• Clinical Research •

Clinical prediction of insufficient vaults after implantable collamer lens implantation

Jun Zhu, Dan Cheng, Xue–Ying Zhu, Fen–Fen Li, Ye Yang, Yu–Feng Ye

National Clinical Research Center for Ocular Diseases, Eye Hospital, Wenzhou Medical University, Wenzhou 325027, Zhejiang Province, China

Co-first authors: Jun Zhu and Dan Cheng

Correspondence to: Yu-Feng Ye. National Clinical Research Center for Ocular Diseases, Eye Hospital, Wenzhou Medical University, Wenzhou 325027, Zhejiang Province, China. yyf0571@mail.eye.ac.cn

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Abstract

● **AIM:** To determine the factors related to preoperative ocular characters that are predictive of insufficient vault (<250 μm) after implantable collamer lens (ICL V4c; STAAR Surgical) implantation.

● **METHODS:** The participants underwent ICL surgery and were divided into the low (<250 μm) and normal (250-1000 μm) vault groups based on the postoperative vault at 3mo. The preoperative biometric parameters and clinical outcomes were compared between the two groups. The relationship between the 3-month vault values and preoperative ocular parameters were evaluated by Generalized estimating equations.

● **RESULTS:** Sixteen (23 eyes) and 36 patients (63 eyes) were in the low and normal vault groups, respectively. All implantation procedures were uneventful with no cataract formation in the early postoperative period. The sulcus-to-sulcus lens rise (STSL) and iris ciliary angle (ICA) were correlated with vault at 3mo after surgery. Every 0.1 mm increase in STSL was associated with 38.9 μm decrease in the postoperative 3-month vault. A rise of 1 degree in ICA is associated with a reduction of 4 μm in vault.

● **CONCLUSION:** Eyes with a narrow ciliary sulcus are associated with a higher rate of low vault after ICL implantation, suggesting a need for adjustments to the ICL size in these patients. Evaluating the characteristics of the ciliary sulcus contributes valuable information to predict low vault after surgery.

● **KEYWORDS:** insufficient vault; implantable collamer lens; ciliary body; posterior chamber

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INTRODUCTION

Implantable collamer lens (ICL; STAAR Surgical) has been used for correction of myopia and astigmatism for almost two decades in clinical practice[1-2]. Owing to its superior visual quality and cornea biomechanics, ICL has been widely implanted to correct a wide range of refractive errors[3-4]. Its efficiency and safety has raised a topic of clinical concern. The vault, defined as the distance between the anterior surface of crystalline lens and the posterior surface of the ICL, was considered as a significant indicator of the surgical safety[5-6]. With the development of the central port, which allows the physiological flow of aqueous humor and decrease the risk of elevated intraocular pressure (IOP), excessively high vault rarely occurred with experienced ICL size selection[7].

However, the consequences of the contact of ICL with crystalline lens remain major concern[8-10]. An insufficient vault was reported to increase the risk for cataract formation, and ICL rotation, even leads to secondary surgery for lens realignment or replacement. And the minimum required central vault to avoid cataract or ICL exchange is still unknown[11-13].

The risk factors of sub-optimal vault remain controversial[10,14]. The traditional calculation formula for ICL implantation size usually use parameters from the anterior chamber, such as white-to-white (WTW) and anterior chamber depth (ACD)[15]. However, the unsatisfactory vault, complications and secondary surgeries confirmed its limitation. With the wide application of ultrasound biomicroscopy (UBM) and anterior segment optical coherence tomography (AS-OCT) in clinic, researchers hypothesized that besides the anterior chamber, the iris, as well as the ciliary body should also be taken into consideration[9,16-17].

Khan *et al*[7] reported that eyes with obviously concave iris were associated with a higher rate of excessively low vault. Recently, researchers demonstrated that variability of vault may be due to unmeasurable anatomic factors of the posterior chamber, especially the ciliary body anatomy[9,18]. However, Chen *et al*[18] only assess the postoperative vault at 1mo after surgery. Moreover, a novel ophthalmic viscosurgical device (OVD)-free ICL implantation method was proved to be safe and effective for myopic surgery[19]. Avoiding the usage of OVDs can prevent the OVD-related complications, and simplify the surgical procedure. The current study aimed to analyze and identify the most relevant indicators of ocular anatomic parameters that leads to an insufficient vault, based on both UBM and AS-OCT. To our known, no study has investigated the relationship between the achieved 3-month postoperative vault and dimensions of anterior, posterior chamber and iris together.

SUBJECTS AND METHODS

Ethical Approval The study was approved by the Ethics Committee of Wenzhou Medical University (H2022-032-K-32-01), and all procedures were performed in accordance with the principles of the Declaration of Helsinki. All participants were informed and signed written informed consent.

Subjects A total of 86 eyes of 52 patients underwent ICL V4c/toric ICL (TICL) V4c implantation at the Affiliated Eye Hospital of Wenzhou Medical University at Hangzhou from February 2022 to February 2023 were included. The participants were divided into two groups based on the postoperative vault at 3mo. Twenty-three eyes with vault <250 μm were in the low vault group, and 63 eyes with vault between 250 and 1000 μm were in the normal vault group. Inclusion criteria were as follows: healthy individuals aged between 18 and 45y, stable refraction status in the last 2y, anterior chamber depth ≥2.8 mm, corneal endothelial cell density ≥2000 cells/mm^2, normal iris and pupil function, transparent lens with no abnormalities in morphology and position and IOP<21 mm Hg. Exclusion criteria were history of ocular trauma or intraocular surgery, presence of other vision-affecting diseases such as glaucoma, diabetic retinopathy, macular degeneration and pathological myopia, presence of ocular infectious diseases such as endophthalmitis and keratoconjunctivitis, inability to obtain clear imaging data, such as cataract.

Preoperative and Postoperative Examinations All patients underwent a complete preoperative ocular examination, which included uncorrected visual acuity (UDVA), manifest refraction and best-corrected visual acuity (BCVA), non-contact tonometry, slit-lamp microscopy, endothelial cell density measurement, and swept-source AS-OCT (CASIA2, Tomey corporation, Nagoya, Japan). Axial length and lens thickness (LT) were measured by an optical biometer (IOL Master 700; Carl Zeiss Meditec, Jena, Germany).

WTW, pupil diameter, central corneal thickness (CCT), anterior chamber angle (ACA), ACD, anterior chamber volume (ACV) were assessed from a Scheimpflug camera (Pentacam HR; Oculus Optikgeräte GmbH). UBM (SW-3200L) were used to measure the sulcus-to-sulcus (STS) diamter, STS lens rise (STSL) iris ciliary angle (ICA), and iris-lens angle (ILA).

Patients were followed up at 1d, 1wk, 1, 3mo postoperatively. UDVA, BCVA, intraocular pressure (IOP), slit lamp, IOL-Master, and AS-OCT were performed at each visit. Pentacam was not done 1d postoperatively. UBM started at postoperative 3mo postoperatively. AS-OCT were performed each visit to assess the vault, and we used the vault at 3mo after surgery to analyze.

The UBM images were measured semi-automatically using Image J. The following parameters were measured at the locations of 2, 4, 8, and 10 o'clock (Figure 1): 1) ICA: the angle between the posterior surface of the iris and the anterior surface of the ciliary body; 2) ILA: the angle between the posterior surface of the iris and the anterior surface of the lens. Each parameter was measured three times and the mean values were calculated. The final values averaged from the parameters at the four quadrants were calculated for statistical analysis.

AS-OCT parameters are measured automatically by built-in software (Figure 2), including the anterior chamber angle distance (ATA), anterior chamber width (ACW), distance between scleral spurs (SS), the volume of iris (iris-volume), iris-curve [a straight line between the contact point between the iris and the lens and the root of the iris, which represents the maximum distance (mm) between a straight line and the posterior surface of the iris], iris thickness at 750 μm from the SS (IT750), iris thickness at 2000 μm from the SS (IT2000), the iris area represents the area of the iris (mm^2) obtained from the horizontal cross-section analysis image (iris-area).

Surgical Procedure The surgical procedure involved hydrating the ICL in balanced salt solution (BSS) and placing it in a prepared ICL injector. Topical anesthesia was administrated by 0.5% proparacaine hydrochloride eye drops. Two side-ports (1.0 mm in size) were made, one to maintain the anterior chamber with continuous infusion of BSS[19] by the patent irrigator, and the other to adjust the haptic position of the ICL into the ciliary sulcus by the patent manipulator. A 3.0 mm vertical clear corneal main incision was made. The ICL or TICL was inserted through a 3.0 mm vertical clear corneal main incision. Its four haptics were tucked beneath the iris, and adjusted to the appropriate axis position. All surgeries were performed by the same experienced surgeon (Yang Y) with no OVDs.

Statistical Analysis Statistical analysis was performed using the SPSS statistical software version 26 (SPSS Inc, Chicago, IL, USA). The data were expressed as the mean±standard deviation. The Shapiro-Wilk test was used to evaluate the normality of data. Generalized estimating equations (GEE) was used to compare variables between groups. The relationship

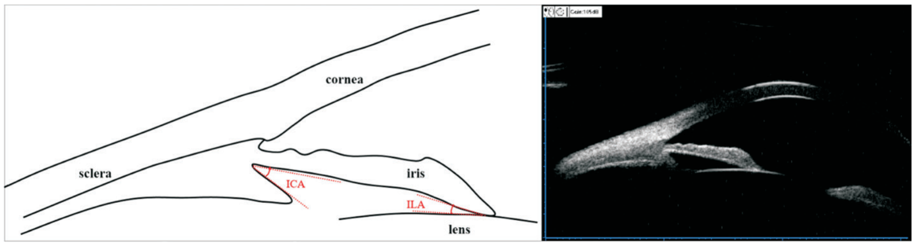

Figure 1 Diagrammatic representation of the ultrasound biomicroscopy (UBM) measurements of ICA and ILA ICA: Iris-ciliary angle; ILA: Iris-lens angle.

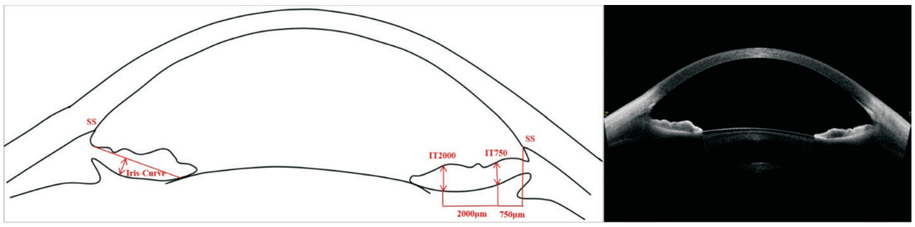

Figure 2 Diagrammatic representation of AS-OCT measurements of iris-curve, IT750, and IT2000 Iris-curve is the maximum distance between the iris posterior surface and the straight line from the iris root to the most peripheral point of contact between the iris and lens; IT750: Iris thickness at 750 μm from the SS; IT2000: Iris thickness at 2000 μm from the SS. AS-OCT: Anterior segment optical coherence tomography; SS: Scleral spur.

between the vault values and preoperative various parameters was evaluated by univariate and multivariate GEE analysis. Chi-square test was used for comparing the haptics position between low and normal vault groups. *P* value of <0.05 was considered statistically significant.

RESULTS

A total of 52 patients (86 eyes) were included and underwent the OVD-free surgery, of which 16 (23 eyes) were in the low vault group and 36 (63 eyes) were in the normal vault group. No intraoperative or postoperative complications were found, and all implantation procedures were uneventful. According to the UBM images, only 4 eyes (18.18%) in the low vault group had four haptics in ciliary sulcus, and 22 eyes (37.10%) in the normal vault had four haptics in the ciliary sulcus. There were 7 (31.82%) and 6 (9.68%) eyes had no haptics in the ciliary sulcus, respectively (P=0.032).

Table 1 summarized the demographics and ocular biological characteristics of the low and normal vault groups. Female gender accounted for 100.0% in the low vault group and 84.13% in the normal vault group. Except for gender, ACD, iris area, IT750, STSL, and ICA, there was no significant difference in other parameters between the two groups. Compared to the normal vault group, ACD and iris area were significant smaller, and IT750 was larger in the low vault group among parameters in the anterior chamber by pentacam and iris by SS-OCT. STSL and ICA were significantly larger in eyes of the low vault group.

Table 2 depicted the comparison of changes in anterior and posterior chamber parameters 3mo postoperatively between the low vault and normal vault groups. There was no significant difference (P>0.05) in the decrease in logMAR UDVA, logMAR CDVA, IOP, ACD, and increase in pupil diameter between patients of the two groups. The average vault is 178.304±68.581 (range 13-249 μm) and 504.063±164.551 μm (range 261-913 μm) in the low vault and normal vault group, respectively (P<0.001). At 3mo after surgery, the decrease in ACV (P=0.003) and ACA (P=0.004) in the low vault group was smaller than that in the normal vault group. The ICA decreased by 2.105°±11.779° in the low vault group, and increased by -10.050°±10.265° (P<0.001) in the normals.

The relationship between preoperative ophthalmic parameters and central vault at 3mo postoperatively were shown in Table 3. We adopted central vault as the explanatory variables in the regression model. According to the univariate GEE, ACD, iris area, iris curve, IT750, STSL, ICA, and LT were correlated with postoperative vault at 3mo (P<0.05). The multivariate GEE showed that STSL (P=0.009) and ICA (P=0.025) were the predictive factors for vault at 3mo after surgery. Moreover, our analysis demonstrated that every 0.1 mm increase in STSL was associated with 38.9 μm decrease in the postoperative 3-month vault. Further, the vault will decrease by 4 μm with every 1 degree increase in ICA. Figure 3 showed one case with vault of 130 μm and Figure 4 showed one cases with vault of 498 μm at 3mo postoperatively. In the UBM images, the former case has a significantly wider ciliary sulcus morphology.

DISCUSSION

In the present study, we investigated the association between postoperative vault and detailed influencing factors, including anterior and posterior chamber parameters, as well as iris

Table 1 Patient demographics and ophthalmic characteristics in the low vault and normal vault groups

Parameters	Low vault	Normal vault	P
No. of eyes/patients	23/16	63/36	
Sex (female, %)	100%	84.13%	0.01[a]
Age (y)	30.39±5.20	27.08±6.24	0.11
SE (D)	-7.95±1.64	-8.21±2.32	0.22
logMAR UDVA	1.10±0.16	1.10±0.23	0.50
logMAR CDVA	0.02±0.04	-0.01±0.03	0.09
IOP (mm Hg)	15.70±1.81	15.62±1.96	0.50
ECC (cells/mm²)	2685.91±280.59	2690.13±265.87	0.70
Axial length (mm)	25.91±1.33	26.67±1.42	0.05
ICL parameters			
T/I	8/15	28/35	0.58
ICL size (mm)	12.42±0.33	12.54±0.44	0.22
SE of ICL power (D)	-8.88±1.65	-9.33±2.34	0.12
Anterior chamber parameters			
CCT (μm)	505.70±28.57	518.29±31.42	0.15
PD (mm)	3.34±0.74	3.22±0.57	0.64
WTW (mm)	11.39±0.33	11.56±0.39	0.07
ATA (mm)	11.38±0.44	11.66±0.42	0.17
ACW (mm)	11.48±0.47	11.75±0.42	0.18
ACA (°)	37.83±4.56	38.37±4.16	0.58
ACD (mm)	2.92±0.17	3.07±0.17	0.01[a]
ACV (mm³)	164.69±29.35	175.69±22.97	0.18
Iris parameters			
Iris volume (mm³)	32.01±3.70	35.26±5.22	0.11
Iris area (mm²)	1.24±0.15	1.43±0.23	0.007[a]
Iris curve (mm)	-0.02±0.15	-0.10±0.10	0.07
IT750 (mm)	0.40±0.05	0.35±0.05	<0.001[a]
IT2000 (mm)	0.48±0.06	0.46±0.06	0.10
Posterior chamber parameters			
STS (mm)	11.77±0.34	11.97±0.46	0.26
STSL (mm)	0.70±0.14	0.52±0.17	<0.001[a]
ICA (°)	51.33±11.50	38.45±9.14	<0.001[a]
ILA (°)	15.99±3.75	15.02±2.61	0.16
LT (mm)	3.81±0.22	3.69±0.22	0.11

SE: Spherical equivalent; UDVA: Uncorrected distance visual acuity; CDVA: Corrected distance visual acuity; IOP: Intraocular pressure; ECC: Endothelial cell density; T/I: The ratio of toric-ICL implanted eyes to ICL implanted eyes; ICL: Implantable collamer lens (STAAR Surgical); CCT: Central cornea thickness; PD: Pupil diameter; WTW: Horizontal white-to-white diameter; ATA: Angle to angle; ACW: Anterior chamber width; AL: Axial length; ACA: Anterior chamber angle; ACD: Anterior chamber depth; ACV: Anterior chamber volume; IT750: Iris thickness at 750 μm from scleral spur; IT2000: Iris thickness at 2000 μm from scleral spur; STS: Sulcus-to-sulcus diameter; STSL: STS lens rise; ICA: Iris-ciliary angle; ILA: Iris-lens angle; LT: Lens thickness. [a]*P*<0.05.

parameters without intraoperative viscoelastic. A multivariate GEE model was employed to determine the most significant indicator affecting vault. Insufficient vault is a common clinical issue that can lead to complications such as cataracts or the need for secondary surgeries. However, limited information is available regarding the correlation between low vault and overall ocular parameters.

Table 2 Comparison of changes in anterior and posterior chamber parameters 3mo postoperatively between the low vault and normal vault groups

Parameters	Low vault	Normal vault	P
logMAR UDVA	-0.057±0.054	-0.067±0.029	0.46
logMAR CDVA	-0.052±0.039	-0.048±0.039	0.733
IOP (mm Hg)	14.339±1.822	13.959±1.929	0.795
ΔACD (mm)	0.114±0.065	0.140±0.074	0.125
ΔACA (°)	12.683±3.343	15.232±3.905	0.004[a]
ΔACV (mm³)	48.243±17.583	63.063±13.950	0.003[a]
ΔPD (mm)	-0.070±0.583	-0.248±0.441	0.483
ΔICA (°)	2.105±11.779	-10.050±10.265	<0.001[a]
Vault (μm)	178.304±68.581	504.063±164.551	<0.001[a]

UDVA: Uncorrected distance visual acuity; CDVA: Corrected distance visual acuity; IOP: Intraocular pressure; ΔACD: Changes in postoperative anterior chamber depth; ΔACA: Changes in postoperative anterior chamber angle; ΔACV: Changes in postoperative anterior chamber volume; ΔPD: Changes in postoperative pupil diameter; ΔICA: Changes in postoperative iris-ciliary angle. [a]*P*<0.05.

Our results showed that the parameters of the posterior chamber, such as STSL and ICA were predictors of the vault at 3mo postoperatively in one multivariate GEE model including all parameters of the anterior and posterior chamber and iris. The mean ICA of the low vault group was significantly higher compared to that of the normal vault group. GEE analysis further showed that for every 1 degree increase in ICA, the vault decreased by 0.005 μm. Latest research has indicated that numerous prediction models established based on corneal horizontal diameter and ACD, as used in the past, do not yield satisfactory results[20]. This suggests that the predictive role of corneal horizontal diameter and ACD in determining postoperative vault is limited. Therefore, other anatomical and physiologic factors should be considered. ICA evaluation by UBM was considered to be associated with the morphology of the ciliary body *in vivo*[18]. Chen *et al*[9] reported that ICA was strongly correlated with vault after ICL implantation. However, the relationship between the ICL vault and the posterior chamber remains unclear[21]. In addition, some previous study could not assess the posterior chamber without UBM imaging, and thus the ICA parameter was not included in analysis[22]. A larger ICA may result in a more spacious ciliary sulcus and a larger actual diameter of the STS. Previous study showed that it is easy to underestimate the distance of the STS in a large ciliary sulcus, when use the WTW method to select ICL size and SE[9,23], leading to insufficient vault. Moreover, as

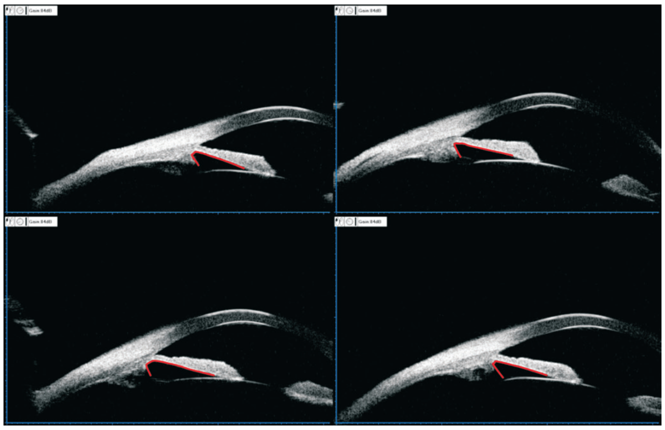

Figure 3 Ultrasound biomicroscopy (UBM) images showing wide ciliary sulcus at 2-, 4-, 8-, 10-o'clock positions of a case with 130 μm postoperative 3-month vault.

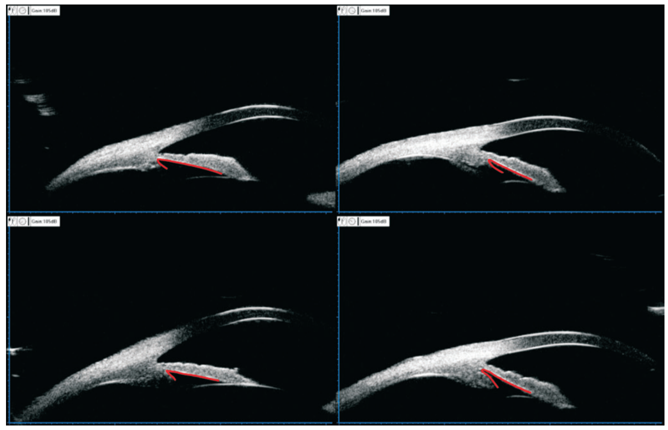

Figure 4 Ultrasound biomicroscopy (UBM) images showing normal ciliary sulcus at 2-, 4-, 8-, 10-o'clock positions of a case with 498 μm postoperative 3-month vault.

Table 3 Correlation between preoperative ophthalmic parameters and vault at 3mo

Parameters	Univariate GEE			Multivariate GEE		
	B	95%CI	*P*	*B*	95%CI	*P*
ICL size (mm)	0.126	-0.004 to 0.255	0.057			
SE of ICL power (D)	-0.023	-0.048 to 0.003	0.081			
AL (mm)	0.047	-0.001 to 0.095	0.053			
Anterior chamber parameters						
CCT (μm)	0.002	-0.000 to 0.003	0.115			
PD (mm)	-0.032	-0.103 to 0.040	0.381			
WTW (mm)	0.147	-0.021 to 0.314	0.744			
ATA (mm)	0.079	-0.077 to 0.234	0.322			
ACW (mm)	0.072	-0.077 to 0.222	0.342			
ACA (°)	0.005	-0.006 to 0.017	0.365			
ACD (mm)	0.450	0.260 to 0.641	<0.001[a]	0.186	-0.004 to 0.377	0.056
ACV (mm³)	0.002	-0.001 to 0.004	0.126			
Iris parameters						
Iris volume (mm³)	0.009	-0.003 to 0.021	0.134			
Iris area (mm²)	0.311	0.094 to 0.528	0.005[a]	-0.128	-0.030 to 0.286	0.111
Iris curve (mm)	-0.576	-1.093 to -0.058	0.029[a]	0.098	-0.338 to 0.534	0.659
IT750 (mm)	-1.573	-2.130 to -1.016	<0.001[a]	-0.342	-0.967 to 0.283	0.284
IT2000 (mm)	-0.452	-1.225 to 0.320	0.251			
Posterior chamber parameters						
STS (mm)	0.05	-0.105 to 0.206	0.524			
STSL (mm)	-0.67	-0.944 to -0.396	<0.001[a]	-0.389	-0.680 to -0.098	0.009[b]
ICA (°)	-0.008	-0.011 to -0.005	<0.001[a]	-0.004	-0.007 to -0.000	0.025[b]
ILA (°)	-0.003	-0.019 to 0.012	0.675			
LT (mm)	-0.291	-0.568 to -0.014	0.039[a]	-0.082	-0.252 to 0.088	0.346

GEE: Generalized estimating equations; CI: Confidence interval; SE: Spherical equivalent; ICL: Implantable collamer lens (STAAR Surgical); CCT: Central cornea thickness; PD: Pupil diameter; WTW: Horizontal white-to-white diameter; ATA: Angle to angle; ACW: Anterior chamber width; AL: Axial length; ACA: Anterior chamber angle; ACD: Anterior chamber depth; ACV: Anterior chamber volume; IT750: Iris thickness at 750 μm from scleral spur; IT2000: Iris thickness at 2000 μm from scleral spur; STS: Sulcus-to-sulcus diameter; STSL: STS lens rise; ICA: Iris-ciliary angle; ILA: Iris-lens angle; LT: Lens thickness. [a]Univariate GEE, $P<0.05$; [b]Multivariate GEE, $P<0.05$.

the ciliary sulcus is axial dependent, the ICL fixation may be affected by the position of the haptics. In our study, the lower vault group had more eyes with no haptics in ciliary sulcus than the normal vault group. Instead, the dislocated ICL haptics were in the ciliary process, under ciliary sulcus or inserted in the ciliary body. Therefore, the ICL might shift downwards and the distance between the ICL and crystalline decreased. This was consistent with the fact that the value of ΔICA were smaller in the low vault group in Table 2. Future study with an instrument capable of providing intuitive and comprehensive scanning of the ciliary sulcus to enhance the precision of ICL surgery.

Unlike ICA analysis, we found no significant correlation between iris parameters and postoperative vault in the multivariate GEE model, though iris area, iris curve and IT750 were associated with postoperative vault in the univariate GEE. This was partly consistent with previous studies that the morphology of iris were associated with a higher rate of insufficient vault[7,24]. As researchers stated that regardless which ICL sizing methodology was chosen, the postoperative vault varied in clinic and reflected unmeasurable ocular factors, such as vertical compression by the iris and dampening effect of the ciliary sulcus structures[9,17]. The negative results of multivariage GEE analysis indicated that among the factors affecting postoperative vault, the control force of the ciliary sulcus has a greater impact than iris compression. Furthermore, in contrast to some studies[25], we did not find an association between postoperative vault and anterior chamber parameters, including ACD. We speculated that the posterior chamber may have a greater impact on vault than the anterior chamber.

All surgical procedures were uneventful with no subcapsular cataract formation observed in the early postoperative period, though cataract formation was one of the most frequently documented complication related to ICL surgery[26-27]. We speculated that this phenomenon was due to several reasons. First, all surgeries in this study were performed by one experienced surgeon[28] with gentle surgical skills, and avoided contacting the natural crystalline lens during the surgical procedure. Second, we used the OVD-free surgical method[19] which reduce the overall time without the need to inject and remove the OVD. Third, with the development of central hole design, the V4c ICL allowed for the natural flow of aqueous humor and avoiding contact with the crystalline lens, minimizing the risk of complications associated with the lens[29]. In this study, we chose to closely follow up instead of ICL realignment or exchange in eyes with the low vault without contact between the crystalline lens and ICL or misalignment.

There were several limitations in the current study. First, we could not exclude the influence of accommodation on the measurements of UBM and OCT. We supposed that there was little difference in the structure of the anterior and posterior chambers when pupils are not dilated. Second, one examiner was selected to measure the ocular parameters semi-automatically in the software. However, this examiner was well trained and skilled to minimize measure bias.

In conclusion, we demonstrated eyes with wide ciliary sulcus showed higher risk of low vault after ICL implantation at postoperative 3mo. The control force of the ciliary sulcus may have a greater impact than iris compression among the preoperative parameters affecting postoperative vault.

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