The Posterior-Chamber Implantable Contact Lens

The ICL offers outstanding refractive accuracy and predictability.

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THE U.S. FOOD AND DRUG ADministration's (FDA) Phase II and III trials of the Staar implantable contact lens (ICL) for myopia required candidates to have less than 2.5 D of cylinder and myopia ranging from -3.0 to -20.0 D. A hyperopic version of the lens is in U.S. clinical trials, and a toric version is in trials internationally.[1,2]

As a clinical co-investigator for the FDA trial of the Staar Myopia ICL, our practice has contributed 18 eyes with preoperative myopia of -7.5 to -20.0 D. These eyes have now been followed for up to three years.

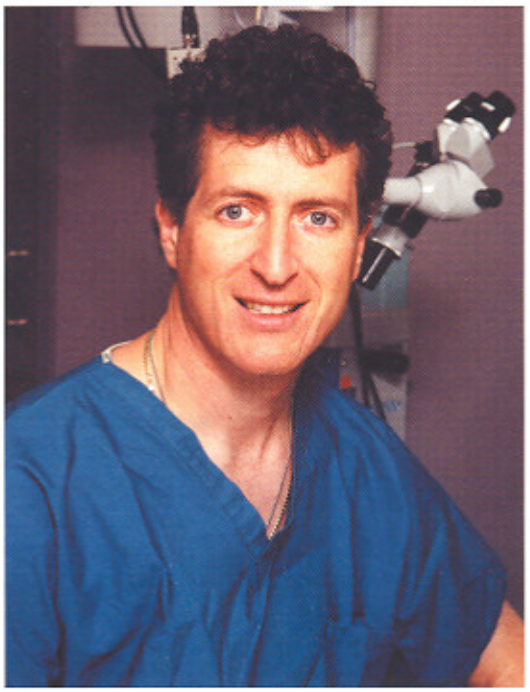
Advantages

In our limited series, 100 percent of eyes demonstrated a postop residual refraction between plano and -0.75 D of the intended spherical equivalent. There were no overcorrections. These results contrast with a recent study of the Artisan phakic IOL in which 67 eyes with a preoperative refraction of -5.38 to -28.00 D were implanted and followed for a mean of 35 months. Results demonstrated that 67 percent of patients were within +/-1.00 D of emmetropia.[3] These studies suggest that the refractive accuracy of the ICL is superior to that of the Artisan IOL. I find the ICL's degree of predictability to be remarkable in light of the high myopic corrections attempted.

A key difference between the phakic IOLs under investigation involves lens design. Anterior-chamber phakic IOLs use a PMMA material, which must fit through a large (6-mm) incision requiring sutures. With these lenses, induced astigmatism becomes a real possibility. By contrast, the foldable posterior-chamber ICL may be implanted far less traumatically through a small (2.7-mm) incision. The patient presents the next day with a clear white eye, no sutures to remove and little induced astigmatism.

The ICL's flexibility also means that it is far less likely than a rigid, anterior-chamber phakic IOL to cause internal damage to the cornea or iris if the eye is subjected to trauma, either in the form of an acute, blunt injury or even chronic eye rubbing.

Additionally, a posterior-chamber phakic IOL is naturally farther away from the corneal endothelium than an anterior-chamber model. As a result, eyes receiving a posterior-chamber lens have less chance of developing long-term corneal endothelial loss than do those with anterior-chamber designs.[3] Moreover, researchers of anterior-chamber phakic IOLs report postoperative iridocyclitis and subjective complaints of glare and night halos. With the Artisan lens in particular, glare and halos have been associated more with the IOL's 5-mm optic than the 6-mm optic.[3] None of these problems have surfaced in the trials of the Staar myopic ICL, and I have never



had a patient complain of unwanted optical images. In fact, subjective visual quality has been very good.

Another advantage of a posterior-chamber phakic IOL concerns cosmetics. An observer looking into the eye of someone who had received an anterior-chamber phakic IOL could, at close range, see the implant. The same observer would be unable to see the posterior-chamber ICL. In fact, an eye-care professional might easily miss the implant on an undilated slit-lamp examination, if he did not know to look for it.

Disadvantages

• *Short term.* Implanting a posterior-chamber phakic IOL requires a delicate surgical touch, due to concerns of traumatic cataract formation at the time of implantation.

Pupillary block glaucoma can develop in the early postop period. For this reason, two YAG peripheral iridotomies must be placed preop. Despite this prophylactic measure, intraocular pressure spikes can still occur, most likely due to the plugging of the peripheral iridotomies with viscoelastic. This complication usually can be managed medically. Early, careful postop follow-up is essential.

• *Long term.* Both phakic IOL designs have strong clinical testing backgrounds, but long-term results have yet to be revealed. For posterior-chamber IOLs, these results relate to whether metabolic cataracts will form over time.[4,5] There is also the possibility of the narrowing of the anterior-chamber angle (in the quadrants over the plate haptics) that could become progressively more crowded as the crystalline lens grows with age. There have been no reports, however, of angle-closure glaucoma from this mechanism in international patients with longer follow-up.

Adequate sizing of the ICL remains the most critical issue. Data shows that appropriately sized ICLs, which have adequate vaulting and a suitable space between the ICL and anterior lens capsule, do not result in cataract formation. The vast majority of lenses implanted during the FDA trials have been sized correctly, using preoperative white-to-white limbal measurement to estimate the diameter of the ciliary sulcus.

The few cataracts that have arisen appear to be due to inadequate ICL sizing; a lens too small in terms of its diameter may not vault at all and can stick to the anterior capsule of the crystalline lens. Under this circumstance, anterior subcapsular cataract formation can still occur, despite the hydrophilic, highly permeable and biocompatible qualities of the collamer ICL material.

Iris chafing and resultant pigment dispersion are other possibilities thought to be more likely with an oversized ICL that excessively vaults. We continue working towards a less subjective system to measure directly the ciliary sulcus diameter and thereby ensure consistent ICL sizing. The ultimate solution seems to be one using ultrasonic biomicroscopy units, and we are working with manufacturers to adapt their machines for this application.[6] Once this preoperative imaging device is available, we believe the incidence of inadequate ICL sizing and the associated problems will be greatly reduced or even eliminated. When we have surmounted this challenge, our studies suggest that the posterior-chamber ICL will be the best choice in phakic IOLs.

Dr. Erdey is a refractive and cornea specialist in group practice. He has no financial interest in the Staar ICL, nor is he a paid consultant.

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