

# Innovative device for cataract surgery in sight

In 1950, the British ophthalmologist Sir Harold Ridley performed the world's first implantation of an artificial intraocular lens (IOL) to restore a patient's vision after cataract surgery. This innovation rose from his observation of WWII pilots, who suffered eye injuries in which acrylic pieces from shattered cockpit windows lodged within their eyes.

The realisation that artificial IOLs can replace the diseased lens removed during cataract surgery, has arguably been one of the medical technologies that have benefited the greatest number of patients worldwide. Today, IOL innovation continues at a rapid pace, and many believe that a quantum leap in IOL performance may be just around the corner and bring rejuvenated, perfect vision to an ageing population.

One hurdle, however, is the delicate capsule that surrounds the lens. In cataracts, the normally optically clear lens becomes cloudy and, if left untreated, it can result in blindness. During surgery, an opening is made by the surgeon using forceps in the paper-thin capsule bag that encases the lens. This capsulotomy procedure allows the physician to remove the diseased lens through the capsulotomy opening, while preserving the bag to hold the IOL.

## Performing the perfect capsulotomy

Capsulotomy is one of the most difficult steps of surgery, and a perfectly round, accurately sized and well-centred capsulotomy is required for optimal patient visual outcome. This is well-recognised for advanced multifocal IOLs currently on the market, whose performance is significantly degraded if misaligned. New IOLs under development place an even greater premium on a perfect capsulotomy, as they either stretch the capsulotomy opening to its limits or depend completely on the centration of the capsulotomy position for IOL alignment on the visual axis.

While some physicians are well-practised in capsulotomy, others are not and may struggle with technique. All agree, however, that making consistently perfect capsulotomies by hand is difficult. Five years ago, femtosecond laser systems were introduced for automated capsulotomies. While effective in making accurate capsulotomies, the femtolasers suffer from their considerable financial outlay that requires the physician to pass on significant costs to the patient and also limit technology accessibility to the majority of surgeons and patients. In addition, the femtolasers add time to each surgery, interrupt patient flow and operating theatre throughput, making this technology less attractive to surgical practices. Lastly, the medical literature indicates a higher capsule tear rate and other complications after femtolasers capsulotomy. The adoption of femtosecond lasers for cataract surgery has slowed significantly since its introduction.

The realisation of upcoming IOL innovations may instead hinge on Zepto, a disposable automated capsulotomy device about to enter the market (Mynosys Inc. Fremont, California, USA). (Zepto is the metric unit of measurement 1 million times smaller than femto). Zepto comes as a handpiece attached to a small control console. The handpiece's tip comprises of a soft, clear silicone suction cup that houses a nitinol super elastic capsulotomy ring, which compresses to enter a small corneal incision and re-expands within the eye to its native circular shape. Suction is applied through the cup to oppose the bottom edge of the capsulotomy ring to the capsule surface, trapping a very thin layer of water. A 4-millisecond pulse train causes a quick phase transition of the water molecules into vapour, and the accompanying volume expansion results in the cutting effect, which occurs simultaneously everywhere along the circular capsulotomy path. The tip is then withdrawn and the surgeon continues with the remainder of the cataract surgery.

**Reaching for Zepto**  
Zepto requires no change to the steps of cataract surgery or patient flow. Instead of forceps, the surgeon simply reaches for Zepto to obtain quick, consistent, perfectly circular capsulotomies of the desired size (~5.2mm diameter). To date, Zepto has been used in over 200 cases worldwide with consistently excellent results. Patient follow-ups 8 months after surgery have shown stable capsulotomies with well-centred IOLs.

## Reaching for Zepto

Test data and surgical experience have highlighted a number of unique

and noteworthy Zepto capabilities. Biomechanical testing showed the Zepto capsulotomy edge to be much stronger and more tolerant of stretching than from the manual method or by femtolasers, due in part to an innovative capsule collagen re-modelling effect that results in a slight upturn of the capsulotomy edge. This upturning provides a rounded capsulotomy edge that presents the undisturbed undersurface of the capsule as the functional edge encountered during surgery. Zepto therefore potentially provides a greater surgical safety margin. Importantly, Zepto's resilient capsulotomy edge is also critical for the safe implantation of the upcoming generation of larger IOLs, designed to change shape in response to the eye focusing at different distances.

Zepto's product design and mechanism of action also help the surgeon avoid potential complications. The use of suction stabilises the lens during capsulotomy and eliminates stretching the delicate zonular tissues that is inherent in the manual capsule tearing method. This significantly benefits patients with weakened zonules from disease or trauma. As Zepto's capsulotomy action also occurs simultaneously everywhere along a circular path, Zepto can be used to instantaneously relieve pressure underneath the capsule in advanced cataracts, and the potential for explosive capsule rupture is eliminated. Thus, patients with these and other co-morbidities benefit when complicated surgery becomes easy with Zepto in the surgeon's hands.

Zepto is the only technology that allows the surgeon to place the capsulotomy intraoperatively precisely on the patient's visual axis. The eye's complex anatomy exists to ensure

that images are focused along the visual axis onto the fovea, the retinal area with the highest visual acuity. In today's surgery, despite available imaging technologies, surgeons are – at best – still guessing at the location of the visual axis when performing capsulotomy. Surgeons are already aware of this limitation for multifocal IOLs that require proper centration. The same limitation presents itself even more acutely for new IOLs that are anchored to the capsulotomy edge. Surgeons can interact with patients looking through the transparent Zepto suction cup and use Purkinje reflections to align the capsulotomy on the patient's visual axis. Zepto will be a real game changer as visually-centred capsulotomies are increasingly used to specify effective lens position.

**ZACS**  
These advantages and unique capabilities of Zepto have engendered much interest in the concept of Zepto assisted cataract surgery (ZACS), as a potential new gold standard in cataract surgery. With ZACS, physicians can offer their patients not only a dimensionally perfect capsulotomy, but also one that has added safety. Complicated cataract cases will become routine while providing patients with the best possible results regarding IOL performance and stability. ZACS, for the first time, allow surgeons to precisely locate the capsulotomy on the patient's functional visual axis. This ability to tailor capsulotomies to the specific patient's ocular anatomy promises to be a new paradigm of personalised cataract surgery with optimised visual outcome.

As an easy-to-use tool that automates the most demanding step in cataract surgery, Zepto and ZACS offer something for every surgeon. For the surgeon

less confident in capsulotomy, it offers quick and perfect results. For surgeons contemplating offering premium IOLs to their patients, it offers capsulotomy quality along with personalised visual centration, to support practice expansion. For the high volume practitioner, Zepto and ZACS offer safety, consistency and efficiency in both simple and complex cases, while at the same time ensuring premium outcomes for patients via visual centration.

Zepto is expected by physician leaders to significantly impact cataract surgery, not only by being a highly versatile clinical tool, but also by being a low cost disposable tool that is easy to learn and integrate into routine cataract surgery. Of note, Zepto can be placed easily into phacoemulsification machines, and is commercially attractive not only as a standalone device, but also as a platform product that can be offered together with premium IOLs, viscoelastics, and cataract surgical packs. Be prepared to see Zepto and ZACS broadly disseminated and potentially become a new gold standard in the years to come.

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John Hendrick  
President and CEO  
Mynosys  
Tel: +1 510 396 1531  
jhendrick@mynosys.com  
www.mynosys.com/