FEMTOSECOND LASERS

Four systems are on the market or close to launch

by Howard Larkin

Industry is betting big on the future of femtosecond laser-assisted cataract surgery. Four systems are on or near market launch and others are in development. While all focus on automating surgical steps including peripheral corneal relaxing incisions, cataract surgical incisions, anterior capsulotomy and lens fragmentation, they vary in their imaging approaches, corneal interfaces and power delivery algorithms. Form factors for ease of use and portability also vary. Below are the four systems that are furthest along.

**LenSx**

With numerous clinical installations around the world and US FDA approval for cataract incisions, relaxing incisions, anterior capsulotomy and lens fragmentation, LenSx is arguably the current market leader. The system consists of a femtosecond laser with an integrated proprietary OCT imaging system that provides real-time views of the anterior and posterior chambers, and allows surgeons to adjust cutting parameters before and during procedures. LenSx uses a disposable curved interface that docks to the eye with guidance from the onboard microscope and OCT.

Clinical trials show that the system is capable of producing nearly perfectly centred and sized capsulotomies, and reducing phaco energy required to aspirate lenses. Studies also suggest a lower deviation in effective lens position, holding out the possibility for more predictable refractive outcomes. Research on cataract incisions also shows they are less prone to leak than manual incisions.

Alcon purchased LenSx in a deal potentially worth $744m. This is not only a powerful endorsement of the economic potential of femto-cataract technology, it also backs LenSx with the market muscle of the global industry leader in cataract surgery. According to a report by Kevin M Miller MD, David Geffen School of Medicine at UCLA, Los Angeles, US, the current purchase price of the LenSx system is about $550,000. He estimates the service agreement cost at $40,000 annually after the first year, and procedure fees of $150 for relaxing incisions, $200 for capsulotomy and $425 per procedure, though there may be volume discounts. Dr Miller presented these data at the 4th Annual International Conference on Femtosecond Lasers In Technology (ICFLO) at Monarch Beach, Dana Point, California, US, June 24-25, 2011.

**OptiMedica**

With CE mark received in August and worldwide launch anticipated this year, OptiMedica’s Catalys Precision Laser System is a product of more than six years of development. The system’s most distinctive features include its novel patient interface and automated 3-D treatment customisation with spectral domain OCT.

After initial clinical tests revealed that a curved application interface can produce folds in the posterior cornea, OptiMedica developed the Liquid Optics® interface. According to CEO Mark Forchette, this produces a more optically perfect system that enhances imaging strength and prevents laser pulses from being misdirected or skipping. Additionally, the interface design minimises intraocular pressure rise. Catalys’ Integral Guidance® system combines proprietary OCT and automated 3-D treatment customisation. Sophisticated algorithms process the OCT to accurately map the relevant ocular surfaces in 3-D and build exclusion zones to prevent laser energy from penetrating the posterior capsule or other tissues. To minimise the time that a patient is under suction, the treatment plan is automatically customised based on imaged anatomy and safety zone margins.

Clinical trials show that Catalys dramatically improves the precision of several key surgical steps. It produces capsulotomies that are within 30 microns of intended size, within 80 microns of intended centre and exhibit near perfect circularity. Lens fragmentation with Catalys has also demonstrated an approximate 40 per cent reduction in CDE.

Long known for its retinal lasers, including the highly regarded PASCAL photocoagulator, OptiMedica sold its retinal product line to Topcon Corp. last year to focus on Catalys. The sale price, service agreement terms and patient interface/procedure fees have not been determined, though Dr Miller projects that a laser cost in the range of $450,000 and per procedure costs of $400 are reasonable expectations.

**LensAR**

Originally conceived to restore accommodation by softening the crystalline lens using femtosecond laser energy, LensAR has been developed for cataract applications and is now FDA approved for anterior capsulotomy and lens fragmentation. Rather than OCT, LensAR uses an integrated 3-D confocal-structured laser illumination imaging system based on the Schiemppflug principle, which the firm says gives the system greater depth of focus and improves imaging of higher-grade cataracts. The laser and the optical system are aligned in the same path allowing precise placement of the laser shots. It uses a BSS fluid, non-corneal contact, non-anaplating suction device to eliminate distortion of the eye’s anatomy, allowing for more accurate treatment and beam delivery. The device is also compact and wheeled, with an articulating treatment arm that can move in any direction, making it suitable for use within the operating suite in a temporal or superior approach according to physician preference.

Over 500 eyes have been treated with the LenSx system, and it has been used in extensive trials to develop nucleus fracturing patterns, including cubes and swirls. With appropriate algorithms, cataracts up to grade five have been removed with significantly reduced phaco energy. LensAR also has been shown to produce uniform anterior capsulotomies, cataract incisions and limbal relaxing incisions with great precision. The 3-D-CSI’s high fidelity low noise images provides the resolution necessary for automated software to work, giving the surgeon the choice of exact capsulorhexis location and incision placement without manually placing cursors on the image.

While no LensAR systems are clinically available yet, Dr Miller estimates the purchase price at about $400,000, service agreements at $40,000 annually after the first year, and procedure fees of $150 for capsulotomy and $200 for relaxing incisions.

**Technolas Perfect Vision**

The femto-cataract procedure is TPV’s latest advancement for its femtosecond laser platform technology. It incorporates real-time OCT for planning and monitoring procedures, and features the firm’s custom Curved Patient Interface combined with Intelligent Pressure Sensors to minimise corneal distortions. Trials led by Gerd Auffarth MD, University of Heidelberg, Germany, in collaboration with Kas Prasad Reddy MD, Hyderabad, India, and Luis Antonio Ruiz MD, Bogota, Columbia, show that the system is capable of producing capsulotomies more precisely than manual, and laser lens fragmentation reduces the phaco energy required. Corneal arcuate incisions have already been available for use with the TPV femtosecond laser platform for a number of years.

The combination of refractive and cataract procedures on a single platform is a key selling point of TPV’s laser. The firm has announced it will be marketed worldwide and an FDA application is pending for US approval.