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COVER
FEATURE

Highlights from ESCRS 2016

Capsulotomy creation made easier

by Vanessa Caceres EyeWorld Contributing Writer

Surgeons focus on new devices that match or exceed manual, laser advantages

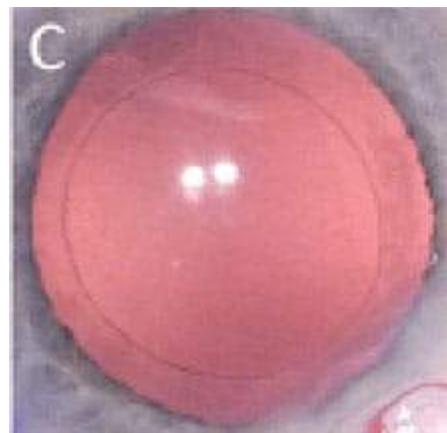
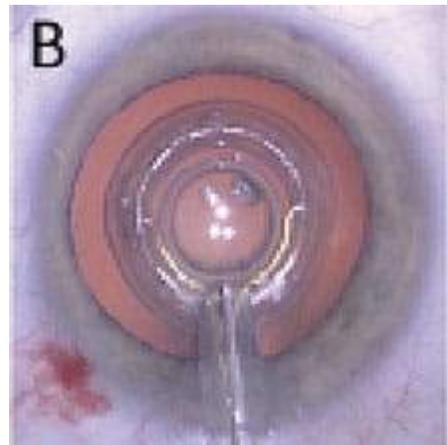
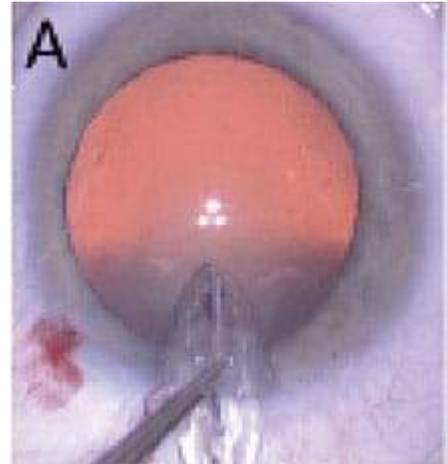
The use of the femtosecond laser to assist with cataract surgery attracts much fanfare among ophthalmologists. It adds more precision to the procedure, including the ability to create a perfectly circular capsulotomy with a consistent diameter.

Yet there are a few drawbacks to the use of the femtosecond laser for the capsulotomy, according to some surgeons. Lasers can be costly, time consuming to add to the operating flow, and they can induce miosis, said Pavel Stodulka, MD, PhD, Gemini Eye Clinic, Prague, Czech Republic.

"That's why laser capsulotomy is still not used in the majority of cases, even in the developed world," he said. At the 2016 European Society of Cataract and Refractive Surgeons (ESCRS) annual meeting, Dr. Stodulka and several other ophthalmologists addressed alternative approaches to creating a capsulotomy.

Zeroing in on ZEPTO

In addition to being circular, properly sized, and centered, the ideal anterior capsulotomy should have a strong edge that is resistant to tearing, said David F. Chang, MD, clinical professor, University of California, San Francisco. "We also want a technology that is inexpensive enough to be used on every patient, and not just on those who can afford extra costs or whose health care systems allow them to pay additional costs," he said. "We'd prefer to use the technology in the normal surgical sequence so that it does not slow our operative workflow. This led to the creation of ZEPTO-assisted cataract surgery (ZACS) based on Precision Pulse Capsulotomy technology [Mynosys, Fremont, California]," Dr. Chang said. The ZEPTO system consists of a disposable tip and handpiece powered by a small portable console. The tip has a clear silicone shell surrounding a circular, 5-mm diameter nitinol capsulotomy ring. After inflating the anterior chamber with OVD, the ZEPTO device is extended into a configuration narrow enough to enter through a 2.2-mm corneal incision and then re-expanded back to a circular shape within the anterior chamber. By applying suction to the silicone shell, the ring is evenly apposed to the anterior capsule. A train of ultrashort, low energy



ZEPTO-assisted cataract surgery. (A) Instead of capsulorhexis forceps, the

nanopulses creates an instantaneous, 360-degree mechanical cleavage of the capsule without tissue burning or cauterization. Although ZEPTO can be centered anywhere on the capsule by the surgeon, the optically clear suction cup permits patient fixation on the microscope light co-axial with the surgeon selected eyepiece to center specifically on the patient's personalized functional visual axis.

Earlier this year, Dr. Chang and fellow researchers published results from human cadaver eyes with use of the ZEPTO.^{1,2} There was no additional zonular stress with the ZEPTO compared to manual capsulorhexis in paired cadaver eyes. Additional strain gauge studies in paired human cadaver eyes showed that ZEPTO capsulotomies were consistently stronger than both manual and femtosecond laser capsulotomies. ZEPTO has recently been used by 12 surgeons in more than 120 surgical cases across the world with cataract grades of 2 to 4. In addition to simple cases, ZEPTO transformed challenging capsulotomies in cases with poorly dilated pupils, intumescent cataracts, and zonular dialysis into routine, Dr. Chang said. Patients have been followed up to 8 months with good vision and capsulotomy results. ZEPTO has CE mark approval, and a clinical trial is currently underway to support U.S. Food and Drug Administration (FDA) 510(k) submission.

Capitalizing on the CAPSULaser

Although laser-created capsulotomies add a dimension of precision and perfect shape, they have their disadvantages, including laser cost and size, Dr. Stodulka said.

The size and centration of the capsulotomy are increasingly important, said Richard Packard, MD, Windsor, U.K., who also presented at the ESCRS meeting. The size and centration can affect IOL centration and stability—especially for multifocal and toric IOLs—as well as IOL effective lens position.

These factors led Dr. Stodulka and Dr. Packard to work with the CAPSULaser (Los Gatos, California), a device that mounts to a surgeon's existing microscope to create a capsulotomy in 1 second. "By staining the anterior capsule with trypan blue, a selective target for the laser is created," Dr. Packard said.

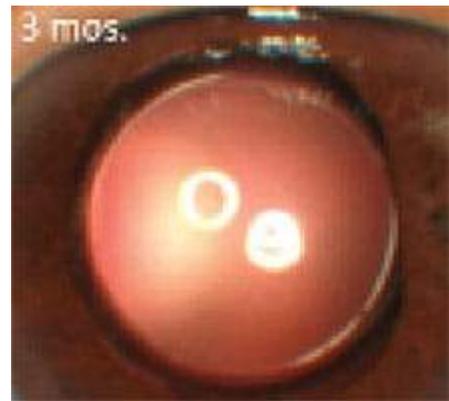
"This laser is not pulsed but is continuous and is scanned in a single circular pattern to create the continuous curvilinear capsulotomy."

At the ESCRS meeting, Dr. Stodulka shared the results of a clinical feasibility study with the CAPSULaser in 10 patients. Most patients had cataracts graded at a 2. The cataract removal steps were standard. At 3 months, the corrected distance visual acuity was 20/20 in 78% of patients and 20/25 or better in all patients. All patients had a well-centered capsulotomy with no flare or corneal edema. There was no capsule fibrosis or fundus abnormality observed.

Use of the device can assist with the fixation of certain newer IOLs, Dr. Stodulka said. This is key with the Femtis IOL (Oculentis, Berlin, Germany), designed for optic fixation.

Additionally, the CAPSULaser has been used to create a posterior capsulotomy in a lab setting, and a human trial will begin shortly, Dr. Packard said. Thus, there could be greater

surgeon inserts the ZEPTO capsulotomy tip into the anterior chamber. (B) After recircularization, the ZEPTO tip can be positioned anywhere on the capsule including centration on the patient's visual axis using patient fixation and Purkinje images. (C) Example of a completed ZEPTO capsulotomy from a second case



Appearance of two different ZEPTO capsulotomies at 3 and 8 months after surgery Source (all): David F. Chang, MD

use of the bag-in-the-lens concept both in adults and children, with the elimination of PCO. More than 200 eyes have been operated on with the device, and a new trial for CE marking has just started, he said. The CAPSULaser is not yet approved in the U.S. "The outcomes with the CAPSULaser are consistent with femtosecond surgeries," Dr. Stodulka said. "It's promising, and it can continue to offer free-floating capsules. It doesn't alter patient flow."

References

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2. Chang DF, et al. Precision pulse capsulotomy: Preclinical safety and performance of a new capsulotomy technology. *Ophthalmology*. 2016;123:255-64.

Editors' note: Dr. Chang has financial interests with Abbott Medical Optics (Abbott Park, Illinois) and Mynosys. Dr. Packard has financial interests with Alcon (Fort Worth, Texas), CAPSULaser, and Shire (Lexington, Massachusetts). Dr. Stodulka has financial with CAPSULaser and Bausch + Lomb (Bridgewater, New Jersey).

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AT A GLANCE

- The creation of capsulotomies with a femtosecond laser offers precision and a perfect shape, but the laser is costly and can be hard to fit into the surgical flow.
- Some cataract surgeons have experience with newer devices to simplify capsulotomy creation.
- ZEPTO-assisted cataract surgery is performed using a disposable device to create a quick, consistent, and strong capsulotomy combined with the option of centering on the patient's personalized visual axis.
- The CAPSULaser device can be mounted to a surgeon's microscope to create a capsulotomy in 1 second.

