New Generation of Femtosecond Lasers Emerges

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

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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. 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. 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 steps in cataract surgery.

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 Manila, Philippines, has laser fragmented and removed cataracts with significantly reduced ultrasound energy as hard as grade 5.

**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...
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.

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

THE PROCEDURE OF THE FUTURE

I believe femtosecond 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.

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

**LEN SX**

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
Budapest, Hungary, was the first to use the LenSx technology clinically. 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, 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.


For video of the procedure: http://eyetube.net/v.asp?todene
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 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-
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 surgery 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.