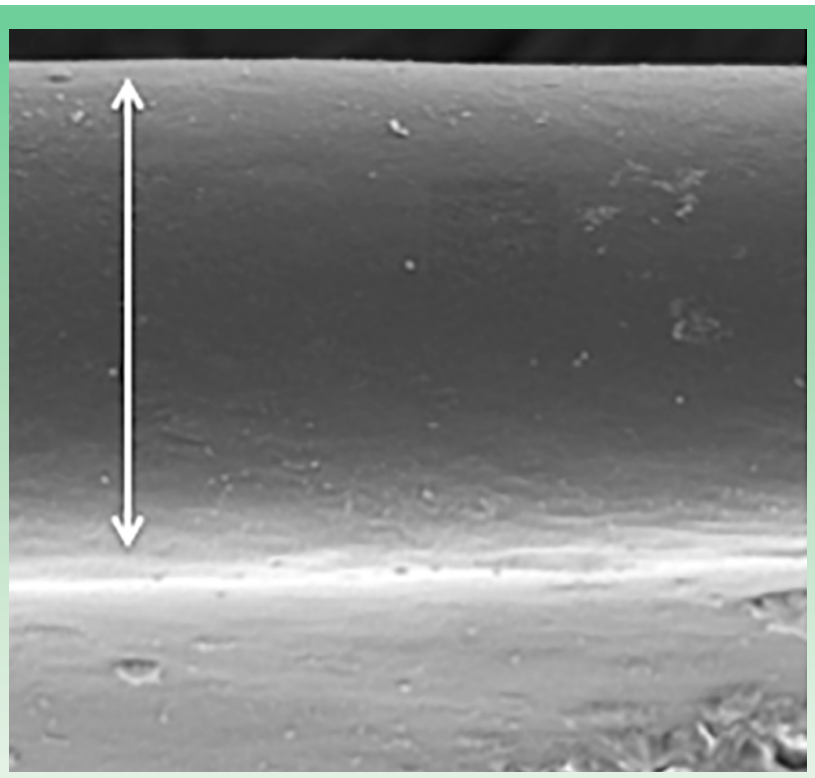
New technology for capsulotomy

by Ellen Stodola EyeWorld Staff Writer



Scanning electron microscopy shows that the Zepto capsulotomy edge has a unique morphology characterized by an extremely smooth functional edge (arrow). Detailed analysis revealed that Zepto not only creates a perfectly round, tag-free opening in the capsule, but at the same time places a microscopic eversion at the edge to present a small amount of the capsule underside for maximal edge integrity during surgery.

A new disposable, handheld device could automate creation of a perfect, circular capsulotomy

At the 2015 American Academy of Ophthalmology (AAO) meeting in Las Vegas, **David F. Chang, MD**, clinical professor, University of California, San Francisco, and in practice in Los Altos, Calif., discussed the Zepto capsulotomy instrument (Mynosys, Fremont, Calif.), a new disposable technology aimed at automating production of a stronger and perfectly sized anterior capsulotomy.

Creating a perfectly round anterior capsulotomy of a precise diameter is one advantage offered by the femtosecond laser. "However, this technology entails significant costs that are usually borne by the patient, if and when such billing is allowed," Dr. Chang said. "The size of the laser and the need for imaging and docking create logistical workflow issues and limit its utility for eyes with small pupils."

Several published studies have raised additional questions about whether the femtosecond laser capsulotomy is more likely to tear compared to a manual continuous curvilinear capsulorhexis (CCC).

Mynosys has developed the Zepto Precision Pulse Capsulotomy (PPC) device, which is a disposable, handheld instrument that would be used in the normal surgical sequence instead of a cystotome and capsule forceps. The instrument tip consists of a circular nitinol ring with an edge that is precision engineered on a micron scale. The ring is elongated and compressed for insertion through a small clear corneal incision. Because nitinol is a super elastic shape memory alloy, the ring immediately reassumes its native circular shape once it enters the OVD-filled anterior chamber. The initial model developed will produce a 5-mm diameter capsulotomy. The cutting ring is surrounded by a thin, clear silicone shell that is used to apply gentle suction to the anterior capsule against which it is apposed. This suction brings the

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ring edge into uniform contact with the anterior capsule. A train of tiny brief electrical pulses causes water molecules trapped between the ring edge and the microscopically stretched anterior capsule to vaporize. This phase transition creates an instantaneous mechanical splitting of the anterior capsule along the entire ring circumference, resulting in a perfectly circular opening of a precise diameter. There is no cautery or burning of tissue, and all 360 degrees of the capsulotomy are created at the exact same instant. A small console placed on top of or integrated into the phaco machine creates the suction and generates the precision electrical pulses.

The device was developed through testing in rabbit and human cadaver eyes, and results of this testing were presented at the AAO meeting. Live rabbit studies done by **Nick Mamalis, MD**, and **Liliana Werner, MD**, at the Intermountain Ocular Research Center at the Moran Eye Center, University of Utah showed no issues with inflammation or endothelial cell loss. In addition, thermocouple probe measurements confirmed that there is negligible temperature change within the anterior chamber associated with PPC. "The tiny and momentary electrical impulses are on the order of just a few milliseconds," Dr. Chang said. "In addition, the surrounding silicone suction cup shields the rest of the eye from any heat or energy that might be momentarily generated."

Based on clinical and SEM findings with the femtosecond laser, a major question with any new capsulotomy method is whether the resulting capsular edge resists tearing as well as a manual CCC. Extensive testing of the PPC edge tear strength was performed using paired human cadaver eyes to compare PPC with either femtosecond laser capsulotomy or manual CCC. "We think that such comparisons should be made using paired eyes from the same human donor," Dr. Chang said. "Comparisons in animal eyes or using eyes from two different human donors are less valid."

The results of these studies performed by Dr. Chang and **Vance Thompson, MD's** group in South Dakota revealed unexpected exciting results. "The PPC capsular edge was consistently stronger than either the femtosecond laser or manual capsulotomies," Dr. Chang noted. "This was true in all 16 pairs of human cadaver eyes—half using femto and half using manual CCC in the fellow paired eye.

"I think that most surgeons would welcome the option of an affordable disposable technology to automatically create a perfectly sized and circular capsulotomy that could be used in the usual surgical sequence without interrupting our OR workflow," Dr. Chang said. "If the resulting capsulotomy was stronger and more tear resistant than a manual CCC, that would be a huge bonus." A clear central window in the silicone shell would permit patients to fixate on the microscope light filament. Additional advantages would be the ability to center the capsulotomy on the visual axis intraoperatively for a refractive IOL and the ability to use the device following mechanical pupil expansion, he said.

The company has received CE mark approval in Europe and has applied for 510K approval in the U.S., Dr. Chang said. Clinical trials will be conducted shortly. **EW**

Editors' note: Dr. Chang has financial interests with Mynosys and Abbott Medical Optics (Abbott Park, Ill.).

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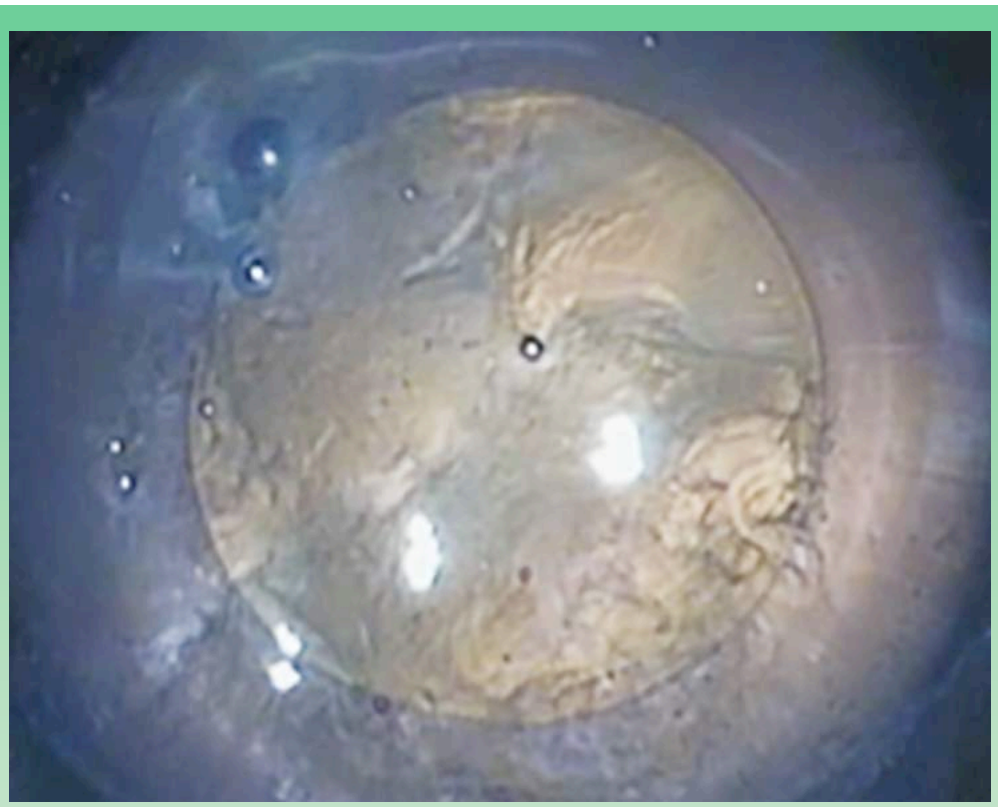
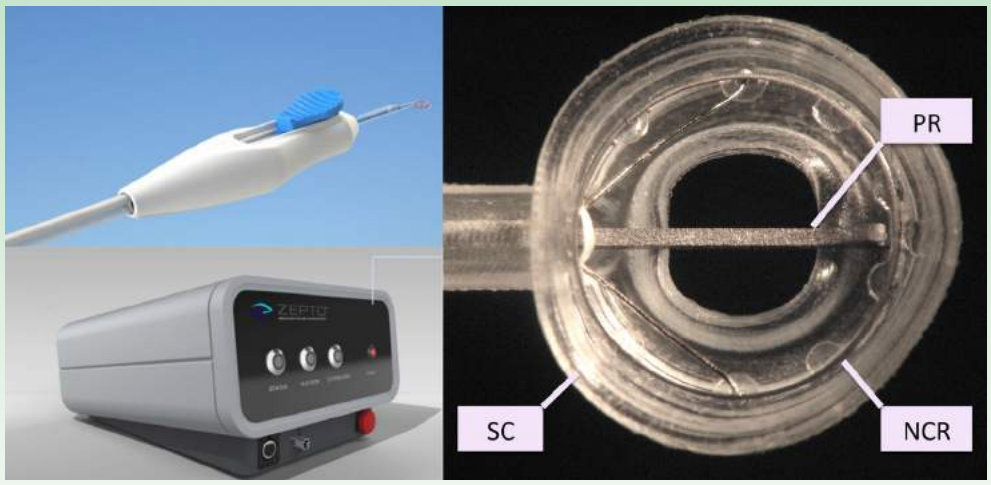


An example of a Zepto capsulotomy in a human cadaver eye



The Zepto capsulotomy system consists of a disposable handpiece attached to a control console that provides power and suction for the capsulotomy (left). The handpiece terminates in a soft, clear silicone capsulotomy tip that houses a circular collapsible super elastic nitonol ring to perform the capsulotomy (right).

Source (all): David F. Chang, MD