ORIGINAL RESEARCH



Long-Term Vault Changes in Different Levels and Factors Affecting Vault Change After Implantation of Implantable Collamer Lens with a Central Hole

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ABSTRACT

Introduction: This study evaluated vault changes in eyes implanted with an implantable Collamer lens (ICL) with a central hole (ICL V4c) for myopia and astigmatism correction as well as factors related to vault changes over time.

Methods: This retrospective study enrolled 169 myopic eyes from 169 patients (137 women and 32 men) who underwent ICL V4c implantation to correct myopia and astigmatism. Vault values were measured quantitatively using a rotating

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Scheimpflug camera. Each patient underwent at least four postoperative follow-up visits at 1 month, 6 months, 1 year, and more than 2 years. We compared postoperative values between groups and identified factors affecting vault changes over time.

Results: The mean vaults at 1 month (baseline), 6 months, 1 year, and the last follow-up time following ICL implantation were $540.83 \pm$ 186.13, 520.00 ± 196.08 , 503.79 ± 198.30 , and $471.42 \pm 211.35 \,\mu$ m, respectively. Eyes with baseline vaults of 250-750 and $\geq 750 \,\mu$ m exhibited a trend of vault decrease over time, and the differences were statistically significant (P < 0.05) at 6 months and 1 year postoperatively, respectively. The variables relevant to the value of vault decrease between baseline and last follow-up time were anterior chamber depth (ACD) and ICL power (adjusted $R^2 = 0.121$, P < 0.001).

Conclusions: We found a trend of decreased mean objective vault values over time, which was more obvious in eyes with higher baseline vault values. The vault value of the ICL decreased more in eyes with shallower ACDs, higher ICL power, or both. Moreover, the decrease in vault values became statistically significant earlier in eyes with higher baseline vaults or shallower ACDs.

Keywords: Implantable Collamer lens; Vault; Myopia

Key Summary Points

Why carry out this study?

Previous studies have reported that the vault has a tendency to decrease over time, but few studies have evaluated factors related to postoperative vault decrease while vault plays an important role in maintaining the safety and stability of the procedure.

In this study, we evaluated vault changes in different levels in eyes implanted with implantable Collamer lens (ICL) V4c and factors related to vault change over the long term.

What was learned from the study?

The result suggests that there was a trend of decreased vault values over time, which was more obvious in eyes with higher baseline vault values. We found that the vault value of the ICL decreased more in eyes with shallower anterior chamber depth (ACDs), higher ICL power, or both.

INTRODUCTION

The Visian Implantable Collamer Lens (ICL, Staar Surgical Co.) is a commonly used posterior chamber phakic intraocular lens (IOL, pIOL) that is demonstrably safe and effective for myopia and astigmatism correction [1, 2]. The V4c model was designed with a 360-µm central hole in the central optical zone to prevent pupillary block and acute angle-closure without degrading optical qualities [3, 4]. Compared with ICL V4, the central hole in the V4c improves the circulation of aqueous humor and helps maintain the intraocular pressure (IOP) without additional peripheral iridotomy [5–7]. ICL V4c may also reduce the risk of anterior capsular opacification and cataract formation [8, 9].

Although postoperative complications of ICL V4c implantation are rarely reported, the vault

(the distance between the posterior surface of the ICL and the anterior surface of the crystalline lens) still plays an important role in maintaining the safety and stability of the procedure. A low vault may lead to mechanical contact with the crystalline lens or inadequate aqueous circulation, which increases the risk of anterior capsular opacification and cataract formation [10, 11]. An excessively high vault causes mechanical contact between the ICL and iris, resulting in inflammation, high IOP, angleclosure glaucoma, and pigment dispersion syndrome [12, 13].

Many studies have attempted to obtain an ideal vault by evaluating associated factors, developing new strategies to determine an appropriate ICL size, and predicting postoperative vault [9, 14, 15]. However, long-term studies have shown that the vault has a tendency to decrease over time [12, 16]. Few studies have evaluated factors related to postoperative vault decrease. However, vault decrease, along with a physiological increase in lens thickness with age, may increase the risk of cataract formation, making long-term vault follow-up of ICL patients an important part of the evaluation of ICL safety.

This study aimed to evaluate vault changes during a period of more than 2 years using a rotating Scheimpflug camera in a large cohort of eyes that had been implanted with ICL V4c for myopia and astigmatism correction, and to evaluate factors related to vault change over the long term.

METHODS

Subjects

This study adhered to the Declaration of Helsinki and was approved by the Ethics Committee of the Fudan University Eye and ENT Hospital. Informed consent was obtained from all patients after the possible risks and benefits of the study were explained to them.

This retrospective study enrolled 169 myopic eyes from 169 patients (137 women and 32 men) consisting of 87 eyes implanted with the myopic ICL V4c and 82 eyes implanted with the

	Mean ± SD	95% CI	Range [min, max]
Age (years)	27.95 ± 6.66	(26.94, 28.96)	[18, 45]
Sphere (D)	-10.88 ± 3.74	(- 11.45, - 10.31)	[- 25.00, - 2.25]
Cylinder (D)	$-$ 1.41 \pm 1.16	(- 1.59, - 1.24)	[- 5.00, 0.00]
ICL size (mm)	13.00 ± 0.46	(12.93, 13.07)	[12.1, 13.7]
ICL power (D)	-12.36 ± 3.24	(-12.85, -11.87)	[- 18.00, - 4.00]
White-to-white (mm)	11.74 ± 0.38	(11.68, 11.80)	[10.70, 12.80]
ACD (mm)	3.16 ± 0.27	(3.12, 3.20)	[2.80, 3.89]

Table 1 Descriptions of patient demographic data and characteristics of implanted ICLs

ICL implantable Collamer lens, ACD anterior chamber depth, SD standard deviation, CI confidence interval

toric ICL V4c (Staar Surgical, Co.). The preoperative data and parameters of the implanted ICL lenses are shown in Table 1.

Preoperatively, all the patients underwent comprehensive ophthalmic examinations and met the surgical requirements for ICL V4c implantation. The examinations included uncorrected distance visual acuity and corrected distance visual acuity using a Snellen chart, manifest spherical and cycloplegic refractions, slit-lamp biomicroscopic and fundoscopic examinations, IOP (noncontact tonometer), corneal topography (Pentacam AXL, Oculus, Germany), central corneal thickness (Pentacam AXL), horizontal corneal diameter (white-towhite, WTW, IOL Master 500, Carl Zeiss, Germany), axial length (IOL Master 500, Carl Zeiss, Germany), anterior chamber depth (ACD, Pentacam AXL, measured from the corneal endothelium to the anterior lens), corneal endothelial cell density (ECD, noncontact specular microscopy, SP-3000P, Topcon Corporation, Japan), optical coherence tomography (OCT, Optovue, USA), and ultrasound biomicroscopy (UBM; Quantel Medical, France).

The inclusion criteria were patients with age between 18 and 45 years, monocular or binocular myopia, $ECD \ge 2000 \text{ cells/mm}^2$, and $ACD \ge 2.8 \text{ mm}$. Exclusion criteria were patients with history of certain ocular diseases (suspicion of keratectasia, corneal or lens opacity, glaucoma, retinal detachment, macular degeneration, or neuro-ophthalmic disease), previous

corneal or intraocular surgery, history of inflammation or trauma, and systemic disease.

ICL Calculation

All eyes included in this study had either myopic or toric V4c ICLs implanted. ICL V4c is a plate-haptic single-piece intraocular lens made of Collamer which can be folded and implanted in the posterior chamber via a 2.8–3.2 mm corneal incision. It comes in four sizes: 12.1 mm, 12.6 mm, 13.2 mm, and 13.7 mm. ICL power calculations were performed using software provided by the manufacturer (Staar Surgical). The size (length) of the implanted ICL was determined on the basis of the patient's WTW and ACD, and UBM measurements, such as sulcus-to-sulcus (STS) distance, were also considered in the process.

Surgical Techniques

The ICL V4c implantation procedures of all patients included were performed by two experienced surgeons (XZ and XW). Before surgery, the pupils were dilated with 2.5% phenylephrine and 1% tropicamide. After topical anesthesia and injection of 1% sodium hyaluronate into the anterior chamber via a puncture site at the 6 o'clock position of the cornea, ICL V4c was implanted via a 3.0-mm temporal corneal incision using an injector cartridge and then placed in the posterior chamber. Subsequently, the viscoelastic surgical agent was completely removed from the eye using a balanced salt solution and a miotic agent was instilled. Postoperative medications included antibiotic eye drops, nonsteroidal anti-inflammatory eye drops, steroidal eye drops, and artificial tears.

Follow-up of Vault Values

The central vault refers to the distance between the posterior surface of the ICL and anterior surface of the crystalline lens, which was quantitatively measured postoperatively using a rotating Scheimpflug camera (Pentacam AXL, Oculus, Germany). Each patient underwent at least four postoperative follow-up visits at 1 month, 6 months, 1 year, and more than 2 years. Vault values obtained 1 month postoperatively were considered as the baseline.

Statistical Analysis

All statistical analyses were performed using SPSS version 26.0 (SPSS Corp., Armonk, NY, USA), and the results were expressed as means \pm standard deviations. The Shapiro-Wilk test was used to determine whether a variable was normally distributed. All eves were classified into three groups based on vault values at 1 month postoperatively (baseline). Repeated measures analysis of variance (ANOVA) with Bonferroni adjusted post hoc comparisons was used to explore trends of vault change and statistical significance of vault changes during follow-up visits. To evaluate the potential factors implicated in vault changes over time, parametric (Pearson's coefficient) correlation analysis and multiple linear regression analysis were used. To verify the correlation between the preoperative ACD and vault change value over time, the sample was divided into three groups according to the preoperative ACD value. Repeated measures ANOVA with Bonferroni adjusted post hoc comparisons was used to explore the differences of vault changes in these groups. Differences were considered statistically significant if the P value was less than 0.05.

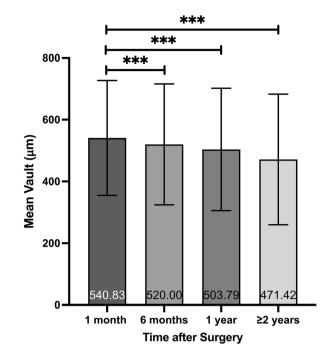


Fig. 1 Descriptive statistics and level of statistical significance for vault changes over time (***P < 0.05)

RESULTS

Vault Changes Over Time

Vault assessment results were obtained from 169 eyes of 169 patients at routine visits over a period of 2 years, with an average follow-up time of 2.5 years (2.50 ± 0.71). We took the vault values at four time points from each patient: 1 month (baseline), 6 months, 1 year, and the last follow-up time (more than 2 years). Figure 1 shows the mean vault value at each visit and the statistical significance of the vault changes over time.

All eyes were divided into three groups based on the vault measurements obtained at 1 month postoperatively (baseline): group 1, vault values $\leq 250 \ \mu\text{m}$; group 2, vault values $250-750 \ \mu\text{m}$; and group 3, vault values $\geq 750 \ \mu\text{m}$. Repeated measures ANOVA with Bonferroni adjusted post hoc comparisons was used to explore the statistical significance of vault changes during each visit, and the main effects were significant (*F* = 10.288, *P* < 0.001, partial eta squared = 0.158), showing that vault

Groups	Time				
	1 month	6 months	1 year	\geq 2 years	
Group 1 (vault	<i>≤</i> 250)				
N	20	20	20	20	
Mean \pm SD	217.50 ± 28.81	202.50 ± 44.71	201.00 ± 58.57	182.50 ± 41.15	
95% CI	(172.05, 262.95)	(146.89, 258.11)	(141.98, 260.02)	(112.81, 252.19)	
D (95% CI)		15.00 (-28.87 to 58.87)	16.50 (- 35.93 to 68.93)	35.00 (- 31.32 to 101.32)	
Р		1.000	1.000	0.964	
Group 2 (250 ·	< vault < 750)				
N	126	126	126	126	
Mean \pm SD	538.73 ± 114.38	519.21 ± 138.78	500.71 ± 144.88	467.70 ± 165.36	
95% CI	(520.62, 556.84)	(497.05, 541.36)	(477.20, 524.23)	(439.93, 495.46)	
D (95% CI)		19.52 (2.05-37.00)	38.02 (17.13-58.90)	71.03 (44.61–97.45)	
Р		0.020*	< 0.001*	< 0.001*	
Group 3 (vault	≥ 750)				
N	23	23	23	23	
Mean \pm SD	833.48 ± 70.04	800.43 ± 92.56	783.91 ± 112.32	743.04 ± 176.59	
95% CI	(791.10, 875.86)	(748.58, 852.29)	(728.88, 838.95)	(678.06, 808.03)	
D (95% CI)		33.04 (-7.87 to 73.95)	49.57 (0.68–98.45)	90.43 (28.59–152.28)	
Р		0.195	0.045*	0.001*	

Table 2 Quantitative results and statistical significance of vault changes during each visit vs. the baseline

N number, SD standard deviation, D difference with baseline, CI confidence interval

*P < 0.05 (compared with baseline value)

Table 3 Results of multiple regression analysis of parameters with vault decreases between baseline and last follow-up

	-				_
Parameters	Mean ± SD	95% CI	Beta	t	Р
ACD (mm)	3.16 ± 0.27	(3.12, 3.20)	- 0.334	- 2.497	0.014*
ACV (mm)	197.10 ± 31.17	(192.20, 202.00)	0.044	0.293	0.770
WTW (mm)	11.74 ± 0.38	(11.68, 11.80)	- 0.194	- 1.515	0.132
Horizontal STS (mm)	11.96 ± 0.50	(11.88, 12.04)	0.101	0.716	0.475
ICL power (D)	-12.36 ± 3.24	(- 12.85, - 11.87)	0.176	2.210	0.029*

Beta standardized beta coefficients, *ACD* anterior chamber depth, *ACV* anterior chamber volume, *WTW* white-to-white, *STS* sulcus-to-sulcus, *ICL* implantable Collamer lens, *SD* standard deviation, *CI* confidence interval *B < 0.05 (compared with baseling volume)

*P < 0.05 (compared with baseline value)

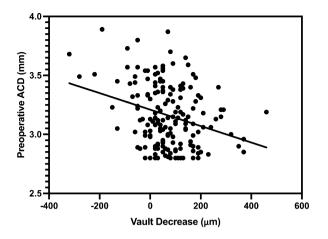


Fig. 2 Correlation between vault decrease and preoperative ACD. *ACD* anterior chamber depth

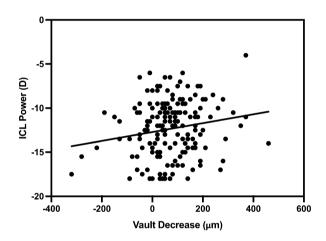


Fig. 3 Correlation between vault decrease and ICL power. *ICL* implantable Collamer lens

decreases were significant over time. The quantitative results and statistical significance are presented in Table 2. For group 1, the differences were not statistically significant (P > 0.05). For groups 2 and 3, there was a significant decrease over time (P < 0.05) at 6 months and 1 year postoperatively, respectively. Furthermore, we observed that higher baseline vault values were associated with a greater decrease over time; however, the difference was not statistically significant (F = 1.006, P > 0.05).

Factors Affecting Vault Changes Over Time

Some preoperative and ICL parameters showed significant correlations with the value of vault decrease during the follow-up period: ACD (r = -0.292, P < 0.001), anterior chamber volume (r = -0.248, P = 0.002), WTW distance (r = -0.184, P = 0.016), horizontal STS distance (r = -0.199, P = 0.014), and ICL power (r = 0.173, P = 0.025). No significant correlations were identified between vault decrease and preoperative anterior chamber angle, axial length, corneal ECD, IOP, age, and ICL size (P > 0.05). The results of the multiple linear regression analyses are shown in Table 3. The variables relevant to the value of vault decrease during the follow-up period were ACD and ICL power (adjusted $R^2 = 0.121$, F = 4.851, P < 0.001). The value of vault decrease was negatively correlated with preoperative ACD and positively correlated with ICL power. The ACD value was the most relevant variable. The relationships between the vault decrease value and ACD as well as ICL power are shown in Figs. 2 and 3.

ACD Effects on Vault Changes

The eyes were divided into three groups according to ACD values before surgery: group 1 $(ACD < 3.0 \text{ mm}), \text{group } 2 (3.0 \le ACD \le 3.4 \text{ mm}),$ and group 3 (ACD > 3.4 mm). Repeated measures ANOVA with Bonferroni adjusted post hoc comparisons was used to explore the difference of vault changes in these groups. The interaction effect of follow-up time and preoperative ACD value was significant (F = 8.986, P < 0.001, partial eta squared = 0.140), indicating that the trends of vault changes were different between these three groups. The quantitative results and statistical significance for each group are displayed in Table 4. For group 1 and group 2, the differences were statistically significant (P < 0.05) 6 months postoperatively, whereas for group 3, the difference was not statistically significant (P > 0.05) even at the last follow-up visit compared with that at the baseline. We

Groups	Time				
	1 month	6 months	1 year	\geq 2 years	
Group 1 (ACI	D < 3.0 mm)				
N	55	55	55	55	
Mean \pm SD	410.00 ± 175.49	374.73 ± 161.20	358.18 ± 171.64	317.45 ± 150.97	
95% CI	(367.98, 452.02)	(332.84, 416.61)	(315.48, 400.88)	(273.18, 361.73)	
D (95% CI)		35.27 (10.00-60.55)	51.82 (21.00-82.63)	92.55 (54.705-130.39)	
Р		0.002*	< 0.001*	< 0.001*	
Group 2 (3.0 ±	\leq ACD \leq 3.4 mm))			
N	78	78	78	78	
$\text{Mean} \pm \text{SD}$	569.74 ± 159.23	539.62 ± 162.61	524.49 ± 158.86	482.69 ± 179.77	
95% CI	(534.46, 605.03)	(504.44, 574.79)	(488.63, 560.35)	(445.52, 519.87)	
D (95% CI)		30.13 (8.90-51.35)	45.26 (19.38–71.13)	87.05 (55.28–118.83)	
Р		0.001*	< 0.001*	< 0.001*	
Group 3 (ACI	0 > 3.4 mm				
N	36	36	36	36	
Mean \pm SD	678.06 ± 121.96	699.44 ± 138.34	681.39 ± 145.11	682.22 ± 157.81	
95% CI	(626.12, 730.00)	(647.67, 751.22)	(628.61, 734.17)	(627.50, 736.95)	
D (95% CI)		- 21.39 (- 52.63 to 9.85)	-3.33 (-41.42 to 34.76)	-4.17 (-50.94 to 42.61)	
Р		0.416	1.000	1.000	

Table 4 Quantitative results and statistical significance of vault changes in groups divided by ACD values

ACD anterior chamber depth, *N* number, *SD* standard deviation, *D* difference with baseline, *CI* confidence interval *P < 0.05 (compared with baseline value)

observed that lower ACD values were associated with greater and earlier decrease over time.

DISCUSSION

Several studies have reported that ICL V4c implantation provides safe, excellent, and predictable results in the correction of myopia and astigmatism [3, 4]. Furthermore, some studies have reported that the ICL vault tends to decrease over time [12, 16]. However, few studies have reported on the factors affecting vault changes. In the present study, vault values decreased significantly after ICL implantation, particularly within the first postoperative year. Several factors have been potentially implicated in this effect.

In the present study, we observed a trend of decreasing mean objective vault values over time, which was statistically significant after the first 6 months (P < 0.05). Postoperatively, the mean vault was $540.83 \pm 186.13 \,\mu\text{m}$ at 1 month, decreasing to $520.00 \pm 196.08 \,\mu\text{m}$ after 6 months, to $503.79 \pm 198.30 \,\mu\text{m}$ after 1 year, and to $471.42 \pm 211.35 \,\mu\text{m}$ after more than 2 years. In addition, we found differences in vault changes between groups categorized by baseline vault values. In the group with a baseline vault $\leq 250 \,\mu\text{m}$, the vault change was not

statistically significant (P > 0.05). For the group with a baseline vault between 250 and 750 μ m and the group with a baseline value \geq 750 µm, the vault decreased significantly (P < 0.05) at 6 months and 1 year postoperatively, respectively. The vault decrease was more obvious in eyes with higher baseline vault values. This corresponds with what was reported by Alfonso et al. [12] in a study with 964 eyes; that study found a statistically significant decrease in vault values of groups with baseline vault > $350 \,\mu m$ at the third postoperative month, but vault changes was not statistically significant in groups with baseline vault $< 350 \,\mu\text{m}$. Some studies have also shown that low vault values tend to increase but this change was not statistically significant over time [12, 17]. Higher initial postoperative vault values evidently make significant decreases more likely over time. The ICL is placed in the posterior chamber, pushing the iris outward as a result of the formation of the vault, so that it receives pressure from the iris, pushing the ICL to the crystalline lens. A relatively high vault may be under a higher pressure , which is maybe a reason why a higher vault had a more obvious decrease while a lower vault tends to be more stable

Vault reduction is considered as a risk factor for anterior subcapsular cataract (ASC) due to the interaction of the ICL with the anterior lens capsule [11]. Gonvers et al. [10] reported there was a high risk of ASC formation when the vault was smaller than 0.09 mm. Another study found that the mean central vault tended to be lower in eyes with cataracts than that in eyes without cataracts 3 months after ICL implantation [18]. However, the ICLs used in these studies did not have a central hole. Since the use of ICL V4c, the occurrence of ASC has decreased. Recent follow-up studies using ICL V4c and more recent ICL versions have not reported cataracts [19, 20]. Longer follow-up time studies are still needed to observe the cataract development after ICL V4c implantation.

The results of our study revealed that vault values of the ICL decreased more over time in eyes with a shallower ACD, higher ICL power, or both. Although ACD and ICL power alone cannot provide a sufficient explanation, as evidenced by the small R^2 value (adjusted $R^2 = 0.121$), ACD played a major role in vault reduction. Further investigation found that for eves with preoperative ACD < 3.4 mm, vault decrease was significant 6 months postoperatively. However, for eves with preoperative ACD higher than 3.4 mm, vault changes were not significant even at the last follow-up. We observed that in 34 eyes vault increased at the last follow-up, and compared their preoperative and ICL parameters with the rest of the eves. We found that the eyes experienced vault increase had a deeper preoperative ACD value compared with the rest of the eyes (3.32 mm and 3.12 mm, respectively), and the difference was statistically significant (*t* test, t = 4.106, P < 0.001). Thus, shallower preoperative ACD values were associated with more obvious vault decreases. We assumed that in eyes with shallower ACDs, the ICL may be under greater pressure from the iris, resulting in vault reduction. And for eyes implanted with higher-power ICLs, vault values tended to decrease more because the lens was thinner and more likely to be affected by the pressure from the back of the iris.

Most studies have investigated factors affecting postoperative vault values; however, few have studied factors affecting the change in postoperative vault values over time. Kamiya et al. reported that variables relevant to the ICL vault were WTW distance and patient age [18]. Alfonso et al. found that for eyes with a higher baseline vault, eyes showing a decrease of vault had a smaller difference between ICL size and WTW distance, a smaller ICL size, a shallower ACD, and a smaller WTW distance [12]. For eyes with a lower baseline vault, vault decreased more in eyes that had a smaller difference between ICL size and WTW distance, a smaller ICL size, and were less myopic [12]. Their study agrees with ours in that the vault decreased more postoperatively in eyes with a shallower ACD or higher ICL power, because the ICLs in less myopic eyes had higher ICL power. Since we used the STS length obtained by UBM to help us calculate the ICL size and orientation of implantation, the patients included in this study might have had a more appropriate ICL size, which may explain why ICL size and WTW

distance were not statistically significant in our outcomes.

Other factors, such as ICL rotation, change of fixed location, physiologic or accommodative pupillary movement and age-related increases in crystalline lens thickness, also account for the decrease in ICL vault over time [18, 21]. If the ICL rotated towards the vertical position, the vault would decrease because the vertical STS length was longer than the horizontal one [22]. In terms of fixed locations for the ICL, the ideal fixed position was resting on the ciliary sulcus. ICL haptics are typically located at either the ciliary sulcus or ciliary body [23]. If the fixation location changes from the ciliary body to the ciliary sulcus, then the vault may decrease. Several studies have reported that pupil constriction leads to a significant decrease in the central vault under photopic conditions as it causes both posterior movement of the ICL and anterior protrusion of the crystalline lens [9, 24, 25]. Du et al. [26] demonstrated that pupillary constriction with the use of topical pilocarpine also cause ICL vault decrease. The central thickness of the crystalline lens increases with age, and a thicker lens may contribute to anterior protrusion of the front surface of the crystalline lens [27, 28].

Our study had several limitations. The first was the short average follow-up time of 2.5 years (2.50 ± 0.71) compared with some studies that had a 10-year follow-up time. To determine whether vault stops decreasing after a certain time point, a longer monitoring time is required. Second, the vault was measured manually using a Pentacam Scheimpflug imaging system, which might not have been accurate considering the image is not that clear. However, Scheimpflug tomography (Pentacam) is a common approach in vault measurements and is demonstrably well correlated with anterior segment OCT, as revealed by a recent study [29].

CONCLUSIONS

The present study showed that vault tended to decrease over time after ICL implantation, particularly in eyes with baseline vault values higher than $250 \,\mu\text{m}$. The vault values of the ICL decreased more over the long term in eyes with a shallower ACD, higher ICL power, or both, and the decrease in vault became statistically

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and higher baseline vault.

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significant earlier in eyes with a shallower ACD

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Disclosures. Boliang Li, Xun Chen, Mingrui Cheng, Yadi Lei, Yinjie Jiang, Yilin Xu, Xiaoying Wang, and Xingtao Zhou all confirm that they have no conflicts of interest to declare.

Compliance with Ethics Guidelines. This study adhered to the tenets of the Declaration of Helsinki and was approved by the Ethical Committee Review Board of Fudan University Eye and ENT Hospital (2016038).

Data Availability. Data and materials are available upon request from the corresponding author at doctxiaoyingwang@163.com or doctzhouxingtao@163.com.

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REFERENCES

- 1. Sanders DR, Doney K, Poco M, ICL in Treatment of Myopia Study Group. United States Food and Drug Administration clinical trial of the Implantable Collamer Lens (ICL) for moderate to high myopia: three-year follow-up. Ophthalmology. 2004;111:1683–92.
- 2. Kamiya K, Shimizu K, Kobashi H, et al. Three-year follow-up of posterior chamber toric phakic intraocular lens implantation for the correction of high myopic astigmatism in eyes with keratoconus. Br J Ophthalmol. 2015;99:177–83.
- 3. Miao H, Chen X, Tian M, Chen Y, Wang X, Zhou X. Refractive outcomes and optical quality after implantation of posterior chamber phakic implantable Collamer lens with a central hole (ICL V4c). BMC Ophthalmol. 2018;18:141.
- 4. Huseynova T, Ozaki S, Ishizuka T, Mita M, Tomita M. Comparative study of 2 types of implantable Collamer lenses, 1 with and 1 without a central artificial hole. Am J Ophthalmol. 2014;157:1136–43.
- 5. Kawamorita T, Uozato H, Shimizu K. Fluid dynamics simulation of aqueous humour in a posteriorchamber phakic intraocular lens with a central perforation. Graefes Arch Clin Exp Ophthalmol. 2012;250:935–9.
- 6. Gonzalez-Lopez F, Bilbao-Calabuig R, Mompean B, et al. Intraocular pressure during the early postoperative period after 100 consecutive implantations of posterior chamber phakic intraocular lenses with a central hole. J Cataract Refract Surg. 2013;39: 1859–63.
- 7. Higueras-Esteban A, Ortiz-Gomariz A, Gutiérrez-Ortega R, et al. Intraocular pressure after implantation of the Visian Implantable Collamer Lens With CentraFLOW without iridotomy. Am J Ophthalmol. 2013;156:800–5.
- 8. Shiratani T, Shimizu K, Fujisawa K, Uga S, Nagano K, Murakami Y. Crystalline lens changes in porcine eyes with implanted phakic IOL (ICL) with a central hole. Graefes Arch Clin Exp Ophthalmol. 2008;246: 719–28.
- Chen X, Miao H, Naidu RK, Wang X, Zhou X. Comparison of early changes in and factors affecting vault following posterior chamber phakic Implantable Collamer Lens implantation without and with a central hole (ICL V4 and ICL V4c). BMC Ophthalmol. 2016;16:161.
- 10. Gonvers M, Bornet C, Othenin-Girard P. Implantable contact lens for moderate to high

myopia: relationship of vaulting to cataract formation. J Cataract Refract Surg. 2003;29:918–24.

- 11. Choi JH, Lim DH, Nam SW, Yang CM, Chung ES, Chung T-Y. Ten-year clinical outcomes after implantation of a posterior chamber phakic intraocular lens for myopia. J Cataract Refract Surg. 2019;45:1555–61.
- Alfonso JF, Lisa C, Abdelhamid A, Fernandes P, Jorge J, Montés-Micó R. Three-year follow-up of subjective vault following myopic implantable Collamer lens implantation. Graefes Arch Clin Exp Ophthalmol. 2010;248:1827–35.
- Chung T-Y, Park SC, Lee MO, Ahn K, Chung E-S. Changes in iridocorneal angle structure and trabecular pigmentation with STAAR implantable Collamer lens during 2 years. J Refract Surg. 2009;25: 251–8.
- Shen Y, Wang L, Jian W, et al. Big-data and artificialintelligence-assisted vault prediction and EVO-ICL size selection for myopia correction. Br J Ophthalmol. 2021. https://doi.org/10.1136/bjophthalmol-2021-319618.
- 15. Choi KH, Chung SE, Chung TY, Chung ES. Ultrasound biomicroscopy for determining visian implantable contact lens length in phakic IOL implantation. J Refract Surg. 2007;23:362–7.
- Schmidinger G, Lackner B, Pieh S, Skorpik C. Longterm changes in posterior chamber phakic intraocular Collamer lens vaulting in myopic patients. Ophthalmology. 2010;117:1506–11.
- 17. Du G-P, Huang Y-F, Wang L-Q, et al. Changes in objective vault and effect on vision outcomes after implantable Collamer lens implantation: 1-year follow-up. Eur J Ophthalmol. 2012;22:153–60.
- Kamiya K, Shimizu K, Komatsu M. Factors affecting vaulting after implantable Collamer lens implantation. J Refract Surg. 2009;25:259–64.
- Packer M. Evaluation of the EVO/EVO+ Sphere and Toric Visian ICL: six month results from the United States Food and Drug Administration Clinical Trial. Clin Ophthalmol. 2022;16:1541–53.
- 20. Yang W, Zhao J, Zhao J, et al. Changes in anterior lens density after Implantable Collamer Lens V4c

implantation: a 4-year prospective observational study. Acta Ophthalmol. 2021;99:326–33.

- 21. Kamiya K, Shimizu K, Kawamorita T. Changes in vaulting and the effect on refraction after phakic posterior chamber intraocular lens implantation. J Cataract Refract Surg. 2009;35:1582–6.
- 22. Oh J, Shin H-H, Kim J-H, Kim H-M, Song J-S. Direct measurement of the ciliary sulcus diameter by 35-megahertz ultrasound biomicroscopy. Ophthal-mology. 2007;114:1685–8.
- García-Feijoó J, Alfaro IJ, Cuiña-Sardiña R, Méndez-Hernandez C, Del Castillo JMB, García-Sánchez J. Ultrasound biomicroscopy examination of posterior chamber phakic intraocular lens position. Ophthalmology. 2003;110:163–72.
- 24. Lindland A, Heger H, Kugelberg M, Zetterström C. Changes in vaulting of myopic and toric implantable Collamer lenses in different lighting conditions. Acta Ophthalmol. 2012;90:788–91.
- Lee H, Kang SY, Seo KY, et al. Dynamic vaulting changes in V4c versus V4 posterior chamber phakic lenses under differing lighting conditions. Am J Ophthalmol. 2014;158:1199-1204.e1.
- 26. Du C, Wang J, Wang X, Dong Y, Gu Y, Shen Y. Ultrasound biomicroscopy of anterior segment accommodative changes with posterior chamber phakic intraocular lens in high myopia. Ophthalmology. 2012;119:99–105.
- 27. Dubbelman M, Van der Heijde GL, Weeber HA, Vrensen GFJM. Changes in the internal structure of the human crystalline lens with age and accommodation. Vis Res. 2003;43:2363–75.
- 28. Dubbelman M, van der Heijde GL, Weeber HA. The thickness of the aging human lens obtained from corrected Scheimpflug images. Optom Vis Sci. 2001;78:411–6.
- 29. Almorín-Fernández-Vigo I, Sánchez-Guillén I, Fernández-Vigo JI, et al. Agreement between optical coherence and Scheimpflug tomography: vault measurements and reproducibility after implantable Collamer lens implantation. J Fr Ophtalmol. 2021;44:1370–80.

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