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Highlights from the Visian ICL
Experts Meeting 2013

Decision-Making in Refractive Surgery

How to determine if a corneal- or lens-based approach is the best option.

BY ALAA EL-DANASOURY, MD, FRCS; ERIK L. MERTENS, MD, FEBOPHTH;
ROBERT P. RIVERA, MD; AMIR M. PARASTA, MD; AND ROBERTO ZALDIVAR, MD

ALAA EL-DANASOURY, MD, FRCS

When deciding between corneal- or lens-based options for refractive correction, I like to keep it simple. Therefore, my decision is to typically implant the Visian ICL or its toric counterpart, the Visian Toric ICL (both by STAAR Surgical), as long as the patient has a satisfactory spectacle corrected visual acuity and there are no surgical contraindications. Three exceptions to this rule are: (1) the patient's anterior chamber depth is less than 3 mm, (2) the eye has signs of nuclear sclerosis, or (3) the patient prefers laser vision correction and is a good candidate for LASIK or PRK.

There are, of course, a few key factors to keep in mind during patient selection. First, it is important to consider the amount of refractive error and the status of the cornea using topography and tomography to determine corneal thickness and posterior elevation and the patient's age. (I seldom implant a phakic IOL in patients over the age of 45 years.) Second, it is important to consider the patient's personal and family history to ensure there are no preconditions or possible pathologies that could negatively affect the postoperative outcome.

With that said, I use the following algorithm (also depicted in Figure 1) to determine my surgical course of action for patients under the age of 45 years who have a refractive error somewhere between -18.00 to 10.00 D. If there is greater than -8.00 D of myopia or 4.00 D of hyperopia, I implant the Visian ICL or the Visian Toric ICL if the patient has astigmatism. I present both options (phakic IOL and LASIK) to the patient if his or her refractive error is between -8.00 and -6.00 D, explaining that the Visian ICL is the better option compared with LASIK. If there are no contraindications to either procedure, I perform whichever is the patient's first choice. Lastly, if the refractive error is between -6.00 and 4.00 D, I implant the Visian ICL or Visian Toric ICL if there is any suspicion of or obvious contraindication to LASIK. If the refractive error is between -1.00 and -6.00 D and there is no risk of ectasia, I usually offer femtosecond LASIK.

As a quick snapshot of the surgical distribution of my procedures in the last 9,536 eyes I treated, 100% of the procedures I performed in eyes with myopia greater than -10.00 D and 90% with a refractive error between

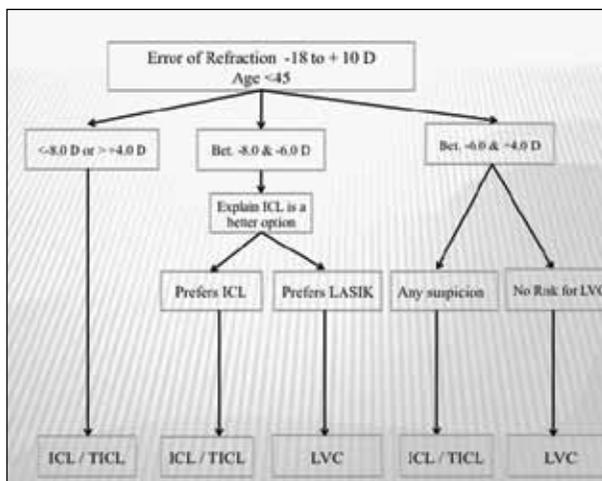


Figure 1. Dr. El-Danasoury's algorithm for refractive surgery.



Figure 2. Distribution of refractive surgery procedures in 9,536 eyes.

-8.00 and -10.00 D were with the Visian ICL. Likewise, in 90% of eyes with a refractive error of more than 6.00 D, I implanted the Visian ICL (Figure 2).

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ERIK L. MERTENS, MD, FEBOPHTH

In today's fast-paced world, patients are looking for a surgical option that not only provides excellent outcomes but ensures fast visual recovery with minimal hassle for the patient.

In my clinic, the Visian ICL plays an integral role in treating refractive errors, and it is what I consider to be a premium choice for my patients. Not only is this lens versatile enough to treat a wide range of refractive errors and can be successfully used in a variety of circumstances—including patients with dry eye—it also eliminates the need for an extra preoperative visit. The Visian ICL CentraFLOW with the KS-AquaPORT* eliminates the need for an iridotomy/iridectomy, causes less ocular inflammation, and provides a more natural flow of aqueous.

For every 10 patients who are happy when they leave my clinic, I can safely assume that two new patients will enter my clinic based on a referral from a friend or family member. However, I also know that it only takes one unhappy patient to scare away 10 others. Patient selection, therefore, is not only a crucial component for successful postoperative outcomes but also for the success of my clinic.

My decision tree for treating refractive errors is depicted in Figure 3. I must decide between three procedures: implantation of the Visian ICL or Visian Toric ICL, LASIK, or laser-assisted cataract surgery. In short, I perform laser-assisted cataract surgery in every patient with a refractive error who is between the ages of 50 and 90 years. In patients between the ages of 30 and 40 years, I prefer laser-assisted cataract surgery only if there is -20.00 to -30.00 D or more than 10.00 D of refractive error. For patients with refractive errors between 10.00 and -20.00 D, I choose between the Visian ICL or Visian Toric ICL and LASIK. I prefer LASIK only for refractive errors between 2.00 and -6.00 D.

Using this algorithm, I have had successful postoperative outcomes and a low rate of lens opacities over the past 8 years, as only 0.3% of the 1,350 eyes implanted with the Visian ICL have developed a cataract. With the Visian ICL CentraFLOW, no eyes to date have experienced cataract formation.

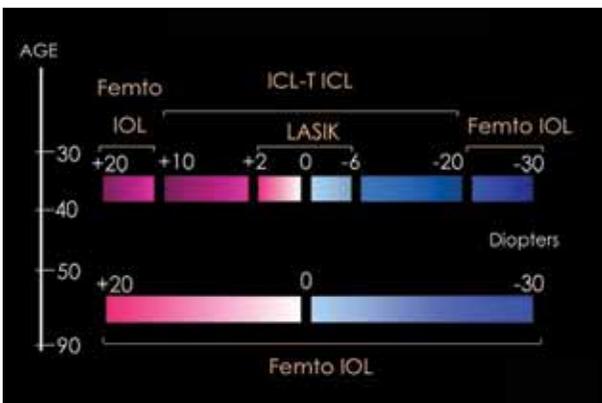


Figure 3. Dr. Mertens' decision tree for treating refractive errors.

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*The KS-AquaPORT was named after and developed in cooperation with Kimiya Shimizu, MD, of Japan.



ROBERT P. RIVERA, MD

A decision tree is a diagram in which the selection of each branch requires that some type of logical decision be made. To me, the Visian ICL is a logical choice in so many instances because not only do patients appreciate the premium nature of the surgery, but its visual results truly equate to ultra-high definition. Likewise, the Visian ICL does not limit future procedures and is easily removed if necessary. Lastly, the Visian ICL works in a broad range of cases that are not suitable for laser vision correction, including treating residual refractive error in patients with stable keratoconus, corneal scars, dry eyes, collagen vascular diseases, and high refractive errors.

Laser vision correction is the appropriate choice in some instances. I perform laser vision correction when: (1) the patient cannot afford premium Visian ICL surgery, (2) the anterior chamber depth is less than 2.8 mm, (3) the patient has multiple iris cysts, detected by ultrasound biomicroscopy, (4) when the refractive error is too small, and (5) in some cases when the patient has tomophobia, the fear or anxiety caused by surgical procedures and/or medical interventions.

I will not perform laser vision correction or implant the Visian ICL if the patient has one of the following: glaucoma, iritis, or early or advanced cataract. In the first two scenarios, it is important to treat the pathology, not the refraction. In the latter, it is acceptable to treat both the pathology and the refraction; however, refractive lensectomy is a better option, and we have had good results with multifocal IOL technologies in these cases.

My first choice is always the Visian ICL. Offering this as a premium procedure differentiates me from my colleagues, and the lens is poised to grow and mature in a world of laser refractive surgery. As more patients continue to investigate their refractive options, Visian ICL surgery will become increasingly attractive to them. As long as there is no contraindication, they will receive this lens at my clinic.

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AMIR M. PARASTA, MD

In our refractive clinic, a refractive advisor (optometrist) always performs the initial consultation with any patient. Most of the time, the consultation lasts 60 minutes, of which



Figure 4. Dr. Parasta's guidelines for recommending the Visian ICL.

20 are spent discussing the available refractive methods we offer (Visian ICL, LASIK, and multifocal IOLs), their advantages, and the aptitude with which we use them. The optometrist then segues into the patient's specific case, and the remainder of the time is used to determine the most suitable method for that patient. In many instances, this is the Visian ICL.

Our guidelines for recommending the Visian ICL are detailed in Figure 4 and outlined here: For patients with a refractive error below -6.50 D and a residual stromal bed above 300 μm and a pupil size smaller than 7.5 mm, we recommend LASIK. If the refractive error is greater than -6.50 D or the pupil is large, we recommend the Visian ICL. Lastly, if the patient is over the age of 50 years and has fewer than 4.00 D of accommodation, we recommend refractive lens exchange with implantation of a multifocal IOL.

When LASIK is performed in an eye with more than -6.50 D of refractive error, there is a higher incidence of halos and starbursts and a greater chance for relift or laser enhancement. It is, however, a cheaper option. Although the Visian ICL is more of a financial investment, there is no risk for starbursts or halos, the lens is removable, and the patient will achieve high-definition vision in both daylight and nighttime conditions. Likewise, eyes with large pupils do better with the Visian ICL, because there is no transition zone.

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ROBERTO ZALDIVAR, MD

Over the years, the breadth of refractive errors I treat with the Visian ICL has expanded. In the early and mid 90s, I implanted the Visian ICL only in eyes with refractive errors between -20.00 and -10.00 D and between

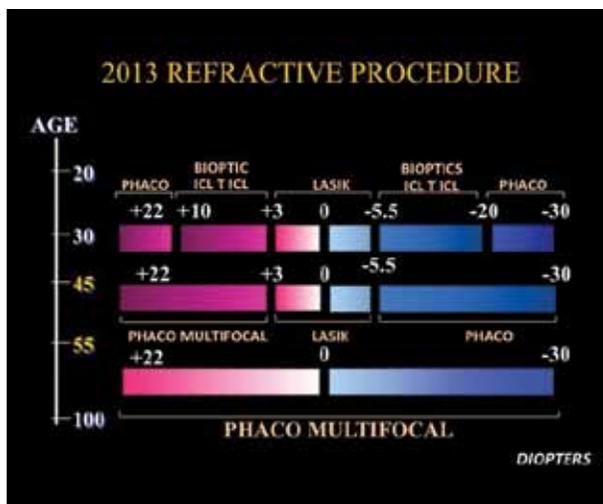


Figure 5. Dr. Zaldivar's algorithm for refractive surgery.

6.00 and 10.00 D. By 1996, I began using bioptics, where I perform LASIK 1 month after phakic IOL implantation in order to treat high and extreme refractive errors. During this time, my indications expanded to include eyes with refractive errors ranging from -22.00 to -8.00 D and from 4.00 to 10.00 D. Then, in 2004, when the Visian Toric ICL became available for the correction of astigmatism, my indications again expanded. Now, I use either the Visian ICL or Visian Toric ICL for refractive errors ranging from -22.00 to 10.00 D. My algorithm for refractive surgery is detailed in Figure 5.

I prefer cataract surgery in the following instances: for refractive errors ranging from 22.00 to 10.00 D and -20.00 to -30.00 D in patients who are between the ages of 20 and 30 years, for refractive errors ranging from 22.00 to 3.00 D and from -5.5 to -30.00 D in patients between the ages of 45 and 55 years, and for 100% of cases in patients over the age of 55 years. I typically use a multifocal IOL in these procedures.

I prefer bioptics in my younger patients (20 to 30 years) when their refractive error is between 10.00 and 3.00 D or -5.50 to -20.00 D. Lastly, I prefer LASIK in all patients between the ages of 20 and 55 years who have refractive errors of 3.00 to -5.50 D.

The Visian ICL or Visian Toric ICL is the best choice if a patient's cornea is suspicious (ie, keratometry greater than 48.00 D), if pachymetry is less than 480 μm, if the posterior corneal surface is suspicious, or in the presence of asymmetric astigmatism.

The indications for Visian ICL implantation at my clinic have grown substantially over the past 20 years, and I suspect that they will continue to grow over the next 20 years.

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Visian ICL: My Preferred Choice

This lens delivers 'high-definition' quality of vision with proven stability and a highly predictable refractive correction.

BY ALAA EL-DANASOURY, MD, FRCS

In my opinion and with my experience, and for more reasons than I can count, phakic IOLs are preferable over corneal laser surgery for the correction of refractive errors. There is, however, a potential for complications as a result of improper implantation or selecting the wrong phakic IOL model. In that vein, the Visian ICL (STAAR Surgical) is my lens of choice.

In order to have success with phakic IOLs, the surgeon must not only adhere to several safety parameters but also select an appropriate lens for implantation. A good phakic IOL will meet the following criteria:

- Excellent biocompatibility, with minimal risk for long-term damage to ocular tissues;
- Complete stability inside the eye;
- Good predictability for a full range of correction, including astigmatism;
- Excellent quality of vision with proven long-term outcomes;
- Fast visual recovery; and
- Easy to remove or exchange.

BIOCOMPATIBILITY

Early phakic IOLs, which were angle-fixated and intended for implantation in the anterior chamber, had a high incidence of endothelial cell loss, decentration, anterior chamber angle damage, glaucoma, and hyphema.¹ Many of today's anterior chamber models usually avoid a majority of these issues after surgery and, according to some studies, can produce postoperative endothelial cell loss that is not any higher than natural atrophy.² Of the two current models, iris- and angle-supported, the latter are the most risky to the endothelium,³⁻⁶ and data suggests that the former may induce significant loss of endothelial cell count. Results of a 10-year study by Tahzib et al,⁶ for instance, showed that the mean endothelial cell loss was $-8.86 \pm 16.01\%$ (standard deviation), with a minimum and maximum of -51.69% and 34.43% , respectively (Table 1).

Endothelial cell loss is the most undesirable long-term complication after phakic IOL implantation. Not only is it irreversible, but it is difficult to treat. Clinically speaking, the typical presentation of endothelial cell loss is patient complaints of transient, steamy vision, especially in the morning (Figure 1). If left untreated, endothelial decompensation can occur (Figure 2). Other problems with selecting an inappropriate phakic IOL or improper implantation include corneal edema (Figure 3) neces-

sitating eventual corneal transplantation and chronic uveitis (Figure 4).

Alternatively, a phakic IOL implanted in the posterior chamber, like the Visian ICL, may provide a safer option for the endothelium. These lenses are implanted behind the iris and further away from the cornea, and in my practice this results in a lower loss of endothelial cells over time.

In my experience, the incidence of cataract formation occurs in less than 0.5% of cases. The unique Collamer material from which the Visian ICL is made may be one of the reasons for this cataract rate.

Cataract formation is more likely to occur in patients over the age of 40 years, with more than 12.00 D of



Figure 1. Patient complaints of transient, steamy vision is an indication of endothelial cell loss.

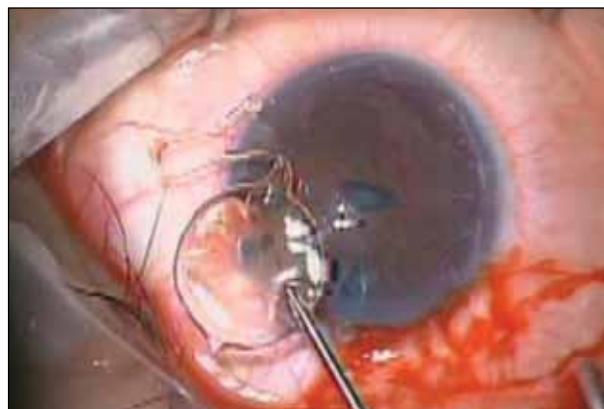


Figure 2. Presence of endothelial decompensation was seen in this eye 3 years after implantation of an angle-supported phakic IOL.

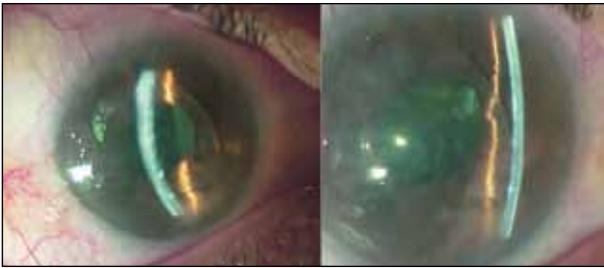


Figure 3. Presence of corneal edema was seen in this eye 11 years after implantation of an iris-fixed phakic IOL.



Figure 4. Chronic uveitis was seen in this eye 1 year after implantation of a foldable iris-fixed IOL.

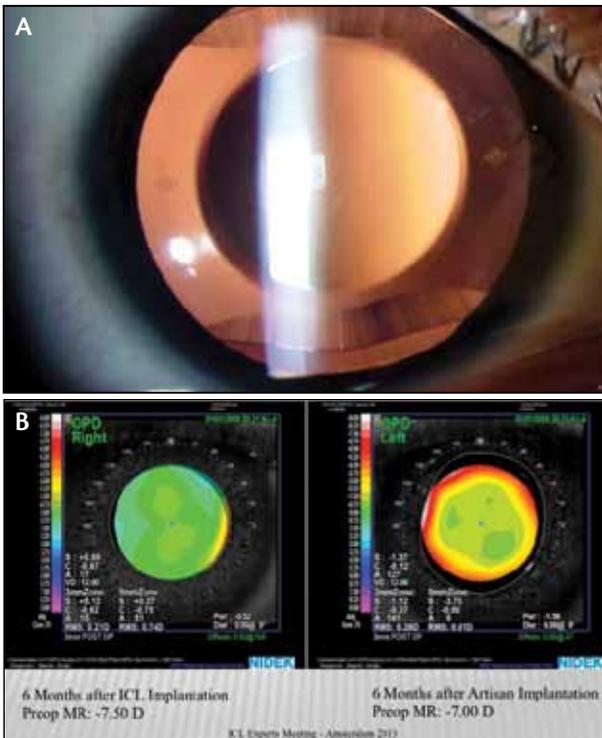


Figure 5. The Visian Toric ICL has great rotational stability (A,B).

myopia, and with fewer than 80 μm of vault. It could also occur if peripheral lens touch occurs after implantation and with a poor surgical technique.

STABILITY INSIDE THE EYE

Once a phakic IOL begins to move inside the eye, there will undoubtedly be negative side effects. First, it can cause chronic low-grade inflammation. Second, it can damage the structures of the anterior chamber. Third, astigmatism is no longer able to be corrected. Additionally, an unstable iris-fixed model can rub against the iris, trigger endothelial damage and refractive changes, and lead to iris piercing and sagging of the lens, and an unstable angle-supported model can rotate.

With the Visian ICL, surgeons can avoid these negative side effects because a properly sized Visian ICL remains stable within the posterior chamber. Using an undersized Visian ICL, however, can cause rotation. Additionally, the Visian Toric ICL is rotationally stable and can be used to correct astigmatism (Figure 5).

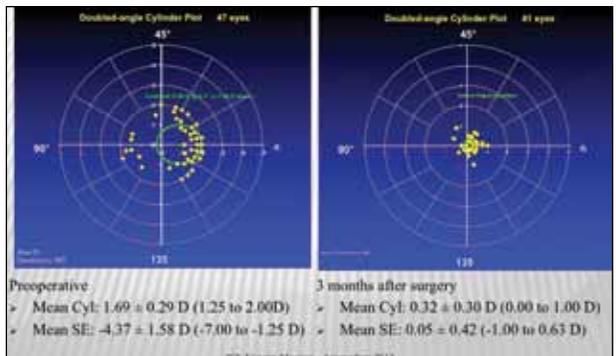


Figure 6. The Visian Toric ICL in eyes with low cylinder.

EFFICACY, PREDICTABILITY, AND QUALITY OF VISION

All phakic IOLs have excellent predictability in correcting myopia; however, toric designs are essential to achieve excellent outcomes in more than 50% of today's patients. The Visian Toric ICL not only offers a wide range of refractive corrections, but it also corrects astigmatism. With more than 10 years of market availability, the Visian Toric ICL has proven itself as an excellent treatment modality for patients with myopia or hyperopia with astigmatism.

According to my results of 47 eyes implanted with the Visian Toric ICL, the mean cylinder improved from 1.69 ± 0.29 D (range, 1.25–2.00 D) preoperatively to 0.32 ± 0.30 D (range, 0.00–1.00 D) 3 months postoperatively. The mean spherical equivalent also improved in this same time frame, from -4.37 ± 1.58 D (range, -7.00 to -1.25 D) preoperatively to 0.05 ± 0.42 D (range, -1.00 to 0.63 D) 3 months postoperatively (Figure 6).

A large functional optical zone (FOZ) is crucial for the success of refractive results and to maintain quality of vision after phakic IOL implantation (Figure 7). Posterior chamber phakic IOLs including the Visian ICL have larger FOZs for the same amount of correction than anterior chamber lenses. Another reason that the Visian ICL has a high quality of vision is because it

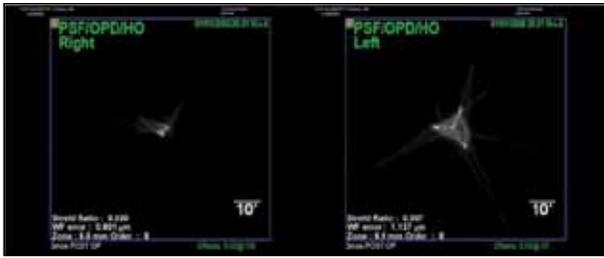


Figure 7. The Vision ICL has a large FOZ, resulting in better quality of vision.

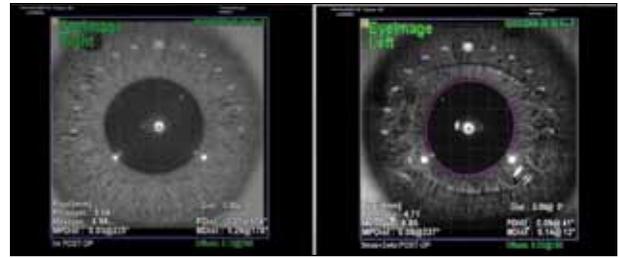


Figure 8. The Vision ICL sits closer to the nodal point than other phakic IOLs.



Figure 9. The Compact Touch software (Quantel Medical) can help with sizing the Vision ICL.

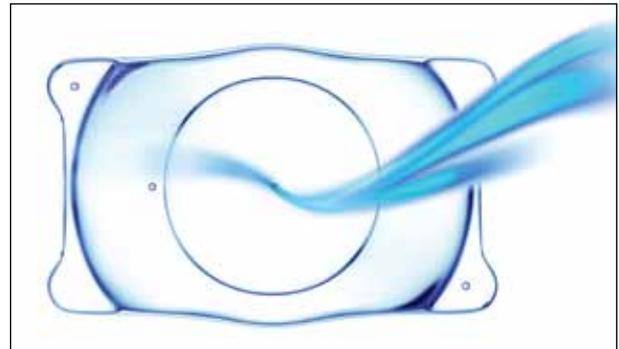


Figure 10. The Vision ICL CentraFLOW ensures better and more physiologic aqueous flow.

sits closer to the nodal point than other phakic IOLs (Figure 8).

OTHER POINTS

In addition to the points mentioned above, sizing of the Vision ICL was made more predictable in my clinic using high-frequency ultrasound and modern anterior segment imaging tools (Figure 9), including optical coherence tomography and Scheimflug imaging. The latest model, the Vision ICL CentraFLOW has a central hole ensuring a better and more physiologic aqueous flow (Figure 10).

No one looks forward to the potential for lens removal or exchange, but the beauty of the Vision ICL is that, in the rare chance that it does need to come out of the eye, explantation is easy.

CONCLUSION

There are many advantages to phakic IOL implantation, and our current postoperative results are excellent. Based on my experience, Vision ICLs are safe, effective, and offer patients a full range of refractive correction. In the future, the availability of new phakic IOL designs, such as aspheric and multifocal, will help refine results even more.

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TABLE 1. MEAN ENDOTHELIAL CELL LOSS

Time after Surgery	Mean (%)	SD (%)	Minimum (%)	Maximum (%)
1 year ⁽¹⁾	-3.3	5.6	-13.0	+8.73
2 years ⁽²⁾	-5.0	5.9	-17.6	0
3 years ⁽³⁾	-5.1	NA	-11.7	-0.7
10 years ⁽⁴⁾	-8.86	16.01	-51.69	+34.43

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The New Visian ICL Preloaded

Increasing efficiency and improving the patient experience, this lens can be implanted in the eye with fewer manual steps.

Just recently, in order to eliminate the need for Nd:YAG capsulotomy in conjunction with phakic IOL implantation, STAAR Surgical introduced CentraFLOW technology using the KS-AquaPORT. This innovation improved not only surgical outcomes but also surgeons' ease of use. Now on the heels of that introduction, STAAR Surgical is releasing soon another innovation that further helps make the Visian ICL the fastest growing refractive technology in the world, the Visian ICL Preloaded (Figure 1).

With the Visian ICL Preloaded system, the lens comes pre-packaged inside a cartridge and injector, thus reducing the number of manual steps required to deliver the lens into the eye while simultaneously maintaining a continuous sterile pathway into the eye. The preloaded model of the Visian ICL is made of the collamer lens material with proven biocompatibility and high-definition optics. The lens is available with a larger optical zone in most diopters.

With the Visian ICL Preloaded system, the lens comes pre-packaged inside a cartridge and injector, reducing the manual steps required to deliver the lens into the eye.

The proprietary system provides surgeons and their surgical teams with the means to (1) increase their efficiency in the operating room, due to a reduced number of instruments required for implantation (Figure 2), (2) maintain a continuous sterile pathway into the eye, (3) enhance reliability of the lens' delivery, and (4) improve the patient experience, as the lens can be delivered through a small incision. Additionally, the Visian ICL Preloaded reduces the learning curve for new Visian ICL users. For a video of the first implantation of the Visian ICL Preloaded, visit eyetube.net/?v=sepih (Courtesy of Juan Batlle, MD).

TIME AND MOTION STUDY

In September 2013, Erik L. Mertens, MD, FEBOPhth, Medical Director and founder of the Medipolis Eye Centre in Antwerp, Belgium, conducted a time and motion study



Figure 1. The Visian ICL Preloaded is a proprietary system.

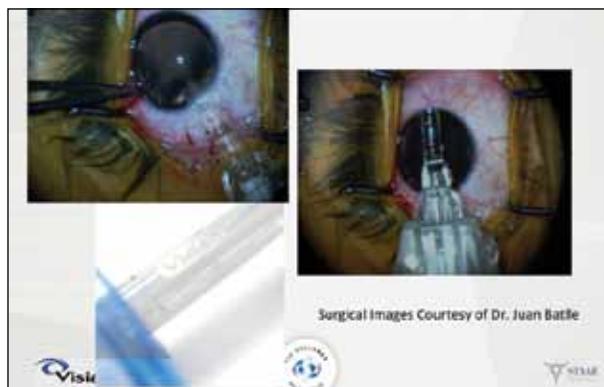


Figure 2. With the new preloaded version, fewer instruments are required to implant the Visian ICL.

Photos courtesy of Juan Batlle, MD

to compare the lens preparation and in vitro injection times with the Visian ICL Preloaded and standard Visian ICL models. Dr. Mertens concluded that the Visian ICL Preloaded saved 12 surgical steps; whereas implantation of the nonpreloaded Visian ICLs required 23 steps, the preloaded model required only 11. For a video illustrating the preparation of the Visian ICL Preloaded, visit eyetube.net/?v=rosuq (Courtesy of Juan Batlle, MD).

Dr. Mertens also found that standard Visian ICLs required more time for lens preparation, including 2:42 for lens handling. However, the Visian ICL Preloaded required only 0:51, representing a 68% reduction in lens preparation time.

"The Visian ICL Preloaded will allow me to focus more on the surgery itself and less on loading the lens," he said. "Experienced Visian ICL users will gain additional time and efficiencies." ■

