Flexible Toric Iris Claw Phakic Intraocular Lens Implantation for Myopia and Astigmatism

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Purpose: To assess the visual and refractive outcomes of flexible toric iris claw phakic intraocular lens implantation for correction of moderate to high myopia with astigmatism.

Methods: In this non-randomized prospective study, 31 eyes of 18 patients including 8 male and 10 female subjects with mean age of 27.62±5.53 (range 19 to 38) years with moderate to high myopia and astigmatism underwent toric Artiflex (Ophtec BV, Groningen, Netherlands) phakic intraocular lens (PIOL) implantation. Uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) were measured in logarithm of minimum angle of resolution (logMAR) notations. Manifest refraction, safety, efficacy, predictability and complications were measured 6 months after surgery.

Results: Pre-operatively, mean spherical equivalent (SE) refractive error was -9.68±1.92 (range -14.00 to -6.00) diopter (D) and mean cylinder was -2.79±1.06 (range -4.75 to -1.00) D. After a minimum of 6 months, mean SE was -0.38±0.27 (range -0.87 to 0.00) D and mean cylinder was -0.66±0.43 (range -1.50 to 0.00) D. SE was within 0.50 D of emmetropia in 63.8% and within 1.0 D of target refraction in 100% of eyes. UDVA was equal or better than 20/20 in 45.1% of eyes while CDVA was equal or better than 20/20 in 67.7%; 83.8% of eyes gained 1 or more Snellen lines of CDVA after surgery. No serious complications occurred in this series of cases.

Conclusions: Implantation of the toric Artiflex PIOL is a safe and effective procedure for correction of moderate to high myopia with astigmatism.

Keywords: Toric Phakic Intraocular Lens; Artiflex; Myopic Astigmatism

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INTRODUCTION

Phakic intraocular lenses (PIOLs) serve as an excellent option for vision correction in patients who are not ideal candidates for laser surgery. The advantages of PIOLs over corneal refractive surgery in high myopia include better stability of refraction over time, better quality of vision due to less induction of higher order aberrations and no chance of corneal haze and ectasia. New versions of PIOLs can also correct concomitant astigmatism.

Currently there are 3 types of PIOLs with regard to their position inside the eye, i.e. angle supported, iris fixated and posterior chamber lenses. Each type of PIOL has its own advantages and disadvantages. The issue of most concern with these lenses is the risk of cataract formation and corneal endothelial cell damage. Advantages of iris fixated lenses are
the lower risk of cataracts, the fact that sizing is not an issue with these lenses and that they have been shown to be safe for the corneal endothelium if patients are properly selected.

The Artiflex (Ophtec BV, Groningen, Netherlands) is an iris fixated phakic IOL which is flexible and can be implanted through a small incision. The toric version of this lens was introduced in September 2009. This toric PIOL is a three-piece lens made of a hydrophobic polysiloxane optic and rigid PMMA haptics. It has a 6-mm optical zone, and an overall diameter of 8.5 mm. It may be inserted through a 3.2 mm incision and is designed for the correction of myopia with regular astigmatism. Spherical refractive power varies from -1.0 to -14.0 diopters (D) and the range of cylinder correction is -1.0 to -5.0 D. Artiflex power is calculated using the Van der Heijde’s formula, which uses vertex distance, subjective spectacle refraction, corneal curvature and anterior chamber depth (ACD).

The purpose of this study was to evaluate the refractive outcomes of artiflex implantation in patients with myopia and astigmatism.

METHODS

This prospective, single center study was performed from March 2010 to June 2011. Patients referred for vision correction surgery, who were not good candidates for corneal refractive surgery due to high refractive error with thin or suspicious corneas, were enrolled in the study. Inclusion criteria was age >18 years, stable refraction for at least 1 year, myopia more than -1.0 but less than -13.5 D, and cylindrical error from -1.0 to -5.0 D. The sum of minus sphere and cylinder could not exceed -14.0 D, since this is the limit of correction with this type of PIOL.

Patients with history of intraocular surgery or diabetes, glaucoma, cataract, keratoconus, uveitis, retinal detachment, shallow anterior chamber depth (internal ACD <3mm) and endothelial cell count less than 2,300 cells/mm were excluded. All patients were informed about the surgical procedure and provided written informed consent.

Preoperatively, all patients underwent a complete ophthalmic examination including determination of uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), subjective and cycloplegic refraction, corneal and anterior segment Scheimpflug imaging (Pentacam HD, Oculus Optikgerate GmbH, Wetzlar, Germany), specular microscopy for evaluation of endothelial cells (Tomey Corp., Japan), slit lamp evaluation of the anterior segment, applanation tonometry and ophthalmoscopy.

Surgical Procedure

All operations were performed by one surgeon (MG). Preoperatively, 2 reference marks were placed on the horizontal meridians of the cornea by means of a corneal marker (Asico LLC, Westmont, IL, USA) while the patient was seated at the slit lamp and both eyes were horizontally aligned. Surgery was performed under topical anesthesia (tetracaine 1%, two drops 5 minutes apart immediately prior to the procedure). The eye was prepped and draped and 2 alignment marks were placed on both sides of the implantation meridian (minus axis of cylindrical correction) with the aid of a Mendes gauge and toric marker. A 3.2 mm clear cornea incision was made, usually superior and perpendicular to the plane of lens enclavation. Viscoelastic substance (OcuCoat, Storz, Bausch & Lomb Surgical, St. Louis, MO, USA) was injected to form the anterior chamber and protect the corneal endothelium. The lens was loaded into the inserter spatula, inserted into the anterior chamber and rotated to the appropriate position. Two 1 mm side-port incisions were made close to the lens haptics and the PIOL was enclavated in the appropriate position. Peripheral iridectomy was performed, viscoelastic was removed and lens alignment was verified after forming the anterior chamber with balanced salt solution (BSS).

The postoperative regimen included ciprofloxacin and betamethasone eye drops 8 times daily for the first week, and betamethasone 4 times daily for the second week. Postoperative follow-up visits were scheduled on day 1, and at 3 and 6 months after surgery which included
UDVA, CDVA, manifest refraction, slit lamp biomicroscopy and applanation tonometry. Specular microscopy was repeated 6 months after surgery. Data before and 6 months after surgery were collected and analyzed. To evaluate rotational stability, manifest refractive cylinder on day 1 and at month 6 after the operation were compared.

**Statistical Analysis**

Statistical analysis was performed using SPSS version 18 (SPSS Inc., Chicago, Illinois, USA). Preoperative and postoperative data were compared with paired t test and P values less than 0.05 were considered as statistically significant. Power vector analysis of astigmatic change (Alpin’s method) was used to quantify the contribution of lens rotation to residual refractive error.

**RESULTS**

The study comprised of 31 eyes of 18 patients including 8 male and 10 female subjects with mean age of 27.62±5.53 (range 19 to 38) years implanted with the toric Artiflex (Ophtec BV, Groningen, Netherlands). Preoperative and 6 months postoperative visual and refractive data are shown in Tables 1 and 2. The efficacy, safety and predictability of the operation are shown in Figures 1 to 4.

**Efficacy and UDVA**

Mean logMAR UDVA improved from 1.11±0.42 preoperatively, to 0.06±0.12 six months after surgery (Table 1). UDVA was 20/20 or better in 14 (45.1%) eyes and 20/40 or better in 31 (100%) eyes at 6 months (Figure 1). The efficacy index, i.e. ratio of postoperative UDVA to preoperative

![Figure 1](image1.png)

**Figure 1.** Postoperative uncorrected distance visual acuity (UDVA) vs preoperative corrected distance visual acuity (CDVA) (operation efficacy).

|                   | Preoperative | Postoperative |
|-------------------|--------------|---------------|
| **UDVA (logMAR)** |              |               |
| Mean±SD           | 1.11±0.42    | 0.06±0.12*    |
| Range             | (1.00 to 1.50) | (-0.1 to 0.30) |
| **CDVA (logMAR)** |              |               |
| Mean±SD           | 0.10±0.10    | -0.002±0.11*  |
| Range             | (0.00 to 0.30) | (-0.1 to 0.22) |

UDVA, uncorrected distance visual acuity; CDVA, corrected distance visual acuity; SD, standard deviation

* P<0.05

![Figure 2](image2.png)

**Figure 2.** Change in lines of best corrected distance acuity (CDVA).
CDVA, was 1.09±0.24 at 6 months. All patients were satisfied or highly satisfied with the visual results of the procedure.

Safety and CDVA

Mean logMAR CDVA improved from 0.10±0.10 preoperatively to -0.002±0.11 after surgery (Table 1). 15 eyes (48.4%) obtained CDVA of 20/16 at 6 months. Safety index, i.e. ratio of postoperative CDVA to preoperative CDVA was 1.27 ±0.27. One eye (3.2%) lost 1 line of CDVA and another eye (3.2%) lost 3 lines. In contrast 26 eyes (83.8%) gained 1 or more line of Snellen CDVA as compared to preoperative levels (Figure 2).

**Table 2. Refraction before and after surgery**

|                   | Preoperative | Postoperative |
|-------------------|--------------|---------------|
| Sphere (D)        | -8.26±1.92  | -0.05±0.22*   |
| Range             | (-12.00 to -4.50) | (-0.50 to 0.75) |
| Cylinder (D)      | -2.79±1.06  | -0.66±0.43*   |
| Range             | (-4.75 to -1.00) | (-1.50 to 0.00) |
| SE (D)            | -9.68±1.92  | -0.38±0.27*   |
| Range             | (-14.00 to -6.00) | (-9.87 to 0.00) |

D, diopter; SD, standard deviation; SE, spherical equivalent * P<0.05

Refractive Outcomes

Preoperative and 6 month postoperative refractive outcomes are shown in Table 2. At six months, all refractive parameters were significantly reduced. Mean manifest refractive sphere decreased from -8.26±1.92 D at baseline to -0.05±0.22 D. Mean manifest refractive cylinder was -0.42±0.42 D on day 1, and -0.66±0.43 D at 6 months (P<0.05). Comparison of astigmatism on day 1 and at month 6 did not show any significant change, confirming excellent rotational stability. Mean spherical equivalent (SE) refraction was decreased from -9.68±1.92 D at baseline to -0.38±0.27 D postoperatively. All changes in

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**Figure 3. Refractive cylinder 6 months after operation.**

**Figure 4. Spherical equivalent (SE) refractive accuracy.**

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refractive data were statistically significant (P<0.05). Regarding refractive cylinder, 26 (83.8%) eyes had less than 1.00 D and 19 (61.3%) eyes had less than 0.50 D of refractive cylinder postoperatively (Figure 3). 100% of eyes were within 1.0 D of intended refraction and 63.8% of eyes were within 0.5 D of intended refraction (Figure 4). Analysis of astigmatism revealed that mean surgically induced astigmatism (SIA) was 0.17±0.81 D, mean difference vector was 0.57±0.39 D, mean absolute angle of error (AE) was 1.27±5.96 degrees, and mean arithmetic AE was 1.74±8.17 degrees six months after surgery.

**Endothelial Cell Count**

Mean preoperative endothelial cell count was 2,774±271 (range 2,390 to 3,370) cells/mm²; these values reached 2,693±327 (range 2,042 to 3,350) cells/mm² at six months. The change in endothelial cell counts was -0.3% (P>0.05, Table 3).

**Complications**

Two eyes developed early postoperative inflammation which was moderate in one eye and severe in the second eye; both responded to frequent application of topical steroid drops (betamethasone 0.5%) with no sequelae. Intraocular pressure (IOP) increased to 27, 30 and 35 mm Hg in 3 eyes after 3 weeks (all had IOP below 20 mm Hg preoperatively); these eyes were treated with timolol 0.5% twice a day for one month, after which IOP returned to normal without treatment. One eye had 15 degrees of misalignment and low vision which was corrected surgically. No other significant complication occurred. Most patients (70%) reported some degree of glare and halos which improved over time. After 6 months no patients had disabling glare.

### Table 3. Endothelial cell counts before and after surgery

|                          | Preoperative          | Postoperative         |
|--------------------------|-----------------------|-----------------------|
| Endothelial cell count (cell/mm) | 2,774.35±271.09      | 2,693.43±327.65       |
| Range                    | (2,390 to 3,370)      | (2,042 to 3,350)      |
| Central corneal thickness (µm) | 506.33±32.65         | 501.6±47.33           |
| Range                    | (455 to 586)          | (455 to 559)          |

**DISCUSSION**

Iris claw PIOLs lack potential size-related complications such as crystalline lens and peripheral corneal contact which may occur with posterior chamber or angle supported PIOLs. Artiflex has the advantage of being implanted through a small incision and toric Artiflex offers the additional advantage of correcting concomitant astigmatism with excellent rotational stability. As an iris claw PIOL, toric Artiflex bears potential complications such as inducing postoperative inflammation and progressive endothelial cell loss. Flexible iris claw PIOL may be more difficult to enclavate as compared to its rigid version and intraoperative alignment may also be more difficult. The other disadvantage of this lens is that currently, it has limited range of correction. Our study was performed to evaluate the efficacy, predictability and possible complications regarding this kind of toric PIOL.

We observed favorable refractive and visual results with toric Artiflex for correction of moderate to high myopia with astigmatism. Most patients gained one or more lines of CDVA and no serious complications occurred. Moderate and severe inflammation occurred in 2 eyes which were controlled by medical therapy. Only one eye had clinically significant misalignment of the PIOL (about 15 degrees) which was corrected by a second surgical intervention. In other eyes, the alignment was acceptable with insignificant residual or induced cylinder. This was assessed by vector analysis of pre- and postoperative cylinder and supported by the very good visual and refractive outcomes, and high patient satisfaction. Glare and halos occurred in most patients but decreased or disappeared with time. No patient had disabling glare at 6 months. All patients were satisfied by the result of surgery.
There are many studies in the literature on the outcomes of collagen copolymer toric posterior chamber phakic intraocular lenses (TICL) and toric Artisan PIOL for myopia and astigmatism,4-10 but regarding the toric Artiflex, studies are very few, since the lens has been launched recently. The first published report on the result of implantation of a toric iris-fixated PIOL (Artisan) came from the European multicenter study published by Dick et al.5 A significant decrease in cylinder was observed from -3.74±1.09 to -0.63±0.53 D in myopic eyes and from -3.70±1.05 to -0.77±0.64 D in hyperopic eyes and no eye in either group experienced loss of CDVA; 46 eyes gained ≥1 line of CDVA from their preoperative level. UCVA was ≥20/40 in 85.4% of myopic and 95.5% of hyperopic eyes. All eyes were within 1.0 D of intended refraction and 83.3% of myopic and 50% of hyperopic eyes were within 0.5 D of intended correction. In the study by Guell et al9 preoperative mean SE of -6.82 D was reduced to -0.09 D and preoperative cylinder of -3.24 D was reduced to -0.83 D.

According to a study on TICL, by Alfonso et al4 mean preoperative SE was -1.98±1.32 (range -0.50 to -5.50) D and mean refractive cylinder was -4.85±0.83 (range -1.50 to 0.00) D. At 12 months, mean cylinder was -0.55±0.52 D with 93.3% of eyes having less than 1.00 D cylinder. Mean SE was -0.31±0.42 (range -1.00 to 0.75) D with more than 70% of eyes within 0.50D of target refraction.

Regarding toric Artiflex, we encountered only two studies in the literature which have been published quite recently by Ruckhoff et al11 and Doors et al.17 Our results are somehow similar to these two studies. According to Ruckhoff et al,11 42 eyes of 24 patients with mean spherical equivalent of -7.52±2.22 (range -2.63 to -13.0) D and mean preoperative cylinder of -1.82±0.96 (range -1.0 to -5.0) D were enrolled. Six months postoperatively CDVA improved by one line in 22 eyes (52%) and by 2 lines in 2 eyes (5%); no eye lost any line of CDVA. Mean refractive astigmatism was -0.18±0.30 D. In our study, CDVA improved by one line in 13 eyes (42%), by 2 lines in 3 eyes (9.7%) and by 3 lines or more in 10 eyes (31.2%). One eye (3.2%) lost 1 line of CDVA and one eye (3.2%) lost 3 lines. Mean manifest refractive cylinder was -0.66±0.43 D at 6 months postoperatively. According to Doors et al17, 150 eyes of 73 patients were implanted with an Artiflex toric PIOL. At 6 months, 99.0% of eyes had UCVA of ≥20/40, and 81.8% of eyes were within 0.5 D of intended refraction. In 75.5% of eyes the remaining cylinder was ±0.5 D. In our study UDVA 20/40 or better was achieved in 100% of eyes at 6 months, all eyes were within 1.0 D of intended refraction and 63.8% of eyes were within 0.50 D of intended refraction. Regarding refractive cylinder, 83.8% of eyes had less than 1.0 D and 61.3% of eyes had less than 0.5 D of refractive cylinder postoperatively.

Despite the potential advantages of flexible toric iris claw PIOL, studies on the rigid version of this type of PIOL had similar results with our study. Well controlled comparative studies are necessary to prove the advantage of flexible toric iris claw PIOL over the rigid version of this PIOL. The results of our study indicate that implanting a toric Artiflex is safe and effective in eyes with moderate to high myopia and astigmatism with excellent rotational stability.

Conflicts of Interest
None.

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