Clinical prediction of insufficient vaults after implantable collamer lens implantation

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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 [19] 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. 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, normal iris and pupil function, 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).

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 (mm²) 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 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
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, 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 \(\mu\)m decrease in the postoperative 3-month vault. Further, the vault will decrease by 4 \(\mu\)m with every 1 degree increase in ICA. Figure 3 showed one case with vault of 130 \(\mu\)m and Figure 4 showed one cases with vault of 498 \(\mu\)m 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...
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 physiologic factors should be considered. ICA evaluation by UBM was considered to be associated with the morphology of the ciliary body \textit{in vivo} [9,23]. Chen et al. \textit{reported that ICA was strongly correlated with vault after ICL implantation. However, the relationship between the ICL vault and the posterior chamber remains unclear [20]. In addition, some previous study could not assess the posterior chamber without UBM imaging, and thus the ICA parameter was not included in analysis. 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 \textit{in vivo} [9,23]. Chen et al. \textit{reported that ICA was strongly correlated with vault after ICL implantation. However, the relationship between the ICL vault and the posterior chamber remains unclear [20]. In addition, some previous study could not assess the posterior chamber without UBM imaging, and thus the ICA parameter was not included in analysis [21]. A larger ICA may result in a more spacious ciliary sulcus and thus the ICA parameter was not included in analysis [21].
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

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Univariate GEE</th>
<th>Multivariate GEE</th>
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<tbody>
<tr>
<td></td>
<td>B</td>
<td>95%CI</td>
</tr>
<tr>
<td>ICL size (mm)</td>
<td>0.126</td>
<td>-0.004 to 0.255</td>
</tr>
<tr>
<td>SE of ICL power (D)</td>
<td>-0.023</td>
<td>-0.048 to 0.003</td>
</tr>
<tr>
<td>AL (mm)</td>
<td>0.047</td>
<td>-0.001 to 0.095</td>
</tr>
<tr>
<td>Anterior chamber parameters</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CCT (μm)</td>
<td>0.002</td>
<td>-0.000 to 0.003</td>
</tr>
<tr>
<td>PD (mm)</td>
<td>-0.032</td>
<td>-0.103 to 0.040</td>
</tr>
<tr>
<td>WTW (mm)</td>
<td>0.147</td>
<td>-0.021 to 0.314</td>
</tr>
<tr>
<td>ATA (mm)</td>
<td>0.079</td>
<td>-0.077 to 0.234</td>
</tr>
<tr>
<td>ACW (mm)</td>
<td>0.072</td>
<td>-0.077 to 0.222</td>
</tr>
<tr>
<td>ACA (*)</td>
<td>0.005</td>
<td>-0.006 to 0.017</td>
</tr>
<tr>
<td>ACD (mm)</td>
<td>0.450</td>
<td>0.260 to 0.641</td>
</tr>
<tr>
<td>ACV (mm³)</td>
<td>0.002</td>
<td>-0.001 to 0.004</td>
</tr>
<tr>
<td>Iris parameters</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Iris volume (mm³)</td>
<td>0.009</td>
<td>-0.003 to 0.021</td>
</tr>
<tr>
<td>Iris area (mm²)</td>
<td>0.311</td>
<td>0.094 to 0.528</td>
</tr>
<tr>
<td>Iris curve (mm)</td>
<td>-0.576</td>
<td>-1.093 to -0.058</td>
</tr>
<tr>
<td>IT750 (mm)</td>
<td>-1.573</td>
<td>-2.130 to -1.016</td>
</tr>
<tr>
<td>IT2000 (mm)</td>
<td>-0.452</td>
<td>-1.225 to 0.320</td>
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<tr>
<td>Posterior chamber parameters</td>
<td></td>
<td></td>
</tr>
<tr>
<td>STS (mm)</td>
<td>0.05</td>
<td>-0.105 to 0.206</td>
</tr>
<tr>
<td>STSL (mm)</td>
<td>-0.67</td>
<td>-0.944 to -0.396</td>
</tr>
<tr>
<td>ICA (*)</td>
<td>-0.008</td>
<td>-0.011 to -0.005</td>
</tr>
<tr>
<td>ILA (*)</td>
<td>-0.003</td>
<td>-0.019 to 0.012</td>
</tr>
<tr>
<td>LT (mm)</td>
<td>-0.291</td>
<td>-0.568 to -0.014</td>
</tr>
</tbody>
</table>

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. *Univariate GEE, P<0.05; **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 AICA 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 were associated with postoperative vault in the univariate GEE. The negative results of multivariate 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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Conflicts of Interest: Zhu J, None; Cheng D, None; Zhu XY, None; Li FF, None; Yang Y, None; Ye YF, None.

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