

Clinical Update

TOOLS AND TECHNIQUES

REFRACTIVE SURGERY

Implantable Contacts Make Their Mark

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After years of study, Staar Surgical's Implantable Contact Lens for myopia is poised to become the first phakic IOL available in the United States.

To date, study of the ICL for myopia includes 523 eyes of 291 patients. The mean spherical equivalent of these eyes is -10 D, ranging from -3 to -20 D, and the mean age is 36 years.

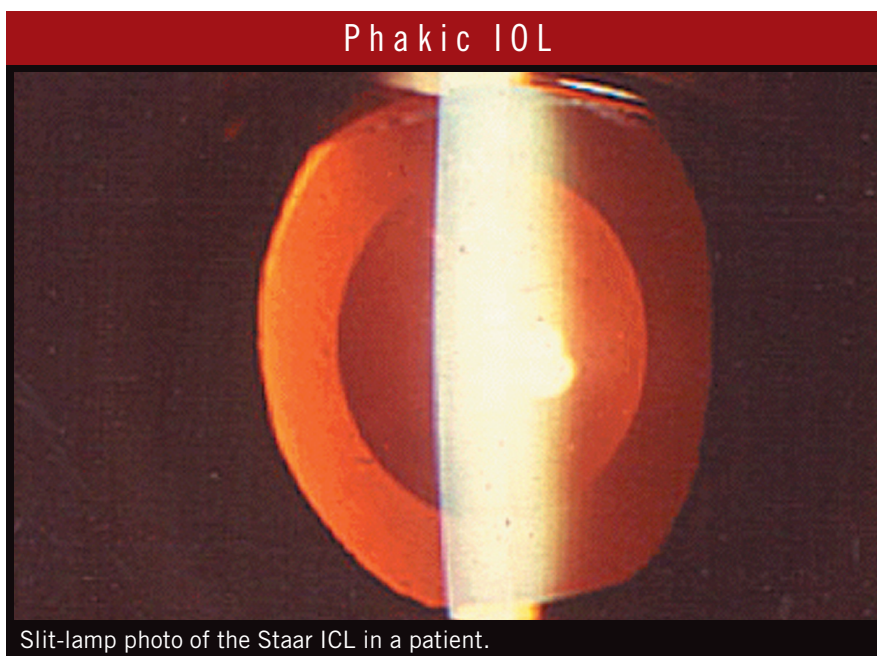
The two-year data included 158 eyes. Of these patients, 92 percent were 20/40 or better and 60 percent were 20/20 or better. "When you take a minus 15 and get them to even 20/60, they are thrilled, so these patients are ecstatic," said James J. Salz, MD, clinical professor of ophthalmology at the University of Southern California. Of these eyes, 85 percent were corrected within +/-1 D, and 62 percent were within 0.5 D.

ICL vs. LASIK

Comparison of results. John Vukich, MD, medical monitor at Staar, compared about 100 high myopes treated with LASIK to a similar number of patients treated with an ICL. The visual results were similar. For uncorrected vision, both groups had more than 80 percent at 20/40. In both groups about 40 percent or so were 20/20, Dr. Salz reported.

Of the LASIK patients, 6 percent lost two lines of BCVA, vs. none in the ICL group. In fact, 9 percent of the ICL patients gained two lines of BCVA, vs. only 6 percent in the LASIK group.

ICL advantages. The ICL seems to have several advantages over LASIK, Dr. Salz



Slit-lamp photo of the Staar ICL in a patient.

reported. For example, if you put in an ICL and the patient doesn't like it, you can take it back out. There is no permanent change to the cornea.

Outcomes are stable with the ICL. "It is not based on wound healing, so if your patient is -10 D, and you require a 10 implant, you are going hit it pretty close. It is not going to change in a month or a year," he explained.

The ICL gives high-quality vision even with high corrections. "We don't like doing LASIK in minus 12s anymore because they usually don't see well," he said.

For LASIK, the high myope must have a thick cornea. With the ICL, it doesn't matter. The pupil size is also less important. The 5.5-millimeter implants

are equivalent to about a 7-mm ablation at the plane of the cornea, Dr. Salz said.

The phakic implant goes up to -20 D. If someone is a -25 D, you can put the implant in the eye to correct most of the refractive error, then do LASIK to complete the correction.

If a patient has a little hyperopia or myopia after cataract surgery, these implants might be used as a piggyback lens for cleaning up refractive error, added David R. Hardten, MD, director of Minnesota Eye Consultants' clinical research department and associate clinical professor of ophthalmology at the University of Minnesota.

ICL disadvantages. Like all intraocular procedures, phakic IOL implantation has inherent risks, such as endophthal-

mitis, cystoid macular edema and cataracts.

When phakic IOLs first appeared, induced cataract was a big concern. An earlier model of the ICL, for example, didn't have a good vault between the crystalline lens and the implant. "They implanted 87 of these, and almost 13 percent of them developed anterior subcapsular opacities, which was way too high," Dr. Salz said.

The current model corrected the vaulting problem and reduced the risk of cataract. In the 523 eyes of the myopia ICL study, the incidence of anterior subcapsular cataracts was 1.4 percent. Clinically significant cataract, meaning the patient has symptoms such as glare and halos at night or has lost some BCVA, occurred in 9.2 percent with the earlier model. With the new model, the incidence was only 0.9 percent, Dr. Salz said.

As for glaucoma, because the ICL rests against the back of the iris, visible pigment is dispersed in the eye and on the lens. "In a couple of reported cases, pigmentary glaucoma did develop," Dr. Salz said.

In addition, these implants are expensive because they are custom-designed. **Astigmatism issues.** The current ICL corrects myopia, and surgeons combine it with limbal-relaxing incisions to reduce astigmatism. Last year, FDA clinical trials began on a toric ICL.

The toric ICL is very similar to the Staar ICL for myopia, with the added benefit of correcting astigmatism. It is injected into the anterior chamber, placed behind the iris in the ciliary sulcus, and then positioned to fix the patient's naturally occurring astigmatism, said Stephen G. Slade, MD, FACS, assistant clinical professor of ophthalmology at the University of Texas, Houston, and national medical director for TLC Laser Eye Centers.

Biometry and Sizing

Power calculations for phakic IOLs are done by the manufacturer. "We don't have a good sizing method yet," Dr. Salz added. "We tell the manufacturer, here is a -12 D patient. This is their anterior chamber depth, and this is the white-to-

Other Phakic IOLs Under Study

Several other phakic IOLs are undergoing clinical trials:

Hyperopia ICL. A study of this Staar lens is still enrolling patients. "We use these for +3 D correction on the hyperopic side," Dr. Hardten explained.

Artisan Anterior Chamber Lens. This Ophtec lens, known as the "iris claw" lens, is in U.S. clinical trials. It will be marketed by Advanced Medical Optics. The Artisan lens is clipped in place in front of the iris in the anterior chamber. It requires a larger incision, does not correct astigmatism and is a visible lens, Dr. Slade pointed out. (In contrast, "The Staar ICL is behind the pupil and can go through an incision about half the size.")

Artiflex Lens. This foldable version of the Artisan is now in trials overseas, Dr. Hardten said. A foldable version could be inserted through a 3-mm incision. A truly flexible lens would not distort the pupil or impinge on the angle creating the risk of glaucoma, Dr. Salz said. "There would be a slight risk to the cornea, but in a myopic eye, with a big anterior chamber depth, most surgeons probably would accept an anterior chamber lens."

Phakic Refractive Lens. This lens, by Ciba Vision (formerly by Medennium), also is in U.S. clinical trials.

white measurement with calipers, and they send you the lens. As ultrasound studies become more sophisticated, we will probably get a better way to size."

If the lens is not big enough, it doesn't pucker up, and the vaulting can be relatively flat and close to the crystalline lens. "If you don't have good flow of aqueous around this lens," Dr. Salz explained, "you get cataracts in some eyes."

Postoperatively, surgeons must grade the vaulting. "We estimate the space between the anterior surface of the crystalline lens and the posterior surface of the ICL using a very fine slit view," Dr. Salz said. "If the space is about the same as the thickness of the cornea, around 500 microns, that is grade one. If there is no space, if it is sitting right on the crystalline lens, then it is grade zero, which will lead to cataract."

It is fairly easy to avoid that situation in larger nearsighted eyes. However, that may not hold true for farsighted eyes, the experts agreed. "In a hyperopic eye, because the anterior chamber is so shallow, cataract is more likely with any phakic implant," Dr. Salz said.

Preferred Candidates

Dr. Hardten currently prefers phakic IOLs for patients who are interested in refractive surgery, still have residual accommodative ability and have more

than -10 D of needed correction, although he has placed phakic IOLs in patients with as low as -7 D of myopia.

"If this turns out to be really good and safe, we might think about this even at around -7 or -8 D, but right now we do LASIK on those people," Dr. Salz said. He noted that he would start at about -8 D, depending on pupil size and corneal thickness. "For a -7 D, if they have a thin cornea and a large pupil, this might be the better procedure."

Right now, he said, "We use these to treat people that LASIK can't treat, such as high myopes. It may turn out that these are better for even lower myopes. We don't really know."

ICLs are not difficult to implant, the experts agreed. A surgeon who is comfortable with temporal, clear-corneal incision cataract surgery with a foldable IOL and topical anesthesia will adapt to this quickly, Dr. Salz said.

"One must be very delicate with surgical technique to avoid traumatizing the lens," Dr. Slade noted. And Dr. Hardten added, "Make sure you have a nice widely dilated pupil, and practice, practice, practice inserting the lens into the injector system."

Dr. Hardten performs research for Ophtec and Staar and Dr. Slade consults for Staar. Dr. Salz has no financial interests.