

Point/Counterpoint: Verisyse Phakic IOL

The Verisyse Phakic IOL is very safe and effective, and patients are satisfied with their vision.

BY GREGORY J. PAMEL, MD



The Verisyse phakic IOL (Advanced Medical Optics, Inc., Santa Ana, CA) is an FDA-approved lens for patients who are 21 years of age and older with myopia between -5.00D and -20.00D with ≤ 2.50 D of astigmatism, and with an anterior chamber depth of at least

3.2mm.¹ Ideal candidates for the Verisyse lens are those whose myopia is greater than -9.00D or whose corneal thickness with respect to their refractive error is insufficient for LASIK treatment. Patients with irregular astigmatism may also benefit from the Verisyse, although this is not an FDA-approved indication for this IOL. The lens is made of PMMA, the material originally used for pseudophakic lens implants. It is a single-piece lens and is available with either a 5- or 6-mm optic diameter, and its length is 8.5mm. The lens requires no sizing, and it attaches to the midperipheral iris by its haptics through a process called *enclavation*.

VERISYSE CANDIDATES

Personal Experience

I primarily use the Verisyse in three types of patients: (1) those who are too nearsighted for LASIK (based on a study² comparing the quality of vision in eyes with the Verisyse versus eyes undergoing LASIK, I have established my cutoff for LASIK at under -9.00D); (2) those whose corneas are too thin for their prescription (eg, a -8.00D prescription with a very thin cornea); and (3) patients with an irregular corneal shape and/or irregular astigmatism, identified via corneal topography, that would not be amendable to LASIK. Every patient I have operated on has had an anterior chamber depth of greater than 3.2mm.

The most important part of the IOL selection process is performing a very accurate refraction and taking into account the vertex distance used at the phoropter. Cycloplegic refractions are critical to avoid overcorrections in myopes who tend to accept more myopia than they need

“The most important part of the IOL selection process is performing a very accurate refraction and taking into account the vertex distance used at the phoropter.”

during dry refractions. I also use the patient's pupil size as a guide to help me select the lens optic size, although not all of my colleagues feel this is necessary. In patients with myopia between -5.00D and -15.00D, the lens has a 6-mm optic. In patients with myopia between -15.00D and -20.00D, the lens has a 5-mm optic. If a patient's prescription is greater than -15.00D, I will use the 5-mm optic to fully correct his vision, provided his pupil size is no larger than 5.5mm. In patients with larger pupil sizes, I will discuss the potential of glare and halos and most of the time implant the larger 6-mm optic and correct residual ametropia with LASIK or surface ablation.

I have treated patients with as low as a -6.50D and as high as a -25.00D prescription and all refractions in between. I really have not found a difference in patients' satisfaction between the lower and higher myopes. Overall, my patients are very satisfied with this lens. In clinical trials, the satisfaction rate reported was greater than 90%.¹ Furthermore, there was no change in mesopic contrast sensitivity (with and without glare) from the preoperative to the postoperative period.

Off-Label Uses

Although the Verisyse is indicated for patients with ≤ 2.50 D of astigmatism, I have operated on many patients that had more than 2.50D of cylinder. I analyzed a subset of patients in the FDA clinical trials who fell outside the astigmatism range and they had very similar results to the primary FDA protocol. I have achieved almost 2.00D of

(Continued on page 64)

Versus Visian ICL

The Visian ICL is cosmetically appealing, and patients have a low incidence of cataract formation.

BY JOHN A. VUKICH, MD



The Visian Implantable Collamer Lens (ICL; STAAR Surgical Company, Monrovia, CA) received FDA approval for the treatment of patients with between -3.00 and -15.00D of myopia and for the reduction of myopia from -15.00 to -20.00D. The extensive indication

makes this lens suitable for a wide range of patients who have differing levels of myopia. Although the Visian ICL is used in patients who have higher degrees of myopia, this lens can be used in patients with as little as -3.00D of correction.

The Visian ICL is made of a highly biocompatible collamer called *polyhemacopolymer* that contains a fraction of a percentage of porcine-derived collagen. Because the material tends to repel proteinaceous deposits, the incidence of keratitis precipitates or inflammatory reactions is very low.

The lens is a single-piece implant that is reminiscent of the plate haptic design of IOLs, but it is different in that the ICL has a specified vaulting aspect intended to clear the normal crystalline lens. The size of the optic varies by the amount of lens power, from a 4.65- to 5.25-mm diameter.

VISIAN ICL CANDIDATES

Personal Experience

I have implanted about 200 Visian ICLs. I am the medical monitor for STAAR Surgical Company, and I oversee the clinical trials as well as participate in all the trials for this particular lens. I have been involved in the myopic, hyperopic, and toric trials. Furthermore, I train physicians about the implantation techniques of the Visian ICL.

A pleasantly surprising finding is that glare and halos are not a significant postoperative problem with the Visian ICL. This lens can be implanted in patients with large pupils. The positioning of the implant posterior to the iris, close to the nodal zone of the visual axis, mitigates edge glare issues. Because the Visian ICL is situated in close

“The extensive indication makes this lens suitable for a wide range of patients who have differing levels of myopia.”

proximity to the crystalline lens, it does not cause glare postoperatively. In my opinion, probably one of the potential indications for this lens is patients with large pupils or those who may not be great candidates for LASIK.

My colleagues and I have not observed late postoperative spikes in IOP relating to the lens. Early in the postoperative period, pressure spikes were noted at a similar distribution rate as what surgeons see in cataract surgery, a problem primarily due to retained viscoelastic of a technique-related issue. We have not observed long-term IOP rises or a conversion of eyes to a glaucomatous state.

Endothelial cell counts continue to be carefully monitored in patients implanted with the lens. Some endothelial cell loss with the implantation does occur. Although the best analysis of our data to date shows that the Visian ICL is not associated with an increase in cellular loss, we do not have the statistical power to say that definitively. The Visian ICL is one of the only lenses approved for use in patients as young as 21. Understandably, the FDA was concerned about patients' potentially having an implant for, say, 80 years or so.

Postoperatively, the quality of vision is quite high, and patients are extremely pleased, especially high myopes. The recovery of vision with the Visian ICL is almost instantaneous. The renewal of vision is not unlike putting a contact lens on an eye. As far as the quality of vision, the relative absence of glare and halos and the promise of sharp visual acuity are something about which patients have been enthusiastic.

(Continued on page 65)

(Continued from page 62)

astigmatism correction in my patients by operating on the axis.

The Verisyse is not indicated for patients with medical conditions such as keratoconus or pellucid marginal degeneration. However, I have used the implant in these types of patients, and they have been very satisfied with their outcomes. I spend additional time counseling the patients on the limitations of Verisyse in eyes with keratoconus and pellucid marginal degeneration. Typically, these patients have spectacle-corrected vision of 20/40 or better and are often contact lens intolerant. I explain the progressive nature of their condition and the possibility that they will need to wear contact lenses again in the future should their corneas become more irregular. For patients who are very nearsighted, are contact lens intolerant, or have adequate spectacle correction of their visual acuity to the 20/40 level or better, I would consider the Verisyse as an option.

The results have been good in the limited amount of patients in whom I have implanted the Verisyse. I have used this lens in a total of four patients, two with keratoconus and two with pellucid marginal degeneration.

Another off-label use for the Verisyse is in a patient younger than the approved age of 21 who is highly myopic. For instance, an infant or child suffering from amblyopia who cannot tolerate the conventional amblyopic therapy could be an off-label candidate for this lens. In patients like the aforementioned, the phakic IOL has been shown in limited instances to be beneficial.^{3,4}

IMPLANTATION

I perform the implantation procedure under peribulbar anesthesia. I instill topical pilocarpine 2% preoperatively. I initiate my incision typically at the 12-o'clock position, unless there is astigmatism greater than 1.00D, in which case I will place the incision on the axis of the cylinder. I make the incision's size either 5 or 6mm, depending on the size of the implant.

I perform the procedure with a cohesive viscoelastic. I make two paracenteses at the 10- and 2-o'clock positions, and I direct them posteriorly toward the 8- and 4-o'clock iris positions. Once I have inserted the lens into the eye, rotated it into position, and centered it over the pupil, I insert an enclavation needle through each of the paracentesis sites, first through the temporal site while holding the lens with my opposite hand. I gently draw a fold of iris in between the two haptics. If I am using a 12-o'clock incision, I will enclavate at the 3- and 9-o'clock positions. Next, I check for centration, and I can release the iris from the haptics and re-enclavate if I need to recenter the lens. I close the suture with a 10-0 nylon running stitch. Prior

to closure, I remove the viscoelastic with manual irrigation using a 3-mL syringe and 25-gauge cannula. I also perform a peripheral iridotomy at the time of the surgery at the 12-o'clock position using Colibri forceps and Vannas scissors (Katena Products, Inc., Denville, NJ).

Postoperatively, I use a fourth-generation fluoroquinolone, topical NSAID, and topical steroid q.i.d. I stop the antibiotic and the NSAID after the first week and taper the steroid during the next 3 weeks.

I have implanted more than 150 Verisyse phakic IOLs since 2000, and I have not had any patients report to me that they notice the lens or that someone else noticed they had the lens. The implanted lens is not generally noticeable to the naked eye.

POSTOPERATIVE REFRACTIVE CHANGE

If a patient's refractive error changes after the implantation of the Verisyse lens, the most likely treatment would be to perform some form of laser vision correction, either LASIK, or LASEK, to correct the residual ametropia. It is rare that one would need to remove the implant. Certainly, under most circumstances, I would not remove the lens because a patient's refractive error had changed.

A surgeon might choose to remove the lens if the patient had chronic iritis as a result of the implantation of the lens, although this type of situation was not reported in the FDA clinical trials.¹ Conversely, the aforementioned pathologic condition might be an indication to remove the lens. A surgeon might choose to take out the lens if a patient subsequently developed a cataract and required surgery. If this happened, one would remove the cataract and insert a pseudophakic lens.

RATE AND TYPES OF COMPLICATIONS

I have not seen any problems with cataract formation, elevated IOP, or endothelial cell loss in any Verisyse patient. I have been following patients now for more than 5 years. I have performed endothelial cell counts on every patient once a year. I have also been surprised at the lack of enhancements needed in these patients, even in those patients with high astigmatism or residual ametropia.

Some Verisyse patients have noted nighttime glare and halos, which have, in a majority of cases, subsided once their second eye received the lens. The rate of nighttime glare and halos in my experience is less than 3%.

CONCLUSION

My patients' response to the Verisyse lens has been overwhelmingly positive. In the FDA clinical trials, surgeons were required to wait 3 months between implantations in the first and second eyes. In the clinical trials,

(Continued from page 64)

every patient was anxious to receive the implant in his second eye. My patients often tell me that they see better with the implant than they ever did with their contact lenses. I am finding that more than 50% of the Verisyse patients gain one or more lines of UCVA.

During the 20-year experience in Europe and the 9-year experience in the US, the Verisyse lens has proven to be very safe and effective. My Verisyse patients are extremely satisfied with their visual outcomes, and the rate of complications has been low. ■

Gregory J. Pamel, MD, is Attending Surgeon at the Manhattan Eye Ear & Throat Hospital in New York and is Medical Director of Pamel Vision and Laser Group in Manhattan. He was the principal investigator for the phase 3 FDA clinical trials for the Verisyse lens implant for myopia. He acknowledged no financial interest in any company or product mentioned herein. Dr. Pamel may be reached at (212) 355-2215; gjpmd@aol.com.

1. Stulting D. Arisan Phakic IOL for the correction of myopia. Paper presented at: The FDA Ophthalmic Panel Devices Advisory Meeting; February 5, 2004; Washington, DC.

2. El Danasoury MA, El Maghrab A, Gamali TO. Comparison of iris-fixated Artisan lens implantation with excimer laser in situ keratomileusis in correcting myopia between -9.00 and -19.50 diopters: a randomized study. *Ophthalmology*. 2002;109:955-964.

3. Bosc, J-M. Phakic IOL in pediatric patients shows encouraging results. *Ocular Surgery News*. 2001;19:21-91-92.

4. Cimperle, M. Children can be safely implanted with Artisan Lens, surgeons say. Available at: <http://www.osnsupersite.com>. Accessed March 29, 2006.

(Continued from page 63)

Off-Label Uses

The Visian ICL offers an advantage over corneal ablation in patients who have atypical corneal patterns, thin corneas, dry eye, and/or eye conditions that may be problematic during or after corneal laser surgery. As mentioned earlier, the Visian ICL is indicated for treating myopia, but, it does not correct astigmatism, at least not the current version of the lens (there is a toric version of the lens that is in the approval process). Technically, implanting the Visian ICL in eyes that have a fair amount of astigmatism would be an off-label use, similar to the use of an IOL in cataract surgery where surgeons can utilize limbal-relaxing incisions to correct astigmatism. The most common off-label use of the Visian ICL will most likely be in terms of the patient's age. The lens is approved for use in patients 21 to 45 years of age. There is not a bright line at age 45, such that the Visian ICL is a great product at age 44 but not useful at age 46. There is a shade of gray in terms of at what age the Visian ICL is most appropriate or of the most benefit.

IMPLANTATION

The implantation of the Visian ICL is done with a topical anesthetic and a clear corneal temporal incision—the same incision that is familiar to most cataract surgeons who are using modern techniques. The minimum incision size is between 2.8 and 3.0mm. Typically, the surgeon employs an injector to insert the Visian ICL through the small incision into the anterior chamber and then he positions the lens posterior to the iris. The surgeon uses a dispersive viscoelastic to position the lens that he removes after the implant is placed. The entire procedure usually takes 3 to 6 minutes.

REFRACTIVE CHANGE POSTOPERATIVELY

If necessary, a surgeon can remove the Visian ICL through the same 3-mm incision through which it originally passed simply by withdrawing it. The lens will fold upon itself and come out easily. If small shifts in refractive power occur postoperatively, however, one may consider an enhancement via corneal or laser surgery versus explantation. The Visian ICL is not designed for removal, servicing, replacing, and updating.

In the FDA clinical trial of the Visian ICL, it was unusual to have a lens removed. In the hyperopic trial, an improper power selection for a lens was made (human error). That particular lens ended up being 2.00D in error, so the patient was made hyperopic by that amount. The lens was exchanged for the appropriate power.

Although explantation of the Visian ICL is rare, an indication for removal is excessive vaulting or narrowing of the anterior chamber.

CONCLUSION

Complications are a part of any intraocular surgery. With experience, however, ophthalmologists get better at identifying suitable patients and treating them appropriately with phakic IOLs. A small percentage of patients may develop cataracts with any implant. The FDA clinical trials for the Visian ICL showed an incidence of cataract of less than 1.9% during a 3-year period. If a cataract does form, however, I believe it is a very manageable problem.

Last, under an unaided examination, the implanted Visian ICL is not visible via normal ambient light. One cannot see this lens in the eye at all, an aspect of the lens that patients found appealing. The only way to observe the implant is to dilate the patients' eyes pharmacologically and use retroillumination. ■

John A. Vukich, MD, is Assistant Clinical Professor at the University of Wisconsin, Madison. He is a paid consultant for STAAR Surgical Company. Dr. Vukich may be reached at (608) 282-2002; javukich@facstaff.wisc.edu.