Implantation of Artisan Toric Phakic Intraocular Lenses for the Correction of Astigmatism and Spherical Errors in Patients With Keratoconus

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ABSTRACT

PURPOSE: To evaluate the correction of astigmatism and spherical ametropia in patients with keratoconus through implantation of an Artisan toric phakic intraocular lens (PIOL) (Ophtec, Groningen, The Netherlands).

METHODS: Artisan toric PIOLs were implanted uneventfully in both eyes of three patients with keratoconus with clear central corneas and contact lens intolerance.

RESULTS: Best spectacle-corrected subjective visual acuity after lens implantation was unchanged in one eye and improved in five eyes. Spherical equivalent refraction was significantly reduced in all eyes (P=.03). The safety index was 1.49.

CONCLUSIONS: The implantation of an Artisan toric PIOL may be an alternative for treating astigmatism and myopia in contact lens intolerant patients with keratoconus with clear central corneas. Especially in patients with associated myopia, this procedure is worth considering before planning a penetrating keratoplasty. [*J Refract Surg*. 2005;21:218-222.]

Keratoconus is a noninflammatory condition characterized by ectasia and thinning of the cornea, inducing myopia and astigmatism. The disease usually starts around puberty and progresses slowly and may stabilize at a later age. In the early stages, spectacles and contact lenses are the usual treatment of choice. If a patient becomes contact lens intolerant, treatment consists of penetrating keratoplasty (PK) or lamellar keratoplasty (LK). Although good visual results usually are achieved with PK in patients with keratoconus,[1] visual recovery after the operation is long.[2] Frequent postoperative follow-up and use of corticosteroids for a prolonged time are necessary, and high astigmatism is a major postoperative complication.

In view of this, other treatment modalities may be preferred in an attempt to delay or avoid PK in select patients with contact lens intolerance and clear corneas. The implantation of a toric phakic intraocular lens might be a surgical alternative, especially as high myopia and an anterior chamber depth >3.0 mm often are associated with keratoconus.[3] The Artisan toric phakic intraocular lens (PIOL) (Ophtec, Groningen, The Netherlands) has been shown to correct high ametropia and astigmatism with a stable and fairly predictable refractive outcome.[4] Artisan toric PIOLs are available with a cylindrical power of up to 7.0 diopters (D) and a spherical power ranging between −3.0 and −23.5 D for myopia and +1 and +12 for hyperopia. Therefore, these lenses can be used to correct high astigmatism and ametropia present in keratoconus.

This article presents three contact lens intolerant patients with keratoconus with clear central corneas who were treated with the Artisan toric PIOL in both eyes.

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Dr Budo is medical monitor and consultant to Ophtec BV (Groningen, The Netherlands). Drs Bartels and van Rij do not have a proprietary interest in the materials presented herein.

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PATIENTS AND METHODS

Artisan toric PIOLs were implanted between May 2002 and April 2003 in six eyes of three patients with keratoconus. All patients had a clear central cornea, were contact lens intolerant in at least one eye, and requested refractive surgery. After informed consent was given, patients underwent implantation of an Artisan toric PIOL.

The Artisan toric PIOL is an iris-fixated anterior chamber implant of Perspex CQ-UV polymethylmethacrylate with ultraviolet filtration. Its overall diameter is 8.5 mm and the optical zone diameter is 5.0 mm. As some surgeons prefer to insert the lens through a temporal incision and to allow optimal implantation to the correct axis, two models are available. In model A, the axis runs through the claws (0°), and in model B, the axis is perpendicular to the line that runs through the claws (90°).

Pre- and postoperative examination of all patients included slit-lamp biomicroscopy, determination of best spectacle-corrected visual acuity (BSCVA), manifest refraction, tonometry, keratometry (autokeratometer), measurement of mesopic pupil diameter (Colvard pupillometer), endothelial cell count (non-contact specular microscopy, Topcon SP-2000 P, Tokyo, Japan), A-scan biometry (measurement of the anterior chamber depth), and indirect ophthalmoscopy. Exclusion criteria were uveitis, previous corneal or intraocular surgery, and systemic disease. The normally used exclusion criterion in refractive surgery of endothelial cell count <2000 cells/mm^2 was not an absolute exclusion criterion in our study with pathologic corneas.

Four days before surgery, patients were asked to apply indomethacine 0.1% four times daily in both eyes. Surgery was performed under general anesthesia by one surgeon (C.B.). Lenses were implanted in both eyes of one patient simultaneously, with a change of gloves and use of separate sets of surgical instruments for the second eye. The surgical technique followed standard protocol as described in the toric PIOL European Multicenter Study.[4] A 5.5-mm corneoscleral incision was made superiorly and two paracenteses were made at 10 and 2 o'clock. After instillation of a cohesive viscoelastic fluid (Healon GV; Pharmacia & Upjohn, Kalamazoo, Mich), the Artisan toric PIOL was implanted and enclavated onto the iris. The enclavation sites on the iris were marked before surgery with an argon laser. An iridotomy was performed at 12 o'clock to prevent angle-closure glaucoma. The incision was closed with a 10-0 nylon running suture.

Upon discharge, patients were prescribed predmycine eyedrops (Allergan, Antwerp, Belgium) four times daily and a combination of dexamethasone/neomycine/polymyxine ointment to be applied at night for 2 weeks. The appropriate power of the toric PIOL was calculated using the Van der Heijde formula.[5]

TABLE 1

Characteristics of Study Patients With Keratoconus Who Underwent Implantation of an Artisan Toric Phakic Intraocular Lens

Patient/ Sex/ Age (y)	Eye	Anterior Chamber Depth (mm)	Endothelial Cell Count	Axial Length (mm)	Mesopic Pupil (mm)
1/M/27	Right	3.56	1625	23.64	4.0
	Left	3.79	2384	24.06	4.0
2/M/26	Right	3.91	3100	25.36	5.0
	Left	3.45	2900	24.04	5.0
3/F/44	Right	3.45	2300	30.11	4.75
	Left	3.56	1800	29.94	4.75

Follow-up took place 2 days, 2 weeks, 6 weeks, and 6 months after surgery. At follow-up, patients were asked to report subjective complaints, such as monocular diplopia, halos, or glare. Patients were asked to rate their overall satisfaction with their vision after implantation on a scale from 1 to 5 (with 1 being very poor and 5 being excellent). To analyze safety index (mean postoperative BSCVA/mean preoperative BSCVA) and efficacy index (mean postoperative uncorrected visual acuity/mean preoperative BSCVA), Snellen visual acuity was converted into logarithm of the minimum angle of resolution notation to calculate the mean and then transformed back into Snellen visual acuity. Vector analysis was used to analyze surgical-induced refractive correction.[6,7] For this purpose, preoperative and 6-month BSCVA refraction results were used. To analyze surgical-induced corneal astigmatism (ie, incisional-induced astigmatism), vector analysis of pre- and postoperative keratometric values was used.[6,7] Student paired t test ($P<.05$) was used to analyze the change in spherical equivalent refraction after implantation.

RESULTS

Implantation of the Artisan toric PIOL was performed uneventfully in all six eyes. Preoperative patient characteristics are shown in Table 1. Preoperatively, intraocular pressure was normal in all eyes (range: 9 to 16 mmHg). No patient had evidence of cataract or had undergone prior ocular surgery. Funduscopy revealed myopic atrophy in the third patient.

TABLE 2

Pre- and 6-month Postoperative Refractive Data of Patients (N=3) With Keratoconus who Underwent Implantation of an Artisan Toric Phakic Intraocular Lens

			Preoperative			Postoperative (6 mo)			
Patient/Eye	PIOL Power	Axis	BSCVA	Subjective Refraction	Keratometry	BSCVA	Subjective Refraction	Keratometry	Endothelial Cell Count
1/R	−12 −5.5 × 0	15	20/50	−11 −6 × 15	52.87/58.37×111	20/30	0 −2.5 × 45	52.87/57.37×105	3500
1/L	−3.5 −5 × 0	135	20/30	−3 −4.5 × 135	46.25/50.75×47	20/30	−1 −2 × 105	46.00/50.25×46	2558
2/R	−4 −2 × 0	45	20/25	−3 −2 × 63	41.25/42.87×120	20/20	plano	41.37/43.00×115	3200
2/L	−4 −3 × 90	28	20/50	−3.5 −3 × 118	41.50/44.37×49	20/30	1 −1.50 × 164	41.25/44.50×44	2800
3/R	−21 −2 × 90	155	20/40	−24.5 −3 × 65	48.75/51.00×121	20/25	1	45.75/47.25×129	2500
3/L	−21 −2 × 90	175	20/60	−27 −4 × 85	47.00/51.25×30	20/40	1.25 −2 × 153	45.75/47.00×31	2100

PIOL = phakic intraocular lens, BSCVA = best spectacle-corrected visual acuity

Contact lens intolerance was present in all patients. Contact lens wear had to be discontinued in the third patient due to the development of corneal neovascularization. All patients had keratoconus and a transparent central cornea. Probably due to the high refractive error and corneal irregularities, there was a low repeatability between different preoperative keratometric and objective refraction measurements in the left eye of the last patient, making appropriate power calculations of the toric PIOL difficult. Moreover, the lens power required by the third patient was not available. She was therefore given the strongest available lens.

Follow-up ranged from 6 months to 1 year. Postoperative BSCVA was stable from 6 weeks onward and improved in five eyes and remained unchanged in one eye. Preoperative and 6-month follow-up refractive data are presented in Table 2. The safety index was 1.49 and the efficacy index was 1.24. Mean preoperative spherical equivalent refraction was −13.88 D (range: −4.00 to −29.00 D). Mean spherical equivalent refraction postoperatively was −0.29 D (range: +1.00 to −2.00 D). Reduction in spherical equivalent refraction was significant (P=.03). Postoperatively, four of the six eyes were within ±1.00 D of emmetropia. The average magnitude of refractive astigmatism was −3.75 D (range: −2.00 to −6.00 D) preoperatively and −1.33 D (range: 0 to −2.50 D) postoperatively. Incisional-induced corneal astigmatism and surgical-induced refractive correction are presented in Table 3. Based on the change in keratometry pre- and postoperatively, the average incisional-induced cylinder was 1.14 D (range: 0.28 to 3.00 D).

None of the patients experienced pigment cell deposits on the crystalline lens or posterior synechia. Two patients reported mild glare (starburst or acuity distortion noted at night but not interfering with function). No patient reported monocular diplopia. All patients were satisfied with the result. Mean subjective response for satisfaction was 4.17 using the previously described scale. All patients tolerate spectacle correction of the remaining refractive error.

DISCUSSION

Many patients with keratoconus can be successfully fitted with modern contact lenses, which can reduce the number of patients requiring surgery. However, some patients cannot be corrected with contact lenses successfully. Patients with globus cones, which may involve a large part of the cornea and may have an inferotemporally thinning in the periphery of the cornea, have trouble with contact lens fitting, and in these patients, a corneal graft may be more difficult to perform and frequently results in a high postoperative astigmatism. For these patients, the implantation of a toric

PIOL can be an alternative to reduce spherical equivalent refractive error and astigmatism.

In our small study, visual acuity improved in almost all eyes compared to preoperative measures, and thereby at least postponed the need for PK. Because keratoconus is a progressive disorder, refraction is not expected to remain stable after the implantation of a toric PIOL. However, a PK in the future is unlikely to be negatively affected by the prior implantation of a PIOL. Furthermore, toric IOLs could be exchanged if necessary. Currently, patients with keratoconus and contact lens intolerance are primarily treated with PK or LK.[8-10] However, slow visual rehabilitation after keratoplasty is a disadvantage. Further surgical options such as laser in situ keratomileusis remain limited as keratoconus is considered a contraindication because of poor refractive stability and the risk of progressive keratectasia.[11,12]

In an effort to postpone or prevent PK and to shorten visual rehabilitation, various other surgical options have been investigated. Colin et al[13] reported the results of Intacs inserts for keratoconus in 10 patients, and Ferrara intrastromal corneal rings were used in a study on 26 patients by Siganos et al.[14] In both studies, the spherical equivalent refractive error and astigmatism were significantly reduced. However, the amount of possible reduction of myopia and astigmatism is probably less with Intacs or Ferrara intrastromal rings than with toric PIOLs. Especially in higher ametropia and astigmatism, such as >-10 D myopia or >-2 D astigmatism, toric PIOLs might be a more suitable option. The large reduction of myopic error in our last patient would not have been possible with Intacs or Ferrara intrastromal corneal ring segments. Progression of the disease is not suspected to slow down after toric PIOL implantation. Although corneal ring segments may reshape or reinforce the abnormal cornea, there is also no evidence that they can stop disease progression. Besides, the predictability of corneal implants in keratoconus is not yet high and a relative high residual refractive error might remain. Epikeratoplasty and LK have also been investigated as alternatives to PK for patients with keratoconus; however, PK was found to be statistically superior with respect to visual outcome.[15,16]

Limitations of the Artisan toric PIOL are a cylindrical power of 7 D, a myopic power of 23.5 D, and an optical zone of 5.0 mm. In high myopia, the small 5.0-mm optical zone may produce halo effects and glare in dim illumination conditions. Two of our patients reported glare after the operation; however, this complaint did not interfere with function. The reduction in spherical error in all six eyes was higher (87.4%) than the reduction in astigmatic error (64.5%), suggesting a high predictability for spherical errors, but a moderate predictability for astigmatic errors. This was partly caused by the limitation of maximum available spherocylindrical correction and may have also been caused by difficulty in measuring the astigmatism.

TABLE 3

Surgical-induced Refractive Correction and Incisional-induced Corneal Astigmatism

Patient/Eye	Surgical-induced Refractive Correction	Incisional-induced Corneal Astigmatism
1/Right	-10.14 -5.22×3	1.44×41
1/Left	-1.30 -3.90×148	0.52×145
2/Right	-3.00 -2.00×63	0.28×74
2/Left	-3.55 -3.40×104	0.65×19
3/Right	-25.50 -3.00×65	0.91×17
3/Left	-26.44 -5.61×78	3.00×120

The Artisan toric PIOL cannot yet be implanted through an incision smaller than 5.5 mm. This can also result in induced astigmatism, adding a level of unpredictability to the final result. Dick et al[4] reported a surgical-induced astigmatism of 0.53 D after implantation of toric PIOLs for correcting ametropia with astigmatism in nondiseased eyes. The contribution of the incisional-induced astigmatism to the level of unpredictability in our small study seems to be relatively low in five eyes (average 0.76 D). Only the left eye of the third patient had a large cylinder. This may be due to a low repeatability of preoperative keratometry and refractive measures. Furthermore, the biomechanics of keratoconic corneas are not the same as those of normal corneas. Although keratometry results can also change due to progression of the keratoconus, it is difficult to analyze only the incisional-induced astigmatism.

Progression of keratoconus leading to refraction change is a concern after implantation. Ideally, toric PIOL implantation should not be performed until keratometry and subjective refraction are stabilized. This implies that toric PIOL implantation should not be performed in recently diagnosed keratoconus or in younger patients with a progressive keratoconus. However, it is possible that there is no stabilization at any time.[17] A longer period of poor vision can have significant implication for young adults. After discussing the risk of an inadequate correction due to possible progression with the patient, we believe that toric PIOL implantation is permitted if keratometry has not changed significantly

over the past 6 months. Preoperative BSCVA should be at least 20/60, otherwise a PK is expected to have a superior visual outcome. Furthermore, patients are only good candidates for toric PIOL implantation if subjective refraction is possible. This is typically complicated by the reduced repeatability of subjective refraction in patients with keratoconus compared to nondiseased eyes, as was certainly a problem in the left eye of the third patient.[18] An average subjective refraction, which was well tolerated by this patient, was used for lens calculation.

Moreover, a possible risk of damage to the endothelium exists with anterior chamber IOL implantation. In our patients, however, we did not observe endothelial cell loss at 6 weeks postoperatively. Endothelial cell count in the right eye of the first patient was incredibly high after implantation compared to preoperative measurement. Inaccuracy of the present counting methods for pathologic corneas might also underlie the inconsistency in endothelial cell count among pre- and postoperative periods. Endothelial cell count might be misleading in patients with keratoconus because of an uneven distribution of endothelial cells. Contact lens wear for a prolonged time is related with higher pleomorphism and polymegatism of endothelial cells in patients with keratoconus.[19] With anterior chamber IOL implantation, there is a risk of damage to the endothelium. This remains a cause for concern. Studies on toric PIOL implantation in nondiseased eyes use endothelial cell count of $<2000/mm^2$ as an exclusion criterion.[4] We believe that in keratoconus eyes, a lower cell density is also permitted if PK is considered as the alternative to restore visual acuity. If PK becomes necessary after toric PIOL implantation, it is always possible to remove the lens at surgery. Implantation of a new Artisan toric lens after transplantation adjusted to postoperative refractive data is also an option.[20] A disadvantage of a possible earlier corneal decompensation after toric PIOL implantation would be a less favorable indication for transplantation (ie, bullous keratopathy instead of keratoconus).[1]

Our short-term results in this small series of patients are encouraging. Visual rehabilitation was rapid in all patients. No serious complications occurred. The implantation of a toric PIOL can be an alternative for correcting astigmatism and myopia in contact lens intolerant patients with keratoconus and clear central corneas. Long-term results and additional patients are needed to draw strong conclusions regarding the predictability for astigmatic correction and the influence of this procedure on the outcome of possible PK. In the meantime, especially in patients with associated myopia, this procedure is worth considering before planning PK.

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