Zepto precision pulse capsulotomy: A new automated and disposable capsulotomy technology

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Despite the appeal of an automated method of creating a perfectly circular anterior capsulotomy, global adoption of femtosecond laser capsulotomy (FSLC) has been limited by its high acquisition and per case cost. In addition, the femtosecond laser's large size and the need for eye docking create surgical efficiency and workflow challenges. The Zepto precision pulse capsulotomy (PPC) technology creates a circular anterior capsulotomy of a precise diameter using a disposable handpiece and tip that are used in the normal surgical sequence. Extensive preclinical and clinical testing has resulted in the US Food and Drug Administration (FDA) approval of the technology. Zepto PPC holds promise for complicated eyes such as those with intumescent or brunescent lenses, zonulopathy, or small pupils. This paper and the accompanying videos describe and demonstrate the technique and review the published studies.

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It is well established that radial tears in the capsulorhexis increase the rate of cataract surgical complications.[1] Therefore, the ability to reproducibly automate a perfectly sized and circular capsulotomy has spurred much of the recent clinical interest in femtosecond laser-assisted cataract surgery (FLACS). Compared to manual continuous curvilinear capsulorhexis (CCC), the FSLC is highly reproducible, uniformly more circular, and has a more precise diameter. However, this comes at a much higher capital and procedural cost and disrupts the normal surgical workflow because the FLACS steps cannot be performed within the usual operative sequence. Furthermore, differing national regulations may ban or restrict the ability to balance bill patients for the additional costs associated with FLACS. An important concern has arisen from published reports of an increased rate of anterior capsule tears following FSLC.[2,3] Scanning electron microscopy (SEM) of FSLC anterior capsule buttons demonstrates a rougher edge when compared to manual CCC specimens. In addition, SEM analysis also reveals scattered aberrant laser shots that could be explained by microscopic eye movements occurring during the FSLC step.[2] These might be postulated to predispose focal areas of the anterior capsular rim to radial tears caused by subsequent surgical forces.

Mynosys (Fremont, California) has developed a novel capsulotomy method and technology called PPC and trade named Zepto. A disposable handpiece and nanoengineered capsulotomy tip are powered by a small console to automatically and instantaneously create a perfectly circular capsulotomy of a precise predesigned diameter [Fig. 1]. The tip consists of a circular nitinol ring covered by a thin soft, clear silicone suction cup (SC)-shaped like a miniature inverted frying pan. Nitinol is a superelastic shape memory alloy which means that a nitinol ring for a 5–5.5 mm diameter capsulotomy can be can be made to fit through a small clear corneal incision. After filling the anterior chamber (AC) with ophthalmic viscosurgical device (OVD), a retractable metal push rod (PR) elongates the ring and the SC cup into a narrower profile that can be inserted through a 2.2 mm or larger clear corneal incision. After retracting this PR, the compressed tip resumes its native circular shape within the AC.

The surgeon gently positions the ring and surrounding suction cup onto the anterior capsular surface before applying a small amount of suction through the external console. Only slight suction is needed to appose the anterior capsule against the bottom edge of the nitinol ring, which has been precisely engineered at the micron scale to enable uniform capsule cutting. A rapid series of electrical pulses totaling 4 ms in duration is used to create the capsulotomy [Video 1]. Phase transition of water molecules trapped between the capsule and nitinol edge causes mechanical cleavage of the stretched capsular membrane circumferentially all at once. Unlike the sequential circular path of a manual capsulorhexis or FSLC, the

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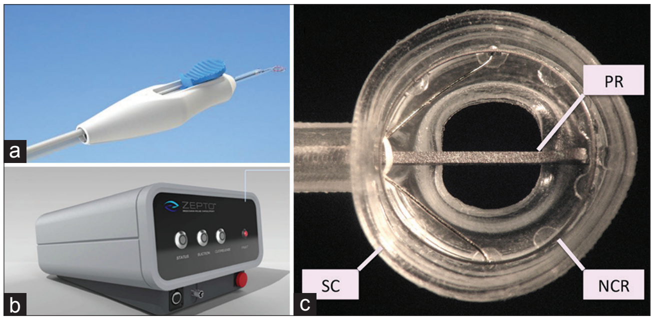

Figure 1: Zepto disposable handpiece (a) connects to a small console (b) that generates suction and the train of brief electrical pulses used for to cut the capsulotomy. The undersurface of the device tip (c) reveals the circular nitinol cutting ring surrounded by a silicone suction cup used to evenly apposed the anterior capsule to the nitinol ring. The retractable push rod extends forward to narrow the device profile for insertion through a clear corneal incision. It then retracts to allow the nitinol ring to reassume its original circular shape

PPC technology mechanically and simultaneously cuts all 360° of the apposed capsule without cauterizing it [Fig. 2]. Collateral ocular tissue safety is achieved through two design features. First, the application of energy is extremely brief and confined only to the microscopic edge of the nitinol ring. Second, during activation, the nitinol ring is completely covered by the SC cup and further insulated by the surrounding OVD.

This device was developed through extensive testing in animal and human cadaver eyes [Video 2].[4] Miyake Apple view video imaging shows insignificant zonular traction compared to manual CCC while performing PPC in paired human cadaver eyes. Preclinical performance and safety testing in live rabbits, including slit-lamp evaluation and histopathology, have been performed at the Moran Eye Center in collaboration with Nick Mamalis and Liliana Werner.[4] These results, including live rabbit thermocouple measurements, showed insignificant inflammation, endothelial cell loss, or heat detection when compared to manual CCC in the opposite eye.

In collaboration with Vance Thompson, John Berdahl, and Joel Solano in South Dakota, we have performed extensive testing of capsulotomy edge strength by comparing Zepto PPC to both manual CCC and FSLC in paired fellow human cadaver eyes.[5] The comparison of edge strength produced by two different capsulotomy methods in paired fellow eyes from the same donor eliminated variables such as age and time interval from death and minimized any other donor factors that might affect lens capsule biomechanics. This was underscored by the surprising interindividual variation in capsular tear strength that was measured in these experiments, regardless of the capsulotomy method used. Capsule edge tear strength was quantified using a tensile force tester developed by Mynosys. The tester consisted of a pair of metal arms with each terminal end shaped into a miniature capsule edge retractor. The PPC edge was noticeably stronger in each of the eight pairs of eyes comparing PPC and manual CCC, and in each of the eight pairs comparing PPC with FSLC [Fig. 3].

The higher strength of the PPC capsulotomy edge is likely due to its unique morphology that is very different from the edges produced by manual CCC and FSLC. On SEM of human cadaver capsules, the PPC capsulotomy edge appears to be microscopically everted to present the underside of the capsule as a smooth, rounded functional edge that circumferentially lines the capsulotomy opening during surgery [Fig. 4].

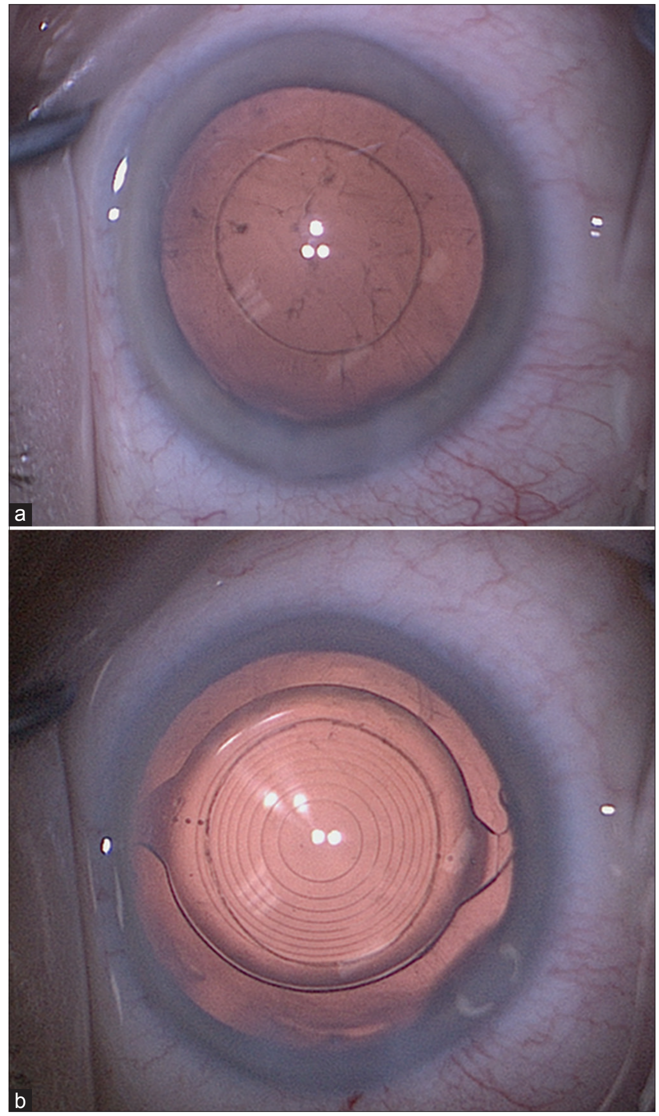

Figure 2: Zepto capsulotomy measuring approximately 5.25 mm in diameter following phacoemulsification and cortical cleanup (a). Same eye following implantation of a Symfony extended depth of focus toric intraocular lens (b). Both the intraocular lens and the capsulotomy are centered on the visual axis

The obvious potential advantage of Zepto PPC would be its ability to reproducibly automate the capsulotomy step with a disposable instrument that is inserted in the conventional surgical sequence and *in lieu* of using capsulorhexis forceps. This method assures a perfectly sized and round capsulotomy without the workflow challenges and increased procedural time of FLACS. As with FSLC, popular indications might be for complicated cases [Video 3] or when using premium refractive intraocular lenses (IOLs). The lower cost should ideally make PPC available to all patients independent of affordability and regional regulations regarding balance billing. Surgeons might also opt for the efficiency of using Zepto routinely rather than only in select cases, particularly if it is on average faster and more consistent than manual capsulorhexis. Although

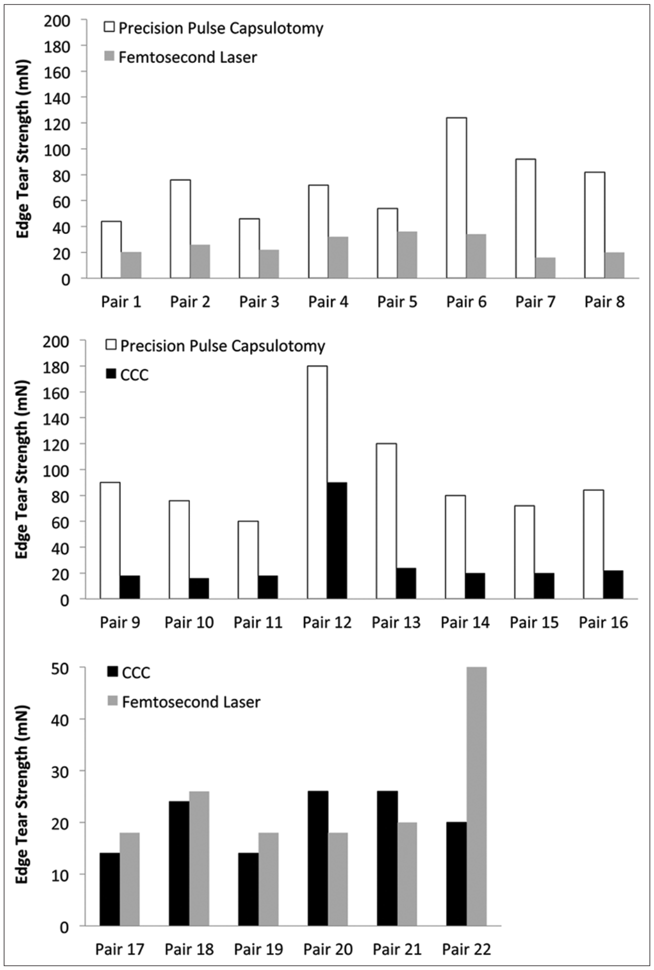

Figure 3: Published results of capsulotomy tear strength testing in paired human cadaver eyes.[5] Paired comparisons were made of Zepto precision pulse capsulotomy versus femtosecond laser capsulotomy (eight paired eyes), Zepto precision pulse capsulotomy versus manual CCC (eight paired eyes), and manual CCC versus femtosecond laser capsulotomy (six paired eyes)

individual patients might still elect FLACS, surgeons could consider Zepto for patients that cannot afford or do not want or qualify for FLACS. The PPC device name was chosen because, in the metric scale, Zepto is 1 million times smaller than femto. Both the small size of the instrument and the several millisecond speed of capsulotomy creation inspired this name.

Because it is an integrated step during conventional phacoemulsification, PPC can be performed after insertion of iris expansion devices for small pupils. The tip is also designed with an angled lip in the suction cup to allow insertion of the device under the iris margin in the event of a smaller diameter pupil if necessary. For white cataracts or eyes with a poor red reflex, capsular staining is not required with PPC. If the PPC edge is indeed more tear resistant, this might improve surgical safety by reducing anterior and posterior capsular tears. Finally, the transparent SC cup has a central window that is designed to permit patient fixation on the light of a coaxial microscope eyepiece during positioning of the device [Fig. 2b]. Being able to center, the capsulotomy on the visual axis would be advantageous when implanting refractive lens implants such as extended depth of focus and multifocal IOLs. The

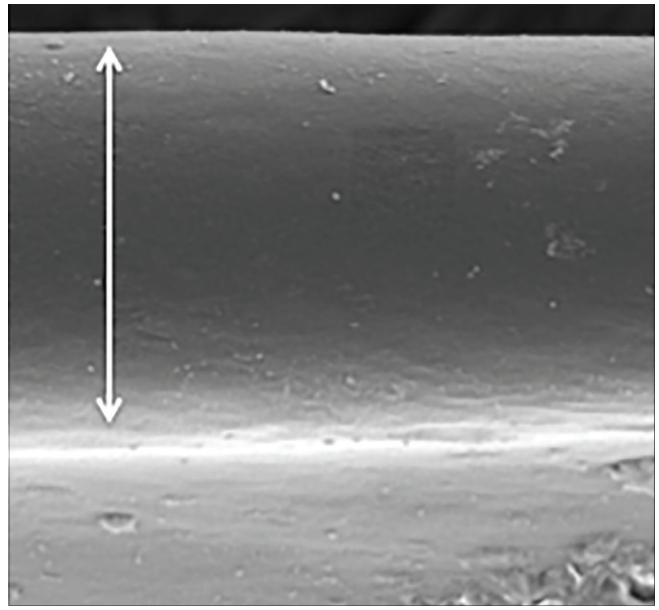

Figure 4: Scanning electron micrograph of the edge of the Zepto precision pulse capsulotomy viewed straight on. The smooth appearance is created by a microscopic eversion of the edge

learning curve is fast because the actual capsulotomy creation is automated. The surgeon, therefore, needs only to master insertion and removal of the device from the AC, along with centration and placement of the nitinol ring on the anterior capsule.

CE Mark was obtained in November 2015, and the first 38 clinical cases were performed in El Salvador in the same year.[6] In this published clinical study, a complete, 360° free-floating capsulotomy was created without complications followed by intracapsular IOL fixation in all 38 cases. In contrast to the femtosecond laser, which must fire into the cortex to ensure that the capsule is cut, Zepto PPC only cuts the anterior capsule which is in contact with the nitinol ring, and no difficulties were encountered during hydrodissection and cortical cleanup.

This series included the use of PPC for a number of challenging cases.[6] In several small pupil cases (4.0 mm diameter), the flared lip of the SC cup was maneuvered entirely under the iris without using any pupil expansion device. This essentially expanded the pupil with the PPC silicone tip for the creation of an approximately 5.5 mm diameter capsulotomy. Successful phacoemulsification with intracapsular IOL fixation was achieved in each case. For mature white lenses, the simultaneous creation of a 360° capsulotomy with a 4 ms pulse train instantaneously decompressed the intumescent capsular bag without generating radial tears. Capsulotomies can be created in white lenses without the need for trypan blue dye staining. Finally, PPC was successful in creating a circular capsulotomy in a case with 6 clock hours of zonular dialysis.[6]

Zepto was commercially launched in India in February 2017, followed by Germany in May and Australia in June. Approximately 100 PPC consoles were placed within the first 4 months following 2017 All India Ophthalmological Society meeting in Jaipur. A US FDA clinical trial was conducted in

2016 involving 100 eyes in 100 patients with nine surgeons at eight clinical sites. The results were submitted to the FDA in March of 2017, and Zepto received 510 (k) clearance in <90 days in June 2017. The US commercial launch is planned for August 2017. So far, >2500 cases have been successfully performed worldwide in markets where Zepto has launched. In India, the power console sells for $10,000 USD and the disposable handpiece sells for approximately $110–$160 USD, depending on volume. These capital and per case costs are substantially lower than those associated with the femtosecond laser.

Conclusion

The Zepto PPC technology creates a precise circular anterior capsulotomy used as part of the normal surgical sequence. The technique holds promise for complicated eyes such as those with intumescent or brunescent lenses, zonulopathy, or small pupils.

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Conflicts of interest

There are no conflicts of interest.

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