Comparison of Toric Implantable Collamer Lens and Toric Artiflex Phakic IOLs in Terms of Visual Outcome: a Paired Contralateral Eye Study

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• PURPOSE: **This study sought to compare the postoperative visual outcomes of toric implantable collamer lens (T-ICL) with toric Artiflex (T-Artiflex) lenses.**

• DESIGN: **Alternating treatment, contralateral eye matched clinical study.**

• METHODS: **This study compared 82 eyes of 41 patients with T-ICL lenses in one eye and toric Artiflex implantation in the contralateral eye to correct myopic astigmatism. Safety, efficacy, predictability, astigmatic vector changes, contrast sensitivity, endothelial cell count, and possible adverse events were assessed at least 12 months postoperatively.**

• RESULTS: **After a mean follow-up of 12 months, the safety index was mean 1.40 ± 0.70 in the T-ICL group and 1.20 ± 0.21 in the T-Artiflex group. Furthermore, their mean efficacy indexes were 1.24 ± 0.42 and 1.08 ± 0.23, respectively ($P = .029$). A total of 39 eyes (95%) in the T-ICL group and 41 eyes (100%) in the T-Artiflex group were within ±1.00 diopter (D) of emmetropia and 33 eyes (80%) and 34 eyes (83%) were within ±0.5 D of emmetropia, respectively. Vector analysis revealed mean index of success as large as 0.25 ± 0.22 in the T-ICL group and 0.24 ± 0.15 in the T-Artiflex group. Postoperative contrast sensitivities were equal in both groups under mesopic conditions for any given spatial frequency. There was an endothelial loss of 2.18% and 1.95% in the T-ICL and T-Artiflex groups, respectively. There were no significant complications in any of the groups.**

• CONCLUSIONS: **Both lenses showed promising results in terms of safety, efficacy, and predictability for correction of myopic astigmatism. As shown in this paired-eye study, most outcomes were almost identical, and neither of these lenses were clinically superior to the other. (Am J Ophthalmol 2020;219:186–194. © 2020 Elsevier Inc. All rights reserved.)**

PHAKIC INTRAOCULAR LENSES (PIOL) HAVE BEEN widely used in patients with higher degrees of refractive errors due to greater safety and better visual outcomes in this group of patients.[1,2] Preserving corneal shape and integrity, saving accommodation, fast visual recovery, reversibility, and a wide range of correction, including spherical and cylindrical error correction, are other advantages of this modality.[3,4] There are 2 main types of these lenses which have been approved and widely used: the iris fixation anterior chamber lenses and the sulcus-supported posterior chamber lenses. Posterior chamber pIOLs are easy to implant and align in the intended meridian and have a wider range of correction and excellent biocompatibility. They are size-dependent and need meticulous measurement to avoid over- or undersizing. On the other hand, flexible iris fixation pIOLs have no sizing issue, but they are more difficult to fixate and align, have a lower range of correction, and may induce inflammatory response in some cases. There are few studies comparing these 2 types of lenses. The present contralateral eye study was designed to compare the safety, efficacy, and predictability of these 2 commonly used lenses, the toric Artiflex (T-Artiflex) (Ophtech BV, Groningen, the Netherlands) and the toric implantable collamer lens (T-ICL; STAAR Surgical, Monrovia, California) lenses. The T-Artiflex is an iris-fixating 3-piece foldable lens with 6-mm hydrophobic polysiloxane optic. The optic is forward-vaulted with a polynomial edge design, and the claw material is made of polymethylmethacrylate. The available dioptric power ranges from −1 to −13.5 D with added cylinder form −1 to −5 D.[5,6] The T-ICL is composed of collagen and hydroxyethyl methacrylate copolymer with an ultraviolet light-absorbing chromophore. To be invisible to the immune system, its surface is covered with fibronectin monolayer. The T-ICL version 4 (V4) is a plate haptic single-piece pIOL, with several types for the treatment of myopia, hyperopia, and astigmatism. It is designed to correct myopia from −3.00 to −23 D and added positive cylinder from +1 to +6 D in T-ICL models.[5,7] To the best of the present authors' knowledge, this is the only contralateral eye study comparing the outcomes of these 2 commonly used pIOLs.

METHODS AND MATERIALS

• PATIENTS: In this observational study, 41 patients (15 males and 26 females) with moderate to high myopia and astigmatism who were scheduled for refractive surgery in the Parsian eye clinic (Esfahan, Iran) between April 2017

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and October 2017 were recruited. The study was conducted in accordance with Good Clinical Practice guidelines and adhered to the tenets of the Declaration of Helsinki. Institutional Review Board/Ethics Committee approval was obtained. All patients provided written informed consent before participation in the study. Records of enrolled patients including a detailed medical history and complete ophthalmologic examination, manifest and cycloplegic refraction, measurement of uncorrected distance visual acuity (UDVA) and corrected distance VA (CDVA), slit lamp examination, dilated fundus examination, and applanation tonometry were also collected. An OrbScan version 3.14 (Bausch & Lomb, Rochester, New York) examination was performed to evaluate the white-to-white distance. Sulcus-to-sulcus diameter was measured by using an automated ultrasonography biomicroscope (Compact Touch sulcus-to-sulcus ultrasound biomicrscopy; Quantel Medical, Cedex, France). Keratometric values and anterior chamber depths (from corneal endothelium) were calculated using Pentacam HR system (Oculus, Optikgerate GmbH, Wetzlar, Germany). Finally, corneal endothelial cell counts were measured for all patients using Tomey EM 3000 specular microscopy (Tomey Corporation, Nagoya, Japan).

Patients were included in the study if they were older than 18 years old with stable refraction. All participants had myopia greater than 4 D. They did not have any systemic or ophthalmic disease and were not pregnant or in the course of breast feeding. Anterior chamber depth had to be 3 mm or greater from the endothelium side, and endothelial cell density had to be more than 2,000 cells/mm^2. Corneal thickness-adjusted IOP greater than 20 was considered an exclusion criterion. Those patients with any form of keratoconus or mesopic pupil size larger than 6 mm were excluded from the study.

• **LENS SIZE AND POWER:** The appropriate size and power of T-ICL for each patient was determined online through calculation and ordering system (http://ocos.staarag.ch) for intended target refraction of plano.

To determine the appropriate power of T-Artiflex lenses, each patient's data, including subjective refraction, K values, and anterior chamber depth (from endothelial side) for intended target refraction of plano, were sent to the manufacturer using a lens power calculation request form for Artiflex and Artisan refractive lenses.

• **SURGERY:** All surgical operations were performed by a single surgeon. According to the operation record, before the surgery, 90- and 180-degree meridians were marked with the patient in an a sitting position using a slit lamp beam. Topical anesthesia was used in all patients. During the operation, the proper corneal meridian for toric lens alignment was determined by means of a Mendez gauge and a corneal marker. All Artiflex lenses were inserted through 3.2-mm superior limbal incisions, and all ICLs were inserted through 3.2 mm temporal incisions and then aligned to the appropriate position. Surgical peripheral iridotomy was performed in all eyes undergoing surgery with[1–48] Artiflex. Hydroxypropyl methylcellulose solution 2% (OcuCoat; Bausch & Lomb) was used during lens implantation. After irregation of viscoelastic substance, wounds were hydrated without suturing. Each patient received toric ICL in 1 eye and a toric Artiflex in the fellow eye in 2 separate operation sessions 1 week apart. The toric ICL implantation was considered for the first eye in all patients. Right and left eyes of the patients for the first operation were chosen one after another in the order of patient enlistment. T-Artiflex lenses were implanted in the fellow eye within an interval of 1 week.

• **FOLLOW-UP:** Participants were followed 1 day, 1 week, 1 month, and at least 12 months postoperatively. They received ciprofloxacin HCL 0.3% eye drops every 6 hours and betamethasone 0.1% eye drops every 3 hours for 1 week postoperatively. Betamethasone therapy continued 3 times a day for 2 additional weeks. At every visit, patients underwent slit lamp examination, tonometry, UDVA and CDVA measurement, and manifest refraction. The refractions obtained and the lens positions were assessed for possible lens rotation or misalignment. At the end of the follow-up, contrast sensitivity was measured under mesopic conditions by using the normalized version of the CSV-1000E chart (VectorVision, Dayton, Ohio). Furthermore, endothelial cell count and cyclorefraction were repeated at the last visit, with the cyclorefraction used for astigmatic vector analysis.

• **STATISTICS:** All data were collected using Excel version 2016 software (Microsoft Office, Redmond, Washington) and analyzed by using SPSS version 19.0 (SPSS Inc., Chicago, Illinois) for Windows (Microsoft). The Kolmogorov-Smirnov test was used to test the normality of variables. The independent samples *t*-test was used to analyze VA and astigmatism parameters between the 2 groups, whereas the paired samples *t*-test was used to compare preoperative and postoperative parameters in each group. The Mann-Whitney *U* test was used to compare 2 groups when data were not normally distributed. The regression equation and Pearson correlation coefficient were used to obtain relationships in predictability curves. Eventually, power vector analysis of astigmatic change (using the Alpins method) was used.[8] Defocus equivalent (DEQ) was calculated for each patient as DEQ = [spherical equivalent] + [cylinder/2]. A *P* value less than .05 was considered statistically significant.

RESULTS

• **VISUAL ACUITY:** A total of 41 patients (15 male and 26 female) were enrolled in the study. They were 18 to 48

TABLE 1. Preoperative and Postoperative Visual Parameters in 2 Groups

Preoperative	Mean ± SD T-ICL (Range)	Mean ± SD T-Artiflex (Range)	*P* Value
Mean LogMAR UDVA	1.96 ± 0.23 (0.5-2)	1.97 ± 0.3 (0.7-3)	.327
Mean LogMAR CDVA	0.13 ± 0.19 (0-1)	0.1 ± 0.1 (0-0.4)	.177
Spherical equivalent, D	−9.85 ± 2.92 (−20.62 to −4.87)	−9.44 ±2.16 (−14 to −5.62)	.328
Sphere, D	−8.28 ± 2.78 (−19 to −4)	−8.12 ± 2.23 (−12.75 to −4.5)	.449
Cylinder, D	−3.17 ± 2.57 (−7.5 to −1)	−2.65 ± 0.97 (−4.75 to −1.25)	.479
Postoperative	T-ICL	T-Artiflex	*P* Value
Mean LogMAR UDVA	0.05 ± 0.11 (−0.08 to 0.52)	0.07 ± 0.1 (−0.1 to 0.3)	.438
Mean LogMAR CDVA	0.01 ± 0.09 (−0.08 to 0.3)	0.02 ± 0.09 (−0.1 to 0.3)	.611
Spherical equivalent, D	−0.33 ± 0.45 (−2.12 to 0.75)	−0.29 ± 0.39 (−1 to 1)	.591
Sphere, D	0.04 ± 0.4 (−1.25 to 1.25)	0.02 ± 0.4 (−0.7 to 1.5)	.890
Cylinder, D	−0.62 ± 0.5 (−2.5 to 0)	−0.62 ± 0.5 (−2.75 to 0)	.589
CS 3 cpd, logarithmic scale	1.81 ± 0.09	1.81 ± 0.13	1.000
CS 6 cpd, logarithmic scale	1.98 ± 0.08	1.95 ± 0.1	.482
CS 12 cpd, logarithmic scale	1.5 ± 0.2	1.47 ± 0.2	.756
CS 18 cpd, logarithmic scale	1.02 ± 0.19	1.02 ± 0.28	.959

CDVA = corrected distance visual acuity; cpd = cycle per degree; CS = contrast sensitivity; D = diopter; LogMAR = logarithm of minimal angle of resolution; T-Artiflex = toric Artiflex; T-ICL = toric implantable collamer lens; UDVA = uncorrected distance visual acuity.

TABLE 2. Preoperative versus Postoperative Visual Parameters in 2 Groups

Parameter	Mean ± SD Preoperative (Range)	Mean ± SD Postoperative (Range)	*P* Value
LogMar UDVA in T-ICL group	1.96 ± 0.23 (0.5-2)	0.05 ± 0.11 (−0.08 to 0.52)	<.001
Logmar CDVA in T-ICL group	0.13 ± 0.19 (0-1)	0.01 ± 0.09 (−0.08 to 0.3)	<.001
Spherical equivalent in T-ICL group, D	−9.85 ± 2.92 (−20.62 to −4.87)	−0.33 ± 0.45 (−2.12 to 0.75)	<.001
Sphere in T-ICL group, D	−8.28 ± 2.78 (−19 to −4)	0.04 ± 0.4 (−1.25 to 1.25)	<.001
Cylinder in T-ICL group, D	−3.17 ± 2.57 (−17.5 to −1)	−0.62 ± 0.5 (−2.5 to 0)	<.001
LogMAR UDVA in T-Artiflex group	1.97 ± 0.3 (0.7-3)	0.07 ± 0.1 (−0.1 to 0.3)	<.001
LogMAR CDVA in T-Artiflex group	0.1 ± 0.1 (0-0.4)	0.02 ± 0.09 (−0.1 to 0.3)	<.001
Spherical equivalent in T-Artiflex group, D	−9.44 ±2.16 (−14 to −5.62)	−0.29 ± 0.39 (−1 to 1)	<.001
Sphere in T-Artiflex group, D	−8.12 ± 2.23 (−12.75 to −4.5)	0.02 ± 0.4 (−0.75 to 1.5)	<.001
Cylinder in T-Artiflex group, D	−2.65 ± 0.97 (−4.75 to −1.25)	−0.62 ± 0.5 (−2.75 to 0)	<.001

CDVA = corrected distance visual acuity; D = diopter; LogMAR = logarithm of minimal angle of resolution; T-Artiflex = toric Artiflex; T-ICL = toric implantable collamer lens; UDVA = uncorrected distance visual acuity.

years old (mean 26.58 ± 5.32 years old). As described above, each patient's eye was preoperatively categorized as either T-ICL or T-Artiflex. There were no significant differences between the 2 groups in terms of mean UDVA, CDVA, sphere, cylinder and spherical equivalent of the subjective manifest refraction (Table 1).

As anticipated, both lenses resulted in a significant improvement in visual as well as refractive outcomes (Table 2). However, the differences between the groups in visual and refractive outcomes were not significant postoperatively (Table 1).

• **EFFICACY, PREDICTABILITY, AND SAFETY:** The mean postoperative UDVA in the T-ICL and T-Artiflex groups was 0.05 ± 0.11 and 0.07 ± 0.1 logMAR, respectively ($P = .438$). Postoperative UDVA was 20/20 or better in 54% (n = 22) and 34% (n = 14) of T-ICL and T-Artiflex eyes and 20/40 or better in 97% (n = 40) and 100% (n = 41) of the eyes in the T-ICL and T-Artiflex groups, respectively. The efficacy index (postoperative UDVA-to-preoperative CDVA) was 1.24 ± 0.42 in the T-ICL group and 1.08 ± 0.23 in the T-Artiflex group, suggesting that T-ICL was more efficient ($P = .029$).

The mean preoperative spherical equivalent of −9.85 ± 2.92 D and −9.44 ± 2.16 D was significantly reduced to the mean postoperative spherical equivalent of −0.33 ± 0.45 D and −0.29 ± 0.39 in the T-ICL and T-Artiflex groups, respectively (Table 2). The mean DEQs of the T-Artiflex

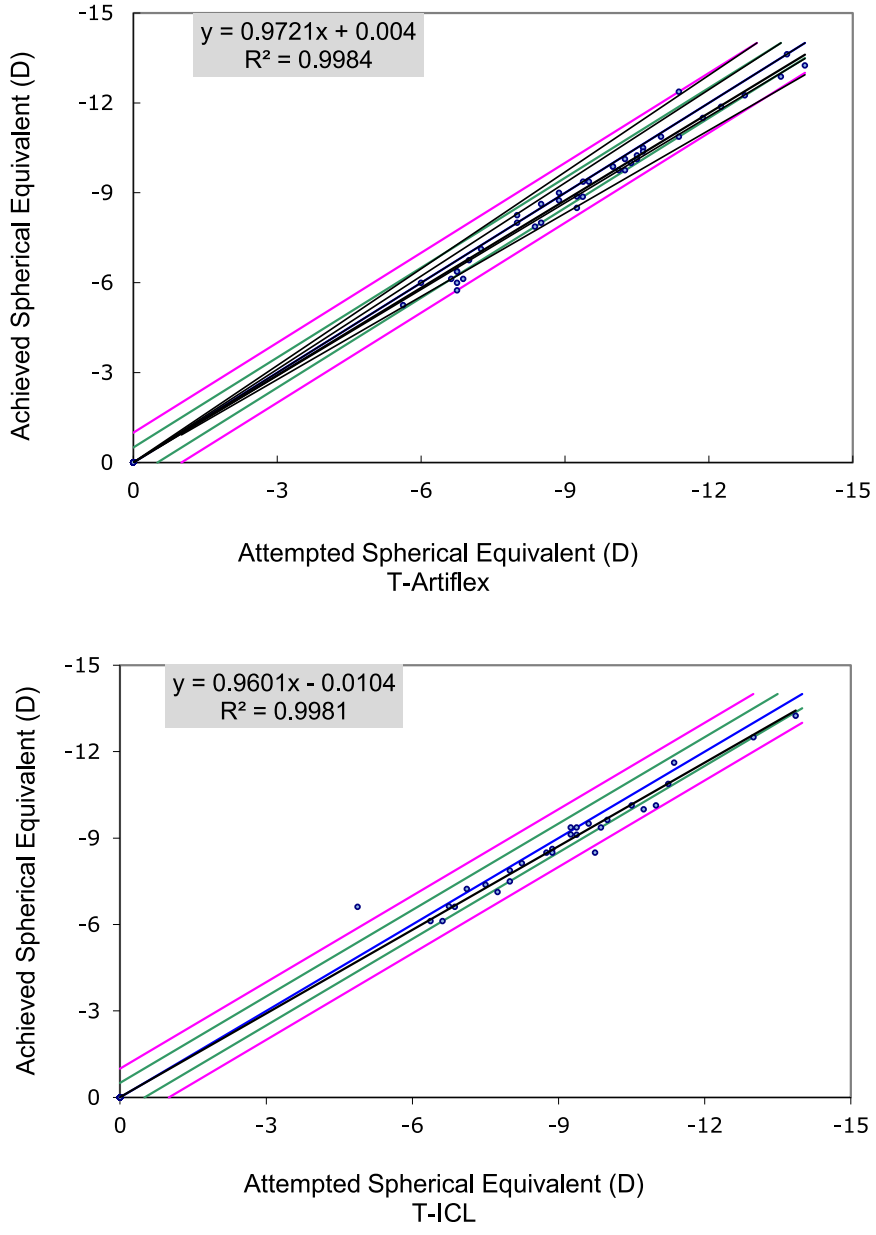

FIGURE 1. Attempted versus achieved spherical equivalent correction (refractive predictability curves for T-ICL and T-Artiflex groups).

group before and after the operation were −10.76 ± 2.19 D and −0.59 ± 0.45 D, respectively, compared to DEQs in the ICL group, −11.43 D ± 3.55 and −0.67 ± 0.65 D postoperatively. No significant differences were found between the 2 groups before ($P = .30$) and after the operations ($P = .51$).

The correlation between the attempted and the achieved myopic correction was highly linear, with a correlation coefficient of 0.9981 in the T-ICL group and 0.9984 in the T-Artiflex group (Figure 1). Twenty eyes (49%) in the T-ICL group and 18 eyes (44%) in the T-Artiflex group were within ±0.25 D of emmetropia. In the T-ICL group, 80% of eyes (n = 33) and 83% of eyes (n = 34) in the T-Artiflex group were within ±0.5 D of emmetropia postoperatively. All eyes in the T-Artiflex group and 39 eyes (95%) in the ICL group were within ±1.00 D of emmetropia. As mentioned previously, there were no statistically significant differences in refractive outcomes between the 2 groups (Table 1).

In both groups, none of the patients lost 2 or more lines of corrected distance VA. Only 1 eye (2%) after T-Artiflex insertion lost 1 line of CDVA. Nine eyes (22%) after T-ICL and 10 eyes (24%) after T-Artiflex insertion had no changes in CDVA. Also, 5 eyes (12%) gained 1 line and 27 eyes (66%) gained more than 1 line of CDVA after T-ICL insertion (78% gained 1 line or more). In the T-Artiflex group, 13 eyes (32%) gained 1 line, and 17 eyes (42%) gained

TABLE 3. Astigmatism Analysis(Alpins Method)

Parameter	Toric IOL Subgroup		*P* Value
	Mean ± SD T-ICL (D)	Mean ± SD T- Artiflex (D)	
SIA	2.93 ± 2.58 at 71°	2.81 ± 1.32 at 118°	.795
TIA	3.17 ± 2.57 at 76°	2.65 ± 0.97 at 119°	.226
DV	0.69 ± 0.61 at 76°	0.62 ± 0.5 at 84°	.589
Magnitude of error	−0.24 ± 0.62	0.17 ± 0.54	.002
Angle of error (degrees)	−0.45 ± 8	−0.24 ± 6	.894
Flattening effect	2.86 ± 2.59	2.76 ± 1.29	.824
Flattening index	0.88 ± 0.24	1.01 ± 0.21	.006
Correction index	0.90 ± 0.22	1.03 ± 0.2	.006
Index of success	0.25 ± 0.22	0.24 ± 0.15	.699

D = diopter; DV = difference vector; SD = standard deviation; SIA = surgically induced astigmatism; T-Artiflex = toric Artiflex; TIA = target induced astigmatism; T-ICL = toric implantable collamer lens.

more than 1 line of CDVA (76% gained 1 line or more). The safety indexes (mean postoperative CDVA/mean preoperative CDVA) were 1.40 ± 0.70 for T-ICL and 1.20 ± 0.21 for T-Artiflex groups, suggesting that both methods are safe and statistically equivalent ($P = .076$).

• **ASTIGMATISM VECTOR ANALYSIS:** Pre- and postoperative astigmatism were analyzed based on the Alpins method.[8] In the T-ICL group, surgically induced astigmatism (SIA) was significantly different from the target-induced astigmatism (TIA) ($P = .027$), and difference vector (DV) was different from zero ($P = .000$). In the T-Artiflex group, the SIA was significantly different from the TIA ($P = .001$), and the DV was different from zero ($P = .000$). The mean TIAs were similar ($P = .226$) in both groups, and the mean SIAs did not show any statically significant differences between the 2 groups either ($P = .795$). Expectedly, the mean DVs did not reveal any statistically significant changes between the groups ($P = .589$). It was true for the mean flattening effect ($P = .824$ and mean index of success of .699). Considering the mean angle of error, there was no statistically significant difference between the groups ($P = .894$). However, the mean flattening index ($P = .006$) and mean correction index (.006) were different statistically (Table 3).

• **CONTRAST SENSITIVITY:** There were no significant differences in postoperative mesopic contrast sensitivity between the T-ICL and T-Artiflex groups in any given spatial frequencies (Table 1, Figure 2).

• **ENDOTHELIAL CELL COUNT:** The mean endothelial cell counts of T-ICL and T-Artiflex groups were 2,722.6 ± 317.83 and 2,776.9 ± 277.87 preoperatively ($P = .416$) and 2,672 ± 310.26 and 2,721.4 ± 294.72 postoperatively, respectively ($P = .485$). The results revealed a cell loss of 1.83% in the T-ICL group, which was not significant ($P = .086$); in the T-Artiflex group, the differences between the 2 were also trivial (−1.98%) although statistically significant ($P = .001$).

On comparing the 2 groups using the Mann-Whitney *U* test, no significant differences were found in endothelial cell density changes before and after operation (*U* test result = 547.50; $P = .14$).

• **COMPLICATIONS:** Two eyes in the T-Artiflex group developed early postoperative inflammation which was moderate in 1 case and severe in the other; both cases responded to frequent topical betamethasone 0.1% treatment, without any residual sequelae. IOP increased to 27, 30, and 35 mm Hg in 3 eyes in the T-ICL group after 3 weeks (all were below 20 mm Hg preoperatively). They were treated with timolol 0.5% twice a day for 1 month, after which IOP remained normal without treatment. One eye in the T-Artiflex group had 15 degrees of lens misalignment and low vision which was repositioned surgically. No other significant complications occurred. Furthermore, 52% and 66% of patients in the T-ICL and T-Artiflex groups, respectively, reported some degrees of glare and halos which improved over time. After 6 months, the patients did not have disabling glare.

DISCUSSION

TO THE BEST OF THE PRESENT AUTHORS' KNOWLEDGE, THIS is the first experience reported with T-ICL and T-Artiflex in contralateral eyes. The results demonstrated excellent corrected and uncorrected vision after surgery in both groups. At the end of follow-up, 80% of eyes in the T-ICL group were within ±0.5 D of emmetropia. Although Kamia and associates[9] reported 91%[10] and Alfonso and associates reported 97%, the present results were very similar

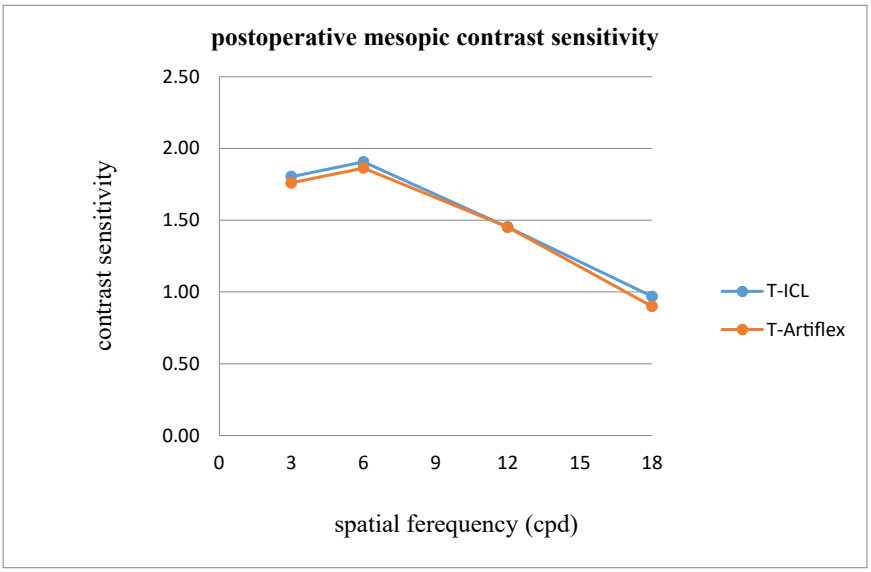

FIGURE 2. Postoperative mesopic contrast sensitivity between the T-ICL and T-Artiflex groups in any given spatial frequencies. T-Artiflex = toric Artiflex; T-ICL = toric implantable collamer lens.

to most of the previous studies of T-ICL[11–15] and better than the results of Ju and associates.[16] In the present cases, 83% of eyes with T-Artiflex were within ±0.5 D of emmetropia, which is in the midpoint between 66.7% previously reported by Muñoz and associates[17] and 100% reported by Ruckhofer and associates.[18] Furthermore, the present study demonstrated that both lenses have predictable refractive outcomes without statistically significant difference between the lenses. In previous studies, the efficacy index for T-ICL was as low as 0.87[13] and up to 1.14.[12] However, in this study, T-ICL was found to be very effective with an efficacy index of 1.24, which is one of the highest reported values.[13,19] Recently, Gomez-Bastar and associates[20] reported an overall efficacy index of 1.93 in different models of ICL and not for toric lenses alone.[20] However, Kamiya and associates[21] reported an efficacy index of 0.94% 3 years after implantation of T-ICL for moderate to high myopic astigmatism. On the other hand, the efficacy index of 1.08 for T-Artiflex in the present survey was very close to those reported previously.[17,18] Although most of preoperative and postoperative visual properties of both lenses were similar, the efficiency index was higher in the T-ICL group. Subsequently, the differences between the 2 groups were statistically significant but not necessarily clinically meaningful.

In both lens types, approximately 3/4 of the of cases gained at least 1 line of corrected VA, which may be related to increased retinal image after elimination of glasses. In accordance to most previous studies,[11,17,20,22,23] the safety indices in this study were greater than 1.1 for both lenses, suggesting they are safe lens implantation procedures. In the current study, the safety index in T-ICL group was 1.40, which is almost twice as large as the 0.75 reported by Pothireddy and colleagues[19] and comparable to the 1.08 value previously reported by Alfonso and associates[9] and the 1.16 value reported by Kamiya and associates.[21] Our results represented a higher safety index for T-ICL than for T-Artiflex lenses, but the differences were not statistically significant.

In terms of vectorial astigmatic analysis using the Alpins method, TIA, SIA, and DV are 3 major vectors commonly used to calculate other parameters for assessment of success or possible errors in the magnitude or angle of astigmatic correction. SIA and TIA were different in each group, and analysis showed an undercorrection of approximately 0.2 D in the T-ICL group, whereas there was an approximate overcorrection of 0.2 D in the T-Artiflex group. Although the means of magnitude of error were statistically different between lenses, such a difference was not clinically significant. Less than 0.3 D of undercorrection in the present series was similar to the undercorrection in a previous report.[24] Rotation of toric lenses less than 15 degrees is not usually clinically important.[25] In our experience, analysis of the angle of error revealed a tendency to counterclockwise rotation in both lenses. In any case, the present results were neither statistically nor clinically different. Under the best circumstances, the flattening effect should be equal to TIA and the flattening index should be equal to 1. In this series, the mean of flattening index indicated little undercorrection in T-ICL group in contrast to the little overcorrection in the T-Artiflex group, and the difference was statistically significant. On the other hand, the index of success, a relative measure of success in the treatment of astigmatism, which is preferably zero, did not show any statistically significant differences between the T-Artiflex and T-ICL. The index of success in this

study was calculated as 0.25 for T-Artiflex, which was greater than the value reported in the study by Visser and associates[26] but far less than the magnitude reported by Muñoz and associates.[17] Moreover, patients in both groups showed residual mixed astigmatism after the operation. Comparison between the 2 groups (reported as mean DEQ) did not show any differences, and the minute amounts of mean DEQ in both groups were in accordance with other promising visual outcomes.

Most candidates for refractive operations are young, hence, they have high visual demands. Accordingly, contrast sensitivity is a good indicator of visual quality in such patients. Previous reports have shown better postoperative contrast sensitivity of myopic patients after pIOL implantation in comparison to corneal ablation methods[27,28] or glasses.[29] Several studies have previously indicated increased contrast sensitivity after phakic lens implantation for myopia[30–32] or myopia with astigmatism.[10,33] Ghoreishi and associates[34] reported that contrast sensitivity improves after non-toric Artiflex or ICL implantation without any statistical significance between groups (nonrandomized paired eyes study).[34] The present study demonstrated that the postoperative contrast sensitivities were equal in both the T-Artiflex and T-ICL groups under mesopic conditions for any given spatial frequency.

pIOL insertion has a potential for endothelial cell loss.[35–37] Furthermore, natural endothelial cell loss that occurs with age[38] must be considered in these young refractive surgery candidates for a long-term corneal clarity. The study by Ruckhofer and associates[18] revealed 0.72% reduction of endothelial cell count 3 months after T-Artiflex insertion. Endothelial cells were found to be diminished by 1.98% at 12 months after T-Artiflex implantation, which was close to the experience reported by Dick and associates[37] with Artiflex[39] (−2.3%) and less than the value found by Dick and associates[37] (−4.5%) or Doors and associates[23] (−4.8%) and Guerin and associates[40] (−6.17%).

With regard to endothelial cell loss after ICL implantation, Edelhauser and associates[41] observed −2.1% in the first 3 months after the operation and approximately 8.5% cumulative endothelial cell loss after 3 years, where the changes were negligible after year 3. Long-term endothelial cell loss was reported from 2.3% to 9.9% in different studies.[4,7,21,24,42–44] In 2010, Kamiya and associates[10] reported 2.9% endothelial cell loss at 1 year after T-ICL implantation. In 2014, the same investigators reported a cell loss of 6.2% at 8 years after ICL implantation.[45] The results were comparable to the results of a US Food and Drug Administration clinical trial (less than 10% cumulative endothelial cell loss after 3 years).[4] In the current study, endothelial cell loss was 1.83% at 12 months after T-ICL implantation, which is in accordance with previously mentioned studies in their first few months of postoperative period and less than 10.3% reported from India[19] and 11% from Hong Kong.[14] From this point of view, both T-Artiflex and T-ICL were equal in the current study.

Because T-Artiflex has a design similar to that of Artiflex and T-ICL resembles ICL, potential complications of these toric lenses would be like those of nontoric lenses. Transient IOP rise without long-term consequences was previously reported after Artiflex[37] and T-Artiflex[23] implantation. This study did not observe such an IOP rise in the T-Artiflex group. Instead, 3 cases (11%) of high IOP were found in eyes with T-ICL, which could have been secondary to iris manipulation and pigment dispersion or remaining of the viscoelastic materials. These authors do not consider it an adverse event because all patients became normotensive after temporary antiglaucoma therapy without long-term sequelae. The early rise of IOP after ICL implantation is relatively frequent and mostly transient.[7] None of the eyes with ICL required lens repositioning, which was in accordance with previously published results.[46,47] Only 1 T-Artiflex patient needed repositioning because of a 15-degrees off-axis misalignment. Early or late onset cataract formation is a major safety concern related to ICL implantation. A peer-reviewed paper published by Fernandes and associates[7] suggested 5.2% of surgically induced lens opacity with earlier generations of ICL. Previous reports indicated 1.6% to 11% anterior subcapsular cataract after implantation of ICL/T-ICL, where only 0% to 2% of cases were visually significant.[4,7,21,42,43,48] However, anterior subcapsular or nuclear opacities[4] or ICL inferior displacement[12] did not occur in the present series. This can be expected after careful lens size and vault calculation and precise surgery. No other serious complications occurred regardless of toric pIOL types. At the end of the follow-up period, none of the patients complained of disabling glare.

CONCLUSIONS

BOTH T-ICL AND T-ARTIFLEX LENSES WERE FOUND TO BE safe, efficient, and predictable for correction of myopic astigmatism with promising results. Regardless of individual differences among patients, none of these lenses are superior to the other in terms of visual function outcomes, and each lens can be used instead of the other.

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