

# Artisan Iris-supported Phakic IOL Implantation in Patients With Keratoconus: A Review of Sixteen Eyes

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## ABSTRACT

**PURPOSE:** To evaluate the clinical outcomes of Artisan phakic intraocular lens (pIOL; Ophtec BV) implantation in patients with stable keratoconus.

**METHODS:** In a prospective, nonrandomized case series, 14 Artisan pIOLs and 2 toric Artisan pIOLs were implanted in 13 patients (16 eyes) with stable keratoconus who had contact lens intolerance. Pre- and postoperative data were collected.

**RESULTS:** Mean follow-up was  $14.2 \pm 7.8$  months. Preoperative uncorrected distance visual acuity (UDVA) was counting fingers in all patients. Mean final logMAR (Snellen equivalent) UDVA and corrected distance visual acuity (CDVA) were  $0.15(20/28) \pm 0.13$  and  $0.11(20/26) \pm 0.10$ , respectively. The improvements in UDVA and CDVA were statistically significant ( $P < .0001$  and  $P < .002$ , respectively). All patients achieved a final UDVA of 20/40 or better, and 84.6% had a final CDVA of 20/32 or better. No postoperative complications occurred except for two cases of sterile uveitis.

**CONCLUSIONS:** Implantation of the Artisan pIOL is effective in improving visual acuity in patients with stable keratoconus. Long-term safety remains to be established as no postoperative endothelial cell counts were performed. [*J Refract Surg.* 2011;xx(x):xxx-xxx.] doi:10.3928/1081597X-20110203-01

**K**eratoconus is a bilateral, noninflammatory eye condition characterized by progressive corneal thinning, protrusion, and scarring.<sup>1</sup> Risk factors for progression include young age of onset, short duration of disease, and steep keratometry.<sup>2</sup> Current treatment options include rigid gas permeable (RGP) contact lenses, lamellar and penetrating keratoplasty, corneal cross-linking (CXL), and intracorneal ring segment implantation. Although contact lenses are one of the best options available for the correction of refractive errors,<sup>3</sup> patients with RGP lens intolerance require surgical intervention.<sup>4</sup>

Implantation of an intraocular lens (IOL) between the cornea and native lens, also referred to as phakic IOL (pIOL), is a relatively new procedure in the correction of refractive error in keratoconic patients. However, the application of this treatment modality has been limited by standard exclusion criteria including, but not limited to, inflammatory disease, shallow anterior chamber depth, and low endothelial cell count. Furthermore, information is limited regarding the indications for pIOL implantation in keratoconus or the long-term effects of the procedure. Although keratoconus is not a currently acceptable indication for pIOL implantation, other surgeons have performed such procedures and reported reasonable outcomes.<sup>5,6</sup>

The aim of this study was to evaluate the efficacy of Artisan pIOLs (Ophtec BV, Groningen, The Netherlands) in keratoconic eyes to determine whether keratoconus is an indication for pIOL implantation.

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TABLE

### Pre- and Postoperative Outcomes of 13 Patients (16 Eyes) Who Underwent Artisan Phakic Intraocular Lens Implantation for Keratoconus

Patient No.	Eye/Age/Sex	UDVA	CDVA	Preoperative		
				Refraction (D)	F/S SimK (D)	S/C
1	OD/24/F	CF	20/32	-12.50 -2.50	54.00/56.00	5.0
2	OS/18/M	CF	20/32	-12.25 -1.75	46.75/49.00	7.0
3	OS/29/F	CF	20/32	-10.50 -0.50	51.75/53.25	21.0
4	OS/25/M	CF	20/32	-12.00 -5.00	53.00/57.75	2.4
5	OD/21/M	CF	20/25	-11.00 -3.50	51.25/55.25	3.1
	OS	CF	20/32	-9.75 -2.50	49.00/51.50	3.9
6	OD/37/F	CF	20/40	-9.75 -3.00	49.00/51.50	3.3
	OS	CF	20/25	-5.75 -0.25	47.75/49.00	23.0
7	OS/27/M	CF	20/50	-22.50 -7.00	49.00/51.00	3.2
8	OD/29/M	CF	20/25	-11.00 -4.75	53.50/55.50	2.3
9	OD/21/M	CF	20/32	-13.25 -3.00	52.00/55.00	4.4
	OS	CF	20/20	-11.00 -1.50	51.00/52.00	7.3
10	OS/27/M	CF	20/20	-9.50 -0.75	46.00/49.50	12.7
11	OS/24/M	CF	20/50	-13.75 -2.00	57.00/58.00	6.9
12	OS/24/M	CF	20/40	-15.50 -3.75	54.00/57.00	4.1
13	OS/26/M	CF	20/63	-20.00 -5.50	53.50/54.50	3.6

UDVA = uncorrected distance visual acuity, CDVA = corrected distance visual acuity, F/S SimK = flat and steep simulated keratometry, S/C = sphere to cylinder ratio, IOL = intraocular lens, OD = right eye, CF = counting fingers, OS = left eye, A6 = 6-mm Artisan pIOL, AT = Artisan toric pIOL  
 Note. Patients aged <25 years underwent cross-linking 6 months prior to pIOL implantation.

#### PATIENTS AND METHODS

In our prospective study, we selected keratoconic patients who were referred to or followed in the Mashad Toos Eye Clinic, Mashad, Iran to undergo Artisan pIOL implantation. All patients had subjective contact lens intolerance and stable keratoconus, defined as unchanged refractive error and topographic pattern during the past 2 years, even in the presence of corneal scarring and thinning. For patients aged <25 years, CXL was performed 6 months prior to pIOL implantation to ensure stability of the refractive error and topographic pattern.

Inclusion criteria were diagnosis of keratoconus determined by slit-lamp examination, retinoscopy, and the interpretation of topographic data using the KISA% index as described by Rabinowitz and Rasheed,<sup>7</sup> as well as a high spherical-to-cylindrical ratio (>2.0) and myopia >8.00 diopters (D). Toric Artisan lenses were implanted in eyes that showed spherical-to-cylindrical ratios <4.0 and gained more than two Snellen lines by adding astigmatism correction in the spectacle plane in subjective refraction. The Van der Heijde formula was used to calculate IOL power. Patients were ex-

cluded if they had crystalline lens opacities, corneal opacities, glaucoma, ocular inflammatory diseases, anterior chamber depth <3 mm, or endothelial cell count <2200 cells/mm<sup>2</sup>.<sup>1</sup>

Two days prior to surgery, Placido-based topography (Humphrey Atlas; Zeiss, Dublin, California) and Orbscan IIz (Bausch & Lomb, Rochester, New York) were performed. Collected patient data included uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), manifest and cycloplegic refraction, retinoscopy, simulated keratometry, anterior chamber depth, axial length, and posterior best-fit sphere pachymetry. Slit-lamp microscopy, applanation tonometry, dilated funduscopy, and endothelial cell counts were also performed.

Informed written consent was obtained from all patients after they were notified about treatment options and possible risks. This investigation was approved by the review board/ethics committee of the Mashad University of Medical Science Eye Research Centre. All surgeries were performed by the same surgeon (M.S.).

Prior to surgery, patients received a preoperative application of a pharmacologic miotic. Depending on

IOL	IOL Power (D)	Follow-up (mo)	Postoperative		
			UDVA	CDVA	Refraction (D)
A6	-14.50	6	20/32	20/25	1.00 -3.00
A6	-13.50	13	20/40	20/40	0.25 -2.75
A6	-11.50	12	20/20	20/20	-3.50 -0.50
A6	-15.00	11	20/25	20/20	-3.50 -3.50
A6	-14.00	20	20/25	20/25	0.75 -2.25
A6	-13.00	14	20/25	20/20	2.25 -1.50
A6	-12.00	28	20/32	20/25	0.50 -2.00
A6	-7.00	26	20/32	20/20	-0.25 -2.00
A6	-23.00	6	20/63	20/40	1.00 -2.50
AT	-11.50/-4.00	7	20/32	20/32	0.75 -2.25
A6	-15.00	8	20/20	20/20	-0.50 -3.00
A6	-13.50	12	20/20	20/20	1.50 -1.25
A6	-10.50	28	20/25	20/25	-3.00 -0.75
A6	-16.50	20	20/32	20/32	2.00 -1.00
A6	-18.50	7	20/25	20/25	0.25 -0.50
AT	-18.00/-3.00	9	20/32	20/25	1.00 -2.00

the size of the optics, a 5- or 6-mm superior clear corneal incision was made using a keratome between 10 and 2 o'clock, and two stab incisions were made at the 10-and 2-o'clock positions. For toric Artisan lenses, the incision was made parallel to the axis of the IOL. The anterior chamber was filled with a Cellugel ophthalmic viscosurgical device (Alcon, Hünenberg, Switzerland). The pIOL was inserted into the anterior chamber. After the IOL was rotated into proper position, it was fixed to the iris with an enclavation needle. A peripheral iridectomy was performed at the end of the surgery. Interrupted 10-0 nylon sutures were used for wound closure. Topical ciprofloxacin 0.3% and betamethasone 1% were used four times a day for 2 weeks with tapered doses of betamethasone for 2 weeks. Patients were examined the next day, 1 week, and 1, 3, and every 6 months after surgery, and UDVA, CDVA, cycloplegic refraction, and refraction coefficient were recorded. All sutures were removed within 3 months of surgery.

**RESULTS**

Sixteen eyes of 13 patients (10 men and 3 women) were included in this study. Mean patient age was

25.4±4.7 years (range: 18 to 37 years). Mean follow-up was 14.2±7.8 months (range: 6 to 28 months). Artisan lenses were implanted in 16 eyes (14 spherical and 2 toric). The Table presents the pre- and postoperative data of all patients.

Preoperative UDVA was counting fingers in all patients, and mean logMAR (Snellen) CDVA was 0.21(20/32)±0.14 (range: 0.00 to 0.50 [20/20 to 20/63]). Mean spherical cycloplegic refraction was 12.50±4.61 D (range: -5.75 to -22.50 D), cylindrical refraction was 2.95±4.06 D (range: 0.25 to 7.00 D), and spherical equivalent refraction was -13.90±4.61 D (range: -5.90 to -26.00 D). Mean average simulated keratometry was 52.28±3.00 D (range: 47.80 to 57.50 D), and the posterior best-fit sphere was 57.87±2.02 D (range: 54.20 to 60.80 D), according to Orbscan IIz topography. Mean axial length was 25.33±1.55 mm (range: 23.04 to 29.81 mm). Mean anterior chamber depth was 3.85 mm (range: 3.20 to 4.47 mm). Mean KISA% index was 3064 (range: 337 to 11 026). Mean axial length was 25.34 mm (range: 23 to 29.8 mm).

Mean final logMAR (Snellen) UDVA and CDVA were 0.15(20/28)±0.13 and 0.11(20/26)±0.10, respec-

tively. All patients had a final UDVA of 20/40 or better, and 84.6% had final CDVA of 20/32 or better. A two line improvement in CDVA was achieved in 50% of eyes. The improvements in UDVA and CDVA were statistically significant ( $P < .0001$  and  $P < .002$ , respectively). Mean final spherical and cylindrical refractions were  $-0.03 \pm 1.81$  D (range:  $+2.25$  to  $-3.50$  D) and  $2.08 \pm 1.04$  D (range:  $0.50$  to  $3.50$  D), respectively. The changes in sphericity were statistically significant ( $P < .001$ ). The change in cylindrical refraction was not significant ( $P > .05$ ) after Artisan lens implantation, indicating that the clear corneal wound did not have a major impact on final astigmatism. Mean final spherical equivalent refraction was  $-0.90 \pm 1.90$  D. A comparison of the spherical CDVA did not reveal a statistically significant difference between the CXL-treated group (patients aged  $<25$  years) compared to the non-CXL-treated group ( $P = .42$ ).

No significant postoperative complications occurred in this series except for sterile uveitis in 2 (12.5%) non-CXL-treated eyes, which presented with increased cell and flare in the anterior chamber on postoperative day 1 and resolved within 1 week following treatment with a topical steroid and oral prednisone (50 mg/day). No long-term complications were seen in these two patients during the follow-up period.

### DISCUSSION

In certain instances, previous contraindications for pIOL implantation may have proven to be too conservative, as in the case of stable keratoconus.<sup>8-10</sup> The use of pIOLs in keratoconic patients has been reported in some case series.<sup>6,11-17</sup> In 2003, Leccisotti and Fields<sup>18</sup> reported the largest case series in this patient population, evaluating the visual outcomes of angle-supported phakic spherical IOLs in early-stage keratoconus in 12 eyes of 8 patients. Postoperative UDVA at 12 months was 20/40 or better in all eyes and the spherical error in all cases was corrected within  $\pm 1.00$  D of emmetropia. The mean preoperative spherical-to-cylindrical ratio in their study was 3.71, compared to our mean of 7.08 (range: 2.3 to 23).

Moshirfar et al<sup>11</sup> inserted spherical pIOLs into two eyes with relatively high astigmatism and high spherical-to-cylindrical ratios; final astigmatism remained high despite relatively well-corrected spherical equivalent refraction and UDVA. Budo et al<sup>6</sup> considered implantation of toric pIOLs in six eyes of three patients with keratoconus and high astigmatism. The mean preoperative spherical-to-cylindrical ratio in their study was 3.2, and four patients had a ratio  $< 2.0$ .

Preoperative CDVA of all selected patients in our series was 20/63 or better. We hypothesize that kera-

toconic patients who have a good preoperative CDVA and a high spherical-to-cylindrical ratio are good candidates for pIOL implantation. These criteria exclude eyes with advanced keratoconus or highly irregular astigmatism. We contend that toric Artisan lenses can be considered for patients who show significant (two line) increases in CDVA with astigmatism correction. These patients have more regular astigmatism, and the axis of astigmatism can be approximated in subjective refraction. Our final spherical refraction shifted to the myopic range in contrast to the results reported by Moshirfar et al.<sup>11</sup> Our results do not indicate a significant change in cylindrical refraction ( $P > .05$ ) after Artisan pIOL implantation, but vector analysis was not used to compare pre- and postoperative astigmatism.

Keratometry in keratoconic eyes is not reliable due to the high level of multifocality in the pupillary zone. We believe the Van der Heijde formula provides acceptable results in pIOL calculation in keratoconic eyes, and that clear corneal incision can be done in keratoconic eyes with no greater change in astigmatism error than would be anticipated in normal eyes. The multifocality of the keratoconic eye may explain the contradictory clinical picture observed in select patients. These keratoconic patients have good postoperative UDVA despite high levels of myopia or astigmatism (eg, CDVA of 20/20 with  $-3.50 -0.50$  (patient 3), 20/25 with  $-3.50 -3.50$  (patient 4), or 20/20 with  $-0.50 -3.00$  (patient 9, OD)).

Although Pflugfelder et al<sup>19</sup> described corneal thickness as an index to differentiate keratoconus from RGP-related ectasia, this was not a specific inclusion parameter in the present study. Another limitation of the present study is the exclusion criterion of endothelial cell count  $< 2200$  cells/mm<sup>2</sup>. Although higher than the limit of 2000 cells/mm<sup>2</sup> set in the original study of pIOL implantation,<sup>20</sup> in young patients, preoperative endothelial cell counts should be higher to permit adequate long-term endothelial survival.<sup>21</sup> Ensuring stability in keratometry is an important criterion for surgery, therefore, it was decided to wait 6 months after CXL before implanting pIOLs in patients aged  $< 25$  years. Outcomes of CDVA did not demonstrate a statistically significant difference between the CXL-treated and non-CXL-treated groups. Furthermore, to address the concern that anterior chamber lenses cause endothelial cell density loss, our study would have benefited from postoperative endothelial cell density measurements.

According to our study and as reflected in some previous case series, pIOL implantation is an effective method for improvement of visual acuity in stable and RGP lens-intolerant keratoconic patients. This proce-

dures may be especially beneficial in patients who have good preoperative CDVA, high spherical-to-cylindrical ratio, and a higher than normal axial length. Suitable cases for toric Artisan implantation will manifest a significant increase in visual acuity with astigmatism correction.

**AUTHOR CONTRIBUTIONS**

Study concept and design (M.S., M.R.A.A., M.Z.G.); data collection (M.S., M.R.A.A., M.Z.G.); analysis and interpretation of data (M.S., M.R.A.A., S.W.D., S.S.); drafting of the manuscript (M.S., M.R.A.A., M.Z.G., S.W.D., S.S.); critical revision of the manuscript (M.R.A.A., M.Z.G., S.W.D., S.S.); statistical expertise (M.S., M.R.A.A., M.Z.G., S.S.)

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