Original Article

Wavefront aberration and contrast sensitivity after implantation of foldable and rigid iris claw phakic intraocular lenses: Artiflex versus artisan

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Aim of study: The aim of this study is to assess wavefront aberration and contrast sensitivity (CS) after implantation of foldable iris claw – artiflex- and rigid iris claw – artisan- phakic intraocular lenses (pIOLs). **Materials and Methods:** A nonrandomized prospective comparative case study was performed on 57 eyes; of which, 54 were myopia and 3 were hyperopia. Twenty-four patients had artisan pIOL implantation and 33 had artiflex pIOL implantation. Higher-order aberration (HOA) and CS were obtained 1 year after surgery. **Results:** Total HOA in artisan group was greater than artiflex group ($P = 0.044$) with a mean HOA of 0.44 ± 0.15 root mean square (RMS) for artisan and 0.35 ± 0.15 RMS for artiflex. Although, there were no significant differences in the vertical trefoil, vertical coma, horizontal trefoil, horizontal coma, secondary astigmatism, quatrefoil, and fourth order spherical aberration in two groups. CS in mesopic conditions was better in artiflex-treated eyes at three spatial frequencies of 6, 12, and 18 cycles per degree (cpd) ($P = 0.003$, $P = 0.007$, and $P = 0.00$, respectively), and no significant difference was seen between two lenses at 3 cpd. **Conclusion:** Although the components of HOA were not significantly different between two groups, total HOA was higher in artisan group, which may be due to the slight differences in each component, increasing the HOA as a total. CS was significantly better in artiflex group.

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For the past decades, laser corneal refractive surgeries have been used as effective and safe procedures to correct a wide range of refractive errors. However, at higher refractive errors, physical limitations of corneal thickness, curvature and tissue remodeling, have limited the use of corneal laser refractive surgeries. In patients with moderate to high-refractive errors in which corneal refractive surgeries are contraindicated, phakic intraocular lens (pIOL) implantation is a better option.[1,2] Previous studies have shown that pIOL methods are effective, safe, predictable, and potentially reversible methods, they also preserve accommodation and corneal shape.[3-7] Two iris claw-fixated lenses (rigid lens-artisan and foldable lens-artiflex) are worldwide accepted. Artisan pIOL, is an iris claw-fixated pIOL with a rigid convex-concave polymethyl methacrylate (PMMA) model with an optic of 6 mm (IOL power up to −15.50 diopter [D]) or 5 mm (IOL power −16.00 D to −24.00 D), with 0.50 D steps. Artisan is implanted through a 5.0–6.0 mm incision. The more recent designed iris-fixated pIOL, artiflex, with a flexible 6.0 mm (IOL power from −2.00 D to −14.5 D), poly-silicone optic and PMMA haptics, potentially affording a lower incidence of surgically induced astigmatism (SIA), can be implanted through a 3.2 mm incision.[8,9]

Higher order aberration (HOA) and contrast sensitivity (CS) influence postoperative visual outcome and patient satisfaction. The aim of this investigation is to compare HOA, CS, and patient satisfaction after implantation of artisan pIOL and artiflex pIOL.

Materials and Methods

Patient selection and examination

This is a nonrandomized prospective comparative case study on 57 eyes seeking refractive surgery who were not indicated for laser corneal refractive surgery. Patients with refraction error between −2.00 D and −14.50 D who could use both artiflex and artisan, were free to choose the type of the lens. Other patients underwent artisan implantation.

Ophthalmic examinations before surgery included cyclo-refraction, uncorrected visual acuity (UCVA), best-corrected visual acuity (BCVA), topography, keratometry, endothelial cell count, pupil diameter, and anterior chamber (AC) depth measurement.

According to patient history and examination, patients who had the following conditions underwent pIOL implantation surgery: Insufficient corneal thickness for refractive corneal surgery, inappropriate corneal curvature and topography, high myopia more than 8 D which could not undergo corneal

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refractive surgery, Negative history of any previous refractive surgery, sufficient internal AC depth (3 mm or greater), no history of intraocular pressure raise and endothelial cell density of 2500 cell/mm^2 or more.

Surgical technique

Lens dioptric power was calculated by van der Heijde formula,[10] using refractive error, refractive cylinder power, AC depth, and topographically derived keratometry values. Emmetropia was the target power of the surgery, when the precise emmetropic lens was not available our choice was to a slight residual myopia.

All surgeries were performed under general anesthesia, for artisan lens implantation, a superior 5 or 6 mm length corneal incision was created at the 12 o'clock position, followed by performing two stab incisions located at 2 and 10 o'clock. The lens was inserted into the AC under protection of intracameral ophthalmic viscoelastic material injection. The lens was enclavated at the appropriate position. An iridectomy was made surgically at 12 o'clock. The Viscoelastic material was changed with balanced salt solution. Finally, the incision was closed with three 10-0 nylon sutures. Artiflex lens implantation was performed similarly, although the lens was inserted through a 3.2 mm incision. Other steps were carried out same as artisan implantation; finally, the wound was closed by stromal hydration without the necessity of suturing. All surgeries were performed by a single surgeon.

Outcome measures

One year after surgery, cyclo-refraction, BCVA, UCVA, CS, HOA and patient satisfaction were assessed. Wavefront aberration measurement was performed with Orbtek (2 years wave). CS was determined by CSV-1000 chart, and refraction was obtained with Topcon Auto Refractometer and then modified by subjective refraction. UCVA and BCVA were measured with Snellen chart. Night vision, day vision, halo, photophobia, dryness, pain, and patient satisfaction were assessed by questionnaire with numerical scales (0 = weak, 1 = moderate, 2 = good, 3 = excellent for day and night vision 0 = none, 1 = mild, 2 = moderate, 3 = severe for halo, photophobia, dryness, and pain). CS function was measured using a CSV-1000E chart (VectorVision) during mesopic condition. The chart consists of four rows corresponding to spatial frequencies of 3, 6, 12, and 18 cycles per degree (cpd). The distance between the patient and the chart was 2.5 m. The test was performed with the patients monocular BCVA to eliminate the effects of SIA and residual post-operative refraction.

Wavefront measurement was performed by Orbtek (2 years wave). The aberrations analyzed were classified in terms of HOA, vertical trefoil, vertical coma; horizontal trefoil, horizontal coma, quatrefoil, second astigmatism, and fourth order spherical aberration.

Statistical analysis

Comparison between artisan and artiflex data were analyzed using parametric paired Student's *t*-test, $P < 0.05$ was considered statistically significant.

Results

A total of 57 eyes were included in the study; of which, 24 eyes were in artisan group and 33 eyes were in artiflex group. The preoperative spherical equivalent (SE) and BCVA were obtained and compared, no statistically significant difference was noticed in the mean preoperative SE (−10.39 ± 8.43 D in artisan group and − 10.39 ± 2.29 D in artiflex group; $P = 0.999$) and BCVA of two groups (0.25 ± 0.21 logarithm of the minimum angle of resolution [LogMAR] for artisan group and 0.19 ± 0.18 LogMAR for artiflex group; $P = 0.56$). The mean postoperative SE was − 0.93 ± 1.28 D in the artisan group and − 0.54 ± 0.82 in the artiflex group, no significant difference was seen in in postoperative SE between two groups ($P = 0.19$).

One year after the operation, 54% of artisan-treated eyes (15/24) and 75.7% (25/33) of artiflex treated eyes were within ± 1.00 D of intended emmetropia [Figs. 1 and 2]. In the artisan group, 37.5% of the treated eyes (9/24 eyes) had three or more snellen line improvement of postoperative BCVA, 12.5% (3/24 eyes) had two snellen line improvement and 25% (6/24 eyes) had loss of two or more snellen lines. In the artiflex group, 51.5% of the treated eyes (17/33 eyes) had three or more snellen line improvement of BCVA, 15.1% (5/33 eyes) had two line improvement, and no eyes had loss of two or more snellen lines of BCVA [Fig. 3].

In this study, total HOA in artisan-treated eyes was significantly greater than artiflex-treated eyes ($P = 0.044$) with a mean HOA of 0.44 ± 0.15 root mean square (RMS) for artisan and 0.35 ± 0.15 RMS for artiflex. There was no significant difference in the vertical trefoil, vertical coma, horizontal trefoil, horizontal coma, quatrefoil, second astigmatism, and fourth order spherical aberration.

The evaluation of CS in mesopic conditions showed higher CS in artiflex-treated eyes at three spatial frequencies 6, 12, and 18 cpd ($P = 0.003$, $P = 0.007$, and $P = 0.00$, respectively), and no

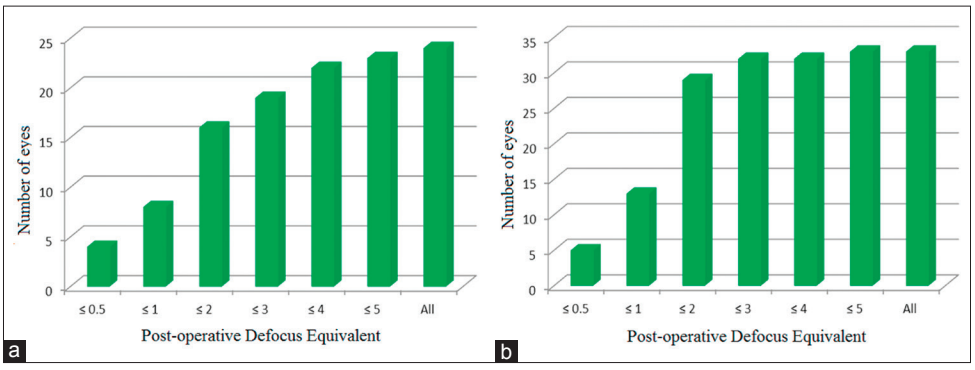

Figure 1: The bar graph shows the postoperative defocus equivalent 1 year after artisan (a) and artiflex (b) implantation

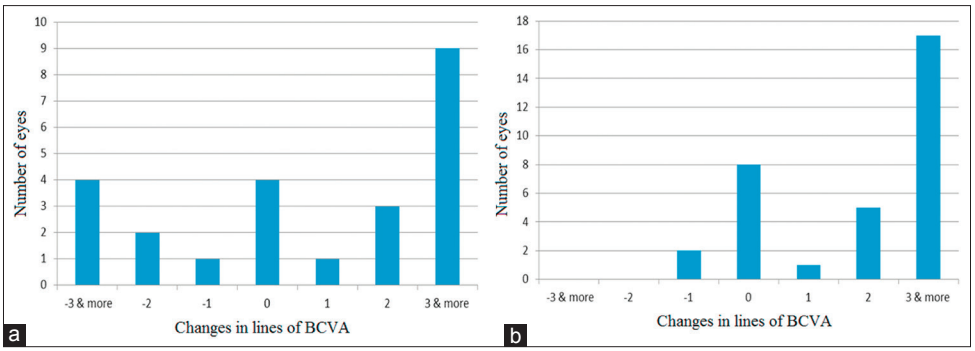

Figure 2: Bar graph of change in best-corrected visual acuity from the preoperative examination to postoperative examination in terms of the number of Snellen line change. Artisan (a), artiflex (b)

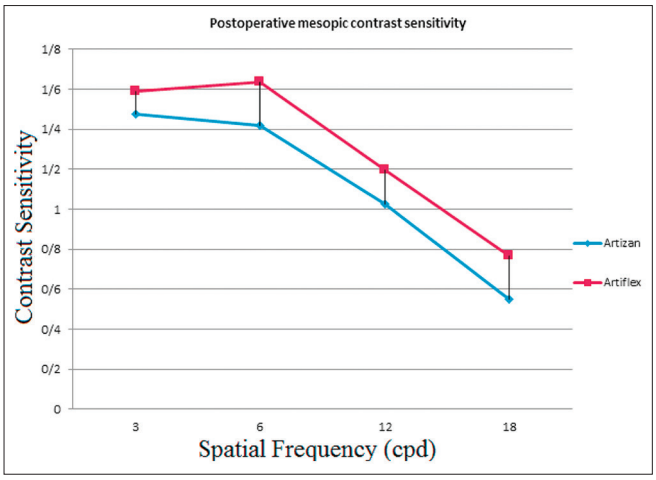

Figure 3: Mesopic contrast sensitivity at spatial frequencies of 3, 6, 12 and 18 degree per cycles

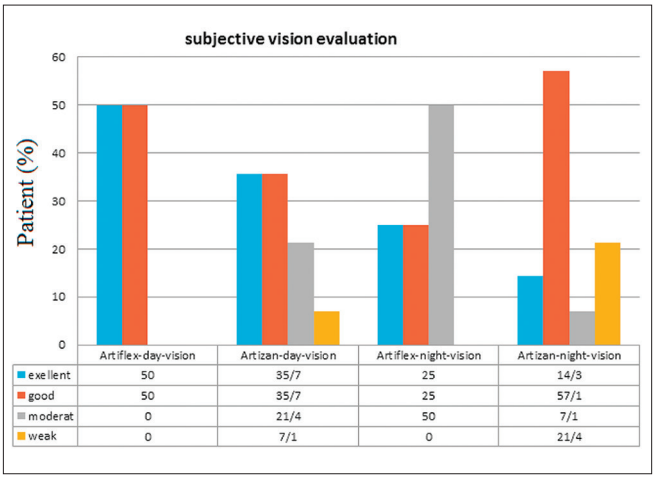

Figure 4: Subjective comparison of day and night vision in artisan versus artiflex treated eyes

significant difference was seen between two lenses at 3 cpd spatial frequency [Table 1 and Fig. 4].

The mean of SIA was 1.65 ± 0.82 D in artisan group, and 1.31 ± 1.05 in artiflex group, which showed no statistically significant difference between the groups (P = 0.19). In a subjective evaluation of day vision, all patients of the artiflex group reported good and excellent vision, in artisan group, 71% of patients reported good and excellent vision, whereas 7.1% complained of weak day vision. In the assessment of night vision, 50% of patients treated with artiflex reported good and excellent vision and no one complained of weak night vision. In artisan group, 71.4% reported good and excellent vision, whereas 21.4% reported weak night vision [Fig. 5].

Table 1: Contrast sensitivity data after phakic intra-ocular lens implantation

Spatial frequency (cycles per degree)	Artisan	Artiflex	*P**
3	1.47±0.25	1.58±0.23	0.106
6	1.41±0.20	1.63±0.27	0.003
12	1.02±0.16	1.19±0.27	0.007
18	0.55±0.14	0.76±0.27	0.00

*Determined with *t*-test

Among artiflex treated eyes, 50% reported moderate halos and in the artisan group 40% reported moderate to severe halos. About 12.5% of artiflex treated eyes experienced moderate photophobia, whereas 35.7% of artisan treated eyes experienced moderate to severe photophobia. In the artiflex group, only 12.5% of treated eyes caused mild pain, whereas 36.7% of artisan treated eyes caused mild to moderate pain. Moderate to severe dryness was reported in 25% of eyes treated with artiflex, whereas no artisan treated eye experienced moderate or severe dryness [Fig. 6].

Satisfaction more than 60% was reported in 100% of patients in artiflex group versus 60% of patients in artisan group [Fig. 7].

Discussion

As it is well-confirmed, the recently Food and Drug Administration approved PMMA artisan pIOL is an effective mean for the correction of refractive errors and have been shown to have acceptable safety and efficacy. However, studies have revealed instances of significant induced astigmatism, attributed to the larger incisions performed in the implantation of the artisan lens.[8,11-13] Artiflex iris-fixated pIOl, a foldable version of artisan, is an improvement of the iris-supported pIOL concept, with a lower incidence of SIA. Artiflex pIOl haptics are made of PMMA and the foldable optical zone is made of silicon. The artiflex pIOL has the advantage.[8,12]

The main purpose of this investigation is to evaluate the differences in optic quality between rigid pIOL versus flexible pIOL by comparing wavefront aberration, CS and patient satisfaction in patients who underwent artisan and artiflex iris-fixated IOL implantation.

In this study, mean postoperative residual SE were −0.93 ± 1.28 D and − 0.54 ± 0.82 D in the artisan and artiflex group, respectively, no significant difference was seen in postoperative SE between two groups ($P = 0.19$). About 54% of artisan group and 75.7% of artiflex group were within ± 1.00 D of intended emmetropia. In a previous study, 58% and 83.9% of artisan and artiflex group had a residual postoperative SE within ± 1.00 D, which was significantly better in artiflex group.[12] Another study reported that emmetropia (±1.00 D) was obtained in 60% and 91.7% of artisan and artiflex group, respectively, the difference was statistically significant [Table 2].[14]

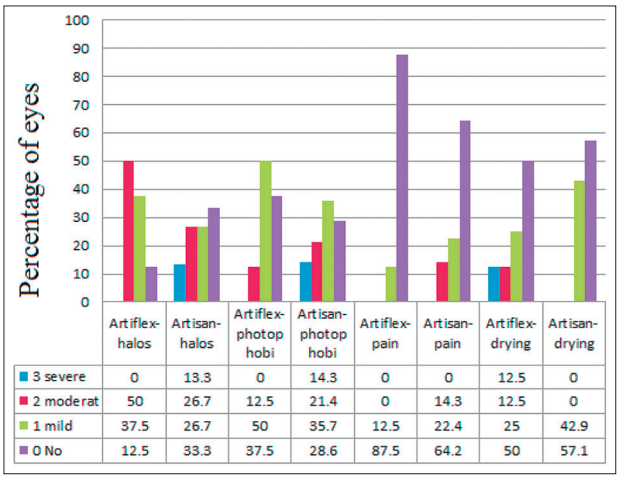

Figure 5: Subjective comparison of halo, photophobia, pain and dryness in artisan versus artiflex treated eyes

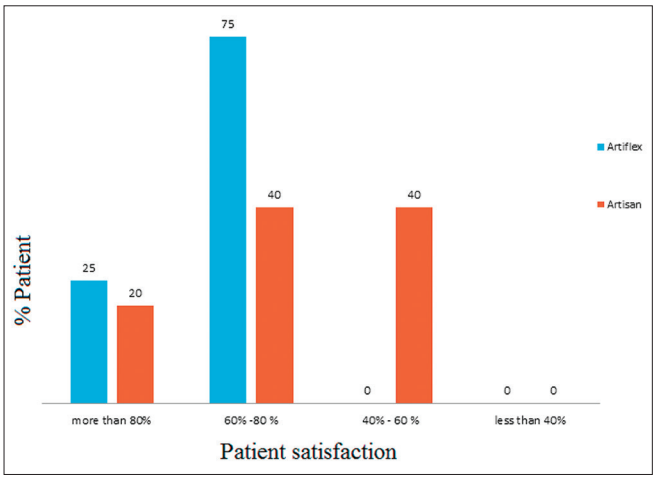

Figure 6: The bar graph of patient's satisfaction in artisan versus artiflex groups

In a retrospective comparative case series on 27 eyes, postoperative SE was within ± 0.5 D in 76.2% and 85.7% of artisan and artiflex treated eyes, respectively.[8] In a study of evaluating the outcome of iris-claw pIOL in fifty high myopic eyes, postoperative SE was evaluated, which showed that 38% and 68% of the eyes were in the range of ± 0.5 D and ± 1.00 D, respectively.[15]

Mean postoperative UCVA was 0.34 ± 0.25 LogMAR in artisan group and 0.12 ± 0.15 LogMAR in artiflex group. Mean postoperative BCVA was 0.21 ± 0.13 and 0.06 ± 0.08 LogMAR in the artisan and artiflex groups, respectively [Table 3]. The differences of UCVA and BCVA in two groups were statistically significant ($P = 0.00$). In another study, postoperative BCVA between artisan and artiflex groups was not significantly different ($P = 0.9$).[16]

In this study, although vertical trefoil, vertical coma, horizontal trefoil, horizontal coma, secondary astigmatism, quatrefoil and fourth order spherical aberration were not significantly different between the artiflex and artisan groups, Total HOA was higher in artisan group, that may be due to the

Table 2: Percentage of postoperative refraction within±1.00 D of intended emmetropia

	Artisan (%)	Artiflex (%)	*P*
This study	54	75.7	
Coullet *et al*.	58	83.9	0.015
Karimian *et al*.	60	91.7	0.017

D: Diopter

Table 3: Postoperative visual acuity (logarithm of the minimum angle of resolution) in artisan group versus artiflex group

	Log MAR	
	Postoperative UCVA	Postoperative BCVA
Artisan	0.34±0.25	0.21±0.13
Artiflex	0.12±0.15	0.06±0.08

LogMAR: Logarithm of the minimum angle of resolution

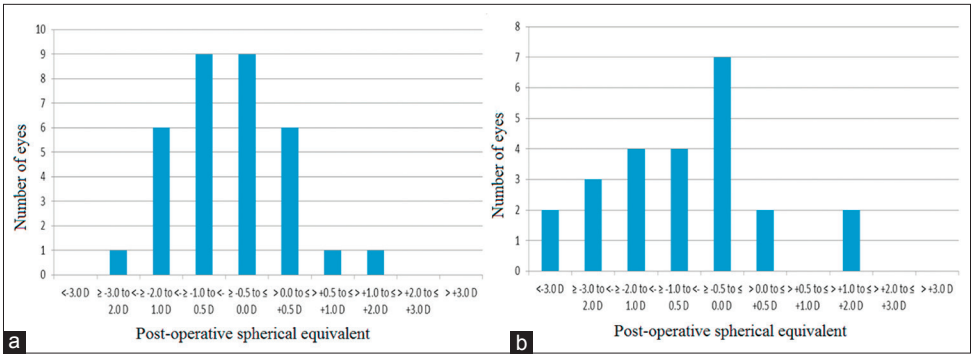

Figure 7: The bar graph presents the postoperative spherical equivalent 1 year after artisan (a) and artiflex (b) implantation. D: Diopter

slight differences in each component, which totally increases the HOA ($P = 0.044$). In a previous study, assessment of HOAs after implantation of rigid versus foldable iris-fixated lenses, showed a significant decrease in postoperative spherical aberration among artiflex group and a significant increase in postoperative spherical aberration in artisan group. In both groups, trefoil-y increased significantly.[8] In another study, vertical trefoil and spherical aberration were higher in artisan group, $P = 0.039$ and $P = 0.001$, respectively.[14]

Assessment of CS in mesopic condition showed no significant difference between two groups at 3 cpd spatial frequency. CS was significantly higher in artiflex-treated eyes at three spatial frequencies 6, 12 and 18 cpd ($P = 0.003$, $P = 0.007$, and $P = 0.00$, respectively). A previous investigation showed that mesopic CS was slightly better in artiflex group in comparison with artisan group, but the difference was not statistically significant, they also measured photopic CS function and found that both groups had poorer performance compared to the normal range. The performance was slightly better under mesopic condition. Performance with the artisan lens was slightly better than performance with artiflex under photopic conditions, but worse under mesopic conditions; neither differences were statistically significant.[16]

In this study, we have used artisan IOL for patients not eligible for the available artiflex (six myopic eye more than −14.5 D and one hyperopic eye), comparison of this two groups may have some biases because of other probable conditions such as retinal involvement or amblyopia, which can alter the results, this was one of our study limitations.

In this study, 25% of patients with artisan lens lost two or more lines of BCVA, we called the patients back and examined them again carefully, we recognized that in one patient both eyes had refractive error postoperatively in spite of implanting a lens with the same power of his preoperative SE improvement in BCVA was not seen with correction of this refractive error by trial-frame. In the other patients, we could not find any reason for the decrease in the BCVA, unless considering pigment deposition on the IOL as a reason for the visual loss.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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