Implantation of an Artisan phakic intraocular lens for the correction of high myopia after penetrating keratoplasty

Majid Moshirfar, MD, Charles A. Barsam, MD, Jared W. Parker

We report 2 cases in which an Artisan phakic intraocular lens (IOL) (Ophtec) was used to successfully treat high myopia after penetrating keratoplasty (PKP). The first case was a 43-year-old man who had a manifest refraction of $-13.75 +3.00 \times 50$ with a best corrected visual acuity (BCVA) of $20/40^{-2}$ after PKP in the left eye. Approximately 9 months after implantation of the Artisan IOL, the manifest refraction was $-2.00 +2.50 \times 60$ with a BCVA of $20/30^{+2}$. The second case was a 31-year-old man who had a manifest refraction of $-10.75 +2.25 \times 122$ and a BCVA of 20/40 after corneal transplantation in the right eye. Ten months after implantation of the Artisan IOL, the manifest refraction was $-2.75 +4.75 \times 80$ with a BCVA of 20/40. Endothelial cell density did not change significantly in either patient after surgery. The Artisan phakic IOL may provide an alternative method to correct high myopia after PKP.

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Penetrating keratoplasty (PKP) has become an effective means to treat a variety of corneal pathologies. Although advances in this procedure have occurred in the past 2 decades, a high postoperative refractive error continues to be a problem for many patients. The refractive error is often corrected by contact lenses or, more recently, by laser in situ keratomileusis (LASIK).[1] Clear lens extraction is also an option.

In some patients, these treatments are not appropriate. Anisometropia can limit the use of contact lenses and spectacles to correct the postoperative refractive error. Dry eyes, corneal vascularization, and lens intolerance may also prevent the use of contact lenses. Furthermore, LASIK is less predictable at correcting higher levels of myopia and is sometimes not feasible because of inadequate corneal thickness.[2] Clear lens extraction has a risk for retinal detachment (RD) and cystoid macular edema and results in the loss of accommodation. An alternative method of myopic correction is needed in these circumstances.

Recent studies demonstrate the success of the Artisan iris-supported phakic intraocular lens (IOL) (Ophtec) to correct moderate to high myopia.[3–7] Although long-term follow-up data are pending, implantation of this IOL shows promise in providing an alternative to improve the refractive error in highly myopic patients. We describe 2 patients who had implantation of the Artisan phakic IOL after PKP for the correction of the postoperative refractive error.

Case Reports

Case 1

A 43-year-old man developed bilateral iatrogenic keratectasia after radial keratotomy and automated lamellar keratectomy for the treatment of myopia. Before presentation at the Moran Eye Center, the patient had had corneal trans-

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

Dr. Moshirfar is a clinical investigator for the United States Food and Drug Administration Phase III clinical trial of the Ophtec Artisan intraocular lens.

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Reprint requests to Majid Moshirfar, MD, John A. Moran Eye Center, University of Utah, 50 North Medical Drive, Salt Lake City, Utah 84132, USA. E-mail: Majid.Moshirfar@hsc.utah.edu.

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Table 1. Manifest refraction, the UCVA, and the BCVA before and after implantation of the Artisan phakic IOL.

	Case 1	Case 2
Preoperative manifest refraction	−13.75 +3.00 × 50	−10.75 +2.25 × 122
Postoperative manifest refraction	−2.00 +2.50 × 60	−2.75 +4.75 × 80
Preoperative UCVA	CF at 2 feet	CF at 2 feet
Postoperative UCVA	$20/40^{+1}$	20/80
Preoperative BCVA	$20/40^{-2}$	20/40
Postoperative BCVA	$20/30^{+2}$	20/40

BCVA = best corrected visual acuity; CF = counting fingers; UCVA = uncorrected visual acuity

plantation in the right eye. The best corrected visual acuity (BCVA) after successful transplantation was 20/300 secondary to a history of RD. At the time of presentation, the BCVA in the left eye was $20/70^{-2}$ because of central corneal scarring and keratectasia. Corneal transplantation was performed in the left eye for visual rehabilitation. All sutures were removed approximately 1 year after successful PKP. Eighteen months after transplantation, the manifest refraction was −13.75 +3.00 × 50 with a BCVA of $20/40^{-2}$. The uncorrected visual acuity (UCVA) was counting fingers (CF) at 2 feet. The crystalline lens in the left eye was clear with no signs of cataract.

Multiple attempts were made to fit gas-permeable contact lenses, but the patient was not tolerant of this correction. Spectacles were not tolerated because of the level of anisometropia. Laser in situ keratomileusis was not considered because of the patient's history of diabetes, high myopia, and low baseline corneal thickness. To relieve the anisometropia and correct the large refractive error in the left eye, the Artisan phakic IOL was implanted.

Because our center was a participant in Phase III of the United States Food and Drug Administration (FDA) study evaluating the Artisan IOL, the institutional review board overseeing the study was petitioned for compassionate use of this IOL. This was granted and after informed consent was obtained from the patient, a 6.0 mm IOL (model 204) was implanted in the left eye.

Before surgery, the anterior chamber depth (ACD) in the left eye was 3.77 mm and the corneal thickness was 497 μm. The preoperative endothelial cell density was 3200 cells/mm^2. A neodymium:YAG (Nd:YAG) iridotomy was performed superiorly at 11 o'clock. Under topical anesthesia, an Artisan IOL with a power of –13.0 diopters (D) was carefully centered and enclaved on the iris along the visual axis. The patient tolerated the procedure well. Postoperatively, the IOL was noted to be well centered in the visual axis.

Visual acuity stabilized at 1 month, and the manifest refraction was −1.50 +2.75 × 50 with a BCVA of $20/40^{+1}$ and a UCVA of 20/50. At 9 months, the manifest refraction was −2.00 +2.50 × 60 with a BCVA of $20/30^{+2}$ and a UCVA of $20/40^{+1}$ (Table 1).

Approximately 6 months after surgery, the patient showed no evidence of corneal decompensation and the endothelial cell density was 3098 cells/mm^2.

Case 2

A 31-year-old man had an alkaline chemical injury in the right eye, which resulted in significant disturbance of the ocular surface. Subsequent conjunctivalization of the cornea with associated corneal scarring and vascularization ensued, and a significant decrease in visual acuity occurred. Shortly after the accident, the patient had conjunctivoplasty, limbal cell autograft transplantation, and tarsorrhaphy in the right eye. After a healing period of 6 months, PKP was performed in the eye.

Five years after the transplantation, the UCVA remained CF at 2 feet. The manifest refraction was −10.75 +2.25 × 122 with a BCVA of 20/40. The patient's ocular surface disease, corneal neovascularization, and persistent dry eye continued. For these reasons, he was unable to tolerate contact lenses or have LASIK to correct the myopia. Spectacles also were not tolerated because of the high level of anisometropia. The patient's young age made clear lens extraction less favorable.

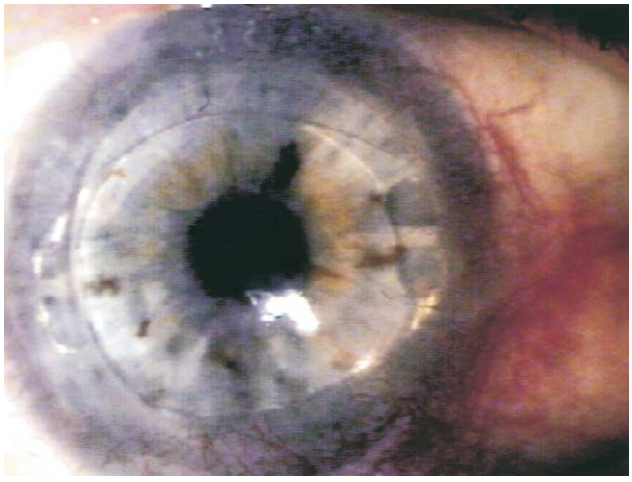

Figure 1. (Parker) The Artisan IOL in Case 2, 10 months after surgery.

The institutional review board overseeing the Phase III FDA study was again petitioned for compassionate use of the Artisan IOL. This was granted and after informed consent was obtained, a 6.0 mm Artisan phakic IOL (model 204) was implanted in the right eye.

Before surgery, the ACD in the right eye was 3.55 mm. The crystalline lens was clear without sign of cataract, and the endothelial cell density was 985 cells/mm^2. Preoperatively, an Nd:YAG iridotomy was performed superiorly at 11 o'clock. A −11.00 D Artisan IOL was well centered over the pupil and fixated to the iris.

One month after surgery, the manifest refraction was −1.75 +4.75 × 86 with a BCVA of 20/30 and a UCVA of 20/100. Approximately 10 months postoperatively, the manifest refraction was −2.75 +4.75 × 80 with a BCVA of 20/40. The UCVA was 20/80 (Table 1, Figure 1). At 5 months, the endothelial cell density was 973 cells/mm^2 with no clinical evidence of corneal decompensation.

Discussion

The Artisan iris-supported phakic IOL provides an alternative method for correcting refractive errors after PKP. Although contact lenses, spectacles, and LASIK remain viable options, these options were not appropriate for our 2 cases. Our cases support the work of Tehrani and Dick,[8] who report the successful correction of high astigmatism with a toric Artisan IOL after corneal transplantation.

The possibility of accelerated endothelial cell loss in patients with Artisan IOLs is a concern.[3–5,9] The rate of endothelial loss in normal eyes is 0.6% per year.[10] Those who have had PKP lose 34.0% (±22.0%) of endothelial cells in the first year posttransplantation.[11] In eyes with corneal transplantation, an endothelial cell loss rate of 7.8% per year has been reported at 3 to 5 years.[11] At 5 to 10 years, an associated endothelial cell loss of 4.2% per year is reported.[12]

In our 2 patients, no significant endothelial cell density loss was found 5 and 6 months postoperatively with an Artisan IOL. Our experience mirrors data accumulated by the FDA in its formal investigation of endothelial cell loss after Artisan IOL implantation. A review of the FDA's 6-month postimplantation data reveals no evidence of accelerated endothelial cell loss.[3] It has not been determined whether the endothelial cell loss rate differs between the FDA study group and patients who have Artisan IOL implantation after corneal transplantation. These patients would be expected to lose endothelial cells at a rate at least comparable to that in patients who have had only PKP.

In our opinion, the long-term risk–benefit ratio of Artisan IOL implantation in postkeratoplasty eyes is not higher than in normal myopic eyes with no history of ocular surgery. The goal of PKP is to improve the optical functioning of the diseased eye; thus, acceptance of certain surgical risks is justifiable. The use of the Artisan IOL in this setting is superior to LASIK or clear lens extraction because there is no manipulation or removal of corneal tissue or the crystalline lens. The reversibility of this procedure is also appealing, as the Artisan IOL is exchangeable or removable. The patients we describe and others who have had successful corneal transplantation were unable to reap the optimal visual benefits of PKP. In these cases, the Artisan IOL may be the only option for improved visual acuity. Subjecting these patients to an additional intraocular procedure and its attendant risks seems to be an acceptable approach that warrants further investigation.

Progress in PKP has been aided by sophisticated tissue banking and the preservation and distribution of corneal grafts. Nonetheless, postoperative myopic astigmatism remains a formidable challenge in postcorneal transplantation visual rehabilitation. With the FDA study in progress, approval of the Artisan IOL would, in our opinion, provide an opportunity for improved vision after PKP in selected patients for whom other visual rehabilitation options do not exist.

References

1. Malecha MA, Holland EJ. Correction of myopia and astigmatism after penetrating keratoplasty with laser in situ keratomileusis. Cornea 2002; 21:564–569
2. Knorz MC, Wiesinger B, Liermann A, et al. Laser in situ keratomileusis for moderate and high myopia and myopic astigmatism. Ophthalmology 1998; 105:932–940
3. Maloney RK, Nguyen LH, John ME. Artisan phakic intraocular lens for myopia; short-term results of a prospective, multicenter study; the Artisan Lens Study Group. Ophthalmology 2002; 109:1631–1641
4. Landesz M, Worst JGF, van Rij G. Long-term results of correction of high myopia with an iris claw phakic intraocular lens. J Refract Surg 2000; 16:310–316
5. Landesz M, van Rij G, Luyten G. Iris-claw phakic intraocular lens for high myopia. J Refract Surg 2001; 17: 634–640
6. El Danasoury MA, El Maghraby A, Gamali TO. Comparison of iris-fixed Artisan lens implantation with exci-

mer laser in situ keratomileusis in correcting myopia between −9.00 and −19.50 diopters; a randomized study. Ophthalmology 2002; 109:955–964
7. Malecaze FJ, Hulin H, Bierer P, et al. A randomized paired eye comparison of two techniques for treating moderately high myopia; LASIK and Artisan phakic lens. Ophthalmology 2002; 109:1622–1630
8. Tehrani M, Dick HB. Korrektur eines höhergradigen Astigmatismus nach Keratoplastik durch Implantation einer phaken torischen Iris-Klauen-Linse. Klin Monatsbl Augenheilkd 2002; 219:159–163
9. Menezo JL, Cisneros AL, Rodriguez-Salvador V. Endothelial study of iris-claw phakic lens: four year follow-up. J Cataract Refract Surg 1998; 24:1039–1049
10. Bourne WM, Nelson LR, Hodge DO. Central corneal endothelium cell changes over a 10-year period. Invest Ophthalmol Vis Sci 1997; 38:779–782
11. Bourne WM, Hodge DO, Nelson LR. Corneal endothelium five years after transplantation. Am J Ophthalmol 1994; 118:185–196
12. Ing JJ, Ing HH, Nelson LR, et al. Ten-year postoperative results of penetrating keratoplasty. Ophthalmology 1998; 105:1855–1865