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Artisan Phakic Intraocular Lens for the Correction of Severe Myopic Astigmatism

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Abstract

***Purpose*:** To determine and evaluate the visual acuity (VA) and refracion of correcting compound severe myopic astigmatism with the Artisan toric intraocular lenses (IOLs)

***Methods*:** In this noncontrolled clinical trial, 15 patients with severe astigmatism and at least 2.0 diopters (D) of astigmatism were enrolled. All patients met the inclusion criteria. Artisan toric IOL implantation was recommended to them, while the procedure and its possible complications were discussed. Preoperative examinations included refraction, uncorrected visual acuity (UCVA), and best corrected visual acuity (BCVA) tests, endothelial cell count (ECC), and anterior chamber depth (ACD) measurement.

***Results*:** Mean UCVA was 1.57 logMAR preoperatively, and increased to 0.21 logMAR 18 months after surgery (P<0.001). Mean sphere was -7.84 ±3.1D (range, -3 to -15) preoperatively, and changed to 0.04±0.47 D (range, 0.75 to -1.5) 18 months after surgery (P<0.001). Cylinder error showed a statistically significant change from -3.53±1.32 D (range, -1.5 to -6.5) to -0.90±0.90 D (range, 0 to -4.5) during the same period (P<0.001). Mean ECC was 3257.8 cell/mm^2 before surgery, and 2761.7 cell/mm^2 18 months later (P<0.001). Mean ACD showed reduction from 3.7±0.23 mm preoperatively to 2.9±0.23 mm after surgery (P<0.001).

***Conclusion*:** When laser refractive surgery is not an option, correcting severe myopia and astigmatism with the Artisan toric IOL has acceptable results, but it's possible complications must be kept in mind.

***Keywords*:** Toric Artisan, High Myopic Astigmatism

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Introduction

In the presence of refractive errors, the eye fails to focus images on the retina sharply. Today, estimates indicate that about 124 million people in the world have some degree of refractive error; this has been reported to range from 1% to 75% in different populations.[1,2] Myopia and astigmatism are the most common type of refractive errors.[3-8] However, regardless of the degree of myopia and astigmatism, there are now easily correctable in developed countries and developing ones as well.[10] In the past two decades, the development of novel correction methods for myopia and astigmatism, laser in situ keratomileusis (LASIK), and intraocular lens (IOL) implantation have revolutionized refractive surgery.

Myopia and astigmatism can be corrected by safe methods such as spectacles or contact lenses. Some patients cannot tolerate contact lenses, and some have no desire to use spectacles because of its own problems. On the other hand, keratorefractive surgical techniques such as photorefractive keratectomy (PRK) and LASIK, which are now very popular, are not possible for everyone because high corrections with these methods are not safe and are accompanied by an increased risk of corneal ectasia, and worsened quality of vision specially in dark conditions. Other complications of these surgeries for these types of patients are halos, decreased contrast sensitivity, and increased higher order aberrations. In addition, some of these patients are not eligible for laser keratorefractive surgery because of insufficient corneal thickness. IOL implantation is one of the techniques used for the correction of high amounts of refractive error. With this technique, accommodation is preserved.[11-15] Correction of high ammetropia with anterior chamber IOLs has gained favor in the past 20 years.[15-17] With the introduction of the toric Artisan (Ophtec, Groningen, The Netherlands), fewer patients need a second surgery to correct the remaining astigmatism. The present study was designed to assess the results of correcting myopic astigmatism with toric Artisan IOLs.

Methods

In this uncontrolled clinical trial, patients aged 20 years or more who had -2.00 diopters (D) or more astigmatism, no pathologic finding in anterior segment and lid function abnormality, and had no desire to wear glasses or contact lenses were enrolled consecutively at Noor Eye Clinic. None were eligible for laser keratorefractive surgery because they had high amounts of refractive error and the corneal thickness was not sufficient for a safe ablation.

Exclusion criteria were anterior segment pathology, eyelid disorder (insufficient closure), endothelial cell count (ECC)<2000 mm^2, anterior chamber depth (ACD)<2.8 mm, abnormal iris, abnormal pupil function, mesopic pupil size>5.0 mm, recurrent or chronic uveitis, cataract, history of ocular surgery, intraocular pressure (IOP)>20 mmHg, glaucoma or its positive family history, retinal detachment or its positive family history, macular pathology, systemic diseases (e.g. collagen vascular diseases, atopia, diabetes), long use of corticosteroids or immunosuppressive medication, and pregnancy.

In terms of refraction, only patients with a stable refraction (i.e. less than 0.5 D change) in the past 18 months were included.

All patients had a thorough ophthalmologic examination before surgery including refraction, uncorrected and best corrected visual acuity (UCVA and BCVA), keratometry, topography, mesopic and scotopic pupil size measurement, slit-lamp examination, tonometry, ECC, ACD and axial length (AL) measurement, and fundus examination. Patients were instructed to discontinue lens wear before initial examinations: 1 week for soft and 3 weeks for hard contact lenses.

All power calculations were performed by Ophtec BV Groningen, The Netherlands, based on the van der Heijide calculation formula: Power=n/(n/k+ps) + n/(n/k-d).

Where *k* is the keratometry in diopters, *ps* is the equivalent spectacle power of the corneal plane in dioprters, *d* is the distance between the IOL plane and the corneal plane in millimeters, and *n* is the refractive index of aqueous or 1.336. Since the distance between the crystalline lens and the toric phakic intraocular lens (TPIOL) is 0.8 mm, the d value was corrected with this number. All surgeries were performed by a single

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ophthalmologist with sufficient experience with Artisan lenses.

Before the operation, after anesthesia with tetracaine, the insulin marker was used to mark the 90 degree and 180 degree axis in the patients' eyes. At the beginning of the surgery, the axis was determined by the Mendez ring and then the lens was fixed at the axis.

Surgeries were done under general or local anesthesia. After peritomy, a 5.5 mm incision was made on the posterior limbus. Then a 1.5 mm tunnel was made into the eye. Methylcellulose viscoelastic was injected, and then the toric lens was placed inside the eye. More viscoelastic was injected over the lens surface, and the wound was sealed with two or three 10/0 nylon sutures. The Mendez marker was then used to adjust the position of the lens according to the cylinder axis, enclavation was completed, and viscoelastic was removed. Finally, peripheral iridotomy was done.

Postoperative examinations were scheduled for the 1st postoperative week, and then at 1, 3, 6, and 18 months. At these visits, UCVA, BCVA, refraction, and IOP were tested and slit lamp examination was done. ECC was done at 1, 3, 6, 12, and 18 months after surgery. Sutures were removed around the second postoperative month.

The initial protocol of the present research was approved by the ethics committee of Noor ophthalmology research center. The procedure and its probable complications were explained to all patients.

The likely risk of pupillary block, uveitis, endothelial cell loss and the increase of IOP after surgery was explained to the patients.

Patients were also informed that the procedure was intended to reduce their dependency on glasses and they all signed an informed consent. Analyses were done with the SPSS version 11.5 software.

Results

During May 2003 to November 2006, the Artisan toric lens was implanted in 26 eyes of 15 patients (32% men, 68% women). The mean age of the patients was 28±6.7 (range, 20 to 42) years. The mean preoperative keratometry in flat and steep meridaian were 43.51±2.39 and 45.84±2.46 respectively.

The mean UCVA was 1.57±0.44 in the logMAR scale preoperatively, which significantly increased to 0.21±0.15 logMAR at 18 months after surgery (P<0.001) (Table 1). The BCVA showed a similar significant improvement (P<0.001) (Figure 1).

The mean preoperative spherical error of -7.84±3.1 D significantly reduced to 0.04±0.47 D at the end of the follow-up period (P<0.001), and the cylinder error showed a statistically significant change from -3.53±1.32 D to -0.90±0.90 D during the same period (P<0.001) (Table 2). The sphere and cylinder correction at the end of this period was not significantly correlated with gender or age (P>0.05).

The mean ECC significantly reduced by 6.1%, 9.8%, and 12.1% in the studied eyes at 3, 6, and 18 months after surgery (P<0.001) (Table 3). These changes were not correlated with age or gender, but the ECC was significantly higher in women at the end of the study period; 3001 cell/mm^2 in women vs. 2600 cell/mm^2 in men (P<0.05). The mean ACD also showed a significant change and reduced from 3.7±0.23 mm preoperatively to 2.9±0.23 mm after surgery; there was no gender correlation but the reduction significantly increased with age (P<0.001, r=-0.738).

Table 1. Mean uncorrected visual acuity in the logMAR scale, preoperatively, and at 3, 6, and 18 months after surgery

Time	Mean	SD	Min	Max
Preop.	1.57	0.44	0.78	2.21
1 month	0.26	0.17	0	0.78
6 months	0.23	0.13	0	0.6
18 months	0.21	0.15	0	0.6

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Table 2. Mean sphere, cylinder, and spherical equivalent in the studied patients before surgery, and at 3 and 18 months after surgery

		Mean	SD	Min	Max
Sphere					
	Preop.	-7.84	3.02	-15	-3
	1 month	0.26	0.46	-1.25	1
	18 months	0.04	0.47	-1.5	0.75
Cylinder					
	Preop.	-3.53	1.32	-6.5	-1.5
	1 month	-1.34	1.17	-5	0
	18 months	-0.9	0.9	-4.5	0
Spherical equivalent					
	Preop.	-9.64	2.99	-16.5	-5
	1 month	-0.26	0.52	-1.5	0.5
	18 months	-0.47	0.61	-2.25	0.5

Table 3. Mean endothelial cell count (cell/mm^2) in the studied patients before surgery, and at 3, 6, and 18 months after surgery

Time	Mean	SD	Min	Max
Preop.	3257.8	595.35	2530	4780
1 month	3057.8	563.24	2400	4500
6 months	2937.8	526.49	2300	4300
18 months	2861.7	534.18	2300	4250

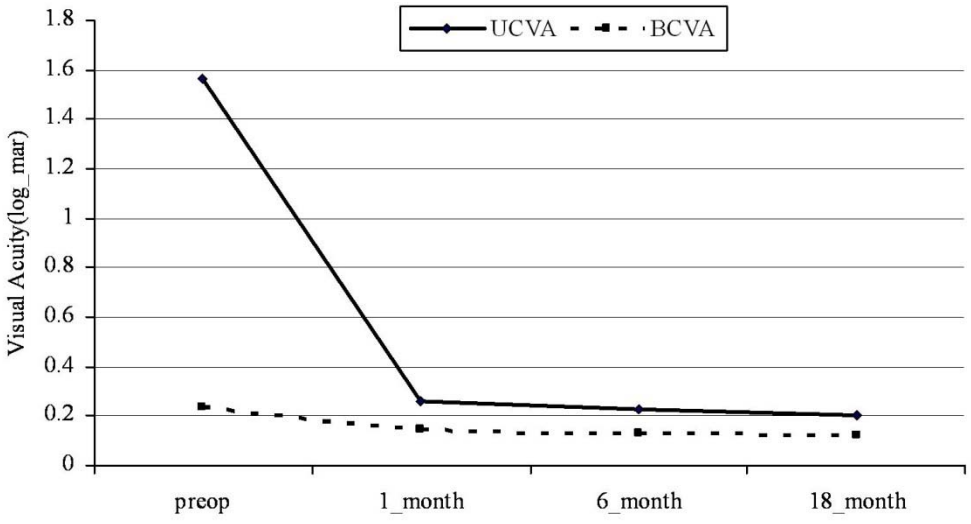

Figure 1. Mean uncorrected and corrected visual acuity of the patients in the logMAR scale at different time intervals

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Discussion

The present study was conducted to determine the visual results of toric Artisan IOL implantation for the correction of high myopic astigmatism. There are a variety of methods for the correction of refractive errors. All keratorefractive surgical procedures, including astigmatic keratotomy (AK), radial keratotomy (RK), PRK, and LASIK change the shape of the cornea from the normal prolate to oblate which can lead to a decreased quality of vision specially in dim light and at night.[18]

Although LASIK is a popular and acceptable procedure today, the results in cases of high myopia, specially when mixed with high astigmatism, can be associated with complications which not only carry the risk of ectasia, but also induce irreversible changes to the posterior curvature of the cornea, and lead to optical aberrations, and halos. Therefore, intraocular procedures such as lens replacement and use of IOLs or phakic lenses are preferred in certain cases.[14,15,19] Removing the crystalline lens can be associated with complications such as retinal detachment, and loss of accommodation, specially in younger persons. In addition, corneal astigmatism cannot be corrected through this procedure.[20,21] At present, phakic lenses show better refractive results for high refractive errors (myopia worse than -10.00 D) than keratorefractive surgery.[15,21] Also, the refractive results of phakic lens implantation in moderate to high refractive errors are more accurate and better than extracting the crystalline lens.

In the present study, the mean cylinder error was -3.6 D preoperatively and significantly decreased to -0.9 D at 18 months after surgery (Table 2). The cylinder error at this time was ≤-0.5 D in 75% of the eyes. The use of toric Artisan lenses in the correction of astigmatism has been reported by several studies,[18,20] and most agree that there is little regression at least during the first postoperative year. In the study by Tehrani et al, the mean cylinder was -1.92 D preoperatively, and decreased to -0.56 D at 6 months after surgery.[22] The multicenter study on these types of lenses showed mean cylinder corrections ranging between 0.0 D and 0.7 D during the three year follow up.[23] In another study by Rudy et al a change of mean cylinder from -6.5 D to -1.43 D was reported.[24] The mean preoperative sphere in the present study was -9.6 D which reduced to -0.5 D at 18 months after surgery (Table 2). Rudy et al report a reduction in the mean spherical equivalent from -5.0 D to -0.9 D during the same follow-up time.[24] Other studies have also shown the long term compatibility and safety of Artisan lenses in the correction of myopia and astigmatism.[21-23]

Results of the present study indicated a statistically significant reduction in the ECC during the 18 month follow-up period. Other studies have reported a similar outcome. In the study by Landesz et al on the long term outcome of Artisan lenses, a 10% loss of endothelial cells was seen at 3 years after surgery.[14] Menezo et al reported a mean endothelial cell loss of 3.9% at six months, 6.6% at one year, 11.7% at three years, and 13.4% at four years after implantation of Worst-Fechner lenses.[13] Perez-Santonja et al used these lenses and reported the mean endothelial cell loss to be 7.2% at three months, 10.6% at 6 months, 13% at one year and 17.6% at two years after surgery.[16] Rudey et al found a 16.6% reduction in ECC at 18 months.[24] The progressive decrease in endothelial cells is one of the main concerns with these lenses. It is also important to prevent IOP increase due to pupillary block by performing peripheral iridotomy prior to or during surgery. Risk factors that increase endothelial cell loss include older age, a shallow anterior chamber, and high power lenses (due to thicker edges). By considering these factors, the efficacy of these lenses in terms of endothelial cell preservation can be increased.

As it was demonstrated in the results, we found pupillary block in 2 patients which eventually they were treated by peripheral iridectomy. In the other reports, pupillary block was reported as a complication of the IOL implantation.[25-27] The reason is the path obstruction between anterior and posterior chamber because of the pupillary block. Consequently the aqueous is locked in the posterior chamber and the IOP increases.

Conclusion

When laser refractive surgery is not an option, correcting severe myopia and astigmatism with the Artisan toric IOL has acceptable

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results, but its possible complications must be kept in mind.

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