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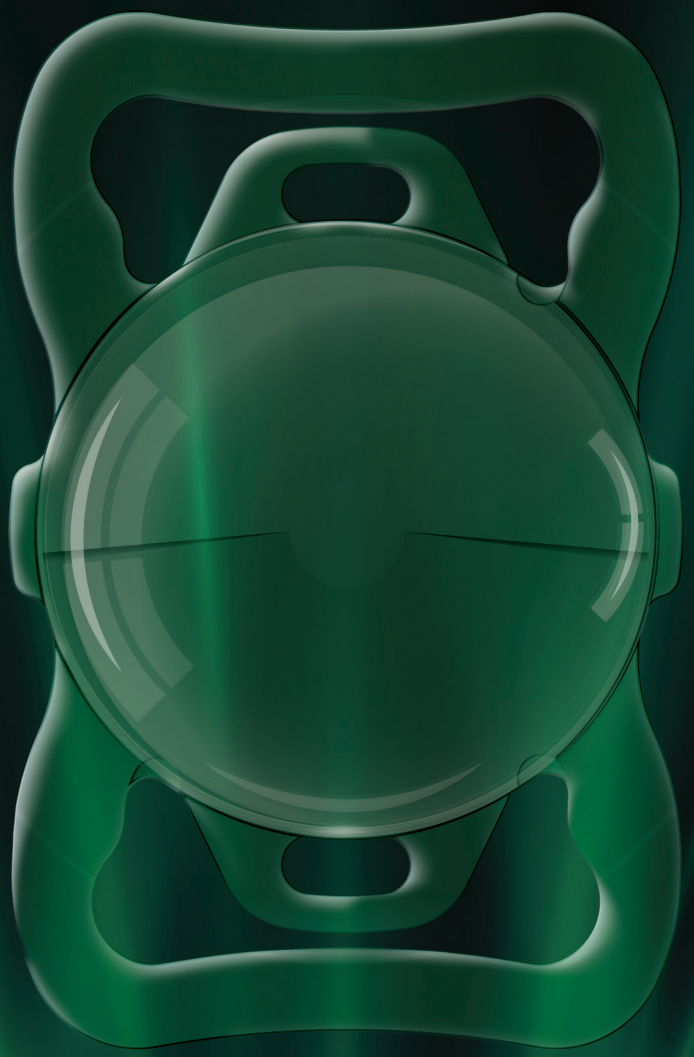

MADE FOR EACH OTHER

FLACS and the FEMTIS IOL Platform

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The Advantages of High-Precision Cataract Surgery

Pursuing the state of the art with automated continuous curvilinear capsulorhexis technologies.

BY SHEETAL BRAR, MD

In recent years, technological advancements have transformed cataract surgery into a procedure with advanced refractive goals. In the pursuit of 20/20 or better UCVA, the continuous curvilinear capsulorhexis (CCC) is still widely considered one of the most important steps for generating consistent and predictable outcomes. Regarding IOLs, notable innovations in advanced refractive optics, IOL platforms, and materials have heightened the importance of creating a perfect CCC during cataract surgery.

The ideal anterior capsulotomy is (Figure 1):

- circular and accurately sized between 4.8 and 5.5 mm;
- centered on the patient's visual axis;[1]
- able to achieve 360° of symmetrical rim-to-optic coverage; and
- capable of producing a strong capsular edge.

In contrast, the consequences of a poorly sized capsulotomy include a malpositioned IOL (e.g., tilt and/or decentration); a potential increase in higher-order aberrations (HOAs); and higher rates of PCO formation (Figure 2).[2]

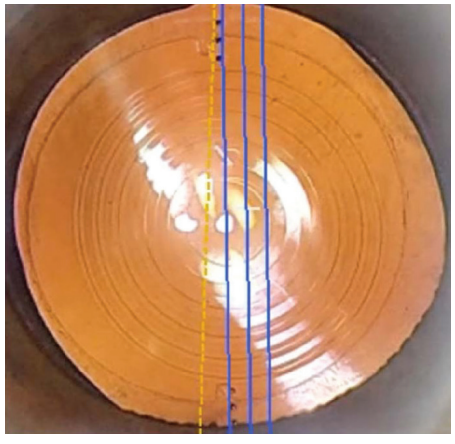

Figure 1. An ideal capsulotomy is circular, with 360° of symmetrical rim-to-optic coverage, has a strong edge, and is centered on the visual axis.

CHALLENGES OF A MANUAL CAPSULOTOMY

Although surgeons can and do achieve reproducible and consistent outcomes

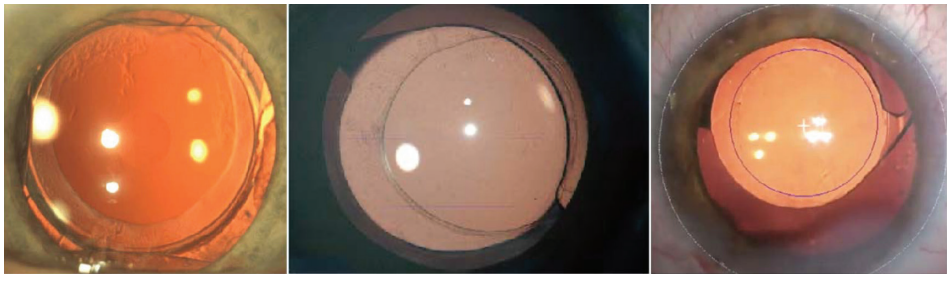

Figure 2. A poorly sized, poorly centered capsulorhexis can cause myriad postoperative complications.

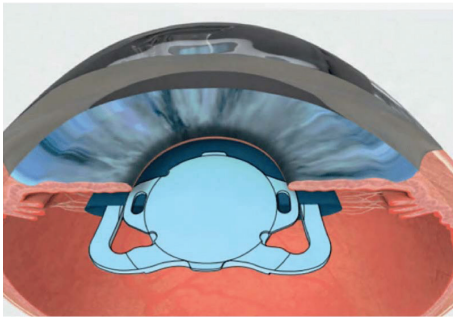

Figure 3. A rendering of the capsule-fixated FEMTIS IOL.

with a manual CCC, this requires considerable skill and surgical judgement gained through years of experience. A CCC's position and shape are influenced by many factors, such as the pupillary dilation, Purkinje images, and the grade of the cataract. To try to improve historical rates of patient dissatisfaction with visual performance and refractive error following cataract surgery, researchers have sought ways to automate the CCC in order to reduce some of the variables from human input.

THE NEED FOR AUTOMATED CCC TECHNOLOGY

Advancements in IOL optics such as toric, multifocal, and extended-depth-of-focus (EDOF) capabilities offer patients increased spectacle independence compared to standard monofocal and enhanced monofocal IOLs, but these premium refractive lenses are very sensitive to alignment, position, and centration. Automating the CCC offers several advantages, including:

- perfect IOL centration with good overlap of the optic rim to stabilize the effective lens position for minimal long-term impact;
- reproducible and repeatable results;
- increased safety in complex cases (e.g., mature & intumescent cataracts, pseudoexfoliation); and
- reduced incidences of PCO.

This article describes several devices that have recently come to market to help surgeons achieve a more reproducible, automated CCC and therefore improve their overall patient outcomes.

> "Femtosecond laser-assisted cataract surgery (FLACS) has challenged the dominance of the manual CCC as the gold standard in cataract surgery."

FLACS

Femtosecond laser-assisted cataract surgery (FLACS) has challenged the dominance of the manual CCC as the gold standard in cataract surgery. Some studies have demonstrated the improved accuracy of centration, consistency of size, and symmetry of circularity with FLACS.[3,4]

The strength of the capsulotomy's edge is particularly important, because a weak edge of a manual CCC has been associated with an increased risk of radial anterior tears.[5,6] These tears can extend posteriorly and lead to undesirable complications, and they will negate the possibility of implanting a capsulotomy-fixated lens such as the FEMTIS IOL (Teleon Surgical; Figure 3).

FLACS WITH THE LENSAR ALLY LASER

The ALLY femtosecond laser (LENSAR) is the first second-generation FLACS laser on the market. It employs an Augmented Reality® imaging system and state-of-the-art laser guidance technologies to facilitate FLACS.[7] In the treatment planning stage, the ALLY laser scans the relevant structures of the anterior chamber and the lens from six different angles. From these images, and using optical ray tracing techniques, the laser's Augmented Reality software reconstructs the anterior chamber in 3D and identifies major interfaces such as the anterior and posterior surfaces of the cornea and lens capsule.

Its software determines lens tilt by analyzing the relationship of the anterior and posterior curvatures of the lens capsule to the optical axis. With this information, the ALLY laser can center the anterior capsulotomy symmetrically over the optical axis (or pupil's center). To make the arcuate incisions, it aligns intraoperative imaging with preoperative corneal biometry, and it performs iris registration to compensate for cyclotorsion. A low-pressure liquid interface enables the capsulotomy's construction with no compression of the cornea, while the laser makes imaging adjustments in real time for the most accurate corneal incisions. The result is a 100% circular, free-floating capsulotomy. To fragment a cataractous lens, the ALLY can define the grade of cataract intra-operatively and then apply preloaded fragmentation patterns for any cataract density with precise spot application.

For astigmatic eyes, the ALLY laser offers the IntelliAxis Refractive Capsulorhexis® toric IOL alignment, which uses small tabs superimposed on the capsular rim to indicate the intended axis, both intra- and postoperatively. Additionally, the laser's Streamline® technology provides precise arcuate incisions.

ZEPTO® PRECISION PULSE CAPSULOTOMY

Approved by the FDA in 2017, the Zepto Precision Pulse Capsulotomy (PPC; Centricity Vision) consists of a small console (ZeptoLink) that connects to a disposable handpiece with a low-profile, transparent silicone suction shell. Inside the eye, the clear suction shell creates a 360° apposition with the surface of the anterior capsule via a flexible nitinol ring. The ring delivers a series of rapid thermoelectric nanopulses to cleave 360° of the anterior capsule in <5 msec.

Early clinical experience with the Zepto device has shown consistent results, with potential value for complex cases such as in eyes with small pupils, zonulopathy, or intumescent or brunescent lenses.[8,9] However, reports of radial tears and incomplete capsulotomies have prompted improvements and modifications, and

there may be a learning curve. Additional studies are warranted to further evaluate PPC with Zepto.

CAPSULASER SELECTIVE LASER CAPSULOTOMY

The CAPSULaser (Excel-Lens, Inc.) is a class 4 solid-state, continuous-wave laser that performs a selective laser capsulotomy (SLC). The device is portable and affixes to the binocular indirect connection points of any operating microscope, and then delivers thermal energy to create a circular capsulotomy in less than 1/3 of a second. Surgeons usually stain the anterior capsule with an enhanced solution of trypan blue dye to give the laser a target. The laser projects a reticule as a guide for the surgeon to follow for centration, which is adjustable from 4.5 to 7 mm in diameter.

In addition to advantages related to efficiency, Daya et al demonstrated that this SLC technique may provide a more stabilized and strengthened anterior capsule compared to manual CCC and FLACS.[10] However, CAPSULaser cannot fragment a lens or create incisions; it is only used for auto-ccc creation.

CONCLUSION

Surgeons continue to seek reliable means for creating reproducible capsulotomies that can optimize outcomes without sacrificing time or efficiency. Notable innovation has occurred in this space, including a trend toward guided or automated approaches for improved reproducibility and precision, particularly for eyes receiving capsulorhexis-fixed advanced-optics IOLs. With time, more comparative studies with automated capsulotomies will help us surgeons evaluate their performance and determine whether their improved geometry translates to meaningful benefits for our patients. ■

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The Surgical Advantages of FLACS

Gains in speed, workflow, and astigmatism management with the ALLY® Adaptive Cataract System.

BY NEDA NIKPOOR, MD

I began using femtosecond laser-assisted cataract surgery (FLACS) regularly as soon as I entered clinical practice, where 80% to 90% of my cataract surgeries included some form of advanced technology. I quickly decided that the laser technique was superior to manual cataract surgery. Although I think I execute manual cataract surgery uniformly and efficiently, there is greater variability and more opportunity for a complication, however rare. To me, FLACS feels safer and more predictable than a manual cataract technique.

HOW THE ALLY® ADAPTIVE CATARACT TREATMENT SYSTEM IMPROVES SURGERY

I have used several different femtosecond lasers in my career, but I prefer the ALLY Adaptive Cataract Treatment System (Lensar). This laser offers specific advantages that I feel will help increase the adoption of femtosecond lasers in the market. The number of ophthalmic surgeons who have access to a femtosecond laser and use it on a regular basis still hovers around 4% in the global marketplace.[1] Part of this low adoption rate may be the perception that FLACS is slower than manual cataract surgery. I think the ALLY addresses that concern in three ways: its speed, its workflow, and its astigmatism management.

SPEED

The ALLY laser is exceptionally fast. I recently completed a case with less than 40 seconds of suction time, and my average is between 45 seconds and 1 minute 20 seconds, depending on the case. A skilled surgeon may be able to do the incisions, LRIs, and a manual capsulotomy in 1 minute 20 seconds, but not with pre-chopping the lens. The speed of a laser-assisted capsulotomy is a huge advantage.

WORKFLOW

Having tried various configurations of the ALLY laser's OR setup and observing how others do it, I am a huge proponent of using a sterile laser arrangement, meaning I use a dedicated femtosecond laser in each OR. My colleagues and I conducted a timed single-site study with ALLY, the endpoints being total surgeon

case time and total patient case time.[2] We found a significant time savings—approximately 7 minutes per case for the surgeon and approximately 14 minutes for the patient—by using two sterile ALLY lasers in two ORs (Figures 1 and 2). In contrast, using one laser between two ORs produces a gap between the laser and the phaco time, not including time for prepping and draping the patient and other setup tasks. I think that high-volume cataract surgeons in particular will benefit from the efficient workflow of the sterile setup.

ASTIGMATISM MANAGEMENT

I consider the ALLY platform superior to other lasers in its astigmatism correction, thanks to the accuracy of its IntelliAxis capsule marks and iris registration. It performs these calculations automatically, thereby removing user bias or error. I estimate that I achieve good registration with the ALLY laser 98% of the time. While I was becoming familiar with this platform, I was simultaneously using other alignment and registration devices in the OR. Every time, the IntelliAxis capsule marks were the most accurate. Without the IntelliAxis capsule marks, I got cylinder, but with them, my outcomes were so much better. I have come to trust that these marks are highly accurate.

ADVANTAGES FOR PREMIUM CATARACT PROCEDURES

Especially for toric, EDOF, and multifocal IOLs, it is important to use a femtosecond laser that makes careful arcuate incisions and performs optical axis centration of the capsulotomy. Interestingly, whereas every other laser makes arcuate incisions perpendicular to the tangent of the cornea, the ALLY makes them perpendicular to the coronal plane, so they are designed to slip instead of gape. Constructed this way, the incisions are less likely to regress. Robert Weinstock, MD, has published a good study showing the impressive stability of ALLY arcuate incisions at 1 year.[3]

Figure 1. Dr. Nikpoor's clinic has a dedicated LENSAR ALLY laser in each OR for a sterile setup.

Figure 2. Dr. Nikpoor and her staff estimate saving 7 mins per case with a dedicated LENSAR laser.

CASE STUDY

Cataract Surgery in a Commercial Pilot With an Intrastromal Corneal Ring

A commercial pilot who required 20/20 BCVA bilaterally to continue working presented to me for cataract evaluation. His UCVA was 20/25 and his BCVA was 20/20-1 in the worse eye (sometimes, he could make out the 20/20 line with correction, but not reliably), and his other eye was uninvolved. At this point, he was still passing his medical exams, but he was worried about his prescription changing or his vision worsening.

He had a previous diagnosis of keratoconus in the affected eye, for which he had undergone corneal cross-linking and received a Keraring intrastromal corneal ring (Mediphacos) outside the US. Despite the irregular topography, his UCVA was still 20/25, maybe 20/30 in that eye. In consulting with the optometrist in my practice, we were concerned that cataract surgery could worsen this patient's prescription. He was just barely bothered by glare. I had a long conversation with the patient about the pros and cons of doing the surgery, and whether to implant an LAL or a toric IOL. He elected the surgery. During the examination, I found that the eye had significant scarring around the corneal ring, which was within the treatment zone for the LAL, so we decided against that lens and chose the toric option.

I wanted to use the IntelliAxis capsule marks, but I was concerned that the corneal ring and its surrounding scarring was within the ALLY laser's firing zone and may block its passage, potentially causing an incomplete capsulotomy. So, in addition to the capsule marks, I placed tiny intrastromal marks on the cornea, 5º apart (the ALLY laser requires a 5º minimum).

Once the laser capsulorhexis was completed, I stained the cornea with trypan blue. Sure enough, an area of the capsulorhexis was incomplete, although it was just barely outside of the IntelliAxis capsule marks. I completed this part manually, and I was able to implant the lens on axis and use the capsulotomy marks and the corneal marks to help align the lens. I find that, because the IntelliAxis capsule marks are right next to the lens, there's no parallax error, and so I am able to reliably place the lens where I want it. Ink marks on the cornea are simply less accurate, in my experience.

At the 1-week postoperative visit, this patient's eye was seeing 20/25 UCVA, and at 1 month it was 20/15 -2 UCVA. He really had a "wow" reaction. He was very impressed that his vision was so much better than he thought it was going to be, given the irregularity of his cornea. I feel this outcome is a testament to the accuracy of the registration on the ALLY laser.

DEVICE COLLABORATION AND SAVED NOMOGRAMS

There are two other benefits of the ALLY laser that I appreciate. First, it works with almost all topographers and biometers, which is very convenient. Second, it reduces the preplanning I have to do for premium cataract surgeries. I have saved my arcuate nomograms in the laser's software, so I don't have to preplan those incisions. I can simply click one button on the laser, and the arcuate incisions are planned according to my nomogram, accounting for age as well as astigmatism measurements. I can even toggle between TK and anterior astigmatism values from my biometer. ■

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The FEMTIS IOL Family

Pairing these capsular-fixation IOLs with femtosecond-laser capsulotomies produces highly calibrated outcomes.

BY PATRICK VERSACE, MBBS, FRANZCO, DIP, ANAES

In my opinion, the next frontier in premium cataract surgery is to resolve three outstanding problems: (1) aligning IOLs to the visual axis; (2) controlling for lens tilt and x-y decentration; and (3) ensuring that an IOL lies in an anterior-posterior direction. If we can resolve these issues, then we can refine our outcomes even further and serve those patients who get an unexpected refractive result. The FEMTIS® IOL Family (Teleon Surgical) presents a distinctive design and optical platform that may offer us novel solutions to these problems.

The design of the FEMTIS IOL is unique among available IOL platforms in that it attaches to the anterior capsulorhexis. Using four clip haptics (Figure 1), the lens reliably fixates in the correct position inside the eye, rather than settling in the space vacated by the crystalline lens (Figure 2). This means that if we make a capsulorhexis that is perfectly aligned with the visual axis—something optimally achieved with a femtosecond laser—then the FEMTIS will be aligned with the visual axis. In contrast, IOLs centered in the capsular bag will align themselves with the equator of the capsular bag, which may or may not correlate with the visual axis.

Figure 1. In addition to its two modified plate haptics, the FEMTIS platform contains four clip haptics (two large, two small) that attach to the anterior capsulorhexis (pink tint).

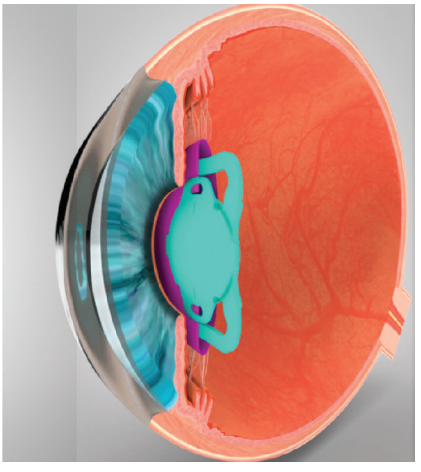

Figure 2. A rendering of the FEMTIS IOL's attachment to the anterior capsulorhexis.

Furthermore, current multifocal and extended depth-of-focus (EDOF) lens designs are engineered to allow for decentration from the visual axis. If the deviation exceeds approximately 600 µm, patients may start to experience unwanted visual phenomena. The FEMTIS lens largely avoids these phenomena by, again, aligning perfectly with the visual axis every time when it is combined with the precise alignment of a femtosecond-created capsulotomy.

THE ADVANTAGES OF A SEGMENTAL MULTIFOCAL OPTIC DESIGN

The FEMTIS® IOL Family, which includes the monofocal FEMTIS, the FEMTIS Comfort, the FEMTIS Comfort Toric, the FEMTIS MPlus, and the FEMTIS Mplus Toric, is based on an optical design that has been in use for more than a decade, first in the LENTIS® IOL (Teleon Surgical) platform. Rather than using diffractive technology to generate near vision, the segmental optic concept of FEMTIS Comfort and FEMTIS Mplus is

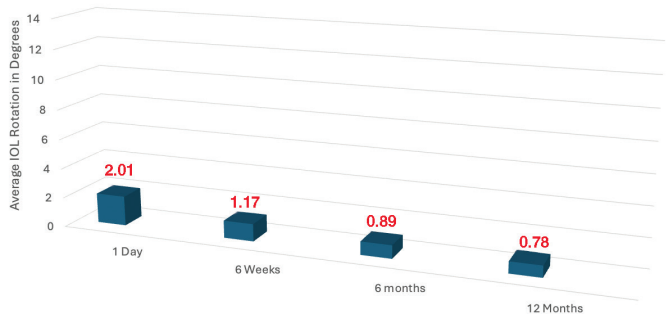

Figure 3. In the FEMTIS multicenter study, the lens' degree of rotation was very low. (Data adapted from Auffarth GU, et al. Stability and visual outcomes of the capsulotomy-fixated Femtis-IOL after automated femtosecond laser-assisted anterior capsulotomy. *Am J Ophthalmol.* 2021.)

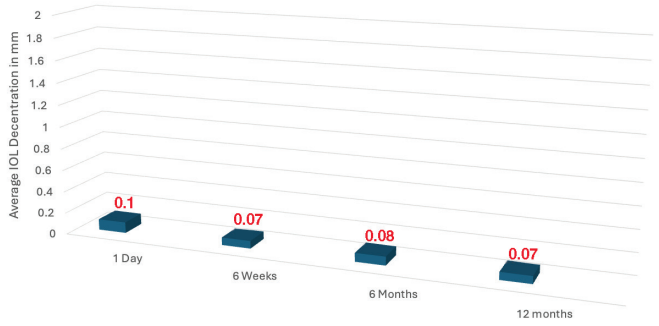

Figure 4. In the FEMTIS multicenter study, the lens' amount of decentration was very low. (Data adapted from Auffarth GU, et al. Stability and visual outcomes of the capsulotomy-fixated Femtis-IOL after automated femtosecond laser-assisted anterior capsulotomy. *Am J Ophthalmol.* 2021.).

purely refractive. Its defocus curve doesn't show sharp peaks for 2 or 3 points of vision, as is seen with a bifocal or trifocal lens. Intrinsic to the asymmetric segmental refractive technology are a smooth defocus curve and transition-free central optics. Its optical segmentation enables a continuous distribution of light throughout the intermediate viewing area, which is called the *varifocal effect*. Thus, the FEMTIS optic design uses light more efficiently, losing only about 8% versus the 15% of light lost by diffractive multifocal lenses. With such light efficiency, patients achieve good functional vision and a wide range of vision without having to accept the compromise of unwanted visual phenomena. In contrast, diffractive multifocals have a significant compromise: haloing at night. It happens with all diffractive IOL technologies; the only question is how much it bothers the patient. Importantly, the FEMTIS IOL technology does not produce halos.[1] These lenses are good for patients because they are effective; they're good for surgeons, because they make patients happy; and they are good for our practices, because they eliminate chair time discussing halos.

HANDLING AND PLACING THE FEMTIS IOL IN THE CAPSULORHEXIS

Whenever I teach surgeons how to implant the FEMTIS IOLs, they're always surprised at how easy it is. We inject the lens into the capsular bag under viscoelastic, just like a standard lens. After removing the viscoelastic from behind the lens and adding a little more in front of the lens, we attach the four enclavation flanges onto the anterior edge of the capsulorhexis. The entire technique adds maybe 20 to 40 seconds to the total surgical time.

ROTATIONAL STABILITY, YET EASY MANIPULATION

The FEMTIS IOL comes in two toric models, the FEMTIS Comfort® toric and the FEMTIS Mplus® toric, which are easy to use. Even after attaching them to the anterior capsulorhexis via the clip haptics, it's easy to rotate them in either direction to accurately align with the toric axis, far better than a lens in the capsular bag. Once rotated, the FEMTIS toric IOL will stay

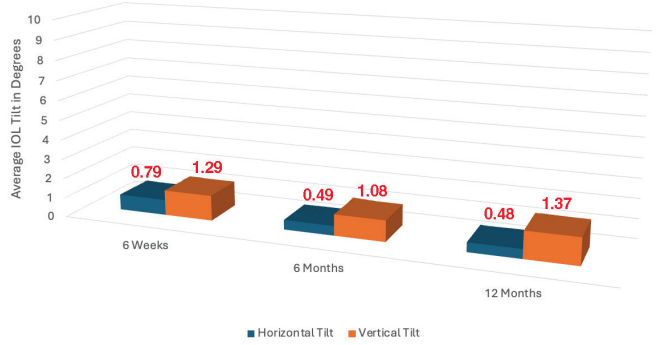

Figure 5. In the FEMTIS multicenter study, the lens' degree of horizontal and vertical tilt was minimal, even at 12 months postoperatively. (Data adapted from Auffarth GU, et al. Stability and visual outcomes of the capsulotomy-fixated Femtis-IOL after automated femtosecond laser-assisted anterior capsulotomy. *Am J Ophthalmol.* 2021.)

exactly where we leave it (Figures 3 through 5). The predictability of alignment with the correct toric axis is one of the strongest features of the FEMTIS toric IOL, especially when used with a digital marker system. Yet, if we need to re-enter the eye to realign the IOL, then the lens is very accessible; we can touch it and reposition it quite easily.

PATIENT SATISFACTION

We have all encountered post-cataract patients who have great vision on paper, but they are miserable with their quality of vision. The FEMTIS IOL gets excellent feedback, both subjectively and objectively. A colleague and I published our 6-month outcomes of the FEMTIS lens 4 years ago,[2] and another group has since published a collaborative, 12-month study with a larger cohort.[1] In both those papers, patient satisfaction was very high. And, because of the lens' superb stability, we can reliably predict its refractive outcome and avoid refractive surprises.

Of course, the visual system of the FEMTIS lens family is different from other IOLs and may require some slight neuroadaptation. To improve its range of vision, I routinely implant the FEMTIS IOL bilaterally, with a near add of 1.50 D in the dominant eye and 3.00 D in the nondominant eye. This strategy provides an extended range of focus by filling out the near and intermediate ranges, yet the distance vision is exactly the same in both eyes. This is not monovision, because both eyes will see 20/20 for distance. Recently, I applied this strategy in a patient who flies a rescue helicopter here in Sydney, which is a highly demanding job that requires him to fly at night in an urban area. With the 1.50 D FEMTIS Comfort in the dominant eye and the 3.00 D FEMTIS Mplus in the other, he is now free of spectacles and has great quality of vision, with no problems flying at night. That's the kind of outcome I'm looking for and expect to get with this lens.

CONSIDERATIONS FOR THE LONG TERM

As the evolving pattern is to perform refractive cataract surgery on younger patients, we need to consider the capability of upgrading IOLs. I have already begun encountering this issue. When I started using the FEMTIS Comfort lens, it only came as a 1.50 near add, which gave patients good vision—60% of recipients never wore reading glasses. I've since had a couple of patients return 4 or 5 years later desiring spectacle-free reading vision for fine print. After some discussion, I agreed to exchange these patients' lenses for the 3.00 D FEMTIS Mplus. Even 4 years later, it was very easy to explant the original FEMTIS and implant a new one attached to the capsulorhexis. Moreover, we don't see the capsular phimosis with the FEMTIS IOLs that is so common after routine cataract surgery. I anticipate that the long-term benefits of the FEMTIS platform will become increasingly valuable to those of us treating an aging population. ■

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Cataract Case Studies With FEMTIS Mplus® Toric IOLs

Surgical outcomes combining capsulorhexis-fixated, segmental multifocal toric IOLs with FLACS.

BY TIM SCHULTZ, MD, FEBO

When planning cataract surgery in astigmatic eyes, there are several steps necessary to achieve a good outcome. First, preoperative measurements must be precise, and for this I mainly use the Pentacam (Oculus). Second, we must ensure accurate toric IOL alignment. In the OR, my favorite tool is the LENSAR femtosecond laser to mark the axis without manual markings. In my hands, femtosecond laser-assisted cataract surgery (FLACS) achieves the highest reliability by stabilizing the eye and ensuring good registration.

A third key step in astigmatic correction is that the toric IOL needs to stay where it is placed. Especially in myopic eyes, in which the capsular bag is often large, there's a chance that a bag-fixated IOL will rotate. Therefore, I prefer to implant capsulorhexis-fixated lenses. Having used the FEMTIS® family of IOLs (Teleon Surgical) for the past few years, I have found several advantages to this design. These lenses stay exactly where I place them. Even when I implant a toric FEMTIS model (either the FEMTIS Comfort Toric or the FEMTIS Mplus Toric), I can rotate the lens in either direction inside the eye, using the alignment marks on the optic for guidance (Figure 1). It won't tilt or become decentered postoperatively. Importantly, the technique to fixate the haptics is fast and easy; it becomes routine after a few cases.

When cataract surgery candidates want independence from glasses, but they also have astigmatism, we must fix the astigmatism, no matter what IOL technology we choose. We surgeons now have a perfectly matched combination for astigmatic patients who seek premium refractive cataract surgery: fully automated IOL markings, registration, and capsulotomy creation with a femtosecond laser, coupled with the FEMTIS Toric IOLs, which fixate securely to the edge of the capsulorhexis and provide excellent astigmatic correction and segmental multifocal optics on a stable platform.

CASE 1: EARLY DENSE CATARACTS WITH ASTIGMATISM

A 42-year-old male patient with metabolic disease presented with early cataracts as well as astigmatism bilaterally. He was a self-described "tech nerd" who worked at a computer each

day. He said that he lived in the city and biked to work, and he wanted to be free of glasses for most activities, but he had concerns about the potential visual phenomena with multifocal IOLs, like starbursts, glare, and halos. The rest of his health history was unremarkable. Because he told me that he was willing to wear reading glasses in some limited situations, I suggested the FEMTIS Comfort Toric IOL of 20.00 D, because it would provide good distance visual acuity and moderate any postoperative visual symptoms.

The patient's preoperative examination revealed a BCVA of 0.2 logMAR in both eyes. His cataracts were mostly in the posterior capsule, and they had developed quite quickly and were fairly dense due to his metabolic disease.

I treated the left eye first, because it was his nondominant eye and its cataract was more severe. Despite the density of the cataract, the zonules were healthy and the surgery and IOL implantation were uncomplicated. Implanting a FEMTIS Comfort Toric IOL is just as easy as a traditional, bag-fixated lens. I use OVD in the same manner, and I stabilize the eye using an instrument made by Geuder AG in Germany, called the "small hammer." The IOL achieved good positioning (Figure 2), and the patient's astigmatism OS reduced to 0.25 D. I targeted mini-monovision of approximately -0.7 logMAR, but his final postoperative refraction was closer to -0.8. He was very happy that he was able to read with this eye without glasses.

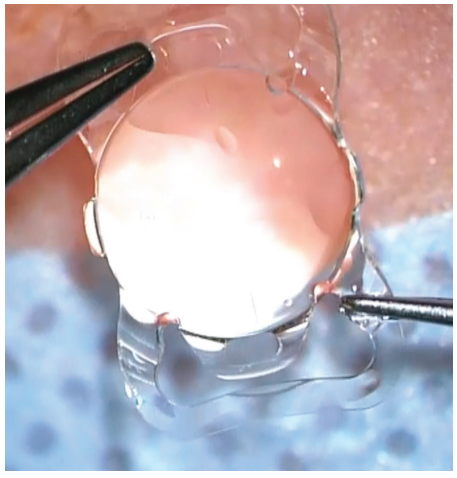

Figure 1. The FEMTIS Comfort Toric IOL with alignment marks.

Because this patient was quite nervous during the surgery and had trouble lying still after he received the topical anesthesia, I was grateful to have the eye stabilization and automated marking features of the femtosecond laser. I had no problems with its detection and marking functions, and the capsulotomy was perfectly complete and symmetrical for 360°. I used the dimple-down technique described by Lisa Arbisser, MD, to ensure a free capsulotomy.[1] The lens fragmentation went smoothly, after which it was very easy to remove the cataractous lens.

I treated the patient's right eye 6 weeks later, targeting emmetropia, which he achieved. Again, the surgery was uncomplicated. At his 3-month follow-up visit, the patient told me he was very happy, and that he was only using his reading glasses occasionally for very fine print. For most tasks, he was able to do without them. I attribute this happy outcome to the excellent optics of the FEMTIS Comfort Toric IOL, combined with the capabilities of the FLACS procedure.

CASE 2: SIGNIFICANT ASTIGMATISM IN A HIGH MYOPE

A 62-year-old female with a very active lifestyle presented for cataract evaluation. Both eyes were highly myopic, and each had 3.00 D of astigmatism. This patient had worn contact lenses for many years, and now she wanted to be as independent as possible from contacts or spectacles. Because of these three challenges—high astigmatism, high myopia (potentially with a large capsular bag), and the desire for complete spectacle independence—I again selected the FEMTIS Comfort Toric IOL for this patient.

I treated the left (nondominant) eye first, which had an axial length of 26.22 mm. I took preoperative images with the Pentacam (Oculus), which I transferred to the femtosecond laser system at the time of surgery. I targeted a correction of -1.00 D for the left eye and emmetropia in the right eye (axial length, 26.45 mm).

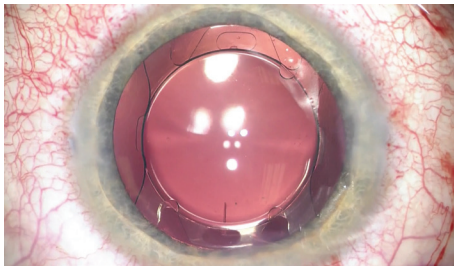

Figure 2. Secure positioning of the FEMTIS Comfort Toric IOL in the nondominant eye of a 42-year-old male patient.

Again, in this case, the laser produced a symmetrical capsulotomy, and then it fragmented the dense nucleus. Due to the amount of astigmatism present, I aimed for mini-monovision to extend the visual benefits of the FEMTIS Comfort Toric IOL. After I treated the second eye, this patient was fully free of glasses.

CONCLUSION

Recent data have shown that the incidence of myopia is increasing throughout the world.[2] Myopia poses unique challenges in eyes that need cataract surgery, not the least of which is the size of the capsular bag. I believe that the FEMTIS family of IOLs, with their optic design seated in a capsulorhexis-fixated platform, are uniquely suited to provide these patients the correction and refractive stability they need to achieve the independence from glasses they seek. Using the FLACS technique, we can find the visual axis, place the FEMTIS lenses in a stable location, and make our patients happy with premium multifocal optics, with toric correction if needed. ■

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- Financial disclosure: Speaker (Teleon Surgical)

The FEMTIS IOL Family–The Perfect Match for FLACS Procedures

Conclusions from a 1-year multicenter study and my 5-year experience with the FEMTIS Comfort MF15 IOL.

BY DETLEF HOLLAND, MD

To capitalize on the greater strength and uniformity of a capsulotomy edge created with a femtosecond cataract laser, Teleon Surgical developed the FEMTIS® family of IOLs as the perfect lenticular complement: a premium platform providing monofocal, multifocal, and extended depth-of-focus (EDOF) options that fixates to the anterior capsulotomy to maximize stability and minimize visual phenomena. The FEMTIS IOL Family includes three models: the monofocal FEMTIS, the FEMTIS Comfort MF15 (EDF), and the FEMTIS Mplus MF 30 (FVR). The latter two models each include a toric option for astigmatic correction.

I now have been implanting the FEMTIS family of IOLs for 10 years, and I continue to recommend these lenses to my patients. This article provides an overview of the lenses and results from a multicenter, multinational study of the FEMTIS Comfort MF15 IOL, and it details my personal 5-year experience implanting this lens.

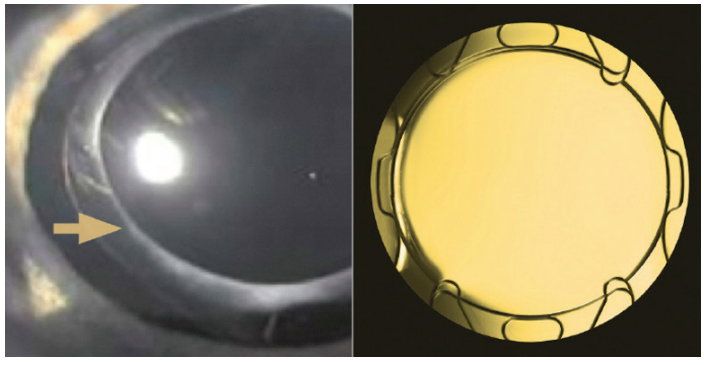

Figure 1. Although the capsulorhexis margin of a standard, bag-fixated IOL has the potential to cause symptoms of negative dysphotopsias (A), the rim of the FEMTIS IOL forms an ideal unit with the rim of the capsulotomy, thereby preventing dysphotopsias (B).

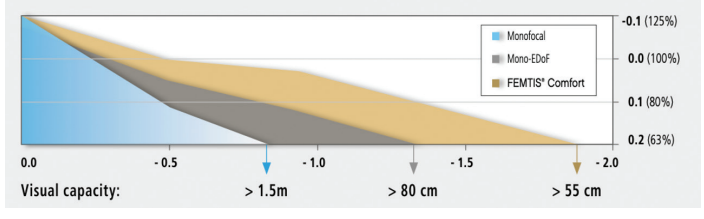

Figure 2. Comparison of defocus capacity of the FEMTIS Comfort IOL, a monofocal IOL, and a monofocal plus IOL.

FEMTIS IOL DESIGN

All the FEMTIS IOLs are constructed in a plate-haptic design with additional clip-style haptics (two large, longitudinal haptics, and two small, latitudinal haptics) to form a secure unit with the rim of the capsulotomy. This design minimizes common complications of premium IOLs such as instability and tilt, decentration/rotation, refractive predictability errors, and dysphotopsias as well as other visual phenomena (Figure 1).

The FEMTIS IOL's total diameter is 10.5 mm, with an optic size of 5.7 mm. The optic is an aspheric, biconvex, aberration-neutral design composed of the company's proprietary Hydrosmart® material, which is a copolymer of hydrophilic acrylates that contain 25% water. Its surface has hydrophobic properties that absorbs UV light, and the entire FEMTIS family offers naturalistic color perception.

FEMTIS COMFORT MF15

The FEMTIS Comfort MF15 IOL is designed for patients who want to prioritize excellent distance and intermediate vision in daily life with a 1.50 D add. This lens offers extended depth of focus (EDOF) with an uninterrupted distribution of light through the optic segments—what the company refers to as a *varifocal effect.* The central optical zone reduces recipients' sensitivity to potential IOL decentration and tilt because the distance visual acuity is not influenced by minor decentration (Figure 2). All patients who desire increased spectacle independence and who have no problems with occasionally wearing reading adds are perfect candidates for this IOL. Also, patients who frequently drive at night will benefit from its very low scotopic phenomena.

The FEMTIS Comfort Toric MF15T IOL offers all the benefits of the Comfort optic, but with additional astigmatic correction of +0.75 D, +1.50 D, +2.25 D, and +3.00 D. Its aberration-neutral optic provides excellent contrast sensitivity and depth of focus for low lighting conditions. Because this lens fixates to the anterior capsulorhexis, it can be rotated in either direction before being enclaved to the edge.[1]

THE FEMTIS MPLUS MF30

The FEMTIS Mplus and Mplus Toric IOLs (FB-313 MF30T) are a multifocal option to correct presbyopia and astigmatism. This model has 3.00 D of near addition and a large aspheric distance optical zone that maximizes light transmission for sharp distance vision with excellent contrast sensitivity.

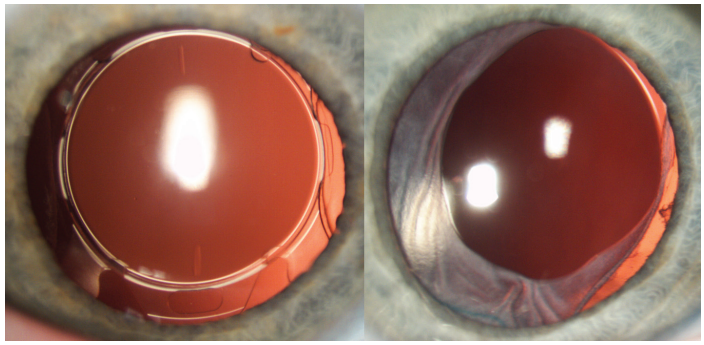

Figure 3. Two years after implantation, an eye with a FEMTIS IOL shows no signs of anterior capsular fibrosis (left), compared to an eye that received a standard in-the-bag monofocal IOL (right).

Yet, its Continuous Transmission Technology and its segmented varifocal optical zones that are spread across the prolate surface enable a smooth transition between distance and near viewing, with minimal photopic phenomena. Because this IOL offers a full range of vision, it is ideal for patients who demand complete spectacle independence.

NO ANTERIOR CAPSULAR FIBROSIS WITH FEMTIS IOLS

What I especially love about the FEMTIS lenses is checking my patients' eyes after implantation and seeing absolutely no part of the anterior capsule in front of the optic. This results in very good optical performance, especially in mesopic conditions and wide pupils. Because of their design, FEMTIS IOLs keep the anterior capsule remarkably free of fibrosis. With standard IOLs, I often find fibrosis a few years after implantation, but not so with the FEMTIS IOLs (Figure 3).

The learning curve for implanting the FEMTIS IOLs is very short. It can be implanted under viscoelastic or simple irrigation (there is an advantage to not having to remove viscoelastic from behind the IOL). The only instrumentation needed is a small hook for assisting with the enclavation of the lens, such as a Sinskey hook. The enclavation maneuver is very quick, in my experience.

RESULTS OF A YEARLONG MULTICENTER STUDY

I participated in a yearlong, multinational case series that encompassed eight study sites across Germany, Spain, Great Britain, and Andorra to determine the stability of the effective lens position of the monofocal FEMTIS Comfort IOL up to 1 year after implantation following femtosecond laser-assisted cataract surgery with the LENSAR laser.[2] Colleagues and I enrolled a total of 183 patients (366 eyes) with senile cataracts. The study's main endpoints were IOL decentration, rotation, and tilt (horizontal and vertical) compared to published data on standard IOLs. Secondary endpoints were the distance between the iris and the IOL's final resting place, and patients' subjective refraction, UCVA, and incidence of posterior capsular opacification (PCO). We performed FLACS in each eye, and then we implanted IOL powers of 15.00 to 27.00 D. We targeted postoperative astigmatism for <1.00 D. The patients were evaluated preoperatively and then at days 1-7, weeks 6-8, and at 6 and 12 months after surgery.

CENTRATION

The centration of the FEMTIS Comfort IOL over 12 months was excellent (Figure 4).

Compared to published studies of capsular-bag-implanted IOLs, the FEMTIS Comfort showed very high rotational stability over 12 months. Whereas some published studies recorded up to 5° of IOL rotation within 6 months of implantation, the FEMTIS Comfort IOL showed no more than 0.78° of rotation out to 12 months.

Decentration of the FEMTIS Comfort lens was also excellent, compared with published results of standard bag-implanted IOLs. Its mean decentration from postoperative day 1 to 6 weeks was 0.07°; from 6 weeks to 6 months, the lens' mean decentration was

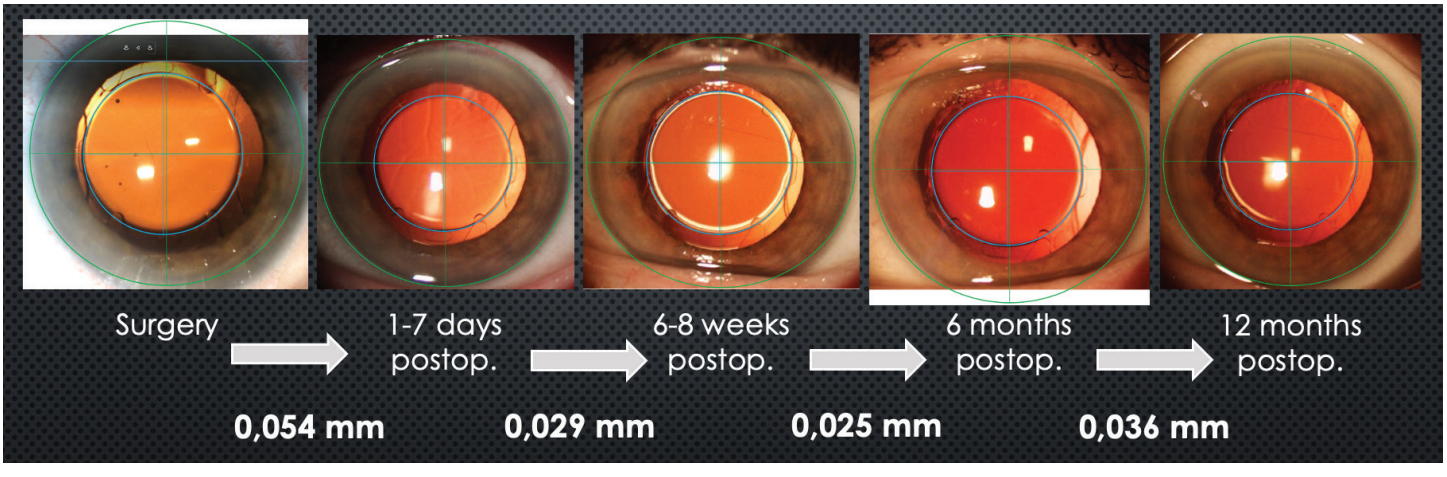

Figure 4. In an international, multicenter study of the FEMTIS Comfort MF15 IOL, the lens' effective lens position was remarkably stable over 12 months.

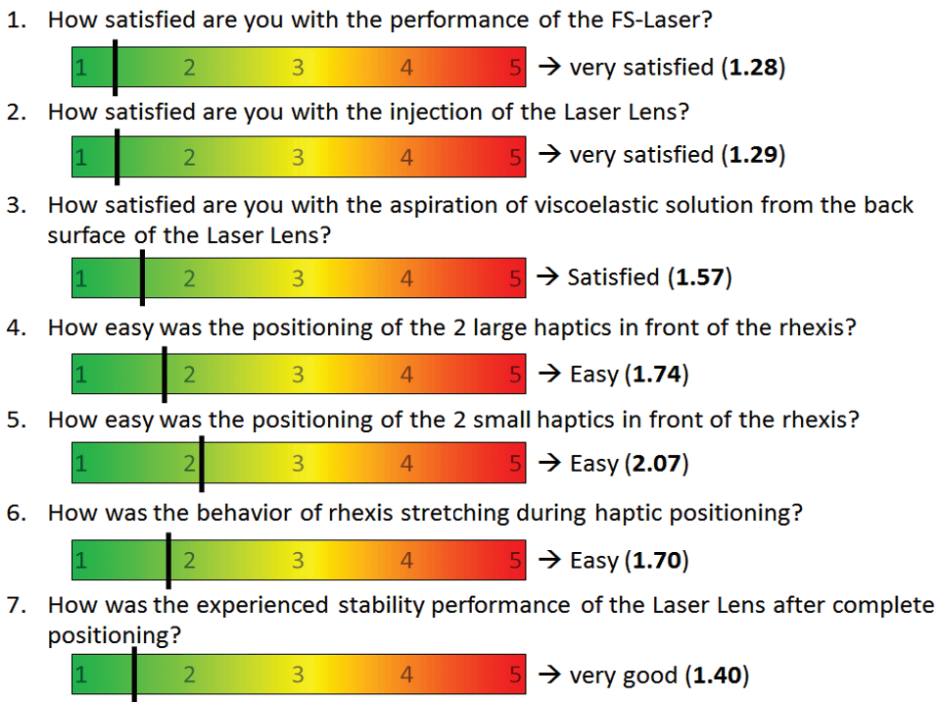

Figure 5. In the FEMTIS multicenter study, surgeons gave high marks to their experience implanting the FEMTIS IOL. (Data adapted from Auffarth GU, et al. Stability and visual outcomes of the capsulotomy-fixated Femtis-IOL after automated femtosecond laser-assisted anterior capsulotomy. *Am J Ophthalmol.* 2021.)

0.08°; and from 6 months to 12 months, the mean was 0.07°. These averages were compared against the published results of three studies, which recorded mean IOL decentration between 6 weeks and 6 months postoperatively as 0.57°, 0.42°, and 0.38°.[3-5]

TILT

In our multicenter study, the FEMTIS Comfort IOL showed a minimal degree of horizontal and vertical tilt. The lens showed a mean horizontal tilt of 0.79° from preoperative measurements to 6 weeks after implantation (compared to a mean of 2.50° in three published studies); 0.49° of horizontal tilt from 6 weeks to 6 months, and 0.48° of tilt from 6 to 12 months. Mean vertical tilt for the FEMTIS Comfort lens was 1.29°, 1.08°, and 1.37° over the same timeframes.

SURGEON QUESTIONNAIRE

Finally, we surgeons in the study filled out a questionnaire about our experience implanting the FEMTIS IOL. Here, the FEMTIS received high marks for injection into the eye, the ease of removing viscoelastic from behind the lens, and positioning the large haptics in front of the capsulorhexis. The positioning of the two smaller haptics in front of the capsulorhexis required slightly more maneuvering but was still deemed "easy" (Figure 5).

VISUAL ACUITY

Patients' visual acuity outcomes remained strong throughout 12 months. Mean distance-corrected visual acuity (DCVA) reached 0.00 ± 0.08 logMAR by 6 months, and -0.01 ± 0.09 logMAR at 12 months. By 12 months postoperatively, 97.5% of the study eyes had achieved 0.1 logMAR DCVA, likely due to the stability of the IOL's centration.

TAKEAWAYS

The FEMTIS Comfort MF15 IOL provides effective uncorrected intermediate and distance visual acuity that is comparable with other EDOF IOLs. It has an excellent defocus curve and gives patients strong visual acuity and contrast sensitivity in mesopic conditions. In 5 years of follow-up with my cohort from the 12-month multicenter study (unpublished data), I've seen safe, stable results, and no intra- or postoperative complications. Compared to published results with standard IOLs, the FEMTIS shows better stability and refractive predictability. I attribute this functional performance to the combined benefits of the FLACS technique with a capsulotomy-fixated EDOF lens. ■

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