Femtosecond laser-assisted cataract surgery

Lingmin He[a], Katrina Sheehy[b] and William Culbertson[c]

[a]Department of Ophthalmology, Stanford University, Stanford, [b]OptiMedica Corporation, Santa Clara, California and [c]Bascom Palmer Eye Institute, University of Miami, Miami, Florida, USA

Correspondence to William Culbertson, MD, Bascom Palmer Eye Institute, University of Miami, 900 NW, 17th Street, Miami, FL 33136, USA
Tel: +1 305 333 7439;
e-mail: wculbertson@med.miami.edu

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Purpose of review
In 2010, the US Food and Drug Administration (FDA) cleared femtosecond laser systems for cataract surgery. Available in 2011, this technology has the potential to significantly impact cataract surgery.

Recent findings
Femtosecond lasers offer surgeons the ability to make very precise cuts in a targeted area without damaging the surrounding tissues. This technology has already dramatically changed refractive surgery and is poised to do the same for cataract surgery. Three companies, OptiMedica, LenSx (acquired by Alcon in September 2010), and LensAR, in different stages of FDA clearance, are developing femtosecond laser systems for cataract surgery. These systems will create the initial corneal incisions, capsulotomy, and also fragment the lens.

Summary
This article outlines the advantages of femtosecond laser cataract surgery and provides an initial comparison of the LensAR, LenSx/Alcon, and OptiMedica systems and early clinical results.

Keywords
capsulotomy, femtosecond, fragmentation, laser cataract surgery, optical coherence tomography, refractive cataract surgery

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Introduction

Lasers have been used in cataract surgery since the 1970s. In 1975, Krasnov [1] reported on the use of phacopuncture with a Q-switched ruby laser (694 nm) to create microperforations in the anterior capsule, allowing gradual release and absorption of the lens material over time. Following this initial work, investigators looked to ultraviolet wavelength lasers (193–351 nm) to aid cataract removal before shifting to the infrared spectrum in the 1980s [2]. The neodymium-doped yttrium aluminium garnet (Nd:YAG) laser was reported as first used for posterior capsulotomy in pseudophakic patients, peripheral iridotomy and lysing of the papillary membranes [3,4]. Around this time, Aron-Rosa and Aron [5] used an Nd:YAG laser to perform anterior capsulotomies prior to conventional surgery. Pioneering work in the field, Aron-Rosa and Aron found marked decreased incidence of posterior capsular opacification in patients treated with laser capsulotomy (3.27 vs. 50%), an intriguing and encouraging finding. However, anterior laser capsulotomy never gained widespread popularity owing to problems with inflammation, rises in intraocular pressure (IOP), and poor mydriasis postlaser [2].

More recently, lasers have been applied to phacoemulsification and photolysis. Initial work by Peyman and Katoh [6] focused light directly onto the nucleus, causing optical breakdown of the lens material. Subsequently, the Erbium:YAG laser was used to for this purpose, with systems varying levels of energy delivery and pulse duration to decrease energy use and resultant endothelial cell loss [2]. In the subsequent Nd:YAG systems, such as the Dodick photolysis system or Paradigm Medical Industries units, laser energy is transferred to a titanium target, which is part of a combination laser/aspiration handpiece [7]. This allows a plasma to be formed at the tip of the target at lower energies. The plasma causes optical breakdown and subsequent shock waves to facilitate acoustic breakdown of the material [8]. Clinical trials with these systems have decreased total energy use, mean operative time, and surgical complications while improving visual acuity [9]. However, adoption is not widespread as phacoemulsification is preferred.

Femtosecond lasers

Femtosecond lasers use a shorter pulse time of 10^{-15} s compared with 10^{-9} s used by photocoagulation (argon), photoablation (excimer), and photodisruption (Nd:YAG) lasers. Because power is a function of energy per unit time, shorter pulse times further decrease energy output for a given effect [10]. This attribute of femtosecond lasers is especially important for cataract surgery, wherein preservation of ocular structures like the cornea, iris, zonules, and capsular bag is critical for good visual outcomes. The laser cuts tissue by essentially vaporizing it. The tight focus of laser energy creates a plasma and then a cavitation bubble that expands and collapses separating the tissue [10]. As the laser's near-infrared wavelength is not absorbed by optically clear tissue, it can be focused precisely at different depths within the anterior chamber.

Femtosecond lasers first became available for refractive surgery in 2001, when they were introduced for the purpose of flap creation in laser in-situ keratomileusis (LASIK) [11,12]. The flaps created by femtosecond lasers were more reproducible, uniform, closer to their intended thickness and centration, and had improved safety profiles compared with those made by manual keratome. Since then, use of femtosecond lasers has been expanded to other corneal surgeries and most recently has been applied to cataract surgery [13].

The need for precision and safety in cataract surgery

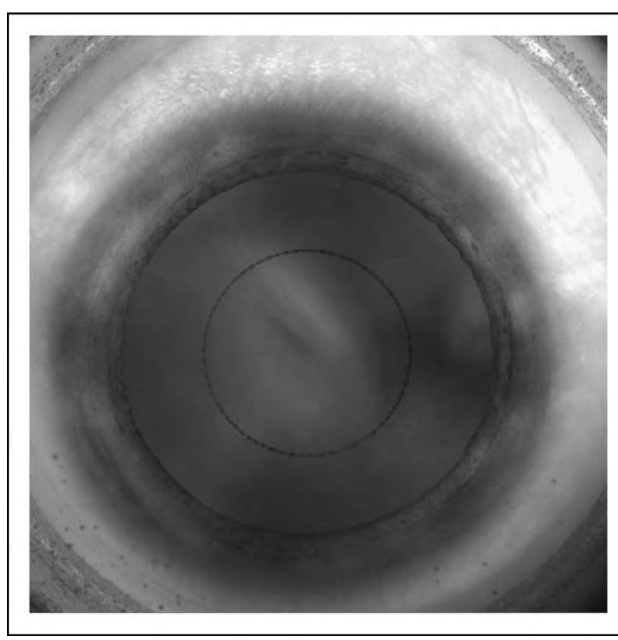
Cataract surgery was the leading diagnosis for US ambulatory surgery center visits in 2006, accounting for approximately 3 million procedures [14]. This number will continue to grow as the population ages. The Eye Diseases Prevalence Research Group in 2004 estimated that 20.5 million Americans in 2000 and 30.1 million Americans by 2020 had or will have a cataract [15]. Until recently, the primary end point of cataract surgery has been functional vision of 20/40 or better with accuracy of ±1 diopter. In 2006, a benchmark study in the UK set a standard for accuracy for refractive outcomes in normal eyes after cataract surgery to target ±0.50 diopter for 55% of cases and ±1.00 diopter for 85% of cases [16]. However, with current biometry and surgical methods, one study reported that only 45% of patients are within 0.5 diopter of their targeted postoperative refraction, and 6% have more than 2 diopter of residual refractive error [17]. With the advent of multifocal and accommodating intraocular lenses and patients pursuing surgery earlier with less tolerance for visual impairment, cataract surgeons are facing increasingly high patient expectations for refractive outcome. Today, the goal of cataract surgery is to achieve near emmetropia. Just as for LASIK, femtosecond laser technology can deliver remarkable gains in reproducibility, centration, and safety in cataract surgery, delivering the necessary accuracy and precision to improve beyond current clinical outcomes. To date, the systems are engineered to perform four groups of incisions: capsulotomy, lens fragmentation, astigmatic relaxing incisions, and clear corneal incisions (CCIs) including the cataract incision and paracenteses, each which will be discussed in detail.

Capsulotomy

Use of the femtosecond laser has the potential to revolutionize cataract surgery with the creation of a capsulotomy, or laser-incised capsulorhexis (Fig. 1). Studies have shown that the size of the capsulorhexis is important to optimize positioning and intraocular lens (IOLs) performance. A small capsulorhexis (<5.5 mm) has been linked to anterior capsule fibrosis and hyperopic shift with a single-piece aspheric IOL [18]. However, when the capsulorhexis is too large and there is insufficient overlap of the IOL by the capsule, there can be increased rates of tilt, decentration, and posterior capsular opacification, sometimes even requiring lens exchange [19–21]. For a dual-optic accommodating IOL designed to produce movement of the anterior optic from ciliary forces, the IOL requires a completely overlapping capsulorhexis to prevent prolapse of the anterior optic out of the capsular bag [22,23]. Another accommodating IOL requires larger capsulotomies for hinged movement [24–27]. Creating precise and predictable capsulotomies should reduce the occurrence of aforementioned complications (Fig. 2). Symmetrical, uniform fibrosis and healing may also be important for accommodating IOLs that rely on symmetrical contractile forces to translate into axial movement.

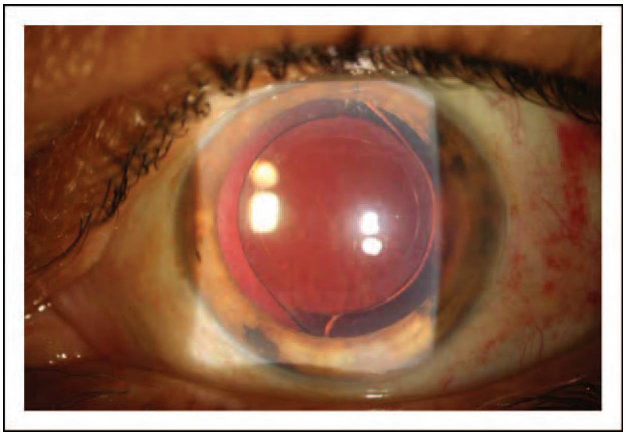
The capsulotomy construction is extremely important for estimating effective lens position (ELP). ELP is a value derived from empirical data of the A constant and surgeon factor, factors that account for variability in surgical

Figure 1 Laser capsulotomy



View from the Catalys near-infrared video system of a precisely sized, shaped and positioned laser capsulotomy.

Figure 2 Intraocular lens with laser capsulotomy



Postoperative slit-lamp view of a laser capsulotomy with uniform overlap of intraocular lens optic.

technique. One study determined that the size of the capsulorhexis has a direct relation to the ELP [28]. Inaccurate prediction of the ELP has been identified as the biggest source of error in IOL power calculations [29]. A difference of only 1 mm in lens position can lead to an approximately 1.25-diopter change in refractive error [18,30,31]. For toric and multifocal IOLs, the window for error is even smaller. Tilt, decentration, or rotation with these IOLs can cause significant deviations from the desired refractive outcome, in addition to visual aberrations like halo and coma that are difficult to tolerate [21,32,33]. Placement of the capsulotomy is thought to aid IOL centration. With current technology, few tools exist to guide the centration of the capsulorhexis other than anatomical landmarks such as the dilated pupil or limbal edge, making patients with irregular dilation challenging. Predictable and controlled IOL placement can be achieved more often when the capsulotomy incision is precisely sized and centered using a femtosecond laser system (Fig. 3).

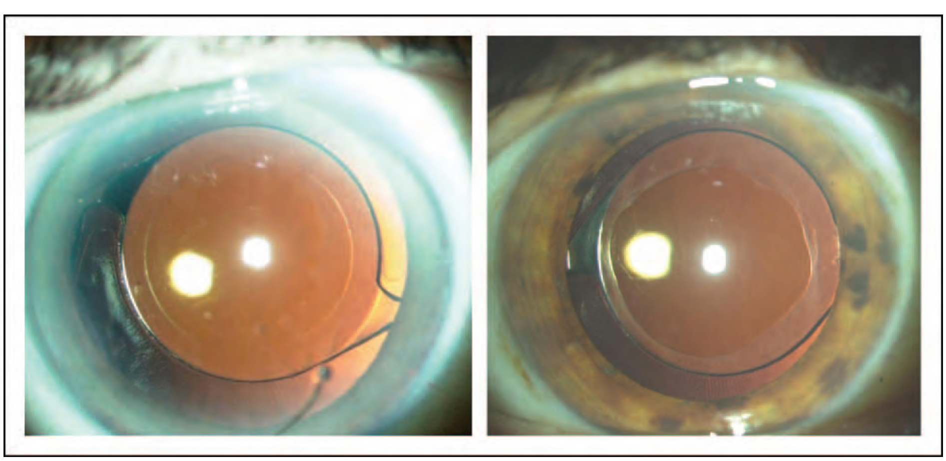
Lens fragmentation

Femtosecond lasers can be used to segment the nucleus, allowing the surgeon to skip the difficult sculpting and chopping steps that most frequently lead to complications [34–36]. Additionally, patterns of cuts can be placed on the nucleus to soften harder cataracts (Fig. 4). These treatments could reduce the amount of ultrasound energy from the phacoemulsification probe, thereby diminishing the risk of capsule complications and corneal endothelial injury [37–39]. There may be added safety benefits from reducing the number of instruments used, intraocular movements, and manipulations of the lens. Finally the treatments may be optimized for the irrigation/aspiration phacodynamics to reduce flow, trampolining, and iris prolapse.

Relaxing incisions

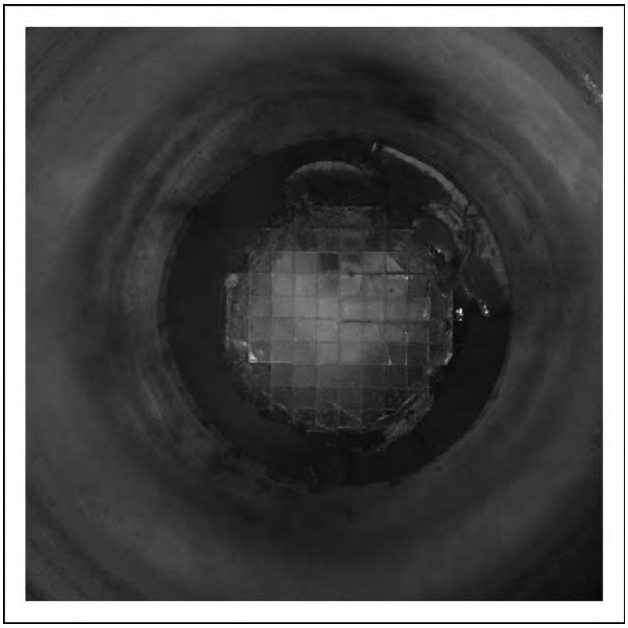
The cataract laser systems can perform corneal or limbal relaxing incisions (LRIs) to correct up to 3.5 diopter of astigmatism, flattening the steepest meridian of the cornea, eliminating a source of refractive error [40]. Only a small percentage of treatable cases are receiving LRIs, however, because the manual incision is technically demanding. An axis misalignment of just 5° results in a 17% reduction in effect [40]. Inconsistencies in the results of manual LRIs are presumed to be related to imprecision in depth, axis, arc length, and optic zone. Conceivably, the improved accuracy afforded by the femtosecond laser could improve the reliability of outcomes of laser LRIs compared with manual LRIs.

Figure 3 1 Month postoperative



Laser vs. Manual. (a) Slit lamp view at 1-month postoperation of the capsulotomy and intraocular lens. (b) Slit-lamp view at 1-month postoperation of a manual capsulorhexis and intraocular lens.

Figure 4 Laser lens fragmentation



View from the Catalys near-infrared video system of a lens fragmentation with 500 μm spacing in the pattern.

Clear corneal incisions

The self-sealing CCI is the preferred method of access into the anterior chamber, used by 72% of US cataract surgeons for the superior visual outcomes and faster recovery it offers [41,42]. The only obstacle keeping this figure from being higher is an increased incidence of endophthalmitis with CCIs [43]. CCIs often have gaping at the internal aspect of the corneal wound, as well as Descemet's membrane detachment and increased thickness at the incision site [44]. Laser-made wounds may show less features of damage and faster healing, either by virtue of the wound properties or from reductions in the mechanical stresses during the operation [45•,46].

Laser cataract surgery procedure

There are four primary steps for the laser cataract surgery procedure: planning, engagement, visualization and customization, and treatment. Two subsystems that are of critical importance to the precision and safety of laser-assisted cataract surgery are the docking interface in the engagement step and the image guidance system for visualizing ocular surfaces and customizing the treatment. The different approaches to the procedure taken by LenSx, LensAR, and OptiMedica are discussed in the following section.

Planning

Prior to cataract surgery, individual variations in pupil dilation, lens thickness, corneal thickness, and other anatomy can be measured. After initial planning, adjustments can be made in real time using drag and drop user interfaces with incision overlays on video and cross sectional images.

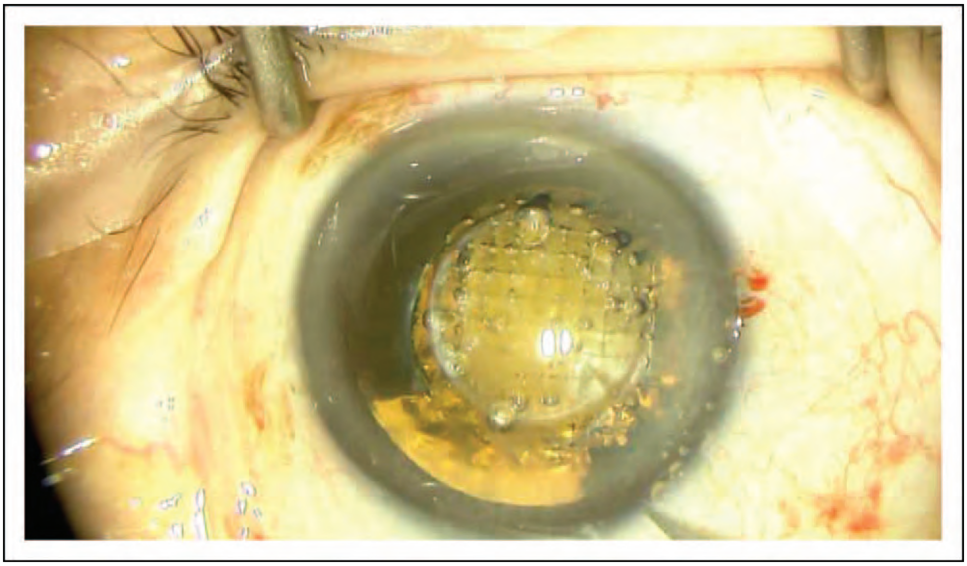
For the capsulotomy, the planning parameters include the size, shape, and desired center for the incision. The primary driver of the capsulotomy planning is the intraocular lens. For lens fragmentation, parameters include depth and diameter of cut, and pattern. These can be customized for lens density and matched to the surgeon's preferred technique, reducing phacoemulsification time and energy. For relaxing incisions, traditional nomograms are used for planning. However, as the effect of pneumodissection from cavitation bubbles is quantified and sub-Bowmans and intrastromal relaxing incisions are explored, new nomograms need to be established. For CCIs, the planning parameters include location, depth, and architecture of incisions.

Engagement

Prior to delivering the laser, a patient's eye must be stabilized relative to the optical system of the laser. In refractive surgery, this is achieved with a curved or flat plate that pulls the eye into a suction ring, distorting the globe. Studies on porcine and in-vivo rabbit eyes comparing real-time IOP during LASIK with femtosecond lasers and mechanical microkeratome have shown that the Intralase interface (Abbott Medical Optics, Santa Ana, California, USA) can cause a rise in IOP of about 89 mmHg and the VisuMax interface (Carl Zeiss Meditec, Dublin, California, USA) can cause a rise of 82 mmHg [47,48]. Although this rise in IOP is well tolerated in refractive surgery patients, the elderly cataract population has much ocular comorbidity and may have increased risk of retinal damage from transient ischemia during the engagement process. An ideal interface would pull a tight vacuum over an annulus design for retention and stability without distorting the eye and causing IOP increase. Additionally, it would have a wide field of view to allow for an-off center, tilted dock, relieving the requirement on the surgeon for tightly centering the suction ring. This allows the surgeon to view the limbus for corneal adjustments and to complete all incisions without having to re-engage. Finally, the interface would have a liquid between the laser system and eye, preventing corneal folds that occur with suction, and allowing for a tight laser focus, thus, minimizing energy, reducing cavitation bubble size, and optimizing treatment results.

All three systems have appeared to be effective in stabilizing the eye and minimizing IOP rise, however, the method and device for docking appears to be an area of differentiation for each platform. OptiMedica's liquid optics interface causes only 8–12 mmHg rise in IOP

Figure 5 Laser cataract surgery



Surgical view after laser cataract surgery with the Catalys Precision Laser System. Minimal petichae and subconjunctival hemorrhages are visible following use with the liquid optics interface.

during engagement and yet maintains good retention of the eye. The annulus design does not pull tissue into the ring and, therefore, minimizes petechiae, subconjunctival hemorrhages, and corneal trauma (Fig. 5). LenSx has reported a curved lens and suction system. LensAR has reported a no-touch, nonapplanating water bath suction fixation device [49].

Visualization and customization

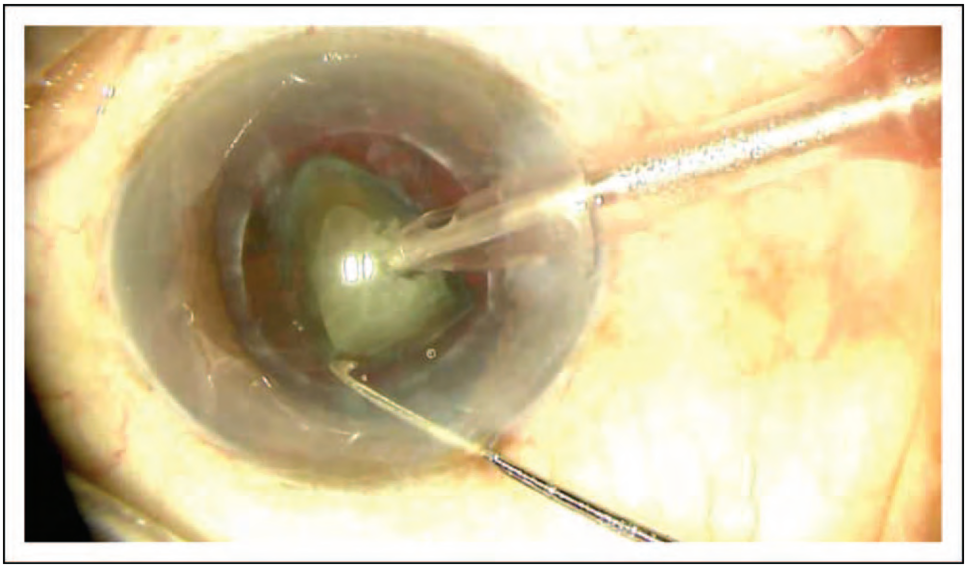
The image guidance system is a critical part of laser cataract surgery as it determines the location and dimension of ocular structures (cornea, iris, and anterior and posterior capsule) and guides the surgeon in customizing the placement of laser incisions and lens fragmentation zones. The systems used must be able to detect the iris boundaries so that the laser can be safely directed within even the asymmetrically dilated iris. They must also generate references for the size and centration of the capsulotomy, improving on current visual cues and the surgeon's estimates. It is critical that the posterior surface of the lens is detected in order to maintain a safety zone and prevent cuts in the posterior capsule. The corneal thickness should be determined so that the architecture of relaxing and surgical incisions can be properly customized for each patient

Anterior segment imaging with Fourier-domain optical coherence tomography (FD-OCT) now allows for real-time, high-resolution measurements of lens position, corneal thickness, iris boundaries, and iridocorneal angle [50–52]. Although visualization of the ciliary body is limited by the pigmentation of the iris, this technology offers several advantages including noncontact application, accuracy in the presence of corneal opacity, ease of use, and high-resolution profile imaging [50]. LenSx and OptiMedica use FD-OCT for three-dimensional, high-resolution viewing of ocular structures. LensAR uses a three-dimensional confocal structured illumination-scanning transmitter very similar to Scheimpflug technology [49]. Scheimpflug imaging systems are capable of determining net corneal power elevation maps, anterior chamber depth, and corneal wavefront [53,54]. Additionally, the lens density can be evaluated and quantified, allowing lens fragmentation settings to be selected automatically [55]. Previews of each company's software indicate that they use varying sizes of safety zones along with physician intervention to ensure that the laser energy does not adversely affect the iris, anterior or posterior capsule (Fig. 6).

Treatment

The final step of laser cataract surgery is the treatment. The laser spot pattern for a single incision is applied from posterior to anterior. This maintains a precise focus, avoiding scatter of the laser beam and also reduces the amount of radiation reaching the retina (Palanker D, Blumenkranz MS, Anderson D, *et al.*, ScienceTranslationalMedicine 17 November 2010 Vol 2 Issue 58). The optimal timing between the laser treatment and subsequent lens removal has not been thoroughly investigated, although it is hypothesized that the treatment

Figure 6 Phacoemulsification after laser cataract surgery



Surgical view of a quadrant of the lens. Outline demonstrates lens fragmentation depth with maintenance of both anterior and posterior capsule safety zones.

causes prostaglandin release and miosis, limiting the time between these steps.

The three companies differ in the order of incision delivery. The OptiMedica system delivers the capsulotomy first, [supplementary digital content 1, http://links.lww.com/COOP/A1 (femtosecond laser created 5.0 mm anterior capsulotomy created with the Optimedica Catalys laser)] and then the lens fragmentation pattern [supplementary digital content 2, http://links.lww.com/COOP/A2 (segmentation and softening of a grade 4 nuclear cataract with the Optimedica Catalys femtosecond laser)]. With accurate surface identification, the capsulotomy depth can be minimized to reduce bubble generation and eliminate interference with subsequent incisions. This sequence reduces the risk of tearing the capsular bag or creating zonular dehiscence because the lens is allowed to relax as it is fragmented. With the LenSx system, the lens is fragmented, the capsule is re-imaged for expansion, then the capsulotomy is made [56].

Clinical results

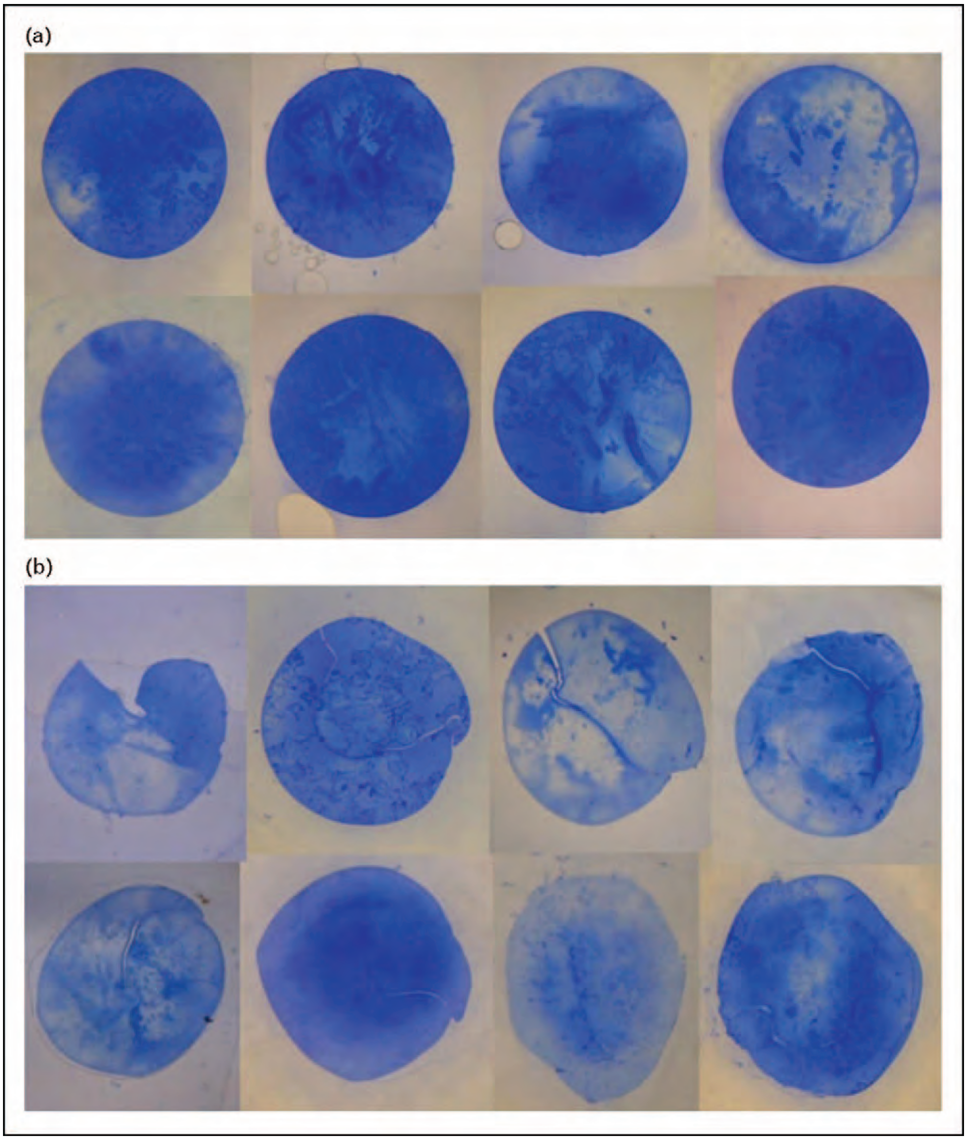
In 2009, Nagy *et al.* [57••] first published the results from their work with the LenSx femtosecond laser system for cataract surgery. They compared laser-created capsulotomies to manual capsulorhexes in porcine eyes on the basis of reproducibility and maximal resistance to stretch. They showed that the capsulotomies were much more reproducible, uniform, and accurately placed [57••]. By scanning electron microscopy, the edges were comparably smooth, and the strength of the laser-created edge could tolerate a higher force of stretch before rupture [57••]. They also used porcine eyes to show that lens fragmentation into quadrants led to a 43% reduction in phacoemulsification power and a 51% reduction in time [57••]. Finally, they treated nine patient eyes with various combinations of laser treatment (three laser capsulotomies only, three lens fragmentation only, and three receiving both) and showed that the eyes had only mild corneal edema, and trace cells and flare in the first postoperative day that resolved completely by the week [57••]. Although they only had a limited number of patients, they demonstrated that femtosecond laser systems for cataract surgery appeared to be well tolerated for use.

Although all three systems have demonstrated a level of capsulotomy precision beyond the manual technique, the accuracy and degree of precision of the three systems is not uniform. A summary follows of the early clinical data from 2010 on the size, shape, and position of the capsulotomy and ease of lens fragmentation. Corneal incision data are still limited [58].

Capsulotomy

OptiMedica reported capsulotomy diameters within 27 μm (SD, 25 μm) of intended diameter (Fig. 7) [59]. This is compared with 183 μm (SD, 246 μm) for LensAR [60]. Although LenSx did not provide absolute numerical data on the median size of their capsulotomy, the

Figure 7 Capsule discs

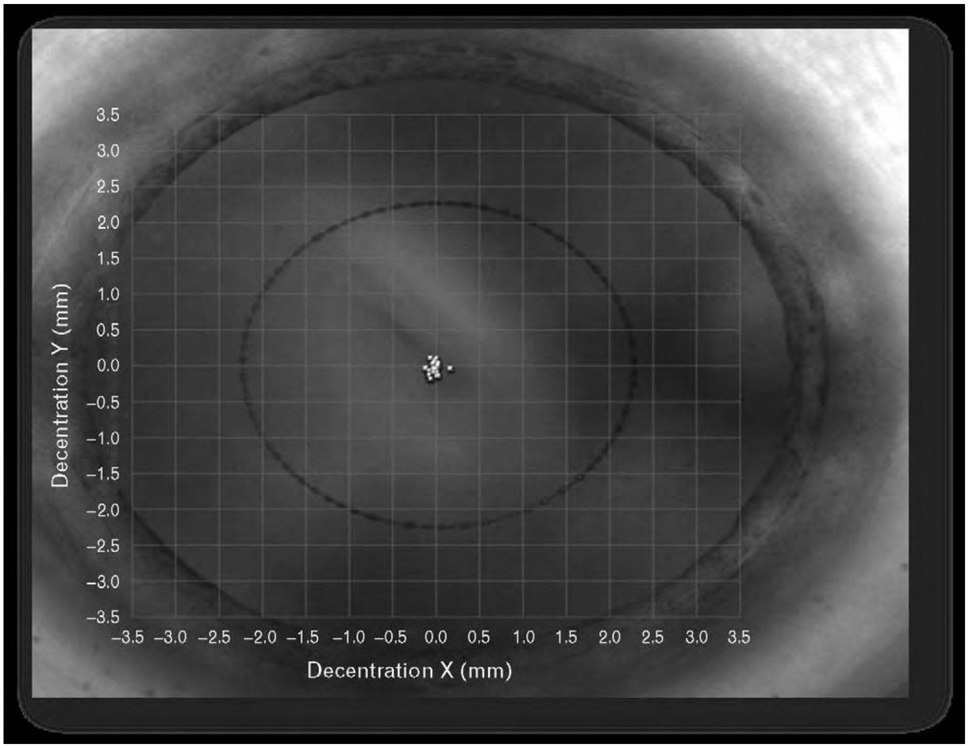


Laser vs. manual. Excised capsule tissue disk samples demonstrating repeatability of size and shape with (a) the laser system as compared with (b) manual samples.

company reported that all capsulotomies are within 250 μm of intended diameter [61]. All companies found that the laser capsulotomy was more precise than manual capsulorhexes with OptiMedica reporting manual results at 339 μm (SD, 248 μm) [59] and LensAR reporting nearly 500 μm for manual capsulorhexis [60]. OptiMedica has also reported initial data on the relationship between the capsulotomy that is created and the aperture in the capsular bag after the lens is implanted, indicating a level of elasticity of the capsular bag after IOL implantation and fibrosis and phimosis with healing at 1-month post-operation [62].

For capsulotomy shape, each company used different measurement techniques, so a comparison is not easily assessed. OptiMedica measured circularity as a function of capsulotomy diameter and area with 1 being perfectly circular. OptiMedica laser capsulotomies measured 0.942 (SD, 0.040) [59]. LensAR used a residuals analysis technique that showed a six-fold increase in circularity for laser over manual (3 ± 5 μm for laser vs. 20 ± 13 μm for manual) [60]. LenSx laser capsulotomies were 'significantly rounder' ($P = 0.028$) than manual continuous curvilinear capsulorhexis [60].

Figure 8 Capsulotomy centration



Overlay graph of capsulotomy center in relation to dilated pupil center. Demonstrates position accuracy and precision from the Catalys Precision Laser System.

For capsulotomy position, OptiMedica reported centration within 86 μm (SD, 51 μm) of intended placement [59], whereas LenSx IOL centration was significantly better ($P = 0.027$) in laser group as compared with manual (Fig. 8) [61]. To date, LensAR has not reported on centration.

Lens fragmentation

Studies are still underway to optimize the available treatment patterns for each commercial system [56,63]. To assess the efficacy of lens fragmentation, all three companies looked at ultrasound phacoemulsification energy output in lenses treated with laser or not and showed a marked reduction in ultrasound energy for cataracts of all lens opacities classification system grades. The percentage reduction varied by company and grade of cataract, but was 33% at least [63,64].

Future applications

Ultrasound biomicroscopy images of normal accommodation in young eyes demonstrate that the predominant action on the intact human lens is at the level of the anterior capsule [62]. Laser cataract surgery, with its improved precision and accuracy, may allow better preservation of the biomechanical properties of the lens capsule, enabling the creation of better accommodative IOLs. Groups have also investigated femtosecond lasers to restore accommodation to an aging, stiffening lens by separating collagen fibrils, or increasing the flexibility of the lens with incisions that act as gliding planes [65••,66–68]. Thus far, these studies have been pursued in porcine and cadaveric eyes, and it remains to be seen if this will be a feasible treatment for cataracts *in vivo*.

Other new applications for the femtosecond laser are being developed, expanding the patient population for which cataract and lens exchange surgeries are possible. Lee *et al.* [69] describe a technique by which they create a flap to remove corneal opacities, allowing better visualization of a cataract and greater ease in maneuvering difficult cases. As control over the capsulotomy becomes more precise, additional uses for intraocular lenses can also be achieved. Nishimoto *et al.* [70] describe using an intentionally decentered IOL for treating vertical strabismus. The future of these procedures will be closely linked to our ability to reliably predict the final placement of the lens, and also treat a large array of corneal and lens abnormalities.

There are also many groups attempting to use the femtosecond laser to reverse some of the accumulated damages contributing to cataracts and presbyopia. Recently, Kessel *et al.* [71•] have shown that the yellowing in lens color can be reduced by femtosecond laser photolysis. The future of cataract surgery may be treatments that allow the lens to be extracted within a wholly intact capsule and replaced with an injectable polymer. It may be that the natural crystalline lens can have its optical properties restored with laser modifications. Throughout all applications, the new femtosecond laser systems usher in the future of cataract surgery and bring us one step closer to an ideal surgery that corrects cataract, astigmatism, and presbyopia.

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References and recommended reading

Papers of particular interest, published within the annual period of review, have been highlighted as:
- • of special interest
- •• of outstanding interest

Additional references related to this topic can also be found in the Current World Literature section in this issue (pp. 000–000).

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