

Avoiding Complications With Phakic IOLs

The Visian ICL

By Theodore Perl, MD



The problems that ophthalmologists may encounter when implanting the Visian ICL (STAAR Surgical Company, Monrovia, CA) can be categorized as preoperative, intraoperative, and postoperative. The pearls I present herein may help to decrease complications with this lens, particularly among surgeons who are learning to implant it.

PREOPERATIVELY

Proper patient selection is critical in avoiding complications with the Visian ICL. For example, the FDA approved this IOL for use in patients who are 21 to 45 years of age. Operating on patients who are older than 45 years is considered an off-label use of the device. Compared with younger individuals, they will have a higher preoperative incidence of opacified crystalline lenses, and some of these patients will develop visually significant cataracts postoperatively due to naturally occurring progression of their cataract.

Shallow anterior chambers predispose the eye to crowding of the angle and thus heighten the likelihood that a patient will develop glaucoma or experience an increased loss of endothelial cells. The FDA approved the Visian ICL for use in eyes with an anterior chamber depth (corneal endothelium to the anterior capsule of the crystalline lens) of 3.0 mm or greater. With experience, many surgeons can safely implant this lens in eyes that have an anterior chamber depth of 2.8 to 3.0 mm, but it is considered an off-label use.

A peripheral iridotomy is mandatory to avoid pupillary block and angle-closure glaucoma. Often, severe myopes have early changes to their crystalline lens, which mysteriously can appear more significant 1 day after the ICL's implantation than during their preoperative evaluation. High myopes therefore may be better candidates for refractive lens exchange. Minimal lenticular opacification or visually insignificant early lenticular changes should not, in and of themselves, be considered a contraindication to the ICL's implantation. A retinal evaluation is mandatory for identifying retinal tears or holes, which should be treated before the ICL's implantation in order to reduce the likelihood of a postoperative retinal detachment. The surgery itself should not significantly increase the patient's risk of a retinal detachment, but high myopes are predisposed to detachments due to an inherent weakness in the retina.

The generally accepted range of cumulative loss of endothelial cells after the ICL's implantation is approximately 9% over the first 4 years. It is therefore important to select patients whose endothelial cell density and morphology are normal. The minimum requirements for preoperative endothelial cell density are based on the patient's age and are available from STAAR Surgical Company (Table).

The ICL is available in four diameters: 12.1, 12.6, 13.2, and 13.7 mm. Suggested sizing and power calculations are available through the company's Web site, and I have found the nomogram to be remarkably accurate. Precise preoperative measurements of the corneal curvature, pachymetry, anterior chamber depth, and horizontal white-to-white are critical to ensuring the lens' proper size and power and reducing the likelihood that the ICL will need to be exchanged.

TABLE. THE MINIMUM REQUIREMENTS ON ENDOTHELIAL CELL DENSITY FOR THE VISIAN ICL

Patient's Age, y	Minimum ECD, cells/mm ²		
	ACD ≥ 3.0 mm	ACD ≥ 3.2 mm	ACD ≥ 3.5 mm
21 to 25	3,875	3,800	3,250
26 to 30	3,425	3,375	2,900
31 to 35	3,025	2,975	2,625
36 to 40	2,675	2,625	2,350
41 to 45	2,350	2,325	2,100
≥ 45	2,075	2,050	1,900

Abbreviations: ECD, endothelial cell density; ACD, anterior chamber depth.



Figure 1. A well-dilated pupil makes it easier to position the Visian ICL's footplates in the posterior chamber.

INTRAOPERATIVELY

Peribulbar anesthesia helps to reduce the incidence of intraoperative complications in surgeons' first cases. With more experience, they will find topical/intracameral anesthesia to be sufficient.

The intraoperative technique begins with loading the ICL into the injector cartridge. It is important to get a substantial bite (all the way up to the proximal centering dot in the lens) prior to pulling the ICL into the tip of the injector. Grasping a smaller piece of the ICL can tear the haptic and render the lens unusable. The surgeon should be certain to line up the positioning holes superiorly so that the lens will unfold properly. The excessive use of viscoelastic in the anterior chamber prior to the ICL's insertion can cause the lens to move anteriorly toward the cornea. If in doubt, the surgeon can inject additional viscoelastic between the ICL and cornea to move the lens posteriorly and to deepen the anterior chamber.

When placing the footplates into the posterior chamber, the surgeon should be certain to engage the haptics as distally as possible. He or she must be careful not to let the instrument slip off the footplate and contact the

crystalline lens. A maximally dilated pupil facilitates positioning the footplates in the posterior chamber (Figure 1) but permits them to dislocate into the anterior chamber more readily. Learning to work through a nearly, but not maximally, dilated pupil will allow for the ICL's easy insertion without dislocation. The surgeon should always avoid contact with the optic of the ICL, which is the thinnest part of the lens and may be as thin as 20 μm . Contact with this area can damage the optic as well as cause anterior subcapsular opacification.

POSTOPERATIVELY

The surgeon should remove all viscoelastic and measure the IOP 1 to 2 hours postoperatively. If the pressure is elevated and the patency of the iridotomy is uncertain, then it may be necessary to enhance the peripheral iridotomy. In order to reduce the likelihood of postoperative glare, halo, or other nighttime visual symptoms, the surgeon should ensure that the ICL is well centered before constricting the pupil with Miochol-E (Novartis Ophthalmics, Inc., Duluth, GA).

CONCLUSION

I recommend that surgeons adhere to the FDA's guidelines in terms of patient selection and operative technique when they are getting started implanting the Visian ICL. With greater experience and full informed consent as to the device's off-label use, ophthalmologists can perform surgery under topical anesthesia in eyes with shallower anterior chamber depths. Precise attention to detail, in their preoperative measurements and surgical technique, is necessary to reduce the likelihood of complications and to maximize outcomes and patients' satisfaction.

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The Verisyse Lens

By David R. Hardten, MD



Phakic IOLs are an important addition to the refractive surgical armamentarium, and they are particularly useful for correcting high ametropia in patients who do not have advanced presbyopia or cataracts. These lenses can address significant refractive error without immediately causing presbyopia (as might refractive lens exchange) or inducing

irregular astigmatism and optical aberrations (as might corneal refractive surgery). Avoiding complications with these versus other types of IOLs, however, may be less familiar to surgeons. The most feared problems are cataract formation, the loss of endothelial cells, glaucoma, endophthalmitis, and damage to the iris. Less severe but still of concern are irregular astigmatism from the wound as well as residual refractive error and dry eye.

The Artisan/Verisyse IOL (Ophtec BV, Groningen, The Netherlands/Abbott Medical Optics Inc., Santa Ana, CA) is an iris-supported phakic lens that is currently approved



Figure 1. Scheimpflug imaging reveals a moderate increase in the lens' density. In an eye with significant nuclear sclerosis or epinuclear thickening, continued cataract progression after a phakic IOL's insertion will necessitate the IOL's removal and cataract surgery in the near future. Refractive lens exchange is typically a better option for the correction of myopia in these eyes.

in the United States for the treatment of myopia. A gap in the haptic of the IOL grasps a portion of the midperipheral iris stroma. This article shares advice on how to minimize complications with this lens.

CATARACT

The risk of cataract with the Verisyse is minimal, because the IOL is placed in the anterior chamber and sits relatively far from the crystalline lens. During the IOL's insertion, however, it is possible to touch the natural lens, so surgeons must take care to avoid touching its anterior portion.

Because cataract is a common condition in the highly myopic population, a close analysis of the crystalline lens preoperatively can help to identify patients with opacity

that could progress after a phakic IOL's insertion. If the patient already has some cataract, then a refractive lens exchange may be a better choice than the implantation of a phakic IOL for correcting his or her refractive error. Scheimpflug analysis of the crystalline lens may also help to identify eyes with significant lenticular density that may be better suited to refractive lens exchange than a phakic IOL's insertion (Figure 1).

If a cataract develops after the Verisyse's implantation, I usually remove the IOL through a separate scleral incision. After this incision's closure, I can use a typical clear corneal incision for the cataract procedure. I may need to adjust the axial length measurement according to a formula published by Hoffer.¹

ENDOTHELIAL DAMAGE

In the FDA clinical trial of the Verisyse lens, investigators measured the anterior chamber with ultrasound, and an anterior chamber depth of more than 3.2 mm from the corneal surface was required for the IOL's insertion.² The investigators visually inspected the angle at the slit lamp to detect abnormally narrow angles. Even with this type of screening, the rate of endothelial loss was quite low, and complications related to iris damage were quite infrequent. In measurements using standardized calibration, endothelial cell counts decreased by $1.7\% \pm 5.4\%$ over 3 years on average.² Much of the early loss is likely a redistribution of the cells from near the incision, so it is likely that the loss of endothelial cells slows over time, except in eyes where the IOL is close to the endothelium in the midperiphery. No patient experienced a persistent increase in IOP. Pupillary ovalization was observed in 1.7% of eyes at the 6-month visit. Nuclear sclerot-

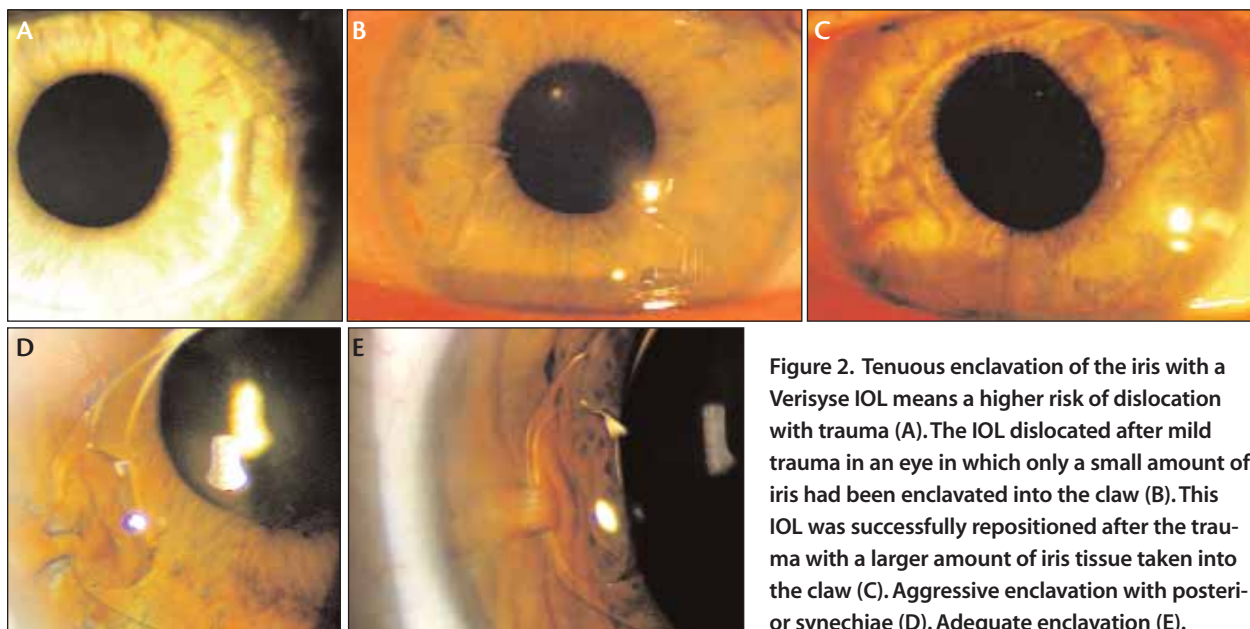


Figure 2. Tenuous enclavation of the iris with a Verisyse IOL means a higher risk of dislocation with trauma (A). The IOL dislocated after mild trauma in an eye in which only a small amount of iris had been enclavated into the claw (B). This IOL was successfully repositioned after the trauma with a larger amount of iris tissue taken into the claw (C). Aggressive enclavation with posterior synechiae (D). Adequate enclavation (E).

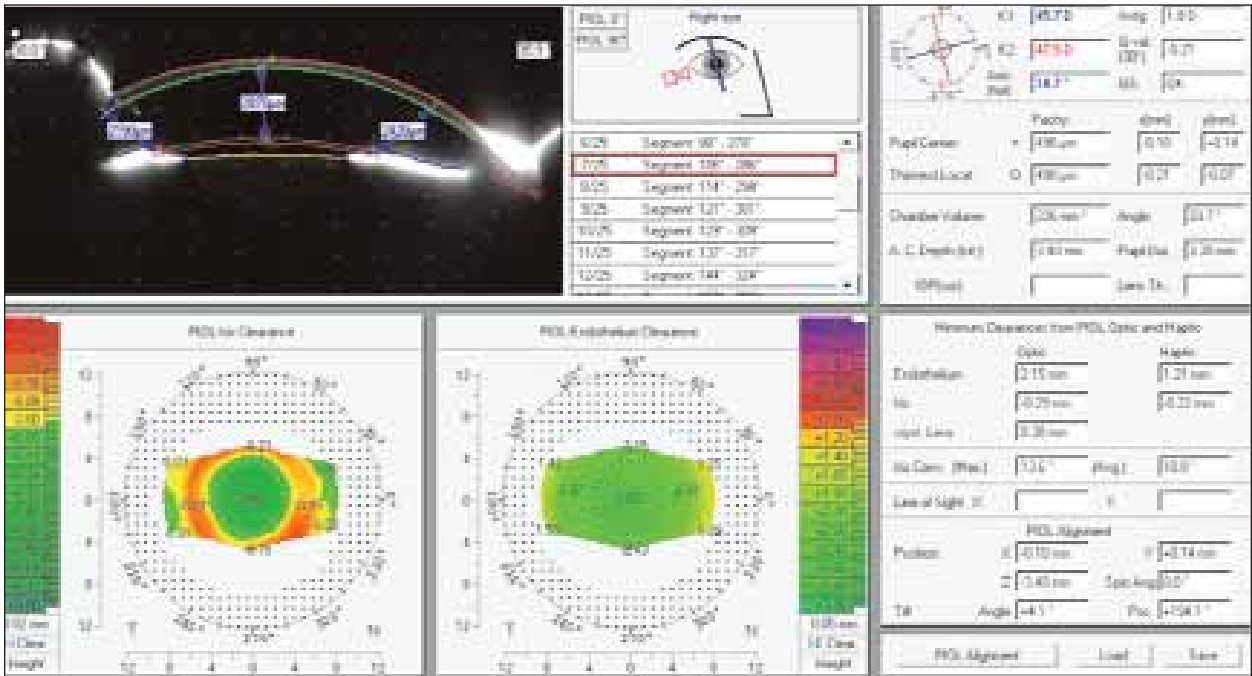


Figure 3. Anterior segment dimensions in a myopic patient for whom the surgeon is considering the Verisyse IOL. The Pentacam’s software can help to predict the clearance between the edge of the IOL and the endothelium. Although the angle cannot be directly visualized with Scheimpflug photography or optical coherence tomography (OCT), the technologies can extrapolate the angle and estimate the rise in the crystalline lens. Ultrasound provides more accurate information than either OCT or Scheimpflug photography about the exact location of the angle.

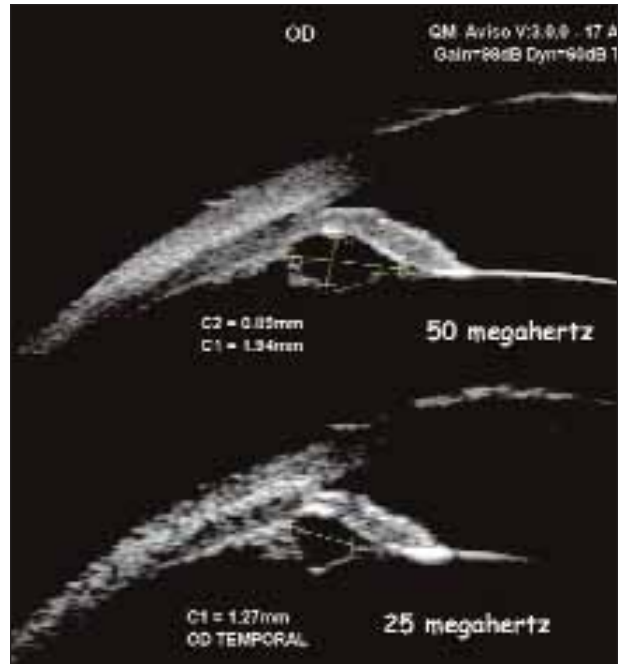
(Courtesy of Thomas C. Prager, PhD.)



Figure 4. High-resolution ultrasound imaging with the ClearScan of the anterior segment structures does not require a water bath.

ic cataract requiring surgery was noted in 0.25% of patients. The lens had to be repositioned in some eyes.

To avoid the need for repositioning and repeat enclavation, the surgeon must take an adequate amount of iris tissue into the claw during the first procedure (Figure 2). Two steps help to reduce the rate of endothelial cell damage and the tendency for inflammation due to close contact between the iris cuff and the IOL. First, surgeons should not place the IOL closer than 1.5 mm to the endothelium in the periphery. If the eye has a very convex iris, then the Verisyse may be located closer to the endotheli-



(Courtesy of Thomas C. Prager, PhD.)

Figure 5. Iris cyst with focal elevation of the iris. Difficult to see in some patients, these cysts can cause problems with the enclavation of the Verisyse IOL, but they can be detected with high-resolution ultrasound imaging of the anterior segment.



(Courtesy of Thomas C. Prager, PhD.)

Figure 6. High-resolution anterior segment ultrasound of an eye with a crystalline lens rise greater than 600 μm , which contraindicates the use of the Verisyse IOL.

um than desired. The IOL may also sit too close to the iris centrally, which can cause pigmentary dispersion from the iris. In general, if the central aspect of the crystalline lens is less than 600 μm farther anterior than the angle, then the eye should do fine after the IOL's implantation.³ The relationship of the iris to the endothelium can be better defined by anterior segment imaging such as OCT, high-resolution anterior segment ultrasound, or Scheimpflug imaging.

The Pentacam Comprehensive Eye Scanner (Oculus, Inc., Lynnwood, WA) has a software program that will analyze the anterior segment's dimensions to predict the relationship between the endothelium and the Verisyse IOL (Figure 3). This testing helps surgeons to predict which eyes may not have adequate clearance for the phakic IOL's implantation.

Ultrasound biomicroscopy is another option for measurements, and new techniques that do not require a water bath have made using high-resolution ultrasound much easier (Figure 4). Surgeons can use ultrasound to assess not only the anterior segment's morphology but also to look for lesions posterior to the iris. The detection of the latter is important, because cysts, for example, may cause a focal elevation of the iris that could make the placement of a phakic IOL problematic (Figures 5 and 6). The ClearScan cover (ESI, Inc., Plymouth, MN) (Figure 4) allows direct imaging of the cornea and sclera over 15 mm from the angle.

Surgeons can use imaging technology postoperatively to follow the IOL's position in relationship to the endothelium. They should also monitor endothelial cell counts postoperatively.

ASTIGMATISM

In the United States, the Verisyse is available in two sizes, a 5- and a 6-mm optic. In general, I use the larger optic, because it is more forgiving if slightly decentered. The 5-mm optic is the only version available for high levels of correction. The IOL is implanted through a wound slightly larger than the optic. I typically use a scleral incision to minimize the induction of irregular corneal astigmatism.

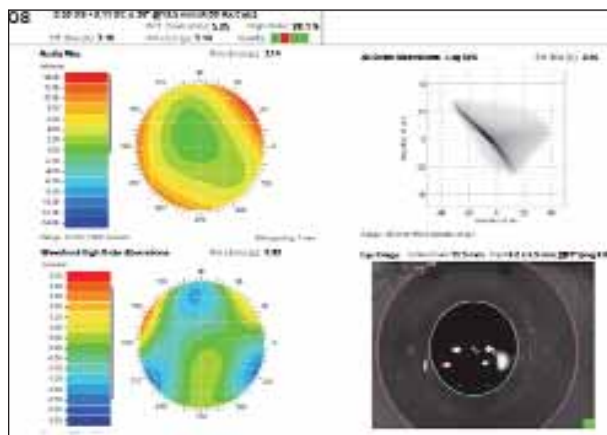


Figure 7. Wavefront analysis shows high coma in an eye that received the Verisyse lens through a clear corneal incision. With subsequent wavefront-guided laser vision correction, the eye's UCVA was 20/20.

In eyes with significant astigmatism or residual spherical refractive error after the IOL's implantation, laser vision correction is often useful for enhancing outcomes. Topography provides important information on astigmatism. It is often possible to capture a wavefront measurement in eyes in which a large wound produced irregular astigmatism. This information can be particularly helpful to the reduction of sphere, cylinder, and higher-order aberrations induced by flattening in the area of the wound (Figure 7).

CONCLUSION

Surgeons who pay careful attention to details during the preoperative and postoperative periods can expect most of their patients to achieve excellent results with the Verisyse IOL. Nearly blind preoperatively, these extremely high myopes become some of the greatest advocates of refractive surgery in my practice. ■

Author's note: Much use of phakic IOLs is off label.

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