• Clinical Research •

Refractive outcomes after V4c Toric collamer lens implantation over 1y of follow-up

Humberto Carreras-Díaz[1], Josefina Reñones de Abajo[1], María del Rosario Carreras-Díaz[2], Amalia Lorente-Velázquez[3]

[1]Vithas Eurocanarias, Las Palmas de Gran Canaria 35004, Spain
[2]University Hospital of Girona Doctor Josep Trueta, Gerona 17007, Spain
[3]Departament of Optometry and Vision, Faculty of Optics and Optometry, Complutense University of Madrid, Madrid 28040, Spain
Correspondence to: Amalia Lorente-Velázquez. Department of Optometry and Vision, Faculty of Optics and Optometry, Universidad Complutense de Madrid, C/Arcos de Jalón 118, Madrid 28037, Spain. alorente@ucm.es
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Abstract

● **AIM:** To evaluate refractive outcomes and corneal astigmatism changes after Toric implantable collamer lens with a central port (V4c T-ICL) implantation over 1y of follow-up.

● **METHODS:** A retrospective study was performed including 50 eyes of 50 patients that underwent V4c T-ICL implantation. Uncorrected (UDVA) and corrected (CDVA) distance visual acuities, refraction, refractive and corneal astigmatism changes and corneal coupling correction were evaluated preoperatively, 1 and 12mo postoperatively. Vector analysis was used for astigmatism changes. Coefficient of adjustment (CAdj) was calculated for corneal coupling analysis.

● **RESULTS:** The mean UDVA achieved was 0.03 logMAR at 1mo and remained unchanged throughout the whole follow-up (P=0.193). At the last visit, 84% of the eyes achieved a CDVA of 0.00 logMAR or better. Regarding spherical equivalent refraction (SEQ), 96% of eyes were ranges of ±1.00 D and 84% of them within ±0.50 D. Also, 94% of eyes had a remaining refractive cylinder within ±1.00 D and 78% of them within ±0.50 D. Both, SEQ and refractive cylinder, remain stable over the postoperative follow-up (P=1.000 and P=0.660, respectively). In terms of surgically induced astigmatism (SIA), no statistically significant differences were found over the follow-up (P=0.102) and under correction was found with a correction index lower than the unit at each visit. A keratometric astigmatism induced of 0.59±0.53 (vector mean: 0.26×73º) D was reached at the last visit. No significant changes in terms of corneal astigmatism orientation were reported over post-surgery visits (P=0.129 and P=0.097 at 1 and 12mo respectively). No clinical significance was found for CAdj on with-the-rule astigmatism. No postoperative complications resulting from the surgery were found.

● **CONCLUSION:** Refractive outcomes suggest that the V4c T-ICL implantation for correction of myopic astigmatism was satisfactory in terms of effectiveness, safety, and stability during 1y of follow-up. Corneal astigmatism induced by the incision around 0.5 D is achieved according to the remaining refractive cylinder found at one-year post-surgery. Corneal coupling analysis results in no unexpected spherical change.

● **KEYWORDS:** V4c Toric collamer lens; corneal astigmatism; surgically induced astigmatism; corneal coupling

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INTRODUCTION

Astigmatism is a common refractive error that causes a blurring of the vision and visual impairment to perform tasks at far and near distance. Over the years, many approaches have been developed to try to solve this surgically: astigmatic keratectomy[1], excimer laser ablation[2] and limbal relaxing incision[3] are some of them. However, the main drawback of these methods is non-reversible and some of them lack predictability or reliability[4]. In recent years, the use of a phakic Toric implantable collamer lens (T-ICL) has become widespread for the correction of astigmatism, proving to be an effective, safe, and predictable surgical procedure[5]. The evolution on the design of this T-ICL along with the improvement of the technical surgery has made this procedure one of the surgeon's first choice for refractive astigmatism correction even among young people and low refractive errors.

The last T-ICL model for correction astigmatism error is the V4c T-ICL (ICL, STAAR Surgical AG, Nidau, Switzerland) which incorporates a central port design allowing the flow of the aqueous fluid through the lens[6] preserving the physiology of the eye and preventing complications when compared to previous T-ICLs[7]. In addition, previous studies concluded that it is a safe and efficient procedure, with stable refractive outcomes and low adverse effects[8-9].

The procedure to implant the T-ICL requires a main incision on the cornea to introduce the lens on the eye. Previous studies have shown the importance of making an incision on the corneal keratometry[10-12] and, consequently, the change on the corneal power and therefore its effect on the vision. Several authors[13-14] reported surgically induced astigmatism with T-ICL implantation of about 0.50 D. Furthermore, the incision causes a change in corneal power in both the meridian in which it is made and in the opposite meridian. The term used in the literature to describe this change is corneal coupling. The term of coupling has been introduced around 50 years ago to evaluate the corneal steeping that occurs at the opposite meridian to the incision meridian. Alpins and Goggin[15] approached a study of corneal coupling in astigmatic treatments proving that coupling is a clinically significant phenomenon that affects the visual outcomes of incisional procedures. Moreover, the knowledge of corneal coupling could help the surgeon to consider the power change on the cornea when the ICL power is estimated.

To our knowledge, there are few studies which have investigated outcomes of the V4c T-ICL model over a long time (1y) that include an analysis of refractive and corneal astigmatism changes or its stability over time. So, the present study aims to analyse refractive outcomes in terms of effectiveness, safety, and stability, investigate the change in corneal and refractive astigmatism from preoperative to postoperative, derive the keratometry surgically induced astigmatism after V4c T-ICL implantation, and to quantify the corneal coupling effect induced by the surgical incision over 1y of follow-up.

SUBJECTS AND METHODS

Ethical Approval This study followed tenets of the Declaration of Helsinki and after receiving a complete description of the possible consequences of surgery, all patients provided informed consent.

Participants This retrospective observational study evaluated eyes who underwent posterior phakic lens implantation for myopia and astigmatism compensation. The phakic lens used was V4c T-ICL model (STAAR Surgical Inc) to correct the refractive error at the Ophthalmological Institute Vithas Eurocanarias, Las Palmas de Gran Canaria, Spain.

A minimum of 32 eyes was required to obtain statistically significant results with a power of 20% and an alpha risk of 5% in unilateral contrast, according to the data of deviations of the variables obtained in the study of Li *et al*[16] and the GRANMO sample size calculator (Institut Municipal d'Investigació Mèdica, Barcelona, Barcelona, Spain, Ver 7.12), considering a variability of astigmatism induced by corneal incisions of ±0.10 D, a minimal detectable difference of 0.05 D and a follow-up loss of 0.1%.

None of the patients had ocular or systemic diseases or previous surgery. Patients using contact lenses must leave them 7 or 14d before the implantation (soft contact lenses or rigid contact lenses respectively). Furthermore, patients had met the general criteria for ICL implantation: refractive error in the range correctable with the V4c T-ICL and anterior chamber depth (ACD) greater than 2.8 mm measured from the corneal endothelium to the anterior lens capsule.

Phakic Intraocular Lens T-ICL power calculation (sphere and cylinder) was selected based on STAAR Surgical Online Calculating and Ordering System (OCOS, Monrovia, CA USA) with a target of emmetropia as postoperative refraction. The size of the T-ICL was individually calculated for each eye based on the measurements of horizontal white-to-white (WTW) distance and ACD measure from the corneal endothelium to the anterior capsule of the crystalline lens.

Surgical Technique All incisions were performed with a bevel-up steel blade (Equipsa S.A., Madrid, Spain). The T-ICL axis alignment was made using image-guided system also the location at the main incision. All surgeries were carried out by the same surgeon (Carreras-Diaz H). Before the surgery, pharmacological mydriasis with tropicamide eye drops in the preoperative surgical area, washing of the conjunctival sac with 5% povidone iodine and disinfection of the eyelids with povidone ensuring correct isolation of the eyelashes were provided. Subsequently, and after placement of blepharostat and eye wash, a paracentesis with a slightly enlarged lancet (1.2 mm) located at 90º to the main incision was performed followed by intracameral lidocaine injection through the paracentesis and the introduction of 2% viscoelastic material (methylcellulose) without pressurisation. Main incision at 135°, limbal and parallel to the iris (2.75 mm) slightly tunnelled was performed. After this, folding and preparation of the T-ICL in the implant cartridge and injector, ensuring correct alignment of the positioning marks joint repositioning of viscoelastic material in anterior chamber was placed. The insertion of the T-ICL into the anterior chamber, placing the distal portion of the cartridge into the main incision was slow and controlled placing the haptics over the iris. Insertion of viscoelastic over the optical zone of the T-ICL to push the lens towards the iris plane and manoeuvres to displace the tabs of

the T-ICL haptics towards the posterior chamber, by means of slight displacements with the ICL spatula, were carried out. Once the T-ICL has been placed and is well centred, the T-ICL is then subjected to profuse suction irrigation manoeuvres to eliminate the remains of viscoelastic, avoiding contact with the optical zone of the lens. Finally, the main incision was closed hydrating the edges with balanced salt solution (BSS) to ensure the tightness of the incisions. Acetylcholine was used in the anterior chamber to reduce the pupil diameter and intracameral cefuroxime was injected as part of the antibiotic prophylaxis protocol.

Postoperative Treatment Postoperative treatment consisted of instilling acetazolamide 250 mg (Edemox®) and Boi-K® (potassium hydrogencarbonate, 1.001 mg and ascorbic acid, 250 mg) in decreasing pattern the first 3d after intervention, ofloxacin (Exocin®, 3 mg/mL) and 0.1% dexamethasone (Maxidex®) in decreasing pattern for 3wk and artificial tears. Neither postoperative complication occurred in any patient.

Preoperative and Postoperative Evaluation Postoperative follow-up was 1y. The study evaluated the outcomes at preoperative, 1, and 12mo postoperative visits. The examinations included measurement of uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) by an optotype proyector (NIDEK SC1600), manifest refraction, slit-lamp examination (TAKAGI 700 model), intraocular pressure (IOP) measured by Goldmann applanation tonometry, endothelial cell count (ECD) measured by a specular microscope (NIDEK CEM 530) and corneal topography measured by Pentacam (Oculus Optikgerate, Germany). Value of visual acuity was taken in decimal units but converted to logMAR units for analyses.

Vector Analysis of Astigmatism The astigmatism changes were evaluated based on Alpins method of vector analysis[17]. First, refractive astigmatism was studied. According to this method, the following vectors were determined and calculated: targeted induced astigmatism (TIA), which represents the intended vector (including magnitude and axis); surgically induced astigmatism (SIA), which represents the actual astigmatic change induced by surgery; difference vector (DV), which represents the difference of astigmatism between the achieved and target astigmatism and correction index (CI), which is calculated by determining the ratio of the SIA to the TIA by dividing SIA by TIA.

Second, corneal astigmatism was estimated. Corneal astigmatism was calculated from simulated keratometry (SimK) from corneal topography data during the follow-up. Arithmetical astigmatism mean and vector mean were performed for each visit using vector analysis[17-18].

Finally, surgically keratometry induced astigmatism (SIA_k) was calculated from preoperative and postoperative SimK values at each visit. Data of arithmetical mean and vector mean were determined using vector analysis[17-18].

Also, vector analysis was performed on the types of astigmatism at each visit. The astigmatism axes were classified as follows: with-the-rule (WTR) astigmatism, 0 to 30 degrees and 151 to 180 degrees; against-the-rule (ATR) astigmatism, 61 to 120 degrees; and oblique astigmatism, 31 to 60 degrees and 121 to 150 degrees.

Corneal Coupling Corneal coupling was evaluated using the methodology proposed by Alpins and Goggin[15]. According to this method, the following parameters were calculated: Coupling Ratio is $-\Delta K_o/\Delta K_T$, where ΔK_o is the change in corneal power at the opposite meridian and ΔK_T is the change in corneal power at the treatment meridian; Coupling Constant (CC) is $\Delta K_{mean}/(\Delta K_T-\Delta K_o)$ where ΔK_{mean} is the change in the mean corneal power; The coupling adjustment (CAdj) is $CC–CC_{Exp}$, where CC is the calculated CC that occurred and CC_{Exp} is the expected CC for this type of surgery. For incisions procedures, CC_{Exp} would be 0. Therefore, CAdj coincides with CC in this surgery.

Statistical Analysis Descriptive statistical analysis was performed using SPSS for windows, version 20.0 (SPSS Inc., Chicago, IL, USA). The refractive analysis toolbox for MATLAB (R2009; MathWorks, Natick, MA, USA)[18] was used for vector analysis and plot representations according to the standard[19]. Normality was first checked with the Kolmogorov-Smirnov test and a repeated-measures analysis of variance (ANOVA) was performed thereafter to compare mean values. Comparison of proportions was performed using McNemar test. Differences were considered statistically significant when the *P* value was less than 0.05.

RESULTS

The study included 50 eyes from 50 patients (18 males and 32 females). The selection of the eye was randomized. All patients completed the follow-up period of 1y and attended all the follow visits. Table 1 summarises preoperative demographic data of the patients and ICL characteristics. All the eyes were implanted with a V4c T-ICL (STAAR Surgical Inc). The distribution of the lens sizes implanted were 12.1 mm in 2 eyes (4%), 12.6 mm in 17 eyes (34%), 13.2 mm in 28 eyes (56%) and 13.7 mm in 3 eyes (6%).

Mean preoperative CDVA was 0.03±0.11 (range: 0.52 to -0.08) logMAR and UDVA was 0.03±0.09 (0.40 to -0.08) logMAR at 1mo after surgery (*P*=0.339) and remained stable throughout the whole follow-up period with 0.03±0.10 (range 0.52 to -0.08) logMAR at 12mo (*P*=0.128; Figure 1A). At one year of follow-up, 78% of eyes achieved an UDVA of 0 logMAR or better. The efficacy index (mean postoperative UDVA/mean preoperative CDVA) was 1.03 and 1.05 at 1 and 12mo after surgery, respectively. The mean CDVA changed

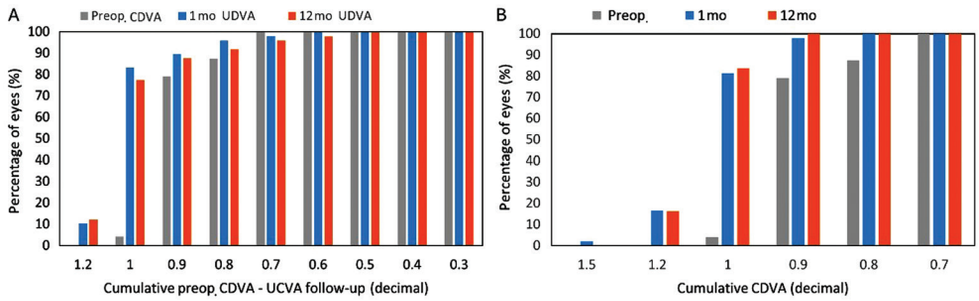

Figure 1 Cumulative CDVA preoperative and UDVA over post-surgery visits (A) and cumulative CDVA over the follow-up (B) CDVA: Corrected distance visual acuity; UDVA: Uncorrected distance visual acuity.

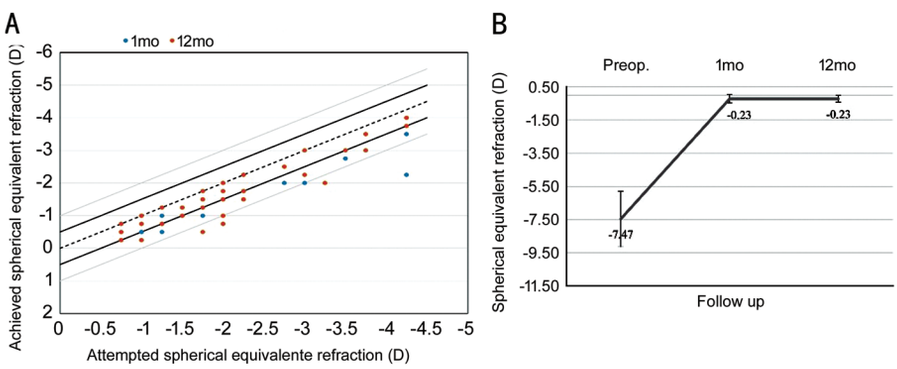

Figure 2 Attempted versus achieved spherical equivalent over follow up visits (predictability, A) and variation of manifest spherical equivalent over the follow-up post operative (stability, B).

Table 1 Preoperative demographic data of the patients and ICL characteristics

Parameters	Mean±SD (range)
Age (y)	29.78±6.75 (18, 46)
CDVA (logMAR)	0.03±0.11 (0.52, -0.08)
Refractive sphere (D)	-6.71±3.14 (-14.25, 0.00)
Refractive cylinder (D)	-1.95±0.90 (-4.25, -0.75)
Spherical equivalent (D)	-7.69±3.05 (-15.50, -2.13)
ECD (cells/mm^2)	2566.54±391.70 (1238, 3303)
IOP (mm Hg)	14.98±3.53 (9, 22)
Mean keratometric (D)	44.38±1.62 (41.20, 48.70)
Corneal astigmatism (D)	1.73±0.94 (0.50, 5.50)
AL (mm)	25.90±1.41 (22.00, 28.59)
ACD (mm)	3.24±0.26 (2.83, 3.81)
WTW (mm)	11.83±0.35 (11.1, 12.7)
ICL power (D)	-9.19±3.39 (-17.50, 2.50)
ICL Cyl (D)	1.92±1.18 (1.00, 5.00)

ICL: Implantable collamer lens; D: Diopters; ACD: Anterior chamber depth; WTW: White-to-white; ATA: Angle-to-angle; ECD: Endothelial cell density; IOP: Intraocular pressure; AL: Axial length; Cyl: Cilynder; SD: Standard deviation.

from the preoperative 0.03±0.11 to 0.00±0.06 (range: 0.30 to -0.18) logMAR at 1mo after surgery (P=0.561) and remained unchanged over the whole follow-up period 0.00±0.05 (range: 0.30 to -0.08) logMAR at 12mo (P=0.193; Figure 1B). At the last visit, 84% of the eyes achieve a CDVA of 0 or better. The safety index (ratio between the postoperative CDVA at the last visit and the preoperative CDVA) was 1.12.

Figure 2A displays the correlation analysis between attempted versus achieved spherical equivalent refraction (SEQ) at 1- and 12-month post-surgery (predictability). At one month, 46 eyes (92%) had an SEQ within ±1.00 D and 42 (84%) within ±0.50 D. At last visit, 96% of eyes were in SEQ ranges of ±1.00 D keeping the same percentage within ±0.50 D. Over the follow-up, SEQ keeps stable reaching a -0.24±0.49 (-2.00 to 0.50) and -0.23±0.41 (range: -1.63 to 0.38) D values at 1 and 12mo post-surgery respectively, showing no significant progression of myopia (stability; P=1.00; Figure 2B).

Figure 3A displays the correlation analysis between attempted versus achieved refractive cylinder at 1- and 12-month post-surgery (predictability). At one month, about 74% of eyes had a remaining cylinder within ±0.50 D and 94% within ±1.00 D. At last visit, 78% of eyes had a remaining cylinder within ±0.50 D and 94% of eyes within ±1.00 D. Over the follow-up, arithmetical mean refractive cylinder was -0.50±0.43 D (range: -2.00 to 0 D; vector mean: 0.28×85º) and -0.48±0.37 D (range: -1.25 to 0 D; vector mean: 0.21×78º) values at 1 and 12mo respectively. Therefore, the refractive cylinder remains stable over the postoperative follow-up (stability; P=0.660; Figure 3B).

Vector representation for refractive astigmatism is described in Figure 4. Arithmetical mean magnitude of TIA was 1.96±0.90 (range: 4.25 to 0.75) D. The mean magnitude of SIA over the

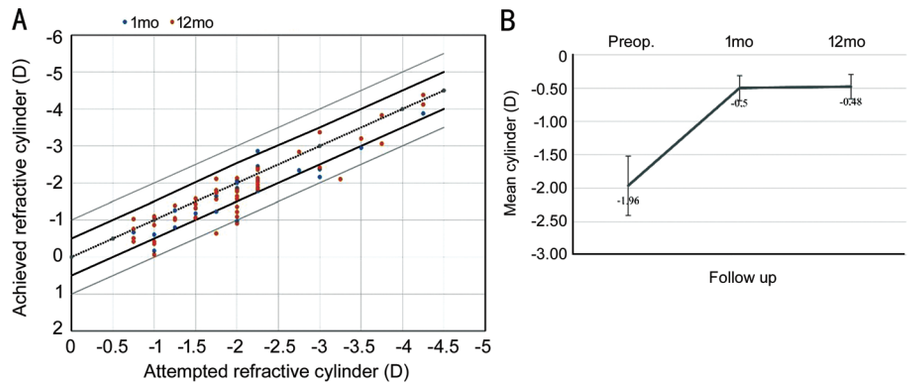

Figure 3 Attempted versus achieved refractive cylinder over follow up visits (predictability, A) and variation of refractive cylinder over the follow-up post operative (stability, B).

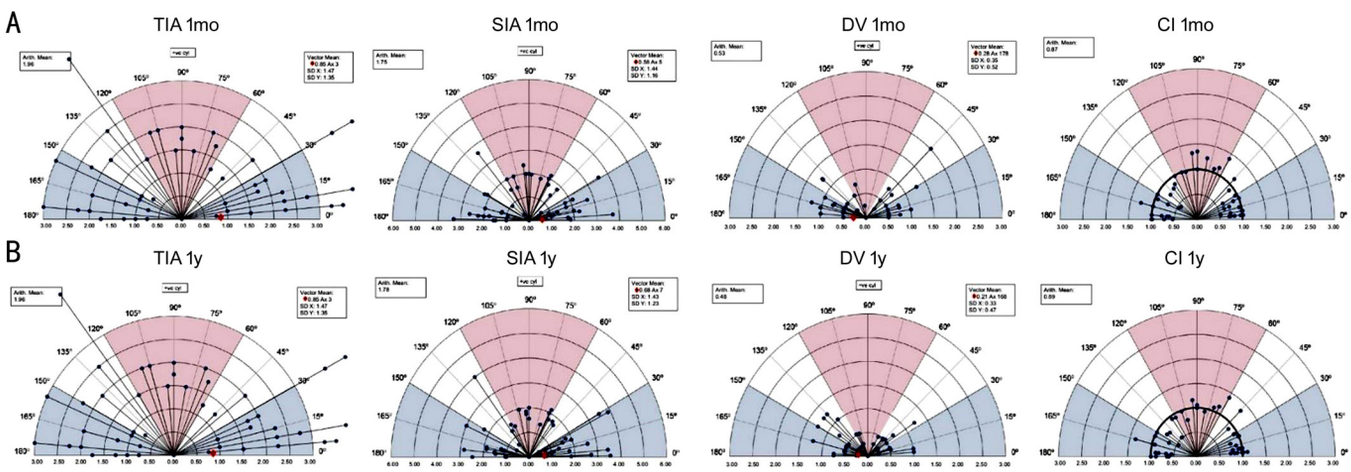

Figure 4 Vector analysis and representation for refractive astigmatism at 1mo (A) and 12mo (B) post-surgery TIA: Target induced astigmatism; SIA: Surgically induced astigmatism; DV: Difference vector; CI: Correction index.

whole follow up was 1.75±0.84 (range: 0.33 to 3.83) D and DV was 0.45±0.43 (range: 0 to 2.01) D at 1mo. At 12mo, SIA was 1.78±0.87 (range: 0.46 to 4.02) D and DV was 0.48±0.37 (range: 0 to 1.25) D. Difference between TIA and SIA was statistically significant at the visits (both P<0.001 at 1 and 12mo). Tendency of slightly under correction was found with CI of 0.87±0.22 (range: 0.46 to 1.40) and 0.89±0.19 (range: 0.46 to 1.40) at each visit. There were no statistically significant differences in SIA over the follow-up (P=0.102).

Applying vectorial analysis to corneal astigmatism over the follow-up (Figure 5), arithmetical mean corneal astigmatism was 1.72±0.94 D (range: 0.50 to 5.50 D; vector mean: 0.99×1º) preoperative and 1.78±0.97 D (range: 0.50 to 4.75 D; vector mean: 1.24×176º) and 1.82±0.93 D (range: 0.25 to 4.50 D; vector mean: 1.20×178º) at 1 and 12mo respectively. There were no statistically significant differences on corneal astigmatism over the follow-up (P=0.400 and 0.210 at 1 and 12mo respectively). Figure 6 summarises corneal astigmatism classification attending to astigmatism orientation over follow-up. The 70% of the eyes showed a preoperative WTR astigmatism and 14% and 16% of the eyes showed an ATR and oblique astigmatism respectively. At last visit, 82% of the eyes did not suffer a change in astigmatism orientation preoperatively. The rest of them, changed from ATR to oblique astigmatism (8%), from WTR to oblique astigmatism (2%) and from oblique to WTR astigmatism (8%). No significant changes in terms of corneal astigmatism orientation were reported over post-surgery visits (P=0.129 and 0.097 at 1 and 12mo respectively) therefore, the corneal astigmatism and corneal coupling analysis were done considering the distribution found at the preoperative visit when orientation is considered for the analysis. Table 2 shows the arithmetical mean values found over the follow-up for each astigmatism orientation. SIA_k was calculated from preoperative and postoperative SimK data and displayed in Figure 7. Arithmetical mean SIA_k was 0.72±0.65 D (range: 0.17 to 3.21 D; vector mean: 0.25×62º) and 0.59±0.53 D (range: 0.10 to 2.92 D; vector mean: 0.25×79º) at 1- and 12-month post-surgery. No statistically significant differences were found for SiA_k over the follow-up (P=0.195). A second analysis of SIA_k according to preoperative corneal astigmatism orientation distribution at last visit, is displayed in Figure 8. Arithmetical mean SIA_k was 0.65±0.66 D (range: 0.17 to 3.21 D; vector mean: 0.38×55º) and 0.56±0.59 D (range: 0.10 to 2.91 D; vector mean: 0.25×76º) at 1- and 12-month post-surgery for WTR corneal astigmatism. SIA_k over ATR and oblique astigmatism was not

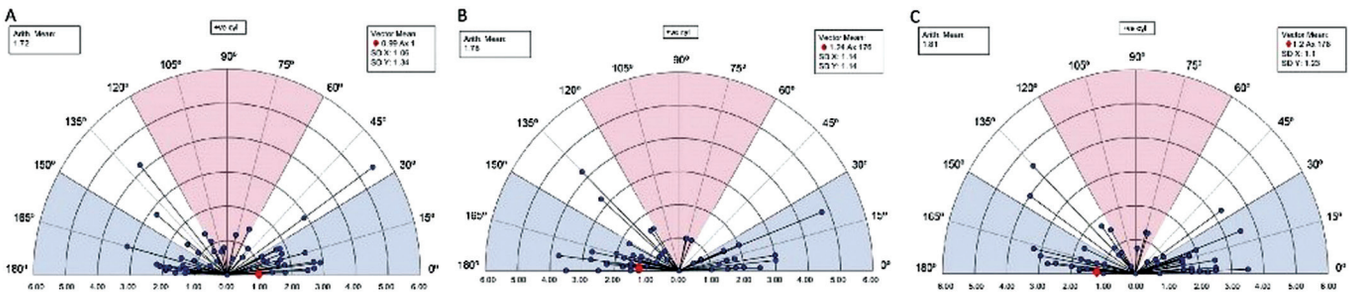

Figure 5 Corneal astigmatism analysis over the follow-up A: Preoperative; B: Postoperative 1mo; C: Postoperative 1y.

Table 2 Corneal astigmatism over the follow-up for each astigmatism orientation mean±SD (range), D

Astigmatism	Corneal astigmatism		
	Preoperative	Postoperative 1mo	Postoperative 1y
WTR (*n*=35)	1.79±0.51 (0.60, 3.20)	1.93±0.65 (0.50, 3.75)	1.93±0.62 (0.75, 3.50)
ATR (*n*=8)	0.80±0.29 (0.50, 1.50)	0.81±0.24 (0.50, 1.50)	0.68±0.43 (0.25, 1.50)
Oblique (*n*=9)	1.84±1.40 (0.50, 5.50)	1.75±1.16 (0.75, 4.75)	1.89±1.25 (0.75, 4.50)

SD: Standard deviation; WTR: Astigmatism with the rule; ATR: Astigmatism against the rule; D: diopters.

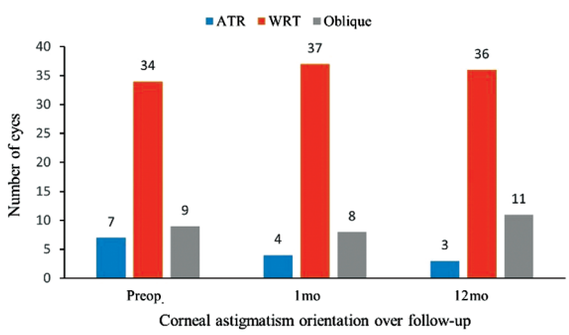

Figure 6 Description of corneal astigmatism orientation over follow-up: with the rule (WTR), against the rule (ATR), and oblique astigmatism.

considered for the analysis due to the low number of eyes (*n*=8 and 9 respectively).

Corneal coupling has been calculated using the CC and the CAdj following Alpins methodology[17] at 1y of treatment. The analyses were developed for WTR astigmatism due to the reduced sample size for oblique and ATR astigmatism. Due to this type of surgery, CAdj coincides with CC. A value of 0.04 for CC and Cadj was reached.

DISCUSSION

Astigmatism is a common refractive error that affects a significant percentage of the population, leading to defocusing and visual impairment. Currently, the T-ICL (STAAR Surgical, Niday, Switzerland) is widely used for myopic astigmatism correction and has been reported to be a predictable and safety option[8-9]. The V4c T-ICL model by the STAAR surgical Company has been the T-ICL under study. Refractive outcomes and keratometry astigmatism changes were analysed for this V4c T-ICL over 1y of follow-up post-surgery. Also, an analysis of corneal coupling was developed.

In the current study, the UDVA and CDVA values at final visit were about 0 logMAR or better for 78% and 84% of the eyes respectively according to previous reports at 1y post surgery[20]. Efficacy index of 1.05 and safety index of 1.12 were found. These results agree with previous study[21] but are slightly better than those reached by Moshirfar *et al*[22] who found values for both indices about 0.92 and 1.10 respectively with a V4 T-ICL model. About this discrepancy, Hyun *et al*[23] developed a study comparing both lenses showing that although the V4c T-ICL group seemed to show better visual outcomes than the V4c group there was no significant difference. Therefore, this study proves that V4c T-ICL keeps a good UDVA and CDVA over the follow-up (1y) in young people.

Regarding the predictability of T-ICLs, in this study, 96% of eyes were corrected within ±1.00 D of the attempted correction, and 84% were corrected within ±0.50 D at final visit. These results are according to previous studies. Hyun *et al*[23] found all eyes were within ±1.5 D and 87.5% of eyes within ±0.5 D. Zhao *et al*[24] showed 100% of eyes within ±1.00 D and 88.23% of eyes within ±0.50 D. Monteiro *et al*[14] found 80.5% eyes within ±0.50 D of the target and 94.6% eyes were within ±1.00 D. Even if, García-De la Rosa *et al*[25] reached 86% of eyes within ±1.00 D joint a 56% of eyes within ±0.50 D of the attempted correction being worse than those values achieved in the current study. The explanation may be due to differences in the study design that includes the range of SEQ (range: -22.25 to-7.00 D in Garcia-De la Rosa *et al*'s[25] study and -15.5 to -2.13 D in the current study). Furthermore, the predictability of V4c T-ICL in the current study was shown to be good and comparable with the previously reported.

In the current study, 78% of eyes had a remaining cylinder within ±0.50 D and 94% within ±1.00 D at 1y post-surgery and all eyes achieves a refractive cylinder ≤1.25 D according to the previous report[23]. Also, the arithmetical mean refractive cylinder was -0.48±0.37 (range: -1.25 to 0) D at last visit. The achieved results indicated that manifest astigmatism

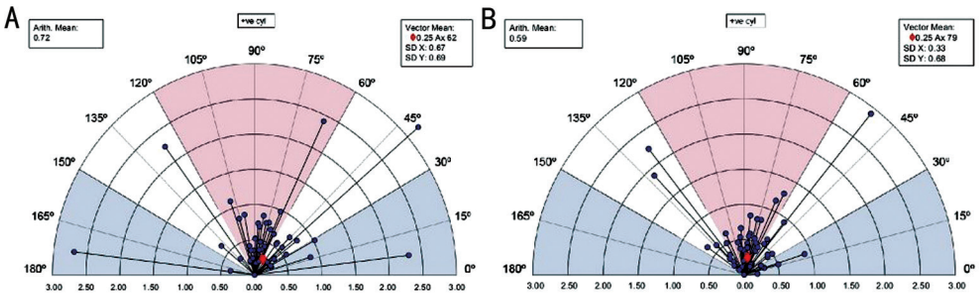

Figure 7 Surgical astigmatism induced (SIA_k) by main incision A: Postoperative 1mo; B: Postoperative 1y.

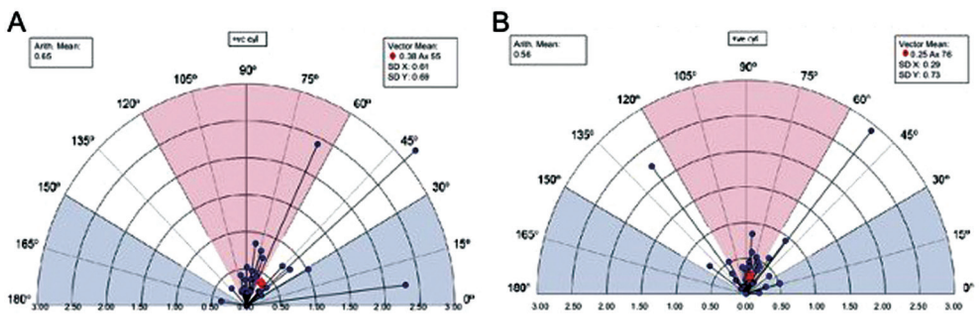

Figure 8 Surgical astigmatism induced (SIA_k) by main incision according with with-the-rule corneal astigmatism (WTR) A: Postoperative 1mo; B: Postoperative 1y.

was significantly reduced, but that approximately 0.50 D of astigmatic error remained after surgery at last visit. Same authors[13-14] found the same result with the Visian ICL™. Authors assumed that remaining manifest astigmatism can be largely attributed to the corneal astigmatism induced by the surgical technique.

To determine the effect of the T-ICL on astigmatic correction, vectorial analysis was performed using Alpins method[17]. Significant differences between TIA and SIA post-surgery were measured (P<0.001), remaining the magnitude of SIA stable over the follow-up. This finding is according to previous studies developed by Hyun *et al*[23] who found significant differences between TIA and SIA when comparing refractive outcomes between V4 and V4c T-ICL models. Monteiro *et al*[14] found the same significance when T-ICL was compared with toric iris-fixated foldable phakic intraocular lens (IOL). In addition, CI value lower than the unit was achieved at the last visit meaning an under correction with the chosen T-ICL. A trend toward under correction of refractive astigmatism was found previously by Lee *et al*[26] who have also reported that trend using vectorial analysis after T-ICL implantation.

To our knowledge, there are few studies to approach corneal astigmatism changes after T-ICL implantation[27] and even fewer when the lens used is the V4c T-ICL model. Following this approach, an analysis of the corneal astigmatism orientation changes at each visit was approached. The 35 eyes (70%) showed a preoperative WTR astigmatism while 7 eyes (14%) and 8 eyes (16%) showed an ATR and oblique astigmatism respectively. This result is according to a previous report[28] which reported that corneal astigmatism exhibits a higher proportion of WTR astigmatism in young people. At 1y of follow-up, 41 eyes (82%) did not suffer a change in astigmatism orientation preoperatively. Even if 4 eyes (8%) changed from ATR to oblique astigmatism, 1 eye (2%) changed from WTR to oblique astigmatism and 4 eyes (8%) changed from oblique to WTR astigmatism. Therefore, 38 eyes (76%) and 9 eyes (19%) showed WRT and oblique astigmatism respectively at final visit. Any orientation change to ATR astigmatism was found. This disagrees with those achieved by Shiga *et al*[27] who carried out long term outcomes (10y) with a T-ICL. In this study, 79% of cases changed to ATR astigmatism. Authors argued that ageing is the reason for this finding. The current study was followed over 1y, so this follow-up time is therefore not long enough for this change to be found. Furthermore, changes in terms of corneal astigmatism orientation were reported not to be statistically different at last visit (P=0.097). For this reason, only preoperative data was considered when corneal coupling analysis was done.

In the current study, 0.59±0.53 D (range: 0.10 to 2.92 D; vector mean: 0.26×73º) surgical induced astigmatism was found after 1y of follow-up. This result is according to those achieved by Kamiya *et al*[13] and Monteiro *et al*[14] who found T-ICL implantation induced corneal astigmatism through a with-the-rule astigmatic shift of approximately 0.50 D. Therefore, this can explain the remaining refractive cylinder measured at last visit post-surgery and which has already been raised in this report.

From refractive surgery to ICL implantation, many studies have approached the effect of the incision onto the cornea[10-12].

Alpins[17] developed a method to estimate the effect of the incision over the opposite meridian in order to give the surgeon a tool to correct the power of the lens to minimize the incision effect by CAdj. This coefficient estimates the spherical change that would have to be implemented in the lens to minimise the corneal coupling effect. In the current study, a CC of 0.04 for WTR astigmatism means that for every diopter change in astigmatism, there was a 0.04 D change in SEQ. The CAdj is the same for incision surgery therefore near to zero and consequently, the surgery went as planned and resulted in no unexpected spherical change. For ATR and oblique astigmatism, the sample size is very small, so that further studies with a large sample size of these preoperative types of astigmatism will be necessary to find conclusive results. On the other hand, it is important to note that the effect of corneal coupling depends on the nomogram used by each surgeon. However, it can be useful to achieve greater success in surgery. Moreover, no postoperative complications such cataract, endophthalmitis, toxic anterior segment syndrome, pigment dispersion, any form of glaucoma, retinal detachment, endothelial cell loss leading to corneal decompensation, sympathetic ophthalmia, traumatic rupture of the globe at the incision site, or infectious keratitis. have been found over the follow-up post-surgery. This result agrees with those found by Alfonso-Bartolozzi *et al*[29] that suggested that central hole of the V4c T-ICL model prevents cataract development. The effect of the hole in a ICL has already been described by previous authors[7] who reported that the increased aqueous humour outflow and the optimisation of the size hole has cataract-inhibiting effects. Albo *et al*[30] developed a single-center retrospective study with EVO and EVO+ implantation in 225 eyes. In this study, authors did not observe any of the postoperative complications listed before and concluded that the ICL maintain the eye's structural and physiological integrity. Zhu *et al*[31] developed an study to investigate changes in macular vessels and thickness in astigmatic eyes after T-ICL implantation. Authors concluded that T-ICL implantation is safe although macular area changes that occur after surgery need attention. The achieved result shows the safety of this model. The study has some limitations. First, the distribution of the different types of preoperative corneal astigmatism attending to orientation requires a larger number of eyes with ATR and oblique astigmatism to ensure that surgery was performed as planned when corneal coupling was estimated. Moreover, the analysis of the corneal coupling has to be performed for each surgeon's nomogram, and the reached results cannot be extended to all surgeons. In conclusion, V4c T-ICL implantation has been proved to be effective, safe and predictable regarding refractive outcomes one-year post-surgery for correcting myopia astigmatism. After corneal astigmatism analysis, main incision induces a SIA of around 0.50 D which can explain the mean remained refractive cylinder found. No clinical significance of the corneal coupling induced by the surgery was found for preoperative WTR astigmatism therefore the surgery went as planned and resulted in no unexpected spherical change. However, it is advisable to expand the study with more eyes to extract conclusions over corneal coupling in ATR and oblique astigmatism. It is important to note that corneal coupling is an effect associated with the incision and therefore with the surgical technique used. The corneal coupling's effect will depend on the nomogram used by each surgeon.

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