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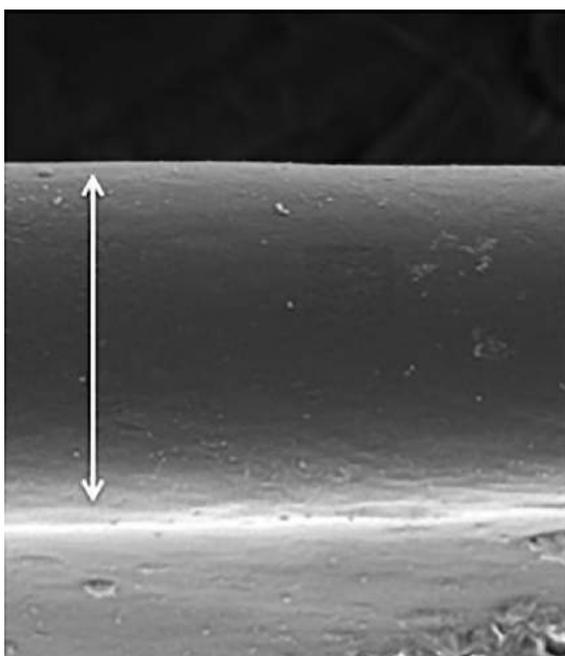
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# CAPSULOTOMY EVOLUTION

EUROTIMES REVIEWS THE EVOLUTION OF CAPSULOTOMY, FEMTOSECOND LASER CAPSULOTOMY AND NEW ALTERNATIVES ENTERING THE PIPELINE



Seam Hematham Posted in: Mar 2016 Cataract and Refractive Top Story



Scanning electron microscopy shows that the ZeptoTM capsulotomy edge has a unique morphology characterised by an extremely smooth functional edge (arrow). Detailed analysis revealed that ZeptoTM not only creates a perfectly round, tag-free opening in the capsule, but at the same time also places a microscopic up-turning or eversion at the edge to present a small amount of the capsule underside for maximal edge integrity during surgery. Image courtesy of Mynosys.

The capsulotomy has often been considered the most difficult component of extracapsular cataract surgery, the last step in a young cataract surgeon's training. A well-centred and stable capsulotomy is more important than ever with the advent of multifocal and toric specialty intraocular lenses (IOLs). Recent years have seen dramatic changes in how this procedure is performed, along with marked improvements in safety and accuracy.

The femtosecond laser approach in particular is said to simplify creation of the capsulotomy, possibly improving outcomes for some premium lens procedures. However, not everyone is convinced that the femtosecond laser results are better, or that the results justify the considerable cost of the equipment.

"A high-quality capsulotomy provides the foundation for the whole of modern cataract surgery. What we're all looking for is a reliable and stable effective lens position with a low incidence of posterior capsular opacity and minimum side effects. Proper capsulotomy size and shape are crucial to achieving these goals," Pavel Stodulka MD, PhD, Gemini Eye Clinics, Czech Republic, told EuroTimes.

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In 1780, Jean-Jacques Desmarres demonstrated the technique of extracapsular cataract surgery in 1780. One hundred years later, Albrecht von Graefe refined the extracapsular approach, using a forceps to lacerate the capsule. Subsequent innovators have attempted to improve on the capsulotomy, increasing the accuracy of the key surgical step, while reducing operative complications.

The 20th Century saw a revolution in cataract surgery in general, and the capsulotomy step in particular. Sir Harold Ridley, who implanted the first IOL in 1950, used forceps to perform the capsulotomy. Cornelius Binkhorst developed the iris clip lens and worked to develop IOLs that would fixate in the capsular bag. He experimented with many different shapes of capsule opening.

The introduction of phacoemulsification by Charles Kelman in the 1960s was another major revolution in cataract surgery, with associated changes in capsulotomy technique. Dr Kelman introduced the "Christmas tree" capsulotomy, so called because of its shape. Dr Richard Kratz advocated a circular serrated edge capsulotomy that became known as the can opener technique. Finally, Calvin Fercho, followed by Howard Gimbel, Kimiya Shimizu and Thomas Neuhann, introduced the idea of using a continuous tear circular capsulotomy, dubbing it continuous curvilinear capsulorhexis (CCC).

As a consequence of the development of the CCC, IOLs could be placed reliably and securely in the capsular bag. This required the development of new phaco techniques including chip and flip, divide and conquer, nucleofractis, phaco chop and prechop. New enhancements for making the CCC also appeared, such as a capsular ring placed in the eye created by Marie-José Tassignon in Belgium.

#### THE FEMTOSECOND REVOLUTION

Zoltan Nagy MD, Head of the Department of Ophthalmology, Semmelweis University, Budapest, Hungary, generated huge enthusiasm and some controversy in 2008 when he reported his first results with femtosecond laser-assisted cataract surgery (FLACS). Here at last was a system that could produce precise circular capsulotomies every time.

Since its debut, the femtosecond laser approach has demonstrated many advantages including higher safety, higher predictability, less phaco energy, shortened treatment time, better results with premium lenses, and significant help in complicated cases like traumatic cataracts, loose zonules, and white and tumescent cataracts, and also in paediatric cataracts, according to Dr Nagy.

"When I heard first about the femtosecond laser for cataract treatment I felt the same excitement as with the excimer laser. I knew that it would be an important part of the future of ophthalmology. The experimental phase of the first femtolaser treatment justified my assumptions. The future is here with the femtolaser," Dr Nagy told *EuroTimes*.

#### FEMTO CAVEATS

However, recently published research suggests there are still caveats about FLACS. For example, published studies comparing FLACS and conventional surgery show few discernible differences from the patient's point of view in terms of visual outcome, notes Dr Packard.

There are also reports of higher rates of certain complications with FLACS, particularly anterior capsular tears (*RG Abell, Ophthalmology, 2014, Volume 121, Issue 1, Pages 17-24*). Scanning electron microscopy (SEM) of femtolaser capsulotomy edges revealed 'postage stamp' type perforations, irregular margins, aberrant pulses and anterior capsule tags. This has been proposed as a mechanism for the capsular tears. SEM of manual capsulotomy edges were much smoother by comparison.

"That was both surprising and puzzling at first. Since that time the leading theories based on the SEM findings suggest that, due to subtle saccadic eye movement, some of the laser shots are actually misaligned and create aberrant microperforations. Theoretically, these eccentric perforations might predispose some areas of capsule edge to tearing if too much manipulation or force occurred," said David F Chang MD, Clinical Professor of Ophthalmology at the University of California, San Francisco, USA, and former president of the ASCRS.

Dr Nagy told *EuroTimes* that a good femtosecond capsulotomy requires a complete understanding of all of the features of the laser. "You need to have perfect patient interface centration, use a low energy level and have perfect optical coherence tomography (OCT) measurements. To avoid anterior tears the surgeon should respect that femtolaser cataract surgery is different from manual phacoemulsification. You have to follow the contour line of femtolaser pretreatment for capsulotomy. If these criteria are fulfilled, the capsulotomy will be perfect," he said.

"All surgeons starting femtolaser cataract surgery should accept that this technology is different in some steps from manual phacoemulsification and needs a different surgical approach. If the surgeon follows the contour of capsulotomy at the beginning they will not experience any anterior tear. If they allow the intralenticular bubble to leave the eye toward the anterior chamber ("rock & roll technique"), they will never have a posterior capsular problem," he added.

Perhaps the biggest caveat for those considering performing femtosecond laser is the price tag. There is a huge initial cost of investment in the technology, and considerable ongoing costs of servicing the equipment. There is also a cost to the patient of providing the patient interface. While this might be justifiable for those offering 'premium' IOL options, national healthcare systems that are already stretched financially may not be as enthusiastic.

#### BEYOND FEMTO

Two new surgical tools now in development, both originating in California's Silicon Valley, could offer many of the same benefits of the femtolaser capsulotomy, at a considerable financial discount.



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"The new press brings the same sort of properties to make more stable, much tougher than type 1 collagen. Our tests indicate that you can stretch the tissue much more than with a manual capsulorhexis, and probably more than with a femtosecond capsulotomy as well," said Dr Packard, who is involved in the development of the new system.

The CAPSULaser bolts underneath the microscope. This means that, unlike most lasers which are very large and may require a break in the normal flow of surgery, with patients first of all going to a laser room to have the laser work done and then returning to the operating theatre, this just fits into the normal work pattern, he explained.

The first clinical results with the CAPSULaser were presented by Pavel Stodulka MD at the XXXIII Congress of the ESCRS in Barcelona (see video at: <https://youtu.be/dU0VbTHjUCQ>). The CAPSULaser produced complete circular capsulotomies in all 10 eyes, and there were no adverse events. The edge was as smooth as the edge of a manual capsulorhexis, and was quite firm. There were no tears or tags at the edge of the rhexis. The dark blue contour of the stained edge with amorphous collagen enhances the capsulotomy visibility and is very firm. A video showing capsule strength can be found at: <https://www.youtube.com/watch?v=djXlB5fm16k&feature=youtu.be>. Dr Stodulka also did not encounter any problems with post-capsulotomy miosis, a problem sometimes seen with laser capsulotomies.

At one month postoperatively, 80 per cent of eyes had a visual acuity of 20/20 or better. All IOLs were well centred. There were no corneal epithelial or stromal issues, no postoperative flare, no iris damage, no capsular fibrosis, no increases in intraocular pressure and no fundus abnormalities.

"My experience with the CAPSULaser capsulotomy is very positive. The latest generation performs capsulotomy in under one second. The strength of the capsulotomy has been demonstrated to be higher compared to any other capsular opening method. I like this approach very much. Because it is more precise than handmade capsulorhexis and still inexpensive compared to femtosecond technology, I believe this is the future of capsulotomy in cataract surgery," Dr Stodulka told *EuroTimes*.

## ZEPHO

Dr David F Chang is involved with the development of another investigative technology called precision pulse capsulotomy (Zepto, Mynosys) which, like CAPSULaser would be used in the normal surgical sequence in lieu of capsulotomy forceps.

The Zepto system consists of a disposable handpiece and capsulotomy tip that are powered by a small console. The tip delivers micropulses of direct current through a circular nitinol ring to produce a precise capsulotomy of a pre-designed diameter. This instantaneously cleaves the capsule simultaneously around all 360 degrees without any cautery. Nitinol is a shape memory alloy allowing the ring to be compressed for insertion through a clear corneal incision, after which it returns to its original shape inside the anterior chamber that has been filled with OVD.

The surgeon apposes the ring to the anterior capsule, and gentle suction is applied through a thin surrounding silicone cover. A central viewing opening in the silicone cover permits capsulotomy centration on the visual axis using patient fixation intraoperatively.

Dr Chang presented early in vivo results of the Zepto system in rabbit eyes at the 2015 annual conference of the American Academy of Ophthalmology in Las Vegas, USA (Chang DF, Mamalis N, Werner L. Precision Pulse Capsulotomy - Preclinical Safety and Performance of a New Capsulotomy Technology. *Ophthalmology* 2016; 123:255-264). The study indicated that the automated system produced consistent, round anterior capsulotomies with a safety profile equal to that of conventional CCC in the fellow eye, he reported.

"Live postoperative slit lamp evaluations, combined with histologic post-mortem exams, showed no differences in terms of inflammation or endothelial cell loss. Anterior chamber thermocouple measurements showed insignificant temperature change. This is because we are using such a brief, confined application of energy of the order of four milliseconds," Dr Chang told *EuroTimes*.

A strain gauge study in paired human cadaver eyes compared the strength of the Zepto capsulotomy with those created by the femtolasers or manual capsulorhexis. The Zepto capsulotomies consistently proved to be strongest of the three (Thompson VM, Berdahl JP, Solano JM, Chang DF. Comparison Of Manual, Femtosecond Laser, And Precision Pulse Capsulotomy Edge Tear In Paired Human Cadaver Eyes. *Ophthalmology* 2016;123:265-274).

A Miyake Apple video study in paired human cadaver eyes showed no increased zonular stress with Zepto compared to manual capsulotomy (Chang DF et al, *Ophthalmology* 2016; 123:255-264).

The Zepto device received the CE mark at the end of 2015 for performing anterior lens capsulotomies during cataract surgery. The company is seeking 510k FDA approval for the device in the US, and plans to begin clinical trials this year.

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