New Generation of Femtosecond Lasers Emerges

Three companies are proposing this technology to perform steps in cataract surgery.

BY LAURA STRAUB, EDITOR-IN-CHIEF OF *CATARACT & REFRACTIVE SURGERY TODAY EUROPE*

The pursuit of flawless surgical outcomes fuels the persistent evolution of cataract surgery. Beginning with the development of phacoemulsification by Charles D. Kelman, MD, continuing advances promise better postoperative results. Phaco machines have expanded margins of safety, and lens designs produce superior visual outcomes. These advances may not equate with improved surgical results, however, if the surgical technique itself is compromised.

Arguably the most important and most difficult step in cataract surgery, the capsulorhexis is critical to the safety and efficacy of the procedure.[1,2] A good anterior capsulorhexis is centered and circular, and it has a clean, undamaged capsular edge. Surgeons use a manual technique with either a bent needle or forceps to create the capsulorhexis. Now, early results with a new generation of femtosecond lasers for intraocular use show promise for the creation of the anterior capsulotomy as well as for nuclear fragmentation and incisional architecture. Many questions require answers. Will this generation of femtosecond lasers pave the way for enhanced outcomes in refractive cataract surgery? Will it reduce the risk of adverse events, including endophthalmitis, posterior capsular rupture, endothelial cell loss, zonular dehiscence, macular edema, and retinal detachment?

Femtosecond-delivered laser pulses to the anterior capsule and crystalline lens during cataract surgery require different parameters than those used by femtosecond lasers for corneal surgery. More specifically, intraocular femtosecond lasers penetrate deeper into the eye—approximately 7,500 µm versus 1,200 µm in corneal surgery.[3] Three companies are developing femtosecond laser cataract surgery technology: LensAR, Inc. (Winter Park, FL), LenSx Lasers, Inc. (Aliso Viejo, CA), and Optimedica Corporation (Santa Clara, CA). These companies are banking on the idea that femtosecond lasers will improve the precision of key surgical

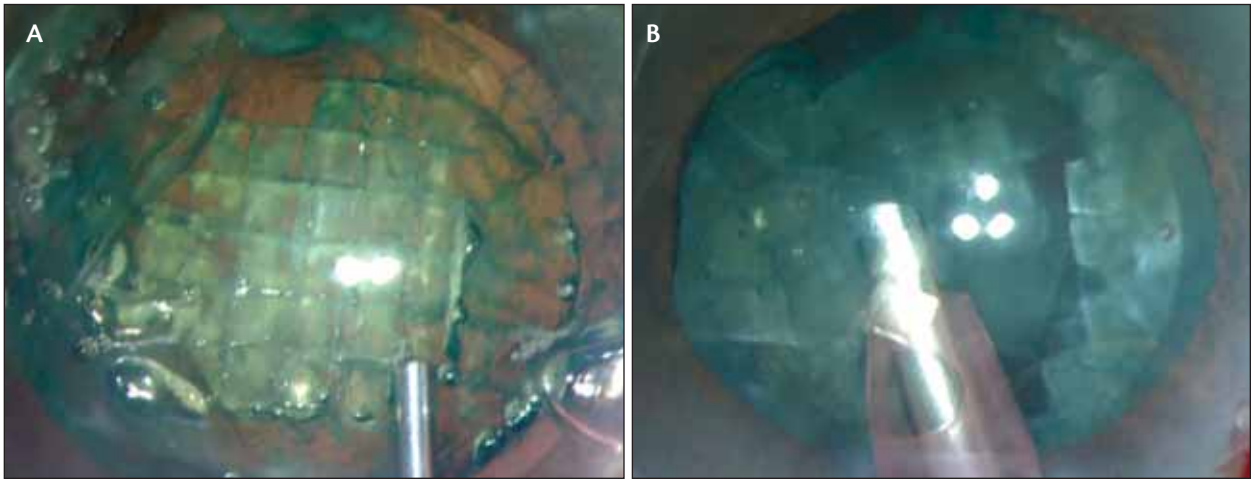

Figure 1. The LensAR Laser System fragments a cataract in a precise pattern of cubes (A). The fragmented cubes are broken up (B) and aspirated.

steps and translate into maximal postoperative outcomes.

In time, surgeons will be able to evaluate femtosecond cataract technologies and determine if they are worth the investment. Until then, ophthalmologists rely on commentary from the companies and the key opinion leaders who have already tested these technologies. All three companies mentioned herein have a unique position in the current marketplace. This article provides an overview of all three femtosecond cataract laser systems and recaps previously released and published clinical results.

LensAR

This platform is now in development for constructing the anterior capsulotomy, fragmenting the nucleus, and creating limbal relaxing and clear corneal incisions (Figures 1 and 2) Company information alludes to a different initial direction for its femtosecond laser—presbyopic correction. Randy W. Frey, the CEO of LensAR, Inc., licensed a patent and patent application to use the technology for softening the natural crystalline lens to restore accommodation. Studies with the prototypic laser quantified a strong safety profile for presbyopic correction and showed that it avoided cataract formation in a sensitive animal model, according to company information.

After some prompting from the LensAR, Inc., board member Richard Keates, MD, Mr. Frey decided to turn his attention to cataract surgery. In the first cataract procedures, the laser accomplished perfect capsulotomies and aspiration of lens material sans phaco ultrasound power. Ramon Naranjo Tackman, MD, director of Corneal Services at APEC Hospital Luis Sanchez in Mexico City, is among the surgeons with clinical experience using the LensAR laser for cataract surgery. According to the company, Dr. Naranjo Tackman has used the laser to cleanly cut cataracts of up to grade 4. After a recent algorithm upgrade, Harvey Uy, MD, from Manilla, Philippines, has laser fragmented and removed cataracts with significantly reduced ultrasound energy as hard as grade 5, Mr. Frey

Cataract Surgery With the LensAR Femtosecond Laser Platform

The most exciting part of femtosecond cataract surgery is not what we see today, but rather what is on the horizon.

BY WILLIAM J. FISHKIND, MD

As an innovator in the area of cataract extraction since the late 1980s, I have been involved in the development of phaco technology for many years. Because of this experience, I was asked to become an advisor to LensAR, Inc. (Winter Park, FL), as the company began testing its femtosecond laser technology for cataract surgery.

About 3 months ago, I traveled to Mexico City to perform 14 surgeries with the LensAR, Inc., platform as part of a clinical trial. While there, my colleagues and I experimented with parameters such as algorithms for softening the nucleus, and we sought to determine the appropriate amount of pressure for docking the laser. Although, in the clinical trial, the procedure progressed differently from how it will when the platform is commercially available, we nevertheless found the laser to be amazing. The eyes we treated had everything from soft to hard nuclei, and in each, we performed a capsulorhexis and were able to soften the nucleus.

COMPONENTS OF THE INTEGRATED DESIGN

The LensAR, Inc., platform employs optical coherence tomography in its integrated design, and the laser docks to the cornea using much less pressure than the IntraLase FS laser (Abbott Medical Optics Inc., Santa Ana, CA), which is a plus for elderly patients. With information obtained from the laser's anterior segment visualization system, we were able to set the device for the desired depth and width of treatment. The platform allowed us to cut the lens fibrils in any pattern. Because the optimal size and shape for removal of the nuclear particulates is not known, we experimented with cubes and spheres of different size.

It is hoped that the femtosecond laser will dramatically reduce the need for phaco energy for the removal of most nuclei. I envision that most soft-to-moderately dense cataracts will be treated with the laser platform and aspirated using a 0.5-mm I/A or phaco I/A tip. In this scenario, the phaco machine would be used to augment aspiration of the lens material. For hard cataracts, phaco energy will still be necessary.

Although phacoemulsification is a wonderful and safe procedure, any time the surgeon can avoid having an ultrasonic probe in the anterior chamber, he or she is eliminating its potentially adverse effects on the blood-aqueous barrier, endothelium, and trabecular meshwork. Without the use of ultrasound during cataract extraction, the eye's environment is safer, and there is

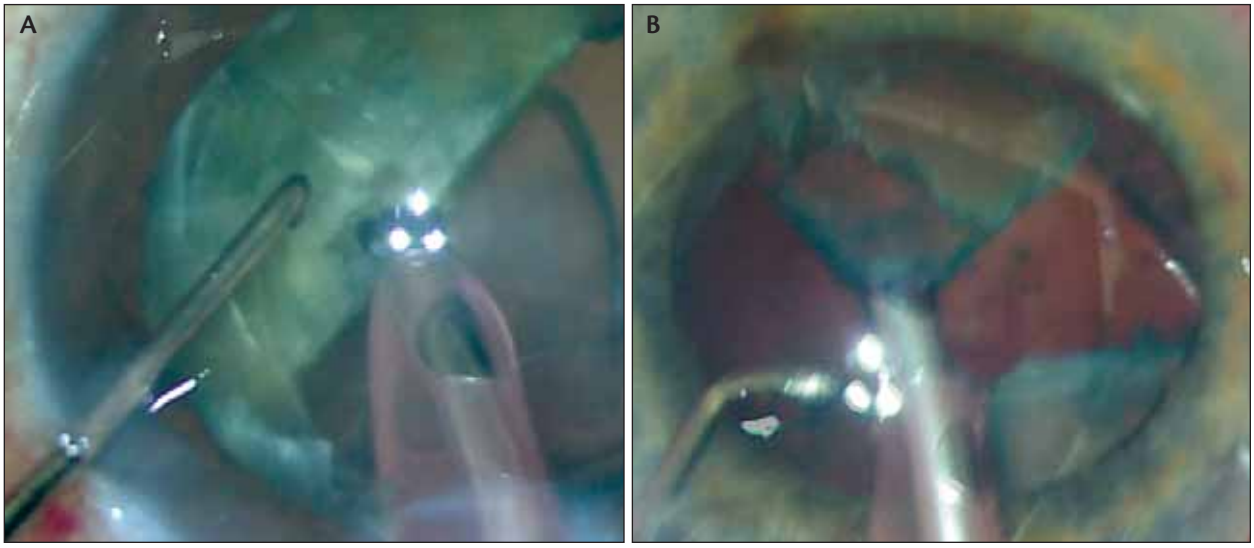

Figure 2. LensAR's Laser System is used to execute sophisticated yet clean quadrant chops (A) that are necessary for dividing hard cataracts (B).

no risk of tearing the posterior capsule with a phaco tip. Femtosecond laser cataract surgery will also be associated with less unexpected vitreous loss and reduced damage to the iris from high-powered interfaces.

QUALITY OF THE CAPSULORHEXES

Surgeons are getting better and better at creating quality capsulorhexes. The LensAR Laser System, however, allows the ophthalmologist to better control the location of the capsulorhexis as well. A multifocal IOL, for example, should be centered on the visual axis, which is very difficult to find during surgery. The femtosecond laser allows the surgeon to identify and create the capsulorhexis around the visual axis. When the implant is centered in the capsulorhexis, it will therefore also be centered on the visual axis.

The size of the capsulorhexis is important for successful cataract extraction. The capsulorhexis must overlap the IOL by 0.25 mm, which can be achieved perfectly in every case with the laser.

Other advantages of femtosecond cataract surgery are that patients love the idea of lasers and femtosecond cataract surgery has applicability for all ophthalmologists. All cataract surgeons will benefit from improved procedural reproducibility and better capsulorhexes, easier removal of nuclei, and decreased surgical times. High-volume surgeons will be able to perform many tasks simultaneously with the LensAR, Inc., platform; they will be able to swing the laser into place for the several steps of the cataract procedure and then move it out of the way so that they may remove the cataract. In this setting, I envision phacoemulsification's taking on a new role, and surgeons may start to think of the cataract procedure as a "femto-phaco" procedure.

THE PROCEDURE OF THE FUTURE

I believe femtosecond laser cataract surgery has real potential. My vision is that a physician will sit down to perform cataract surgery, the patient will be brought into the room, and the femtosecond laser will be put into position. Before it is docked, the laser will perform a corneal topographical and wavefront analysis. It will find the visual axis and place registration marks. Then, the surgeon will program the refractive goal into the system. The laser will analyze this input and determine an algorithm for the nuclear treatment. It will then perform a "demolition" by cutting the nucleus into the size and shape selected. Next, it can make the capsulorhexis around the visual axis, create limbal relaxing incisions for the treatment of preexisting astigmatism, and perform a paracentesis wherever the surgeon desires. The LensAR Laser System can even make a locking incision which is guaranteed to be watertight as well as correct for the induced cylinder.

William J. Fishkind, MD, is the co-director of Fishkind and Bakewell Eye Care and Surgery Center in Tucson, Arizona, and he is a clinical professor of ophthalmology at the University of Utah in Salt Lake City. He is a consultant to LensAR, Inc. Dr. Fishkind may be reached at (520) 293-6740; wfishkind@earthlink.net.

told *Cataract & Refractive Surgery Today* in an e-mail. "The detailed algorithms really matter on the higher grade cataracts," Mr. Frey said.

The LensAR Laser System offers measurement-guided beam delivery for automated measurements and for cutting ocular anatomy using proprietary, modified Scheimpflug imaging. According to the company, results with this technology were accurate in animal studies and confirmed in human clinical studies. The company continues to research LensAR's applications for cataract surgery.

Mr. Frey said that the company is near approval on the first indication for anterior capsulotomy with the laser. "We are working the trials for nuclear lens fragmentation now and that will be the next 510(k) approval sought. We would then seek approval on the cataract incision—clear corneal incision—and limbal relaxing incisions (astigmatic) as well." Upon FDA approval, a software upgrade will be available for presbyopic algorithms.

Figure 3. Programming the capsulotomy at the LenSx Laser. The capsulotomy was created using the laser, and then the patient was moved to the cataract surgery OR for lifting of the capsulotomy and cataract removal.

LenSx

Image-guided clinical applications of the LensX Laser include liquefying, softening, or fragmenting the lens; forming the anterior capsulotomy; and creating all corneal incisions (Figures 3 and 4). Company literature explains that integration of proprietary optical coherence tomography allows precise localization of surgical laser pulses.

Zoltan Nagy, MD, professor at Semmelweis University in

First Cataract Surgeries With a Femtosecond Laser Performed in the United States

Improved refractive outcomes and fewer complications associated with this technique are anticipated.

BY STEPHEN G. SLADE, MD

During the last week in February, I had the privilege of being the first ophthalmic surgeon in the United States to perform cataract surgery using a femtosecond laser. The procedures that my team and I performed over a 2-day period with the LenSx Laser (LenSx Lasers, Inc., Aliso Viejo, CA) are the beginning of what I believe will be the next evolution in refractive cataract surgery.

The LenSx Laser received FDA clearance for anterior capsulotomies in August 2009 followed by clearance for corneal incisions in December 2009. I used the LenSx Laser to create anterior capsulotomies and corneal incisions for the cataract procedure. In the future, it is hoped that the FDA will allow the use of the LenSx Laser for the splitting, chopping, and softening the nucleus.

PROCEDURE AND PATIENTS' ACCEPTANCE

I performed these first surgeries at my ambulatory surgery center in Houston with the second laser the company has manufactured (the first unit is in Europe). The surgical outcomes were even better than I had expected. I have performed eight cases, and all patients saw 20/25 or better on postoperative day 1. All of the capsulotomies that I attempted were perfectly centered and achieved a diametric accuracy of ±0.25 mm. The laser effectively created precise corneal incisions, and all were self-sealing postoperatively. After cataract removal using phacoemulsification, all of the eyes received a premium IOL. Anecdotally, both my partner and I independently felt that the corneas on day 1 were exceptionally clear, perhaps due to less intraocular

First Cataract Surgeries With a Femtosecond Laser Performed in the United States *(Continued)*

maneuvering and manipulation of the corneal tissue.

I believe that patients will benefit from a lower complication rate associated with the femotsecond laser technology and from what I anticipate will be improved refractive results. The ability of the laser to make reproducible corneal incisions and capsulotomies will allow surgeons to optimize the lens' position, more effectively manage preexisting astigmatism, and reduce induced astigmatism. In fact, in the future, ophthalmologists will be able to make corneal astigmatic incisions to deal with preexisiting or induced cylinder with the laser.

As impressive as the performance of the LenSx Laser was, the overwhelmingly positive response from the patients was even more exciting. Then again, patients have always thought that cataract surgery was performed using a laser, which may have helped overcome any concerns they had about being the first US patients to undergo surgery with this new technology. I believe femtosecond refractive cataract surgery will become the preferred method for performing this surgery. Patients are extremely excited about laser cataract surgery, and surgeons will find the procedure more precise and reproducible as well as simply more fun.

HISTORICAL PERSPECTIVE

The initial clinical evaluation of the LenSx Laser began in 2008 with Zoltan Nagy, MD, of Semmelweis University in Budapest, Hungary.[1-3] He has now successfully performed over 500 surgeries with the LenSx Laser, including the first image-guided refractive cataract surgeries with the laser in December 2009. This surgery involved lens fragmentation, the capsulotomy, and corneal incisions.

My initial experience of performing the capsulotomy and corneal incisions has been extremely positive. In my years as a refractive and cataract surgeon, I have had the good fortune to be involved in the introduction of a number of new procedures, including the first customized ablation for LASIK and the femtosecond laser for the creation of corneal flaps. Without a doubt, my first surgeries with the LenSx Laser were as smooth and routine as I could have hoped.

In the past 15 years, several companies have attempted to deliver a laser for cataract surgery. With the LenSx Laser, I believe that surgeons will soon have a cataract technology that allows their technique to match the advanced nature of premium IOLs. The result will be improved outcomes.

Stephen G. Slade, MD, is a surgeon at Slade and Baker Vision in Houston. He serves as the medical director for LenSx Lasers, Inc. Dr. Slade may be reached at (713) 626-5544; sgs@visiontexas.com.

1. Nagy Z. Application of an integrated OCT in novel femtosecond laser cataract surgery. Paper presented at: The 14th Winter ESCRS Meeting; February 14, 2010, Budapest, Hungary.
2. Nagy Z. Use of femtosecond laser system in cataract surgery. Paper presented at: XXVII Congress of the ESCRS; September 15, 2009; Barcelona, Spain.
3. Nagy Z. Intraocular femtosecond laser applications in cataract surgery. *Cataract & Refractive Surgery Today Europe*. 2009;4(8):29-30.

Budapest, Hungary, was the first to use the LenSx technology clinically.[4,5] In his study, the laser was used for anterior capsulotomy in 60 cases; all capsulotomies had smooth, uniform edges, and there were no capsular tears or adverse events. Dr. Nagy compared these results with those for 60 control individuals in whom manual capsulotomy was performed. The diameter of the capsulotomies created with the LenSx was significantly more reproducible. Dr. Nagy reported that the diameter of the capsulorhexis was individualized for each treatment, with the diameter of his typical capsulotomy ranging from 4.5 to 5.0 mm for a 6.0-mm optic. According to ex vivo testing and scanning electron microscopy in animal models, similar smoothness and mechanical strength of the capsulotomies were seen with the femtosecond laser and manual capsulotomy.

The LenSx Laser is also being evaluated for lens fragmentation. In Dr. Nagy's initial series, softer lenses were successfully fragmented into small pieces that were removed with I/A and required no phacoemulsification. Harder lenses were successfully fragmented into quadrants for more efficient removal with low phaco power and energy. He reported no complications and, in an earlier article in *CRSToday Europe*, said that the technology "eliminates the need for manually creating grooves with the phacoemulsification handpiece."[6] Furthermore, less total ultrasound power was used compared with other phaco techniques.

LenSx Lasers, Inc., has established a second clinical site in Houston, where Stephen Slade, MD, performed the first femtosecond laser cataract surgery procedures in the United States in February.

Ronald Kurtz, MD; Tibor Juhasz, PhD; and Eric Weinberg are the cofounders of LenSx Lasers, Inc. The LenSx Laser is

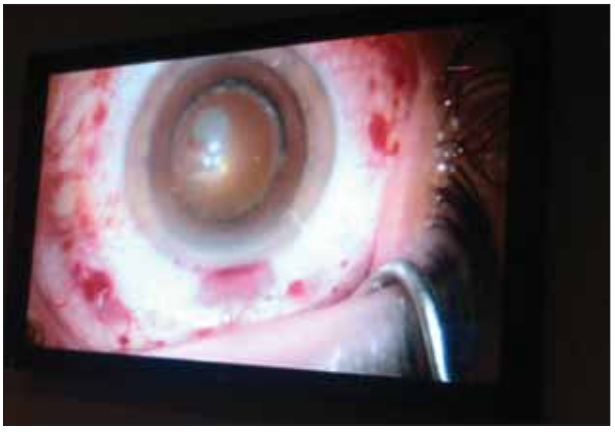

Figure 4. View of the OR screen following removal of the capsulotomy opening.

currently the only femtosecond laser to receive 510(k) clearance by the FDA for the creation of anterior capsulotomies and corneal incisions.

OPTIMEDICA

With an outstanding reputation in the field of retinal surgery and retinal lasers, Optimedica Corporation recently extended its reach to cataract surgery. Behind the scenes, the company worked to develop a noninvasive, intraocular femtosecond technique for some of the most technique-driven steps of cataract surgery. Company literature reports that this laser is capable of creating precise corneal incisions and capsulorhexes and of fragmenting the lens (Figures 5 through 7).

Safety studies are complete, with ongoing clinical trials reportedly showing promising results. According to the company, its femtosecond laser is en route to providing significant benefits to both surgeons performing and patients undergoing the cataract procedure. Ongoing trials will provide optimized treatment algorithms, according to company literature.

A cataract surgical video featuring Optimedica Corporation's femtosecond laser was shown at the 2009 AAO Annual Meeting in San Francisco. The technology uses real-time intraoperative optical coherence tomography visualization in the anterior chamber and on the cornea to determine the relevant dimensions and thicknesses of the lens and cornea and to guide treatment.

DIFFERENTIATION OF PLATFORMS

In an interview with *CRSToday*, John Vukich, MD, said how the three companies will differentiate their lasers remains to be seen.

"All three of the platforms use similar concepts and view the market similarly in terms of the platform's appeal," he said. "It will come down to the delivery of the unit, including such things as are the ergonomics consistent with OR flow? Is it easy to use? Is the interface friendly for the surgeon? Does it provide a rapid turnaround?" Dr. Vukich is a partner at the Davis Duehr Dean Center for Refractive Surgery in Madison, Wisconsin, and is a consultant to and investigator for Optimedica Corporation. He said that the technology has to be efficient and smooth; it has to be a platform that is easy to use.

PERFECT TIMING

"It has been a decade or more since there has been real innovation in cataract surgery," said William J. Link, PhD, in an interview with *CRSToday*. "The femtosecond laser tech-

Figure 5. Intraoperative view after capsulotomy created with the laser from Optimedica Corporation and subsequent lens fragmentation.

Figure 6. Initial nuclear division after capsulotomy performed with the Optimedica Corporation laser and subsequent lens fragmentation.

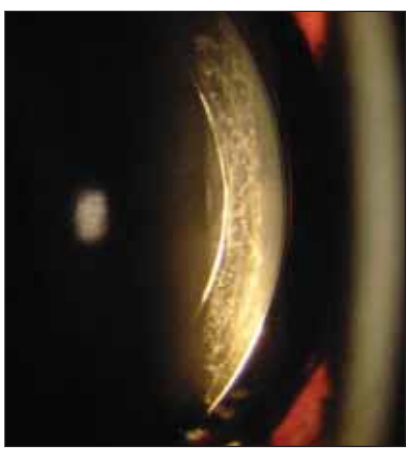

Figure 7. Consistent outcomes demonstrated with a concentric capsulotomy created by the laser from Optimedica Corporation and IOL implantation.

Femtosecond Cataract Surgery With the Optimedica Platform

Femtosecond laser cataract surgery is compelling for its ability to provide a uniform outcome.

BY JOHN A. VUKICH, MD

Optimedica Corporation (Santa Clara, CA) currently produces and markets advanced therapeutic lasers for the treatment of retinal diseases. The company has also recently developed a femtosecond laser platform that enables ophthalmologists to perform laser cataract surgery. In the evolving market for premium IOL surgery, this technology is designed to deliver a more accurate, metered, and consistent approach to cataract surgery to optimize the utility and performance of new-technology IOLs. Three companies are presently exploring the application of femtosecond laser technology for cataract surgery.

My colleagues and I are participating in an ongoing clinical trial at Centro Laser in Santo Domingo, Dominican Republic, using Optimedica Corporation's femtosecond laser platform. I hope this technology will be available for my patients in the very near future.

Optimedica Corporation's integrated optical coherence tomography (OCT) system maps the anterior segment. It measures the pupil size, the anterior chamber depth, the lens' thickness, and the position of the anterior lens capsule immediately prior to laser surgery. The treatment software subsequently optimizes pattern parameters, such as the diameter and depth of lens fragmentation in real time.

FLEXIBLE SURGERY WITH LASER PRECISION

A number of cutting patterns are available. The system today performs several corneal incisions, which can be used as primary cataract incisions, paracentesis, and relaxing incisions. With OCT-guided accurate placement, the platform delivers capsulotomies of any size and shape that the surgeon requires. These are features that one would expect on a platform like this and that expand its clinical utility.

Optimedica Corporation's femtosecond laser system provides effective options for lens fragmentation, with patterns chosen based on the clinical examination, nuclear density, and OCT data. The treatment facilitates the removal of the nucleus and minimizes the required amount of phaco energy. In some cases, the laser treatment can eliminate phacoemulsification from the process.

CONSISTENT OUTCOMES

The Optimedica platform allows the surgeon to optimize the primary cataract incision as well as the paracentesis so that they are reproducible with predictable results. Consistency of the capsulotomy is a key factor for ensuring optimal premium IOL implantation and for achieving targeted refractive endpoints. Exact placement of the lens is becoming increasingly important for accommodating lenses that require some optical-mechanical engagement of the ciliary body-capsular bag complex with a consistent (or at least reproducible and predictable) movement and noncircular capsulotomies. No surgeon believes he or she can create a capsulotomy freehand as precisely and reproducibly as the laser can.

In femtosecond cataract surgery, combining integrated OCT with flexible cutting patterns and laser precision contributes to a consistent outcome. This is why I find femtosecond cataract surgery using the platform from Optimedica Corporation appealing.

John A. Vukich, MD, is a partner at the Davis Duehr Dean Center for Refractive Surgery in Madison, Wisconsin. He is a consultant to and investigator for Optimedica Corporation. Dr. Vukich may be reached at (608) 282-2000; javukich@facstaff.wisc.edu.

eyetube Ophthalmic Video Resource

For video of the procedure: http://eyetube.net/v.asp?dirufe

nology advanced LASIK surgery nicely, and it provided ideas about how it could be developed for use in cataract surgery." Dr. Link is the founder and managing director of Versant Ventures, a leading health care-focused venture capital firm specializing in early-stage investments in medical devices, biotechnology and pharmaceuticals, health care services, and health care information technology. The firm is located in Menlo Park, California.

"I am optimistic that femtosecond technology will penetrate the cataract market substantially," Dr. Link said. "The

initial customers will be surgeons who are implanting premium IOLs for presbyopia as well as performing cataract removal. Experts believe that the femtosecond laser will deliver some services in the cataract procedure that are currently uncovered and could demand premium pricing."

Although the early adopters will be cataract practices and surgeons already in the premium channel, Dr. Link predicts that, as the technology is refined and used more broadly, it will penetrate into standard cataract procedures.

"Ophthalmic surgeons are wonderful customers for new technology, because they are familiar with laser technology," he said. "This will be a refreshing opportunity for surgeons to use those skills in the cataract procedure. I think it's a natural fit."

Regarding the appeal of femtosecond cataract technology to patients, Dr. Link said they have always wanted to believe surgeons were doing laser cataract surgery. So there is an openness on the part of consumers that laser surgery is better than traditional surgery.

"This is a natural and important evolution in cataract surgery," Dr. Link remarked. "This is the way innovation can work, where technology is developed and refined in one application—in this case LASIK—and then it is refocused and redeployed in another application. The timing is perfect for cataract sugery to advance to the next level."

CONCLUSION

The latent potential of intraocular femtosecond lasers is surfacing, with growing support from the industry to develop this technology for prime-time use. If surgical results with the femtosecond laser continue to improve the precision, reproducibility, and predictability of cataract surgery (including lens fragmentation, the incision's creation, and the capsulorhexis), it may be wise for ophthalmologists to consider investing in an intraocular femtosecond laser. The next few years will be telling. ■

1. Dooley IJ, O'Brien PD. Subjective difficulty of each stage of phacoemulsification cataract surgery performed by basic surgical trainees. *J Cataract Refract Surg.* 2006;32:604-608.
2. Oetting TA, Lee AG, Beaver HA, et al. Teaching and assessing surgical competency in ophthalmology training programs. *Ophthalmic Surg Lasers Imaging.* 2006;37:384-393.
3. Phend C. AAO: femtosecond lasers promising for safer cataract surgery. Medpage Today Web site. www.medpagetoday.com/tbprint.cfm?tbid=16706. Accessed March 12, 2010.
4. Nagy Z. Use of femtosecond laser system in cataract surgery. Paper presented at: XXVII Congress of the ESCRS; September 15, 2009; Barcelona, Spain.
5. Nagy Z, Takacs A, Filkorn T, Sarayba M. Initial clinical evaluation of an intraocular femtosecond laser in cataract surgery. *J Refract Surg.* 2009;25(12):1053-1060.
6. Nagy Z. Intraocular femtosecond laser applications in cataract surgery. *Cataract & Refractive Surgery Today Europe.* 2009;4(8):29-30.