

## Correction of High Myopia with Foldable Artiflex Phakic Intraocular Lenses: 1 Year Follow-up Results

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**Abstract-** To assess the one year results of Artiflex Phakic intraocular lens (IOL) implantation in the treatment of high myopia. In this non-random interventional study, myopic patients with spherical equivalent worse than -5.0 diopters (D) who were not eligible for laser surgery were assessed. All patients had refraction, uncorrected and best corrected visual acuity tests (UCVA and BCVA), endothelial cell count (ECC), and measurement of the anterior chamber depth and intraocular pressure before surgery and at 1, 3, 6, and 12 months after surgery. Main outcome measures of this study were refractive stability, refractive predictability, safety, and efficacy after implanting Artiflex IOLs. We studied 53 eyes of 20 female and 8 male patients. The mean preoperative spherical equivalent was  $-10.22 \pm 3.02$  D which reached  $-0.69 \pm 1.08$  D one year after surgery ( $P < 0.001$ ). On the last follow-up visit, 75% of the eyes were within  $+0.5$  D of emmetropia, 2 eyes had lost one line of BCVA, 18.75% had gained one line and 31.25% had gained 2 or more lines of BCVA. Others showed no change in BCVA. At one year after surgery, 72.2% of the eyes had 20/25 vision or better. The safety and efficacy indices were 1.16 and 1.05, respectively. ECC showed 3.04% decrease ( $P = 0.176$ ). In cases where laser surgery is not an option for myopic patients, use of Artiflex IOLs can have good results with acceptable safety and efficacy.

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### Introduction

Laser surgical correction of myopia is one of the most common surgical procedures in the world. However, cases with inadequate corneal thickness and high amounts of refractive errors may not be eligible for laser refractive surgery. In such cases, implantation of intraocular lenses (IOL) is suggested. Artisan lenses are a set of IOLs for high refractive errors (1,2). Artisan lenses can be used for treating spherical errors, but since they are not foldable, they need a 5.5- to 6-mm incision for insertion (depending on the lens type), and there are reports concerning induced astigmatism after their application (3,4).

In recent years, a new generation, the Artiflex lenses, have become commercially available. They can be implanted through a 3.2 mm incision with possibly less induction of astigmatism. A better uncorrected visual acuity (UCVA) has been reported with the Artiflex lens (5,6). Coulet *et al.* (7) reported faster recovery and

better UCVA with the implantation of the Artiflex IOLs. In addition, Tahzib *et al.* (8) reported decreased induced spherical aberration after Artiflex lens implantation. Dick *et al.* (5) reported that two-year follow-up results of the Artiflex lens implantation for the correction of myopia proved it to be effective and predictable. Since there are few reports available on surgical outcomes of Artiflex lenses, we designed this one-year follow-up study. Our purpose was to evaluate the safety, efficacy and predictability of the Artiflex lens in Iranian patients for the correction of myopia.

### Materials and Methods

In this non-random prospective interventional study, we included patients with 5.0 diopters (D) of myopia or more who were not eligible for laser surgery. After patient selection, the nature of the study was explained to every patient and they signed informed consents for participation. The proposal of this project was approved

by the Institutional Review Board of Noor Ophthalmology Research Center.

All patients had complete ophthalmic examinations including optometry examinations for refraction, uncorrected and best corrected visual acuity tests (UCVA and BCVA), keratometry, topography, endothelial cell count (ECC), and measurement of the pupil diameter, axial length, and anterior chamber depth (ACD). Examinations by the ophthalmologist included a slit lamp examination and applanation tonometry.

Exclusion criteria were anterior segment pathology, eyelid disorder (insufficient closure), endothelial cell count (ECC) < 2000 cell/mm<sup>2</sup>, abnormal iris, abnormal pupil function, mesopic pupil size > 5.0 mm, recurrent or chronic uveitis, cataract, history of ocular surgery, 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.

The studied sample was 53 eyes of 20 female and 8 male patients. The mean age of the participants was 26.18±4.54 (range, 19 to 36) years. Table 1 summarizes demographics and preoperative findings.

After patient preparation and administering topical anesthesia, a superior corneal tunnel incision was created 3.2 mm long and 1.5 mm wide. Cohesive viscoelastic was injected into the anterior chamber and 2 stab wounds were made at 2 and 10 o'clock positions. The IOL was then slid into the anterior chamber using a special insertion spatula. Viscoelastic was re-injected onto the lens which was then placed in its proper position using a manipulator. Enclavation was done using special forceps to hold the IOL and an enclavation needle. Peripheral iridectomy (PI) was performed, and after washing out the viscoelastic material, the anterior

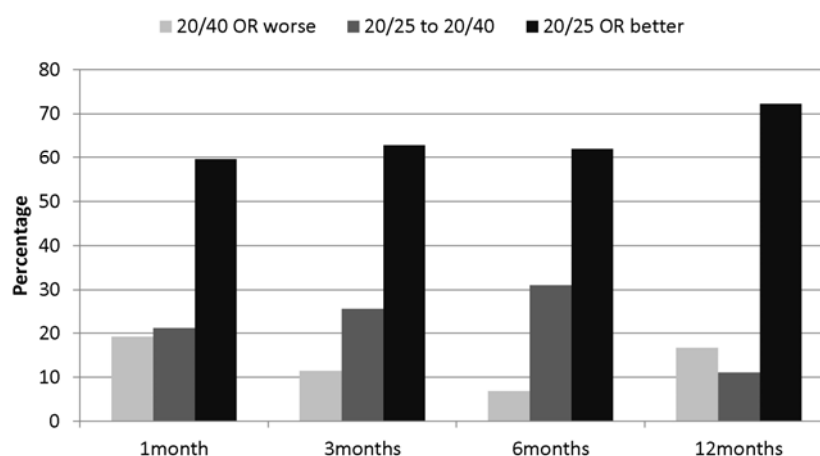
chamber was filled with balanced saline solution (BSS). Stromal hydration of the main incision was performed and fluid outflow was checked. Finally, the eye was patched and covered with a shield which was removed the next day. Postoperative medication included betamethasone and chloramphenicol eye drops every 4 and 6 hours, respectively for 3 days; the former was continued 6 times daily for one week, and the latter was continued 4 times daily for 4 weeks. IOL power calculation was done using non-cycloplegic refraction, the adjusted anterior chamber depth (ACD), and the keratometry reading from the table provided by Ophtec. All preoperative examinations were repeated 1, 3, 6, and 12 months after surgery.

### Statistical analysis

In this study, we analyzed refraction, UCVA, and BCVA data. To determine predictability, we calculated the percentage of cases with a spherical equivalent within 0.5 D and 1.0 D at 1 year after surgery. The safety index was defined as the ratio of postoperative BCVA over the preoperative BCVA based on the LogMAR results. The efficacy index was calculated as the ratio of postoperative UCVA to the preoperative BVCA, and the percentage of cases with a UCVA equal to or worse than 20/40 at 12 months after surgery. We used repeated measures analysis of variance to compare preoperative and postoperative results.

### Results

The mean preoperative spherical error was -9.67 D and reached -0.18 D at 1 year after surgery ( $P<0.001$ ), and the improvement in mean cylinder error was 0.51 D ( $P<0.001$ ) in the operated eyes.



**Figure 1.** Mean spherical equivalent refraction before surgery and at 1, 3, 6, and 12 months after surgery.

**Predictability**

Preoperatively, the mean spherical equivalent error was  $-10.22 \pm 3.02$  D which reached a mean of  $-0.69 \pm 1.08$  D at one year after surgery ( $P < 0.001$ ). As demonstrated in figure 1, the spherical equivalent was relatively stable over time, and there were no significant changes according to the repeated measures analysis of variance ( $P = 0.289$ ). Table 2 demonstrates predictability values based on the spherical equivalent; at least 71.4% of the eyes were within 0.5 D of emmetropia at 1, 3, 6, and 12 months after surgery.

**Efficacy**

Based on our findings, the mean UCVA improved from the preoperative value of 1.96 to 0.085 LogMAR at 6 months after surgery. At one month after surgery, 59.6% of the patients had UCVA of 20/25 or better, and this rate was 62.1% at one year (Figure 2). The efficacy index was  $1.05 \pm 0.27$ .

**Safety**

Mean BCVA was  $0.10 \pm 0.12$  LogMAR preoperatively, and 0.05, 0.05, 0.03, and 0.03 LogMAR at 1, 3, 6, and 12 months after surgery, respectively. All patients had BCVA of 20/40 or better at all postoperative visits. At 12 months after surgery, 67.7% of cases had BCVA of 20/20 or better.

In 43.75% of cases, there was no change in BCVA; 18.75% gained one line and 31.25% gained 2 lines or

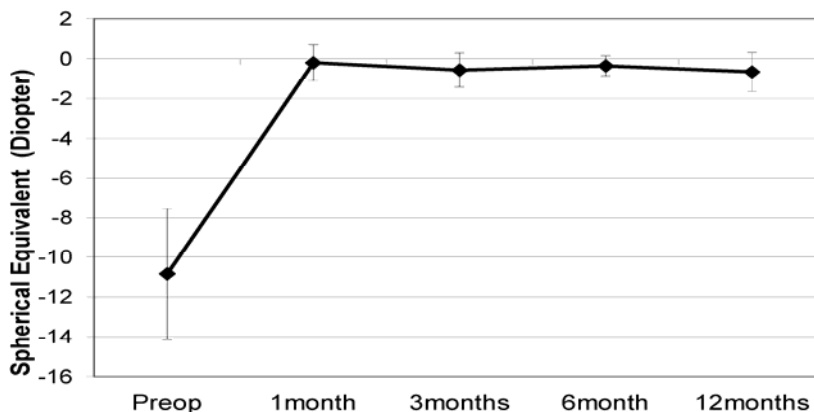
more of BCVA. Nonetheless, 2 eyes lost one line of BCVA, and the safety index of the surgery was  $1.16 \pm 0.27$ .

Mean preoperative ECC was 2976.3 cells/mm<sup>2</sup> which decreased about 3.04% by the final follow-up visit and reached 2885.8 cells/mm<sup>2</sup>; the change was not statistically significant ( $P = 0.241$ ). At 12 months after surgery, the IOP had increased by about 0.8 mmHg which was not statistically significant ( $P = 0.189$ ). The ACD however, had decreased significantly by 0.17 mm ( $P < 0.001$ ). Three eyes in 2 patients showed signs of inflammation.

**Table 1.** Patients' age and preoperative findings.

	Mean±SD	Range
Age (year)	26.18±4.55	19 to 36
Sphere (diopter)	-9.67±2.86	-5.0 to -18.5
Cylinder (diopetr)	-1.16±0.54	-0.25 to -2.00
SE (diopter)	-10.22±3.02	-5.25 to -19.5
CCT (micron)	509.69±40.49	416 to 582
ECC (cells/mm <sup>2</sup> )	2976.3±516.5	2190 to 5280
AL (mm)	26.66±2.79	12.0 to 32.16
UCVA (LogMar)	1.96±0.19	1.0 to 2.0
BCVA (LogMar)	0.10±0.12	0.0 to 0.4
IOL (diopter)	-10.76±2.4	-6.0 to -14.5

SE: Spherical equivalent, CCT: Central corneal thickness  
 ECC: Endothelial Cell Count, AL: Axial length  
 UCVA: Uncorrected visual acuity, BCVA: Best corrected visual acuity  
 IOL: Intraocular lens



**Figure 2.** Postoperative uncorrected visual acuity in the treated patients.

**Table 2.** Percentage of Spherical equivalent refractive predictability

Spherical equivalent (diopter)	1month	3months	6months	12months
Over 0.5	9.5	0	8.3	0
0.5 to -0.5	71.4	78.6	83.3	75.0
-0.5 to -1	9.5	7.1	8.3	15.0
lowest -1	9.5	14.3	0	10.0

## Discussion

Artisan IOLs are used to correct myopia, astigmatism, hyperopia, and myopic astigmatism. Results with the Artisan lenses have been assessed in various studies (1,9,10), and in the past few years, they have been reported to have acceptable safety and efficacy for the correction of refractive errors. Nonetheless, there are instances of significant induced astigmatism (3,4). The next generation of Artisan lenses is the foldable Artiflex IOL which is used for myopic correction. In terms of their convex-concave design, the Artiflex resembles the Artisan; however, it can be inserted through a 3.2 mm incision and requires no suturing. The first report concerning the outcome of Artiflex lenses was by Tehrani *et al.* (11) in 2005 who reported the 6 month results in myopic patients. Dick *et al.* (5) have published their 2 year results with this type of lenses.

### Predictability

As mentioned, 75% and 90% of our cases had a spherical equivalent within 0.5 D and 1.0 D of emmetropia, respectively. In comparison, Tehrani *et al.* (11) reported a spherical equivalent within 0.5 D in 91% at 6 months. In 2008, Dick *et al.* (5) reported their one year results, and 75.2% and 96% of cases had a spherical equivalent within 0.5 D and 1.0 D of emmetropia, respectively. In another report, Kohnen *et al.* (12) gave one year rates of 80% for Artiflex type 1, and 100% for Artiflex type two lenses with a spherical equivalent within 0.5 D. In the study by Coulet *et al.* (13), 84% of the eyes were within 1.0 D of emmetropia at 1 year after surgery. In a comparison study, Tahzib *et al.* (8) found that at 1 year after surgery 85.7% of the eyes with the Artiflex IOL were within 0.5 D of emmetropia, while the rate was 76.2% with the Artisan lens. Overall, results with the Artiflex IOLs indicate very good predictability of these lenses in the correction of refractive errors. In addition, the stability of the results has been shown in other studies, as well as ours. Compared to the predictability index for the Artisan lens reported in other studies (14-16), Artiflex IOLs have shown better refractive outcome and stability. The overall results with Artiflex lenses in terms of 20/25 and 20/20 vision seem to be better as well; in the comparative study by Coulet *et al.* (7), the rate of 20/25 vision was significantly better in the Artiflex group (29% vs. 19.3%). The better efficacy and UCVA with Artiflex lenses can be attributed to the smaller incision size and less induced astigmatism. The safety of Artiflex and Artisan lenses may be similar, but the better efficacy

is more important in reducing one's dependence to spectacles.

### ECC

The ECC in our study showed an average decrease of 3.04% at 1 year. Results in other studies were as follows: 1.79% decrease by one year in the study by Dick *et al.* (5), 2.3% decrease by 6 months in the study by Tehrani *et al.* (11), and 9.0% in the study by Coulet *et al.* (7) (compared to 9.4% in their Artisan group). As with the Artisan IOLs, Pop *et al.* reported a 17.4% decrease in ECC over 5 years, and the 1-year declines reported in other studies range between 1 and 10% (17-19). Overall, ECC changes seem to be less with the Artiflex lens, which is expected in light of the smaller incision size.

### Safety

As demonstrated by our findings, Artiflex implantation had favorable results in terms of BCVA. All patients had 20/40 vision or better and 67% had 20/20 vision. On the other hand, about 50% of the cases had gained one line or more compared to their preoperative status and only 2 cases lost one line. In the first report on this type of lenses, Tehrani and Dick (11) stated that 78% of their cases had gained 1 line or more at 6 months after surgery, and the rest of the patients showed no difference in BCVA. Similar to our findings, in another study by Dick *et al.* (5), all samples had a 1-year postoperative BCVA of 20/40 or better, about 42% had gained 1 line of BCVA, and 0.7% had gained 2 lines or more (5). Tahzib *et al.* (20) found no case with any loss of BCVA in their Artiflex group, while BCVA loss was observed in one eye in their Artisan group. Reports concerning the Artisan IOLs by Stulting (21), Tahzib (14), and Budo (22) show that the safety index with the Artiflex IOLs is comparable to that with the Artisan IOLs, and the difference between them is not large. According to Joosse *et al.* (23), the safety and gained lines of BCVA with these lenses are even better than that with photorefractive keratectomy. van Philips *et al.* (24) has also shown the safety of these lenses in the correction of moderate and high myopia.

### Efficacy

The efficacy index in the study by Dick *et al.* (5) was close to that in our study (1.01), and Coulet *et al.* (13) reported this value to be 0.79 based on decimals. Considering the overall results, Artiflex IOLs have acceptable efficacy, and compared to results with the Artisan lens, the efficacy is even better. In agreement

## Foldable artiflex for high myopia

with this observation, the comparison study by Coulet *et al.* (13) revealed better efficacy for Artiflex lenses. The reported efficacy in different studies was not based on a standard definition, and assessment of the postoperative UCVA seems to be more useful in this regard. In our study, 83.3% of cases had 20/40 or better UCVA at 1 year; this rate was 97.4%, 100%, and 77.4% in the studies by Dick *et al.* (5), Tehrani *et al.* (11), and Coulet *et al.* (13), respectively. The smaller decrease in ECC can be due to the smaller incision created for their insertion, nonetheless, parameters such as ACD and patient age are important as well.

### Astigmatism

The major difference between the two Artisan and Artiflex IOLs is that Artiflex is foldable. This feature allows for creating a smaller incision for lens implantation with the Artiflex. Studies have demonstrated that larger incisions are associated with the induction of astigmatism (3,4). In the present study with the Artiflex, we observed 0.5 D of astigmatic correction, and this was about 0.25 D more than that seen in the study by Tahzib *et al.* (8) at 1 year. In the study by Coulet *et al.* (13), the amount of astigmatic correction showed a significant inter-group difference; it was 0.46 D better in the Artiflex group.

### Inflammation

We observed 3 cases of inflammation among our patients, which started after the second week as pigmentary sediments on the anterior and posterior surface of the implanted IOL. These patients were treated with steroids which decreased the amount of inflammation, and the remaining pigmentary sediments did not affect vision. In a study by Zuberbühler *et al.* (25), 2 of their 34 eyes showed prolonged intraocular inflammation after Artiflex implantation. There are other reports of inflammation with IOL implantation, and it is necessary to start steroids in time to deal with this complication. In conclusion, when laser refractive surgery is not an option for cases of high myopia, using Artiflex IOLs is a safe alternative that can provide acceptable results. The lenses come with high efficiency and can minimize patient dependence on glasses.

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