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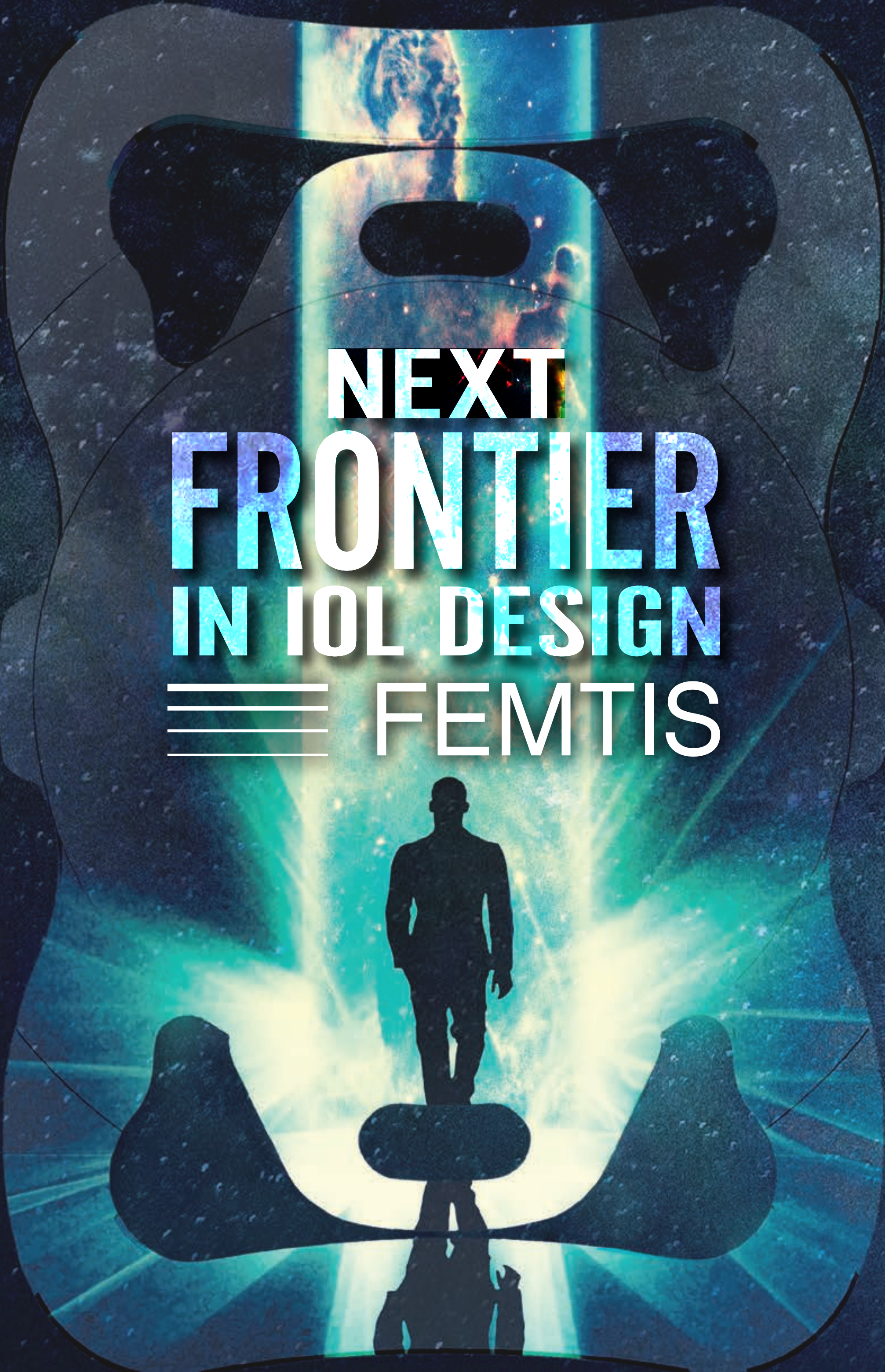
NEXT FRONTIER IN IOL DESIGN

FEMTIS



FEMTIS IOL: PROMISING RESULTS AT 2 YEARS

Clinical experience and four pearls for best practices.

BY DETLEF HOLLAND, MD

The use of the femtosecond laser for several important steps in cataract surgery is growing all over the world. Besides the known advantages, like the decrease in effective phaco time and the ability to correct corneal astigmatism with arcuate incisions done in the same procedure, the perfectness of the capsulotomy is another key advantage of the technology. There is significant clinical evidence that the laser capsulotomy is superior to the manual continuous curvilinear capsulorrhexis (CCC) regarding not only the roundness and centration but also in the postoperative result of the overlapping of the optic and the tilt of the lens. There seems to be also a potential benefit regarding the decrease in postoperative aberrations after laser-assisted cataract surgery (LACS) compared to routine surgery with phacoemulsification.

In our more than 3 years' experience with LACS, the strength of the capsulotomy (Figure 1) and the incidence of capsular tears has been comparable to our results with CCC (personal data). Therefore, we have come to rely regularly on the use of the femtosecond laser for capsulotomy creation as well as other important steps in cataract surgery.

OPTIMIZING LENS FUNCTION

Surgical revision after cataract surgery due to problems with the IOL is fairly uncommon, but by far the largest reason for postoperative adjustments is lens decentration or tilt. This can occur because the capsulotomy size was either too big or too small or because phimosis of the capsulotomy occurred. With lens stability in the capsular bag playing an increasingly integral part in achieving excellent postoperative results, especially with premium IOL technologies, a perfectly round and appropriately sized capsulotomy with perfect centration becomes even more significant.

In addition to using the femtosecond laser to perform a capsulotomy with these characteristics, the femtosecond laser can also help to optimize IOL function in other ways. One example is when the laser capsulotomy is paired with an IOL designed to clamp into the capsulotomy, such as the FEMTIS IOL (Oculentis; Figure 2). In addition to two standard plate haptics, the FEMTIS lens design is characterized by four additional haptics that are enclaved in front of the capsulotomy. This eliminates the risk for the lens to dislocate postoperatively by becoming decentered or tilted.

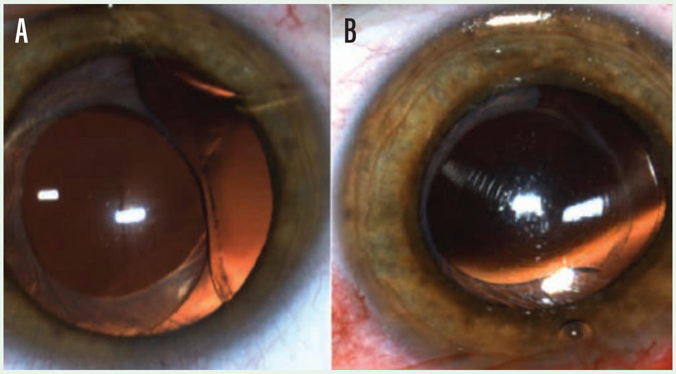


Figure 1. Decentration of a multifocal IOL, before (A) and after (B) rotation.

LONG-TERM FOLLOW-UP

We now have 24-month follow-up in more than 90 eyes that have been implanted with the FEMTIS IOL. In all cases, the Lensar Laser System was used for capsulotomy and the Catarhex OS3 system (Oertli) for phacoemulsification. A total of 66 patients were enrolled; the mean age in these patients was 75 years.

In all cases, there were no complications during lens implantation, and there were no cases of the lens becoming decentered postoperatively. Furthermore, the enclavation of the capsulotomy behind the additional haptics led to no complications, and the optic was free of any overlap with the anterior capsule in all cases.

Mean DCVA in the operated eye increased from 0.5 decimal preoperatively to 0.91 ±0.22 decimal postoperatively; mean binocular DCVA was 1.0 ±0.26 decimal.

We also looked at pigment dispersion, as the four additional haptics are placed in front of the capsular bag, touching the pigment. There was no evidence of this postoperatively, and, at 24 months, no eyes had experienced problems with pigment epithelium or pigment glaucoma (Figure 3). Further, IOP had decreased to 13.79 ± 3.0 mm Hg by 24 months postoperatively, from 16.6 ±1.73 mm Hg preoperatively.

We have found the design of the FEMTIS IOL to be very stable, with no signs of postoperative rotation; this will be of great benefit in any future toric and multifocal IOL designs. Additionally,

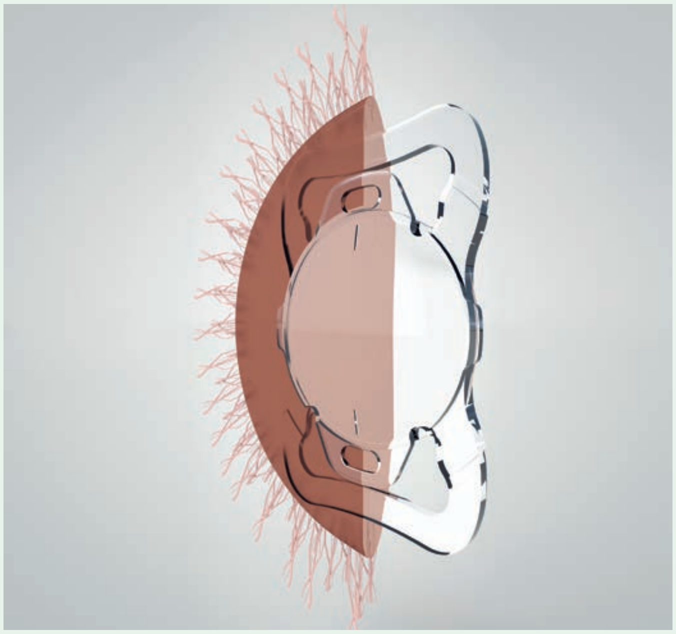


Figure 2. The design of the FEMTIS IOL.

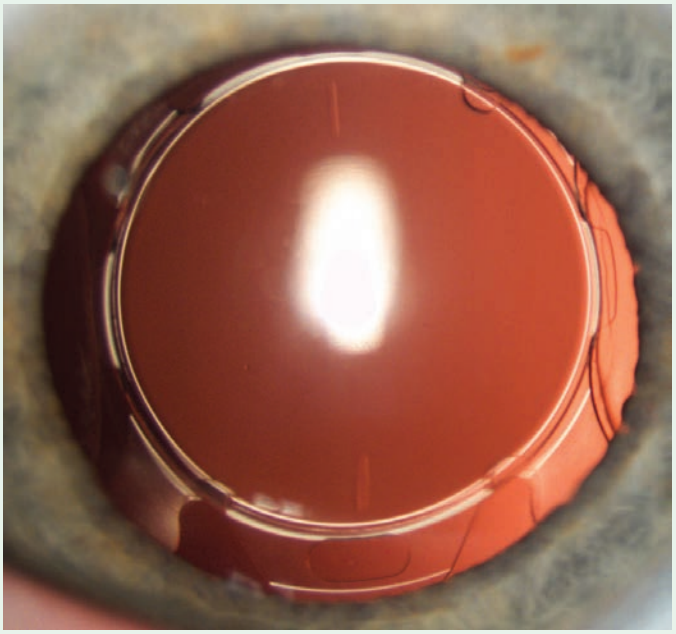


Figure 3. FEMTIS IOL in situ, 24 month after implantation.

the fact that the lens's optic does not overlap with the anterior capsule, leading to fewer symptoms of dysphotopsia, may be advantageous in younger patients and in those with large pupils. We have started to use the Comfort EDOF version of the FEMTIS IOL with 1.50 D addition recently. Our results in this series have been promising, but longer-term follow-up and a prospective comparison to the standard model must be conducted.

BEST PRACTICES

Below I offer four best practices with the FEMTIS IOL.

Best practice No. 1: Capsulotomy size. The total diameter of the aspheric FEMTIS lens, made of hydrophilic acrylic material, is 10.5 mm, and the optic diameter is 5.7 mm. In my experience, it should be clamped into a Lensar laser capsulotomy of about 4.8 to 5 mm in order to achieve the best results. After consultation with colleagues using other femtosecond laser systems, it seems that we have a difference between adjusted capsulotomy sizes for a perfect enclavation behavior of the FEMTIS IOL. For example, the LenSx (Alcon) needs to be an entered capsulotomy size of about 5 to 5.2 mm to easily fixate the additional haptics of the lens.

Best practice No. 2: Positioning the additional haptics. Thus far in my experience with the FEMTIS, totaling about 100 implantations, I have not had one lens-related complication. The only learning curve I experienced was figuring out how to position the four additional anterior haptics (two large longitudinal and two smaller latitudinal) into the capsulotomy to secure and center the IOL, but it was very short. Through my experience I have found that, by adding a simple Sinskey hook to the other instruments I use during lens implantation, I am able to position the FEMTIS IOL quite well.

Best practice No. 3: Implant the IOL under an OVD. After insertion of the lens into the capsular bag, it is important to aspirate the OVD completely from behind the lens. Subsequently, using an OVD when enclaving the additional four haptics is useful. Of particular note is the importance of removing the OVD completely after the haptics are in position.

Best practice No. 4: Use Mydraisert. I have found it helpful to use Mydriasert (tropicamide and phenylephrine HCl; Thea Pharmaceuticals) to expand the pupil every time I perform LACS. Enlarging the pupil size to greater than 6 mm facilitates ease of enclavation and reduces the risk for iris capture.

CONCLUSION

We believe that every patient who elects LACS is a candidate for the FEMTIS IOL. More specifically, those with high myopia and large-diameter capsular bags often do well with this design, as there is less risk of IOL decentration postoperatively. I do not recommend this lens to be used with a Lensar laser capsulotomy of less than 4.5 mm, as enclavation of the haptics becomes too tricky. Also, because the IOL has plate haptics, it is not recommended to implant the FEMTIS IOL in patients with loose zonulas.

With those two caveats, I believe that, compared with standard IOL designs, the FEMTIS lens has many advantages. The biggest advantage is that it allows perfect centration of the lens to the center of capsulotomy. ■

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- Financial disclosure: The multicenter study mentioned in this article was financed by Oculentis

LACS AND THE FEMTIS IOL: BEST PRACTICES WITH THE CAPSULASER

When using these technologies together, virtually no IOL movement occurs postoperatively.

BY PAVEL STODULKA, MD, PhD

A circular opening in the lens capsule is a gateway inside the eye for cataract surgery. For years, the most common technique to open the capsule was a manual capsulorrhexis, with handheld forceps introduced through the main or sideport incision to punch the capsule and create the circular opening. As we have come to learn, the size and shape of the capsular opening can play an integral role in postoperative outcomes and in IOL centration. Although the manual capsulorrhexis is extremely effective, it is not always circular and, occasionally, can be smaller or larger than the IOL optic, thereby compromising long-term IOL stability.

More recent innovations, such as the femtosecond laser, can be used to cut the capsule with higher precision than a manual technique, producing a so-called *free-floating capsulotomy*. The femtosecond laser is especially advantageous today, as more premium lens technologies, which rely on a precise capsulotomy for long-term IOL centration, are being implanted. There are drawbacks to the use of current femtosecond laser platforms for cataract surgery, however. These include that the systems are bulky, they are expensive, and they also can require a dedicated operating room. Such burdens have contributed to the prevention of widespread use of femtosecond laser technology.

Nevertheless, due to the highly predictable size, shape, and position of the laser capsulotomy, the femtosecond laser has been found to be a helpful tool to improve IOL centration. In fact, it

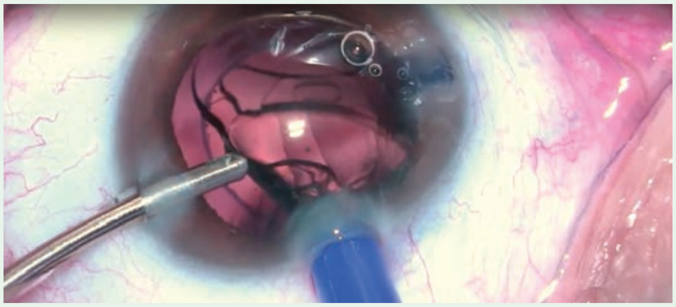

Figure 1. The FEMTIS IOL is inserted into the capsular bag.

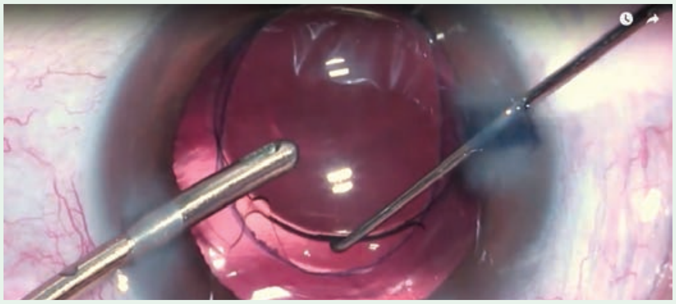

Figure 2. One of the large haptics is clipped onto the capsule.

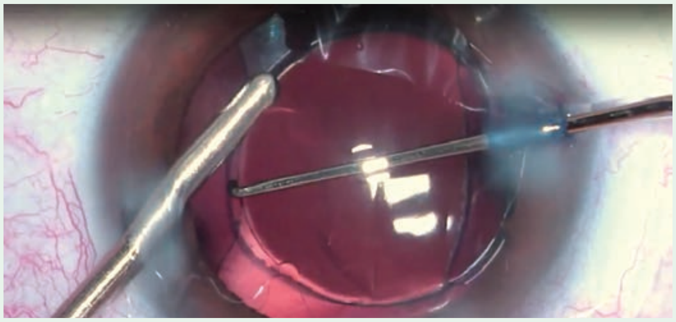

Figure 3. The smaller haptics are manipulated in front of the capsule.

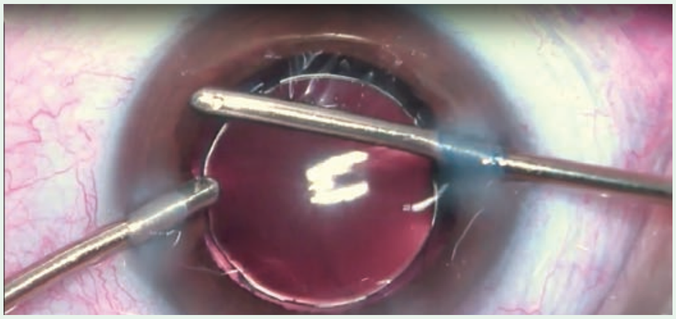

Figure 4. The IOL is perfectly fixed in the capsule opening.

CASE STUDY

I recently implanted the FEMTIS IOL in a professional truck driver who often drives at night. Surgery was uneventful, and, by 1 month postoperative, he had achieved 20/20 UCVA in his right and left eyes, with -0.75 D cylinder in his left. By 3 months postoperative, the patient reported that he had no problems with glare or halos and no negative dysphotopsias. Upon clinical evaluation, I noted that the circular capsulotomy continued to hold the IOL in place (Figure 1). The microclips, which remained well positioned on the capsulotomy edge, had very little fibrosis (Figure 2), and there were no signs of secondary capsular opacity (Figure 3) or posterior capsular opacification.

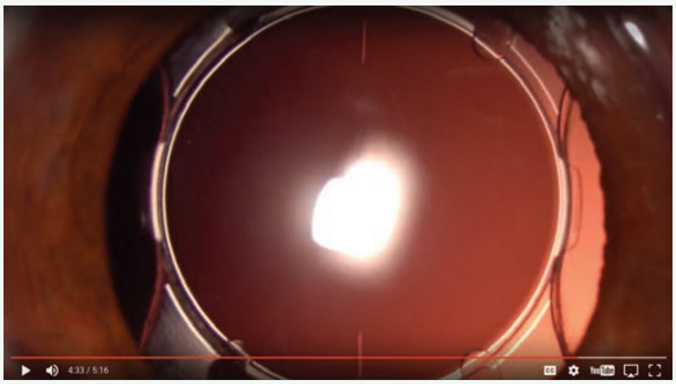

Figure 1. The IOL is held in place by the circular capsulotomy.

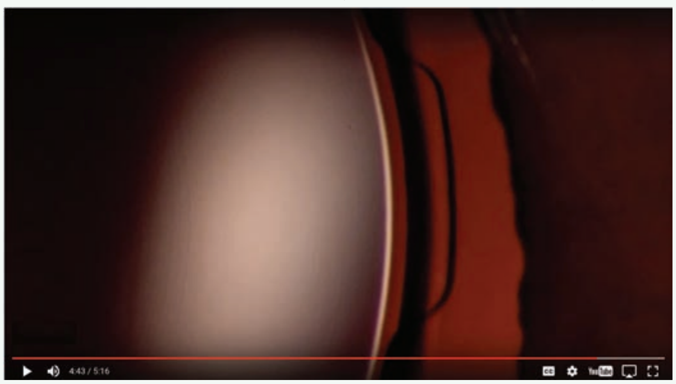

Figure 2. The microclips are well positioned on the capsular edge.

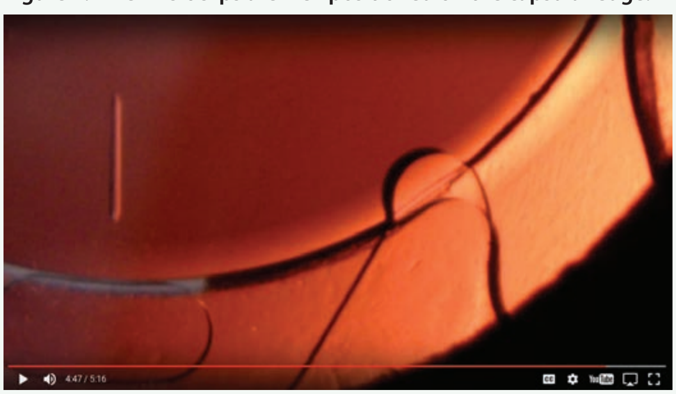

Figure 3. No signs of secondary capsular opacity.

can be combined with a lens designed for use with a laser capsulotomy, the FEMTIS IOL (Oculentis), to achieve even better centration and, thus, better postoperative outcomes. The FEMTIS IOL is currently in clinical trials, in which I am participating.

A compact, cheaper alternative to the femtosecond laser for capsulotomy creation is the CapsuLaser (CapsuLaser). This device, mounted under the surgical microscope, can create a precise and reliable capsulotomy with a firm and elastic edge in about 1 second. Laboratory measurement has shown that the CapsuLaser capsulotomy is significantly more stretchable than a manual capsulorrhexis.[1] I recently began using the CapsuLaser device with the FEMTIS IOL, and to date my results have been impressive. Thus far, I have implanted about 30 monofocal and 10 multifocal lenses in combination with the CapsuLaser.

SURGERY

After trypan blue dye is washed out of the eye, the anterior chamber is filled with OVD. Then, the aiming beam is focused through the handheld contact lens of the CapsuLaser, and the laser is focused by a footswitch. The capsulotomy is then performed in 1 second.

The central capsule is removed, followed by cataract removal. The FEMTIS IOL, which is designed for optic fixation in the laser capsulotomy by means of dedicated microhaptics, is placed in the cartridge and implanted through a 1.8- to 2-mm incision (Figure 1), depending on the power of the lens to be implanted. Before fixating the FEMTIS optic into the capsulotomy, the leading haptics are introduced straight into the capsular bag and the trailing haptic into the anterior chamber. Then, the trailing haptic is manipulated to the capsular bag. The next step is to clip the large haptic onto the capsule at the 6-o'clock position, followed by the microhaptic at the 12-o'clock position (Figure 2). Finally, the smaller haptics are manipulated in front of the capsule at the 3- and 9-o'clock positions (Figure 3). The IOL optic is perfectly fixed in the capsule opening, promoting reliable IOL centration and preventing IOL rotation (Figure 4).

ADVANTAGES AND TIPS

I first used the FEMTIS IOL combined with the CapsuLaser 2 years ago. In this time, I have noticed advantages and learned valuable tips.

Advantage No. 1: The CapsuLaser creates a perfect and well-centered capsulotomy, and the IOL is always well-centered. In my experience, there is virtually no movement or rotation of the IOL after the haptics are in place and the microhaptics are clipped onto the capsulotomy.

Advantage No. 2: An alternative to implanting the FEMTIS IOL under OVD is that it can be implanted with a hydro-assisted implantation technique. The advantage to this technique is that there is no OVD to aspirate from both the capsular bag and the anterior chamber after the lens is implanted. This makes surgery shorter.

Advantage No. 3: The design of the IOL eliminates almost all presence of dysphotopsias. This includes rainbows, streaks, crescents, rings, halos, glare, haze, and fog.

Tip No. 1: The FEMTIS IOL will work better with slightly larger capsulotomy performed with the CapsuLaser. In my hands, I size the capsulotomy between 5 and 5.2 mm.

Tip No. 2: Use trypan blue dye. Staining improves visibility of the capsular edge for the entire surgery, including IOL fixation.

Tip No. 3: Center on the visual axis. When using the CapsuLaser to create the capsulotomy, the FEMTIS should be centered on the visual axis, not the pupil.

Tip No. 4: Personalize your A-constant. At first, I used the A-constant that was suggested by Oculentis. Over time, I figured out that adding 0.1 to the A-constant produced even better results.

CONCLUSION

Laser capsulotomy serves as a perfect support for premium IOLs and creates a platform for excellent long-term IOL centration. In my experience, fixating the FEMTIS IOL on the capsulotomy opening of the anterior capsule is straightforward, with little additional surgical time.

The combination of a CapsuLaser capsulotomy and the FEMTIS IOL is a promising new way to provide patients with excellent postoperative outcomes, to create a stable lens position, and to promote long-term IOL centration. ■

1. Packard R. A new approach to laser capsulotomy. *CRST Europe*. https://crstodayeurope.com/articles/2015-oct/a-new-approach-to-laser-capsulotomy. Accesed July 4, 2017.

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- Financial disclosure: None acknowledged

A NEW APPROACH TO INCREASE VISUAL PERFORMANCE

Compared with a monofocal IOL, patients can achieve better vision with the FEMTIS.

BY SUNIL SHAH, MBBS, FRCOPHTH, FRCS(ED)

It is no secret that today's cataract surgery patients have high expectations for their postoperative vision, and it is not uncommon for them to come in desiring spectacle independence. Unfortunately, though, there is no single IOL that we can offer that provides the crisp, clean spectacle-free vision that patients enjoyed as 20-year-olds. Every IOL has trade-offs, so to speak, and I have experimented with many different models in attempt to find the perfect solution for my patients.

Most recently, my experimentation has led me to the FEMTIS IOL (Oculentis), which I have been using for the past year. When combined with laser-assisted cataract surgery (LACS), the three major benefits of the IOL are: (1) excellent centration and stability, (2) perfect overlap of the rhexis and the optic, and (3) excellent refractive outcomes. In essence, these benefits are all afforded by the IOL's special haptics system, which allows the lens to be clamped into the capsulotomy.

The promise of an IOL that can achieve a consistent effective lens position and promote the absence of IOL tilt is attractive as the next step forward in IOL design. Currently, I consider the FEMTIS IOL in any patient in whom a monofocal IOL is indicated. In the future, as toric and multifocal IOL models of the FEMTIS become available, I will further extend the indications in which I recommend this platform. In my opinion, these future uses of the FEMTIS technology are even more exciting.

STUDY

I am currently investigating the FEMTIS IOL as part of a multicenter study to determine the lens' safety and efficacy. Thus far, in total, 163 patients have been enrolled across nine centers. Specifically at Midland Eye, we have already enrolled 50 eyes. In all cases, the FEMTIS IOL was implanted bilaterally in patients between the ages of 67 and 88 (mean, 76.96 ±6.35 years) with a target refraction of plano. The Haigis formula was used to calculate IOL power, and the mean IOL power was 20.50 D.

Patients were examined preoperative and at 1 to 7 days, 6 to 8 weeks, 6 and 12 months postoperatively. The main endpoints of the study were IOL decentration, rotation, tilt, the distance between the iris and the IOL, refraction, and visual acuity.

Surgery was uncomplicated in all cases. After pupil dilation with Mydriasert (Thea Pharmaceuticals), the Lensar Laser System (Lensar) was used to create a capsulotomy with a diameter of 4.9 to 5 mm; it was also used for lens fragmentation. A manual corneal incision of about ≥2.4 mm was made to aid in lens implantation.

Once the FEMTIS IOL was positioned completely in the bag,

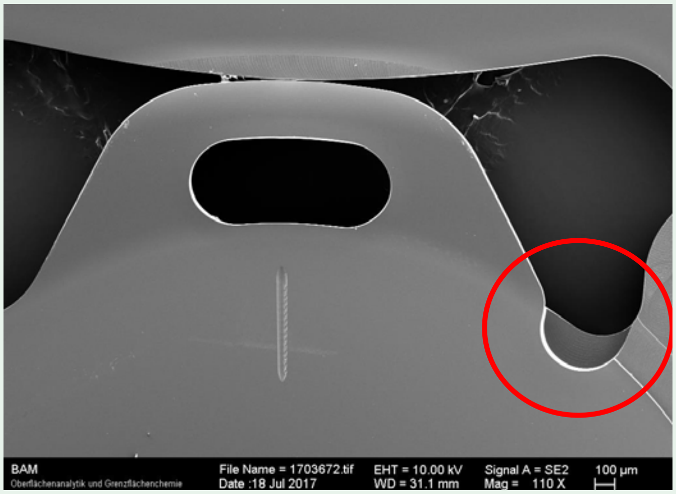

Figure 1. The small optic hole of the FEMTIS IOL.

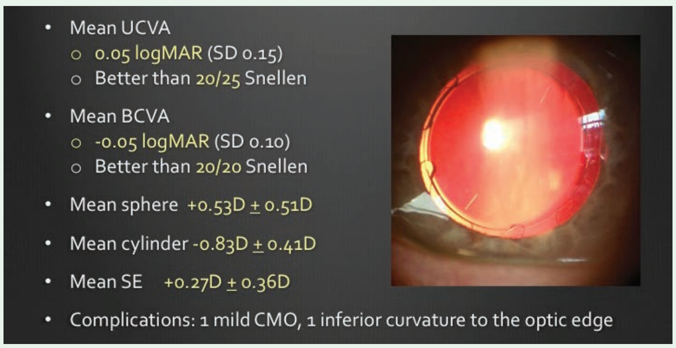

Figure 2. Six to 8 weeks postoperative visit.

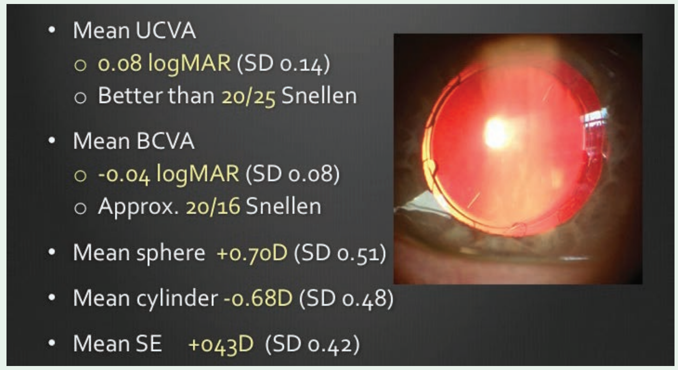

Figure 3. Six month postoperative visit.

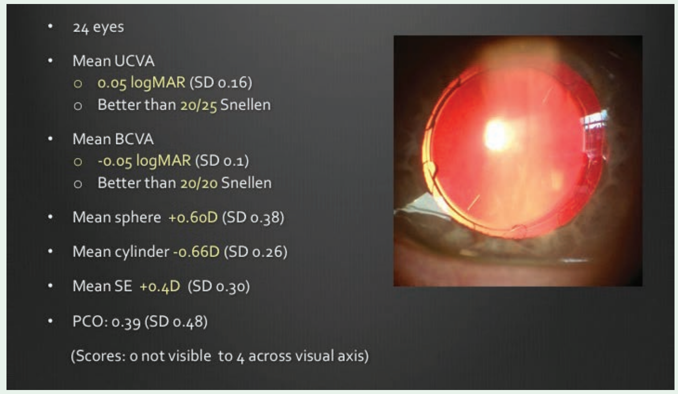

Figure 4. Twelve month postoperative visit.

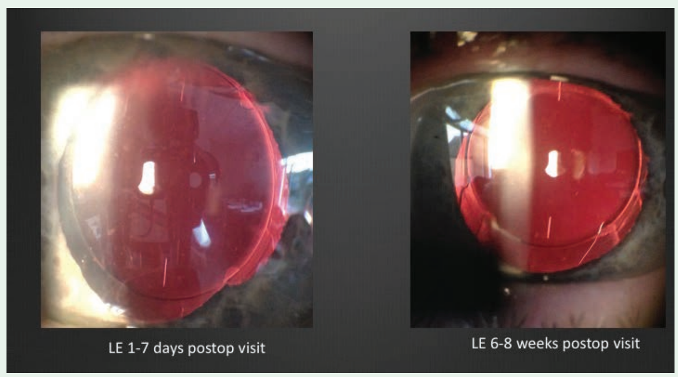

Figure 5. At all time points, the FEMTIS IOL was centered and stable.

OVD was aspirated from behind the IOL, through the small optic holes (Figure 1). The lens' two large longitudinal haptics, followed by the two small lateral haptics, were then enclaved in the capsulotomy. Miochol-E (acetylcholine chloride intraocular solution; Bausch + Lomb) and pilocarpine 2% were instilled.

There was virtually no learning curve with the FEMTIS IOL. Although it might take a little more time to implant due to the need to flip the haptic flaps of the IOL over the anterior capsule once the lens is in the bag, implantation is quite straightforward. The lens is injected through a standard injector system and behaves just like the rest of the Oculentis IOLs. When starting with this lens, however, I would recommend selecting patients with good pupil dilation.

RESULTS

All eyes were available for follow-up through 6 months. At 12 months, only 24 eyes were available. Generally speaking, the results are so impressive because they are better than one would typically expect to achieve in this age group with a standard monofocal IOL. Furthermore, although patients did not have any means to compare their vision with this IOL and another—since the FEMTIS was implanted bilaterally—all were happier than one would normally expect patients in a monofocal IOL study to be.

Days 1 to 7. At the first follow-up, the mean UCVA was 0.14 ±0.19 logMAR, which is better than 20/32 on the Snellen chart. Although iris capture with the haptics occurred in eight eyes, all were early in our learning curve. Of these, four resolved with pupil dilation and four required repositioning of the IOL.

Weeks 6 to 8. By 6 to 8 weeks postoperatively (Figure 2), mean UCVA improved to 0.05 ±0.15 logMAR, which is better than 20/25 on the Snellen chart. Furthermore, the mean BCVA was -0.05 ±0.10 logMAR, which is better than 20/20 on the Snellen chart. The mean sphere, cylinder, and spherical equivalent (SE) were 0.53 ±0.51 D, -0.83 ±0.41 D, and 0.27 ±0.36 D, respectively. There was one case of mild cystoid macular edema and one inferior curvature to the optic edge.

Month 6. At 6 months postoperatively (Figure 3), the mean UCVA remained stable and was still better than 20/25 on the Snellen chart (0.08 ± 0.14 logMAR). The mean BCVA had improved slightly to -0.04 ±0.08 logMAR, which is about 20/16 on the Snellen chart. The mean sphere, cylinder, and SE at this follow-up were 0.70 ±0.51 D, -0.68 ±0.48 D, and 0.43 ±0.42 D, respectively.

Month 12. In addition to mean UCVA (0.05 ±0.16 logMAR; better than 20/25 Snellen), BCVA (-0.05 ±0.1 logMAR; better than 20/20 Snellen), sphere (0.60 ±0.38 D), cylinder (-0.66 ±0.26 D), and SE (0.40 ±0.30 D), we also looked at the incidence of posterior capsular opacification (PCO) at 12 months postoperative (Figure 4). A score of zero indicated no PCO, whereas a score of 4 indicated PCO spread across the entire visual axis; the mean score was 0.39 ±0.48.

CONCLUSION

As our study results have shown thus far, the FEMTIS IOL is not only capable of achieving excellent refractive outcomes but of also achieving exceptional centration and stability (Figure 5) and perfect overlap of the rhexis and the optic. Although we only have a small subset of patients who have completed 12-month follow-up, our results in the current FEMTIS IOL study are significantly better than the results of other clinical trials with 12 months' follow-up, including the UK National Cataract Survey, the National Eyecare Outcomes Network, the Swedish National Cataract Register, and the Cataract National Dataset Electronic Multicentre Audit.

Even more exciting than our current outcomes is the promise that the FEMTIS IOL platform holds for the future, once toric and multifocal versions emerge. ■

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TILT EVALUATION AFTER FEMTIS IOL IMPLANTATION

Have we taken a step forward?

BY LUIS SALVÁ, MD; AND SCOTT ANDERSON GARCIÁ, MD

Technological advances in cataract surgery have greatly improved postoperative visual results. In return, patient expectations and demands in terms of their optical and refractive effects have increased. The use of the femtosecond laser in cataract surgery has been a great step forward in providing safety and reproducibility in the critical stages of cataract surgery, such as the capsulorrhexis and nucleus fragmentation. The FEMTIS IOL (Oculentis) takes advantage of the perfectly circular capsulorrhexis made by the femtosecond laser to anchor the IOL with specially designed haptics. As a result, the lens has greater stability and centration in the long-term.

In this preliminary phase of the lens' development, the FEMTIS is only available as a monofocal lens; however, it is expected to be very useful as a toric and multifocal platform in the near future, since these could be the designs that benefit the most from this novel idea.

In traditional lens implantation, the IOL is kept in place in the capsular bag by the back-pressure of the capsule against the haptics. Capsular shrinkage and fibrosis increase the pressure on the haptics, which can lead to decentration, tilt, and rotation of the lens and can result in induced higher-order aberrations (HOAs) and decreased optical quality of the visual system.

We recently investigated the tilt of the FEMTIS IOL, and these results are part of an international multicentered study led by Gerd U. Auffarth, MD, PhD, from the International Vision Correction and Research Centre and the David J. Apple Laboratory, University of Heidelberg, Department of Ophthalmology.

WHAT WE KNOW ABOUT IOL TILT

According to theoretical reports, coma increases with rising IOL tilt and decentration.[1,2] The impact of this misalignment depends on IOL design, and aberration-correcting IOLs seem to be very sensitive to decentration and tilt.[3] On the other hand, tilt angle has statically significant effects on the HOA profile using a physical eye model and traditional IOL inserted in capsular bag. In this last report,[3] the mean tilt was 5.7º. Further, Peng et al found that the IOL tilt in horizontal and vertical directions in eyes in which a manual capsulorrhexis was created was significantly higher than those in which a laser capsulotomy was created, with a mean tilt over 2.3°.[4]

On average, a 2º to 3º tilt is common. More than a 10º tilt and

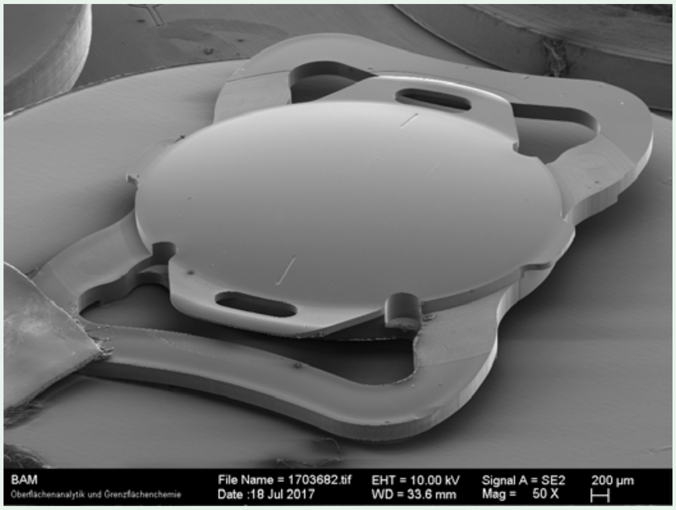

Figure 1. Image of the FEMTIS IOL taken by reflection electron microscope.

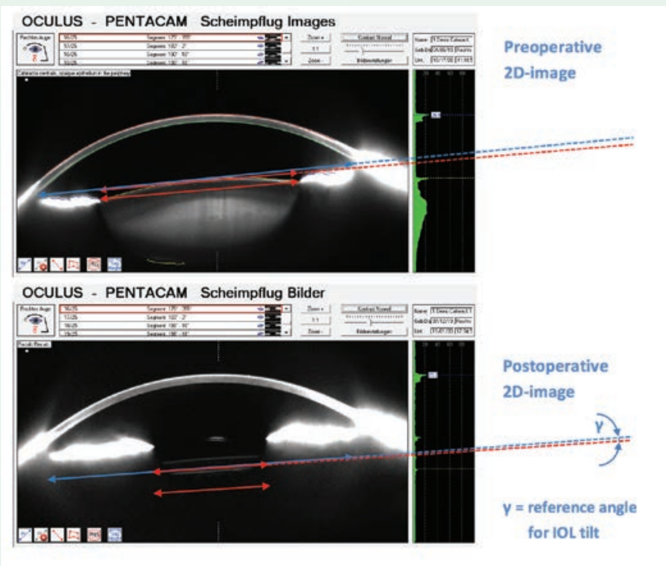

Figure 2. Method to assess IOL tilt.

above 1 mm decentration are occasionally reported with modern cataract surgery (about 10% of the pseudophakic population).[5] Mester et al compared the tilt and decentration of a one-piece aspheric IOL and the position of the natural crystalline lens in young individuals. As a result, all lenses were tilted upward (mean 2.2º, crystalline lens; 2.5º, IOL) and to the temporal side (mean 3.1º, crystalline lens; 2.6º, IOL).[6] Another report showed a mean optic tilt of 2.89º ±1.46 standard deviation (SD) for the spherical IOL and 2.85º ±1.36 SD for the aspheric IOL.[7] This finding indicates that a significant relationship is found between aspheric IOL tilt and internal coma aberration and suggests that the tilt of aspherical IOLs should be reduced as much as possible.[8]

ASSESSMENT OF FEMTIS IOL TILT

The FEMTIS IOL is a foldable hydrophilic acrylic lens (its material is known as *Hydrosmart*), with a biconvex aspheric optic with a continuous 360° barrier edge; the lens has marks on the front surface to aid in measuring rotation. The lens haptics have a clip design with barrier edge, with two longitudinal flaps and two small lateral flaps to hold the rhexis (Figure 1).

In the study, we implanted the FEMTIS IOL bilaterally in 25 patients, after a 4.8-mm capsulorrhexis was performed with the Lensar Laser System. In all cases, the capsulorrhexis was centered on the pupil. However, with this laser it is also possible to center the capsulorrhexis other references, such as the central axis of the lens, the visual axis, and, in special cases, kappa or alpha angle variations. Limbal markings at 0° and 180° were made preoperatively with the patient sitting upright and focusing on a distant target.

Measurement of lens position was performed at mydriasis with Pentacam Scheimpflug 2-D imaging before surgery and at 6 to 8 weeks and 6 months postoperatively. To achieve this, we drew a blue line on the Pentacam image to represent the plane of iridocorneal angle and a red line to represent the plane of visible crystalline lens (preoperative) or the implanted FEMTIS (postoperative). The angle γ between both is the lens position, which was evaluated both horizontally and vertically. Tilt (movement) was evaluated by calculating the differences between the pre- and postoperative lens positions (Figure 2).

PROMISING OUTCOMES

A total of 25 patients (average age, 75 years; range, 63–87) were included in the study. Preoperatively, the mean position of the crystalline lens was 0.04º horizontal and -0.17º vertical, which represents the natural angulation of capsular bag. Six to 8 weeks after cataract surgery and FEMTIS IOL implantation, the mean IOL position was -0.04º horizontal and -0.09º vertical. The most significant variable in this assessment was the average difference between preoperative and 6- to 8-week postoperative lens position showing the absolute value of tilt movement, which was quite low: 0.73º horizontal and 1.04º vertical (Table 1).

Six months after implantation, the mean IOL position was -0.12º horizontal and -0.28º vertical. The average tilt movement between preoperative and 6-month postoperative was 0.70º horizontal and 0.95º vertical. Finally, the mean tilt movement between 6 to 8 weeks postoperative and 6 months postoperative was 1.08º horizontal and 0.71º vertical. These results are, to date, much lower than those reported in the revised publications.

Optical and refractive variables were also promising. On average, from a preoperative UDVA of 0.56 logMAR (corrected 0.34), the group of patients implanted with the FEMTIS IOL achieved an UDVA of 0.15 logMAR within the first 7 days postop, 0.08 logMAR at 6 to 8 weeks, and 0.15 logMAR at 6 months. The mean preoperative spherical equivalent of refraction was 0.74 D, and then 0.09 D at 6 to 8 weeks postoperative and 0.16 D at 6 months.

From this study, we determined that the tilt evaluated with the FEMTIS IOL is quite low compared with the position of the lens preoperatively, and is also stable up to the preliminary follow-up of 6 months.

TABLE 1. HORIZONTAL AND VERTICAL LENS POSITIONS AND TILT AFTER FEMTIS IOL IMPLANTATION	Horizontal (degrees)	Vertical (degrees)
Lens position (Preoperative)	0.04	-0.17
IOL position (6 to 8 weeks)	-0.04	-0.09
Tilt (Pre- to 6 to 8 weeks postoperative)	**0.73**	**1.04**
IOL position (6 months)	-0.12	-0.28
Tilt (Preop to 6 months postoperative)	**0.70**	**0.95**
Tilt (6 to 8 weeks to 6 months)	**1.08**	**0.71**

CONCLUSION

We are currently expanding our experience with FEMTIS IOL implantation and extending follow- to assess long-term stability. While emerging designs of new IOLs offer improved quality of vision and therefore better quality of life, the optimum performance is widely affected by the position of the implanted IOL in the eye.

The FEMTIS system of hooking into the capsulorrhexis is a breakthrough that must be studied in the long-term as an option to enhance the predictability and stability of the IOLs. It is also possible that, in the future, this design could be used for toric and multifocal IOLs. ■

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ZEPTO: A VIABLE ALTERNATIVE TO THE FEMTOSECOND LASER FOR FEMTIS IOL IMPLANTATION

The Zepto creates a capsulotomy that is easy to stretch, making it ideal for use with a lens designed for fixation to a laser capsulotomy.

BY FLORIAN T.A. KRETZ, MD, FEBO

I started using the FEMTIS IOL (Oculentis) in 2014, when it first became available, as part of a multicenter clinical trial. At the time, I was practicing at the University of Heidelberg, one of nine centers participating in the multicenter trial. Like my colleagues, I was very impressed with the results we had with the IOL, and it was an easy technology to incorporate into practice. About 2 years ago, however, I started working at a new practice, Eyeclininc Ahaus-Raesfeld-Rheine, and I no longer had access to a femtosecond laser.

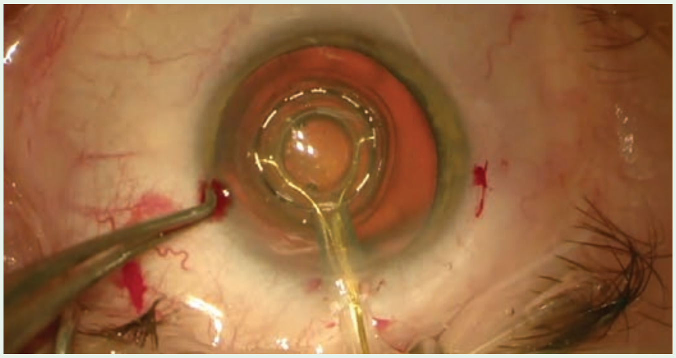

Figure 1. The Zepto is used to create a capsulotomy.

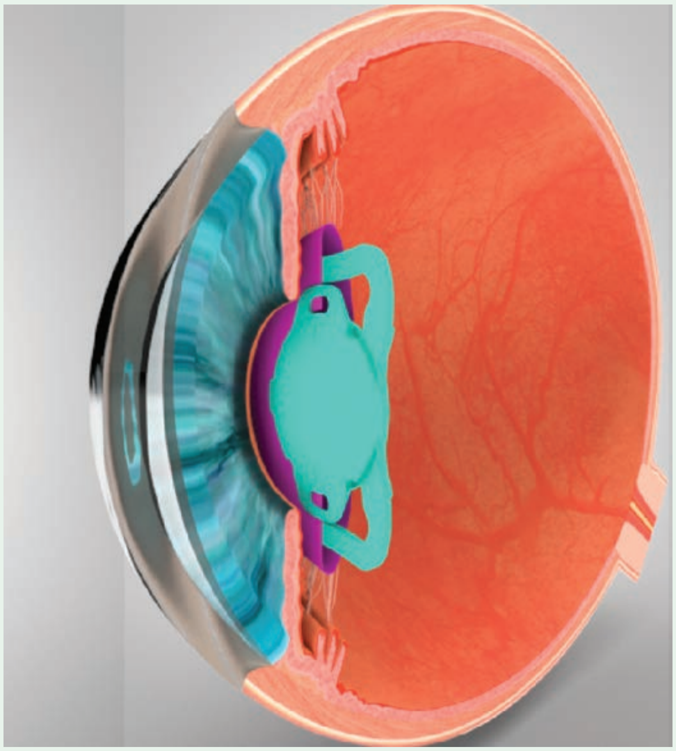

Figure 2. Due to the positioning of the FEMTIS IOL in the capsulotomy, there is no chance of IOL rotation or decentration.

As a result, I had to set aside the FEMTIS IOL, simply because it was not beneficial to implant without a femtosecond laser capsulotomy to clip it into—or so I thought.

About 2 months ago, Eyeclininc Ahaus-Raesfeld-Rheine purchased the Zepto Precision Pulse Capsulotomy device (Mynosys). From the first time that I used it, I found the capsulotomy produced by the Zepto was far more stable than a manual capsulorrhexis. I also noticed that the capsulotomy was much easier to stretch than the capsulotomy created manually or by a femtosecond laser.

The lightbulb immediately went off: Would it be possible to implant the FEMTIS IOL into a capsulotomy created by the Zepto? The FEMTIS lens has two standard plate haptics and four additional haptic flaps, or microhaptics, on the periphery on the lens optic. The two plate haptics are positioned in the capsular bag, and the four microhaptics pull over the edge of the capsulotomy, so that the whole lens is enclaved in the capsulotomy. Because of the stretchiness of the Zepto capsulotomy, I thought it would be an ideal combination with the FEMTIS IOL.

I spoke to Oculentis about my idea and asked if I could be the first to try implanting the FEMTIS within the Zepto-created capsulotomy (Figure 1). I was keen to do this because, the more I used the Zepto, the more I was convinced that the capsulotomy was far superior to those created manually or even with the femtosecond laser. Once I got the okay from Oculentis, immediately I lined up my first case.

CURRENT EXPERIENCE

I am the only person using the combination of the FEMTIS IOL and the Zepto, and to date I have completed four cases. Even with little clinical experience, I have already noticed several benefits. First, with regard to the FEMTIS IOL, I do not need to implant the lens under an OVD. Many surgeons do use an OVD during lens implantation, but with this lens I can use balanced saline solution, which unlike OVD does not have to be removed from the anterior capsule and from behind the IOL. One of the largest advantages this affords is that there is no chance of IOL rotation or decentration during aspiration (Figure 2).

PEARLS WITH THE ZEPTO AND FEMTIS

Centration of the Zepto capsulotomy can be a little bit challenging. There is a wire inside the device to guide the treatment; that wire is pulled back to apply the vacuum. If pulled too quickly, the suction cap of the device could shift, and the capsulotomy could become decentered. I recommend pulling the wire back with the vacuum pump already switched on. This will ensure that there is immediate suction on the anterior capsule when the wire is gone and that the device stays in place. Otherwise, the concept of the FEMTIS IOL—being locked in the capsulotomy in a stable position—is not advantageous, as it might be dencentered. Using this trick ensures the lens is positioned on the optical axis, whereas an intracapsular IOL would center on the capsular bag.

Another pearl is regarding patient selection. The FEMTIS IOL can be implanted in any eye in which a monofocal IOL is appropriate; however, I do recommend that the anterior chamber depth be around 2 mm if using the Zepto, so that there is enough space for the Zepto device to go inside and also for the instruments to fixated the FEMTIS IOL in the anterior capsulotomy.

Second, with regard to the Zepto, it is also possible to implant the FEMTIS IOL in eyes with small pupils. In these cases, the Zepto is simply placed underneath the iris. Third, the Zepto creates the capsulotomy in one complete motion, whereas with the femtosecond laser it is created with several. As a result, the femtosecond capsulotomy can have perforations that enlarge to tags.

CONCLUSION

In the little more than 2 months that I have been using the Zepto Precision Pulse Capsulotomy device, I have come to the conclusion that the capsulotomy it creates is more stable than the manual capsulorrhexis or the femtosecond capsulotomy and, therefore, more prudent for use with the FEMTIS IOL. ■

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THE ADVANTAGES OF A CAPSULE-CENTERED IOL

Controlling IOL centration is easy with the FEMTIS.

BY PATRICK VERSACE, MD

Lens implant surgery is now so accurate and predicable that up to 90% of patients can achieve spectacle independence after surgery. In large part, this is because lens materials, optical designs, and mechanical configurations give lasting refractive stability and biocompatibility. Another piece of this puzzle is that presbyopia and astigmatism are now commonly addressed at the time of lens implantation; however, the penetration of presbyopia-correcting IOLs remains relatively low—between 5% and 15% of all lens implants. In the next few years, the spread of postoperative results will continue to tighten, and nuanced advances in improved refractive predictability and quality of vision should occur. With it, the reduction of unwanted visual phenomena should allow presbyopia-correcting IOL use to become more mainstream.

The wide variety of approaches to presbyopia-correcting IOL design point to the fact that no single model is perfect and universally applicable. Most multifocal IOLs, whether bifocal, trifocal, or extended depth of focus (EDOF), use diffractive optics to generate the different focal points, otherwise called *range of focus*. Diffractive optics have the downside of producing unwanted visual phenomena in the form of glare, halos, and reduced image intensity due to loss of light inherent with the destructive component of the interference pattern (Figure 1), but they are an improvement on the refractive optics that were originally applied to multifocal IOLs. The refractive optic, as a symmetric zonal optic with concentric rings of different power, transmitted 100% of light but produced severe halos and glare.

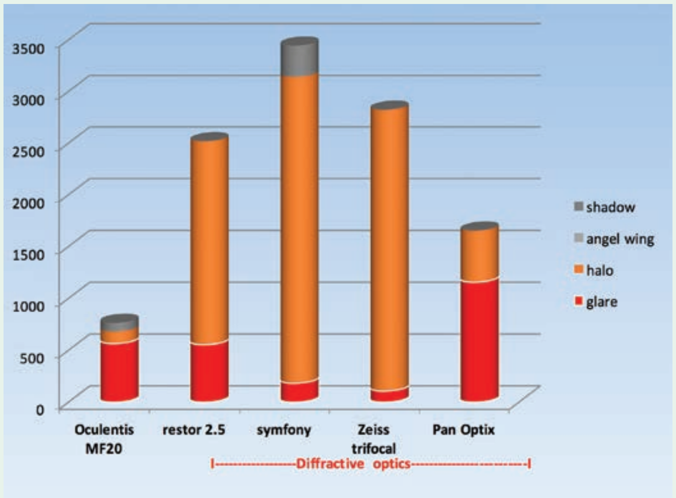

Figure 1. Glare and halos by IOL type

Another approach to achieving multifocality is an asymmetric segmental IOL. This type of IOL design, which can produce near and far images with minimal unwanted visual phenomena, is the basis for the range of presbyopia-correcting lenses made by Oculentis (Figure 2). The latest lens in this family is the FEMTIS Comfort IOL.

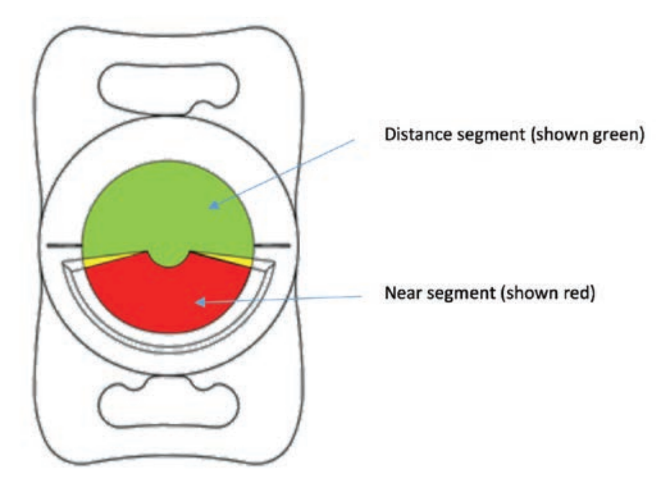

Figure 2. The LENTIS MF20 is designed as an asymmetric segmental refractive extended depth of focus IOL.

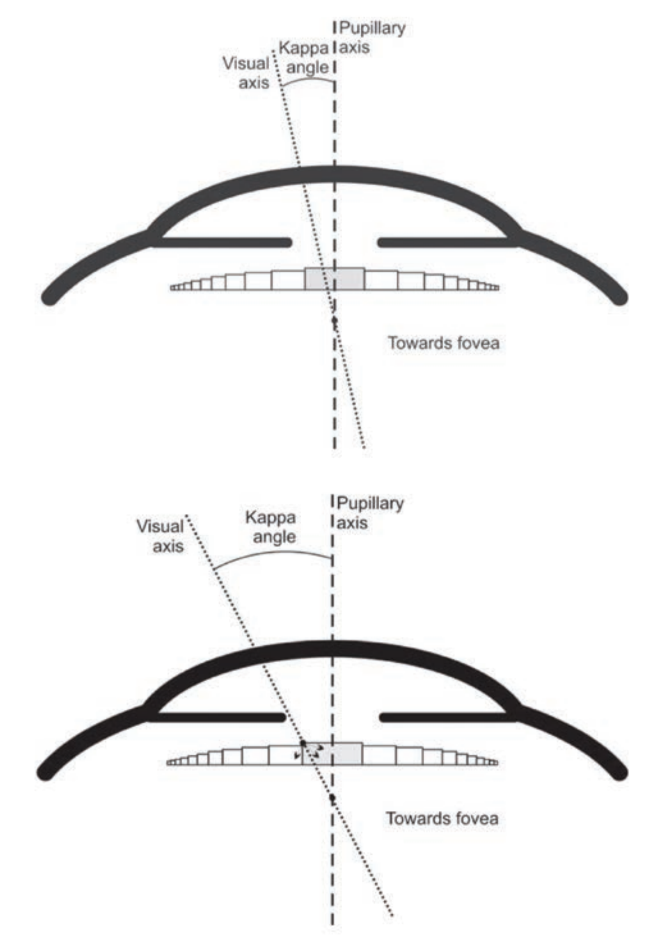

Figure 3. Critical value for angle Kappa: The offset of the visual axis required to cause a central ray to strike the first refractive ridge on the IOL.

IOL CENTRATION

Because multifocal IOLs have complex optics and rely on an excellent refractive outcome to produce high patient satisfaction, predictable effective lens position is crucial. In fact, it is the main source of refractive error after cataract surgery and refractive lens exchange. While the exact role of centration is poorly defined, there is evidence to show situations in which decentred multifocal IOLs cause problems.

Although it has been shown that visual phenomena can increase when a diffractive IOL is displaced temporally,[1] other studies have had mixed outcomes with IOL decentration. At the 2016 ESCRS meeting in Copenhagen, Denmark, we presented a study that looked at the size of angle kappa as it correlated to visual outcomes with both diffractive and asymmetric segmental refractive IOLs.[2] Our research confirmed that the most significant correlation of halos was IOL design, with diffractive optics having a significantly greater chance of resulting in large and intense halos as compared with an asymmetric segmental refractive lens. A large angle kappa also significantly correlated with subjective reporting of halos.

Diffractive multifocal IOLs are required to tolerate up to a 1-mm decentration before there is a reduction in modular transfer function. In practice, angle kappa will rarely be large enough to account for poor vision (an estimated critical value for angle kappa is 0.7 to 1-mm offset; Figure 3). For example, in our study, no IOL had a kappa offset of greater than 0.42 mm, which is well below critical values. It is, however, conceivable that the combination of a large nasal angle kappa and a lens displaced temporally could result in a large-enough displacement of the IOL center from the visual axis to cause visual problems.

A segmental refractive IOL has different requirements for centration. It is essential that the visual axis passes through the distance segment of the IOL. A superiorly displaced lens (with the near segment inferior) could result in the visual axis passing through either the near vision segment or the junction of the near and far segments. IOL centration becomes even more complex when we consider that the visual axis may be able to change after surgery.[3]

BENEFITS OF IOL ALIGNMENT WITH CAPSULORRHEXIS

Regardless of what may constitute correct IOL centration and the desired placement of an IOL in the eye, we have not been able to predictably alter the location of the lens at the time of surgery. The idea of nudging the IOL nasal after implantation is imprecise, and good lens design will cause an IOL to center on the capsular bag equator regardless of the offset of the visual axis. One approach to IOL positioning that does work, however, is attaching the IOL to the capsulorrhexis.

Femtosecond capsulorrhexis creation allows alignment of the capsulorrhexis with a known axis in the eye. The capsuorrhexis may be created to be concentric with the pupil, centered on the visual axis or on the capsular bag.

Attaching the IOL to the capsulorrhexis means the lens will

Figure 4. The FEMTIS Comfort's flange elements are placed anterior to the rim of the capsulorrhexis.

be perfectly aligned with the chosen axis, such as on the pupil, which may be beneficial for an apodized diffractive IOL, or on the visual axis, which compensates for angle kappa—something previously not possible. Perfect alignment of the IOL also allows more refined IOL design, as there is no longer a need to allow tolerance of up to 1 mm decentration from visual axis.

A CAPSULE-FIXATED IOL DESIGN

The FEMTIS (Oculentis) is an asymmetric refractive segmental, one-piece foldable acrylic IOL with an overall length of 10.5 mm, an optic of 5.7 mm, and soft flanges that allow easy attachment to the capsulorrhexis opening. Following routine femtosecond capsulotomy and cataract removal, the IOL is implanted into the capsular bag through a 2.2-mm incision and then attached to the capsulorrhexis margin. As there is a continuous flange into which the edge of the capsulorrhexis sits, the IOL is securely attached and the rhexis aperture held open.

The FEMTIS lens design incorporates docking apertures in the flanged element that sit anterior to the lip of the capsulotomy. This has future application for attaching clip-on secondary IOLs.

An EDOF version of the FEMTIS, based on the existing LENTIS Comfort IOL (Oculentis) platform, is now under clinical investigation. I first implanted the FEMTIS Comfort (Figure 4) 2 years ago, and I am now conducting a formal prospective trial to investigate the long-term stability and centration and general performance. Thus far, patients have achieved excellent spectacle independence and minimal unwanted visual phenomena. The ability to align this lens perfectly with the visual axis will ensure that the distance and near segment are always optimally positioned.

Even during the first implantations of the FEMTIS Comfort, surgery was routine with minimal extra effort to achieve attachment to the capsulorrhexis margin. Visual outcomes have been excellent, and patients seem to favor the assymetric segmental refractive design because of the absence of halos and the infrequency of other unwanted visual phenomena.

CONCLUSION

Alignment of the IOL with the visual axis by fixation to the capsulotomy makes sense and brings many benefits. The introduction of laser-assisted cataract surgery has made such alignment possible and has opened up new opportunities in lens design. ■

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Which lens would you rather have implanted?

Two-year postoperative comparison between a FEMTIS IOL implanted after an automated laser-assisted capsulotomy and a monofocal IOL implanted after routine manual capsulorrhexis. Both eyes belong to the same patient.

Courtesy of Detlef Holland, MD, nordBLICK Augenklinik Bellevue, Germany