATARACT PATIENTS

During the past few years, I have worked closely with my fellow ophthalmologists and the physicists and engineers at OptiMedica Corporation to develop a high-performance system tailored specifically for cataract patients. Of the many parts of the system that we have tested, iterated, and refined, two have a particularly significant impact on precision and clinical performance: the patient interface and the integrated imaging system.

Our preliminary clinical work revealed shortcomings in

Figure 1. A perfectly rounded and shaped 5-mm anterior capsulotomy floats free in the anterior chamber just after its creation with the OptiMedica laser cataract system.

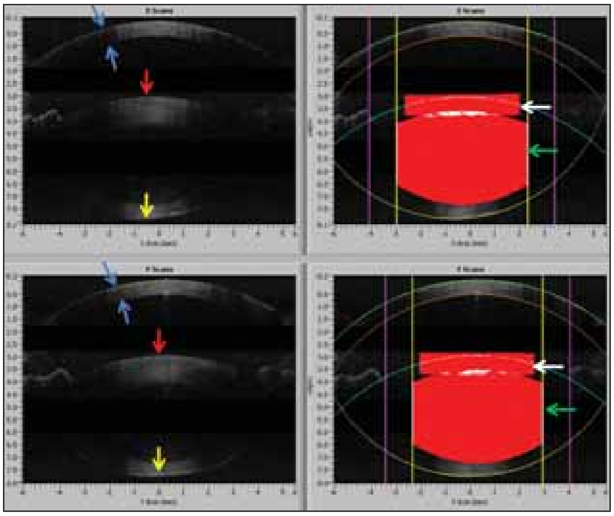

Figure 2. Imaging of the crucial structures of the anterior segment with real-time optical coherence tomography (OCT) prior to treatment with the OptiMedica laser cataract system. Blue arrows point to the anterior and posterior surfaces of the cornea. Red arrows show the anterior capsule, and yellow arrows point to the posterior capsule. White arrows indicate the planned zone of anterior capsular treatment (in red), and green arrows point to the planned area of nuclear softening and segmentation (in red).

patients' comfort and incisional quality with the patient interfaces used in refractive surgery. We now have a novel means of stabilizing the eye with minimal corneal distortion and a minimal increase in IOP. The interface provides a wide field of view for visualizing the limbus and centering and placing incisions. The optical design focuses the laser beam so that less energy is required, resulting in cleaner incisions with the creation of less gas.

INTEGRATED IMAGING FOR SAFE LASER DELIVERY

With the eye stabilized for treatment, the integrated imaging system ensures the safe delivery of laser energy and guides my treatment—most importantly, with system-calculated options for centering my capsulotomy. Customized spectral-domain OCT captures the anterior segment in three high-resolution dimensions. After the system detects the iris and the anterior and posterior surfaces of both the cornea and capsule with redundant video and OCT imaging, complex algorithms process the images. The treatment plan is automatically refined to customize the incision's placement for the architecture of the patient's eye while the eye is docked to the laser at the time of surgery. The pattern-scanning control system then accurately directs the laser pulses

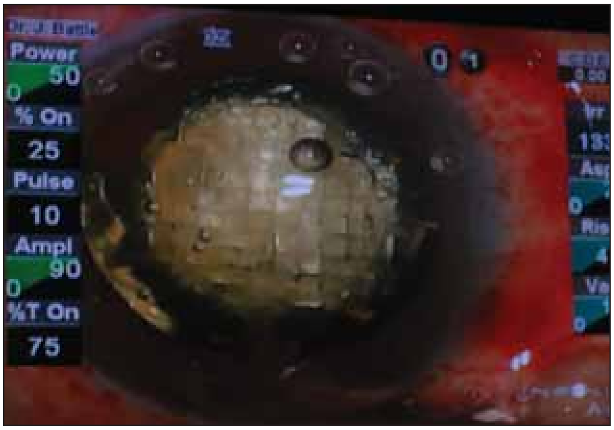

Figure 3. The appearance of a grade 4 nuclear cataract after segmentation into four quadrants and dicing (or prechopping) into 0.5-mm cubes. This process facilitates separation of the lens into quadrants and phaco-aspiration of the hard lenticular fragments.

both laterally and in depth to targeted sites on the cornea, capsule, and lens.

LASER CAPSULOTOMY

I believe the laser capsulotomy is much safer than a manually torn capsulorhexis. Although there is not yet a large multicenter trial, the evidence so far from the companies developing femtosecond laser cataract systems is astounding. With the OptiMedica system, I can achieve a perfectly round and perfectly sized capsulotomy every time. The risks of tags, radial tears, and posterior capsular ruptures during the creation of anterior capsulorhexes are greatly reduced. Some of my laser capsulotomies have floated free with the injection of viscoelastic prior to phacoemulsification (Figure 1). The laser capsulotomies formed with micron-sized cavitation bubbles are at least as strong as my manual capsulorhexis. They are also resistant to trauma during the manipulation of instruments in phacoemulsification and the IOL's insertion. Laser capsulotomies should greatly reduce the surgical challenges and risk of complications from floppy irides, dense nuclei, shallow chambers, and zonular weakness.

Together with my colleagues in Santo Domingo, Juan Battle, MD, and Rafael Feliz, MD, I have compared excised tissue from our manually torn capsulorhexes with tissue from our laser capsulotomies. The full results will be presented later this year, but our analysis so far shows that our laser capsulotomies are an order of magnitude more circular and within 100 µm of our intended diameter. Based on the consistency of the capsulotomy's sizing and elastic properties of the capsular bag, we program the laser to cut a circle that has a smaller diameter than our intended aperture size. We can then program a capsulotomy that matches the design objective of the IOL with optimal overlap of the lens or an oversized capsulotomy to allow for hinged accommodating IOLs. This is just one example of how femtosecond laser cataract surgery, and the knowledge we gain from our experience, will refine the surgical procedure.

THE LENS' FRAGMENTATION

The OptiMedica system's integrated imaging provides additional safety for the lens' fragmentation. OCT detects the surfaces of the capsule so that customized laser patterns can facilitate complete, safe, and efficient nuclear disassembly (Figure 2). In our cases, we have used a 500-µm safety zone that follows the natural radius of curvature of the posterior capsular surface. As a result, we have never seen a laser-induced posterior capsular rupture.

The most obvious benefits in terms of intraoperative safety for the lens' fragmentation are reduced ultrasound energy and time. I have found that applying a cube softening pattern results in a grade 4 nucleus' being phacoaspirated as easily as a grade 2 nucleus (Figure 3). Softening the lens improves the followability of lenticular material to reduce flow, "trampolining," iris prolapse, and damage to endothelial cells from lenticular fragments. The use of fewer instruments means less manipulation and fewer insertion and removal motions, all of which can be beneficial in terms of postoperative healing.

ATTENTION TO DETAIL

OptiMedica Corporation's focus on the development of a novel patient interface and the integration of advanced imaging with the cutting precision of a femtosecond laser pulse are providing a new level of safety and security. The advanced technology, the attention to patients' comfort in product design, and the ultimate control for the surgeon translate as a premium treatment for all laser cataract surgery patients. In my experience, outcomes are spectacular, with less residual spherical refractive error (probably related to precise capsulotomies) and less astigmatism (presumably due to more accurate limbal relaxing incisions). Patients' acceptance of the surgery and technology has exceeded my expectations. I look forward to the day (not too distant) when millions of cataract patients, with the same enthusiasm as Maria, will realize the benefits of better uncorrected vision after cataract surgery.

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The LensAR Laser System

By Ronald R. Krueger, MD

The LensAR Laser System (LensAR Inc., Winter Park, FL) is designed to provide laser cataract surgery and all related incisional procedures. These include the clear corneal incisions and paracentesis incisions, limbal relaxing or astigmatic keratotomy incisions when indicated, the anterior capsulotomy, and the lens' fragmentation.

IMAGING

The LensAR Laser System achieves highly accurate, ultrashort-pulse laser cutting of the cornea and the densest cataracts by means of a new and uniquely advanced three-dimensional imaging system, which accurately measures the lens' and cornea's anterior and posterior position and shape. The internal project name for what the company describes as its fourth-generation measurement technology is "3D-CSI," because it contains a confocal, structured illumination-scanning transmitter that enhances the accuracy of three-dimensional reconstruction. The ultrahigh-resolution infrared imaging system has lateral (x, y) and longitudinal (z) pixelated resolution of approximately 10 µm. Its ability to determine the position of anterior and posterior surfaces is even greater because of the extraordinarily high contrast that the optical system generates at the anatomical edges. The high-contrast images mean great reliability and speed for the automated software algorithms that determine and execute three-dimensional laser treatment without the surgeon's intervention. Software automation is the key to patient throughput and efficiency for surgeons and surgery centers. Accuracy is integral to safety and efficacy.

An important feature of the 3D-CSI technology is its ability to rapidly image the entire anterior segment from the bottom of the lens to the top of the reference glass—including the full untouched cornea—with one high-resolution image. No combining of separately scanned images is needed. Overall, the laser system's accuracy is enhanced because the image scanning is accomplished directly in the coordinate system of the treatment laser, with sophisticated algorithms for calibration and to compensate for distortion. The full image is instantly captured with an angled focal plane array that provides great depth of field from the anterior cornea to the posterior lens. When in edge detection mode, the scanned 3D-CSI transmitter is less sensitive to bulk lens scatter and can effectively image the highest-grade cataracts, which can be more challenging with optical coherence tomography (Figure 1). In bulk image mode, fine structural details of the cataractous lens can be captured, with the potential for automatic grading of the cataract's opacity/density. Future features may include automatic fragmentation-algorithm selection based on the three-dimensional volumetric scattering assessment.

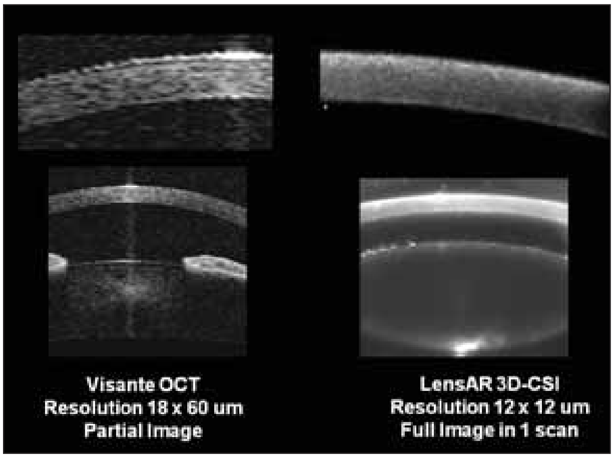

Figure 1. Traditional optical coherence tomography (left; Visante OCT [Carl Zeiss Meditec, Inc., Dublin, CA]) versus 3D-CSI (right) of the cornea, anterior chamber, and crystalline lens. 3D-CSI can achieve detailed measurements of the cornea and lens interfaces and density, which makes it possible to localize the exact position of the laser application within 12 µm and image (grade) the density of nuclear sclerosis.

NO-TOUCH INTERFACE

The LensAR Laser System's patient interface is a nonapplanating suction fixation device, which preserves the natural anatomy of the ocular structures (cornea, lens, anterior chamber, and posterior chamber). The interface is essentially an automatically filled miniature water bath that cancels the optical power of the cornea without touching it with a curved or flat glass interface. The cornea's shape naturally varies among patients. Pressing it into a fixed, curved interface can add a biomechanical variable. The hope is that this no-touch interface will have a beneficial effect on astigmatic outcomes.

VERSATILITY

One of the challenges for laser companies is developing a platform that can function in many different surgical configurations. The LensAR Laser System is designed for use in either a separate laser room outside the surgical theater or within the OR itself. Thanks to the system's large range of motion, the laser can be positioned over the patient's eye either in a superior or temporal orientation in the OR. The system can measure and apply the laser cutting and then be moved away with the touch of a button, so the ophthalmologist can complete cataract surgery with his or her standard operating microscope. Sterile and nonsterile interfaces are provided for surgical convenience and speed. The idea is to improve efficiency for more users.

LASER CAPSULOTOMY

The LensAR Laser System has FDA clearance for use in anterior capsulotomy. Data presented at the AAO/ISRS meeting in 2009 showed that the laser capsulotomy with this platform was significantly closer to the intended diameter than a manual continuous curvilinear capsulorhexis.[1] The mean deviation from the intended diameter was 0.18 mm for the laser group compared with 0.46 mm for the manual group. Analysis of residuals to determine consistency of shape was 0.003 for the laser capsulotomies and 0.02 for the manual capsulorhexis. There is no doubt that a laser capsulotomy produces a more regularly shaped capsular opening (Figure 2) that is significantly closer to the intended diameter than a manually torn capsulorhexis.

THE LENS' FRAGMENTATION

Data from lens-fragmentation studies by LensAR Inc. have been presented at several meetings, including ASCRS.[2] These data look at reductions in phaco cumulative dispersed energy (CDE) when using laser lens fragmentation compared with cases undertaken using conventional phacoemulsification. Most recent data suggest that reductions in CDE of greater than 95% are possible with low-grade (ie, 1 and 2) cataracts, with only aspiration needed in many cases. LensAR Inc. is currently the only company presenting data on harder grades of cataract (ie, 3 and 4+) and has shown reductions in CDE of more than 66% in grade 3 (Figure 3) and more than 27% in grades 4 and higher. Aspiration only has been achieved for nuclei of up to grade 4. An analysis of clinical results presented at the ARVO annual meeting showed a trend toward faster visual recovery with laser-treated cases as well as a lower anterior segment reaction after cataract surgery using laser lens fragmentation.[3]

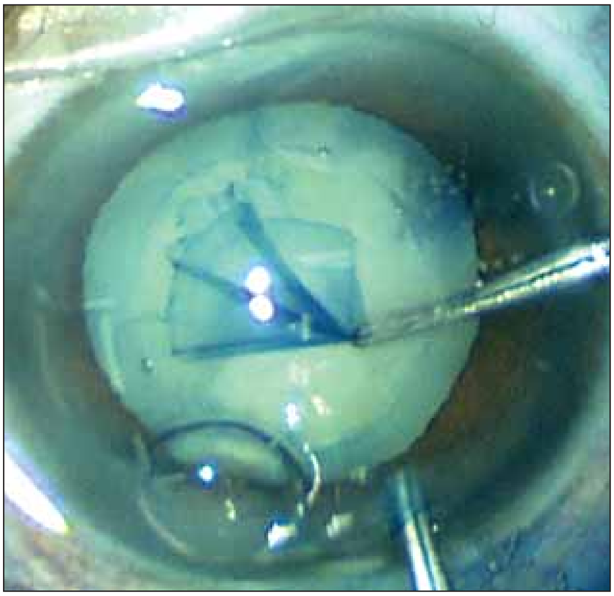

Figure 2. Surgical view of ultrashort-pulse laser capsulotomy reveals perfect centration, sizing, and ease of removal.

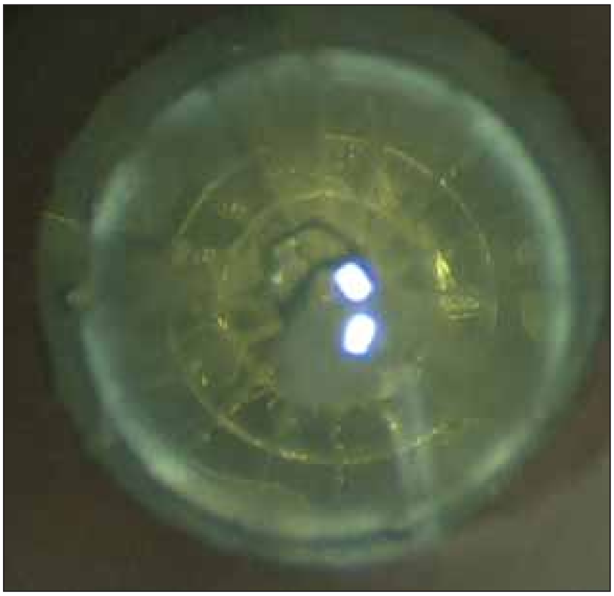

Figure 3. Surgical view of ultrashort-pulse laser nuclear fragmentation of a grade 3 nuclear sclerotic cataract. A multi-layered, pie-shaped pattern of pulses fragments the lens into easily removable pieces that are often extracted with only aspiration (no phaco power).

INCISIONS

Work on corneal incisions continues. It is clear that a laser incision for corneal astigmatic correction will be more consistent and predictable than a manual incision. LensAR Inc. has spent considerable time developing a finite element analysis model of the cornea in an effort to assess and refine the best treatment algorithms prior to the treatment of patients. At the same time, the company is collecting definitive information on patients treated with manual methods for the purpose of comparison with the outcomes achieved from the model.

The potential for the LensAR Laser System to create corneal penetrating incisions that are repeatable and self-sealing has been demonstrated in the laboratory. Clinical experience will guide the development of appropriate architectures.

PATIENTS' ACCEPTANCE

Patients in the clinical studies to date have been eager to undergo surgery using the latest technology. Their attitudes are especially favorable to laser procedures, which they perceive as more automated and precise. Participants have been delighted with their outcomes to date.

CONCLUSION

The precision of femtosecond lasers in cataract surgery will enhance outcomes, especially with premium IOLs, which depend on a regular and well-centered capsulotomy as well as the elimination of residual corneal astigmatism. The accuracy of corneal incisions will make astigmatic correction more repeatable and predictable. Moreover, the predictability of the corneal incision's architecture should lead to safer cataract surgery. Femtosecond laser systems will drastically reduce the learning curve for the steps of the cataract procedure that they perform, and they will level the playing field for cataract surgeons with less experience and those who are not exclusively dedicated to cataract surgery.

It is worth noting that LensAR Inc. is working to correct presbyopia by restoring the crystalline lens' accommodative ability with the laser. Several patients have been treated to date. ■

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