• Clinical Research •

Comparison of toric implantable collamer lens alignment accuracy: VERION image-guided system versus manual marking

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Abstract

● **AIM:** To compare the accuracy of manual marking versus an image-guided system for toric implantable collamer lens (TICL) implantation and evaluate the short-term postoperative rotational stability of TICL and corneal surgically induced astigmatism vector (SIA).

● **METHODS:** Retrospective analysis was conducted on eyes with TICL alignment achieved through manual marking (n=75) or VERION image-guided system-assisted marking (n=83). Each group was further classified into horizontal and vertical subgroups based on implant orientation. Additionally, patients were categorized into superior and temporal incision subgroups according to the position of main corneal incision. The misalignment and rotational stability of TICL were analyzed using slit-lamp anterior segment photography. Surgical predictability, efficacy, safety, and corneal SIA were also evaluated.

● **RESULTS:** In general, the TICL implantation with manual and digital image-guided systems all achieved robust predictability, efficacy, and safety. The misalignment of TICL was comparable between the manual and VERION groups (0.16°±3.97° *vs* 0.52°±5.59°, P=0.633), while a significant difference was observed in the absolute misalignment of TICL between the two groups (3.02°±2.55° *vs* 4.28°±3.61°, P=0.043). There were no significant differences in the distribution of TICL misalignment between the manual and VERION groups or between horizontal and vertical implant orientation groups (P>0.05). Furthermore, different orientations of TICL placement did not show statistically significant differences in rotational stability (P=0.46). Statistically significant differences were found in anterior corneal SIA between the manual and VERION groups (0.46±0.27 *vs* 0.33±0.21 D, P=0.001), especially for superior incision position (0.60±0.27 *vs* 0.35±0.23 D, P<0.0001). The anterior SIA exhibited a significant difference between superior and temporal incisions in the manual group (0.60±0.27 *vs* 0.35±0.20 D, P<0.0001).

● **CONCLUSION:** Compared with the conventional manual marking method, this study indicates that the digital image-guided system with VERION is safe and effective in TICL implantation. The digital system offers the advantage of minimizing corneal SIA compared to the manual method.

● **KEYWORDS:** toric implantable collamer lens; misalignment; rotational stability; surgically induced astigmatism; digital marking; VERION

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INTRODUCTION

Recently, toric central-hole implantable collamer lenses (TICLs; Visian ICL V4c, EVO models; STAAR Surgical Company), a phakic posterior chamber intraocular lens (IOL), have gained widespread usage in correcting myopic astigmatism up to 6.00 D and myopic spherical equivalence up to 18.00 D. Multiple studies have demonstrated the efficacy and safety of TICL implantation for correcting myopic astigmatism[1-4]. Along with a suitable vault following implantation, accurate intraoperative TICL axis alignment and postoperative rotational stability of the TICL are essential for successful TICL implantation. Previous research has shown that off-axis rotation of 10° can reduce the astigmatic flattening effect by approximately 6%, while off-axis rotation of 30° can result in a shift of preoperative astigmatism axis by as much as 30° without any change in magnitude[5-7]. Therefore, precise TICL axis alignment is critical for archiving optimal surgical outcomes.

To ensure precise alignment of TICL, marking the implantation axis is a crucial step. As ocular cyclotorsion invariably occurs when a patient transitions from an upright seated position to a supine position, the marking process should be completed preoperatively while in a seated position. Manual marking of the eye's horizontal meridian (0 to 180°) under slit-lamp guidance with a rotatable slit is a simple and commonly used method for correcting posture-related cyclotorsion. However, this manual marking method has limitations including being labor-intensive, causing patient discomfort, potentially harming the corneal epithelium, and introducing subjective errors. With advancing technology, several digital image-guided systems have been developed to overcome these limitations and particularly reduce the subjective errors associated with manual marking. The digital image-guided systems can automatically recognize the ocular feature and mark the implantation position of TICL axis, significantly facilitating the surgery. The VERION image-guided system (Alcon, Fort Worth, TX, USA), Truevision 3-dimensional (3D) computer guided visualization system (True Vision Systems, Inc., USA), and Callisto Eye System (Carl Zeiss Meditec AG, Jena, Germany) have been utilized in cataract surgery with toric IOL placement and demonstrated accurate alignment achievement along with streamlined workflow resulting in satisfactory outcomes[8-11]. Regarding phakic IOLs specifically, the Callisto Eye System has proven its efficacy and safety for toric marking by yielding similar visual and refractive outcomes compared to the slit-lamp manual marking method[12]. However, the digital guided approach also presents drawbacks such as high equipment costs and potential limitations in recognizing and registering ocular features effectively. The accuracy of axis orientation, visual and refractive outcomes of TICL implantation using the image-guided VERION system were investigated by Emerah[13], without a control group. To our knowledge, there is currently no reported comparison of postoperative outcomes between TICL implantation surgeries using the image-guided VERION system versus manual marking. Therefore, it would be valuable to assess the overall performance of these two approaches, particularly in TICL implantation surgery.

Given the current availability of only four sizes of TICL, separated by 0.5 mm increments, surgeons must carefully plan the orientation for TICL implantation to achieve optimal postoperative vault and avoid improper direct contact between the TICL footplates and iris cysts. This emphasizes the crucial role of accurate intra-operative alignment during implantation and ensuring rotational stability postoperatively in different placement orientations such as vertical, horizontal, and oblique. Furthermore, specific TICL implant orientations require surgeons to make corneal incisions in various directions to minimize intraoperative rotation angles. It is worth noting that surgically induced astigmatism vector (SIA), resulting from these corneal incisions made in different directions, may also significantly impact the outcome of TICL implantation.

In this study, we aimed to compare the accuracy of TICL axis alignment and postoperative outcomes between the digital image-guided system by VERION and traditional slit-lamp manual marking methods. Besides, to further analyze the factors which may influence the validity of TICL surgery, the short-term rotational stability of TICL with different implant orientations and the corneal SIA with varied positions of the main corneal incision were also evaluated. Our work ought to be contributory to optimize the efficacy of TICL surgery in terms of TICL axis marking method, implant orientation design and astigmatic diopter selection, *etc*.

PARTICIPANTS AND METHODS

Ethical Approval The present study utilized retrospective data from patients who underwent bilateral phakic IOL implantation on the same day at the Eye Center, Second Affiliated Hospital, Zhejiang University, Hangzhou, China. Approval for this study was obtained from the hospital's ethics committee (approval number: 2023-0444) and it adhered to the principles outlined in the Declaration of Helsinki.

The enrollment eligibility criteria were as follows: 1) age 18-45y; 2) myopic (-0.50 to -18.00 D) with astigmatic (-0.50 to -6.00 D) and spherical equivalent refraction (SER)≥-18.00 D; 3) stable refraction for a minimum of 2y (no increase in refraction greater than 0.50 D per year); 4) anterior chamber depth (ACD)≥2.80 mm; 5) corneal endothelial cell density (ECD)≥2000 cell/mm²; 6) clear crystalline lens. Patients with the following conditions were excluded from the study: 1) history of ocular trauma and previous ocular surgery; 2) presence of coexisting ocular diseases, including severe dry eyes, keratoconus or topographic suspicions of keratoconus, glaucoma or suspected glaucoma, uveitis, and retinopathy; 3) pregnancy or breastfeeding; 4) presence of systematic diseases that may interfere with corneal healing, such as diabetes mellitus and connective tissue disorders.

All patients underwent a comprehensive ophthalmologic examination prior to surgery, which included slit-lamp biomicroscopy, intraocular pressure (IOP), manifest and cycloplegic refraction, uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), ECD, tear break-up time, ultrasound B scan, and fundus photography. Corneal tomography (Pentacam HR, Oculus Optikgerate GmbH) was employed for measuring white-to-white (WTW), ACD, and corneal astigmatism. Axial length (AL) was measured with optical biometry (IOLMaster 700, Carl Zeiss Meditec AG). The sulcus-to-sulcus (STS) and ciliary body morphology were examined using ultrasound biomicroscopy (UBM, Model SW 3200L, Tianjin Suowei Electronic Technology Co., Ltd., China). Patients were instructed to refrain from wearing soft contact lenses for at least 1wk, rigid gas-permeable contact lenses for at least 1mo, and orthokeratology lenses for at least 3mo before undergoing the preoperative examination.

Based on preoperative examinations and utilizing the STAAR surgical calculator as the primary guide, the surgeon determined both the size and implantation orientation of TICL. In cases where subjective astigmatism exceeded 0.75 D or if correction of astigmatism could achieve a CDVA improvement beyond 2 lines, TICL was selected.

Preoperative Slit-Lamp Manual Marking Method Patients were instructed to lay their jaw on the chin rest and forehead against the strap, look straight ahead, and have the slit beam positioned horizontally at their corneal apex. The horizontal meridian was marked with a subcutaneous needle scratch at the limbus, which was then stained with a sterile blue marker.

Preoperative VERION Image-Guided System Marking Method Patients were instructed to fix their gaze on the target while their chin and forehead were supported by rests. The imaging device of the reference unit captured an image of the eye, recording measurements such as limbus, pupillary diameter, pupillary position, and corneal reflex. During surgery, the digital marker aligns conjunctival vasculature, limbus, and iris structures with previously measured parameters from the reference unit to correct posture-related cyclotorsion.

Surgical Procedures All surgeries were performed by the same experienced refractive surgery specialist (Han W) under topical anesthesia and aseptic conditions. The pupil was dilated with tropicamide phenylephrine eye drops 30min before surgery. After topical anesthesia with 0.5% proparacaine hydrochloride, 0.6 mm side-port incisions were made at either 9 o'clock (vertical implantation for right or left eye), 6 o'clock (horizontal implantation for the right eye), or 12 o'clock (horizontal implantation for the left eye) and 2.8 mm clear main corneal incisions were made at either 12 o'clock (vertical implantation) or 3/9 o'clock (horizontal implantation). TICL was then implanted using an injector cartridge through the main incision, followed by injection of a moderate viscoelastic device into the anterior chamber. Each flexible footplate of TICL was positioned in the ciliary sulcus using a TICL manipulator, and subsequently rotated to achieve the desired axis alignment. In the manual group, angular graduation instrument verified TICL axis alignment, while in the VERION group, VERION digital-guidance system displayed and aligned TICL axis with intended axis shown in microscopy field. After washing out viscoelastic device from anterior chamber using a balanced salt solution, all incisions were hydrated without stitch applied. Final verification of lens centration and alignment was conducted after incision hydration.

After surgery, patients received tobramycin dexamethasone eye drops four times daily for 1wk, followed by tapered fluorometholone eye drops (0.1%) for 3wk. Artificial tears (0.3% sodium hyaluronate) were used four times daily for 3mo. Follow-up examinations were scheduled at 1wk and 1mo after the surgery. Each clinical visit included slit-lamp biomicroscopy, IOP measurement, UDVA and CDVA assessment, anterior segment optical coherence tomography (AS-OCT, SS-1000 CASIA, Tomey Corp.), and slit-lamp anterior segment photography. Corneal tomography (Pentacam HR) was performed at the 1-month follow-up visit.

Measurement of TICL Rotation After the pupil was dilated, patients sat with their head supported by a forehead- and chin-rest and looked straight ahead. Six photographs were taken per eye to capture the anterior segment. The photographs of the anterior segment were processed and analyzed using Image J, developed at the National Institutes of Health (NIH; Figure 1). To eliminate fixation errors, participants blinked and looked straight ahead again after each measurements. At least three photographs with six measurements differing within 1 degree were averaged for subsequent analysis. Negative misalignment indicates clockwise rotation of the achieved TICL axis compared to the intended axis, while positive misalignment indicates counter-clockwise rotation. The mean of three measurements was used for analysis.

Statistical Analysis The astigmatic vectorial analysis were calculated with the method described by Alpins and Goggin[14], which included calculating SIA, the target induced astigmatism vector (TIA), correction index (CI), difference vector (DV), and angle of error. Statistical analysis was conducted using SPSS (version 21.0, IBM Corp.). Data were presented by mean±standard deviation (SD). The Shapiro-Wilk test was used to access data normality. Pearson's Chi-square test was used for categorical variables. Student's *t*-test or Mann-Whitney *U* test was used for group-wise comparisons. The paired-sample *t*-test was utilized to compare pre- and post-operative parameters. A *P* value less than 0.05 indicated statistically significant.

RESULTS

Altogether 75 eyes of 47 patients for the manual group and 83 eyes of 50 patients for the VERION group were recruited, respectively. No statistical significance in the basic clinical characteristics and parameters was observed between the two groups, with exception of age, IOP, ECD, and WTW (Table 1).

Predictability Figures 2A1 and 2A2 displayed scatterplots of attempted versus achieved SER corrections for the manual and VERION groups. At 1mo postoperatively, all SER achieved

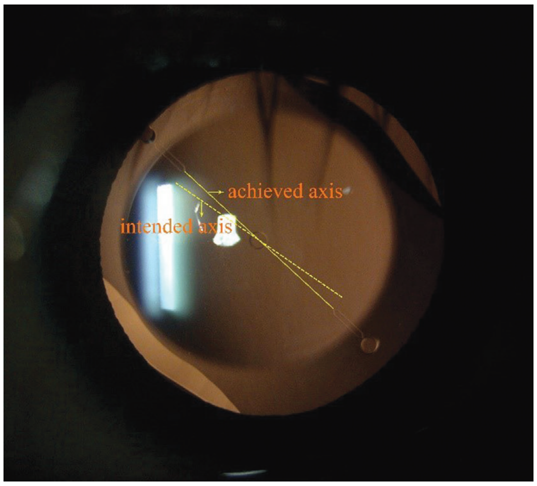

Figure 1 Anterior segment photograph after TICL implantation TICL: Toric implantable collamer lens.

Table 1 Group-wise comparison of baseline and postoperative parameters

Parameters	Manual (*n*=75)	VERION (*n*=83)	*P*
Age (y)	26.47±6.25	28.22±5.73	0.029
Gender, *n* (%)			0.287
Male	22 (29.33)	31 (37.35)	
Female	53 (70.67)	52 (62.65)	
TICL size, %			
12.1/12.6/13.2/13.7	11/51/36/3	12/34/46/8	
TICL implanted orientation, %			
Horizontal/vertical/oblique	45/37/17	67/30/2	
Corneal optical data			
Anterior cornea			
Astigmatism magnitude (D)	1.93±0.83	1.84±0.61	0.813
Posterior cornea			
Astigmatism magnitude (D)	-0.45±0.16	-0.44±0.13	0.825
Spherical diopter (D)	-8.64±2.96	-8.39±2.27	0.564
Cylindrical diopter (D)	-1.8±0.8	-1.73±0.73	0.777
Spherical equivalence (D)	-9.54±2.97	-9.26±2.24	0.512
IOP (mm Hg)	15.40±2.94	14.47±2.76	0.030
ACD (mm)	3.25±0.25	3.3±0.25	0.172
WTW (mm)	11.56±0.41	11.72±0.4	0.006
AL (mm)	27.11±1.43	27.38±1.55	0.296
ECD (cell/mm²)	2655.8±213.17	2736.95±218.82	0.020
CCT (μm)	520.4±32.49	517.41±35.38	0.509
Postoperative 1wk			
Misalignment (°)	0.16±3.97	0.52±5.59	0.633
Absolute misalignment (°)	3.02±2.55	4.28±3.61	0.043

ACD: Anterior chamber depth; AL: Axial length; CCT: Central corneal thickness; D: Diopter; ECD: Endothelial cell density; IOP: Intraocular pressure; WTW: White-to-white; TICL: Toric implantable collamer lens.

were within 1.0 D of the attempted SER. The postoperative SER was within ±0.50 D in 74 of 75 eyes (98.67%) in the manual group and in 79 of 83 eyes (95.18%) in the VERION group (Figures 2C1 and 2C2), with no statistically significant difference between the two groups (*P*=0.093). Moreover, refractive astigmatism within ±0.50 D was achieved by 74 out of 75 eyes (98.67%) in the manual group, while all eyes achieved it within ±1.00 D as well; similarly, in the VERION group, refractive astigmatism within ±0.50 D was attained by 79 out of 83 eyes (95.18%), and 82 out of 83 eyes (98.8%) achieved within ±1.00 D (Figure 2E1 and 2E2).

Efficacy In the manual group, all eyes and 82 of the 83 eyes (98.8%) in the VERION group had at least the same postoperative UDVA as preoperative CDVA (Figures 2B1 and 2B2). The UDVA (logMAR) was similar between the manual group (0.004±0.088) and VERION group (-0.018±0.082) with no significant difference (*P*=0.14). The efficacy index (a ratio of postop-UDVA/preop-CDVA) at the last follow-up visit was 1.05±0.15 in the manual group and 1.09±0.21 in the VERION group (*P*=0.247).

Safety The surgeries were uneventful with no complications such as cataract formation or glaucoma observed. The mean postop-CDVA (logMAR) was -0.005±0.083 in the manual group, and -0.036±0.060 in the VERION group (*P*=0.008). The safety index (a ratio of postop-CDVA/preop-CDVA) was 1.07±0.14 for the manual group and 1.13±0.17 for the VERION group (*P*=0.016). One month postoperatively, both groups showed no loss of CDVA (Figures 2D1 and 2D2). In the manual group, 54 eyes (72.0%) had no change in CDVA, 15 eyes (20.0%) gained one line, 5 eyes (6.7%) gained two lines, and only one eye (1.3%) gained three lines (Figure 2D1). In the VERION group, 43 eyes (51.8%) exhibited no change in CDVA, while 29 eyes (34.9%) gained one line, 10 eyes (12.1%) gained two lines, and only one eye (1.2%) gained 3 lines (Figure 2D2).

Vectorial Analysis of Astigmatism Scatterplots of SIA magnitude versus TIA magnitude at 1mo postoperatively were presented in Figures 3A1 and 3A2 showed for the manual and VERION groups. The polar display of SIA (Figure 3B1 and 3B2), TIA (Figure 3C1 and 3C2), and DV (Figure 3F1 and 3F2) for both groups, along with their arithmetic and vector means, were depicted in Figure 3. The manual group exhibited an arithmetic mean SIA of 1.42 D, while the VERION group showed a mean of 1.37 D. The vector means for SIA were calculated as 1.20×178 in the manual group and as 1.12×178 in the VERION groups. In terms of TIA, the manual group had an arithmetic mean of 1.45 D compared to a mean of 1.41 D in the VERION group; corresponding vector means were determined as 1.19×178 and 1.16×179 in the manual and VERION groups, respectively. The arithmetic means of DV were 0.11 D in both groups, while the vector means of DV were 0.02×129 and 0.05×13 in the manual and VERION groups, respectively. The CI for both groups were found to be 0.98. Moreover, in the manual group, a total of 85% eyes (64 eyes) achieved an angle of error within 5°, whereas in the VERION group, this percentage was slightly lower at 84% (70 eyes).

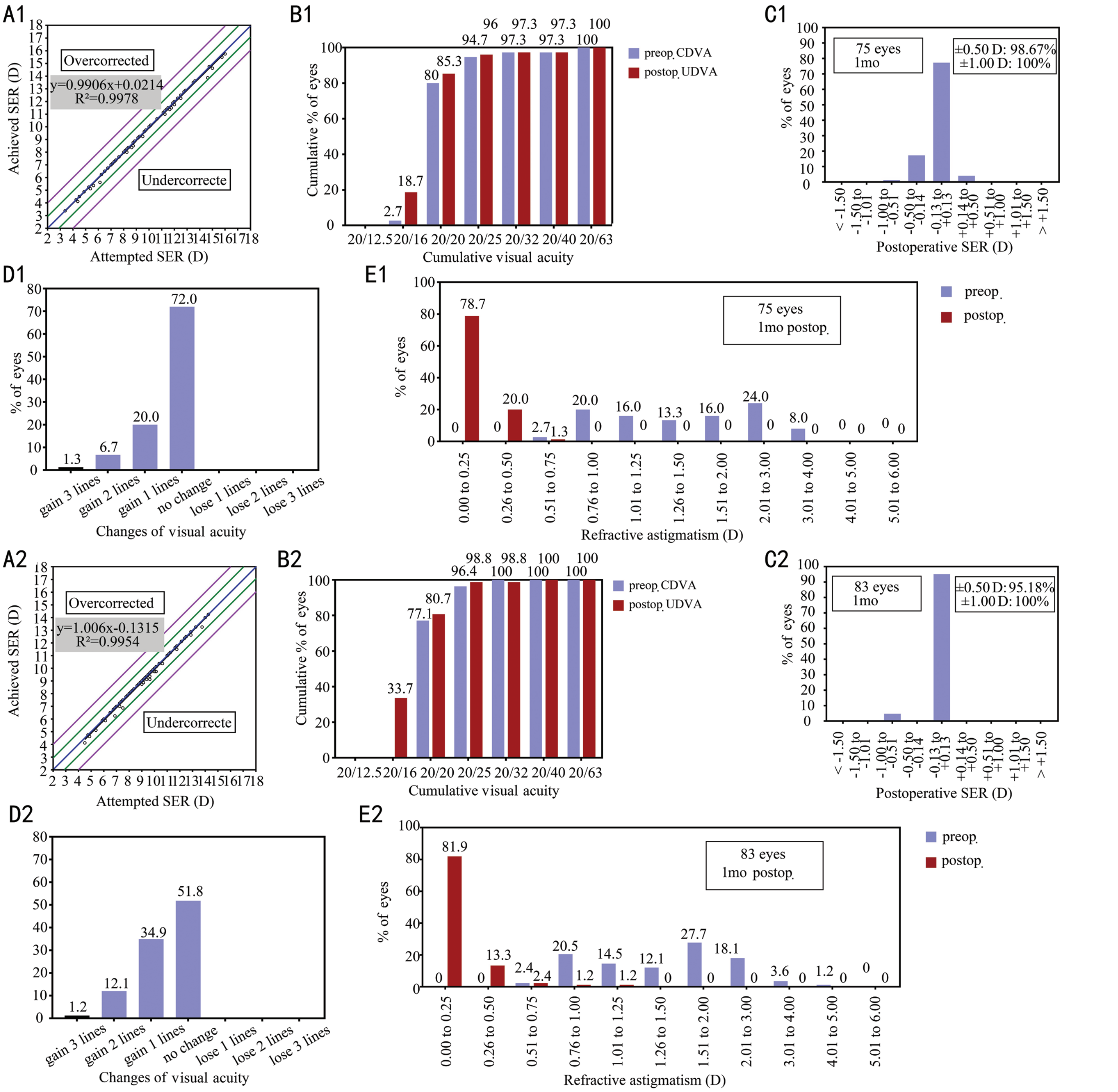

Figure 2 Refractive outcomes at 1mo after TICL implantation using the VERION image-guided system (the VERION group) and the slit-lamp manual marking methods (the manual group) A1, A2: Attempted versus achieved SER in the manual (A1) and VERION (A2) groups; B1, B2: Cumulative preoperative CDVA, postoperative UDVA, and postoperative CDVA in the manual (B1) and VERION (B2) groups; CI, C2: Postoperative SER in the manual (C1) and VERION (C2) groups; D1, D2: Changes in visual acuity postoperatively in the manual (D1) and VERION (D2) groups; E1, E2: Distribution of pre- and postoperative refractive astigmatism in the manual (E1) and VERION (E2) groups. TICL: Toric implantable collamer lens; SER: Spherical equivalent refraction; UDVA: Uncorrected distance visual acuity; CDVA: Corrected distance visual acuity.

TICL Axis Misalignment At 1wk postoperatively, the VERION group exhibited a statistically higher absolute misalignment of the TICL axis compared to the manual group (4.28°±3.61° *vs* 3.02°±2.55°, *P*=0.043). However, there was no significant difference in TICL axis misalignment between both groups (0.52°±5.59° *vs* 0.16°±3.97°, *P*=0.633; Table 1). Figure 4A illustrates the distribution of TICL axis misalignment, with approximately 78% of eyes (59 eyes) in the manual group and 66% of eyes (55 eyes) in the VERION group showing misalignment within ±5°; similarly, around 97% of eyes (73 eyes) in the manual group and 93% (77 eyes) in the VERION group showed misalignment within ±10° (Tables 2 and 3). There was no statistically significant difference between the manual and VERION groups in the

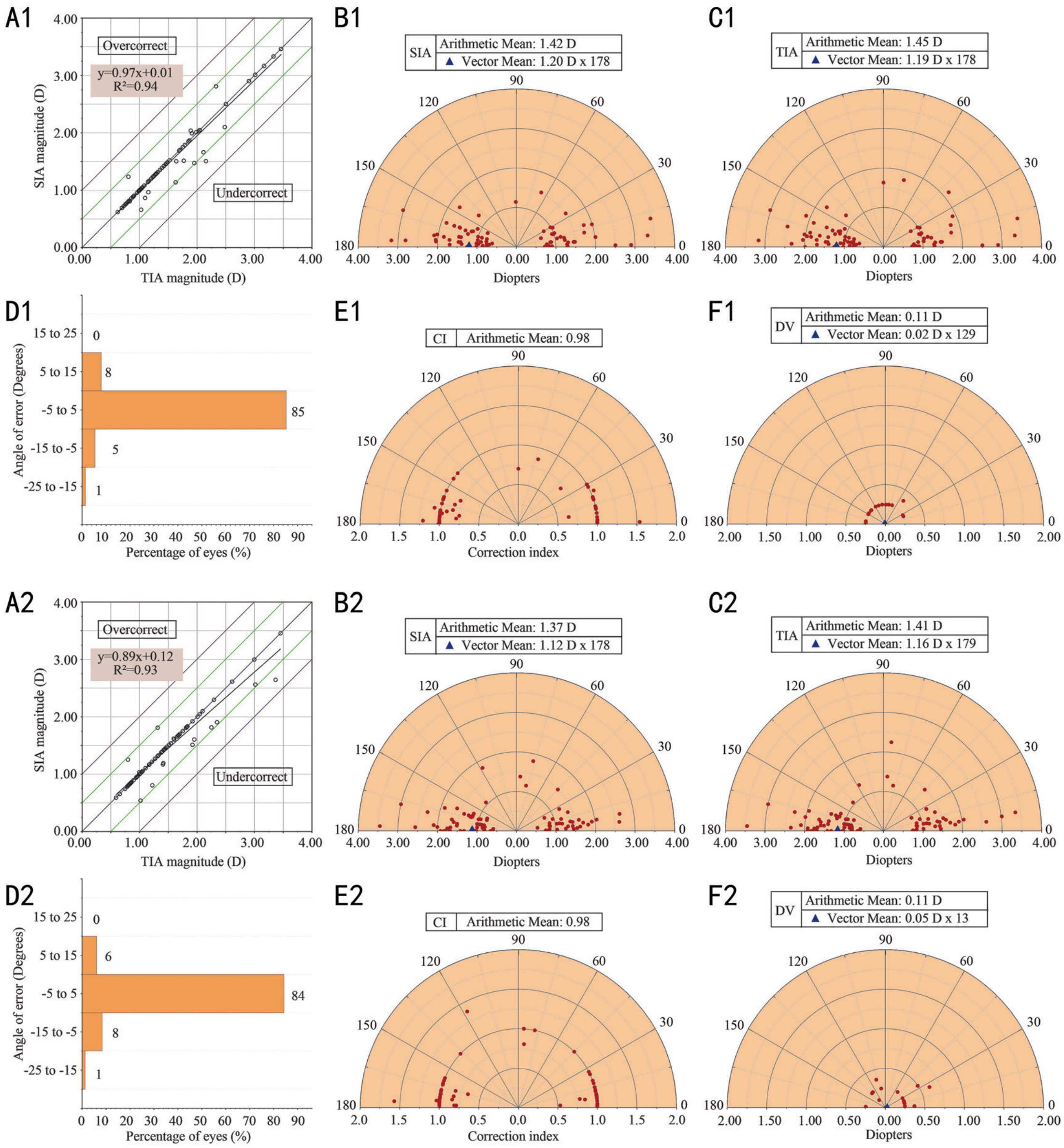

Figure 3 Vectorial analysis of astigmatism A1: Scatterplot of surgically induced astigmatism vector (SIA) magnitude versus target induced astigmatism vector (TIA) magnitude in the manual group; B1: Polar display of SIA in the manual group; C1: Polar display of TIA in the manual group; D1: Distribution of angle of error in the manual group; E1: Correction index (CI) in the manual group; F1: Polar display of difference vector (DV) in the manual group; A2: Scatterplot of SIA magnitude versus TIA magnitude in the VERION group; B2: Polar display of SIA in the VERION group; C2: Polar display of TIA in the VERION group; D2: Distribution of angle of error in the VERION group; E2: CI in the VERION group; F2: Polar display of DV in the VERION group.

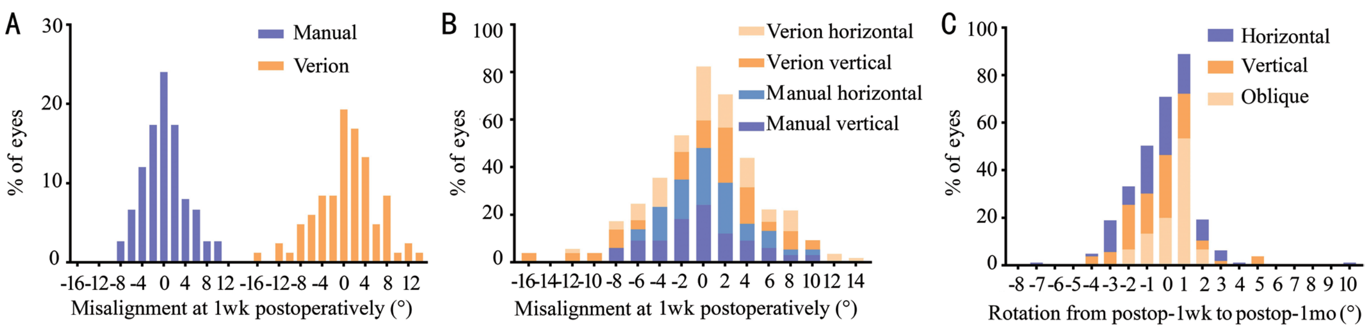

Figure 4 Distribution of misalignment at 1wk postoperatively under different grouping condition A: The distribution of misalignment at 1wk postoperatively in the manual and VERION groups; B: The distribution of misalignment at 1wk postoperatively grouped by TICL implant orientation; C: Rotational stability from 1wk to 1mo postoperatively in groups with different TICL long-axis positions at postoperative 1wk. TICL: Toric implantable collamer lens.

Table 2 TICL axis misalignment distribution at 1wk postoperatively *n* (%)

Groups	<-10°	-10° to -5°	-5° to 0	0 to 5°	5° to 10	>10°	*P*
Manual	0	7 (9)	31 (41)	28 (37)	7 (9)	2 (3)	0.160
Vertical	0	5 (15)	14 (41)	11 (32)	3 (9)	1 (3)	
Horizontal	0	2 (5)	17 (41)	17 (41)	4 (10)	1 (2)	
VERION	3 (4)	10 (12)	21 (25)	34 (41)	12 (14)	3 (4)	0.627
Vertical	2 (8)	4 (15)	4 (15)	12 (46)	4 (15)	0	
Horizontal	1 (2)	6 (11)	17 (30)	22 (39)	8 (14)	3 (5)	

TICL: Toric implantable collamer lens. Manual *vs* VERION (*P*=0.422).

distribution of TICL axis misalignment (*P*=0.422) and absolute axis misalignment (*P*=0.071; Tables 2 and 3). Furthermore, our study identified 8 eyes (5%) that exhibited absolute TICL misalignment >10°, 2 eyes (25%) were from the manual group and 6 eyes (75%) were from the VERION group. The manual group exhibited absolute TICL misalignment of 10.021° and 10.095° for the two eyes, whereas in the VERION group, the range of absolute TICL misalignment was between 11.648° and 15.313°, indicating a higher degree of misalignment compared to the manual group. Table 4 presents details on implanted orientation, main corneal incision position, misalignment, preoperative refraction and postoperative refraction for eyes with absolute TICL misalignment exceeding 10° at 1wk postoperatively.

Considering the TICL implantation with different orientations (horizontal or vertical), patients were divided into four groups: 1) VERION horizontal group, 2) VERION vertical group, 3) Manual horizontal group, and 4) Manual vertical group (Figure 4B). Both VERION and manual groups showed no significant differences in distributions of misalignment or absolute misalignment between the vertical and horizontal implant orientations (Figure 4B, Tables 2 and 3).

TICL Rotation Stability To assess the rotational stability of TICL, the rotation angle was analyzed between 1wk and 1mo after surgery. Based on the long axis position of the TICL at 1wk postoperatively, three subgroups were categorized as follows: horizontal group (deviation of TICL's long axis from the horizontal meridian ≤22°), vertical group (deviation of TICL's long axis from the vertical meridian ≤22°), and oblique group (deviation of TICL's long axis from both horizontal and vertical meridian >22°).

In total, 88 eyes (97.8%) in the horizontal group showed a rotation within ±5°, while all eyes in the vertical and oblique groups exhibited a rotation within ±5°. No statistically significant difference was observed among the groups (*P*=0.46; Figure 4C).

Parameters of eyes with TICL rotation >5° at postoperatively 1mo were showed in Table 5 and the corresponding UBM examination were showed in Figure 5.

Corneal SIA Figure 6 illustrates the anterior and posterior corneal SIA in both the manual and VERION groups. This study provides both arithmetic and vector means of SIA. The anterior corneal SIA in the manual group (arithmetic means: 0.46±0.27 D, vector means: 0.14@33) was significantly greater than that in the VERION group (arithmetic means: 0.33±0.21 D, vector means: 0.05@172; *P*=0.001). However, there was no significant difference between groups for posterior corneal SIA (arithmetic means: 0.11±0.07 *vs* 0.09±0.05 D, manual *vs* VERION group, *P*=0.15, vector means: 0.01@126 *vs* 0.02×@76). Based on the location of the main corneal incision, patients were further categorized into two subgroups: a superior group with a main incision at 12 o'clock and a temporal group with a main incision at 3 or 9 o'clock. For the manual group, the superior incision group showed statistically higher anterior corneal SIA compared to the temporal incision group (arithmetic means: 0.60±0.27 *vs* 0.35±0.20 D, *P*<0.0001, vector means: 0.45@25 *vs* 0.16@101; Figure 6A). However, there were no significant differences in posterior corneal SIA between the temporal and superior incision groups (arithmetic means: 0.11±0.06 *vs* 0.12±0.07 D, *P*=0.496, vector means: 0.05@17 *vs* 0.08@114; Figure 6B). For the VERION group, no significant differences were observed between the superior and temporal incision groups in terms of both anterior corneal SIA and posterior corneal SIA (anterior corneal SIA: arithmetic means: 0.35±0.23 *vs* 0.33±0.20 D, *P*=0.617, vector means: 0.28@19 *vs* 0.18@100; posterior corneal SIA: arithmetic means: 0.11±0.06 *vs* 0.09±0.05 D, *P*=0.066, vector means: 0.07@118 *vs* 0.05@9; Figures 5C and 5D). Additionally, the anterior corneal SIA was significantly higher in the manual group's in superior incision subgroup than that in the VERION

Table 3 The TICL axis absolute misalignment distribution at 1wk postoperatively *n* (%)

Groups	0-5°	5°-10°	>10°	*P*
Manual	59 (79)	14 (19)	2 (3)	0.316
Vertical	25 (74)	8 (24)	1 (3)	
Horizontal	34 (83)	6 (15)	1 (2)	
VERION	55 (66)	22 (27)	6 (7)	0.517
Vertical	16 (62)	8 (31)	2 (8)	
Horizontal	39 (68)	14 (25)	4 (7)	

TICL: Toric implantable collamer lens. Manual *vs* VERION (*P*=0.071).

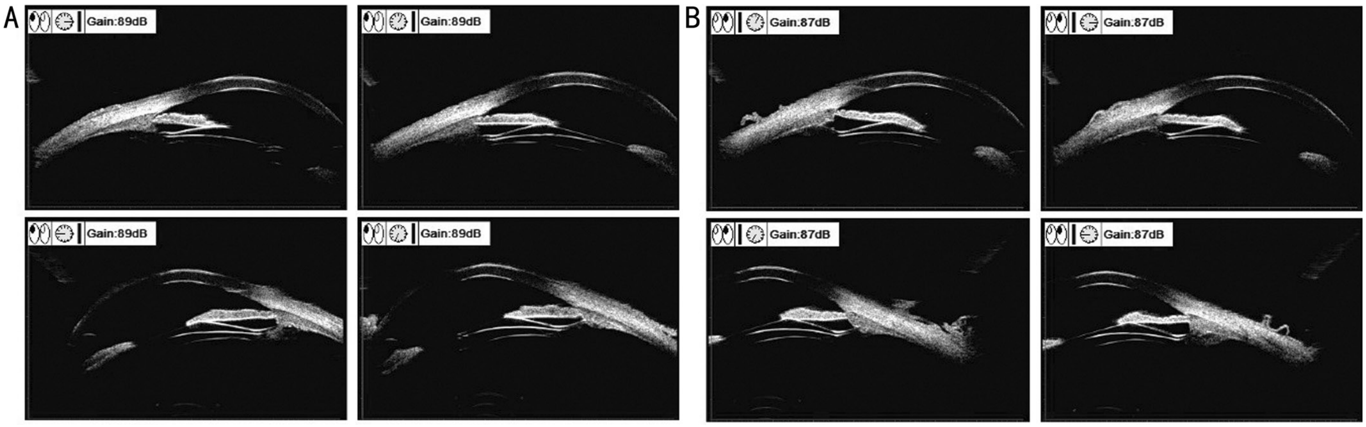

Figure 5 The report of postoperative UBM examinations of eyes with rotation >5° from postoperative 1wk to 1mo at postoperatively 1mo A: Eye 1; B: Eye 2. UBM: Ultrasound biomicroscopy.

Table 4 Parameters of eyes with absolute TICL misalignment >10° at postoperatively 1wk

No.	Marking method	Eye	Implanted orientation	Main corneal incision position	Misalignment (°)	Preop-refraction	Postop-refraction
1	Manual	OS	Vertical	Superior	10.021	-7.50/-1.25×28=1.0	pl=1.5
2	Manual	OD	Horizontal	Temporal	10.095	-6.25/-1.75×5=1.0	pl=1.0
3	VERION	OD	Horizontal	Temporal	12.917	-6.50/-1.00×175=1.0	pl=1.2
4	VERION	OS	Horizontal	Temporal	12.084	-5.50/-0.75×180=1.0	pl=0.8, -0.50×169=1.0
5	VERION	OD	Vertical	Superior	-15.373	-4.50/-1.75×12=1.0	pl=1.0
6	VERION	OD	Horizontal	Temporal	-11.649	-3.25/-2.50×85=1.0	pl=0.8, -0.75×106=1.0
7	VERION	OD	Vertical	Superior	-12.678	-7.75/-3.75×7=0.8+	pl=0.9, -1.00×40=1.0+
8	VERION	OS	Horizontal	Temporal	13.455	-6.00/-1.00×13=1.0	pl=1.0

TICL: Toric implantable collamer lens; pl: Plano lens; Preop-refraction: Preoperative refraction; Postop-refraction: Postoperative refraction; OS: Left eye; OD: Right eye.

Table 5 Parameters of eyes with TICL rotation >5° from postoperative 1wk to 1mo at postoperatively 1mo

No.	Eye	Implanted orientation	Intended axis (°)	TICL size	Misalignment (°)	Rotation (°)	Vault (μm)	Position of TICL haptics	Postop-refraction
1	OD	Horizontal	14	12.1	5.689	9.807	644	Figure 5A	pl=1.0
2	OS	Horizontal	179	12.1	-2.458	-7.377	550	Figure 5B	pl=1.0

TICL: Toric implantable collamer lens; pl: Plano lens; Postop-refraction: Postoperative refraction.

group's subgroup with a similar type of incision (arithmetic means: 0.60±0.27 *vs* 0.35±0.23 D, $P<0.0001$; vector means: 0.45@25 *vs* 0.28@19; Figures 5A and 5C). Additionally, the flattening effect (FE) of corneal SIA at the 90° meridian has been calculated in our study. As anticipated, the manual group's superior incision group exhibited the largest FE (-0.34 D; Figure 6).

DISCUSSION

TICLs can correct astigmatism ranging from 0.50 to 6.00 D, with an interval of 0.50 D, and have been extensively utilized for the correction of myopic astigmatism[4,15-16]. This study demonstrates satisfactory predictability, safety, and efficacy of TICL implantation with either manual or digital image-guided approaches (Figure 2). It is worth to noting that since there was no TICL power that precisely matches the preoperative astigmatism, surgeons tend to select a slightly undercorrected TICL power to avoid potential overcorrection. Moreover, unexpected intra-operative misalignment or postoperative rotation of the TICL may diminish its efficacy in correcting astigmatism. Consequently, our patients experienced a slight undercorrection of their astigmatism (Figures 2E1, 2E2, 3E1, 3E2). In addition, it is reasonable to observe a significantly improvement in CDVA after surgery compared to preoperative CDVA due to the reduction in image magnification caused by spectacle frames (Figures 2B and 2G). Overall, both manual marking and digital image-guided systems exhibited comparable performance based on postoperative outcomes. Given that manual marking and alignment are conventional and widely used methods, the similar performance observed with the digital image-guided system indicates promising application prospects and suggests it could serve as a potential alternative to manual method.

The VERION image-guided system corrects posture-related cyclotorsion by matching the characteristic structure of the eye images in the sitting and supine position, including the perilimbal conjunctival vasculature, limbus, and iris structures.

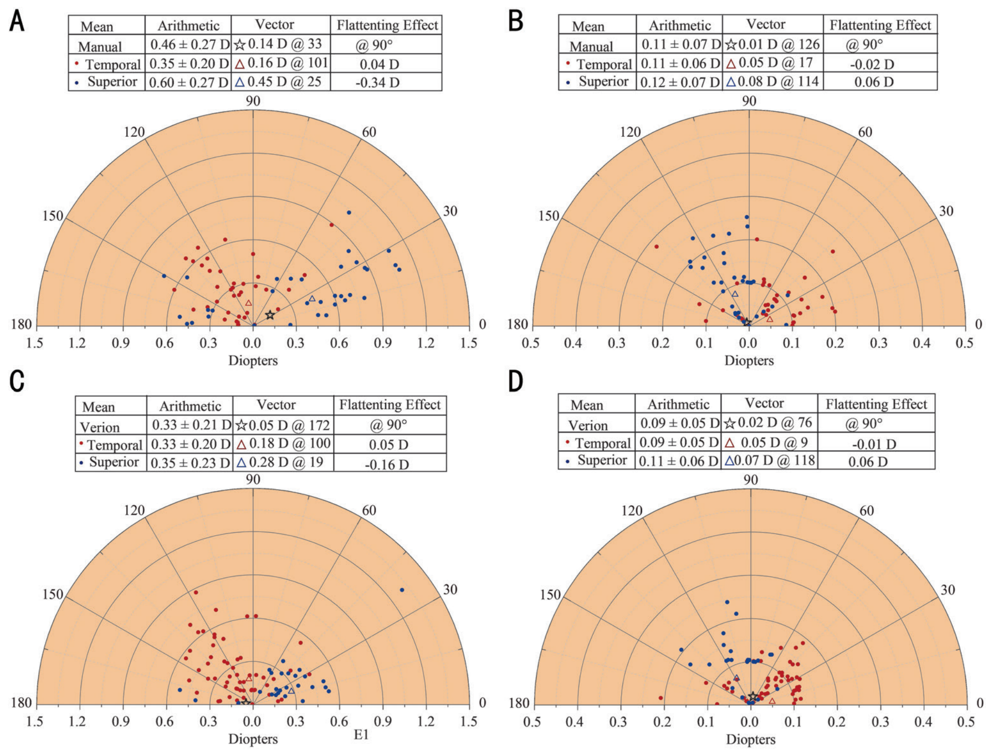

Figure 6 Anterior and posterior corneal surgically induced astigmatism vector (SIA) grouped by main corneal incision positions A: Anterior corneal SIA in the manual group; B: Posterior corneal SIA in the manual group; C: Anterior corneal SIA in the VERION group; D: Posterior corneal SIA in the VERION group. The red dots denote the temporal incision group and the blue dots denote for the superior incision group. The black star, red triangle, and blue triangle denote the vector means of SIA in corresponding groups.

It provides the intended axis mark line based on the manual input of the TICL rotation angle. The digital image-guided approach enables surgeons to promptly align the TICL axial marker with the intended TICL axis line displayed in the microscope image, eliminating repetitive checking and adjusting maneuvers using angular graduation instruments in manual marking method. This results in faster overall surgical time. Moreover, instead of relying on manually made limbal point markers that may harm corneal epithelium, this image-guided system uses a linear marker as a reference axis, significantly improving alignment accuracy and convenience.

Our data suggested no significant difference in major surgical outcome parameters between the digital image-guided and manual methods. However, it is important to note that slight changes in ocular characteristic involved in the image registration procedure of image-guided system may occur due to the application of topical mydriatics, anesthetics, and flushing fluid. These changes can potentially lead to image registration failure or image matching errors. This could explain why there was no difference in TICL axial misalignment between the two methods (Table 1). Notably, 6 out of 8 eyes with large misalignments (>10°) were from the VERION group, which suggests a possible error in the image registration matching process for VERION (Table 4). Emerah[13] investigated the accuracy of axis orientation of TICL implantation using the image-guided VERION system and reported a mean TICL misalignment of 1.9°±1.45°, slightly smaller than our findings (4.28°±3.61°), possibly due to variations in measurement devices (OPD-scan III *vs* anterior segment photograph) and inclusion of several eyes with significant misalignment in our study. Tognetto *et al*[17] demonstrated that IOL rotation within 10° might not affect image quality significantly but noted a higher decay occurred between rotations of 10 and 20°, indicating that IOL rotation greater than 10° requires repositioning. Therefore, at present stage, conventional manual marking method remains indispensable especially when dealing with poor digital image registration quality. Nonetheless, digital systems still hold value particularly for institutes conducting surgeries on a large scale as they facilitate surgery procedures effectively. Additionally, for novice surgeons, digital system can ensure the accurate TICL implantation.

The rotational stability of TICL is consistently a critical concern for surgical success. Several studies reported the impact of TICL orientation on postoperative rotation, with vertical implantation demonstrating superior stability compared to horizontal implantations[18]. Some studies have identified the intraoperative fixation angle of TICL as a risk factor for postoperative rotation[19-20], while others have found no significant correlation between intraoperative fixation angle and postoperative rotation[21-22]. These conflicting results may be attributed to multiple factors contributing to postoperative rotation. First, the positioning of TICL haptics plays an important role, particularly if they are not perfectly located in the ciliary sulcus. Zhang *et al*[23] reported that in most cases the ICL haptics were not located in the ciliary sulcus. The condition of TICL haptics under ciliary sulcus or in broad ciliary sulcus may be more susceptible to the occurrence of rotation after surgery. The position of TICL haptics can be influenced by various factors such as the morphology of the ciliary sulcus and ciliary process, pupil diameter during surgery, surgeon's manipulation of positioning the haptics, sequence of TICL haptic insertion into the posterior chamber, *etc*. Additionally, undersized TICLs resulting in a low vault are more prone to rotate after surgery; therefore, a larger size is preferred to enhance stability if there is sufficient ACD[24]. Lastly, it should be noted that TICLs may rotate form a horizontal to vertical orientation due to differences in their respective STS size[25]. All these factors highlight the challenge posed by high precision standards and cautious requirement in both design and implantation techniques for TICLs.

The postoperative short-term TICL position primarily reflects the accuracy of surgical design and TICL axis alignment maneuver, which can be achieved through manual or digital image-guided methods. However, the positioning at 1mo postoperatively may be influenced by other factors such as ciliary sulcus morphology. Our data demonstrates that satisfactory rotational stability was observed in most cases from 1wk to 1mo postoperatively, regardless of implantation orientation and whether manual or digital image-guided methods were used (Figure 4C). These results also validate our preoperative design and confirm the efficacy of alignment procedures based on both manual and digital systems.

Notably, two eyes in our patients who received horizontally implanted TICLs with a size of 12.1 showed rotation angles exceeding 5° (7.4° and 9.8°, respectively; Table 5). Postoperative UBM revealed imperfect positioning of the TICL footplates in the ciliary sulcus for these two eyes (Figure 5). The combination of a small TICL size, horizontal implantation position, and suboptimal haptic placement may have contributed to greater postoperative rotation of the TICL.

The corneal SIA is of particular interest to us due to its potential impact on postoperative visual outcomes[26-28]. In comparison to the VERION group, we observed greater anterior corneal SIAs in the manual group (Figure 4). The longer operation time and repeated adjustments procedure in manual group may account for this difference. According to our manual method protocol, only a horizontal limbal mark was made, which necessitates more checking and adjusting of TICL position and subsequently leads to longer surgical times for precise alignment, especially in cases involving vertical and oblique TICL implantation with superior corneal incisions. Prolonged operative maneuver could potentially affect corneal incision healing and result in increased SIA. Our previous reports have identified that the distance from the incision to cornea apex center is a critical contributing factor for corneal SIA in cataract surgery[29-30]. Similarly, our data from ICL surgery demonstrated that a superior incision with a shorter distance from the incision site to the corneal center can lead to higher anterior and posterior corneal SIAs. However, compared to the manual group, significant reductions in SIA were observed in the VERION group, highlighting the advantages of using a digital image-guided system for postoperative optical quality improvement. Therefore, both marking methods and incision locations are all contributory factors influencing corneal SIA. To achieve high standards of visual quality in ICL surgery, these potential factors should be considered carefully with an aim towards minimizing SIA.

There are several limitations in this study: 1) The retrospective nature of the study should be acknowledged. 2) Ideally, the TICL axis should be measured immediately after TICL implantation as the initial achieved TICL axis. However, in this study, the TICL axis measured at 1wk after surgery was considered as the initial achieved TICL axis, which may potentially impact the accuracy of both marking methods and rotational stability of TICL after surgery. 3) Only visual acuity and refractive outcomes were analyzed in this present study; parameters related to visual quality such as higher-order aberrations, contrast sensitivity, and questionnaire surveys were not included. Therefore, further investigation is warranted through prospective studies involving immediate post-implantation measurements and the examination of correlations between TICL misalignment and visual quality.

In conclusion, our data demonstrated that the VERION-based digital image-guided system showed good performance in terms of precision for TICL astigmatism alignment, comparable to the results obtained through manual marking methods performed by our skillful clinician team. The short-term postoperative rotational stability of the TICL with different placement positions is satisfactory in both the digital image-guided and manual marking groups. Moreover, corneal SIA is a crucial consideration in surgical design as it can be influenced by both marking methods and incision position following TICL surgery.

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