

Artisan Toric Lens Implantation for Correction of Postkeratoplasty Astigmatism

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Purpose: To determine the efficacy of Artisan toric iris-fixated lens implantation after penetrating keratoplasty to correct high ametropia and astigmatism.

Design: Prospective, noncomparative case series.

Participants: Artisan toric lens implantation was performed in 16 eyes of 16 patients who were contact lens intolerant or were unable to wear glasses because of anisometropia, high astigmatism, or both.

Intervention: Sixteen eyes of 16 patients received Artisan toric lenses for postkeratoplasty astigmatism, anisometropia, or both.

Main Outcome Measures: Manifest refraction, uncorrected and spectacle-corrected visual acuity, and corneal topography were performed before surgery and 1, 3, 6, 12, and 18 months after surgery. Efficacy, percent reduction of refractive astigmatism, topographical astigmatism, anisometropia of defocus, and the astigmatism correction index were determined. A patient satisfaction questionnaire and specular microscopy results were assessed.

Results: The mean \pm standard deviation of the preoperative refractive cylinder was -6.66 ± 1.93 diopters (D; range, -4.0 to -10.0 D), which was reduced to -2.08 ± 1.33 D, -2.14 ± 1.76 D, -1.98 ± 1.65 D, -1.84 ± 0.77 D, and -1.42 ± 0.78 D at 1 month, 3 months, 6 months, 12 months, and the final follow-up examination (8.4 ± 4.9 months), respectively. Spherical equivalent was reduced from -4.90 ± 5.50 D before surgery to -0.96 ± 0.86 D at the final follow-up. The uncorrected and best-corrected visual acuities were $\geq 20/40$ in 42% and 100% of eyes, respectively. There was no loss of best-corrected visual acuity and a gain of at least 2 lines in 50% of eyes. The percent reduction in refractive astigmatism, topographical astigmatism, and anisometropia of defocus were $78.0 \pm 11.5\%$, $20.3 \pm 34.9\%$, and $77.0 \pm 12.0\%$, respectively. The astigmatism correction index was $102.8 \pm 18.6\%$. Satisfaction increased from 3.2 to 8.3 after implantation. The endothelial cell loss was $7.6 \pm 18.9\%$ at 3 months and $16.6 \pm 20.4\%$ at the last follow-up. In 1 patient, a reversible graft rejection occurred.

Conclusions: Artisan toric lens implantation after penetrating keratoplasty was effective for reduction of refractive astigmatism and ametropia. All patients were suitable for spectacle correction after implantation. A longer follow-up and a larger number of patients are needed to assess the safety and the effect of the lens on the corneal graft endothelium. *Ophthalmology* 2004;111:1086-1094 © 2004 by the American Academy of Ophthalmology.

The purpose of the present study was to determine the efficacy of toric iris-fixated intraocular lens implantation for the reduction of anisometropia and astigmatism to allow spectacle wear in patients with contact lens intolerance after keratoplasty. Although visual function may show substantial improvement after keratoplasty,¹ many series that have

examined the results of corneal grafting have reported significant astigmatism of 4 to 5 diopters (D).²⁻⁵ It is well known that patients do not tolerate spectacle correction for more than 3 to 4 D of astigmatism or anisometropia. Therefore, contact lenses are fitted in 10% to 30% of patients, and in keratoconus, this value may increase up to 50%.^{6,7} Contact lenses may be effective in 80% of cases, but contact lens intolerance in the postkeratoplasty population may be high because of ocular problems such as topographical abnormalities, blepharitis and dry eye, poor manual dexterity, occupational problems, and lack of motivation. Surgical correction of postkeratoplasty astigmatism has been performed by corneal relaxing incisions,^{8,9} wedge resections,¹⁰ and intraocular lens (IOL) exchange or piggyback implantation.^{11,12} Recently, excimer laser photorefractive keratectomy and LASIK have been used for corneal tissue ablation. However, photorefractive keratectomy causes significant haze in corneal grafts and induces irregular astigmatism and regression.¹³⁻¹⁵ LASIK surgery is able to treat a greater range of postkeratoplasty refractive error, but the corneal

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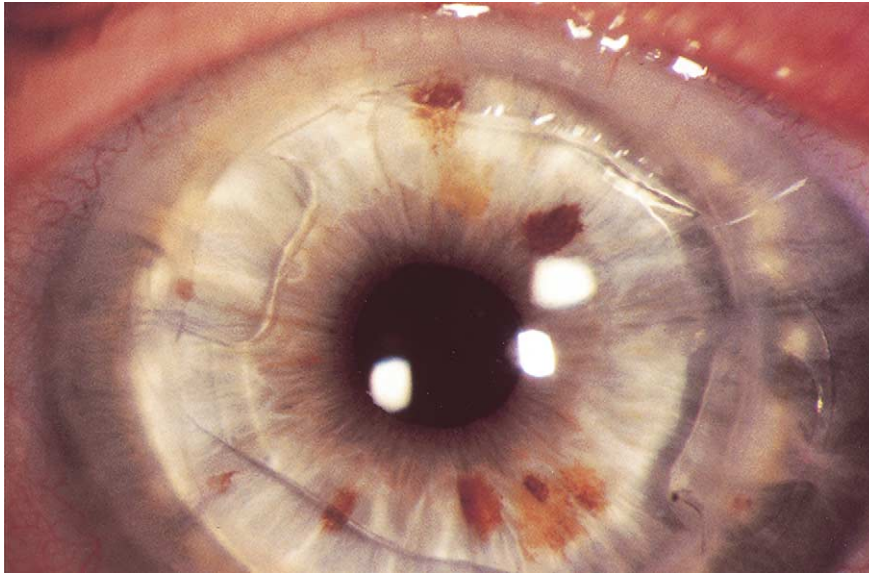


Figure 1. Artisan toric lens implantation for correction of postkeratoplasty astigmatism (patient 9; Table 1). Before surgery, the best-corrected visual acuity was 20/50 with -9.0 to $6.0 \times 165^\circ$. Six months after implantation of an Artisan toric lens with a power of -8.5 to $5.5 \times 0^\circ$ and enclavated in the axis 165° , best-corrected visual acuity increased to 20/32 with plano $-2.0 \times 50^\circ$ and uncorrected visual acuity increased to 20/40.

graft thickness and the amount of ametropia and astigmatism suitable for correction limit the efficacy of the procedure. In addition, wound dehiscence resulting from the high vacuum pressure, flap complications in steep corneas, and a high rate of retreatments may occur.^{16–21}

Patients and Methods

Patient Population

The 16 eyes of 16 patients included in this study could not be corrected by spectacle wear because of anisometropia, because of the magnitude of refractive cylinder, or because the patients were contact lens intolerant. Exclusion criteria were as follows: a preoperative spectacle-corrected visual acuity worse than 20/50, an anterior chamber depth less than 3.0 mm, glaucoma, retinal pathologic features, or an endothelial cell count lower than 500 cells/mm². Investigational review board approval was obtained from the Academic Hospital Maastricht.

Patient Examination

Patients were examined before surgery and at day 1, week 1, month 1, month 3, month 6, and subsequently at 6-month intervals. Before surgery, uncorrected visual acuity (UCVA) and best spectacle-corrected visual acuity (BCVA) with subjective refraction, cycloplegic refraction, slit-lamp microscopy, applanation tonometry, dilated fundus examination, and pupil size measurement at dim illumination with the Colvard pupillometer (Oasis, Glendora, CA) were performed. On postoperative day 1, UCVA, BCVA, and biomicroscopic examination with registration of intraocular pressure were performed. Thereafter, UCVA and BCVA with subjective refraction, slit-lamp microscopy, applanation tonometry, and corneal topography were assessed. The simulated keratometry values of the steep and flat meridians were used for calculation of the topographically induced surgical astigmatism. Before surgery and at 3 months, 6

months, and 1 year after surgery, specular microscopy of the corneal endothelium using a noncontact specular microscope (Noncon Robo, SP 8000, Konan, Hyogo, Japan) was performed.^{22,23} Before surgery and at 3 months after surgery, the patients were asked to rate the quality of vision of the eye with their present correction on a visual analog scale of 1 to 10 (1 being very poor, and 10 excellent), based on a previously validated questionnaire.²⁴

Surgical Technique

The Artisan toric intraocular lens (Ophtec BV, Groningen, The Netherlands) has a convex-concave toric optic with a spherical anterior surface and a spherocylindrical posterior surface. This single-piece lens is composed of polymethyl methacrylate and is manufactured using compression molding technology. The toric lens is iris claw fixated and has a 5-mm optical zone (Fig 1). Refractive error, refractive cylinder power, anterior chamber depth, and topographically derived keratometric dioptric values were inserted into the Van der Heijde formula²⁵ to calculate the dioptric power of the lens for 2 meridians. The axis of the cylinder identified by the subjective refraction was used to determine the axis of surgical enclavation. The power of the lens was chosen to obtain emmetropia (14 eyes) or a postoperative spherical equivalent of -1.0 D (2 eyes) resulting from myopia in the untreated eyes. In these 2 eyes, the spherical equivalent of the fellow eyes was -3.0 D and -3.75 D. The intraocular lens is available in dioptric powers of -3.0 to -20.5 D, $+2.0$ to $+12.0$ D, and in cylindrical powers of 2.0 to 7.5 D. The cylinder is in line with the haptics or at an angle of 90° with the haptics. In 6 of 16 eyes, the cylinder dioptric power of the toric lens had less power than required for full correction of the cylinder. All surgery was performed under general anesthesia by one surgeon (RN). Before surgery, the horizontal and vertical axes of the eye were marked at the limbus, and perioperatively, the axis for lens enclavation was marked. A 2-plane 5.3-mm corneoscleral incision was centered at 12 o'clock. Two stab incisions were performed at 2 and 10 o'clock and were directed toward the enclavation sites. After an intracameral injection of acetylcholine and under an ophthalmic viscoelastic device (Healon GV; Pharmacia, Uppsala, Sweden), the lens was

Table 1. Refractive and Visual Outcome Data of Individual Patients

Patient No.	Eye	Gen-der	Age (yrs)	Graft Indication	Graft to Toric Intraocular Lens Interval (mos)	Before Toric Lens Implantation		After Toric Lens Implantation		Follow-up (mos)		
						Refraction	Un-corrected Visual Acuity	Best-Corrected Visual Acuity	Refraction		Un-corrected Visual Acuity	Best-Corrected Visual Acuity
1	Left	F	75	Fuchs' dystrophy	51	+3.50-8.00 × 170	20/200	20/32	+1.00-3.50 × 110	20/100	20/32	14
2	Right	F	45	HSV keratitis	46	+4.00-8.00 × 120	20/200	20/50	-1.00-0.75 × 95	20/50	20/32	18
3	Left	F	82	Fuchs' dystrophy	37	+0.50-5.50 × 50	20/125	20/50	+1.25-1.25 × 20	20/50	20/32	18
4	Right	F	69	PBK	36	-6.50-6.50 × 8	<20/400	20/50	-1.00-1.50 × 85	20/80	20/32	12
5	Left	F	68	Fuchs' dystrophy	64	+0.75-5.50 × 115	20/125	20/25	Plano-2.00 × 75	20/32	20/25	8
6	Right	M	75	HSV keratitis	65	+3.50-6.50 × 135	20/125	20/50	+0.75-1.50 × 155	20/63	20/32	6
7	Left	M	61	HSV keratitis	35	+4.00-4.00 × 180	20/160	20/25	+0.25-1.25 × 100	20/50	20/25	12
8	Left	F	39	Keratoconus	90	+7.50-4.00 × 110	20/125	20/25	-1.00	20/32	20/25	6
9	Left	F	72	Fuchs' dystrophy	43	-9.00-6.00 × 165	<20/400	20/50	Plano-2.00 × 50	20/50	20/32	6
10	Right	M	69	BKP	51	-5.50-4.00 × 5	<20/400	20/25	-0.75-1.25 × 10	20/50	20/25	6
11	Left	F	58	Corneal scar	34	-0.50-7.00 × 152	<20/400	20/32	Plano-1.00 × 60	20/32	20/25	6
12	Left	F	81	PBK	26	-2.00-10.00 × 162	<20/400	20/50	-0.75-2.25 × 65	20/63	20/25	6
13	Right	F	71	Corneal scar	40	+3.50-5.50 × 39	20/160	20/50	-0.75-1.25 × 170	20/125	20/50	6
14	Right	F	76	Fuchs' dystrophy	48	-2.00-7.50 × 140	<20/400	20/25	-0.50-1.00 × 145	20/50	20/32	4
15	Left	F	63	Keratoconus	80	-10.00-8.50 × 85	<20/400	20/63	+1.00-1.50 × 150	20/50	20/32	3
16	Right	F	73	Fuchs' dystrophy	36	-4.00-10.00 × 170	<20/400	20/63	-2.50-0.75 × 110	20/63	20/32	3

BKP = bullous keratopathy; F = female; HSV = herpes simplex virus; M = male; PBK = pseudophakic bullous keratopathy.

introduced by forceps with a Budo forceps (Duckworth and Kent, Ltd, Baldock Herts, England). After gentle rotation, the lens was fixated with a disposable enclavation needle in the marked axis (Ophtec). A slit iridotomy was performed at 12 o'clock to avoid pupillary block glaucoma. The viscoelastic material was exchanged with BSS Plus (Alcon). The wound was sutured with 3 to 4 interrupted 10-0 nylon sutures (Alcon). After surgery, topical tobramycin 0.3% combined with dexamethasone 0.1% (TobraDex, Alcon, Couvreur, Belgium) and ketorolactometamol 0.5% (Acular, Westport Co., Mayo, Ireland) were used 4 times daily for 3 weeks in a tapered schedule and 3 times daily for 1 week, respectively. In cases with an initial diagnosis of herpes simplex virus keratitis, acyclovir 400 mg 3 times daily (Glaxo SmithKline, Zeist, The Netherlands) was used for 6 months. Selective suture removal was performed depending on the subjective refraction.

Outcome Measures and Statistics

Main outcome measures were refractive and visual outcome as reflected by uncorrected visual acuity and efficacy (reduction in refractive and topographic astigmatism, reduction in anisometropia of spherical and defocus equivalent, and the number of eyes losing or gaining lines of UCVA), BCVA, and short-term safety (number of eyes losing more than 2 lines of BCVA).²⁶ A patient satisfaction questionnaire, specular microscopy, and incidence of complications were assessed. Snellen UCVA or BCVA measurements were converted to logarithm of the minimum angle of resolution values to facilitate statistical analysis. Comparison between preoperative and postoperative data was performed by paired *t* test (SPSS for Windows; SPSS Inc., Chicago, IL). All averages in the text are mean ± standard deviation.

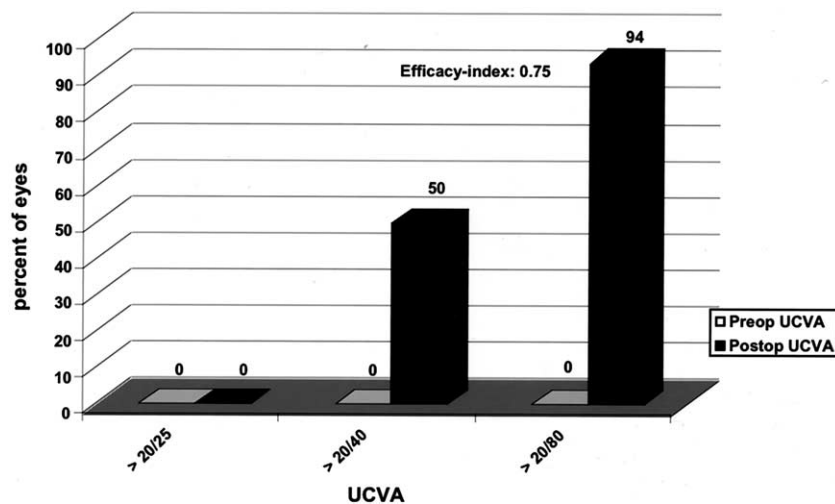


Figure 2. Percentage of eyes within a given range of uncorrected visual acuity (UCVA) before surgery (preop) and at last follow-up after toric lens implantation (postop) (n = 16). Efficacy-index = mean postoperative UCVA/mean preoperative best-corrected visual acuity.

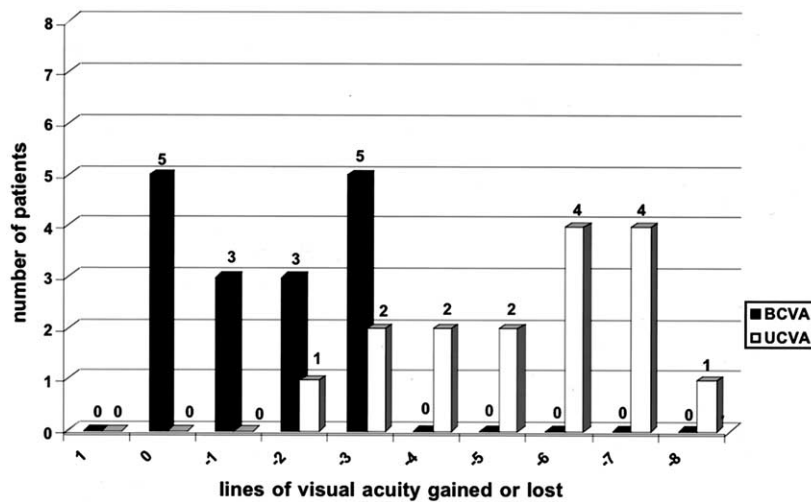


Figure 3. The number of gained or lost lines of uncorrected visual acuity (UCVA) and best-corrected visual acuity (BCVA) at last follow-up after toric lens implantation (n = 16).

Analysis of Astigmatism

Both vector analysis and nonvector analysis of the cylinder were performed. The efficacy of the procedure (i.e., the proportion of astigmatism correction achieved) was quantified using the correction index expressed as a percentage of the surgically induced astigmatism divided by the target-induced astigmatism for each individual eye and aggregated.²⁷ The Holladay method to convert polar values (cylinder and axis) to a Cartesian (x and y) coordinate system was used to determine the mean ± standard deviation value of the refractive and topographical keratometric astigmatism.²⁸ To distinguish the mean value of the cylinder calculated in this manner, the term *centroid* has been proposed. The coordinates were plotted in a double-angle plot and the centroid was determined.

67.3 ± 11.9 years (range, 39–81 years). The mean interval between penetrating keratoplasty and toric lens implantation was 48.9 ± 17.7 months (range, 34–90 months), and the interval between suture removal and lens implantation was 21.3 ± 9.6 months (range, 8–37 months). Twelve eyes were pseudophakic after previous implantation of a posterior chamber intraocular lens. The initial diagnosis requiring corneal transplantation was Fuchs' endothelial dystrophy (6 eyes), pseudophakic bullous keratopathy (2 eyes), herpes simplex keratitis (4 eyes), keratoconus (2 eyes), and corneal scarring (2 eyes). The refractive and visual outcome data of individual patients are summarized in Table 1.

The baseline parameters were a mean sphere of -0.77 ± 5.13 D (range, +7.5 to -10.0 D), a mean spherical equivalent refraction of -4.09 ± 5.50 D (range, +5.5 to -14.25 D), a mean baseline refractive cylinder power of 6.66 ± 1.93 D (range, -4.0 to -10.0 D), a mean defocus equivalent of 7.50 ± 2.96 D (range, +3.25 to +14.25 D), and a mean baseline topographically derived simulated keratometric cylinder of 6.96 ± 2.33 D (range, +4.93 to +11.61 D). The mean follow-up was 8.4 ± 4.9 months (range, 3–18 months).

Results

Patient Population

Thirteen patients were female and 3 were male. The mean age was

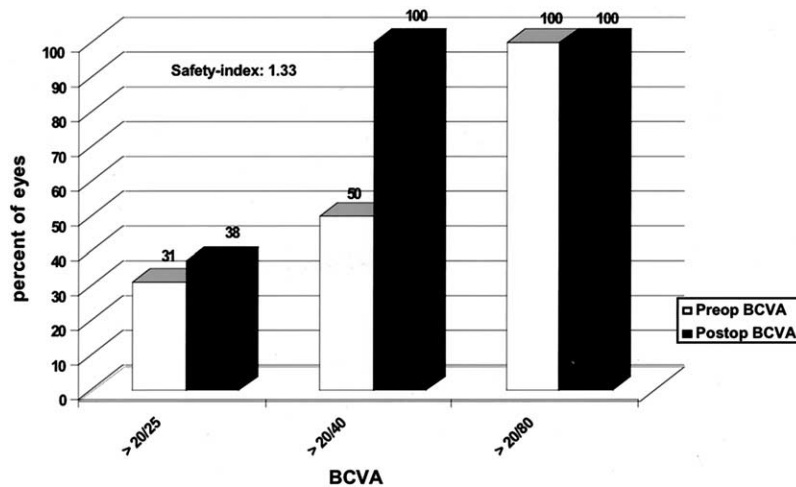


Figure 4. Percentage of eyes within a given range of best-corrected visual acuity (BCVA) before surgery (preop) and at last follow-up after toric lens implantation (postop) (n = 16). Safety-index = mean postoperative BCVA/mean preoperative BCVA.

Table 2. Results of Comparative Studies for

Reference	No. of Eyes	Technique	Follow-up, mos [Mean (Range)]	Refractive Astigmatism, Mean ± Standard Deviation		
				Before Surgery	After Surgery	Reduction (%)
Donnenfeld et al*	23	LASIK	7.6 (1–14)	3.64±1.7	1.64±1.14	64.6
Webber et al†	25	LASIK	(1–12)	8.67±3.22	2.92±1.71	66.3
Forseto et al‡	22	LASIK	10.1 (6–18)	4.44±2.1	1.75±1.1	60.6
Nassaralla and Nassaralla§	8	LASIK	6	3.5±1.22	1.25±0.74	64.3
Rashad	19	LASIK	7.0 (6–10.5)	9.21±1.95	1.09±0.33	87.9
Koay et al¶	8	LASIK	8.6	6.79±3.3	1.93±1.2	71.6
Kwitko et al**	14	LASIK	26.9 (12–42)	5.37±2.1	2.82±2.4	47.5
Busin et al‡‡	9	Flap cut	3	5.03±1.35	3.42±1.29	32.0
Malecha and Holland§§	19	LASIK	5 (1–14)	4.05±1.71	1.22±1.14	69.9
Gayton et al	7	Piggyback lens	7.5	NA	NA	NA
Current study	16	Toric iris-fixated lens	8.4 (3–18)	-6.66±1.93	-1.42±0.78	78.0

DLK = diffuse lamellar keratitis; NA = not available.

*Donnenfeld ED, Kornstein HS, Amin A, et al. Laser in situ keratomileusis for correction of myopia and astigmatism after penetrating keratoplasty.

†Webber SK, Lawless MA, Sutton GL, Rogers CM. LASIK for post penetrating keratoplasty astigmatism and myopia. Br J Ophthalmol 1999;83:1013–8.

‡Forseto AS, Francesconi CM, Nose RA, Nose W. Laser in situ keratomileusis to correct refractive errors after keratoplasty. J Cataract Refract Surg

§Nassaralla BR, Nassaralla JJ. Laser in situ keratomileusis after penetrating keratoplasty. J Refract Surg 2000;16:431–7.

||Rashad KM. Laser in situ keratomileusis for correction of high astigmatism after penetrating keratoplasty. J Refract Surg 2000;16:701–10.

¶Sphere.

**Koay PY, McGhee CN, Weed KH, Craig JP. Laser in situ keratomileusis for ametropia after penetrating keratoplasty. J Refract Surg 2000;16:140–7.

**Kwitko S, Marinho DR, Rymer S, Ramos Filho S. Laser in situ keratomileusis after penetrating keratoplasty. J Cataract Refract Surg 2001;27:374–9.

‡‡Myopic sphere.

§§Busin M, Arffa RC, Zambianchi L, et al. Effect of hinged lamellar keratotomy on postkeratoplasty eyes. Ophthalmology 2001;108:1845–51.

|||Malecha MA, Holland EJ. Correction of myopia and astigmatism after penetrating keratoplasty with laser in situ keratomileusis. Cornea 2002;21:564–9.

|||Gayton JL, Sanders V, Van der Karr M, Raanan MG. Piggybacking intraocular implants to correct pseudophakic refractive error. Ophthalmology

Visual Acuity Outcome

The mean logarithm of the minimum angle of resolution UCVA before surgery was 1.35±0.51 and increased to 0.41±0.18 at the last follow-up ($P<0.001$, paired t test). After surgery, 50% of eyes had a UCVA better than 20/40 as compared with 0% before surgery (Fig 2). The mean number of gained lines of UCVA was 5.44±1.86 (range, 2–8 lines; Fig 3). The mean logarithm of the

minimum angle of resolution BCVA before surgery was 0.28±0.16 and increased to 0.16±0.07 ($P = 0.018$, paired t test). After surgery, 100% of eyes had a BCVA better than 20/40 as compared with 50% before surgery, and 38% had a BCVA better than 20/25 (Fig 4). The mean number of gained lines of BCVA was 1.50±1.26 (range, 0–3 lines). There were no eyes with a loss of 2 lines of BCVA (Fig 3). The predictability of intended versus achieved cylinder correction showed 14 of 16

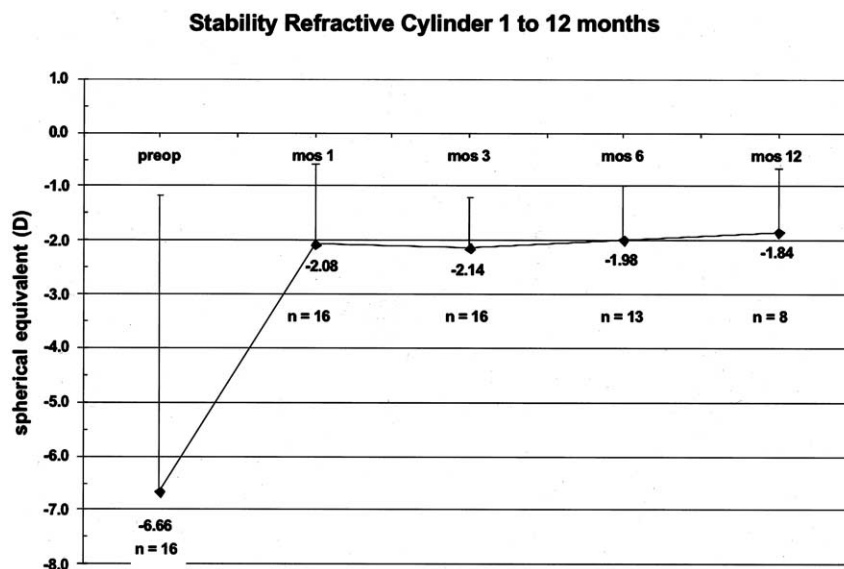


Figure 5. Mean refractive cylinder before surgery and at postoperative intervals. Number of patients at each time point are shown. D = diopters.

Correction of Postkeratoplasty Astigmatism

Spherical Equivalent, Mean ± Standard deviation			Uncorrected Visual Acuity ≥20/40 (%)	Best-Corrected Visual Acuity ≥20/40 (%)	Best-Corrected Visual Acuity ≥2 Lines Gain (%)	Best-Corrected Visual Acuity ≥2 Lines Loss (%)	Additional Procedures or Complications
Before Surgery	After Surgery	Reduction (%)					
6.88±4.4	1.42±1.05	79.3	36.0	74.0	26	4.3	9.1% enhancements
-5.2±2.31	-1.31±1.63	74.8	28.0	83.0	12	0	53.8% arcuate keratotomy, 1 perforation
-4.55±3.66	-0.67±1.24	85.3	54.5	90.9	18	9.1	1 flap perforation, 1 flap dislocation
-4.50±1.52	-0.75±0.75	83.3	37.5	87.5	25.0	0	None
-2.14±2.11 ^{††}	+0.43±0.82	79.9	73.7	100.0	42	0	53% enhancements
-6.79±4.17	-0.64±1.92	90.6	12.5	NA	37.5	0	1 buttonhole
-7.51±3.87	-1.25±2.30	83.3 ^{††}	28.6	85.7	21	7.1	42.9% enhancements, 1 buttonhole, 2 epithelial ingrowths
-5.40±1.69	-4.37±1.72	19.1	0	77.8	33	0	None
4.24±2.81	0.85±0.84	80.0	73.7	89.5	0	5.2	3 DLK, 3 enhancements
3.41±1.15	0.98±0.81 ^{††}	71.3	42.9	71.0	NA	0	None
-4.09±5.50	-0.96±0.86	76.5	50.0	100.0	50.0	0	None

Ophthalmology 1999;106:1966-74.

1999;25:479-85.

1999;106:56-9.

eyes (87.5%) within 2 D and 6 of 16 eyes (37.5%) within 1 D of the intended correction. The predictability of intended versus achieved defocus equivalent showed 15 of 16 eyes (93.8%) within 2 D and 6 of 16 eyes (37.5%) within 1 D of the intended correction.

Refractive Outcome

The mean sphere at the last follow-up was -0.25 ± 0.98 D (range, +1.0 to -2.50 D), the mean spherical equivalent refraction was -0.96 ± 0.86 D (range, +0.63 to -2.88 D), and the mean defocus

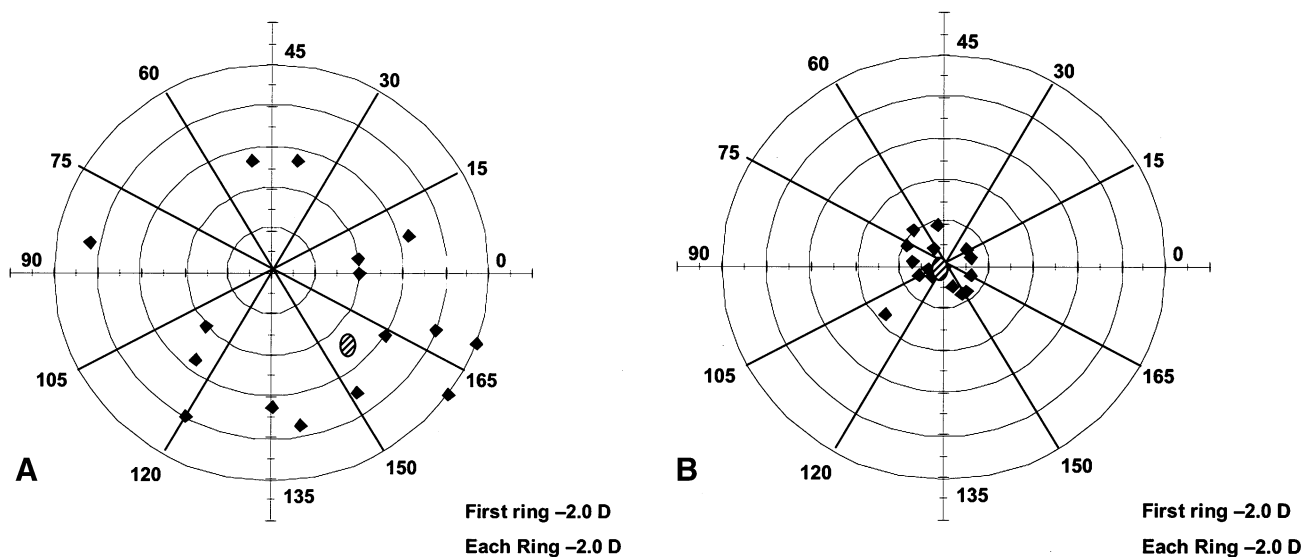


Figure 6. The centroid (± standard deviation) in the double-angled plot changed from (A) -2.85 diopters (D) at 156.2° (±6.50 D) before Artisan toric lens implantation to (B) -0.33 D at 90.3° (±1.62 D) at the last follow-up after implantation.

equivalent was $+1.49 \pm 0.65$ D (range, $+2.88$ to $+0.5$ D). The refractive cylinder was reduced to -2.08 ± 1.33 D, -2.14 ± 1.76 D, -1.98 ± 1.65 D, -1.84 ± 0.77 D, and -1.42 ± 0.78 D at 1 month, 3 months, 6 months, 12 months, and the final follow-up examination (8.4 ± 4.9 months), respectively ($P < 0.001$ for all time points, paired t test). Concerning stability, there was no significant change in refractive cylinder values from 1 month after surgery to 1 year after surgery (Fig 5; $P = 0.065$, paired t test).

At the last follow-up, 5 of 16 eyes had a refractive cylinder less than 1 D, 14 of 16 eyes had a refractive cylinder less than 2 D, and all eyes had a cylinder less than 4 D. The mean topographically derived simulated keratometric cylinder did not change significantly from 6.26 ± 2.39 D at 1 month after surgery to 6.63 ± 2.47 D at 3 months ($P = 0.204$, paired t test), and to 5.47 ± 2.66 D ($P = 0.204$, paired t test) at the last follow-up. The percent reduction in refractive and topographical astigmatism was $78.0 \pm 11.5\%$ and $20.3 \pm 34.9\%$, respectively (Table 2). There was a reduction of $91.0 \pm 23\%$ and $77.0 \pm 12\%$ in sphere and defocus equivalent, respectively. Based on the limited correction that could be achieved in the 6 eyes that required a dioptric power that exceeded the available cylindrical power of the toric lens, the reduction in refractive astigmatism was $90.5 \pm 21.9\%$. The correction index (surgically induced astigmatism divided by the target-induced astigmatism) was $102.8 \pm 18.6\%$ at the last follow-up. The centroid (\pm standard deviation) in the double-angled plot changed from -2.85 D at 156.2° (± 6.50 D) before surgery to -0.33 D at 90.3° (± 1.62 D) after surgery (Fig 6; $P < 0.001$, paired t test). The mean surgically induced astigmatism of the topographical cylinder by the placement of the corneoscleral incision centered at 90° was 1.85 ± 1.35 D (range, 0.02 – 4.00 D) at 6 months after surgery. Patient satisfaction increased from 3.2 before surgery to 8.3 after surgery ($P < 0.001$, paired t test).

The intraocular pressure was 14.6 ± 2.5 mmHg before surgery, 15.6 ± 4.9 mmHg at 1 month after surgery, 14.2 ± 2.7 mmHg at 3 months after surgery, 13.9 ± 2.7 mmHg at 6 months after surgery, and 14.4 ± 2.1 mmHg at the last follow-up ($P = \text{ns}$, paired t test for all time points).

The endothelial cell loss was $7.6 \pm 18.9\%$ at 3 months, $21.7 \pm 22.3\%$ at 6 months, and $16.6 \pm 20.4\%$ at the last follow-up ($P = 0.003$, paired t test). In one eye (patient 6, Table 1) a reversible endothelial rejection period occurred.

No complications such as cystoid macular edema, chronic inflammation of the anterior chamber, or retinal detachment were noted.

Discussion

This prospective study of 16 eyes demonstrates the efficacy and stability of the Artisan toric IOL for correction of postkeratoplasty astigmatism. Until now, LASIK seemed to be the preferred technique for correction of anisometropia and astigmatism after keratoplasty (Table 2).^{16–21} The use of the Artisan toric IOL, with a power range of 7.5 D of cylinder and -20.5 D of myopia to $+12.0$ D of hyperopia, provides a wide field for correction of postkeratoplasty astigmatism and ametropia. In our series, this is reflected by the magnitude of baseline spherical error (range, $+7.5$ to -10.0 D) and cylindrical error (range, -4.0 to -10.0 D), which is much higher than in most postkeratoplasty LASIK series. To our knowledge, the reduction of the refractive cylinder by $91 \pm 21\%$ (without any enhancements) is better than in most reported LASIK series. The reduction of re-

fractive astigmatism after LASIK varies from 48% to 88% (Table 2). However, enhancements were reported in 9.1%,²⁹ 15%,³⁰ 42.9%,¹⁷ 45%,³¹ and 53%¹⁹ of cases, and in 1 study, LASIK was combined with arcuate incisions in the stromal bed in 56% of eyes.²

Improving the UCVA of 20/40 or better from 0% to 50% of our cases illustrates the efficacy of the Artisan toric IOL procedure. In most LASIK series, UCVA better than 20/40 varied from 28% to 74%.^{2,17,19,21,29,30} With respect to short-term safety, no eye lost BCVA and 8 of 16 eyes gained at least 2 lines of BCVA. This is in accordance with 2 recent randomized studies that showed a greater gain of BCVA with the Artisan phakic intraocular lens implantation as compared with a greater loss of BCVA with LASIK and a better quality of vision with the Artisan lens in moderate to high myopia.^{32,33} After LASIK for postkeratoplasty astigmatism, a more than 2-line loss of BCVA occurred in 4.3%,²⁹ 7.1%,¹⁷ and 9.1% of cases.²¹ LASIK surgery may be complicated by flap complications in steep corneas and has limitations because of corneal graft thickness and the amounts of ametropia and astigmatism suitable for correction.^{16–21} LASIK-related complications like diffuse lamellar keratitis,³⁰ buttonhole flaps,^{17,21} wound dehiscence, and epithelial ingrowth¹⁷ have been reported. Because most eyes in the reported LASIK series were grafted in young patients for keratoconus with a rapid wound healing, wound dehiscence problems were less likely to occur than in a group of older patients grafted for Fuchs' endothelial dystrophy or bullous keratopathy.³⁴ In our series, only 2 of 16 eyes were grafted for keratoconus, and the mean age was 67.3 ± 11.9 years (range, 39–81 years), which may present greater risks when using LASIK. Because the effect of the flap cut alone may induce a significant reduction of refractive astigmatism in up to 50% in some patients and because of the high enhancement rate, a 2-stage LASIK procedure has been proposed.^{16,35,36} However, it is unclear whether a 2-stage procedure bears a higher risk for complications like epithelial ingrowth, wound healing problems, and flap dislocation.

After LASIK, progressive changes were seen in refraction and topography in 35.7% of cases after a mean follow-up time of 26.9 months.¹⁷ The stability of the postoperative refractive error up to 12 months after Artisan lens implantation was adequate, but because of the short follow-up, no conclusions can be made on the long-term effects. Also, the number of patients in our study is limited, and because of the short follow-up, measures of safety like corneal decompensation, graft failure rates, retinal detachment, macular edema, and efficacy need to be followed more extensively in a future long-term study.

A potential limitation of the Artisan toric IOL for the correction of postkeratoplasty astigmatism is surgically induced astigmatism by implantation of the rigid polymethyl methacrylate IOL through a 5.3-mm incision. In a recent series of implantations of the Artisan toric IOL for correction of myopia or hyperopia with astigmatism, the surgically induced astigmatism was 0.53 D.³⁷ However, after keratoplasty the biomechanical response of the corneoscleral tissue to the incision may be somewhat unpredictable, and a greater variability in surgically induced astigmatism

may be seen. Indeed, in our series the mean surgically induced astigmatism was 1.85 D 6 months after surgery and varied from 0.02 D to 4.00 D. Because of this variability, we believe that the surgically induced astigmatism cannot be incorporated into the power calculation of the lens. Because the goal of correcting postkeratoplasty astigmatism is mainly to reduce the refractive astigmatism and ametropia to enable patients to wear spectacles, we believe that a lesser predictability of astigmatism reduction may be acceptable.

Concerns have been raised with respect to the development of complications like endothelial cell loss, chronic inflammation, and cystoid macular edema after Artisan lens implantation. A study using fluorometry showed inflammation comparable with cataract surgery at 6 months after surgery,³⁸ whereas a study using a flare-cell meter found chronic inflammation 1 to 2 years after implantation of the older Worst-Fechner intraocular lens.³⁹ The mean endothelial cell loss after 6 months in the present study was $15.2 \pm 7.6\%$ at 6 months. This is much higher than the reported cell loss in other studies of Artisan lens implantation in high myopia that show values of less than 8% at 1 year after surgery.^{32,33,39-42} However, the higher cell loss in the present series may be related to the natural endothelial cell loss after penetrating keratoplasty, which has an annual rate of 7.8% from 3 to 5 years after transplantation and of 4.2% from 5 to 10 years after transplantation.^{43,44} Nevertheless, we believe that an endothelial cell density of at least 500 cells/mm² as an exclusion criterion is permitted because no other treatment methods exist but corneal re-grafting, and the Artisan lens is perfectly removable at future re-grafting procedures. Of course, a longer follow-up and a larger numbers of patients followed up for longer periods of time are needed to assess the effect of Artisan lens implantation on the corneal graft endothelium. We found no chronic inflammation by slit-lamp examination in the present study, and cystoid macular edema is not to be expected because none of the eyes had a reduction in BCVA. One reversible rejection period occurred in patient 6 (Table 1) that did not result in loss of visual acuity.

Based on the objective medical outcomes, the subjective patient satisfaction that increased from 3.2 before surgery to 8.3 after surgery (scale, 1-10), and the suitability of all patients for spectacle correction, Artisan toric lens implantation seems to be a valuable option for correction of postkeratoplasty astigmatism and anisometropia. A longer follow-up is needed to identify the risk factors for progressive endothelial cell loss and a randomized study of Artisan lens implantation versus LASIK with larger numbers of patients could clarify the advantages and disadvantages of both techniques with respect to efficacy, safety, and complications.

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