Iris-Supported Artisan Phakic Intraocular Lenses for Treatment of Moderate to High Myopia

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Abstract

***Purpose*:** To evaluate the efficacy and safety of the Artisan Phakic Intraocular Lens (PIOL) for the correction of high myopia.

***Methods*:** In this prospective study of 22 eyes of 14 patients with high myopia, Artisan PIOLs (Ophtec BV) were implanted. Uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA), refraction, astigmatism, safety, and predictability were analyzed.

***Results*:** The mean of preoperative spherical equivalent was -11.1±3.3 D. An Artisan myopia lens was implanted in 28 eyes of 14 patients with preoperative myopia ranging from -6.0 to -20.0 D. The mean of patient age was 22.7±4.3 years. At three months follow-up, all eyes had a postoperative refraction within±1 D emmetropia. Mean uncorrected visual acuity improved from less than $^{20}/_{200}$ to $^{20}/_{50}$, and mean best corrected visual acuity improved from $^{20}/_{39}$ to $^{20}/_{30}$. The mean endothelial cell loss was 4.45% at three months, which was not significant. Postoperative complications included anterior chamber reaction in 10 (45%) patients that resolved with medical treatment in all of them. No other serious complications developed in any of the treated eyes during follow-up period.

***Conclusion*:** Artisan PIOLs can correct moderate to high myopia with good refractive results. There were no serious complications in this study.

***Keywords*:** Artisan, phakic intraocular lens, refractive surgery, high myopia

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Introduction

For many years the only ways for correction of myopia were contact lenses and spectacles. However, spectacles have a lot of optical difficulties (such as aberration, and miniaturization) especially in high myopia, and also contact lenses' complications were not acceptable by many patients.

Recently, refractive surgeries (e.g. LASIK, PRK) have made myopic patients hopeful. On the other hand, refractive surgeries could be harmful for myopia more than 6 D and is not proper in high myopia compared to low myopia.[1,2] Glare and halo is more common in high myopia due to smaller optical zone.[3] Postrefractive ectasia after high myopic surgeries (due to thinning of cornea) has also been reported[4,5] and decrease in BCVA in high myopia is more than in low myopia.[6-8]

Intraocular surgeries such as clear lens extraction (CLE) have also suggested, but CLE with intraocular lens (IOL) implantation could theoretically increase the chance of retinal detachment and also can abolish accommodation in young people.[9]

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Phakic intraocular lenses (PIOLs) are a good substitute for surgical correction of high myopia.[10-13] These lenses optically are similar to pseudophakic IOLs[13] and because are implanted near to iris, have less halo compared to laser refractive surgery. On the other hand, PIOLs could have many complications such as cataract, glaucoma, endophthalmitis, corneal decompensation, retinal detachment, and change in configuration of pupil.

The purpose of this study was to evaluate the clinical and refractive results of Artisan PIOLs (Ophtec BV) implanted in patients with high myopia.

Methods

In a prospective study, all patients who underwent Artisan PIOL implantation at our center between January 2005 and August 2005 was evaluated. All patients had high myopia (myopia >6 D). A total of 22 eyes of 14 patients with mean follow-up of 6 months were included. A written informed consent was taken from all patients before the procedure.

Patients>18 years old with stable refractive error for at least one year and anterior chamber depth>2.9 mm, endothelial cell count>2000/mm^2, IOP<20 mmHg and not suitable for LASIK due to thin cornea were offered for undergoing this procedure. Patients with connective tissue disorders, corneal or anterior segment pathology, uveitis, glaucoma, maculopathy or retinopathy and those with previous corneal or intraocular surgery were not considered for this procedure.

A complete preoperative ocular examination was done on all patients, including an A scan biometry, Goldmann applanation tonometry (Haag Streit, Bern, Switzerland), keratometry and pachymetry and endothelial cell count (Topcon 2000-p, Tokyo, Japan). The preoperative refraction required for calculating the power of the IOL was performed with and without cycloplegia (cyclopentolate hydrochloride 1.0%). Best spectacle corrected visual acuity (BSCVA) was measured before and after surgery. Dilated fundus examination including peripheral retinal screening was done.

The Artisan myopia lenses used in our patients were convex-concave (models 206 and 204) iris fixated IOLs, designed by Jan Worst and manufactured by Ophtec BV, Groningen, The Netherlands. The overall length of the lens was 8.5 mm. Type 206 has an optic with 5 mm diameter and type 204 has an optic diameter of 6 mm. The 6 mm lens is available from -3 to -15.5 D in half D steps and the 5 mm lens from -3 to -23.0 D in half D steps. Both lens designs are exactly the same and differ only in optical diameter and effective optical zone size. The height of the either lenses does not exceed 0.95 mm. The power of the lens was calculated with the Van der Heijde's formula[14] and was based on the refractive power of the cornea (mean corneal curvature, K), adjusted anterior chamber depth (ACD) and the patients spherical equivalent refractive error (spectacle correction at a 12.0-mm vertex).

The surgery was performed under general anesthesia in all patients. One drop of 2% pilocarpine was instilled in the morning and 30 min prior to surgery. The surgical protocol was the same for all patients. Two side port incisions were made at 2 o'clock and 10 o'clock positions. The anterior chamber was filled with methylcellulose. All incisions were at the superior limbus (scleral tunnel) and length of incision was 6 to 6.5 mm (depends on size of optic). The Artisan myopia lens was then introduced toward the 6 o'clock position. The lens was rotated using a lens rotator such that the haptics were at 3 and 9 o'clock positions. The PIOL was then held at the outer part of the optic and the enclavation needle passed through the paracenteces and iris tissue was enclavated. A peripheral iridectomy was performed with vannas scissors. After removing the viscoelastic from the anterior chamber the wound was closed with 10.0 nylon. Subconjunctival betamethasone and gentamycin was administered.

Postoperatively, betamethasone eye drops, six times daily tapering over four weeks and chloramphenicole eye drops four times daily for one week were used. Follow-up examinations were performed at one day, one week, two weeks, one month, and three months postoperatively. Patients with complications were examined more frequently.

Statistically significant differences between the means of the data samples were determined by student *t*-test and one-way analysis of variance (ANOVA). A probability

value<0.05 was considered statistically significant.

Results

Our patient population included 22 eyes from 14 patients (6 female and 8 male with a mean age of 22.7±4.3 years (range: 18-33 years) (Table 1). All patients were followed up for 188.5±38.9 days (range: 123-270 days). Preoperative myopia ranged from -6.0 to -20.0 D. Mean spherical equivalent refraction was -11.100±3.3 D. The ACD ranged from 2.91 to 3.97 mm and the axial length (AL) ranged from 24.22 to 33.48 mm. Mean ACD was 3.34±0.18 mm and mean AL was 26.68±9.34 mm. The mean IOL power implanted was -13.11±4.04 D (range: -5 to -22.5 D).

Table 1. Characteristics of patient population who received Artisan PIOL implantation for the correction of myopia.

Sex	6F/8M
Mean age (years)	22.7±4.3
BCVA	
Preoperative	20/39
Postoperative	20/30
UCVA	
Preoperative	<20/80 in all patients
Postoperative	20/50
Myopia (range) (D)	-6.0 to -20.0 D
Mean spherical equivalent (D)	-11.100±3.3 D
Astigmatism (D)	
Preoperative	-1.48±0.9
Postoperative	-1.14±0.58 D
Axial length (mm)	26.68±9.34 mm
AC depth (mm)	3.34±0.18
IOL power implanted (D)	-13.11±4.04
Endothelial cell count (cells/mm^2)	
Preoperative	2436±157
Postoperative	2328±132
Postoperative complication (Iritis)	10 (45%)

The mean preoperative astigmatism was -1.48±0.9 D (range: 0 to -3.5 D). By three months, the mean postoperative astigmatism was -1.14±0.58 D (P=0.87).

The mean BCVA improved from $^{20}/_{39}$ preoperatively to $^{20}/_{30}$ (logMAR= 0.21±0.13) postoperatively (p<0.001). The mean UCVA preoperatively was less than $^{20}/_{80}$ in all patients that improved postoperatively to mean $^{20}/_{50}$ (logMAR=0.37±0.19, range: $^{20}/_{120}$ to $^{20}/_{20}$).

The endothelial cell count loss postoperatively was not statistically significant (ANOVA P=0.288). Mean density was 2436±157 cells/mm^2 preoperatively, 2328±132 cells/mm^2 at three months postoperatively.

In our study, postoperative complication included only iritis. Severe anterior uveitis was observed in 10 eyes (45%) during second to 20th day of operation of which 3 eyes had an inflammatory membrane with hypopyon. All responded well to topical and sub-conjuctival betamethasone and systemic prednisolone (1 mg/kg) for 10 days and resolved completely.

Discussion

Currently two different surgical techniques (LASIK and PIOL) are available for correcting moderately high myopia that lead to similar predictability.[15] Nevertheless, LASIK is not the best choice for myopia superior to −8 D, mainly because of the risk of corneal ectasia and impairment of the quality of vision.[15,16]

In our study the primary outcome measure was to assess the effectiveness of refractive surgery was unaided postoperative visual acuity. In our study, at three months, postoperative UCVA was logMAR=0.3±0.15 that relative to pre-operative BCVA (logMAR=0.37±0.19) showed improvement. This result could show the predictability of surgical results. Postoperative BCVA was logMAR=0.2±0.13 that improved significantly relative to pre op BCVA (logMAR=0.37±0.19) (p value<0.001) that is comparable with previous reports.[17-19] This could be due to increase in optical quality of lenses and also magnification of lenses due to position of Artisan lenses relative to glasses.

Secondary outcome measures included postoperative refraction within±1.0 D, postoperative astigmatism. In our series, postoperatively all patients were within±1 D of target refraction. This was better compared to other published series where the postoperative refraction within±1 D ranged from 62.1% to 79.8%.[14,18] In the US FDA study, 65% had a postoperative refraction of ±0.5 D and 93% within±1 D.[17] Mean

preoperative astigmatism in our study was 1.48±0.9 D. By three months, the astigmatism had reduced to -1.14±0.58D. This was comparable to other studies where preoperative astigmatism of 1.12±0.8 D had reduced to 0.82±0.62 D.[19]

The second main objective of this study was to compare the safety of Artisan PIOLs. The mean endothelial cell loss in our series was 4.45% at 3 months that is similar to or lower than other studies. The cell loss was more in the first few cases reflecting our learning curve.[20-24]

We had not intraoperative complications like hyphema, traumatic cataract or iris prolapse. Postoperative IOP rise was not observed in our cases. Postoperative iritis was noted in 10 eyes (45%). This may be due to manipulation, materials in our viscoelastic or quality of instruments or racial differences. Inflammatory reaction in various studies ranged from 0-9.3%.[18,25] An important complication associated with PIOLs is retinal detachment.[14,25-27] We did not encounter any retinal detachment.

Conclusion

In summary, our study results support the efficacy of PIOL as a refractive surgical procedure for correction of high myopia. It resulted in stable improvement in both UCVA and BSCVA over a three-month period with a few complications. This technique has good results in high myopic patients that can not be corrected by other methods. Longer follow-up is necessary for monitoring late complications. Due to high incidence of iritis in our series, we suggest to perform this operation for both eyes at least 1 month apart and simultaneous operation could be harmful for patients.

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