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Zepto Provides Cheap New Capsulotomy: Inventors overcome long odds to create innovative cataract device

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The technological advancements in the cataract surgery field have been swift and very impressive over many years. The ophthalmic surgical community and industry have demonstrated a particularly remarkable ability to innovate, iterate and adopt new technologies, especially for cataract surgery. Approximately 3.9 million cases are performed annually in the U.S., with about 80 percent of this total covered by Medicare.

Following the long tradition of relentless medical technology innovation, ten years ago two newcomers to the medical device field decided to work together to create a new cataract surgery device. In spite of minimal funding, no track record in ophthalmology and an absence of management experience, David Sretavan, a doctor and Christopher Keller, an engineer, embarked on their mission and appear to have truly succeeded.

Their small private company, called [Mynosys Cellular Devices](#), Inc., of Fremont, Calif., has invented a unique device that could have a major impact on the cataract surgery market.

The device called [Zepto](#), features a small control console and a disposable handpiece. Its precision pulse technology creates an accurate and reproducible capsulotomy that is quick, safe and affordable likely costing \$100-\$150 per case.

Capsulotomy or capsulorhexis, the removal of a piece of the natural lens capsule, is the most technically demanding and critical aspect of cataract surgery. Poor technique can result in radial tearing and capsular rupture while a suboptimal size, shape and centration of the rhexis can lead to poor effective intraocular lens position and increased risk of posterior capsule opacification (PCO). The former may result in a disappointing visual outcome, possibly requiring a LASIK "touch-up," while PCO often entails a post-op YAG laser procedure.

The excitement of femtosecond (FS) lasers, which were developed for cataract surgery over ten years ago, was heavily based on their ability to perform a perfect capsulotomy each and every time. They have been a huge commercial success – data from Market Scope indicated that a total of about 1,800 FS lasers have been installed since their market introduction. Roughly half of this installed base is in the U.S. Market Scope believes that approximately 500,000 FS laser procedures were done globally in 2015, with 60 percent emanating from the domestic installed base.

Medical Device Daily estimated that FS lasers have captured about 15 percent of the cataract surgery cases while the remaining 85 percent are currently performed manually.

Certainly, the commercial success of femtosecond lasers has been fostered by their perceived clinical benefits, notably the perfect capsulotomy. In addition, cataract surgeons have been able to leverage the device's laser pedigree to promote an "all laser" cataract procedure. For many consumers, a laser-based procedure, whether it for a cataract surgery or something else, is a powerful lure.

FS Lasers have their drawbacks

Despite their commercial success, there are myriad disadvantages of FS laser technology. The shortcomings include: (1) an enormous initial capital outlay (about \$400,000), (2) an annual service contract, typically \$45,000 per year, (3) a large footprint, (4) incremental "per click fees" (approximately \$350 to the surgeon), and (5) increased surgical time.

Zepto appears to offer the crucial advantage of an FS laser, the perfect capsulotomy, without all its drawbacks.

The first-in-human clinical evaluation of Zepto took place in El Salvador about three weeks ago with a total of ten patients enrolled in the study. Kevin Waltz, Eye Surgeons of Indiana, in Indianapolis, and Gabriel Quesada of Grupo Oftalmo y Plastico clinic, in San Salvador, El Salvador, co-investigators for the study, performed the surgeries.

Cataract surgery, then standard phaco-emulsification of the natural lens, was followed the implantation of a foldable one-piece acrylic IOL. All ten patients had capsulotomies created by the two surgeons using the Zepto capsulotomy device.

Several of these cataract surgery cases were challenging and Zepto was very helpful in completing the capsulotomy in all cases. Three patients had pterygiums (a benign growth of the conjunctiva) that limited visualization of the capsule, Two patients had poorly dilating pupils and Zepto's soft silicone suction cup and sealing lip could be manipulated under

the iris. Two patients had poor red reflexes due to very dense cataracts.

Looking ahead, Zepto was developed as a stand-alone disposable instrument to be used with a small control console. It seems quite feasible that Zepto could be a natural fit for any one of the existing phacoemulsification platforms.

As a disposable, physicians could benefit from Zepto being offered as part of the phacoemulsification pack in terms of convenience and cost. Since Zepto is such a unique product, it is logical to assume see how it could drive adoption of other cataract products.

In a telephone interview, Waltz told *MDD* that "It is hard to overstate Zepto's superb cutting ability. Despite some challenging cases, we created perfect capsulotomies in all ten cases."

Waltz also noted that he uses an FS laser in his ambulatory surgical center (ASC). He stated that "Zepto will make a better capsulotomy than my femtosecond laser" and thus could reduce his use of the laser in the future.

He stressed that Zepto will be a money saver because it will shorten the time to do a cataract procedure by about three-to-five minutes.

"With OR time in a hospital costing about \$50 per minute and \$30 per minute in an ASC, reduced surgical time can add up to a significant amount of dollar savings."

Importantly, Waltz believes that there is little to no learning curve with Zepto and that it will make "an average surgeon better and a very good surgeon outstanding."

Zepto received the CE mark in November and is expected to gain FDA 510(k) approval in the next few months. //

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