Two-year follow-up of the Artisan/Verisyse iris-supported phakic intraocular lens for the correction of high myopia

Majid Moshirfar, MD, Huck A. Holz, MD, Don K. Davis, MD

PURPOSE: To evaluate the implantation of Artisan/Verisyse phakic intraocular lenses (pIOLs) (Advanced Medical Optics) as an effective and safe method for the correction of high myopia.

SETTING: Department of Ophthalmology, John A. Moran Eye Center, University of Utah Medical Center, Salt Lake City, Utah, USA.

METHODS: This retrospective outcomes trial examined the implantation of Artisan/Verisyse pIOLs in 85 highly myopic eyes (mean spherical equivalent −12.2 diopters). Patients were followed for 2 years and examined postoperatively at 1,6,12, and 24 months. Data collected included best spectacle-corrected visual acuity (BSCVA), uncorrected visual acuity (UCVA), corneal endothelial cell density, and adverse events.

RESULTS: Six months postoperatively, 5 (7%) eyes lost 1 line of the BSCVA; no eye lost 2 or more lines. The UCVA was better than 20/40 in 83% of eyes and better than 20/25 in 32%. Endothelial cell density decreased by 3.3% and 6.5% over the 1-year and 2-year intervals, respectively. Glare and halos, the most common complications of surgery, were reported by 6% of patients at 1 month and by 3% at 2 years.

CONCLUSION: Implantation of the Verisyse/Artisan pIOL yielded accurate refractive results with acceptable safety in highly myopic eyes.

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Photorefractive keratectomy (PRK) and laser in situ keratomileusis (LASIK) offer less predictable results for the treatment of high myopia than for low myopia[1,2] and may lead to excessive corneal thinning and ectasia.[3,4] Refractive lens exchange offers stable refractions and good predictability but is accompanied by the risk for retinal detachment and loss of accommodation.[5]

In September 2004, the U.S. Food and Drug Administration (FDA) approved the implantation of the iris-claw Artisan/Verisyse phakic intraocular lens (pIOL) (Advanced Medical Optics) for the correction of myopia from −5.0 diopters (D) to −20.0 D. Phakic intraocular lenses provide better quality of vision in myopia with a lower risk for loss of best spectacle-corrected visual acuity (BSCVA) and ectasia than LASIK and PRK. Other advantages of anterior chamber pIOLs are preservation of accommodation, the potential for reversibility, and a stable, predictable refractive outcome that is independent of corneal healing and corneal epithelial changes. Unfortunately, the reported complications of pIOLs, which include corneal decompensation, cataract, glaucoma, endophthalmitis, and pupillary ovalization, can be devastating.[6–8]

We report the experience of a single surgeon with the Artisan/Verisyse anterior chamber pIOL since its FDA approval.

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From the John A. Moran Eye Center, Salt Lake City, Utah, USA.

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Corresponding author: Majid Moshirfar, MD, John A. Moran Eye Center, Old Mill Medical Center, 6360 South 3000 East, Suite 200, Salt Lake City, Utah 84121, USA. E-mail: majid.moshirfar@hsc.utah.edu.

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PATIENTS AND METHODS

Implantation of the Artisan/Verisyse pIOL was used to correct axial myopia from −5.0 to −20.0 D in phakic eyes. Model 204 was used for the correction range of −5.0 to −15.0 D, and model 206 was used for the correction range of −16.0 to −20.0 D. The pIOLs were available in 0.5 D increments.

Inclusion criteria for the study included the following: (1) anterior chamber depth (ACD) of 3.2 mm or greater with regular iris configuration and insertion; (2) preoperative endothelial cell count (Konan Noncon Robo clinical specular microscope) of 2000 cells/mm^2 or greater; (3) scotopic pupil of smaller than the pIOL optic size; (4) preoperative astigmatism less than 2.5 D; (5) stable refraction, defined as less than 0.5 D change for more than 1 year.

Exclusion criteria for the study were as follows: (1) abnormal iris, cornea, pupil, or retina; (2) acute inflammation; (3) any form of cataract; (4) glaucoma; (5) chronic or recurrent uveitis; (6) preexisting macular degeneration, retinopathy, or family history of retinal detachment within 2 degrees of relation; (7) intraocular pressure (IOP) greater than 21 mm Hg. All patients met FDA guidelines for safety and efficacy standards.

For pIOL implantation, a superior scleral tunnel incision was used. One surgeon (M.M.) performed all procedures using a technique similar to that described elsewhere.[9] Surgeries were performed between September 2004 and June 2005 at the John A. Moran Eye Center, affiliated with the University of Utah Medical Center.

Safety was the primary outcome measure of the study and was quantified by change in the BSCVA. Efficacy was measured by the postoperative uncorrected visual acuity (UCVA).

Table 1. Patient demographics.

Demographic	Value
Number of patients (eyes)	56 (85)
Bilateral cases (%)	
Sex, n (%)	
Female	40 (71)
Male	16 (29)
Age (y)	
Mean ± SD	40.9 ± 9.1
Range	21.3 to 59.8
Race, n (%)	
White	51 (91.0)
Asian	3 (5.4)
Hispanic	2 (3.6)
Ocular parameters (D)	
Refractive error range	−8.25 to −20.00
Spherical equivalent	
Mean ± SD	−12.20 ± 2.79
Range	−7.9 to −18.9
Implanted IOL Power (D)	
Mean ± SD	−12.80 ± 2.51
Range	−8.00 to −19.00
IOL model (%)	
204	91
206	9

IOL = intraocular lens

RESULTS

Study Population

Fifty-six patients, 71% women and 29% men, were enrolled in the study. Eighty-five myopic eyes with corrections ranging from −8.25 to −20.00 D had Artisan/Verisyse pIOL implantation. Table 1 shows the patients' demographics.

Safety

Preoperatively and 6 months postoperatively, all patients had a BSCVA of 20/40 or better. At 6 months, 13 eyes (19%) gained 2 lines of BSCVA and 29 (43%) gained 1 line. Twenty-one eyes (31%) had no change in BSCVA. Five eyes (7%) lost 1 line of BSCVA; in all 5, acuity dropped from 20/20 preoperatively to 20/25 postoperatively. No eye lost 2 or more lines of BSCVA, and 63 of 68 (93%) eyes had no change in lines of BSCVA or improved by at least 1 line (Figure 1).

Efficacy

At 6 months, the UCVA was 20/40 or better in 57 of 69 eyes (83%) and 20/25 or better in 22 eyes (32%) (Figure 2). At 1 year, the UCVA was 20/40 or better in 57 of 61 eyes (93%) and 20/25 or better in 25 eyes (41%). At 2 years, the UCVA was 20/40 or better in 32 of 38 eyes (84%) and 20/25 or better in 13 eyes (34%).

Spherical Equivalent Refraction

The mean SE was −0.26 D 6 months postoperatively, −0.40 D at 1 year, and −0.50 D at 2 years. Table 2 shows the number and percentage of eyes within ±0.5 D, ±1.0 D, and ±1.5 D of emmetropia at 6

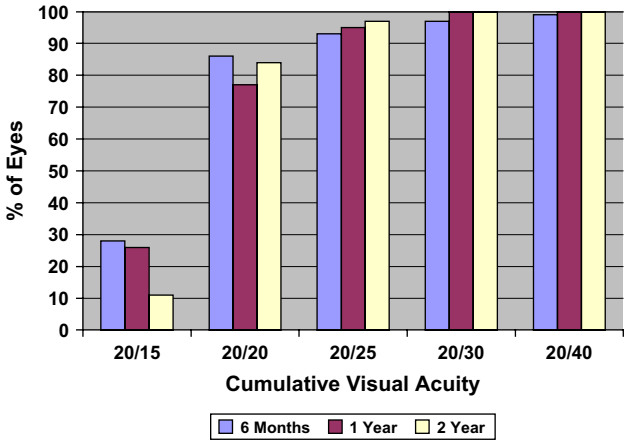

Figure 1. Cumulative BSCVA 6 months, 1 year, and 2 years postoperatively.

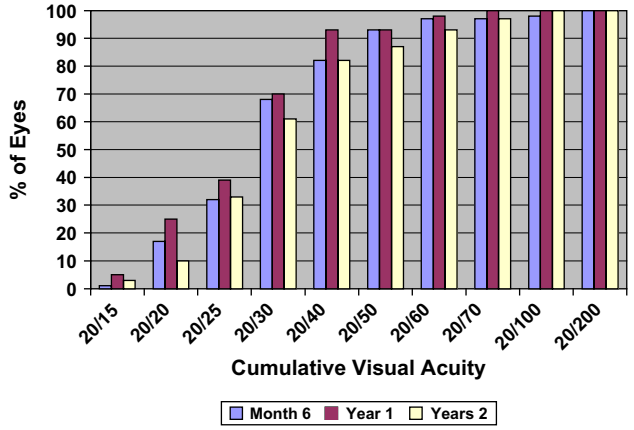

Figure 2. Uncorrected visual acuity 6 months, 1 year, and 2 years postoperatively.

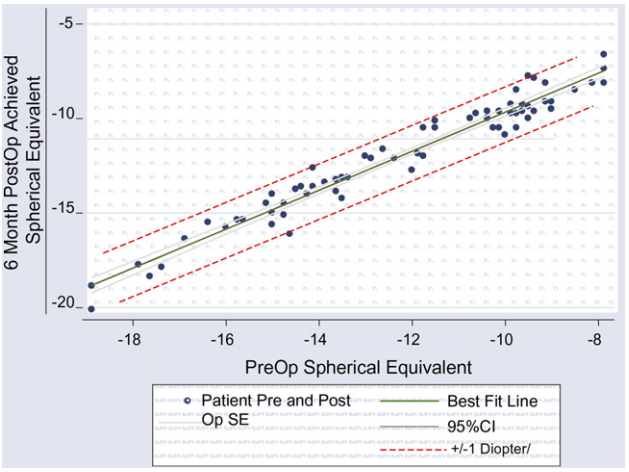

Figure 3. Linear best-fit plot (with 95% confidence interval bounded by green lines) of attempted preoperative refraction versus achieved postoperative refraction 6 months after pIOL placement.

months, 1 year, and 2 years. Figure 3 shows a linear best-fit plot of attempted preoperative refraction versus achieved postoperative refraction 6 months after pIOL implantation. Some eyes were intentionally undercorrected to avoid anisometropia.

Corneal Endothelium

Table 3 shows the mean endothelial cell density and cell density changes over time. The mean endothelial cell density increased by 0.69% at 6 months, 3.30% at 1 year, and 6.49% by 2 years. When compared to preoperative total endothelial cell count, there was a statistically significant decrease in cell count at 1 year ($P = .009$) and 2 years ($P = .002$) (Table 3). After adjusting for a 0.6% per year basal cell loss in the postoperative endothelial cell population, there was still a statistically significant endothelial cell loss from preoperatively to 1 year postoperatively ($P = .05$) and 2 years postoperatively ($P = .02$) (Table 4).

Complications and Adverse Events

Several secondary surgical interventions were necessary during the postoperative period. Of the 8 eyes with blunt trauma, 2 required pIOL repositioning. Both pIOLs were decentered and in 1 eye, both haptics were disenclaved. Another patient required pIOL repositioning for poor centration, resulting from surgeon error, to improve visual acuity and glare. Another patient elected to have the pIOL exchanged in 1 eye because of myopic undercorrection. One patient developed an IOP spike, probably as a result of retained ophthalmic viscosurgical device (OVD) after implantation. This patient developed an anterior subcapsular cataract and had pIOL removal followed by uneventful cataract extraction with posterior chamber IOL placement.

Table 2. Predictability of postoperative SE correction over time (categories not mutually exclusive).

	Number (%)		
Correction (D)	6 Months (N = 69)	1 Year (N = 60)	2 Years (N = 38)
Within ±0.5	39 (57)	34 (57)	21 (55)
Within ±1.0	60 (87)	50 (83)	32 (84)
Within ±1.5	68 (99)	59 (98)	35 (92)

Table 3. Mean endothelial cell density with interval cell density changes.

Exam	Mean Density (cells/mm^2) ± SD	Mean Change* (%) ± SD	Mean Change Adjusted*,† (%) ± SD
Preoperative	2713.2 ± 361.5	NA	NA
Postoperative			
6 mo	2729.8 ± 376.4	0.69 ± 13.65	0.99 ± 13.65
1 y	2641.3 ± 361.4	−3.30 ± 7.92	−2.70 ± 7.93
2 y	2534.4 ± 394.7	−6.00 ±10.75	−4.80 ± 10.7

NA = not applicable

*The Mean Change column compares the interval postoperative endothelial cell count with the preoperative endothelial cell count; the Mean Change Adjusted column compares the interval postoperative endothelial cell count adjusted for basal cell loss with the preoperative endothelial cell count.

†To account for a possible basal cell rate loss of 0.5% per year, adjusted values calculated as follows: for 6 months, adjusted cell count = 6-month count + (preop count × 0.003); for 1 year, adjusted cell count = 1-year count + (preop count × 0.006); for 2 year, adjusted cell count = 2-year count + (preop count × 0.012).

Table 4. Endothelial cell density interval change comparison based on Bourne et al.'s[10] reported mean rate of endothelial cell loss of 0.6% per year in unoperated eyes.

	P Value*	
Comparison	Total Cells†	Adjusted Cell Density†
Preop to 6 mo postop	.4088	.6691
Preop to 1 y postop	.0088	.0466
Preop to 2 y postop	.0018	.0157
6 mo postop to 1 y postop	.0342	.0841
1 y postop to 2 y postop	.0379	.1386

*Wilcoxon signed rank rest (comparisons of eyes with measurements at both time points)
†The Total Cells column compares the interval postoperative endothelial cell population with the preoperative endothelial cell population; the Adjusted Cell Density column compares the interval postoperative endothelial cell population that was adjusted for basal cell loss with the preoperative endothelial cell population.

Other complications included glare or halos, with 6.0% of patients reporting symptoms 1 month after surgery and 2.7% reporting halos at 2 years. Two patients (2.4%) had ovalization of the pupil. Mild corneal edema developed in 2 patients (2.4%) after prolonged, but uneventful, surgery; the edema persisted for 1 week in 1 patient and 1 month in the other. One patient (1.2%) had cell and flare that persisted for 1 month postoperatively. No other significant complications were noted.

DISCUSSION

In this study of the implantation of Artisan/Verisyse pIOLs for the treatment of high myopia, there was a significant and stable improvement in UCVA, similar to that reported by other authors.[11–13] In our population, the mean SE was corrected from −12.00 D preoperatively to −0.26 D 6 months postoperatively. Stability was good. The mean SE was −0.53 D at 2 years, with 84% of patients remaining within ±1.0 D of the intended correction. Because the use of spectacles to correct high myopia can produce a smaller image on the retina, postoperative increases in BSCVA are likely because of a magnification effect. Although patient satisfaction was not assessed in this study, a randomized study by El Danasoury et al.[13] of patients who received the Artisan/Verisyse pIOL, LASIK, or both for the correction of high myopia found that patients preferred the Artisan/Verisyse pIOL because of better quality of vision. The study also describes other advantages of the Artisan/Verisyse pIOL over LASIK including improved UCVA and BSCVA, better contrast sensitivity, a lower enhancement rate, and the possibility of pIOL exchange. Tahzib et al.[9] found a 98.3% patient satisfaction rating.

Posterior chamber pIOLs have been associated with vaulting problems, endothelial cell loss,[14,15] cataract formation,[15] and centration problems.[16] Anterior chamber angle-supported pIOLs have led to endothelial cell loss,[17] cataract formation, glare/halos, glaucoma, pupil ovalization, and retinal detachment.[18] The present generation of Verisyse pIOLs is reported to induce lower rates of endothelial cell loss, which may be explained by improvements in the structural configuration of the lens. The design places the pIOL in close proximity to the cornea, although with an ACD of 3.2 mm, the anterior surface of a −12.0 D lens lies approximately 1.71 mm from the corneal endothelium. The convex–concave design places the optic vault anterior to the pupil to avoid iris chafing.[19]

In our study, there was minimal endothelial cell loss over a 2-year postoperative window. The cell counts increased by 0.7% from baseline at 6 months and decreased by 3.3% and 6.5% from baseline after 1 year and 2 years, respectively. The improvement in endothelial cell count at 6 months may be an artifact of discontinuation of contact lens use or an artifact of measurement error. In comparison, several reports commenting on endothelial cell loss are mentioned. A longitudinal study of unoperated eyes set the baseline of mean endothelial cell loss at 0.6% ± 0.5% per year.[10] The 1-year and 2-year results in this study are similar to those reported by Asseto et al.[17] (3.9% loss at 1 year and 5.4% loss at 2 years). Menezo et al.[20] report a mean endothelial cell loss after placement of a pIOL of 3.9% at 6 months, 6.6% at 1 year, 9.2% at 2 years, 11.7% at 3 years, and 13.4% at 4 years. The 1-year postoperative mean endothelial cell loss after phacoemulsification is estimated to be from 8% to 10%.[21] Despite acceptably low endothelial cell loss rates reported in studies of the Artisan/Verisyse pIOL, long-term studies are needed to ensure the IOL can reside in the anterior chamber for decades without corneal decompensation.

In our study, the most common complication was the occurrence of glare and/or halos. However, patient reports of glare/halos decreased from 6% at 1 month to 2.7% by 2 years. Other studies found similar postoperative results. Asseto et al.[17] reported glare in 6.4% of eyes, and Budo et al.[12] reported glare in 6% of eyes and halos in 8.8% of eyes. A study by Tahzib et al.[9] found glare to be much more problematic, with a 44.1% increase in glare at night compared with that noted preoperatively. It is thought that glare after refractive surgery is induced by optic–pupil size disparity, with less contribution from pIOL centration. However, Tahzib et al. found that the scotopic pupil

size had a weak negative correlation with glare and no correlation with night-vision or night-driving scores. Phakic IOLs increase the vertical component of dilation more than the horizontal component. This change in pupil shape could induce higher orders of aberration, which also produce glare and halos.

Corneal edema occurred in 2 patients (2.4%) postoperatively and persisted to 1 month postoperatively in 1 case. Similarly, in a multicenter study, Budo et al.[12] found persistent corneal edema in 2 eyes (0.8%).

An irregular pupil was noted in 2.4% of our patients, a finding reported in previous studies using the Artisan/Verisyse pIOL.[8,11,21] The pupil ovalization might be explained mechanically by asymmetric enclavation or by enclavation of the haptics in the more central iris. Bootsma et al.[22] found a restriction in pupil dilation in the horizontal axis after horizontal Artisan/Verisyse pIOL implantation that was attributed to mechanically induced prevention of pupil dilation by the iris claw.

High IOP was observed in 1% of our cases and was likely caused by retained OVD and cataract formation. Menezo et al.[19] also reported increases in IOP after implantation of the Artisan/Verisyse pIOL but did not find the increases to be statistically significant. They found that age and axial length were prognostic indicators for increased formation of nuclear cataract after Artisan/Verisyse pIOL implantation. Maloney et al.[11] also found a higher incidence of cataract and increased IOP after implantation of the Artisan/Verisyse pIOL. They hypothesize that the increase in IOP is likely secondary to pupillary block or angle compromise.

The risk for cataract formation is higher in people with high myopia. Phakic IOL placement may induce oxidative stress or a metabolic abnormality, which could also increase the incidence of cataract at a later age in patients with pIOLs. Therefore, long-term studies are needed to determine whether the incidence of cataract formation in those with the Verisyse pIOL differs from that in those with high myopia alone.

In our study, 8 cases of blunt trauma were reported, with 2 resulting in pIOL decentration and dislocation that required repositioning of the lens. Suboptimal enclavation of lens haptics was thought to contribute to 1 of the cases requiring reenclavation.

Studies have demonstrated the stability, predictability, and accuracy of the Verisyse pIOL.[19,21,23] Similarly, the conclusion of this study is that implantation of the Artisan/Verisyse pIOL for the correction of high myopia yields favorable refractive results with acceptable short-term safety. The results in this study support the body of literature showing excellent outcomes with the Artisan/Verisyse pIOL; nonetheless, further studies are needed to elucidate long-term lens refractive stability and the safety of intraocular implantation.

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First author:
Majid Moshirfar, MD

John A. Moran Eye Center, Salt Lake City, Utah, USA