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Research article

The rate of vault changes after ICL V4c implantation and its correlation with anterior segment parameters

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ABSTRACT

Purpose: To investigate the rate of vault changes after implantation of ICL V4c and the correlation with anterior segment parameters.
Methods: A total of 64 eyes were studied from the 37 myopic subjects recruited. CASIA2 was used to record the vault at 1 week, 1 month, 3 months and 6 months after the operation as well as the preoperative anterior segment parameters including pupil diameter, lens vault, anterior chamber depth, anterior chamber width, iris area (IA), iris thickness, angle opening distance, angle recess area, trabecular iris space area, and trabecular iris angle. The rates of vault change in different time intervals were compared and the correlations between the rates and anterior segment parameters were analyzed. $P < 0.05$ was considered statistically significant.
Results: The rate of vault decrease was -19.53 ± 111.28 μm/month between 1 week and 1 month, -19.90 ± 29.71 μm/month between 1 month and 3 months and -4.25 ± 18.10 μm/month between 3 months and 6 months; hence the rate was shown to slow down significantly from 3 months post-operation ($P = 0.024$). The average rate of vault changes showed a significant positive correlation with IA ($R^2 = 0.140$, $F = 4.980$, $P = 0.01$). No significant correlation was found with other anterior segment parameters (all $P > 0.05$).
Conclusion: The rate of decreasing vault significantly slowed down from 3 months post-operation. A larger IA may imply a lower decreasing rate of vault change.

1. Introduction

The implantable collamer lens (ICL) with a central hole (ICL V4c) has been widely reported as a safe and effective surgical method for correcting myopia and hyperopia, because it can maintain natural adequate humor flow [1–3]. However, the ICL V4c is also a posterior chamber phakic intraocular lens and has the corresponding limitations, which may lead to complications such as secondary glaucoma, pigment diffusion, cataract development, and loss of endothelial cells [4–7]. Hence, the vault has come to be considered one

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of the most vital parameters after ICL V4c surgery. The vault is defined as the distance between the posterior surface of the ICL V4c and the anterior surface of the crystalline lens, and an overly high (>1000 μm) or overly low vault (<250 μm) may lead to the above complications [8–10].

Several studies of changes of the vault after ICL implantation have shown a slight decline for both conventional ICLs (ICL V4) and central-hole ICL V4cs over time [9–11]. However, there is little literature on the rate of vault change following ICL V4c surgery. Most previous studies have analyzed the amount of postoperative vault change and its related factors [12,13]. However, the rate of vault change illuminates the effect of time on the vault, which can more accurately reflect the pattern of vault change.

In recent years, many studies have focused on the factors affecting the postoperative vault and have found that anterior segment parameters may play a key role [10,12]. The second generation of anterior segment optical coherence tomography (AS-OCT) CASIA2 (Tomey, Nagoya, Japan) allows for a 360° global scan to obtain local and circumferential anterior segment parameters [14,15], which can more comprehensively reflect the conditions of the anterior segment. Hence, this study aims to investigate the rate of vault change after ICL V4c implantation and analyze the effect of anterior segment parameters on this rate of change.

2. Methods

2.1. Subjects

In this study, a total of 37 subjects (64 eyes) who underwent ICL V4c implantation for the correction of myopia at the Shanghai Eye and ENT Hospital of Fudan University were recruited. The inclusion criteria were an age of at least 20, stable refraction (change in refraction of less than 0.50 D per year in the past 2 years), and a strong desire for the correction of myopia. The exclusion criteria were acute ocular inflammatory disease, systemic disease, a history of ocular surgery, an anterior chamber depth (ACD) of less than 2.8 mm, an endothelial cell density (ECD) of less than 2500 cells/mm^2, and suspicion of keratoconus. The study was approved by the Ethics Committee of the Shanghai Eye and ENT Hospital and adhered to the tenets of the Declaration of Helsinki. Written informed consent was obtained from all subjects.

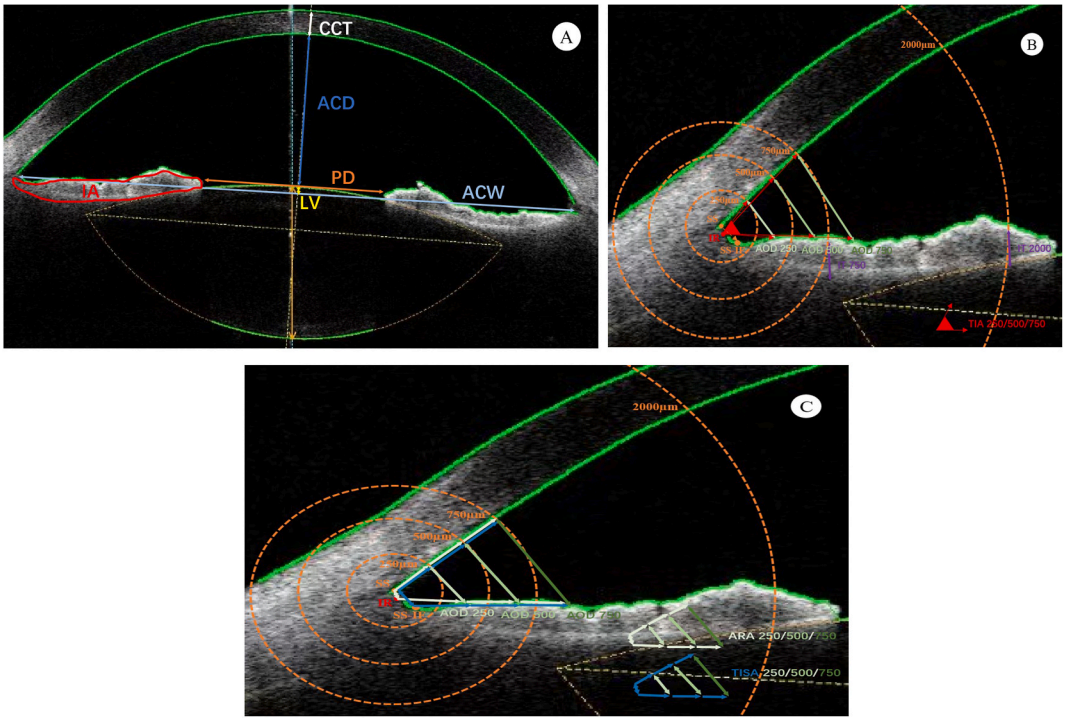

Fig. 1. Representative images with anterior segment parameters of the CASIA2. A. An overall CASIA2 image of CCT, PD, LV, ACD, ACW and IA. B. A partial CASIA2 image of SS, IR, SS-IF, IT750/2000, AOD 250/500/750 and TIA 250/500/750. C. A partial CASIA2 image of the area bounded (ARA 250/500/750 and TISA 250/500/750) in the anterior chamber. CCT: central corneal thickness; PD: pupil diameter; LV; lens vault; ACD: anterior chamber depth; ACW: anterior chamber width; IA: iris area. SS: scleral spur; IR: iris recess; SS-IF: the intersection point of the iris and a line which was drawn from SS and perpendicular to the plane of the inner scleral wall. IT 750/2000: iris thickness at 750 μm and at 2000 μm; AOD 250/500/750: angle opening distance at 250 μm, at 500 μm and at 750 μm; TIA 250/500/750: trabecular iris angle at 250 μm, at 500 μm and at 750 μm; ARA 250/500/750: angle recess area at 250 μm, at 500 μm and at 750 μm which is the area bounded by SS, IR and AOD 250/500/750; TISA 250/500/750: trabecular iris space area at 250 μm, at 500 μm and at 750 μm which is the area bounded by SS, SS-IF and AOD 250/500/750.

2.2. Preoperative examinations

All subjects underwent preoperative ophthalmic examinations including: (1) uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) at 5 m using a Snellen chart; (2) manifest refractions; (3) slit-lamp examination; (4) intraocular pressure; (5) IOL Master 500 (Carl Zeiss Meditec, Jena, Germany); (6) AS-OCT CASIA2 (Tomey, Nagoya, Japan).

We used CASIA2 to acquire anterior segment parameters, including: (1) central corneal thickness (CCT); (2) pupil diameter (PD); (3) lens vault (LV); (4) ACD; and (5) anterior chamber width (ACW). In addition, an automated circumferential (360°) angle scan was adopted to acquire: (1) iris thickness at 750 μm and at 2000 μm (IT 750/2000); (2) the iris area (IA); (3) the angle opening distance at 250 μm, at 500 μm and at 750 μm (AOD 250/500/750); (4) the angle recess area at 250 μm, at 500 μm and at 750 μm (ARA 250/500/750); (5) the trabecular iris space area at 250 μm, at 500 μm and at 750 μm (TISA 250/500/750); and (6) the trabecular iris angle at 250 μm, at 500 μm and at 750 μm (TIA 250/500/750). Fig. 1A, B and 1C show the details of these anterior segment parameters.

2.3. ICL calculation

The EVO ICL V4c (Staar Surgical, Nidau, Switzerland) was used for implantation in this study. ICL V4c is a plate-haptic single-piece intraocular lens with a 360 μm central hole. The ICL V4c offers a wide range of spherical correction (from −0.50 to −18.00 DS) and cylindrical correction (from +0.50 to +6.00 DC). ICL V4c includes four lengths, namely 12.1 mm, 12.6 mm, 13.2 mm, and 13.7 mm. The length was selected based on the subject's ACD and white-to-white (WTW) used in the previous studies [8,16]. When the value of ACD was between 2.8 and 3.0 mm, the value of ICL length was equal to the value of WTW plus 0.2–0.4 mm. When the value of ACD was between 3.0 and 3.5 mm, the value of ICL length was equal to the value of WTW plus 0.4–0.6 mm. When the value of ACD was between 3.5 and 3.7 mm, the value of ICL length was equal to the value of WTW plus 0.6–0.8 mm. Additionally, the ICL power was calculated by the manufacturer (STAAR Surgical) using a modified vertex formula based on the spherocylindrical refraction, ACD, CCT and keratometric power.

2.4. ICL V4c surgical procedure

All ICL V4c implantation surgeries were performed by the same surgeon (XTZ). The surgical procedure was the same as that reported in our previous studies [8,16]. All toric and non-toric ICL V4c were aligned the 180-degree meridian. We administered 1.0 % prednisolone acetate (Pred Forte; Allergan, Irvine, CA, USA) 4 times daily for 4 days, 0.5 % levofloxacin (Cravit; Santen, Osaka, Japan) 4 times daily for 1 week, pranoprofen (Senju, Osaka, Japan) 4 times daily for 2 weeks, and artificial tears 4 times daily for 1 month postoperatively.

2.5. ICL V4c vault measurement

With good accuracy and reproducibility, CASIA2 has been widely used in the evaluation of anterior segment following ICL implantation [17–19]. In this study, we used CASIA2 to record the ICL V4c vault at 1 week, 1 month, 3 months, and 6 months post-operation. The vault is defined as the distance between the posterior surface of the ICL V4c and the anterior surface of the crystalline lens. To prevent observer variability in the measurements of the vault, all measurements were conducted by the same examiner. Totally 10 subjects following ICL V4c implantation were recruited prior to the study. The vault values were acquired separately by two examiners (Feng Lin and Fang Liu). The coefficients of variation and intraclass correlation coefficients were evaluated. To obtain good agreement within examiner, the examiner Feng Lin conducted the examination in this study. Additionally, the vault value was acquired three times at each follow-up. The average of the three vault values was used for analysis.

2.6. Definition of the rate of vault changes per month

We defined the rate of vault change per month at the early stage, middle stage and late stage based on different time intervals. The rate of vault change per month in the early stage was the value: vault value at 1 month - vault value at 1 week. The rate of vault change per month in the middle stage was given by the value: (vault value at 3 month - vault value at 1 month)/2. The rate of vault change in the late stage per month was the value: (vault value at 6 months - vault value at 3 months)/3. In addition, we defined the average rate of vault changes per month within 6 months as the value: (vault value at 6 months - vault value at 1week)/6.

2.7. Statistics

We used SPSS software (Version 26.0) in this study. The results were presented as mean ± SD. The normality of the distribution of parameters was determined with the Kolmogorov–Smirnov test. The vaults at different time-points and rates of vault change at different stages were compared by repeated-measures analysis of variance (normally distributed parameters) or related samples Friedman's two-way analysis of variance (non-normally distributed parameters). Additionally, post hoc analysis was conducted to reveal pairwise difference. The relationship between the rates of vault change and the preoperative anterior segment parameters were evaluated by Pearson's correlation analysis (normally distributed parameters) or Spearman's correlation analysis (non-normally distributed parameters). Significantly correlated preoperative anterior segment parameters based on Pearson's or Spearman's correlation analysis were further included in the multiple linear regression model for analysis. $P < 0.05$ was considered statistically

significant.

3. Results

3.1. Baseline characteristics

A total of 64 eyes of 37 subjects (7 males and 30 females) were included in our study. The baseline characteristics are presented in Table 1. The mean age was 27.95 ± 4.06 years. The mean spherical equivalent was −8.00 ± 2.46 D.

3.2. The rate of vault change

The mean vault values after ICL V4c implantation were 668.23 ± 209.72 μm at 1 week, 648.70 ± 224.39 μm at 1 month, 608.91 ± 216.93 μm at 3 months, and 596.16 ± 228.18 μm at 6 months post-operation, respectively. The vault values were significantly different over time ($P < 0.01$). Though the mean vault value at 1 month post-operation was not significantly different from that at 1 week ($P > 0.05$), the mean values at 3 months and 6 months post-operation were significantly lower than that at 1 week (all $P < 0.01$). The values showed a downward trend postoperatively (Fig. 2).

The postoperative rate of vault change was −19.53 ± 111.28 μm/month in the early stage, −19.90 ± 29.71 μm/month in the middle stage, and −4.25 ± 18.10 μm/month in the late stage. The rate of vault change was significantly different over time ($P = 0.014$). Though the rate of vault change in the middle stage was not significantly different from that in the early stage ($P > 0.05$), the rate of vault changes in the late stage was significantly higher than that in the early stage ($P = 0.024$). Fig. 3 shows the upward trend in the rate of vault change over time (Fig. 3).

3.3. Correlation of the preoperative anterior segment parameters with the average rate of vault change

The average rate of vault change within 6 months post-operation was −12.01 ± 18.02 μm/month. The correlations of the anterior segment parameters with the average rate of vault change are shown in Table 2. IT 2000 ($r = 0.249$, $P = 0.047$) and IA ($r = 0.348$, $P < 0.01$) were positively significantly correlated with the average rate of vault change. No significant relationship was found between the average rate of vault change and other anterior segment parameters, including CCT, PD, LV, ACD, ACW, AOD, ARA, TISA, and TIA (all $P > 0.05$).

The significantly correlated parameters, IA and IT 2000, were further included in the multiple linear regression model for analysis ($R^2 = 0.140$, $F = 4.980$, $P = 0.01$). The IA showed a significant positive correlation with the average rate of vault change (Beta = 0.298, t = 2.358, $P = 0.022$) (Fig. 4). However, no significant correlation was found between IT 2000 and the average rate of vault change (Beta = 0.148, t = 1.169, $P = 0.247$).

4. Discussion

The vault has always been one of the most important observation indicators after ICL V4/ICL V4c implantation surgery. Many studies have found that postoperative vault decreased over time [9,11,20]. However, low vault may lead to mechanical contact between the ICL V4c and the crystalline lens, causing anterior capsular opacification and cataract [11]. Though the ICL V4c greatly improved the aqueous humor dynamics and reduced the risk of developing cataract, the downward trend of the vault was still inevitable [9,12]. In this study, we found that the vault decreased over time postoperatively and the rate of decrease slowed down from 3 months post-operation. In addition, we reported that the IA was significantly correlated with the average rate of vault decrease.

That the vault decreases over time has been identified in many studies [9,10,12,20–22]. Alfonso et al. classified the subjective vault into 5 levels from 0 (ICL apparently touches the anterior surface of the lens) to 4 (separation between the posterior surface of the ICL and the anterior surface of the lens about twice the corneal thickness) [10]. They reported that the mean vault of ICL V4c decreased from 2.30 ± 0.87 1 week after surgery to 2.10 ± 0.92 at 1 year and to 2.06 ± 1.05 at 3 years postoperatively. Additionally, for subjects with higher baseline vault values, the vault decreased greater overtime. Kazutaka et al. also reported that the vault value for ICL V4c

Table 1
Baseline characteristics.

Characteristics	Mean ± SD	Range
No. of eyes	64	
Age (year)	27.95 ± 4.06	21.00 to 38.00
Gender (male/female)	7/30	
Sphere (D)	−7.37 ± 2.44	−13.25 to −3.75
Cylinder (D)	−1.26 ± 0.83	−3.50 to 0.00
SE (D)	−8.00 ± 2.46	−13.63 to −4.13
CDVA (logMAR)	0.00 ± 0.01	−0.08 to 0.00
AL (mm)	26.81 ± 1.43	22.91 to 30.99

D: diopters; SE: spherical equivalent; CDVA: corrected distance visual acuity; LogMAR: logarithm of the minimal angle of resolution; AL: axial length.

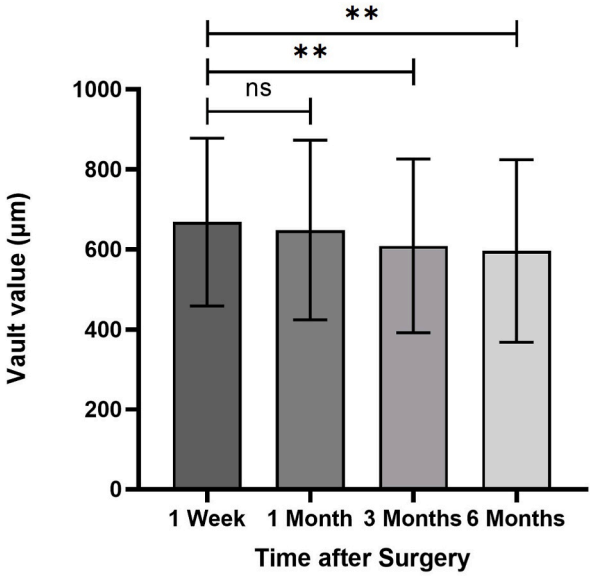

Fig. 2. Time course of vault value following ICL V4c implantation. Implantable collamer lens (ICL); ns, not significant; **, $P < 0.01$.

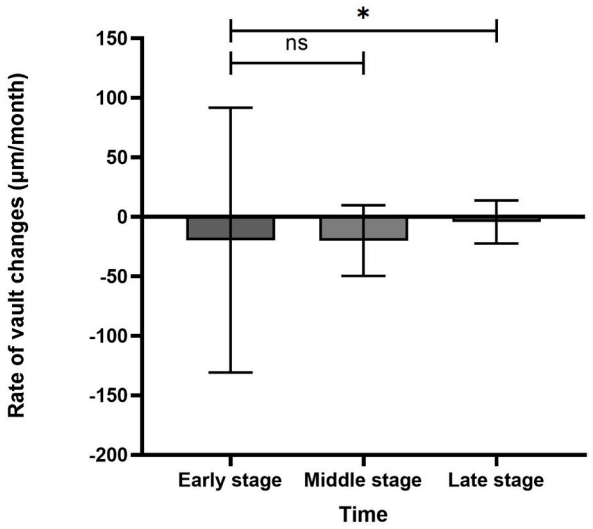

Fig. 3. Rates of vault changes over time following ICL V4c implantation. The rate of vault changes per month in the early stage was the value: (vault value at 1 month - vault value at 1 week). The rate of vault changes per month in the middle stage was the value: (vault value at 3 month - vault value at 1 month)/2. The rate of vault changes per month in the late stage per month was the value: (vault value at 6 months - vault value at 3 months)/3. Implantable collamer lens (ICL); ns, not significant; *, $P < 0.05$.

showed a decreasing tendency over time from 603 ± 276 μm at 1 week postoperatively to 482 ± 245 μm at 1 year postoperatively [9]. Our results were consistent with their studies [9,10]. The vault value showed a decreasing tendency after the operation and had a significant decrease at 3 months and 6 months. The postoperatively decreasing vault may be attributed to the pressure from the iris and changes of the fixated position of ICLV4c. On the one hand, as the ICL V4c was implanted in the posterior chamber, the back surface of the iris was attached to the ICL V4c optics. The iris was further pushed forward and the iridocorneal angle was narrowed [23]. The ICL V4c would be conversely under backward pressure by the iris, causing the decreasing vault over time. On the other hand, changes of the fixated position of ICL V4c may lead to vault decrease. While the ICLV4c haptics should be ideally fixated on the ciliary sulcus, several ICLV4c haptics slipped backwards initially and may be fixated on the ciliary body temporarily [24]. As the fixated position of haptics changes from the ciliary body to the ciliary sulcus over time, the vault may decrease [25].

In addition to vault value at different time points, we evaluated the difference in rate of vault changes at different stages. The decreasing rate of vault was stable within 3 months post-operation and significantly slowed down from 3 months onward. This slowing in the rate of vault decrease was also identified in another study [20]. Du et al. reported that the vault value significantly decreased

Table 2
Correlation of anterior segment parameters with the average rate of vault changes.

Parameters	Mean ± SD	r	*P* Value
CCT (μm)	512.81 ± 31.43	0.114	0.372
PD (mm)	7.08 ± 0.76	−0.216	0.087
LV (mm)	−0.19 ± 0.16	−0.161	0.205
ACD (mm)	3.31 ± 0.23	0.13	0.305
ACW (mm)	11.96 ± 0.34	0.121	0.343
IT 750 (mm)	0.41 ± 0.05	0.071	0.579
IT 2000 (mm)	0.48 ± 0.10	0.249	0.047
IA (mm^2)	1.18 ± 0.15	0.348	<0.01
AOD 250 (mm)	0.56 ± 0.20	−0.015	0.906
AOD 500 (mm)	0.83 ± 0.25	−0.007	0.956
AOD 750 (mm)	1.09 ± 0.27	0.001	0.993
ARA 250 (mm^2)	0.14 ± 0.06	−0.029	0.819
ARA 500 (mm^2)	0.31 ± 0.12	−0.015	0.909
ARA 750 (mm^2)	0.55 ± 0.18	−0.011	0.931
TISA 250 (mm^2)	0.11 ± 0.04	−0.029	0.82
TISA 500 (mm^2)	0.29 ± 0.10	−0.021	0.868
TISA 750 (mm^2)	0.53 ± 0.16	−0.011	0.931
TIA 250 (°)	69.48 ± 12.30	−0.022	0.863
TIA 500 (°)	61.72 ± 11.01	0.015	0.908
TIA 750 (°)	57.63 ± 8.98	0.017	0.894

CCT: central corneal thickness; PD: pupil diameter; LV; lens vault; ACD: anterior chamber depth; ACW: anterior chamber width; IT 750/2000: iris thickness at 750 μm and at 2000 μm; IA: iris area; AOD 250/500/750: angle opening distance at 250 μm, at 500 μm and at 750 μm; ARA 250/500/750: angle recess area at 250 μm, at 500 μm and at 750 μm; TISA 250/500/750: trabecular iris space area at 250 μm, at 500 μm and at 750 μm; TIA 250/500/750: trabecular iris angle at 250 μm, at 500 μm and at 750 μm.

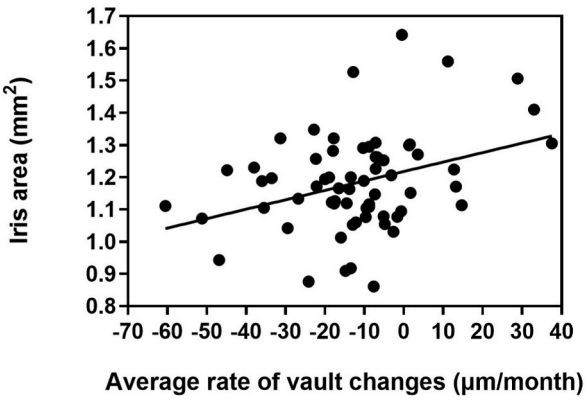

Fig. 4. Relationship between the average rate of vault changes and the iris area. The average rate of vault changes per month within 6 months was the value: (vault value at 6 months - vault value at 1week)/6. ($r = 0.348$, $P < 0.01$).

within 1 month post-operation and stabilized afterwards [20]. We attributed the slowing down in the rate of vault decrease to the changes of pressure from the iris. Initially, the ICL V4c was implanted at a relatively high vault and was under relatively high backward-pushing pressure created by the back surface of the iris. As the ICL V4c vault decreased over time, the pressure created by the iris on the ICL V4c may weaken, which may slow down the rate of decreasing vault.

Vault changes were correlated with various anterior segment parameters, such as pupil movement, WTW distance, and ACD [8,12,13]. First, Chen et al. reported that pupil size changes were significantly correlated with vault changes [8]. As the pupil contracted, the ICL V4c vault value decreased significantly; as the pupil dilated, the ICL V4c vault value conversely increased. Secondly, a small difference between the WTW distance and ICL size may imply decreasing vault changes [10]. Alfonso et al. reported that eyes which had a decrease of vault or developed anterior segment cataract had a smaller difference between the white-to-white distance and the ICL size [10]. Third, shallower ACD may imply a greater decrease of vault [12]. Li et al. showed that a vault decrease of ICL V4c 2 years post-operation was significantly negatively correlated with the value of the preoperative ACD [12]. However, no significant correlation between ACD and vault change was found in our study. This may be attributed to a different device for evaluation of vault and a different length of follow-up time. Firstly, we recorded the vault using the CASIA2 at each follow-up, while Li et al. evaluated vault changes using the Scheimpflug camera. Secondly, the length of follow-up time was different, as we evaluated the correlation between preoperative ACD and vault changes 6 months post-operation, and they analyzed the correlation of ACD with vault changes 2 years after the operation. The impact of preoperative shallow ACD on the vault decrease may begin to be significant after the late stage.

In this study, we used CASIA2 and further found that a larger IA implied a lower decreasing rate of vault. The IA is the cross-

sectional area from spur to pupillary margin of the iris. As the ICL V4c optics were in contact with the back surface of the iris after implantation, a larger IA may suggest a larger contact area between ICL V4c and the back surface of iris and deeper embedding depth of the ICL V4c in the back surface of iris. With a larger contact area and deeper embedding depth, the back surface of iris may have a stronger adsorption and fixation effect on the ICL V4c. Therefore, though the ICL V4c vault would still decrease over time, the rate of vault decrease with a larger IA may be lower.

There were some limitations to our study. First, we recorded the rate of vault changes within 6 months after the operation. The longer-term rate of vault change is worth further analysis. Second, the posterior chamber could not be recorded by CASIA2 and the exact structural relationship between the back surface of the iris and the ICL V4c optics was unknown. It would be worth further recording the structural relationship between the iris and the ICL V4c with an ultrasound biomicroscope at each time-point post-operation.

5. Conclusions

In conclusion, we recorded the rates of vault change in different time intervals and found that the vault decreased over time and the rate of decreasing vault significantly slowed down from 3 months after the operation. In addition, a larger IA may imply a lower rate of decreasing vault. In fact, while various researchers reported the difference in vault values at each follow-up visit [10–12], rapid vault changes in a short period of time may have a greater impact on the anterior segment. As lower vault postoperatively may induce anterior subcapsular cataract [10,26], it is critical to detect and deal with the low vault in the early stage postoperatively. Therefore, we evaluated and compared rate of vault change over different time intervals postoperatively. As the rate of vault decrease was shown to slow down from 3 months post-operation, it may be critical to pay attention to the vault changes within 3 months after ICL V4c implantation. Additionally, for subjects with smaller IA, relatively higher rate of vault decrease should be highlighted to avoid the mechanical contact of ICL V4c with the anterior lens capsule from the early stage postoperatively.

Declarations

Ethics statement

This study was reviewed and approved by the Ethics Committee of Fudan University Eye and ENT Hospital Review Board (Shanghai, China), with the approval number: 2016038. All participants provided informed consent to participate in the study.

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Data availability statement

Data will be made available on request.

CRediT authorship contribution statement

Feng Lin: Writing – original draft, Software, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Fang Liu:** Writing – original draft, Software, Methodology, Formal analysis, Data curation, Conceptualization. **Lingling Niu:** Software, Methodology, Data curation. **Peijun Yao:** Supervision, Methodology. **Xiaoying Wang:** Supervision, Resources, Methodology. **Xingtao Zhou:** Writing – review & editing, Project administration, Funding acquisition, Conceptualization. **Jing Zhao:** Writing – review & editing, Supervision, Methodology, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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