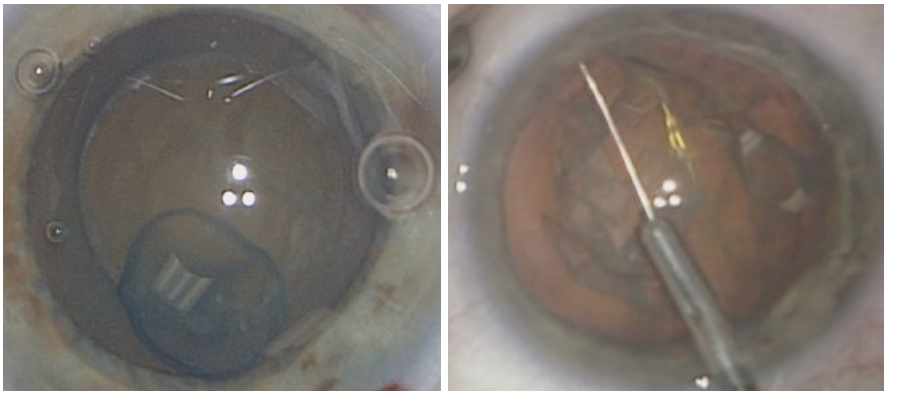
Out of Femto's Shadow: Two New Devices Seek to Change Cataract Surgery

Anterior capsulotomy and nucleus fragmentation are two of the most important steps in cataract surgery. And since its FDA approval in 2010, the femtosecond laser has introduced a way to automate these key maneuvers. However, the technology has been met with mixed reviews and uneven acceptance.

To begin with, the femtosecond laser is unavailable to many surgeons around the world. Moreover, its use requires a large outlay of capital and additional space within the surgery center or OR, adds procedural time, and results in significant extra costs. In addition, clinical studies have shown higher incidences of postoperative corneal edema and capsular tears with its use compared with manual cataract surgery.[1,2]

Enter two femto-free alternatives for facilitating capsulotomy and nucleus fragmentation: Zepto and miLoop.



CLOSER LOOK. *A Zepto capsulotomy in a mature cataract with no red reflex (left). The capsular button is stained with trypan blue and shows contracted edges. The miLoop (right) is shown encircling the nucleus with the capsular bag.*

Zepto

How it works. The Zepto (Mynosys) consists of a single-use, disposable handpiece with an elastic nitinol cutting ring at its tip. (Nitinol is a nickel-titanium alloy with superelastic and shape memory characteristics.) This tip is encased in a soft silicone suction cup. Once the cutting ring is inserted through a 2.2 mm or larger corneal incision, a pushrod is retracted, and the ring unfolds into a circular shape.

The ophthalmologist then centers the silicone cup over the visual axis and applies the necessary suction to gently draw the capsular membrane toward the ring. A 4-ms pulse of energy is delivered to the ring via a small console, instantaneously creating a complete "precision pulse capsulotomy"[3] roughly 5.2 mm in diameter, along with a free-floating capsular button.

Because the surgeon can simply replace normal capsule forceps with the Zepto during the surgical sequence, there is no disruption to the normal surgical workflow, said Joobin Hooshmand, MBBS, at the Sydney Eye Hospital in Australia.

Cost. With an initial price of $12,500 for the portable console, each single-use handpiece runs $135.

The device may be particularly attractive for ophthalmologists who want a perfectly round, reproducibly sized capsulotomy centered on the visual axis, such as when implanting premium IOLs, said Dr. Hooshmand. "For this purpose, the Zepto might be a more efficient and less expensive alternative to the femtosecond laser," commented David F. Chang, MD, in private practice in Los Altos, California.

Pearls for success. Although the device does require a surgical assistant to apply the energy and release the suctioning, "it's quite easy to incorporate into routine cataract surgery," Dr. Hooshmand said. "The learning curve is short—it takes roughly 15 to 20 cases to get comfortable."

Proper suction. In order for the Zepto to create the circular capsular opening, it's important that the surgeon achieve consistent suction on the capsule. "To do so, the central pushrod must be fully retracted all the way back to its starting position" before suction is applied, Dr. Chang said. "Otherwise,

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David F. Chang, MD

the insufficient suction could result in an uneven cut and possibly a late radial anterior capsular tear."

Dr. Hooshmand added, "If the suction cup isn't fully opened to 360 degrees, the nitinol ring won't be in the correct proximity to the capsule. But in this case, you can always disengage the suction, reapproximate the device, and then move forward."

Patient selection. The Zepto has particular benefits for complicated cases involving a poor red reflex, inadequate corneal visibility, or anterior capsular fibrotic bands, Dr. Chang said. "In my experience, there is no better technology for intumescent lens in which the liquefied cortex raises the intralenticular pressure," he said. "This is because the device cuts the entire circumference of the capsulotomy simultaneously, at once, preventing any radial splitting."

And because the Zepto bypasses the cornea altogether, Dr. Hooshmand said that he finds the device particularly useful for patients with corneal morphology or scarring that prevents good visualization of the anterior capsule.

Pupil size. In Dr. Hooshmand's experience, a dilated pupil larger than 6 mm is also necessary to achieve the best results with the Zepto. "In marginal pupils, the device tip can slip under the pupil, but bear in mind that you only get to insert the device once," he said. "So if you're in doubt regarding a patient's pupil size, take the necessary steps to enlarge the pupil beforehand."

Is it safe? "In our initial study [of Zepto], we found high incidences of incomplete capsulotomy in addition to a significant number of radial tears," said Dr. Hooshmand. "We communicated these findings to the manufacturer, and after several design improvements, a subsequent review of the device resulted in a drastic improvement in the number of complete, free-floating capsulotomies. But tear rates remained high, considerably higher than what you get with manual capsulorrhexis."[4,5]

Electron microscopy studies performed by Dr. Hooshmand and his team also revealed areas of irregular capsule margins and frayed collagen fibers at the edge of the capsulotomy button, which might be the result of dissipated thermal energy from the cutting ring.[4-6]

However, Dr. Chang explained, "Because of the way in which Zepto utilizes suction to create a capsulotomy, the button edge geometry is completely different than that of the anterior capsulotomy rim edge, which is what is important. Human cadaver studies have suggested that the rim edge is structurally smooth and strong."[3,7,8]

It remains to be seen whether or not Zepto is widely accepted, said Dr. Hooshmand. "The promise of perfect, repeatable capsulotomies is enticing," but any lingering safety concerns should be investigated, he said.

miLoop

How it works. The miLoop (Carl Zeiss) is a single-use, disposable instrument designed to mechanically fragment any grade of nucleus without the need for ultrasound energy. The device uses a retractable nitinol loop and is designed to encircle and manually bisect the lens into full-thickness segments.

"I hold the slender handpiece like a pencil," said Dr. Chang. After the capsulotomy is performed, he added, "the microfilament loop is retracted into the instrument tip and inserted into the anterior chamber via a clear-corneal incision. Advancing the sliding actuation button on the handle opens this loop in the horizontal plane, so that it expands within the capsular bag, but on top of the nucleus."

Once expanded, the loop is rotated around and behind the nucleus. The act of sliding the button backward contracts the loop and initiates the cut.

Cost. The device carries a single-use cost of $150 with no capital investment.

Pearls for success. The miLoop is particularly appealing to those ophthalmologists who are uncomfortable with chopping, said Rengaraj Venkatesh, MBBS, at the Aravind Eye Hospital in Pondicherry, India. "It eliminates the need to sculpt the nucleus and therefore the need to use ultrasonic phaco power. And because the lens is cut from periphery to center without aggressive manipulation, there is much less trauma to the capsule and the zonules."

Notes on technique. The miLoop is particularly adept at cutting through extremely dense nuclei, said Dr. Venkatesh. Even so, the surgeon must be careful not to traumatize the zonules by displacing particularly large nuclei with the loop, Dr. Chang said. "It is important to master the technique with softer and medium density nuclei before attempting brunescent cataracts."

Dr. Chang added, "The cut will tend to prolapse the distal pole of a denser nucleus. So I use a second instrument to prevent a firm nucleus from tipping and having its nasal pole prolapse through the capsulorrhexis. Many surgeons then rotate the nucleus to make a second cut 90 degrees from the first, which produces nuclear quadrants."

Patient selection. Given the miLoop's ability to cut through dense nuclei, "its use definitely benefits the surgeon working with harder and mature cataracts—especially the brunescent and black cataracts that are more common in the developing world," said Dr. Venkatesh. "The amount of phaco energy required to emulsify these cases is very high, so the miLoop provides a more efficient and beneficial alternative."

Is it safe? In a recent study of 101 patients with advanced (grades 3-4) cataracts, researchers compared outcomes in those who underwent phacoemulsification alone (n = 48) and those who underwent phaco in combination with the miLoop (n = 53). They found that the device improved overall phaco efficiency and was 100% effective in delivering ultrasound-free, full-thickness nucleus disassembly.[9] Four cases of posterior capsular tears occurred in the miLoop/phaco group, while five cases occurred in controls.

A note on humanitarian applications. Dr. Chang is part of a group convened by ianTech, the company that originally designed the miLoop, to develop a small-incision, manual extracapsular cataract extraction method using a version of the miLoop that is less expensive than the original.

The hope, Dr. Chang said, "is that a low-cost miLoop might provide a safer and more cost-effective alternative to phaco in settings where phaco training and proficiency is limited."

Game Changers?

Looking ahead, can a small box of pen-like tools such as the Zepto and miLoop truly revolutionize cataract surgery? It all comes down to affordability, Dr. Venkatesh said.

"Will there be new iterations of these devices that allow for multiple uses in multiple patients? And just how cheaply can the manufacturers deliver these products around the world? If these issues are further refined, the future is very bright for these new technologies," Dr. Venkatesh said.

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See disclosure key, page 8. **For full disclosures,** see this article at aao.org/eyenet.

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