

# Phakic IOLs

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My first experience with phakic IOLs came in 1996 during my refractive surgery fellowship. While working with Roberto Zaldivar, MD, at the Instituto Zaldivar in Mendoza, Argentina, I participated in many of the earliest surgeries using the Visian Implantable Collamer Lens (ICL; STAAR Surgical Company, Monrovia, CA), and I analyzed data from the first 300 patients implanted with the lens. In addition, I examined many of patients treated with the original anterior chamber lens developed by Georges Baikoff, MD, and worked with him on potential new designs. It was as clear to me back then as it is today that this technology requires the utmost attention to detail and must account for the smallest margins of error. Complications with phakic IOL technologies can be serious. No one wants to induce a cataract in highly myopic but otherwise healthy 20- or 30-year-old patients and expose them to the unacceptably high odds of retinal detachment associated with performing phacoemulsification in such young patients. When phakic IOLs are implanted successfully, however, they provide highly myopic and hyperopic patients with a quality of vision that outshines any outcome they can achieve with LASIK or surface ablation. It was a challenge to return to the United States in 1997 knowing that these technologies would not be available on the US market for another 5 years or more.

Twelve years later, phakic IOLs are gaining acceptance and popularity in the United States. For this month's edition of the "Peer Review" column, I have selected articles that highlight the most current published data on these lenses. *Cataract & Refractive Surgery Today's* senior associate editor, Julia T. Lewandowski, has done a remarkable job weaving these articles into a brief overview of the current state of phakic IOL technology. We hope you enjoy this format and welcome comments to help guide us in the future.

—Mitchell C. Shultz, MD, Section Editor

## THE VERISYSE PHAKIC IOL

The Verisyse (Abbott Medical Optics Inc., Santa Ana, CA; also marketed as the Artisan in Europe by Ophtec USA, Inc., Boca Raton, FL) was the first phakic IOL approved for clinical use in the United States. Several studies have evaluated the safety and efficacy of this iris-supported ACIOL.

Investigators for the Verisyse Study Group implanted 1,179 Verisyse phakic IOLs into the eyes of 662 myopic adults (range, -4.50 to -22.00 D). Most of these subjects (92%; 609 of 662) had preoperative UCVA of 20/400.

Of the 231 eyes that were available for analysis after 3 years, 84% (194 of 231) had UCVA of 20/40 or better, and 51.9% (120 of 231) had UCVA of 20/25 or better. The investigators observed few transient complications (eg, elevated IOP, inflammation, corneal edema), all of which resolved by 2 months postoperatively. Due to a change in the study's protocol, the investigators were not able to measure definitively the effect of the Verisyse on endothelial cellular density. Based on data from a subset of 57 eyes, however, the investigators esti-

mated that the density of endothelial cells decreased by  $3.8\% \pm 9.8\%$  from baseline during the 3-year study.<sup>1</sup>

A retrospective, nonrandomized, interventional case series showed that the Verisyse consistently improved visual acuity in myopic ( $n = 274$ ), hyperopic ( $n = 41$ ), and astigmatic ( $n = 84$ ) eyes. By 5 years postoperatively, the investigators noted a significant improvement in the mean spherical equivalent of myopic eyes ( $n = 101$ ) implanted with the 5-mm Verisyse ( $-19.8 \pm 3.23$  to  $-0.5 \pm 0.89$  D [ $P < .001$ ]) and myopic eyes ( $n = 173$ ) implanted with the 6-mm Verisyse ( $-11.27 \pm 3.11$  to  $-0.64 \pm 0.80$  D [ $P < .001$ ]). They also observed an improvement in the mean spherical equivalent of hyperopic eyes ( $n = 41$ ;  $4.97 \pm 1.7$  to  $0.02 \pm 0.51$  D [ $P < .001$ ]) during the same period. The toric Verisyse lens significantly reduced the mean cylinder in 84 astigmatic eyes from  $-3.24 \pm 1.02$  to  $-0.83 \pm 0.74$  D. By 4 years postoperatively, all of the eyes had lost some endothelial cells ( $5.11\%$  [ $P < .001$ ]), but the change from baseline was statistically significant only in myopic eyes.<sup>2</sup>

Tahzib et al found that 68.8% of 89 moderately to highly myopic eyes implanted with the Verisyse IOL had refractions that were still within 1.00 D of the originally targeted correction by 10 years postoperatively. Overall, the mean postoperative spherical equivalent was stable at  $-7.00 \pm 1.00$  D, and the mean endothelial cellular density had decreased by  $8.86\% \pm 16.01\%$  from baseline.<sup>3</sup>

In a small prospective study, the Verisyse lens appeared temporarily to increase the total number of mean higher-order aberrations under photopic conditions in 25 eyes (15 patients). By 1 month postoperatively, the investigators found that the number of higher-order aberrations had increased from a baseline of  $0.34 \pm 0.15$  to  $0.40 \pm 0.15$ . This change did not reach statistical significance, and the measured value had decreased to  $0.39 \pm 0.11$  by 3 months postoperatively.<sup>4</sup>

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### THE VISIAN IMPLANTABLE COLLAMER LENS

Unlike the Verisyse lens, the Visian Implantable Collamer Lens (ICL) and the Visian Toric Implantable Collamer Lens (TICL) (both from STAAR Surgical Company, Monrovia, CA) are designed to sit in the posterior chamber between the iris and the crystalline lens. Although the Visian ICL is currently approved for the correction of myopia in the United States, the Visian TICL is still under review by the FDA.

During the multicenter FDA clinical trial of the Visian TICL, investigators implanted 210 lenses in the eyes of 124 patients. By 1 year postoperatively, 76.5% of the eyes had UCVA that were better than or equal to their preoperative BSCVA, and 97.3% (181 of 183) of the eyes had refractive outcomes that were within 1.00 D of the targeted correction. The investigators also noted a 73% decrease ( $1.94 \pm 0.84$  to  $0.51 \pm 0.48$  D) in mean cylinder with the Visian TICL.<sup>5</sup>

A potential complication associated with the Visian ICL and Visian TICL is the development of cataracts. In this study, however, only six eyes (2% of the total cohort) were found to have trace opacity in the anterior lens postoperatively, and only one of the cataracts was clinically significant.<sup>5</sup>

A randomized, prospective, comparative trial conducted at the Naval Medical Center in San Diego

showed that the Visian TICL consistently produced better clinical outcomes than PRK with mitomycin C ( $n = 45$ ) when both procedures were used to correct moderate-to-high myopic astigmatism. The investigators observed differences in favor of the Visian TICL for all outcome measures, including UCVA (97% of TICL patients saw 20/20 at 12 months vs 82% of PRK patients), predictability (76% of TICL patients had refractions within 0.50 D of their intended correction vs 57% of PRK patients), and contrast sensitivity (63% of TICL patients gained one line of BSCVA at 25% mesopic levels vs 9% of PRK patients). The TICL patients also appeared to have a lower incidence of dry eye complaints compared with PRK patients (as measured by the self-reported use of artificial tears).<sup>6</sup>

### IMAGING PHAKIC IOLs

Phakic IOLs are designed to occupy a specific space in the anterior or posterior chamber. If the lens is incorrectly sized for the space, or if its movement is incompatible with that of the other structures in the eye, it could cause serious complications such as a loss of endothelial cells, pigmentary dispersion syndrome, gonial synechiae, and glaucoma.

Baikoff described how physicians can use anterior-segment optical coherence tomography to set safety parameters for the implantation of phakic IOLs. This technology is useful for implanting the Artisan/Verisyse and angle-supported ACIOLs, because it provides an accurate measurement of the anterior chamber's depth. One can then use this information to choose the correctly sized phakic IOL preoperatively and to determine how long a patient can retain the lens in his eye (the “safety period”) before age-related changes increase his risk of developing complications.<sup>7</sup>

Partial coherence interferometry (AC Master; Carl Zeiss Meditec AG, Jena Germany) of 28 eyes showed that the process of accommodation shifted the Artisan/Verisyse iris claw phakic lens anteriorly by a mean of  $70 \pm 59$   $\mu\text{m}$ . The anterior surface of the crystalline lens also moved anteriorly by a mean of  $85 \pm 81$   $\mu\text{m}$  during accommodation.<sup>8</sup>

Güell et al randomized 11 myopic patients to receive an Artisan IOL in one eye and an Artiflex phakic IOL (Ophtec USA, Inc., Boca Raton, FL) in their fellow eye. The Artiflex (known in the United States as the Veriflex [Abbott Medical Optics Inc]; currently under review by the FDA) is a foldable silicone version of the Artisan that can be inserted in the anterior chamber through a 3-mm incision. Images obtained from both of the patients' eyes with the Visante OCT (Carl Zeiss Meditec, Inc., Dublin, CA) showed that the mean distance between the anterior surface of both phakic IOLs and the

corneal endothelium decreased significantly during the process of accommodation ( $P < .001$ ). The investigators did not observe a similar decrease in the mean distance between the IOLs' posterior surface and the anterior surface of the crystalline lens during accommodation.<sup>9</sup>

Kohnen et al used Scheimpflug photography (EAS-100; Nidek, Inc., Fremont, CA) to evaluate the intraocular stability of the Artisan, Artiflex I, and Artiflex II phakic IOLs in 45 eyes of 26 patients. In addition to helping the investigators obtain accurate measurements of the median distance between the IOLs' anterior surface and the corneal endothelium and between the IOLs' posterior surface and the anterior surface of the crystalline lens, this device provided information on how the lens' materials affected these distances. Measurements obtained 12 months postoperatively showed that the rigid PMMA optic of the Artisan lens consistently maintained a greater distance from the corneal endothelium ( $2.63 \pm 0.11$  mm) than the silicone optics of the Artiflex I ( $2.44 \pm 0.19$  mm) and Artiflex II lenses ( $2.48 \pm 0.10$  mm).<sup>10</sup>

## COMPLICATIONS

### Density of Endothelial Cells

An analysis of 318 eyes (173 patients) implanted with the Artisan phakic IOL showed a significant negative correlation between the progressive loss of endothelial cells and the depth of the anterior chamber ( $P \leq .03$ ).

By 5 years postoperatively, the mean density of endothelial cells in eyes implanted with the Artisan had dropped from  $2,817 \pm 356$  to  $2,518 \pm 293$  cells/mm<sup>2</sup>, an overall change of -8.3% from baseline. Even when the investigators corrected the observed rate of loss for natural attrition (approximately 6% per year), the rate of loss (5.3%) was still higher than that reported by other studies. Based on these results, the investigators suggest that surgeons carefully consider candidates ages as well as the depth of their anterior chambers and their preoperative endothelial cellular density when screening them for phakic IOLs.<sup>11</sup>

A prospective analysis of 26 eyes of 15 highly myopic patients by Silva et al investigated the rate of endothelial cellular loss in patients implanted with the Artisan lens. By 5 years postoperatively, the mean density of endothelial cells had dropped from  $2,481 \pm 291$  to  $2,156 \pm 495$  per mm<sup>2</sup>, a total loss of 14.05% from baseline. Although the mean rate at which cells were lost decreased as patients were further removed from surgery (7.18% at 1 year, 1.18% at 3 years, and 3.15% at 5 years), the investigators were concerned by the overall trend.<sup>12</sup>

### Cataract

A literature-based review of 6,338 eyes noted a higher incidence of postoperative cataracts among patients

with posterior chamber phakic IOLs (9.60%) than among those with anterior chamber angle-fixated (1.29%) or anterior chamber iris-fixated phakic IOLs (1.11%). The prevalence of different types of cataract also varied according to the type of phakic IOL. Whereas nuclear sclerotic opacities were most common in eyes with anterior chamber angle-fixated and iris-fixated IOLs, anterior subcapsular cataracts occurred predominantly in eyes with PCIOLs. The investigators suggested that the high incidence of anterior subcapsular cataracts in the last group could be due to the IOLs' proximity to the crystalline lens. Contact between these structures could potentially disrupt the crystalline lens' metabolism and contribute to the development of cataracts.<sup>13</sup>

Data from a 5-year postapproval study found that a lower percentage of patients (5.9%; 31 of 256) developed subcapsular cataracts 7 years after they received a Visian ICL than was predicted by Kaplan-Meier survival analysis (approximately 7.0%). The number of clinically significant cataracts observed was also lower than predicted (1.3% vs 2%).<sup>14</sup> ■

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