Higher-order aberrations after implantation of iris-fixated rigid or foldable phakic intraocular lenses

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PURPOSE: To evaluate higher-order aberrations (HOAs) after implantation of Artiflex phakic intraocular lenses (pIOLs).

SETTING: Department of Ophthalmology, Academic Hospital Maastricht, Maastricht, The Netherlands.

METHODS: This retrospective comparative case series comprised 27 eyes (14 patients) that had Artiflex pIOL implantation and 22 eyes (13 patients) that had Artisan pIOL implantation. Refractive data, pupil size, IOL decentration, and HOA values were recorded and compared. Laboratory analysis was performed. Follow-up was 1 year.

RESULTS: In the Artiflex group, the mean spherical equivalent (SE) changed from −9.95 diopters (D) ± 1.43 (SD) (range −6.75 to −12.13 D) to −0.30 ± 0.53 D (range −1.94 to 0.56 D). Postoperatively, trefoil-y increased (increase factor 1.73) and spherical aberration decreased (increase factor 0.55). The mean pIOL decentration was 0.24 ± 0.12 mm; 96.3% were decentered 0.5 mm or less. There was a significant correlation between pIOL decentration and postoperative spherical aberration and coma-y. In the Artisan group, the mean SE changed from −9.90 ± 2.74 D (range −4.00 to −14.50 D) to −0.20 ± 0.42 D (range −0.75 to 0.50 D). Postoperatively, trefoil-y and spherical aberration increased (increase factors 3.32 and 6.84, respectively). Laboratory analysis confirmed the negative and positive spherical aberration profile of the Artiflex pIOL and Artisan pIOL, respectively.

CONCLUSIONS: Artiflex pIOL implantation decreased spherical aberration, while Artisan pIOL implantation increased spherical aberration. Trefoil-y increased in both groups. These changes might be explained by incision size differences in relation to trefoil and differences in optic design in relation to spherical aberration.

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Refractive surgery techniques have the goal of correcting the spherical and cylindrical refractive error in patients with visual complaints who desire to be independent of spectacles and contact lenses.

We now know that naturally occurring and surgically induced optical abnormalities exist; these are also referred to as optical aberrations. Optical aberrations include lower-order aberrations and higher-order aberrations (HOAs). Higher-order aberration, also referred to as irregular astigmatism, may influence postoperative visual outcomes and patient satisfaction and must be included in the preoperative evaluation and selection of refractive surgery candidates.[1–3] The literature contains several clinical studies of changes in HOA after refractive surgery for the correction of myopia, particularly after myopic laser in situ keratomileusis (LASIK) and photorefractive keratectomy (PRK).[4–13] One study[4] reports that the amount of achieved correction was correlated with the changes in ocular HOA. Another report[6] found that the total HOA increased by a factor of 1.53 and that spherical aberration increased by a factor of 1.6.

Several clinical reports[14–24] confirm the excellent levels of efficacy, predictability, and safety of implantation of the Artisan phakic intraocular lens (pIOL) (Ophtec B.V.) for the correction of moderate to high myopia. The Artisan iris claw–fixated pIOL has a convex–concave PMMA optic that is 6.0 mm (for IOL powers up to −15.50 diopters [D]) or 5.0 mm (for IOL powers from –16.00 D to –24.00 D). It is available in 0.50 D steps.

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The recently designed Artiflex (Ophtec B.V.) is an iris-fixated pIOL that can be implanted for the correction of myopia[25]; the IOL is currently under clinical investigation in Europe. The Artiflex pIOL is 3 piece and consists of a 6.0 mm convex–concave flexible silicone optic of ultraviolet-absorbing polysiloxane (for IOL powers from −2.00 to −14.50 D) and rigid haptics of compression-molded Perspex CQ UV poly(methyl methacrylate) (PMMA). It is available in 0.50 D steps. To our knowledge, a few case reports[26,27] and 2 clinical studies[28,29] have evaluated the clinical and refractive results of Artiflex pIOL for the correction of myopia.

In the early design of the Artiflex pIOL, the vault between the haptic–optic junction and the iris plane was 0.13 mm versus 0.20 mm for the Artisan pIOL. Recently, the manufacturer redesigned the Artiflex pIOL and increased the vault between the optic–haptic junction and the iris plane to 0.20 mm, with the goal of preventing accumulation of cell and pigment deposits on the pIOL.[27] The foldable Artiflex pIOL may offer an advantage over the PMMA Artisan pIOL in that it can be inserted through a 3.4 mm incision rather than the 6.3 mm incision required for implantation of the Artisan pIOL. The smaller incision provides quicker rehabilitation and induces less trauma and postoperative inflammation.

The purpose of this study was to evaluate changes in HOA after Artiflex pIOL implantation and to compare them with those in a matched group of patients who had Artisan pIOL implantation for the correction of a similar level of myopia.

PATIENTS AND METHODS

Study Design

The Artiflex patient group consisted of 27 eyes of 14 patients who had Artiflex pIOL implantation for the correction of myopia. The Artisan group consisted of 22 eyes of 13 patients who had Artisan pIOL implantation for the correction of myopia. Comparisons of preoperative and postoperative clinical data were performed for all eyes. Investigational review board approval was obtained from the Academic Hospital Maastricht.

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Inclusion criteria were identical in both pIOL groups as follows: stable refraction during the previous 2 years; preoperative best spectacle-corrected visual acuity 20/50 or better; anterior chamber depth (ACD) 3.0 mm or greater (IOLMaster, Carl Zeiss Meditec AG); endothelial cell density of 2000 cells/mm^2 or greater (Pachy SP-9000, Noncon Robo, Konan Medical); normal pupil and iris configuration; no history of glaucoma; no preexisting corneal, lenticular, or retinal pathology likely to alter vision; and no history of chronic or recurrent uveitis.

Clinical Evaluation

Preoperatively and postoperatively, subjective and objective refraction was determined by measurement of Snellen uncorrected visual acuity (UCVA) and best corrected visual acuity (BCVA). Slitlamp microscopy, corneal topography (EyeMap EH-290, Alcon), intraocular pressure (IOP) measurement with Goldmann applanation tonometry, and dilated fundus examinations were performed. All patients included in the study had a stable postoperative refraction and were examined preoperatively; 1 day, 1 week, and 1, 3 and 6 months postoperatively; and then at 6-month intervals.

Pupil Size and Intraocular Lens Decentration

The low mesopic (illumination level 0.4 lux) pupil size was measured with a digital infrared pupillometer (P2000 SA, Procyon Instruments Ltd.). This device has been described.[14,30] The amount of pIOL decentration was determined by measuring the deviation of the center of the pIOL from the center of the pupil using the digital photography mode within the pupillometer.

Wavefront Measurement

Wavefront measurements were performed with a Hartmann-Shack wavefront sensor (Zywave aberrometer, software version 3.21, Bausch & Lomb-Technolas) with pupil diameter of 6.0 mm. The aberrations analyzed in the comparative study were classified in terms of HOA; trefoil-x, Z(3,3); trefoil-y, Z(3,−3); coma-x, Z(3,1); vertical coma-y, Z(3,−1); and spherical aberration, Z(4,0). All values are in Optical Society of America order and sign convention. The Zywave aberrometer and technique of Zywave measurements have been described.[14,31–33]

Laboratory Higher-Order Aberration Analysis

To study the changes in HOA for each IOL type, a laboratory investigation was performed at the Center for Visual Science at the University of Rochester. For this purpose, 2 Artiflex and 2 Artisan myopic IOLs with a power of −9.0 D and 2 Artiflex and 2 Artisan myopic IOLs with a power of −12.0 D were mounted vertically in a wet cell and measured with a high-resolution Shack-Hartmann-type wavefront sensor developed at the Center for Visual Science at the University of Rochester to measure the aberration profile of the ophthalmic lenses. Collimated light (632.8 nm) was directed at the lens, and aberrations to the 10th order were collected. The spacing between the lenslets was 133.33 μm and the focal length, 3.75 mm. There were 745 wavefront sensing spots in a 6.0 mm pupil, which were sufficient to reliably calculate up to 10th-order Zernike aberrations. The HOAs were measured over a 6.0 mm pupil and were renormalized to 5.0

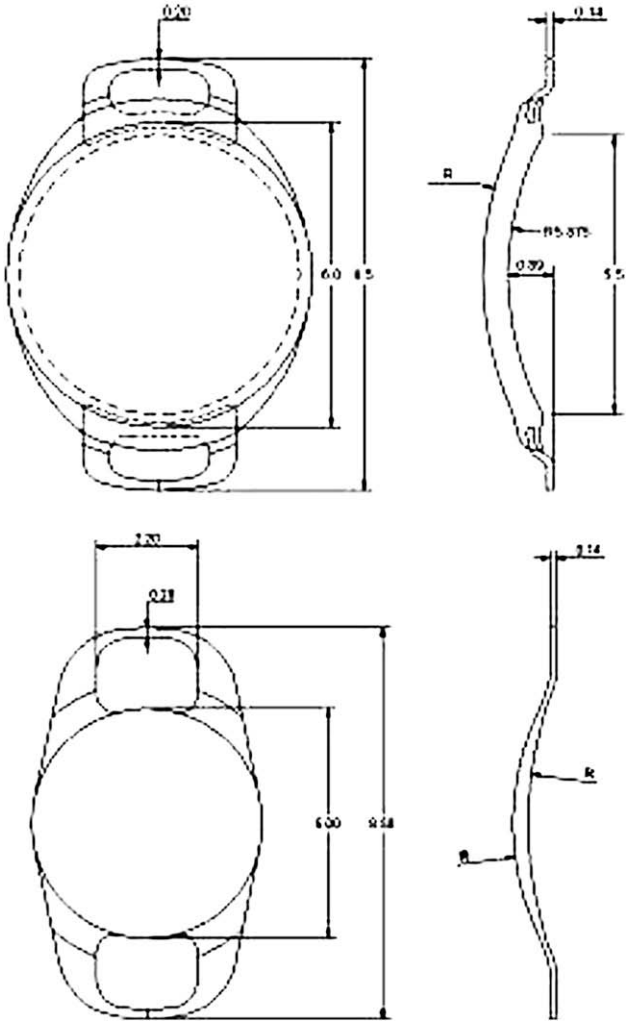

Figure 1. Schematic of Artiflex pIOL (*above*) and Artisan pIOL (*below*) design.

mm and 4.0 mm diameters (with decentrations up to 200 μm). Spherical aberration corresponds to Zernike mode 12; that is, Z(4,0).

Intraocular Lens Design and Power

Figure 1 shows the design of the Artisan and Artiflex pIOLs used in the study. The Artiflex had a vault between the haptic–optic junction and the iris plane of 0.13 mm and the Artisan, of 0.20 mm.

The dioptric power of the pIOL was calculated using the refractive error, refractive cylinder power, ACD, and topographically derived keratometric dioptric values (EyeMap EH-290); these values were inserted into the Van der Heijde formula.[17] The IOL power was chosen for emmetropia. When the emmetropic pIOL was not available, the power was estimated for slight residual myopia.

Surgical Technique

All operations were performed by the same surgeon (R.N.) at the Academic Center for Refractive Surgery, University Eye Clinic of Maastricht. Surgery was performed using general anesthesia. Differences between the Artiflex and Artisan surgical procedures included incision size (3.4 mm Artiflex; 6.3 mm Artisan) and wound closure with a single 10-0 nylon after the Artiflex pIOL implantation and with 5 interrupted 10-0 nylon after Artisan pIOL implantation. At the end of the Artiflex procedure, a 1.0 cc subconjunctival betamethasone (Celestone) injection was administered. The surgical technique for the enclavation of the pIOL and postoperative medication was basically the same as that used with standard Artisan pIOLs and has been described.[14,20–22]

Statistical Analysis

A parametric paired Student *t* test was used for statistical analysis and comparisons between preoperative and postoperative data; a *P* value less than 0.05 was considered significant. The absolute values were compared because a shift to more negative aberration values does not automatically indicate a reduction of the wavefront error if preoperative values are negative. To maintain an overall level of less than 0.01 for multiple tests, a Bonferroni correction was performed (SPSS for Windows, SPSS, Inc.). Increase factors were used to reflect the wavefront change in relation to the preoperative value (absolute values used). Snellen visual acuities were transformed to logMAR values for statistical comparison.

Wavefront analysis was performed for pupil diameters of 6.0 mm. Results in the wavefront examinations were transformed into absolute values for statistical analysis. Zernike coefficients up to the 4th order were included in the measurements. Calculations were performed using HOA, trefoil-x, trefoil-y, coma-x, coma-y, and spherical aberration.

Correlations between clinical parameters, such as visual acuity and refractive outcomes, were determined for data obtained at the 12-month follow-up examination and assessed with the Pearson *r* coefficient of correlation. Intergroup comparisons were by an independent-samples Student *t* test. All values are reported as mean ± SD.

RESULTS

Table 1 shows the patients' characteristics and preoperative data by group.

Clinical Outcomes

Table 2 shows the visual and refractive data in both groups. In the Artiflex group, the mean spherical equivalent (SE) was −9.95 ± 1.43 D (range −6.75 to −12.13 D) preoperatively and −0.23 ± 0.40 D (range −1.25 to 0.75 D) postoperatively. After 1 year, 85.7% of eyes were within ± 0.50 D of the desired refraction. The mean refractive cylinder was −0.77 ± 0.53 preoperatively, −0.57 ± 0.54 D 1 week postoperatively, −0.49 ± 0.49 D at 1 month, −0.54 ± 0.47 D at 3 months, and −0.51 ± 0.52 D at 1 year. The improvement in logMAR BCVA from preoperatively (range −0.08 to 0.15) to postoperatively (range −0.18 to 0.00) was statistically significant ($P = .001$). No eye lost Snellen lines of BCVA.

In the Artisan group, the mean preoperative SE was −9.90 ± 2.74 D (−4.0 to −14.50 D) preoperatively and

Table 1. Patient characteristics and preoperative data.

Variable	Artiflex Group	Artisan Group
Age (y)		
Mean ± SD	41.0 ± 7.8	40.0 ± 12.0
Range	26 to 51	18 to 52
Eyes (n)	27	22
Women (n)	8	9
ACD (mm)		
Mean ± SD	3.66 ± 0.33	3.71 ± 0.29
Range	3.20 to 4.72	3.00 to 4.00
IOP (mm Hg)		
Mean ± SD	14.77 ± 2.63	14.19 ± 3.04
Range	10.0 to 19.0	10.0 to 20.0
Implanted IOL power (D)		
Mean ± SD	−9.57 ± 1.11	−10.82 ± 2.69
Range	−8.00 to −12.50	−5.00 to −15.00
Low mesopic pupil size (mm)		
Mean ± SD	4.95 ± 1.11	3.84 ± 0.79
Range	3.34 to 6.69	2.64 to 5.32

ACD = anterior chamber depth; IOL = intraocular lens; IOP = intraocular pressure.

−0.21 ± 0.45 D (−1.0 to 0.75 D) postoperatively. After 1 year, 76.2% of eyes were within ±0.50 D of the desired refraction. The mean refractive cylinder was −1.14 ± 0.65 preoperatively, −2.35 ± 1.39 D 1 week preoperatively, −0.79 ± 0.76 D at 1 month, −0.63 ± 0.58 D at 3 months, and −0.48 ± 0.53 D at 1 year. The improvement in logMAR BCVA from preoperatively (range −0.10 to 0.22) to postoperatively (range −0.10 to 0.10) was statistically significant ($P = .003$). One eye (4.8%) lost 1 or more Snellen lines of BCVA.

There was a significant difference between the Artiflex group and the Artisan group in refractive cylinder at 1 week ($P = .001$). From 1 month on, there was no significant difference between the groups.

The mean postoperative IOP was 16.76 ± 3.36 mm Hg (range 10 to 24 mm Hg) in the Artiflex group and 15.5 ± 2.71 mm Hg (range 10 to 19 mm Hg) in the Artisan group. The difference was not statistically significant ($P = .23$).

Clinical Higher-Order Aberrations Changes

Table 3 and Figures 2 to 7 show the mean numerical changes and comparisons in HOA between preoperatively and postoperatively. In the Artiflex group, there was a statistically significant difference in trefoil-y (increase factor 1.73) and spherical aberration (increase factor 0.55). In the Artisan group, there was a statistically significant difference in HOA (increase factor 1.68), trefoil-y (increase factor 3.32), and spherical aberration (increase factor 6.84). The difference between the increase factors for spherical aberration was statistically significant ($P = .04$).

Laboratory Higher-Order Aberrations Evaluation

Laboratory analysis showed the Artiflex pIOL had a negative primary spherical aberration and the Artisan pIOL had a positive primary spherical aberration. Figure 8 shows an analysis overview of the spherical aberration profiles in the 2 groups. Spherical aberration changed negligibly with 100 µm and 200 µm decentrations with a 4.0 mm and 5.0 mm pupil diameter.

Pupil Size and Intraocular Lens Decentration

In the Artiflex group, the mean low mesopic pupil size was 4.95 ± 1.11 mm (range 3.34 to 6.69 mm). The mean amount of pIOL decentration was 0.24 ± 0.12 mm (range 0.06 to 0.54 mm). Decentration greater than 0.5 mm occurred in 1 eye (3.7%). There was a significant correlation between pIOL decentration and postoperative spherical aberration ($r = −0.42$, $P = .03$) and coma-y ($r = 0.44$, $P = .02$).

In the Artisan group, the mean low mesopic pupil size was 3.84 ± 0.79 mm (range 2.64 to 5.32 mm). The mean amount of pIOL decentration was 0.25 ± 0.12 mm (range 0.10 to 0.46 mm). No eye had

Table 2. Visual and refractive data.

	Artiflex Group (n = 27)		Artisan Group (n = 22)	
Variable	Preoperative	Postoperative	Preoperative	Postoperative
Mean sphere (D) ± SD	−9.57 ± 1.43	0.02 ± 0.46	−9.33 ± 2.72	0.02 ± 0.45
Mean cylinder (D) ± SD	−0.77 ± 0.53	−0.51 ± 0.52	−1.14 ± 0.65	−0.48 ± 0.53
Mean SE (D) ± SD	−9.95 ± 1.43	−0.23 ± 0.40	−9.90 ± 2.74	−0.21 ± 0.45
Mean logMAR BCVA	0.00 ± 0.07	−0.11 ± 0.07	0.05 ± 0.10	−0.01 ± 0.08
Snellen BCVA ≥20/20 (%)	—	100	—	77.0
Loss of ≥1 Snellen BCVA lines (%)	—	0	—	4.8

BCVA = best-corrected visual acuity; pIOL = phakic intraocular lens; SE = spherical equivalent.

Table 3. Higher-order aberration values.

	Artiflex Group (n = 27)					Artisan Group (n = 22)				
Type (μm)	Preop Mean*	Postop Mean*	Change†	Increase Factor	*P* Value‡	Preop Mean*	Postop Mean*	Change†	Increase Factor	*P* Value‡
HOA	0.57 ± 0.22	0.54 ± 0.17	−0.03	1.05	.085	0.60 ± 0.26	0.88 ± 0.48	0.28	1.68	.006§
Trefoil-x	0.02 ± 0.22	0.00 ± 0.28	0.04	3.81	.128	0.07 ± 0.29	−0.03 ± 0.26	−0.06	1.03	.042
Trefoil-y	−0.05 ± 0.15	−0.13 ± 0.19	0.04	1.73	.003§	−0.04 ± 0.20	0.09 ± 0.24	0.05	3.32	.004§
Coma-x	−0.10 ± 0.32	−0.04 ± 0.25	−0.06	1.55	.036	−0.12 ± 0.33	−0.16 ± 0.52	0.14	3.35	.129
Coma-y	0.03 ± 0.19	−0.01 ± 0.23	0.02	3.73	.055	0.01 ± 0.19	0.00 ± 0.31	0.11	5.11	.147
SA	0.29 ± 0.18	0.03 ± 0.16	−0.19	0.55	<.001§	0.19 ± 0.20	0.60 ± 0.34	0.38	6.84	<.001§

Means ± SD
HOA = total higher-order root aberrations value; SA = spherical aberration
*Signed values
†Between preoperative and postoperative absolute aberration values
‡Preoperative versus postoperative
§Statistically significant

decentration greater than 0.5 mm. No significant correlations with postoperative aberrations were found.

DISCUSSION

The aim of this study was to evaluate changes in total and individual HOA after Artiflex pIOL implantation for the correction of myopia and to compare results with those in a matched patient group after Artisan pIOL implantation.

It is well established that the PMMA Artisan pIOL, which was recently approved by the U.S. Food and Drug Administration, is a safe, effective, and predictable means for the surgical correction of moderate to high myopia.[14,22,24,29,34–36] The foldable Artiflex iris-fixated pIOL, on the other hand, is a relatively new development in the area of lenticular refractive surgery for the correction of myopia[25,28,29] and is currently being evaluated in a European multicenter study.

The Artiflex pIOL design is based on the Artisan pIOL design, with haptics comparable to those of the Artisan IOL for myopia. The Artiflex pIOL haptics are also PMMA, while the foldable optical zone is of silicone and has the advantage of allowing insertion through a smaller (3.4 mm) incision. The Artiflex pIOL theoretically represents an improvement in the iris-supported pIOL concept, leading to a lower level of surgically induced astigmatism.

Recently, a randomized paired-eye study[29] compared the Artiflex pIOL and the Artisan pIOL and

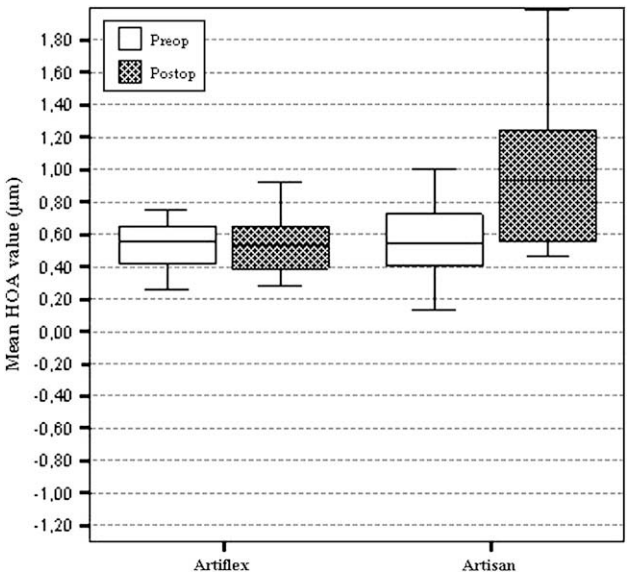

Figure 2. Changes in total HOAs before and after surgery.

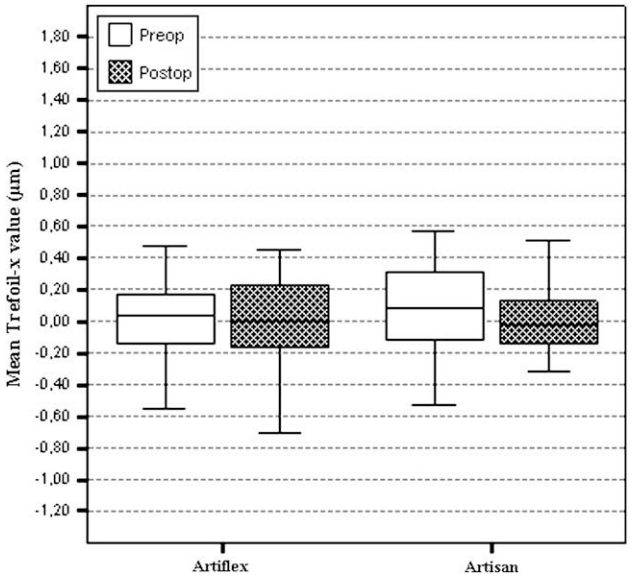

Figure 3. Changes in trefoil-x before and after surgery.

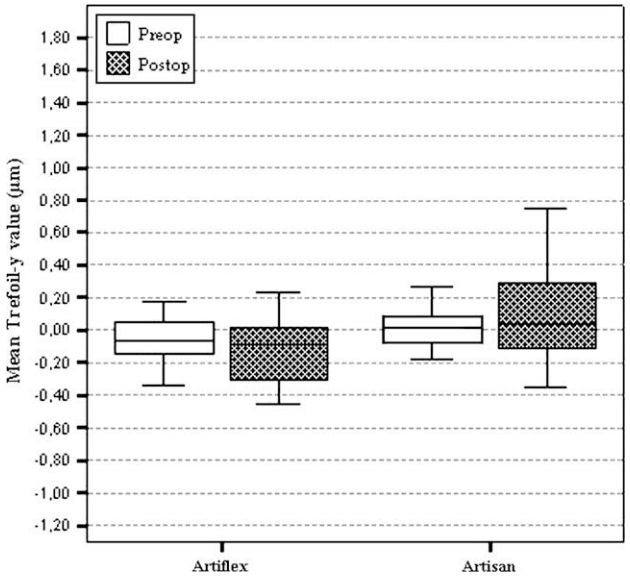

Figure 4. Changes in trefoil-y before and after surgery.

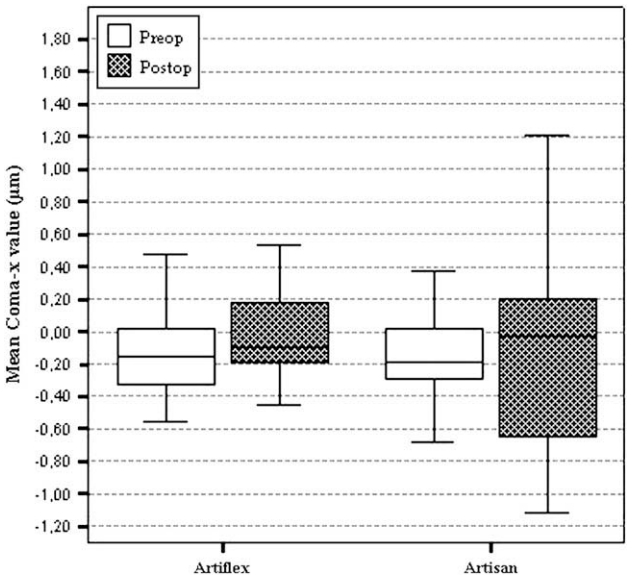

Figure 5. Changes in coma-x before and after surgery.

found that 1 year after surgery, the percentage of eyes with a UCVA of 20/40 or better was statistically significantly higher with the Artiflex pIOL. The efficacy index was also higher in the Artiflex group, and visual recovery was faster. In another study of the Artiflex pIOL,[28] there was no loss of Snellen BCVA 6 months after surgery; 91% of eyes were within ±0.50 D of the targeted refraction, and 82% attained a Snellen UCVA of 20/25 or better.

The evaluation of changes in HOA in the field of refractive surgery is not new. Several studies[4–6,37–40] have found that laser refractive surgery techniques such as PRK and LASIK can lead to a significant increase in postoperative total and individual HOAs. Other studies[3,41] evaluated the changes in HOA after pIOL implantation, in most cases after Artisan pIOL implantation in myopic eyes. One of the studies[41] found higher postoperative trefoil, which the authors attributed to the incision size, and higher postoperative spherical aberration, which they believed to be IOL related. A recent study[42] of changes in HOA after Artiflex IOL implantation found no significant tendency toward increasing HOA (eg, coma and spherical

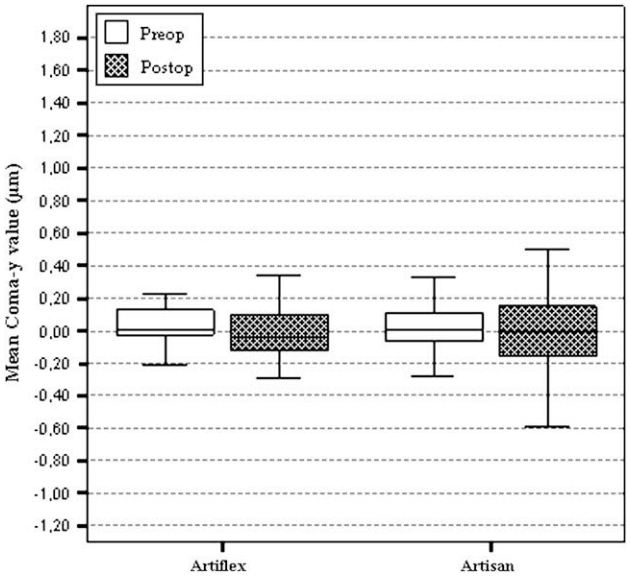

Figure 6. Changes in coma-y before and after surgery.

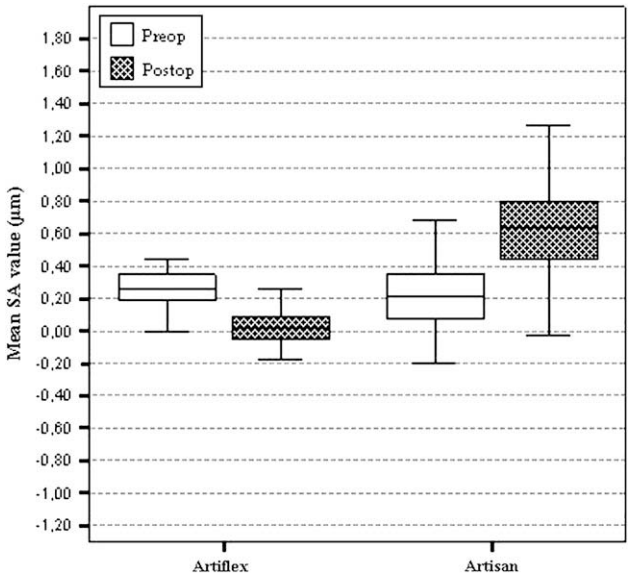

Figure 7. Changes in spherical aberration before and after surgery.

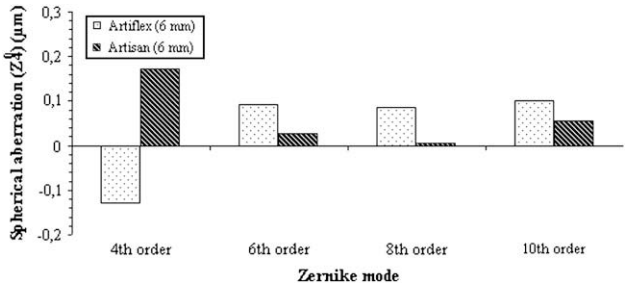

Figure 8. Laboratory HOA measurements over a 6.0 mm pupil.

aberration), which the authors attributed to preservation of corneal asphericity.

Evaluation of changes in aberration profiles showed that postoperative spherical aberration decreased significantly in the Artiflex group and increased significantly in the Artisan group. The reduction in spherical aberration in the Artiflex group may be attributed to the negative spherical aberration noted in bench testing of the Artiflex lens. The negative spherical aberration may help compensate for the positive spherical aberration in the normal preoperative population.[43] Thus, the total amount of positive spherical aberration may be reduced after Artiflex pIOL surgery. In contrast, there was a modest amount of positive spherical aberration in the Artisan group, which may have added to the positive spherical aberration present in the normal preoperative eye, thus increasing the amount of positive spherical aberration postoperatively. In addition, differences in spherical aberration profiles between the 2 pIOL groups may be the result of differences in incision size and wound healing. Differences in the spherical aberration profile between the Artiflex pIOL and the Artisan pIOL with a 6.0 mm pupil may be due to differences in IOL rim design (Figure 1). At present, the exact cause of spherical aberration and the relationship to IOL design are unknown and require further investigation.

In both pIOL groups in our study, trefoil-y increased significantly. This might have been the result of the smaller incision used in the Artiflex group. Previous studies of HOA changes in cataract surgery also suggest that trefoil changes may be related to the surgical procedure, for example, the incision size and position.[44] Further studies may help clarify the findings in our small cohort.

The refractive results at 1 year were similar in the Artiflex and Artisan groups. In both groups, the postoperative SE was close to zero, with approximately 80% of eyes within ± 0.50 D of the desired refraction. Refractive astigmatism was significantly different between groups only at the 1-week follow-up and was comparable thereafter, despite the different incision sizes. This agrees with results in a study by Coullet et al.,[29] who also found no significant difference in postoperative astigmatism between the Artiflex pIOL and the Artisan pIOL beyond 3 months postoperatively. The resulting decrease in corneal astigmatism in the Artisan group was attributed to the suture removal after this time point.

In conclusion, our study showed a decrease in spherical aberration after implantation of a foldable Artiflex pIOL in myopic eyes. This decrease may be related to the pIOL compensating for the positive spherical aberration preoperatively. We also found an increase in postoperative spherical aberration after rigid Artisan pIOL implantation. The aberration differences may also be related to other factors such as incision size and deserve further study.

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