# **Artisan Phakic Intraocular Lens in Patients** With Keratoconus

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#### ABSTRACT

**PURPOSE:** To assess the safety, efficacy, predictability, and refractive outcome of implanting Ophtec Artisan phakic intraocular lenses (pIOLs) in eyes with keratoconus.

**METHODS:** In this retrospective study, 18 eyes of 11 patients diagnosed with keratoconus who underwent toric or myopic pIOL implantation were followed for 1 year postoperatively. Mean patient age was  $41\pm10.97$  years (range: 23 to 64 years). Preoperative manifest refractive sphere was  $-4.64\pm2.74$  diopters (D) (range: -9.75 to 0.00 D) and cylinder was  $-3.07\pm2.04$  D (range: -7.75 to -0.50 D). Inclusion criteria were preoperative best spectacle-corrected visual acuity (BSCVA) of 0.30 or better and stable refraction ( $\leq 0.50$ -D change in manifest refractive outcomes and endothelial cell counts were analyzed primarily for 6-month follow-up and when available for 1-year follow-up.

**RESULTS:** The mean postoperative MRSE was  $-0.46\pm0.60$  D (range: -1.88 to 0.13 D). Twenty-two percent (4/18) of eyes had an uncorrected visual acuity (UCVA) of 1.0 or better and 94% (17/18) of eyes had a UCVA of 0.63 or better. Sixty-one percent (11/18) of eyes had an MRSE within  $\pm0.50$  D of the intended correction and 72% (13/18) of eyes gained one or more lines of BSCVA and no eyes lost lines of BSCVA. Mean endothelial cell counts decreased by 23 cells/mm<sup>2</sup> at 6 months postoperatively.

**CONCLUSIONS:** The implantation of Artisan iris-fixated plOLs in patients with stable keratoconus for correction of astigmatism and myopia is safe, predictable, and effective with minimal complications. Due to the progressive nature of keratoconus, proper patient counseling is necessary. [*J Refract Surg.* 2009;25:759-764.] doi:10.3928/1081597X-20090813-01

eratoconus is a progressive noninflammatory disease characterized by corneal steepening, apical thinning, and ectasia. The progressive nature of this disease leads to increased myopia and irregular corneal astigmatism causing a reduction in best corrected visual acuity and visual quality.<sup>1</sup> The onset of this disease is generally within the second and third decades of life. Typically, contact lenses and spectacles are used to manage the degradation of vision associated with the progression of keratoconus. Initially, spectacles can be used to manage vision deterioration followed by soft contact lenses and eventually rigid gas permeable lenses. However, contact lens therapy can cause complications such as neovascularization, apical scars, corneal abrasions, and ocular discomfort. Hence, contact lens intolerance can reduce the options available for maintaining functional vision, leading to earlier surgical intervention.<sup>1,2</sup>

Surgical options include epikeratoplasty, intrastromal rings, phakic intraocular lens (pIOL), and penetrating keratoplasty (PK).<sup>3,4</sup> Currently, PK is considered the final surgical intervention for keratoconus due to high success rates.<sup>4-6</sup> The disadvantages of PK include slow recovery of vision, irregular astigmatism, and the risk of graft rejection.<sup>4</sup>

One potential alternative to managing the loss of vision in contact lens-intolerant patients who have clear central corneas is pIOL implantation.<sup>7-9</sup> Compared to PK, pIOLs are less invasive and can result in faster recovery of vision, optimal centration within the eye, and maximization of visual quality. Phakic IOLs have been used to successfully treat high myopia, hyperopia, and astigmatism in normal eyes.<sup>10,11</sup> To our knowledge, there are three published reports of pIOLs for the treatment of keratoconus, one of which is a case report of two

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eyes.<sup>7-9</sup> The current study assessed the safety, efficacy, predictability, and refractive outcome of implanting Artisan (Ophtec BV, Groningen, The Netherlands) iris-fixated pIOLs in eyes with keratoconus.

#### PATIENTS AND METHODS

# PATIENTS

This was a retrospective study of 18 eyes of 11 patients diagnosed with keratoconus who underwent Artisan pIOL implantation. All patients were 21 years or older, with a mean age of 41±10.97 years (range: 23 to 64 years). Inclusion criteria were patients with an unsatisfactory optical correction who had exhausted all nonsurgical options with a clear cornea centrally, a best spectacle-corrected visual acuity (BSCVA) of 0.30 or better (decimal notation), a stable refraction for 2 years prior to surgery defined as a change of 0.50 diopters (D) or less in manifest refraction spherical equivalent (MRSE) yearly, and stable corneal topography as determined by the surgeon (J.V.). Exclusion criteria were an endothelial cell count  $<2000/mm^2$ , anterior chamber depth <3 mm from the anterior lens capsule to the endothelium, glaucoma, uveitis, previous intraocular or corneal surgery, cataract, macular pathology, diabetic retinopathy, and pregnancy. The Rabinowitz diagnostic criteria,<sup>12</sup> consisting of three corneal topography-derived indices, were used in the diagnosis of keratoconus. All corneas diagnosed with keratoconus exceeded Rabinowitz diagnostic criteria or had clinical signs of keratoconus.

# **PRE- AND POSTOPERATIVE EXAMINATION**

Pre- and postoperative ophthalmic examination included measurement of distance uncorrected visual acuity (UCVA) and BSCVA, pupillometry, manifest refraction, cycloplegic refraction (in patients <40 years old), slit-lamp examination, tonometry, corneal topography, autokeratometry (NIDEK Co Ltd, Gamagori, Japan), endothelial cell count, corneal pachymetry, gonioscopy, ultrasonography, and a dilated fundus examination. Postoperative examinations were conducted at 1 week and 1, 3, 6, 12, and 18 months after surgery.

# SURGICAL PROCEDURE

An experienced surgeon (J.V.) implanted all lenses. Both toric and myopic Artisan lenses were implanted. Myopic Artisan lenses (non-toric lenses) were used in patients with astigmatism up to -2.00 D; toric Artisan lenses were used in patients with astigmatism >-2.00 D. The Van der Heidje formula<sup>13</sup> was used to calculate the lens implant power. All calculations were done at Ophtec BV, Groningen, The Netherlands.

Prior to surgery the enclavation sites were marked on the cornea using a Codman surgical marker (Johnson & Johnson Gateway, Piscataway, NJ) with the patient sitting behind the slit lamp using a Mendez Degree gauge (Duckworth & Kent, Baldock, United Kingdom). Subsequently, one drop of topical anesthetic was instilled followed by delivery of peribulbar anesthesia. The eye undergoing surgery was prepared using a povidone-iodine solution and the surgical field isolated. Two paracentesis were made for instrument access followed by instillation of Miochol (Novartis Ophthalmics, Hanover, NJ) and a viscoelastic agent. A 5.20-mm clear corneal incision was made and the Artisan toric phakic IOL with a 5-mm optic zone was implanted using the closed system method described previously.<sup>14</sup> The correcting axis for the toric IOL was based on the preoperative autokeratometry. Autokeratometry results were compared to keratometry values generated from the Orbscan corneal topographer (Bausch & Lomb, Rochester, NY) or the Pentacam eye scanner (Oculus Optikgeräte GmbH, Wetzlar, Germany). For Artisan myopic pIOL implantation, a 6.20-mm clear corneal incision was made to account for the 6-mm optic zone. After successful implantation, the viscoelastic agent was removed by irrigation and a surgical iridectomy performed. Two single 10/0 Vicryl self-dissolving sutures were used to obtain a watertight sealing incision in all cases. Postoperatively, patients were instructed to instill one drop each of topical antibiotic and topical steroid four times a day for 2 weeks.

# DATA ANALYSIS

Data were collected and entered in a refractive outcomes analysis program (Datagraph, Wendelstein, Germany). Efficacy, safety, refractive outcome, stability, and predictability were calculated. Intra- and postoperative complications were recorded. Follow-up data are presented primarily for 6 months and, where available, up to 1 year postoperatively.

#### RESULTS

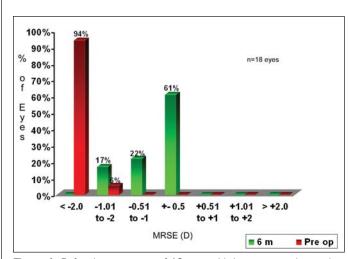
Mean patient age was  $41\pm10.97$  years (range: 23 to 64 years). Of the 11 patients, 36% (n=4) were women and 64% (n=7) were men. Thirty-nine percent (7/18) of right eyes and 61% (11/18) of left eyes underwent phakic IOL implantation. Twelve eyes received the toric Artisan lens and 6 eyes received the myopic Artisan lens. At 6 months postoperatively, all 18 eyes were available for follow-up. Nine eyes were available for follow-up at 9 months postoperatively and 5 eyes were available for follow-up at 1 year postoperatively.

Pre- and postoperative refractive parameters are shown in the Table. By 6 months postoperatively all

IOL = intraocular lens, Sph = spherical power, Q/I = cylinder power, SEQ = spherical equivalent refraction, BSCVA = best spectacle-corrected visual acuity (decimal notation), UCVA = uncorrected visual acu-ity (decimal notation), SD = standard deviation BSCVA 1.00 1.00 1.00 1.00 0.80 1.00 1.00 1.00 1.251.250.80 1.00 1.00 1.00 1.00 1.00 0.80 1.00 Pre- and Postoperative Parameters of 11 Patients With Keratoconus Who Underwent Artisan Phakic UCVA 0.50 0.63 Postoperative Manifest Refraction 1.00 0.80 0.63 0.63 1.00 0.63 1.00 0.80 0.63 0.80 0.80 0.80 1.00 0.80 0.63 0.80 SEQ (D) -0.460.125 -0.63 -0.38 -0.63 -0.38 -1.88 -0.63 -0.13 -1.500.125 -1.38 -0.63 0.125 -0.5 0.60 0 0 0 0 Axis 115 110 150 06 135 125 135 135 85 06 20 177 30 155 85 80 09 55 -0.75 Cyl (D) -1.50-0.25 -0.50 -0.75-0.25-0.25-1.25 -1.25-0.50 -0.25 -0.75 -0.50 -1.75-1.25-0.50 -1.25-2.00-0.86 0.55 <u>e</u> -0.50 -0.75 -0.50 -1.00-0.50 -0.03 -0.25 0.50 0.00 0.25 0.00 0.47 0.50 0.25 0.25 0.25 0.00 0.25 0.75 0.00 Sph ( -7.50-2.50-4.00-3.00 -2.50 -3.50 -4.00 -3.50 -6.50 -5.00-3.50 -7.50CVI (D) Intraocular Lens Implantation Lens Power **IOL** Information Sph (D) -9.50 -4.00-2.00 -4.50 -4.50 -4.00 -1.00-10.50-7.00-9.00-9.00 -8.50 -6.50 -2.50 -4.50-5.00-6.50 0 Myopic Myopic Myopic Myopic Myopic **Myopic** Type Toric TABLE BSCVA 0.80 0.50 0.80 1.00 0.50 0.63 0.80 1.00 0.80 0.80 1.00 1.00 1.00 0.63 0.80 0.80 0.80 0.32 Preoperative Manifest Refraction SEQ (D) -10.25-5.38 -6.00 -7.75 -5.75 -5.13-5.38 -4.75-4.13-4.88 -4.88-1.50-4.25-6.00 -10.00-9.88 -9.63 -5.63 -6.172.39 Axis 40 140 ດ 133 115 35 95 20 6 50 145 95 75 16 107 147 167 165 -2.50-7.75 -0.75 Cyl (D) -3.50 -2.25 -6.00 -0.50 -2.00-3.75 -3.25 -1.50-6.25 -4.75-3.25 -3.00 0.50 -1.50-2.252.04 -3.07 Sph (D) -8.50 -3.50 1.50 1.25 -5.75 9.75 -5.00 -5.00 2.00 -4.25-3.75 3.75 3.25 -8.00 8.00 7.00 -3.25 -4.64 2.74 0.00 Eye 00 OS OS 00 OS OS 00 OS OS QO OS 00 SO 00 OS QD OS OS Postop 2430 2649 2613 3146 2786 2387 2794 2832 2082 3296 2452 2713 2344 2474 2350 2621 2122 2457 3254 352 Endothelial (cells/mm<sup>2</sup>) Cell Count Preop 2644 2397 2459 2590 2650 2715 2879 2217 2104 3400 2650 2697 2455 2299 2282 2192 3205 2985 3421 401 No./Sex Patient Average 11/M 10/F 10/F 1/M 8/M 9/M 1/N 2/M 3/F 4/M M/27/M 8/M M/6 5/F 6/F 3/F 5/F SD Journal of Refractive Surgery Volume 25 September 2009

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#### **Phakic IOL for Keratoconus/Venter**



**Figure 1.** Refractive outcomes of 18 eyes with keratoconus that underwent Artisan phakic intraocular lens implantation. Preop = preoperative, 6 m = 6 months postoperatively, MRSE = manifest refraction spherical equivalent

sutures had dissolved. The majority of eyes were within 0.50 D of the intended correction 6 months postoperatively (Fig 1). Predictability is shown in Figure 2.

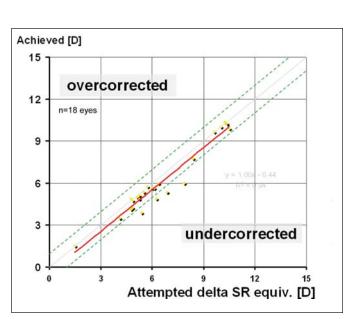
At 6 months postoperatively, 22% (4/18) of eyes saw 1.0 or better without correction (Fig 3). Six months after Artisan IOL implantation, no eyes lost BSCVA and 33% (6/18) of eyes gained 2 or more lines of BSCVA (Fig 4).

Eighteen months postoperatively, keratoconus progressed in one eye, which required an exchange of the Artisan IOL. In this case, the patient's (patient 4, Table) preoperative manifest refraction in the left eye was -3.25  $-3.25 \times 115^{\circ}$ . A toric Artisan lens with -4.00 D sphere and -3.50 D cylinder was implanted in November 2004. Three months postoperatively, the manifest refraction was  $-0.25 - 1.25 \times 125^{\circ}$ . Over the course of the year, the astigmatism in the left eye increased from -1.25 to -3.00 D. The patient was monitored and once the cylinder and topography stabilized, the lens was replaced with a toric Artisan lens with -4.00 D sphere and -6.50 D cylinder. One year after exchange, the topography and refraction remained stable. One patient (patient 5, Table) had superior oblique muscle paralysis of the left eye with BSCVA of 0.3 preoperatively and was asymptomatic due to the poor BSCVA. Following pIOL implantation, the patient complained of diplopia, which was likely due to the four line gain of BSCVA postoperatively.

Endothelial cell counts remained stable throughout the course of this study (Table). Figure 5 shows the refractive stability of the procedure over time.

#### DISCUSSION

The outcomes from this trial indicate that the use of the Artisan pIOL for the correction of myopia and



**Figure 2.** Predictability of attempted versus achieved change in manifest refraction spherical equivalent (SR equiv) 6 months after Artisan phakic intraocular lens implantation in 18 eyes diagnosed with keratoconus. Dotted lines represent  $\pm 1.00$  D.

astigmatism in patients with stable keratoconus is safe, predictable, and effective with minimal complications.

Although PK is the favored treatment of keratoconic patients who are contact lens intolerant, pIOL represents an alternative that may delay PK and allow functional vision for daily activities. Compared to PK and epikeratoplasty, pIOL implantation offers faster visual rehabilitation, greater safety, and is much less technically demanding.<sup>3,15</sup> The risk of graft failure, cystoid macular edema, decrease in endothelial cell density over a period of years, and ocular surface disease are long-term disadvantages of PK.<sup>15</sup> A diminution of low contrast visual acuity and loss of BSCVA has been reported with PK.<sup>16</sup>

Some cases of keratoconus become contact lens intolerant while the patient is still socially and physically active. Fast visual rehabilitation after pIOL implantation allows the patient to maintain his/her lifestyle with little delay. For example, in our study, we found that all patients had UCVA of 0.50 or better postoperatively (see Fig 3).

Akin to pIOLs, intrastromal corneal ring segments represent a reversible surgical alternative and are less technically challenging than PK. The advantage of corneal ring segments over pIOLs is that inserts are placed in the cornea obviating entry in the anterior chamber. Similar to pIOL implantation, this procedure allows relatively fast visual rehabilitation. However, Artisan pIOLs can reduce a broader range and much higher levels of refractive sphere and cylinder associated with

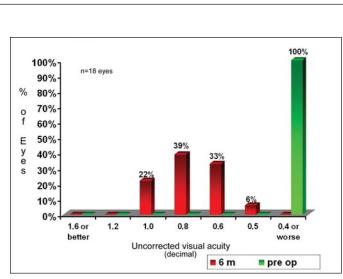


Figure 3. Efficacy 6 months after Artisan phakic intraocular lens implantation in eyes diagnosed with keratoconus.

keratoconus. In the current study, we treated patients with >7.00 D of cylinder, which would not be treatable with intrastromal corneal ring segments.<sup>7</sup>

The refractive outcomes obtained in our study are comparable to those reported for similar studies with corneal ring segments. Siganos et al<sup>17</sup> used corneal ring segments on eyes with keratoconus with a similar mean preoperative MRSE as our study and reported a mean MRSE of -1.11 D 6 months postoperatively, which is higher than our outcome of -0.46 D postoperatively (see Fig 5). Currently, only two studies of outcomes with pIOL implantation exist in the peer-review literature reporting sample sizes larger than two eyes.<sup>7,8</sup> Both studies, however, have smaller sample sizes than our study. The mean MRSE postoperatively from our study is similar to Budo et al<sup>7</sup> (-0.29 D) and lower than that reported by Leccisotti and Fields<sup>8</sup> (-1.31 D) at similar follow-up points (see Fig 5).

Safety was demonstrated in our study with no eyes losing BSCVA 6 months postoperatively (see Fig 4). Similarly, no eyes lost BSCVA in the Budo et al study<sup>7</sup> or the Leccisotti and Fields study.<sup>8</sup> Using corneal ring segments to treat keratoconus-associated refractive error on a similar sample size and mean preoperative MRSE as our study, Kymionis et al<sup>18</sup> report that 6% (1/15) of eyes lost BSCVA whereas Siganos et al<sup>17</sup> found no loss of BSCVA.

Thirty-three percent (6/18) of eyes gained two or more lines of BSCVA after Artisan pIOL implantation (see Fig 4). Gain of BSCVA after corneal ring segment implantation is not available in the Siganos et al or Kymionis et al studies.<sup>17,18</sup> Leccisotti and Fields<sup>8</sup> report less than 10% (1/12) of eyes had a similar increase in BSCVA whereas this parameter was not reported by

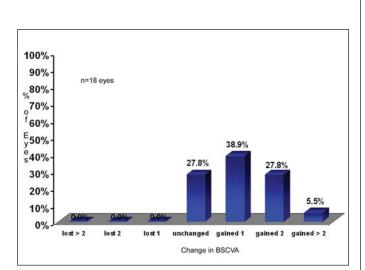
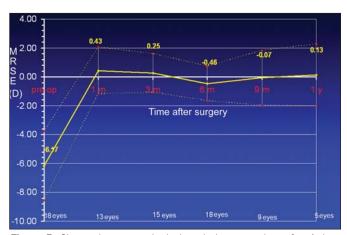


Figure 4. Change in best spectacle-corrected visual acuity (BSCVA) 6 months after Artisan phakic intraocular lens implantation in eyes diagnosed with keratoconus. Gained >2 denotes greater than 2-line gain of BSCVA, lost >2 indicates greater than 2-line loss of BSCVA



**Figure 5.** Change in mean spherical equivalent over time after Artisan phakic intraocular lens implantation in eyes diagnosed with keratoconus. Error bars represent standard deviation. MRSE = manifest refraction spherical equivalent

Budo et al.<sup>7</sup> The increase in BSCVA reported in the current study is likely due to the optical effect of implanting the Artisan pIOL within the optical system of the eye rather than correction at the spectacle plane.<sup>19</sup> Implantation of an IOL causes magnification on the retina and a decrease in spot size, which can increase BSCVA.<sup>19</sup> This combination of magnification and spot size have been shown to increase BSCVA up to 7 lines in adult amblyopes who underwent pIOL implantation.<sup>19</sup>

Complications of iris-fixated Artisan pIOL implantation include the potential for endothelial cell damage, cataract formation, glare, disengagement of the haptics, pigmentary dispersion, and a large corneal incision.<sup>8,20</sup> However, no such complications occurred in our study. We counsel patients about the possibility of glare postoperatively; however, to date we have not had to remove pIOLs due to complaints of glare. The use of iris-fixated pIOLs such as the Artisan are less likely to induce cataract due to the increased distance from the crystalline lens, thereby reducing the chances of lenticular touch.<sup>21</sup> Endothelial cell damage can be caused by surgical trauma or lens touch. However, there seem to be minimal adverse sequelae associated with endothelial cell damage or loss due to pIOL implantation.<sup>11</sup> The use of a large incision (5.2 mm) can cause residual astigmatism and must be considered during surgery. Newer foldable pIOLs will likely mitigate this effect. The long-term effects of iris fixation require further study. Pigmentary dispersion can cause pigmentary glaucoma necessitating regular follow-up of patients at risk. A recent study of the long-term (10 years) outcomes of 89 myopic eyes that underwent iris-fixated Artisan pIOL implantation from an experienced surgeon reported no pigmentary glaucoma.<sup>22</sup>

One drawback of this study is the small sample size, which does not allow us to provide conclusive evidence of the benefits or complications of this procedure. To date, this is the largest sample size of patients with stable keratoconus and a clear central cornea who were treated with the Artisan pIOL.

Use of Artisan iris-fixated pIOLs in patients with stable keratoconus for correction of astigmatism and myopia is safe, predictable, and effective with minimal complications. Long-term results are required to evaluate predictability and stability as keratoconus can be a progressive disease. Patients must be informed that progression of keratoconus can lead to change in refraction and visual quality.

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