

The Origins of Laser Cataract Surgery

Three companies' pathways from development to commercialization.

BY STEPHEN DAILY, NEWS EDITOR

This year, the technology behind one of the most anticipated advances in years—laser cataract surgery—begins its transition from testing laboratories to physicians' offices. The precision of femtosecond lasers in cataract surgery is expected to enhance outcomes in practically all areas of measurement, especially with premium IOLs, which depend on a well-centered capsulotomy. The three major players in the laser cataract surgery market are Alcon, Inc. (Hünenberg, Switzerland), which purchased LenSx Lasers, Inc.; LensAR, Inc. (Winter Park, FL); and OptiMedica Corp. (Santa Clara, CA). These companies plan to commercially launch their devices this year and will go down as the pioneers of the technology. The path each company took to make it to commercialization, however, was unique.

INTRALASE TO LENSx

Similar to many other innovative devices in ophthalmology, femtosecond lasers were originally conceptualized and developed for use unrelated to their potential. The roots of laser cataract surgery can be traced to the work of Ron Kurtz, MD, and Tibor Juhasz, PhD, the founders of IntraLase Corp., who between 1995 and 1997 developed the IntraLase Femtosecond Laser at the University of Michigan in Ann Arbor. The new technology was built for corneal surgery. Knowing the potential to improve LASIK and corneal refractive procedures, Dr. Kurtz and Dr. Juhasz raised \$1.4 million in seed money and then approached

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William Link, PhD, who previously founded American Medical Optics and Chiron Vision and was, at the time, a partner with Brentwood Venture Capital (Los Angeles, CA).

“When I decided to invest, I said to those guys, ‘I think to do this well, I need you to move to Southern California nearby where we can build a business together,’” Dr. Link said in an interview with *Cataract & Refractive Surgery Today*.

Dr. Kurtz and Dr. Juhasz made the move to Irvine, California, with the intention to build technology to improve LASIK and corneal refractive procedures, Dr. Link said. During the reduction-to-practice phase, they found in early 2000 that the intrastromal procedure did not work, despite the investment of 5 years and \$11.5 million. Dr. Link and the rest of the team decided to refocus their efforts on developing the best device for creating LASIK flaps and later for corneal transplants. They raised \$95 million at the initial public offering. Dr. Link attributed the company's ultimate success to “a talented team, substantial capital, and ruthless focus.”

In March 2007, IntraLase was acquired by Advanced Medical Optics, Inc., for \$808 million in cash. Advanced Medical Optics was acquired by Abbott Laboratories in February 2009, and Abbott Medical Optics Inc. (AMO; Santa Ana, CA) became Abbott's eye care unit. The femtosecond laser developed by IntraLase and now owned by AMO is still trademarked under the name IntraLase.

Before IntraLase was sold to AMO, Dr. Kurtz left the company to pursue the use of femtosecond technology to improve cataract surgery. In 2008, he founded LenSx Lasers, Inc.

The venture capital backers of LenSx include Versant Ventures (Menlo Park, CA), SV Life Sciences (Boston, MA), Interwest Partners (Menlo Park, CA), and Venture Investors (Madison, WI). LenSx received FDA clearance for its laser to create anterior capsulotomies in August 2009, followed by clearance for the creation of corneal incisions in December 2009. In February 2010, Stephen G. Slade, MD, the medical director for LenSx, performed the first laser cataract surgery in the United States on 50 consecutive eyes.¹ Dr. Slade, chief medical editor of *CRSToday*, said that all of the patients he operated on saw 20/25 or better the first day after surgery, and all of the capsulotomies were perfectly centered and achieved a diametric accuracy of ± 0.25 mm. In July 2010, Alcon, Inc., announced its purchase of LenSx for a total deal consideration of \$744 million, validating the value and interest of the new technology in the ophthalmic marketplace.

LENSAR

The pathway to commercial viability for LensAR's femtosecond laser traces back to an original intention of presbyopic correction. Randy Frey was the founder and CEO of Autonomous Technologies Corp. (Orlando, FL), which later merged with Summit Technology (Waltham, MA) and was eventually acquired by Alcon. In 2004, he founded Lasersoft Vision, the predecessor of LensAR, and brought with him some of his partners from Autonomous. Throughout his career, Mr. Frey has been awarded dozens of patents in the area of excimer laser radar tracking, small-beam scanning, and wavefront-guided customized treatments. When he founded Lasersoft Vision, the idea was to research a laser in situ treatment for presbyopic correction, Monty Allen, chief financial officer of LensAR, told *CRSToday*.

Unlike LenSx, which had venture capital-backed money to help develop and test the technology from the beginning, when Lasersoft Vision started, it was angel funded. Mr. Frey lined up investors who knew of his skills, his capabilities, and his history in ophthalmology, Mr. Allen said. Even Mr. Frey himself was a significant investor in the early stages of the company.

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In the course of studying laser techniques for presbyopia, medical advisors at Lasersoft Vision pointed out that the procedure would be ideal for ease of removal of lenticular material as a function of a cataract procedure, especially the lenses that surgeons have the most difficulty breaking up and removing such as higher-grade cataracts.

“In some of the work done in both porcine and human cadaver eyes initially, it was noticed how easily the lens extracted after these treatments, when you needed to extract the lens, for example, to run tests on it,” Mr. Allen said. “Some of our physician consultants just simply said we should use this for cataracts. It would make extraction of the lenticular material so much easier, so much faster, and so much less traumatic in terms of the negative side effects from the pounding of the ultrasound energy that causes waves of energy to ripple through the globe. [Potentially] a major cause of anterior segment trauma and endothelial cell loss.”

In 2007, after system software upgrades and successful animal trials, Mr. Frey turned his attention to cataract surgery. The company changed its name to LensAR and acquired venture capital. The new focus was to design and develop a highly integrated measurement technology within a three-dimensional scanning laser system. The result was the LensAR Laser System. The primary venture capital partner is Aisling Capital (New York, NY), which was also previously involved as an investment banker for Autonomous Technologies.

The focus on cataracts allowed LensAR to move toward 510(k) clearance, a shorter approval pathway than the full premarket approval the company seeks for its presbyopic indication. An analysis of clinical results with the LensAR Laser System showed a trend toward faster and better anterior capsulotomies with respect to centration and regularity. Also shown were speedy visual recovery, a much reduced use of ultrasound in high-grade cataracts, and the elimination of ultrasound in the lowest-grade nuclei during cataract surgery using laser lens fragmentation versus traditional techniques.² In May 2010, the com-

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pany received FDA 510(k) clearance for use of the LensAR Laser System to create the anterior capsulotomy during cataract surgery. Clearance for laser fragmentation (chop and cylinder patterns) is under active review at the FDA. Other indications are being pursued as well, and the company expects to commercially launch the product in the second half of 2011.

OPTIMEDICA

The development of femtosecond laser technology at OptiMedica occurred more behind the scenes.

The company was founded in 2004 by five entrepreneurs, including Mark Blumenkranz, MD, chair of ophthalmology at Stanford University. The other founders were George Marcellino, PhD, David Mordaunt, Dan Andersen, and Mike Wiltberger.

Mark Forchette, who has been the president and CEO of OptiMedica since 2007, said there were three areas of focus when the company began—retina, glaucoma, and in the background, in a really “stealthy way,” laser cataract surgery.

“We kept it very quiet. Even in the original funding presentation, femtosecond laser cataract surgery was part of it,” said Mr. Forchette, who spent 23 years at Alcon before moving to OptiMedica.

Mr. Forchette said the initial investors in the company saw the potential of a precisely controlled capsulotomy and the synergistic effect with the lens that could be there. Those investors include Kleiner Perkins Caufield & Byers (Menlo Park, CA), Alloy Ventures (Palo Alto, CA), DAG Ventures (Palo Alto, CA), and Blackrock Private Equity Partners (Plainsboro, NJ).

The prized possession of OptiMedica up until 2010 was the Pascal Photocoagulator—pattern-scanning laser technology used for retinal surgery. More than a million patients were treated with the Pascal system, according to OptiMedica, and more than 600 systems were sold in 40 markets all over the world.

In August 2010, OptiMedica sold its glaucoma and retina assets, including its proprietary Pascal photocoagulation system, to Topcon Corp. (Tokyo, Japan). The deal allowed OptiMedica to focus exclusively on the contin-

ued development and commercialization of its Catalys Precision Laser System. The sale also provided OptiMedica with significant funding for the global market launch of its laser cataract surgery system in 2011.

“The whole time, from the founding of the company until the acquisition last year, we were working on [laser] cataract surgery in the background quietly,” Mr. Forchette said. “There’s a lot of intellectual property that we filed early that was very forward-thinking, and it was all about image-guidance of femtosecond laser for cataract, capsulotomy, fragmentation, softening, corneal incisions, astigmatic correction, and so those things we’ve been thinking about since day 1.”

Mr. Forchette said the company immediately involved physicians to collaborate with scientists and engineers in the research and development process at OptiMedica. For example, William W. Culbertson, MD, the chair of OptiMedica’s Medical Advisory Board, was involved right from the beginning.

The Catalys Precision Laser System combines a femtosecond laser, integrated optical coherence tomography imaging, and OptiMedica’s pattern-scanning technology. The platform helped surgeons achieve greater precision during several critical steps of cataract surgery when compared with manual techniques, according to a study published in *Science Translational Medicine*.³ The system is not yet approved for sale in the United States, but Mr. Forchette expects it to launch worldwide this year like its competitors.

TECHNOLAS PERFECT VISION

A fourth company, Technolas Perfect Vision GmbH (Munich, Germany), recently announced its plans to enter the laser cataract surgery market. At the 2010 European Society of Cataract and Refractive Surgeons meeting in Paris, Technolas introduced a customized lens module for cataract surgery. The company’s laser, not yet available in the United States, is also able to perform refractive, intrastromal, and therapeutic procedures. ■

Mr. Allen may be reached at (407) 641-4889; monty.allen@lensar.com

Mr. Forchette may be reached at (408) 850-7488; mforchette@optimedica.com.

Dr. Link may be reached at (949) 729-4500; bill@versantventures.com.

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