Creation of consistently sized, centrally located, circular capsulotomies has long been the goal of the cataract surgeon. It has been believed that such capsular openings minimize changes in effective lens position after cataract surgery. Manual techniques, even in the best hands and utilizing mechanical or optical devices, are unable to guarantee this.

The advent of the femtosecond laser, for the first time, made the consistent achievement of central, appropriately sized, circular capsulotomies a possibility, but this capability came at considerable initial and ongoing costs.

Development of the CapsuLaser technology (CapsuLaser) was inspired by the challenge of creating a cost-effective laser capsulotomy device. Lasers have the ability to deliver energy to selected, pigmented target tissue in certain ophthalmic applications. The main challenge of using a laser for capsulotomy is that the anterior capsule is transparent, so there is no naturally occurring chromophore that the laser can selectively target.

Historically, two methods have been used to create capsulotomies with a laser, and both rely upon plasma formation. First, Nd:YAG lasers have been used for decades to create posterior capsulotomies to address posterior capsular opacification. This is accomplished by focusing nanosecond bursts of laser energy in the vitreous humor, causing a plasma-induced vapor bubble that collapses to form a mechanical-acoustic wave. This wave applies shear stress to the posterior capsule, creating an opening. Second, more recently, in femtosecond laser-assisted capsulotomy, a high-peak–powered laser pulse is focused on a small volume to cause direct plasma-induced ablation of capsular tissue. A sequence of several hundred thousand ablation pulses creates two to five circles at different depths, essentially micromachining the capsulotomy. To focus the femtosecond laser in the region of the capsule, a diagnostic tool is needed to locate the capsule; therefore, femtosecond laser cataract systems are a combination of a diagnostic component and a scanning laser device. This is what leads to the relatively high cost of acquisition and operation of these systems.

CapsulaLaser offers cataract surgeons a precise means of using a laser to create a strong, consistent, circular capsular opening at much reduced cost compared with femtosecond laser technology and with no change in normal surgical patterns.

The diameter of the capsulotomy can be varied by the controls of the system from 4.5 to 7 mm.

In preclinical studies, the CapsuLaser demonstrated a high degree of consistency, with 100% free-floating capsules created in more than 1,000 porcine eyes.

Capsular staining
The CapsuLaser innovation is to introduce staining of the anterior capsule with a vital dye, thus creating a chromatically selective target for the laser. This is a continuous laser, not pulsed, which is scanned in a single circle pattern to create the continuous curvilinear capsulotomy. In the region of irradiation, the laser energy facilitates the molecular phase change of type IV collagen to elastic amorphous collagen. As the collagen undergoes this phase change, it creates the capsulotomy with a rim that has the high degree of elasticity and tear strength associated with amorphous collagen.
The CapsuLaser method utilizes proven cataract surgery techniques and relies upon the surgeon to control and position the location of the capsulotomy. In surgery, the eye is prepared in the normal manner, including dilating the pupil with appropriate solution and then creating the standard sideport paracentesis incisions. The anterior capsule is stained with vital dye, and then the anterior chamber is fully rinsed of residual dye and an OVD injected to stabilize the anterior chamber.

The CapsuLaser device is attached to a standard operating microscope (Figure 1) and integrates into the surgeon’s routine cataract workflow. After this, a surgical contact lens is placed on the cornea to stabilize the patient’s eye, and the CapsuLaser projects an alignment reticule onto the eye. The surgeon can then adjust the focus on the anterior capsule and locate the position of the desired capsulotomy. The device has a good depth of focus that is tolerant of tilt.

Once the reticule pattern is positioned correctly in the pupil center or centered on the visual axis, the footswitch is depressed for the full treatment duration (approximately 3 seconds). This laser-based approach creates a circular capsulotomy in a single pass (Figure 2). The rest of the surgery is completed as a standard cataract procedure.

**PRECLINICAL STUDIES**

In preclinical studies with the CapsuLaser, the capsulotomy diameter has been accurately sized with a standard deviation of 27 µm. The diameter of the capsulotomy can be varied by the controls of the system from 4.5 to 7 mm.

The CapsuLaser was compared with manual and femtosecond capsulotomies (Table 1). The CapsuLaser and femtosecond techniques had similar degrees of accuracy in diameter. The CapsuLaser achieved a high degree of circularity. The femtosecond capsulotomies were placed 43 µm closer to the target. As expected, both laser techniques had more precise diameters, circularity, and centration compared with manual capsulorrhexes.

Figure 1. The CapsuLaser device mounts on a standard operating microscope.

Figure 2. The CapsuLaser creates the capsulotomy in one pass.

Figure 3. In more than 1,000 porcine eyes, the CapsuLaser created 100% free-floating capsules (A,B).
TABLE 1. COMPARISON OF CAPSULOTOMY TECHNIQUES IN PORCINE EYES

<table>
<thead>
<tr>
<th>Technology</th>
<th>Deviation From Intended Diameter (µm)</th>
<th>Circularity (%)</th>
<th>Decentration (µm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manual*</td>
<td>377 ±258</td>
<td>80</td>
<td>500 ±150</td>
</tr>
<tr>
<td>Femtosecond*</td>
<td>29 ±26</td>
<td>94</td>
<td>77 ±47</td>
</tr>
<tr>
<td>CapsuLaser</td>
<td>1 ±27</td>
<td>99</td>
<td>120 ±40</td>
</tr>
</tbody>
</table>


As femtosecond laser systems have evolved over time, the occurrence of free-floating capsules has improved, from initial reports of 17% to closer to 100% success rates more recently.\(^1\,2\) In preclinical studies, the CapsuLaser demonstrated a high degree of consistency, with 100% free-floating capsules created in more than 1,000 porcine eyes (Figure 3).

The elasticity of the capsular rim has been investigated and compared with manual capsulorrhexis utilizing a strain gauge technique.\(^4\) With the crystalline lens removed, the pure elasticity and fracture strength of the capsular rim can be assessed, and CapsuLaser capsulotomies were determined to be more than four times stronger and more elastic than manual capsulorrhexes. For a more realistic measure, when the crystalline lens was left in the capsule for the strain gauge test, the CapsuLaser remained elastic and the capsulotomy could be extended from 5 to 12 mm without fracture or tear. This compared with extension of the manual capsulorrhexis from 5 to 10 mm without fracture. The practical interpretation of these results is that the CapsuLaser capsulotomy can be resistant to tearing with extension of up to 12 mm (Figure 4).

Preclinical studies have also demonstrated the safety profile of the CapsuLaser technique. Peak temperature elevations were measured with infrared imaging and thermocouple techniques at the iris, corneal endothelium, and irradiated retina. In all three locations, the temperature rises were minimal (less than 0.2°C). The CapsuLaser system conforms to multiple national and international laser safety standards.\(^5\,7\)

CONCLUSION

An initial clinical trial of this technology has been fully enrolled, and all surgeries to date have been successful. Investigators continue to optimize the CapsuLaser technique to make it intuitive and appropriate for all cataract surgeon practices. We recently reported the clinical trial results and our initial experience for the first time at the 2015 annual meeting of the European Society of Cataract and Refractive Surgeons (ESCRS)\(^8\) and will again present them at the American Academy of Ophthalmology (AAO) meeting in November.

CapsuLaser offers cataract surgeons a precise means of using a laser to create a strong, consistent, circular capsular opening at much reduced cost compared with femtosecond laser technology and with no change in normal surgical patterns. The CapsuLaser creates this capsulotomy in 3 seconds; the device is small and attached under the operating microscope with no other special equipment required.\(^\)