

# Factors leading to realignment or exchange after implantable collamer lens implantation in 10 258 eyes



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**Purpose:** To evaluate the incidence, causes, and outcomes of implantable collamer lens (ICL) realignment or exchange after implantation of the EVO-ICL.

**Setting:** Eye and ENT Hospital of Fudan University, China.

**Design:** Retrospective study.

**Methods:** The study included 10 258 consecutive eyes after ICL implantation. Preoperative refractive and biometric measurements were compared between eyes with and without realignment or exchange. For eyes with ICL realignment or exchange, visual and biometric outcomes were also compared before and after ICL realignment or exchange.

**Results:** The overall incidence of ICL realignment or exchange was 0.21% 22 eyes. 12 eyes (0.12%) underwent ICL realignment by axis rotation (10 eyes) or ICL exchange (2 eyes) due to toric ICL

(TICL) misalignment. After realignment, uncorrected distance visual acuity improved, and residual cylinder decreased from  $-1.75 \pm 0.48$  diopters (D) to  $-0.87 \pm 0.59$  D ( $P = .01$ ). 10 eyes (0.10%) underwent vertical rotation of ICL (3 eyes) or ICL exchange (7 eyes) due to excessive vault. After either vertical rotation or ICL exchange, vault decreased significantly ( $P < .05$ ).

**Conclusions:** The incidence of ICL realignment or exchange after ICL implantation is low. TICL misalignment and excessive vault are 2 main causes. Implant exchange may be performed for excessive vault or misalignment with an insufficient vault. In addition, vertical rotation of an ICL may be a less invasive method to treat excessive vault in certain cases.

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The EVO Visian implantable collamer lens (ICL; model V4c; STAAR Surgical Co) with a central hole was shown to be an effective, safe, and predictable phakic IOL to correct a wide range of refractive errors.<sup>1–3</sup> To achieve the planned outcome, the toric version (toric ICL [TICL]) must be accurately placed in the desired axis. Misalignment of a TICL will result in unsatisfactory refractive outcomes.<sup>4</sup> In addition, all models must be appropriately sized. Oversized ICLs may result in an excessive vault, thereby increasing the risk for complications such as angle-closure glaucoma, whereas undersized ICLs may result in an insufficient vault and increase the risk for

cataract formation and/or ICL rotation. In these circumstances, secondary ICL surgeries may be required.<sup>3,5</sup>

Among the secondary ICL surgeries, the most frequently reported types are the realignment of the TICL and the exchange of the ICL.<sup>2,6–11</sup> However, these studies did not primarily focus on the incidence of ICL realignment or exchange, and the sample size of each study was relatively small; therefore, the incidence of ICL realignment or exchange may be underestimated or overestimated.

In this study, to our knowledge, we report the incidence of ICL realignment or exchange after ICL implantation for the first time in 10 258 consecutive eyes at the Eye and ENT

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Hospital of Fudan University, an EVO-ICL refractive surgery center with the largest single-center surgical volume in China. Characteristics of eyes requiring ICL realignment or exchange and outcomes of both procedures were also analyzed.

## METHODS

### Patients and Design

This study included 10 258 consecutive eyes that underwent EVO-ICL (model V4c) implantation to correct refractive errors. All operations were performed by 2 surgeons (X.Z. and X.W.) at the Eye and ENT Hospital of Fudan University (China) from November 2014 to April 2020. Demographic data, uncorrected distance visual acuity (UDVA), and corrected distance visual acuity (CDVA), manifest refractions, anterior chamber depth (ACD, Pentacam HR, Oculus Optikgeräte GmbH), white-to-white (WTW) distance (Pentacam), and the ICL parameters were documented and analyzed. For eyes that underwent secondary surgery due to TICL misalignment, TICL eyes without additional surgery were used as the control group. For eyes that underwent secondary surgery due to excessive vault, TICL and nontoric ICL eyes without any secondary surgical intervention were used as the control group. Patients with missing preoperative data were excluded from the analysis. The mean follow-up periods were 20 months (ranging from 1 to 68 months). Seventy-two percentage of patients were followed up for more than 1 year. The funding organization had no role in the design or conduct of this research.

Currently, there is no widely accepted set of indications for ICL realignment or exchange. In this study, the criteria to determine whether to perform ICL realignment or exchange were as follows: For TICL misalignment, the main criteria were the actual axis displacement. When the deviation from the planned axis of implantation was greater than 10 degrees and when there is (1) postoperative UDVA worse than 0.2 logMAR and/or (2) residual, correctable astigmatism causing patient dissatisfaction with postoperative UDVA, the secondary surgery was considered. When selecting the procedure for misalignment (realignment or exchange with a larger size), if the postoperative vault was less than 250  $\mu\text{m}$ , the initial ICL was considered as undersized and was replaced with a larger implant; otherwise, realignment was performed. For eyes with an insufficient vault ( $<100 \mu\text{m}$  and with high risk of contact between ICL and the crystalline lens) whether there is a misalignment that affects visual quality or not, the initial ICL was replaced with a larger implant. For an excessive vault, the indication for ICL realignment or exchange was mainly determined by the postoperative intraocular pressure (IOP), anterior chamber angle (ACA, Pentacam), and vault (Pentacam). When selecting the procedure (vertical rotation or exchange with a smaller implant), for eyes implanted with nontoric ICL and with a great difference between vertical and horizontal sulcus-to-sulcus (STS) distance ( $\geq 0.5 \text{ mm}$ ), vertical rotation could decrease the vault to some extent; otherwise, an exchange was performed. Dislocated ICLs or other situations due to trauma requiring secondary surgery were excluded from our analysis. ICL realignment or exchange was performed after careful discussion of available options with the patients. All patients signed written informed consent.

The study adhered to the tenets of the Declaration of Helsinki. The protocols were approved by the Ethics Committee of the Fudan University EENT Hospital Review Board (No. 2016038).

For 22 eyes of 20 (3 male and 17 female) patients who underwent ICL realignment or exchange, ocular examinations were performed (Section Main Outcome Measures) before the initial surgery ( $T_0$ ), at the last follow-up before ICL realignment or exchange ( $T_1$ ), and at the last available (longest) follow-up after the secondary surgery ( $T_2$ ).

Data that support the findings of this study are available from the corresponding author upon reasonable request.

### Surgical Techniques

The EVO-ICL power calculation (STAAR Surgical Co) was performed according to the manufacturer's instructions with a

modified vertex formula based on the preoperative refractive parameters. The size of ICL was chosen according to the ACD (Pentacam HR) and WTW (Pentacam). The surgical technique was conducted as previously described.<sup>12</sup> In brief, after the injection of an ophthalmic viscosurgical device (sodium hyaluronate 1.7%; Bausch & Lomb, Inc.), the ICL was inserted with an injector cartridge (STARR Surgical Co) through a 3.0 mm clear corneal incision. After the ICL was placed in the intended position, the ophthalmic viscosurgical device was completely removed using lactated Ringer's solution by irrigation only.

For ICL repositioning, that is, realignment and vertical rotation, patients were administered dilating and cycloplegic agents (tropi-camide 0.5% and phenylephrine hydrochloride 0.5%, Mydrin-P, Santen, Inc.) on the day of surgery. Preoperatively, the zero horizontal axis was marked at a slitlamp with the patient sitting upright to control for potential cyclotorsion upon laying supine. The previous incision from the initial ICL implantation was reopened and the ophthalmic viscosurgical device was injected into the anterior chamber. A Mendez ring was used to measure the required rotation from the horizontal axis (the originally intended position for realignment and 90 degrees for vertical rotation). The ICL was rotated and the ophthalmic viscosurgical device was then washed out completely with lactated Ringer's solution by irrigation only.

For the ICL exchange, the size of the new ICL was chosen according to the ACD, WTW, and STS. Patients were administered dilating and cycloplegic agents. Again, the prior incision was reopened, and the ophthalmic viscosurgical device was injected. A manipulator (Mingren Eye Instruments) was used to rotate the ICL and move the haptic near the incision into the anterior chamber. Then, the ICL was removed with forceps (Mingren Eye Instruments) through the incision, and the ophthalmic viscosurgical device was washed out. The new ICL was afterward inserted as previously described.<sup>12</sup>

After any surgical intervention (initial lens implantation, ICL realignment, or exchange), patients received topical levofloxacin 0.5% 4 times daily for 7 days, prednisolone acetate 1.0% 4 times daily for 4 days, and pranopfen 4 times daily for 14 days.

### Main Outcome Measures

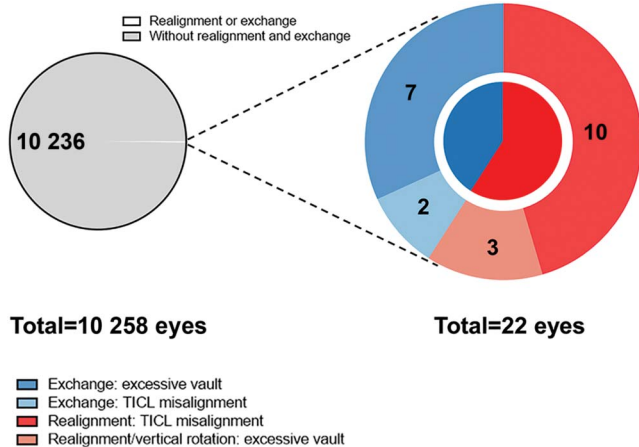
Before ICL implantation, all patients underwent the same ocular examination. Parameters measured were as follows: (1) visual acuity, manifest refraction, and cycloplegic objective refraction; (2) standard slitlamp evaluation and dilated fundus examination; (3) axial length (IOL Master), IOP, and endothelial cell density (ECD, Topcon SP-2000P, Topcon Corp.); (4) Pentacam examination, including ACD (defined as the maximum vertical distance from the corneal endothelium to the anterior surface of the lens), ACA, anterior chamber volume, and WTW; (5) STS diameter (Compact Touch STS ultrasound biomicroscope [UBM], Quantel Medical).

After initial ICL implantation and after any secondary surgery, patients underwent standardized postoperative examinations that included the following: (1) visual acuity and manifest refraction; (2) slitlamp evaluation; (3) IOP and ECD; and (4) Pentacam examination, including ACD (defined as the maximum vertical distance from the endothelium to the anterior surface of the ICL), ACA, and vault. For patients undergoing ICL realignment or exchange due to misalignment, a subjective visual quality questionnaire was asked regarding the severity of glare, halos, double vision, and blurred vision before and after secondary surgery. At the most recent follow-up, they were surveyed about satisfaction with the results of the secondary surgical procedure and the overall ICL surgery.

For measurement of the TICL orientation, the pupils were dilated with Mydrin-P until the orientation marking on TICL was visible with the retroillumination slitlamp. The axis displacement of TICL was obtained by comparing the TICL orientation with its target position.

### Statistical Analysis

Data were analyzed using R version 3.6.2 (R Project for Statistical Computing, <http://cran.rproject.org>). Continuous variables were



**Figure 1.** Incidence and causes of ICL realignment or exchange after EVO-ICL implantation (eyes). TICL = toric ICL

presented as mean  $\pm$  SD and categorical variables as frequency and percentage. Data normality was evaluated using the Shapiro-Wilk test, with paired *t* tests and Wilcoxon signed-rank tests being used to compare normally and nonnormally distributed continuous variables between  $T_1$  and  $T_2$ . Linear mixed-effects models were used to compare eye-level continuous variables between the secondary surgery group and the control group. The  $\chi^2$  test and the Fisher exact test were used to examine differences in percentages. A *P* value of less than 0.05 was considered statistically significant.

## RESULTS

### Incidence and Causes

Of the 10,258 eyes that were treated with EVO-ICL implantation, 22 eyes (0.21%) of 20 patients underwent ICL realignment or exchange (Figure 1 and Supplementary Table 1, <http://links.lww.com/JRS/A583>).

Among these 22 eyes, 13 eyes (0.13%) of 12 patients underwent repositioning, including realignment for misaligned TICL (10 eyes, 0.10%) and vertical rotation for nontoric ICL with excessive vault (3 eyes, 0.03%). Nine eyes (0.09%) of 8 patients underwent ICL exchange. Seven (0.07%) of these 9 eyes underwent exchange due to excessive vault of the ICL and 2 (0.02%) eyes due to TICL misalignment combined with low vault (220  $\mu\text{m}$  and 240  $\mu\text{m}$ , respectively) (Supplementary Table 1, <http://links.lww.com/JRS/A583>).

### Characteristics of Eyes

Overall, 12 eyes of 11 patients underwent ICL realignment or exchange due to misalignment of the TICL (Supplementary Table 2A, <http://links.lww.com/JRS/A583>). When comparing the baseline of these eyes and TICL eyes without secondary surgical intervention, a higher preoperative cylinder was detected in eyes that required surgical intervention due to misalignment ( $P = .001$ , Table 1).

In these eyes, the most common initial symptom was blurred vision, which was reported in 78% (7/9) of eyes, followed by double vision (22%, 2/9) and severe halos (11%, 1/9). One eye had both blurred and double vision. The median onset of symptoms was 1 day (range 0 to 60 days) after ICL implantation. If excluding the outlier (1 eye at 60 days), 8 of the 9 eyes reported symptoms within 1 week

after implantation. All patients denied a history of ocular trauma. The mean UDVA was  $0.15 \pm 0.12$  logMAR, and the mean cylinder was  $-1.75 \pm 0.48$  diopters (D).

Ten eyes of 9 patients underwent ICL realignment or exchange because of the excessive vault (Supplementary Table 2B, <http://links.lww.com/JRS/A583>). Its incidence in eyes with ICL was 0.10% (10/10,258). Compared with ICL/TICL eyes without secondary surgery, the 10 eyes exhibited greater differences between ICL size and WTW (size – WTW) ( $P < .001$ , Table 2). Before ICL realignment or exchange, all eyes were normotensive with IOP less than 25 mm Hg. The mean ACD was  $1.37 \pm 0.26$  mm, and the mean ACA was  $9.36 \pm 5.15$  degrees. The mean vault was  $1025.0 \pm 143.1$   $\mu\text{m}$  in these eyes, whereas the mean vault was  $519.1 \pm 192.7$   $\mu\text{m}$  in eyes without secondary procedure ( $<0.001$ ).

### Safety

All surgeries were uneventful, and no intraoperative or postoperative complications were observed. Among eyes requiring ICL realignment or exchange, 78.3% (17 eyes total, 12 for repositioning, 5 for exchange) were followed up for more than 1 month after ICL realignment or exchange. For these eyes, the median follow-up period was 18.4 months (range 3.4–46.3 months). The safety index (post-ICL realignment or exchange CDVA/preimplantation CDVA) of repositioning and exchange was  $1.15 \pm 0.16$  and  $1.15 \pm 0.14$ , respectively. No eye lost lines of CDVA (Figure 2).

There was no significant change in ECD between pre-ICL implantation ( $T_0$ ,  $2559.1 \pm 284.6$  cells/ $\text{mm}^2$ ) and last follow-up after ICL realignment or exchange ( $T_2$ ,  $2680.0 \pm 263.2$  cells/ $\text{mm}^2$ ,  $p_{T_0 \text{ vs } T_2} = 0.26$ ).

### Realignment and Exchange due to TICL Misalignment

For 10 eyes with misaligned TICLs, realignment was performed at a median of 19 days (range 2 to 192 days) after implantation. Nine eyes of 9 patients had at least 1 follow-up record, and refractive outcomes are summarized in Supplementary Table 3 (<http://links.lww.com/JRS/A583>). In all eyes, CDVA remained unchanged at  $-0.06 \pm 0.06$  logMAR (20/20), whereas UDVA significantly improved from  $0.15 \pm 0.12$  logMAR (20/30) to  $-0.02 \pm 0.08$  logMAR (20/20) ( $P = .01$ ). There was a reduction in residual cylinder from  $-1.75 \pm 0.48$  D to  $-0.87 \pm 0.59$  D ( $P = .01$ ) and a decrease in spherical error from  $0.94 \pm 0.44$  D to  $0.36 \pm 0.28$  D ( $P = .01$ ).

At the most recent follow-up after realignment, all eyes reported improvement in subjective visual symptoms (Figure 3). Seven of 9 patients (78%) were satisfied with realignment surgery, and all patients reported being satisfied with ICL. The remaining patients reported that they were neutral (neither satisfied nor dissatisfied), largely due to their expectation to get a good outcome at the initial implantation rather than after the secondary surgery.

For patient 11, both eyes experienced significant ICL rotation because of undersized TICLs (ICL size: 12.6 mm OU), and ICL exchange was required. The vault after the initial implantation was 220  $\mu\text{m}$  in the right eye and 240  $\mu\text{m}$  in the left eye. According to her preoperative

**Table 1.** Profiles of TICL misalignment group and group without secondary surgery

Characteristics <sup>a</sup>	Secondary procedure due to misalignment <sup>b</sup> (n = 12)		Control TICL <sup>b</sup> (n = 5459)		P value
	Mean ± SD	Range	Mean ± SD	Range	
Age (y)	29.6 ± 7.2	20, 42	27.7 ± 6.3	20, 56	.32
Sex (M, %)	27.3		24.8		1.00
Sphere (D)	-8.23 ± 3.34	-12.50, -3.00	-9.15 ± 3.01	-20.50, 0.75	.40
Cylinder (D)	-2.71 ± 0.79	-4.00, -1.50	-1.94 ± 0.94	-6.50, -0.50	.001*
SE (D)	-9.58 ± 3.42	-13.75, -3.75	-10.12 ± 3.07	-23.38, -0.50	.73
ACD (mm)	3.34 ± 0.24	2.97, 3.71	3.22 ± 0.24	2.80, 4.50	.18
WTW (mm)	11.76 ± 0.27	11.4, 12.2	11.66 ± 0.37	10.1, 12.9	.17
Size - WTW (mm)	1.23 ± 0.23	0.9, 1.6	1.22 ± 0.22	0.5, 2.0	.66
Fixation angle  (°)	3.67 ± 2.77	0.0, 10.0	5.08 ± 4.82	0.0, 22.0	.42

ACD = anterior chamber depth; |Fixation angle| (°) = absolute value of angle between target position of TICL and horizontal meridian of 180 degrees; SE = spherical equivalent; Size - WTW = difference between ICL size and WTW; TICL = toric ICL; WTW = white-to-white distance

\*Statistically significant

<sup>a</sup>Sphere cylinder, SE, ACD, and WTW were measured preoperatively. ICL size and fixation angle were designed preoperatively.

<sup>b</sup>Misalignment group included eyes that underwent ICL realignment or exchange for TICL misalignment; control TICL group included eyes without secondary surgery

examination results, WTW (Pentacam) was 11.50 mm in both eyes, but horizontal STS (UBM) was 12.76 mm in both eyes, and vertical STS was 13.23 mm in the right eye and 13.26 mm in the left eye. The TICL was exchanged for a 13.2 mm TICL. Postexchange UDVA improved from 0.2 logMAR in the right eye and 0.1 logMAR in the left eye to 0 logMAR in both eyes, and astigmatism decreased from -4.00 D in the right eye and -1.75 D in the left eye to -0.25 D in both eyes. The postexchange vault was 510 μm in the right eye and 530 μm in the left eye.

#### Exchange and Vertical Rotation due to Excessive Vault

Among 10 eyes of 9 patients who underwent ICL realignment or exchange to manage excessive vault, 7 eyes of 6 patients underwent ICL exchange with smaller ICLs and 3 eyes of 3 patients underwent vertical ICL rotation. The secondary surgery was performed at a median of 11 days (range 2-1142 days). When the outlier was

excluded, 9 of the 10 eyes underwent realignment or exchange within 2 months. The outlier value was due to a lack of a regular follow-up after initial implantation. The patient pursued graduate study overseas after initial implantation and did not return to China before she completed her program.

After the exchange, the vault decreased from 1098.6 ± 63.1 to 615.7 ± 139.6 μm ( $P < .001$ ). The ACD and ACA significantly increased (both  $P < .05$ , Supplementary Table 4, <http://links.lww.com/JRS/A583>).

After the vertical rotation, the vault decreased from 853.3 ± 130.5 to 425.0 ± 149.1 μm ( $P = .02$ ), and the ACD significantly increased ( $P = .046$ , Supplementary Table 4, <http://links.lww.com/JRS/A583>).

At the last follow-up, 75% of the patients (3/4) were satisfied with the exchange, and all patients (3/3) were satisfied with vertical rotation; 86% of patients (6/7) were satisfied with ICL.

**Table 2.** Profiles of excessive vault group and group without secondary surgery

Characteristics <sup>a</sup>	Secondary procedure due to excessive vault <sup>b</sup> (n = 10)		Control <sup>b</sup> (n = 9345)		P value
	Mean ± SD	Range	Mean ± SD	Range	
Age (y)	32.1 ± 9.9	22, 49	28.5 ± 6.6	20, 56	.35
Sex (M, %)	0.0		26.9		.15
Sphere (D)	-9.83 ± 3.04	-15.50, -5.75	-9.81 ± 3.94	-29.25, 0.75	.79
Cylinder (D)	-1.40 ± 1.51	-4.50, 0	-1.14 ± 1.19	-6.50, 0	.43
SE (D)	-10.53 ± 3.36	-16.75, -6.00	-10.38 ± 3.90	-29.25, -0.50	.69
ACD (mm)	3.11 ± 0.19	2.88, 3.60	3.20 ± 0.24	2.80, 4.50	.26
WTW (mm)	11.64 ± 0.33	11.2, 12.2	11.64 ± 0.37	10.1, 13.0	.94
Size - WTW (mm)	1.48 ± 0.25	1.1, 1.7	1.22 ± 0.23	0.40, 2.10	<.001*

ACD = anterior chamber depth; SE = spherical equivalent; Size - WTW = the difference between ICL size and WTW; TICL = toric ICL; WTW = white-to-white distance

\*Statistically significant

<sup>a</sup>Sphere cylinder, SE, ACD, WTW, and ICL size were measured or determined preoperatively

<sup>b</sup>Excessive vault group included eyes that underwent ICL realignment or exchange due to excessive vault; the control group included patients without secondary surgery



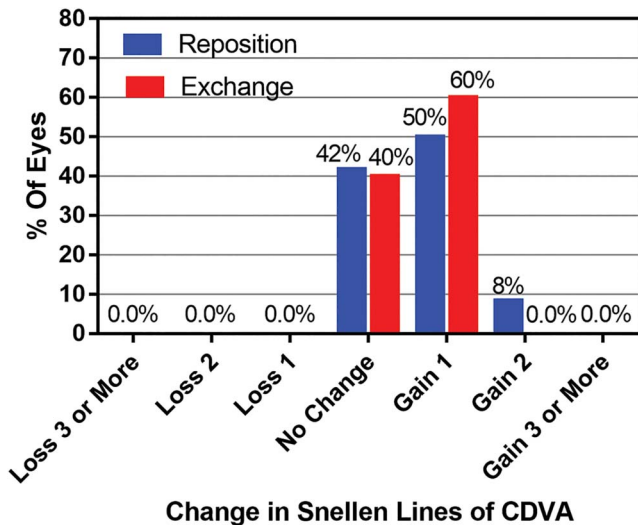


Figure 2. Changes in Snellen lines of CDVA after ICL realignment or exchange compared with the CDVA before initial implantation.

## DISCUSSION

Although the EVO-ICL has been proven to be safe and effective for the correction of refractive error, accurate prediction of postoperative axis position and vault remains a challenge. Cases with misalignment or excessive/insufficient vault may require ICL realignment or exchange. This study analyzed 10 258 eyes that underwent ICL implantation and reported the incidence of ICL realignment or exchange and their outcomes.

We observed a low overall incidence of 0.21% after EVO-ICL implantation. The incidence of ICL realignment or exchange was 0.13% and 0.09%, respectively. This is in accordance with current literature. Packer et al. summarized a 0.47% incidence of secondary surgical intervention in 2970 eyes from 28 articles.<sup>3</sup> Kamiya et al. observed 351 eyes for 12 months in a multicenter study and reported 2 eyes that underwent exchange due to incorrect initial sizing or power.<sup>2</sup> In addition, there were sporadic reports of TICL realignment.<sup>2,6-11</sup> This study confirms that the incidence of ICL realignment or exchange is low, thus suggesting that the ICL has a favorable safety profile.

ICLs have typically been shown to have good rotational stability; however, this study identified 12 eyes that required ICL realignment or exchange due to misalignment.<sup>13,14</sup> A possible factor contributing to spontaneous rotation is the placement of undersized ICLs, which leads to insufficient fixation in the ciliary sulcus and poor rotational stability. Although no significant variation in the difference between TICL size and WTW was found between the ICL realignment or exchange and control groups, for cases with a much greater STS compared with WTW or with a unique morphology of the ciliary sulcus, such as patient 11, the ICL could be undersized when using the standard WTW/ACD-based sizing, as proposed by the manufacturer (STAAR Surgical).<sup>15</sup> Another possible explanation is that the misalignment may be related to surgery, such as intraoperative misalignment or dislocation of the haptics. It is worth clarifying that the axis

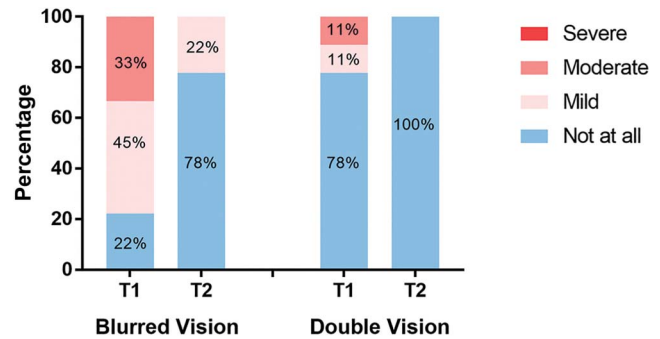


Figure 3. Visual symptoms before and after realignment. T<sub>1</sub> = last follow-up before ICL realignment; T<sub>2</sub> = last follow-up after the ICL realignment

placement using systems such as the VERION or Zeiss Calisto can improve the precision of placement of the TICL during the initial surgery. In addition, inadvertent rotation of the ICL could also occur under mechanical forces such as ciliary muscle contraction or gravity.

This study also found that the preoperative cylinder was, on average, higher in eyes that underwent ICL realignment or exchange for TICL misalignment than in eyes without secondary surgery. However, Lee et al. demonstrated that there was no association between the preoperative cylinder and TICL rotation 6 months after implantation.<sup>14</sup> A possible explanation for the results in this study is that the misalignment of a TICL with a high cylinder is more notorious to the refractive and visual outcome compared with a TICL with a low cylinder and therefore is more likely to be noticed and require secondary surgical intervention to correct. Surgeons are suggested to carefully explain the risk for realignment to patients with a high preoperative cylinder. Mori et al. reported that the intraoperative fixation angle was significantly correlated with the postoperative TICL rotation, but in this study, no statistically significant difference in fixation angle was found between the eyes that underwent ICL realignment or exchange due to misalignment and the eyes without secondary surgery.<sup>16</sup>

Eleven eyes underwent realignment due to misaligned TICL. After ICL realignment, visual acuity improved and residual cylinder decreased. It should be noted that in 2 eyes, the cylinder decreased by  $\leq 0.25$  D, and UDVA was not improved at the most recent follow-up compared with presurgery levels. After ICL realignment, misalignment could be corrected for a short time, but the ICL later rotated again, which was in line with the case report of Zhang et al.<sup>17</sup> An underlying reason may be that the ciliary sulcus was overly oval, resulting in an unstable position of the TICL. For these patients, customized sizing and positioning of TICLs may be helpful.

For eyes with an excessive vault that required ICL vertical rotation or exchange, a statistically significant difference between the ICL size and WTW (size – WTW) was detected. This is in agreement with previous observations of Zhao et al., which had shown that this difference was positively correlated with the postoperative vault.<sup>18</sup> ICL sizing formulas or nomograms based on more ocular

parameters or using machine learning may improve the predictability of the vault compared with conventional WTW/ACD sizing.<sup>19–21</sup> In 7 eyes that underwent ICL exchange, the vault significantly decreased and ACA and ACD simultaneously increased. Zeng et al. reported outcomes of ICL V4 exchange and observed a decrease in the vault from  $1213 \pm 170$  to  $491 \pm 174 \mu\text{m}$ , which is consistent with the results of this study.<sup>22</sup> This study also suggests that vertical rotation of a nontoric ICL could be a less-invasive but still an effective method to manage an excessive vault of up to  $1000 \mu\text{m}$  after ICL implantation. Vertical STS is shown to be greater than horizontal STS; therefore, it is expected that the vault decreases when the ICL is rotated vertically.<sup>23</sup> Matarazzo et al. and Srirampur et al. also described successful outcomes of this approach in case reports; this study confirms the efficacy of vertical rotation in decreasing the vault.<sup>24,25</sup>

As this study demonstrated, the safety index was  $1.17 \pm 0.14$  for repositioning and  $1.15 \pm 0.14$  for ICL exchange with no significant loss of CDVA and endothelial cells compared with those before initial implantation. However, the criteria for ICL realignment or exchange should still be strict. When residual astigmatism is considered tolerable by the patient, ICL realignment or exchange is not necessary. In cases with excessive vault, the goal of ICL realignment or exchange was to prevent potential complications such as angle closure. For ICLs with vault  $>1000 \mu\text{m}$  but a low risk for angle closure, a close follow-up is encouraged since the vault can decrease over time without intervention.<sup>26,27</sup> However, for eyes with small ACA, which can predict a high risk for angle closure, ICL realignment or exchange is recommended even if the vault is less than  $1000 \mu\text{m}$ . It is worth noting that in this study, eyes with insufficient vault but without misalignment or contact between the crystalline lens and ICL were closely followed up instead of ICL realignment or exchange. The indication for ICL realignment or exchange in these scenarios could be an area for further investigation.

This study has some limitations. First, the relatively short follow-up duration and loss to follow-up at 1 year postoperatively for the consecutive population could lead to underestimation of the incidence of realignment or exchange. However, most procedures of realignment and exchange are performed within 1 year after initial implantation. In addition, for patients with appropriate vault and alignment of ICL, the interval of follow-up is allowed to be extended in our center. Therefore, most cases lost to follow-up are likely to have appropriate vault and alignment. Second, the patients who underwent realignment or exchange were relatively few due to the low incidence. Thus, the outcomes of secondary procedures need to be interpreted with caution. The nonstatistically significant difference in ACA between prevertical and postvertical rotations may be because of a small sample size. Third, because the temporal distribution of ICL realignment or exchange is scattered, the duration of follow-up after secondary procedure was inconsistent. A future study with a longer and more consistent follow-up is therefore warranted.

In summary, the EVO-ICL has a low incidence of ICL realignment or exchange. TICL misalignment and ICL excessive vault were the 2 main causes. The preoperative cylinder was higher in eyes that required surgical intervention due to misalignment and the difference between the ICL size and WTW was greater in eyes that required surgical intervention due to excessive vault compared with eyes without additional surgery. Realignment and exchange for larger ICLs are possible approaches for patients with TICL misalignment. ICL exchange for smaller lenses and vertical rotation of nontoric ICLs are available options for the management of excessive vault.

#### WHAT WAS KNOWN

- To achieve clinically safe and desirable outcomes, the ICL must be accurately and stably placed with an appropriate vault. An insufficient or excessive vault remains a risk factor for complications while TICL misalignment may result in unsatisfactory visual outcomes.
- The realignment of the TICL and the exchange of the ICL were described in case reports as possible approaches for inappropriate alignment and vault.

#### WHAT THIS PAPER ADDS

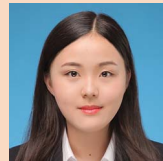
- EVO-ICL has a low incidence of ICL realignment or exchange. Both procedures are safe, and the main causes are TICL misalignment and ICL excessive vault.
- The preoperative cylinder was higher in eyes that underwent secondary surgery for TICL misalignment than in eyes without secondary surgery, while the difference between ICL size and white-to-white was greater in eyes that underwent secondary surgery for excessive vault than in eyes without secondary surgery.
- Implant exchange may be performed for misalignment or excessive vault, while vertical rotation of an ICL may be a less-invasive method to treat excessive vault in certain cases.

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