Visual and Refractive Outcomes With the Eyecryl Phakic Toric IOL Versus the Visian Toric Implantable Collamer Lens: Results of a 2-Year Prospective Comparative Study

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ABSTRACT

PURPOSE: To compare the 2-year visual and refractive outcomes with the Eyecryl Phakic Toric IOL (EP TIOL) (Biotech Vision Care Pvt Ltd) and Visian Toric ICL (TICL) (STAAR Surgical) for correction of high myopic astigmatism.

METHODS: This prospective, interventional, non-randomized comparison study included eligible patients who underwent toric phakic IOL surgery in one or both eyes with either the EP TIOL or TICL for myopic astigmatism. Two years postoperatively, both lenses were compared for their safety, efficacy, stability, and patient satisfaction. Vector analysis of astigmatism was performed using the Alpins method with the ASSORT software (ASSORT Party Ltd).

RESULTS: A total of 50 eyes were included, of which 25 eyes received EP TIOL implantation and the remaining 25 received TICL implantation. Preoperative mean ± standard deviation of spherical equivalent (SE) and cylinder was -10.15 ± 4.04 and -2.08 ± 0.86 diopters (D) in the EP TIOL group and -10.21 ± 3.97 and -2.17 ± 0.95 D in the TICL group, respectively. At 2 years of follow-up, there was no significant difference between the mean uncorrected distance visual acuity, corrected distance visual acuity, spherical equivalent, and residual astigmatism between the two groups (P > .05 for all parameters). Ninety-two percent of eyes in the EP TIOL group and 88% of eyes in the TICL group were within ±0.50 D of refractive astigmatism. Vector analysis of astigmatism showed a comparable Correction Index of 0.98 in the EP TIOL group and 0.94 in the TICL group, signifying a mild undercorrection of 2% and 6%, respectively. Two eyes in the TICL group underwent exchange for high vault and one eye required realignment due to significant postoperative rotation.

CONCLUSIONS: At least for the first 2 years postoperatively, both toric phakic IOLs were safe and effective in managing high myopic astigmatism with comparable visual results and patient satisfaction.

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Phakic intraocular lenses (IOLs) are now accepted as a proven modality for correction of refractive errors, especially in patients not amenable to treatment with corneal refractive procedures.[1-3] Their various advantages (eg, high visual quality, reduced induced aberrations, less postoperative dry eye, magnification of image, and nil risk of corneal ectasia) make them a preferred refractive modality over corneal procedures for some refractive surgeons.[4-6] Until recently, the Implantable Collamer Lens (ICL) from STAAR Surgical was the only posterior chamber phakic IOL available, which has been shown to be safe, effective, and predictable for correction of ametropia across various ranges.[7-9] These lenses have been shown to be safer and associated with fewer postoperative complications (eg, endothelial decompensation, iris chafing, pigmentary glaucoma, and angle damage) compared to the anterior chamber phakic IOLs, due their retropupillary position.[10-12] However, some newer phakic IOLs introduced recently have also been shown to deliver promising results with good safety in various studies.[13,14]

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The Eyecryl Phakic Toric IOL (Biotech Vision Care Pvt Ltd) (EP TIOL), which is a foldable, hydrophilic acrylic, plate-haptic, posterior chamber phakic IOL, was reported to be safe and effective for treatment of high myopia in a 24-month follow-up study.[15] A toric version of the same phakic IOL was also recently evaluated in a 6-month follow-up retrospective study.[16] However, no prospective comparison study evaluating the long-term outcomes between the EP TIOL and the Visian Toric ICL (V4c model) (TICL) (STAAR Surgical) has been published so far.

The current study was thus conducted with the aim of comparing the long-term clinical outcomes and patient satisfaction between the EP TIOL and TICL for the treatment of high myopic astigmatism. In this 2-year follow-up study, we compared the safety, efficacy, predictability, vault, rotational stability, complications, and patient satisfaction between the two currently available phakic IOL models.

PATIENTS AND METHODS

This prospective study was approved by the institutional ethics committee of Nethradhama Super Speciality Eye Hospital, Bangalore, India, and adhered to the tenets of the Declaration of Helsinki. Written informed consent was obtained from all patients participating in the study. Fifty eyes from 27 non-consecutive patients satisfying the inclusion criteria received phakic IOL implantation with either the TICL or the EP TIOL, with 25 eyes in each group. Twenty-three of the total 25 patients (11 in the EP TIOL group and 12 in the TICL group) underwent bilateral surgeries, whereas the remaining 4 patients (3 in the EP TIOL group and 1 in the TICL group) underwent unilateral surgery. After surgery, results were evaluated monocularly, treating each eye separately. The choice of phakic IOL to be implanted was mainly based on the availability of the lens and the patient's preference.

Eligibility criteria were: age between 21 and 40 years, patients with myopic astigmatism within a spherical equivalent (SE) range of -3.00 to -20.00 D and a minimum astigmatism of -1.00 D, stable refraction (0.50 D or less change in the past 12 months), corrected distance visual acuity (CDVA) of 20/30 or better, healthy tear film and ocular surface, minimum anterior chamber depth from corneal endothelium of 2.8 mm, endothelial cell count of 2,500 cells/mm^2, absence of corneal ectatic diseases, corneal scars, absence of retinal pathologies, and assured follow-up visits.

Preoperative Evaluation

All patients underwent a thorough preoperative evaluation including anterior and posterior segment examination, manifest refraction, assessment of CDVA, corneal topography using Orbscan topography (Orbscan II; Bausch & Lomb), Pentacam HR (Oculus Optikgeräte GmbH), specular microscopy (Tomey Corporation), dry eye evaluation, and aberrometry with iTrace (Tracey Technologies Corporation).

Study Phakic IOLs and Treatment Planning

Table A (available in the online version of this article) shows the characteristics and technical specifications of the two study lenses. The EP TIOL shares similar characteristics except for the toricity, and is manufactured on the same platform as the non-toric model.[14] For both groups, power calculations were performed using the online calculators available at their respective websites (www.biotechcalculators.com and ocos.staarag.ch for EP TIOL and TICL, respectively).

In both groups, the size of the toric phakic IOL was selected based on the predicted vault values shown by Compact Touch STS ultrasound biomicroscopy (Quantel Medical), with a linear scanning frequency of 50 MHz, scanning depth and width of 9 × 16 mm, and axial and vertical resolution of 35 and 60 µm, respectively.[17] To reduce measurement error,[4-6] ultrasound biomicroscopy images were taken and the average sulcus-to-sulcus value was computed. Following this, the "ICL Simulator" option was selected, into which the power of the toric phakic IOL (EP TIOL or TICL) derived from the online calculator was entered. This suggested to us the predicted postoperative vault using all available sizes of the phakic IOL (smallest to largest), of which the size resulting in a central vault height of 250 to 500 µm was finally selected for implantation.

All surgical procedures in both groups were performed by a single experienced surgeon (SG), using a standard surgical technique.[18] The EP TIOL was loaded into its butterfly cartridge, which can be inserted into the eye through a 2.7-mm corneal incision.[15] The TICL was loaded into its front-loading cartridge system and inserted through a recommended wound size of 3.2 mm.[19]

The markerless Callisto Eye system (Carl Zeiss Meditec) was used to guide the intraoperative alignment of the toric phakic IOL. Under topical anesthesia and the ophthalmic viscosurgical device 1% hyaluronic acid (Hyal 2000TM; LG Life Sciences, Seoul, Korea), the phakic IOL was inserted through a temporal, 2.8-mm limbal incision (for the TICL group, a wound-assisted injection was performed) and carefully positioned posterior to the iris using a Ganesh ICL manipulator (Epsilon Surgical) in the intended axis as per the rotation diagram provided by the manufacturer. During insertion, correct orientation was ensured by checking the holes on the leading footplates of both toric phakic IOLs, which is present on the left side of the EP TIOL and on the right side of the TICL. Once all four footplates were positioned in the

TABLE 1

Preoperative Baseline Characteristics of All Patients (N = 50 Eyes)[a]

Parameter	Eyecryl Phakic Toric IOL	Visian Toric ICL	*P*
Age (years)	24.04 ± 2.01	23.44 ± 2.38	.41
Sphere (D)	-10.15 ± 4.04 (-4.50 to -18.00)	-10.21 ± 3.97 (-4.25 to -18.00)	.95
Cylinder (D)	-2.08 ± 0.86 (-1.00 to -5.00)	-2.17 ± 0.95 (-1.00 to -4.50)	.70
SE (D)	-11.19 ± 3.40 (-5.50 to -19.25)	-11.30 ± 3.98 (-6.00 to -20.25)	.58
CDVA (logMAR)	0.03 ± 0.06 (-0.1 to 0.22)	0.04 ± 0.10 (-0.1 to 0.22)	.72
K1 (D)	42.53 ± 1.23	43.45 ± 1.50	.10
K2 (D)	45.22 ± 1.84	45.45 ± 1.60	.62
CCT (µm)	487.04 ± 32.12	475.58 ± 101.02	.59
ECD (cells/mm^2)	2,831.20 ± 186.55	2,837.28 ± 179.42	.90
WTW (mm)	11.70 ± 0.46	11.68 ± 0.46	.93
ACD (mm)	3.13 ± 0.41	3.21 ± 0.44	.50
IOP (mm Hg)	14.40 ± 2.36	14.52 ± 1.98	.84

IOL = intraocular lens; D = diopters; SE = spherical equivalent; CDVA = corrected distance visual acuity; K1 = flat keratometry; K2 = steep keratometry; CCT = central corneal thickness; ECD = endothelial cell density; WTW = white-to-white distance; ACD = anterior chamber depth; IOP = intraocular pressure

[a]Values are presented as mean ± standard deviation.

The Eyecryl Phakic Toric IOL is manufactured by Biotech Vision Care Pvt Ltd and the Visian Toric ICL is manufactured by STAAR Surgical.

ciliary sulcus, the ophthalmic viscosurgical device was aspirated through the central hole, with a coaxial irrigation aspiration cannula using a flow of 60 cc/min and a vacuum of 650 mm Hg. This was followed by final positioning of the toric phakic IOL guided by the overlay of the markerless system, and hydration of the corneal wounds. All patients had intraocular pressure measurements by non-contact tonometry hourly for 4 hours postoperatively, while being observed for any symptoms due to intraocular pressure spikes.

Postoperative medications included topical 0.3% ofloxacin (Exocin; Allergan) and 0.1% prednisolone acetate eye drops (Pred Forte; Allergan) four times a day for 2 weeks, and lubricants four times a day for 4 weeks or more. Follow-up examinations were conducted on 1 day, 2 weeks, and 3, 6, 12, and 24 months. At all follow-up visits from 2 weeks onward, assessment of UDVA, manifest refraction, CDVA, topography, and anterior segment optical coherence tomography (Optovue) for vault was performed.

Statistical Analysis

SPSS software for Windows version 17.0.0 (IBM Corporation) was used for statistical analysis. All values were expressed as mean ± standard deviation. An independent sample *t* test was used for intergroup comparison and a paired *t* test was used for intragroup comparison of means. A *P* value of .05 or less was considered statistically significant.

Journal of Refractive Surgery standard graphs were generated using Datagraph-med 5.20 software (Microsoft Corporation). Vector analysis was performed using the Alpins Statistical System for Ophthalmic Refractive Surgery Techniques (ASSORT) software (ASSORT Pty Ltd) that uses the Alpins method for vectorial analysis of astigmatism.

Vector Analysis of Astigmatism

Change in refractive astigmatism was analyzed with vector analysis using the Alpins method incorporated in the ASSORT software (version 5.64), considering the change in the astigmatic axis, measuring three vectors (ie, target induced astigmatism [TIA], surgically induced astigmatism [SIA], and difference vector, and the relationships among them.[20,21]

RESULTS

The two study groups were matched with no statistical difference in the mean age, preoperative SE, cylinder, CDVA, white-to-white distance, anterior chamber depth, and endothelial cell density (**Table 1**). Mean follow-up was 23 ± 4 months.

Efficacy (Postoperative UDVA/Preoperative CDVA)

At 2 years postoperatively, 76% of eyes in the EP TIOL group and 72% of eyes in the TICL group had a UDVA of 20/20 or better (**Figure 1**). Mean postoperative UDVA (logMAR) was marginally better in the EP TIOL group compared to the TICL group; however, the differences were not significant ($P > .05$ at all visits, **Table B**, available in the online version of this article). The mean efficacy index in the EP TIOL and TICL groups was 1.09

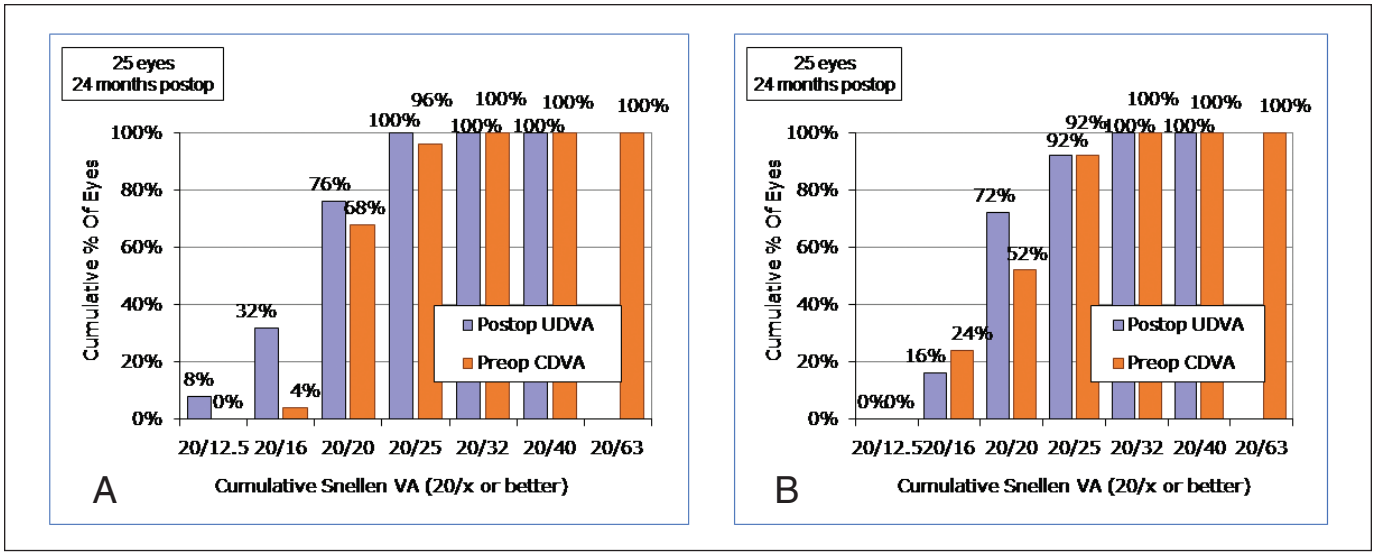

Figure 1. Cumulative postoperative mean uncorrected distance visual acuity (UDVA) (logMAR) for the (A) Eyecryl Phakic Toric IOL (Biotech Vision Care Pvt Ltd) and (B) Visian Toric ICL (STAAR Surgical). CDVA = corrected distance visual acuity

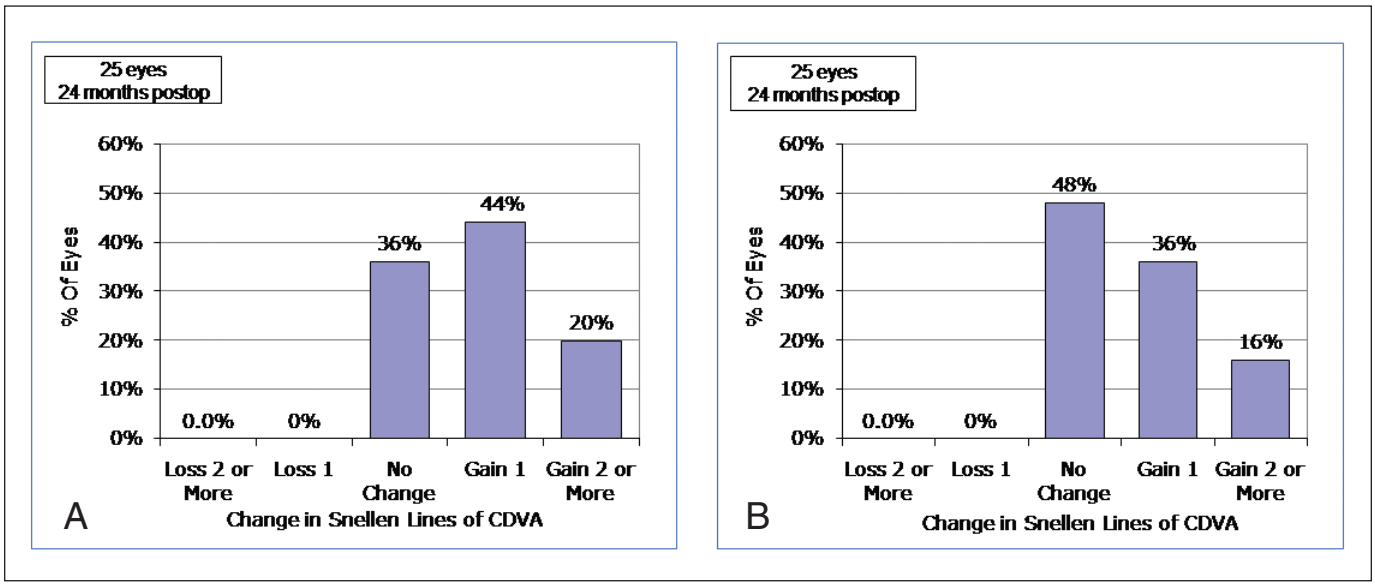

Figure 2. Safety: postoperative corrected distance visual acuity (CDVA)/preoperative CDVA for the (A) Eyecryl Phakic Toric IOL (Biotech Vision Care Pvt Ltd) and (B) Visian Toric ICL (STAAR Surgical).

and 1.04, respectively, with no statistical difference between the two groups (P = .80). Ninety-two percent of eyes in the EP TIOL group and 80% of eyes in the TICL group had postoperative UDVA the same or better than preoperative CDVA (**Figure A**, available in the online version of this article).

Safety (Postoperative CDVA/Preoperative CDVA)

At 24 months postoperatively, 64% of the eyes in EP TIOL group showed a gain in CDVA of one or more lines compared to 52% in the TICL group (**Figure 2**). No eye in either group showed a loss of CDVA. The mean safety indices for the EP TIOL and TICL groups were 1.2 and 1.17, respectively (P = .42).

Refractive Outcomes

There was no statistically significant difference between the postoperative residual SE of both groups at all postoperative visits (**Table B**). However, the accuracy of SE correction was better in the EP TIOL group because the SE predictability of all eyes in this group was within ±1.00 D compared to the TICL group, where 88% eyes were within ±1.00 D (**Figure 3**, **Figure B**, available in the online version of this article).

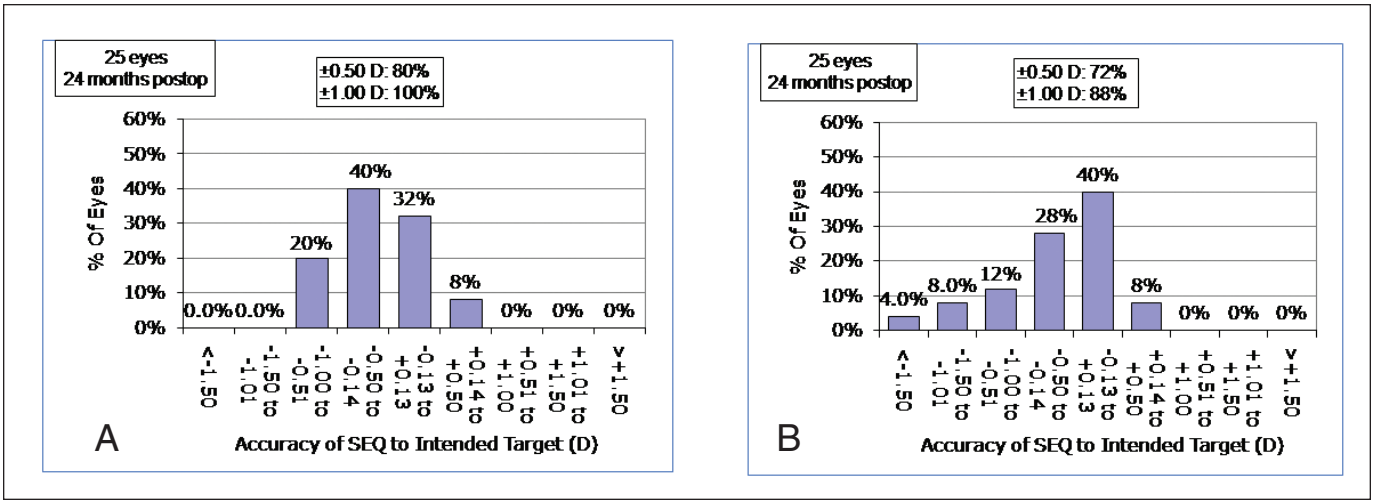

Figure 3. Histogram showing the accuracy to the intended spherical equivalent refraction (SEQ) at 24 months for the (A) Eyecryl Phakic Toric IOL (Biotech Vision Care Pvt Ltd) and (B) Visian Toric ICL (STAAR Surgical). D = diopters

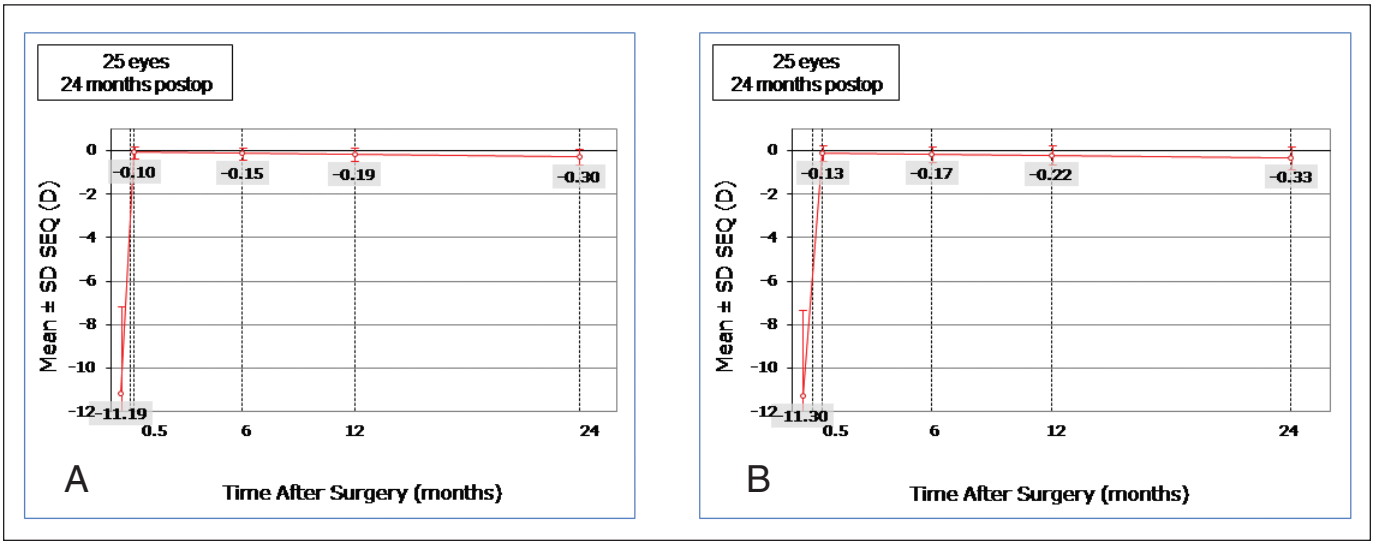

Figure 4. Spherical equivalent refraction (SEQ) stability for the (A) Eyecryl Phakic Toric IOL (Biotech Vision Care Pvt Ltd) and (B) Visian Toric ICL (STAAR Surgical). SD = standard deviation; D = diopters

Stability

Both groups showed good stability with a trend toward mild residual myopia of -0.30 ± 0.35 D in the EP TIOL group and -0.33 ± 0.53 D in the TICL group, compared to 2 weeks of postoperative follow-up (**Figure 4**).

Astigmatism Outcomes

In terms of astigmatism correction, 92% of eyes in the EP TIOL group and 88% of eyes in the TICL group were within ±0.50 D of cylinder correction. All eyes in the EP TIOL group had cylinder predictability within ±1.00 D, whereas all eyes in the TICL group were within ±1.50 D (**Figures 5-6**).

Vector analysis of astigmatism showed that the preoperative TIA of both groups was comparable, and following the surgery there was no significant difference in the outcomes of SIA, correction index, difference vector, magnitude of error, index of success, and angle of error between both groups ($P > .05$ for all parameters; **Table 2**, **Figure C**, available in the online version of this article). The correction index was comparable in the two groups (EP TIOL = 0.98; TICL = 0.94), suggesting a mild undercorrection of 2% and 6%, respectively.

Higher Order Aberrations and Modulation Transfer Function

At 24 months, total higher order aberrations assessed using the iTrace at a 4-mm scan size were 0.298 and 0.332 µm in the EP TIOL and TICL groups, respectively, the difference being not significant ($P = .70$). Similarly, the whole

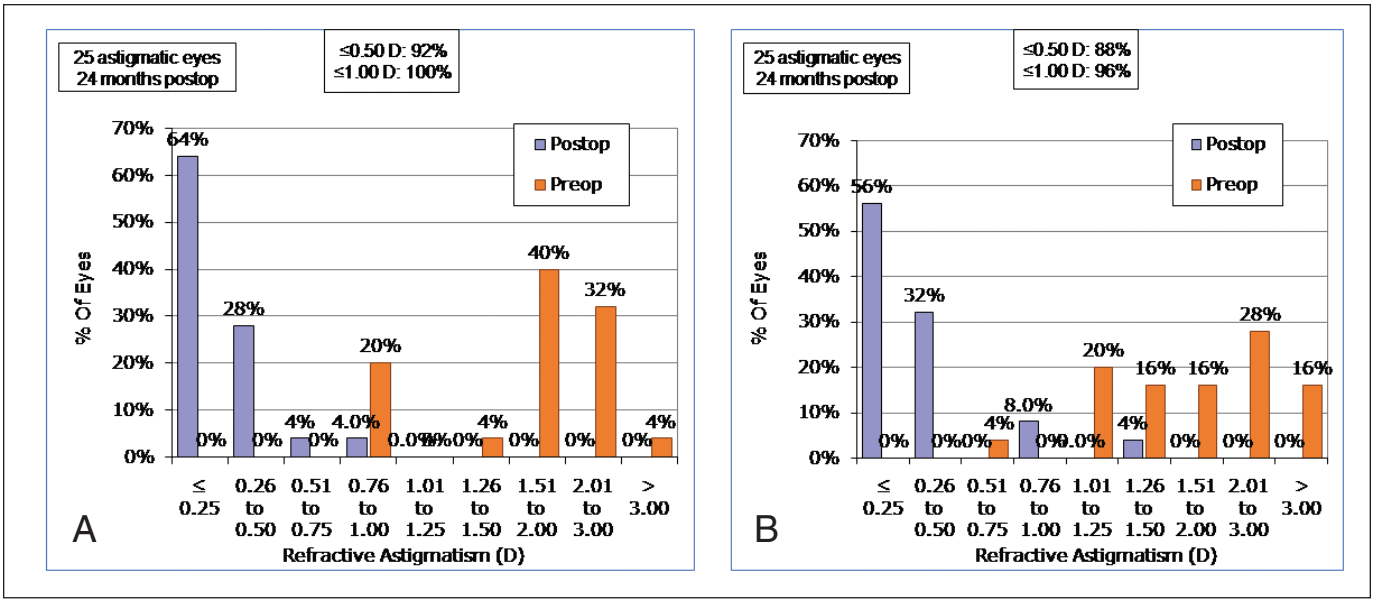

Figure 5. Histogram showing change in refractive astigmatism for the (A) Eyecryl Phakic Toric IOL (Biotech Vision Care Pvt Ltd) and (B) Visian Toric ICL (STAAR Surgical). D = diopters

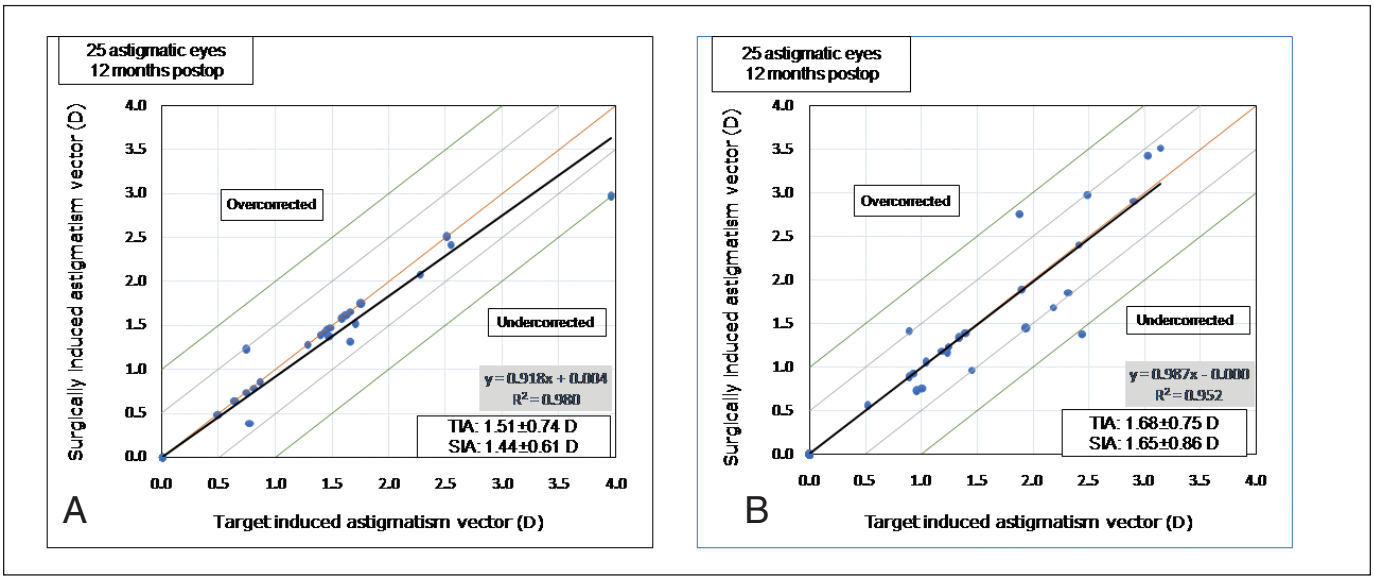

Figure 6. Target induced astigmatism (TIA) vs surgically induced astigmatism (SIA) scatter plot for the (A) Eyecryl Phakic Toric IOL (Biotech Vision Care Pvt Ltd) and (B) Visian Toric ICL (STAAR Surgical). D = diopters

eye modulation transfer function (mean height of modulation transfer function) was also comparable between the groups (0.391 for EP TIOL versus 0.363 for TICL, $P = .99$).

Vault Height and Rotational Stability

There was a reduction in the mean central vault height in both groups at 24 months compared to 2 weeks postoperatively. The vault reduced from 545.4 to 527.92 µm ($P = .04$) in the EP TIOL group and from 584.36 to 571 µm ($P < .001$) in the TICL group. Rotational stability, as measured by the iTrace, showed mild rotation of both phakic IOLs at 24 months compared to the 2-week position. At 2 weeks, the mean deviation from the target axis was 3.2° and 3.6° in the EP TIOL and TICL groups, respectively, which changed slightly to 4.8° and 5.1°, respectively, at 24 months.

Endothelial Cell Count

At 24 months, the mean percentage of endothelial cell loss compared to the preoperative count was 2.69%

TABLE 2

Comparison of Vector Analysis Between the Eyecryl Phakic Toric IOL and Visian Toric ICL Groups at 24 Months Postoperatively[a]

Parameter	Eyecryl Phakic Toric IOL	Visian Toric ICL	*P*
TIA (D)	1.51 ± 0.74	1.68 ± 0.75	.39
SIA (D)	1.44 ± 0.61	1.65 ± 0.86	.30
CI[b]	0.98 ± 0.18	0.94 ± 0.21	.51
DV	0.17 ± 0.28	0.31 ± 0.32	.10
MOE (arithmetic)	-0.07 ± 0.24	-0.06 ± 0.31	.95
MOE (absolute)	0.11 ± 0.23	0.21 ± 0.23	.11
IOS	0.12 ± 0.23	0.23 ± 0.40	.25
AOE (arithmetic)	-0.44 ± 5.77	-0.48 ± 6.55	.96
AOE (absolute)	3.68 ± 4.53	4.64 ± 4.55	.52

IOL = intraocular lens; TIA = target induced astigmatism; D = diopters; SIA = surgically induced astigmatism; DV = difference vector; MOE = magnitude of error; IOS = index of success; AOE = angle of error
[a]Values are presented as mean ± standard deviation.
[b]CI: 1 is ideal, > 1 overcorrection, < 1 undercorrection.
The Eyecryl Phakic Toric IOL is manufactured by Biotech Vision Care Pvt Ltd and the Visian Toric ICL is manufactured by STAAR Surgical.

and 3.19% in the EP TIOL and TICL groups, respectively. Endothelial cell density reduced from 2,837.28 ± 179.42 cells/mm^2 preoperatively to 2,761 ± 160.85 cells/mm^2 at 24 months in the EP TIOL group and from 2,831.20 ± 186.55 cells/mm^2 preoperatively to 2,740.64 ± 180.80 cells/mm^2 at 24 months in the TICL group (P < .001).

Long-term Complications

In the TICL group, 1 eye of 1 patient required realignment for significant rotation at 9 months postoperatively, wherein the TICL rotated again after 2 months. The TICL was slightly undersized with a vault of 180 µm. The patient was advised to exchange the TICL with one size larger lens; however, he opted to wear glasses for residual astigmatism. Both eyes of another patient required TICL exchange with a TICL of smaller size for postoperative high vault at 3 months postoperatively. In both groups, however, no long-term and sight-threatening complications, such as secondary glaucoma due to pupillary block or pigment dispersion, prolonged inflammation, cataract, retinal detachment, or endophthalmitis, were observed.

Patient Satisfaction

Both groups reported dysphotopsia symptoms in the immediate postoperative period, which gradually reduced over time. At 24 months, the spectacle independence score was comparable in both groups. Overall patient satisfaction score was 97.6 and 96.2 in the EP TIOL and TICL groups, respectively (P = .79) (**Table C**, available in the online version of this article).

DISCUSSION

Numerous long-term studies have already established that the TICL with and without CentraFLOW technology is safe, efficacious, and predictable in managing high myopic astigmatism, with excellent stability of cylinder correction.[19,22,23] The EP TIOL is a recent introduction to the phakic IOL market that also demonstrated good safety, efficacy, and rotational stability in a 6-month follow-up retrospective study.[16] Our prospective study compared the EP TIOL and TICL for long-term clinical outcomes. The fundamental differences between the two toric phakic IOLs in terms of their material, handling, loading, injection system, and surgical manipulation involved prompted us to conduct this study.

Kamiya et al[23] reported 3-year clinical outcomes of the TICL for moderate to high myopic astigmatism, wherein the safety and efficacy indices were 1.16 ± 0.20 and 0.94 ± 0.28 and there was a manifest refraction change of 0.15 ± 0.31 D from 1 month to the last postoperative visit. In another TICL study by Sari et al,[24] SE was within ±0.50 D in 52.9% and within ±1.00 D in 82.4% of eyes at 3 years of follow-up.

Our results suggested that the outcomes of the EP TIOL were comparable to the TICL at 24 months, with good patient satisfaction. Although the mean deviation from target axis increased at 24 months from 2-week values, it remained within 5° in both groups (4.8° in the EP TIOL group and 5.1° in the TICL group), and did not lead to a significant change in residual cylinder in either group.

Although the materials of both toric phakic IOLs are different, both lenses showed good biocompatibility with the ocular tissues. No eye developed excessive postoperative inflammation requiring topical steroid use for more

than 2 weeks. At 24 months, both phakic IOLs exhibited comparable modulation transfer function values, which indirectly suggests that the optical quality achieved was no different in both groups. However, the nature of the material may have a bearing on the loading, injection, and intraoperative maneuvering. Being extremely soft and flexible, the TICL needs careful handling, especially while pulling it forward within the cartridge, to prevent its potential tearing.[25,26] However, the EP TIOL is slightly stiffer and thus allows for easier handling. The loading is relatively straightforward and similar to that of an IOL, a maneuver most the ophthalmologists are familiar with.[15] However, the slight stiffness of the EP TIOL did not pose any significant difficulty while tucking its footplates under the iris.

The choice of ophthalmic viscosurgical device in this study was 1% hyaluronic acid in contrast to the more commonly used hydroxypropyl methylcellulose.[27] This was based on our experience with a previously published study comparing the surgical time and intraocular pressure spikes with two ophthalmic viscosurgical devices following Visian ICL (V4c model) insertion in the immediate postoperative period,[27] in which we found that 1% hyaluronic acid significantly reduced the total surgical time and the incidence of acute spikes was lower compared to 2% hydroxypropyl methylcellulose when used for the TICL (V4c model).

Because the maximum degree of rotation required for the EP TIOL is 15° in contrast to that of the TICL, wherein it may be up to 22° (clockwise or counterclockwise),[28] this may reduce the intraoperative manipulation to rotate the lens inside the posterior chamber, making it technically less challenging.

In the current study we performed a wound-assisted injection of the TICL through a 2.8-mm incision, but the recommended incision size for the same is 3.2 mm,[29] which is larger than that of the EP TIOL (2.8 mm). Hence, the induced astigmatism following TICL implantation is expected to be higher, which may potentially affect the final outcomes of cylinder correction. It would be interesting to compare the two lenses for postoperative induced corneal astigmatism and its effect on the final refractive correction.

The mean height of the central vault showed reduction over time, but none of the eyes in either group developed cataract due to low vault. This is consistent with previous studies of the Visian ICL, wherein a slight reduction in the vault height was shown due to changes in accommodation and increase in size of the crystalline lens over time.[30] This could explain the slight myopic shift observed at 24 months postoperatively in both groups. A potential limitation of our study was that we did not measure axial length preoperatively. Hence, it cannot be confirmed if the observed myopic shift was due to the progression of the myopia or the decrease in the postoperative vaults seen with both phakic IOLs over time, as stated above.

Despite using the sulcus-to-sulcus measurements for toric phakic IOL sizing, 2 eyes in the TICL group had high vaults requiring exchange with a smaller sized lens. However, sulcus-to-sulcus measurements, by themselves, were not shown to improve the vault predictability.[31] This may suggest that better technologies are still required for accurate estimation of phakic IOL sizing.

No eye developed cataract until the last follow-up visit, suggesting that the presence of the central hole in both phakic IOLs was beneficial in preventing cataract by allowing sufficient diffusion of aqueous and nutrients to the crystalline lens. This has been confirmed and reported by previously published studies on both phakic IOLs used in the study.[32] Also, the size of the central hole being the same (360 µm) (personal communication, D. G. Khalsa, Biotech Vision Care Ltd, India, June 1, 2020), the incidence of dysphotopsia experienced by the patients was similar in both groups in the early postoperative period (**Table A**).

Our study has a few limitations, the first being the nonrandomized nature of the study. However, randomization was not feasible because sometimes the availability of the TICL of a specific power and axis is a limiting factor, wherein the lens needs to be customized or takes a longer time for delivery. Second, we included both eyes from the same patient in the analysis. This was again done to achieve a comparable number of eyes within the time frame of the study recruitment, which otherwise would be difficult if we included 1 eye from 1 patient. Also, the model of Visian TICL used in the study was not the latest one because the advanced models (EVO and EVO+) have been currently available. However, these models were not available in India at the time of approval of the study, and hence could not be compared.

The EP TICL delivered satisfactory outcomes in terms of refractive efficacy and stability, resulting in high levels of patient satisfaction at 2 years of follow-up. However, long-term safety with respect to the biocompatibility needs further data and longer follow-up periods. Results were comparable with the already established TICL for correction of moderate to high myopic astigmatism. The ease of handling and easier availability due to toric axis customization may particularly make this lens a viable and preferable option for astigmatism management with myopia.

AUTHOR CONTRIBUTIONS

Study concept and design (SG); data collection (MG, SSS, SP); analysis and interpretation of data

(SB); writing the manuscript (SB); critical revision of the manuscript (MG, SSS, SP, SG); statistical expertise (MG, SSS); supervision (SG)

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TABLE A

Comparison of Eyecryl Phakic Toric IOL and Visian Toric ICL Characteristics

Chacteristic	Eyecryl Phakic Toric IOL	Visian Toric ICL
Optic type	Aspheric	Non- aspheric
Optic size (mm)	4.65 to 5.5	4.9 to 5.8
Overall size (mm)	12 to 13	12.1 to 13.7
Refractive index	1.46	1.45 at 35 °C
Diopter range (D)	0.00 to -23.00[a]	-0.50 to -18.00[b]
Cylinder range (D)	0.50 to 5.00[a]	1.00 to 6.00[a]
Sizes available (mm)	12, 12.5, 13, 13.5	11.6, 12.1, 13.2, 13.7
Material	Hydrophilic acrylic CQ UV	Collamer[c]
Consistency	Slightly firm	Extremely flexible
Holes	2 holes on haptic area, 1 hole at center	2 holes on haptic area, 1 hole at center
Size of the central and haptic hole (µm)	360	360
Orientation marks	Left end of leading haptics and right end of trailing haptics	Right end of leading haptics and left end of trailing haptics
Toric axis customization (degrees)	Available at 0, 30, 60, 90, 120, and 150 axis	Customizable
Maximum intraoperative rotation required (degrees)	15	22
Loading	Easy	Relatively complex
Incision (mm)	2.8	3.2

IOL = intraocular lens; D = diopters
[a]With 0.50-D step increments.
[b]With 0.25-D step increments from -0.50 to -2.75 D and 0.50-D step increments from -3.00 to -18.00 D.
[c]60% poly-hydroxymethylmethacrylate (HEMA), water (36%), benzophenone (3.8%), and 0.2 porcine collagen.
The Eyecryl Phakic Toric IOL is manufactured by Biotech Vision Care Pvt Ltd and the Visian Toric ICL is manufactured by STAAR Surgical.

TABLE B

Postoperative Visual Outcomes of the Eyecryl Phakic Toric IOL and Visian Toric ICL Groups[a]

Postoperative Visit	Sphere (D)	Cylinder (D)	SE (D)	UDVA (logMAR)	CDVA (logMAR)
1 day					
Eyecryl Phakic Toric IOL	-0.12 ± 0.43	-0.30 ± 0.40	-02.8 ± 0.44	0.03 ± 0.08	-0.05 ± 0.07
Visian Toric IOL	-0.24 ± 0.03	-0.10 ± 0.20	-0.30 ± 0.30	0.04 ± 0.10	-0.03 ± 0.05
P	.26	1.00	1.00	.50	.40
2 weeks					
Eyecryl Phakic Toric IOL	-0.50 ± 0.23	-0.10 ± 0.25	-0.10 ± 0.26	-0.50 ± 0.08	-0.80 ± 0.07
Visian Toric IOL	-0.08 ± 0.30	-0.09 ± 0.36	-0.13 ± 0.36	-0.02 ± 0.07	-0.06 ± 0.60
P	.69	.91	.78	.09	.24
3 months					
Eyecryl Phakic Toric IOL	-0.07 ± 0.24	-0.12 ± 0.27	-0.13 ± 0.28	-0.04 ± 0.08	-0.08 ± 0.07
Visian Toric IOL	-0.10 ± 0.27	-0.12 ± 0.34	-0.16 ± 0.34	-0.01 ± 0.07	-0.50 ± 0.05
P	.68	1.00	.73	.09	.10
6 months					
Eyecryl Phakic Toric IOL	-0.90 ± 0.26	-0.12 ± 0.27	-0.15 ± 0.29	-0.03 ± 0.08	-0.08 ± 0.07
Visian Toric IOL	-0.11 ± 0.30	-0.12 ± 038	-0.17 ± 0.37	-0.00 ± 0.07	-0.05 ± 0.04
P	.80	1.00	.83	.10	.08
12 months					
Eyecryl Phakic Toric IOL	-0.12 ± 0.26	-0.13 ± 0.30	-0.19 ± 0.32	-0.03 ± 0.07	-0.07 ± 0.06
Visian Toric IOL	-0.15 ± 0.36	-0.13 ± 0.40	-0.22 ± 0.43	0.01 ± 0.08	-0.04 ± 0.06
P	.73	1.00	.78	.07	.08
24 months					
Eyecryl Phakic Toric IOL	-0.21 ± 0.31	-0.18 ± 0.32	-0.30 ± 0.35	-0.01 ± 0.10	-0.05 ± 0.07
Visian Toric IOL	-0.25 ± 0.44	-0.19 ± 0.49	-0.33 ± 0.53	0.02 ± 0.08	-0.03 ± 0.06
P	.64	.93	.66	.47	.55

IOL = intraocular lens; D = diopters; SE = spherical equivalent; UDVA = uncorrected distance visual acuity; CDVA = corrected distance visual acuity
[a]Values are presented as mean ± standard deviation.
The Eyecryl Phakic Toric IOL is manufactured by Biotech Vision Care Pvt Ltd and the Visian Toric ICL is manufactured by STAAR Surgical.

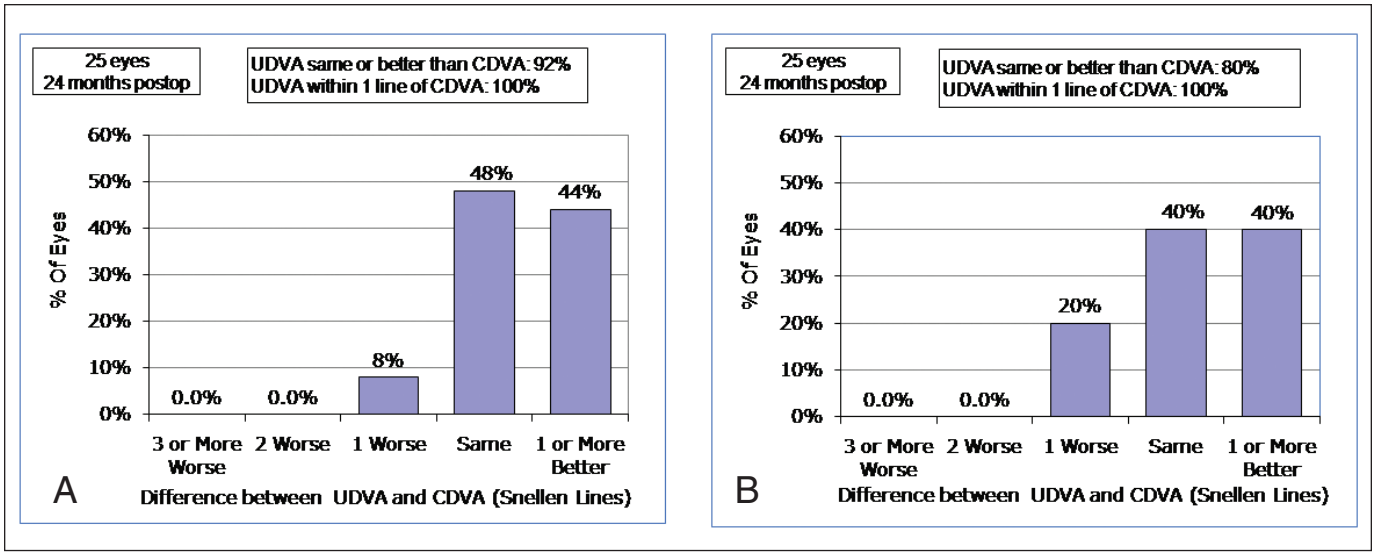

Figure A. Efficacy: postoperative uncorrected distance visual acuity (UDVA)/preoperative corrected distance visual acuity (CDVA) for the (A) Eyecryl Phakic Toric IOL (Biotech Vision Care Pvt Ltd) and (B) Visian Toric ICL (STAAR Surgical).

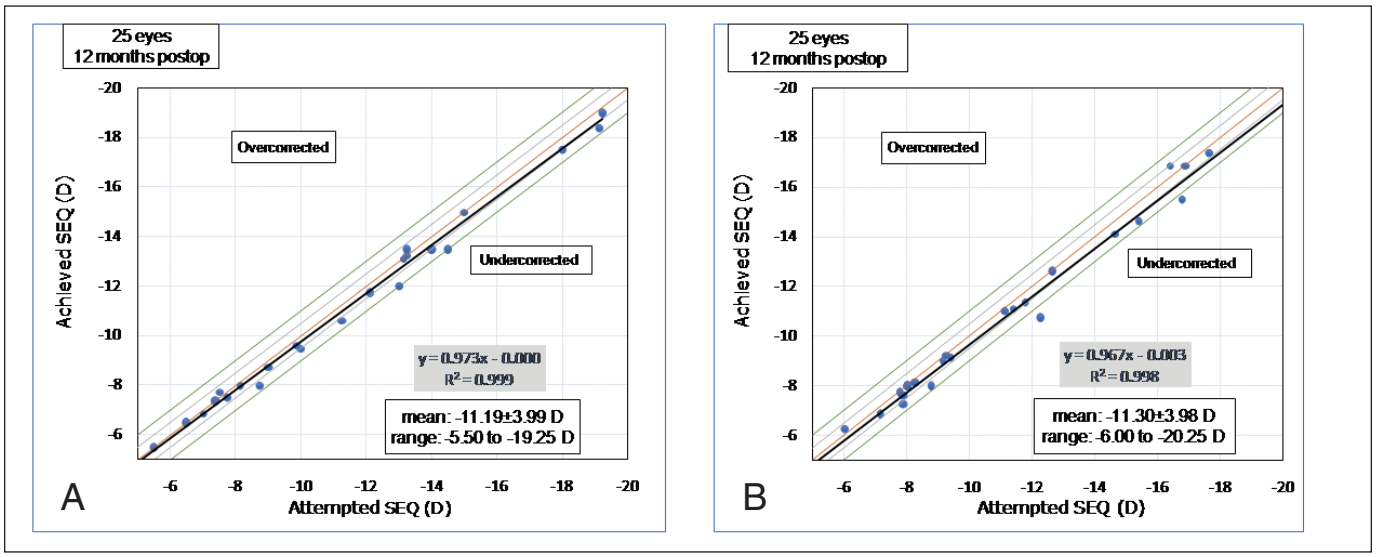

Figure B. Spherical equivalent refraction (SEQ) attempted vs achieved scatter plot for the (A) Eyecryl Phakic Toric IOL (Biotech Vision Care Pvt Ltd) and (B) Visian Toric ICL (STAAR Surgical). D = diopters

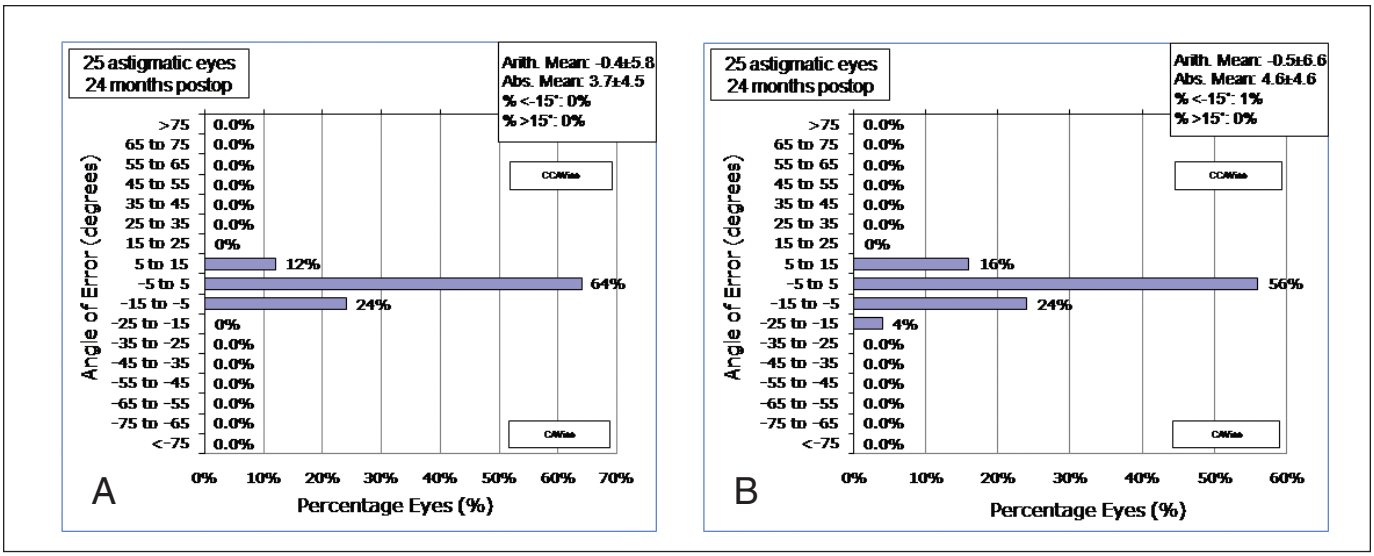

Figure C. Refractive astigmatism angle of error for the (A) Eyecryl Phakic Toric IOL (Biotech Vision Care Pvt Ltd) and (B) Visian Toric ICL (STAAR Surgical).

TABLE C

Postoperative Patient Satisfaction and Dysphotopsia Scores

Parameter	2 Weeks	6 Months	12 Months	24 Months	*P*
Dysphotopsia symptoms (0 to 10)[a]					
Eyecryl Phakic Toric IOL	5.4	3.4	1.8	0.7	.43
Visian Toric ICL	5.8	3.2	1.6	0.5	
Spectacle independence score (0 to 10)[b]					
Eyecryl Phakic Toric IOL	–	8.5	8.7	8.8	.88
Visian Toric ICL	–	8.7	8.2	8.4	
Overall patient satisfaction score (0 to 100)					
Eyecryl Phakic Toric IOL	–	92.6	94.8	97.6	.79
Visian Toric ICL	–	94.2	95.4	96.2	

IOL = intraocular lens
[a]0 to 2 = mild, 3 to 7 = moderate, 8 to 10 severe.
[b]Feel the need to use glasses.
The Eyecryl Phakic Toric IOL is manufactured by Biotech Vision Care Pvt Ltd and the Visian Toric ICL is manufactured by STAAR Surgical.