

Update on Laser Cataract Surgery

Several companies are developing lasers for use in cataract surgery.

BY JOHN A. VUKICH, MD

Laser cataract surgery has generated a great deal of interest among surgeons around the world. Anticipating significant demand from patients, several companies have made substantial financial investments to bring this technology to market. Currently, four lasers are at or near the point of commercial use, including systems from Alcon Laboratories, Inc.; LensAR, Inc.; OptiMedica Corporation; and Technolas Perfect Vision GmbH. Given the level of attention and the potential size of the global market, it is not surprising that additional companies, including Abbott Medical Optics Inc., have announced that they are working on laser applications for use in cataract surgery.

The common attributes of the lasers for cataract surgery are their ability to create a corneal incision, perform the anterior capsulotomy, and fragment the lens. How the devices accomplish these steps varies primarily in terms of the technology used to image, plan, and deliver the treatment. Early differences in technology are evident in the FDA's clearance summary documentation,¹⁻⁶ particularly regarding the lasers' technology, patterns and indications, docking, and imaging.

LASER TECHNOLOGY

Ultra-short refers to both pico- and femtosecond pulse durations. Although the surgical community may refer to the procedure as *laser cataract surgery*, it should be noted that the pulse durations of the systems vary and may not all be less than 1,000 femtoseconds. In the clearance documentation, the pulse durations are described as *ultra-short* and *femtosecond*, not as a specific number of femtoseconds. In its summary of safety and effectiveness, the LensAR Laser System is described as a mode-locked ND:YVO₄ laser of ultra-short, low-energy pulses of 1,064 nm. The summaries of safety and effectiveness for

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the LenSx 550 system (Alcon Laboratories, Inc.) specify that it uses focused femtosecond laser pulses and notes that the laser repetition rate was increased to 33 kHz for the corneal incision clearances.³⁻⁶

TREATMENT PATTERNS

FDA clearances for the LensAR Laser System describe a cylindrical pattern for the anterior capsulotomy and two fragmentation patterns consisting of radial sections or concentric cylindrical cuts through the radial sections. The LenSx laser's phacofragmentation pattern divides the lens into quadrants with two intersecting ellipsoidal planes. In a second filing, the laser was cleared for expanded ranges of diameter and depth for phacofragmentation. The system has also received clearances for corneal incisions, specifically for partial- and full-thickness stepped cuts/incisions for lamellar keratoplasty, penetrating keratoplasty, and cataract surgery.

DOCKING

The systems from LensAR Inc. and OptiMedica Corporation accomplish docking with a fluid-filled suction ring assembly that is affixed to the eye and then docked to a device mounted on the unit. The LenSx 550 and the system from Technolas Perfect Vision GmbH

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use a curved, disposable applanating lens and suction ring assembly that contacts the cornea directly.

IMAGING

One of the notable differences between the systems is the method of imaging and subsequent ranging for the desired treatment. Currently, the emphasis of all of the platforms is on image-guided treatments. Although there is no mention of imaging in the summary of clearances for the LenSx laser, it uses optical coherence tomography to assess the location of intraocular structures. The surgeon must inspect the image and choose the location of the incisions while the patient is under applanation. The laser made by OptiMedica Corporation uses optical coherence tomography as well but has automated the interpretation and treatment planning. The LensAR Laser System's fragmentation pattern is customized and based on a built-in optical measuring system, which uses a variation of Scheimpflug technology.

EARLY DIFFERENCES IN CLINICAL DATA

The systems from Alcon Laboratories, Inc.; LensAR Inc.; and most recently, OptiMedica Corporation have received initial FDA clearance. Technolas Perfect Vision GmbH has presented clinical data from systems in development and under review by the FDA. As of December 2011, an estimated 8,000 patients worldwide had been treated via the four systems for combinations of anterior capsulotomies, phacofragmentation, and corneal incisions. During the past 2 years, it has become increasingly apparent that the accuracy and precision achieved with laser refractive cataract surgery are already evolving. An analysis of clinical data for the anterior capsulotomy presented at past AAO and ASCRS meetings has shown that the accuracy of achieving a capsulotomy of the intended diameter ranges from less than $\pm 250 \mu\text{m}$ with the LenSx 550 Laser to $\pm 27 \mu\text{m}$ with OptiMedica Corporation's Catalys Laser Precision System.⁷⁻¹⁰

The LenSx Laser System was the first on the US market. Alcon Laboratories, Inc., has placed multiple systems and has the most complete portfolio of approved uses in this country. Given the short time that this technology has been available, one of the expected criticisms has been

the lack of peer-reviewed studies substantiating the benefits of a laser technique compared with manual approaches. Several papers have been presented at major conferences that demonstrate improved accuracy of the shape and size of the capsulotomy^{8,11-14} as well as improved phaco times.^{15,16} Randomized trials looking at outcomes, however, have not been presented. The lack of clear evidence showing a clinical benefit has not seemed to dampen enthusiasm among the early adopters.

CONCLUSION

Indisputably, the biggest obstacle that all of the lasers for cataract surgery face is financial: will it be paid for? (See the articles on this subject by Kevin Corcoran and by Alan Reider and Allison Weber Shuren on pages 64 and 67, respectively, in this issue, as well as a late-breaking announcement from the AAO and ASCRS on page 7.) Nevertheless, laser systems are being installed in the United States and around the world. For now, most surgeons are watching and waiting. ■

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