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ORIGINAL RESEARCH

The Distribution of Crystalline Lens Rise in High Myopia Population and Its Influence on Vault After Implanting Intraocular Collamer Lens

Ziyu Zhou · Xiaoyu Zhao · Xiaohang Jiao · Wenxin Xue · Jing Yang · Weiqun Wang · Yanhui Bai

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ABSTRACT

Introduction: As a result of the insufficient ocular anatomical parameters used to customize implantable collamer lens (ICL), many patients still cannot achieve a suitable vault after ICL implantation surgery. This study analyzed the characteristics of a new anatomical parameter crystalline lens rise (CLR) in a population with high myopia and explored the influence of CLR on the vault after ICL implantation.

Methods: Patients (298 eyes) with high myopia who underwent ICL implantation were enrolled to study CLR characteristics. Postoperatively, patients (159 eyes) were divided into five groups according to the value of CLR (A, CLR ≤ -150; B, $-150 < \text{CLR} \leq 0$; C, $0 < \text{CLR} < 150$; D, $150 \leq \text{CLR} < 300$; E, CLR ≥ 300 μm), and to investigate the correlation between CLR and vault.

Results: In the 298 eyes, the CLR had a normal distribution ($P = 0.35$) and the mean CLR was 67.93 ± 150.66 μm. Ninety-nine eyes (33.22%) had a CLR ≤ 0 μm, of which 20 eyes (6.71%) had a CLR ≤ -150 μm; 199 eyes (66.78%) had a CLR > 0 μm, of which 20 eyes (6.71%) had a CLR ≥ 300 μm. In 159 eyes, the CLR was negatively correlated with the vault at 1 day ($R = -0.497$, $P < 0.001$), 3 months ($R = -0.505$, $P < 0.001$), and 6 months ($R = -0.505$, $P < 0.001$) postoperatively. At 6 months, the vault of group A was statistically significantly different compared to groups B–E (all $P < 0.05$), and that of group E was statistically significantly different compared to groups A–D (all $P < 0.001$). The remaining groups did not show statistically significant differences (all $P > 0.05$).

Conclusion: The CLR had a normal distribution in the high myopia population, and 13.42% of the CLR values were extreme (CLR ≤ -150 μm or CLR ≥ 300 μm). A larger ICL diameter than that recommended by the manufacturer should be considered when the CLR is ≥ 300 μm and a smaller ICL diameter should be considered when the CLR is ≤ -150 μm.

Keywords: Crystalline lens rise; Intraocular collamer lens; Vault; Refractive surgery; High myopia

Ziyu Zhou and Xiaoyu Zhao contributed equally and should be considered as joint first authors.

Z. Zhou · X. Zhao · X. Jiao · W. Xue · J. Yang · W. Wang · Y. Bai (✉)
The First Affiliated Hospital of Zhengzhou University, Zhengzhou 450000, China
e-mail: anui5533@163.com

Key Summary Points

Why carry out this study?

More anatomical parameters of eyes are needed to improve the accuracy of lens size selection.

Previous studies have shown that the crystalline lens rise (CLR) value could have an influence on the postoperative vault.

This study aimed to analyze the characteristics of a new anatomical parameter crystalline lens rise in a population with high myopia and explore the influence of CLR on the vault after implantable collamer lens (ICL) implantation.

What was learned from the study?

CLR in the high myopia population had a normal distribution. The mean CLR value was 67.93 ± 150.66 μm (range − 350 to 480 μm; and 95% confidence interval 50.76–85.11 μm).

CLR was negatively correlated with the postoperative vault. When CLR was from − 150 to 300 μm, it has little effect on the vault. When CLR ≥ 300 μm, the achieved vault is lower; when CLR ≤ − 150 μm, the achieved vault is higher.

To achieve the ideal postoperative vault, if the CLR is ≥ 300 μm, a larger ICL diameter should be considered, and if the CLR is ≤ − 150 μm, a smaller ICL diameter or an intraoperative ICL rotation to a certain angle might be good choices.

INTRODUCTION

Intraocular collamer lens (ICL) implantation is currently the mainstream intraocular surgical method used to correct refractive errors in the clinic and has the advantages of reversibility, a wide range of correction degrees, and high postoperative visual quality. The vault is defined as the vertical distance between the posterior surface of the ICL and the anterior surface of the crystalline lens, which is an important indicator for evaluating the safety of ICL implantation surgery, and its ideal range is 0.25–0.75 mm [1, 2]. The postoperative vault is affected by ocular anatomical parameters, ICL diameter, and their interaction [3]. An abnormal postoperative vault is the leading cause of complications. Previous studies have found that if the ICL size is selected only on the basis of white-to-white (WTW) and anterior chamber depth (ACD), as usual, more than 20% of patients do not achieve the ideal vault after surgery [4–6]. As a result of the complexity of intraocular anatomy, and despite surgeons comprehensively considering the sulcus-to-sulcus (STS) distance [7, 8], some patients still experience an abnormal vault after surgery [9], and 2.6% require ICL replacement [10–12]. The accurate selection of the appropriate diameter of the ICL to prevent an abnormal vault remains a problem. Related studies have found a link between crystalline lens rise (CLR) and vault [4, 13–16]; therefore, this study further explored the distribution characteristics of CLR in high myopia populations and the effect of CLR on vault, with the aim of providing more reference indicators to improve the safety of ICL implantation after surgery.

METHODS

Study Design

This prospective study included two parts. In the first part, all patients (298 eyes) who underwent ICL V4c implantation at the Refractive Center of the First Affiliated Hospital of Zhengzhou University between June 2020 and December 2022 were included to measure preoperative CLR and analyze its distribution characteristics in a high myopia population. In the second part, after surgery, patients (159 eyes) who were followed up regularly for more than 6 months were included to investigate the

vault. They were further divided into five groups according to the value of CLR (A, CLR ≤ -150; B, $-150 < CLR \leq 0$; C, $0 < CLR < 150$; D, $150 \leq CLR < 300$; E, CLR ≥ 300 μm) to explore the links between preoperative CLR and postoperative vault. All patients underwent implantation using the ICL model recommended by the manufacturer. All of the patients were included in the monocular group. The right eye was enrolled if both eyes satisfied the inclusion requirements. Patients who did not meet the ICL implantation criteria were excluded. This study was conducted in compliance with the tenets of the Declaration of Helsinki, and the study protocol was approved by the Ethics Committee of the First Affiliated Hospital of Zhengzhou University (2023-KY-1354). All patients provided informed consent after receiving a detailed explanation of the surgical procedure before the operation.

Anterior Segment Optical Coherence Tomography (AS-OCT) Imaging

Anterior segment imaging was performed using anterior segment optical coherence tomography (AS-OCT) (Visante). The parameters measured by AS-OCT were defined as follows: The vault was defined as the vertical distance between the posterior surface of the ICL and the anterior surface of the crystalline lens. The ACD was defined as the distance between the posterior apex of the cornea and the front apex of the crystalline lens. Angle-to-angle (ATA) diameter was defined as the distance between the angle recesses on the nasal and temporal sides. CLR was defined as the vertical distance between the anterior pole of the crystalline lens and the horizontal line that joins the two anterior chamber angle crypts (Fig. 1) [17]. When the line was above the anterior pole of the crystalline lens, the CLR value was recorded as positive (CLR > 0 μm), otherwise as negative (CLR < 0 μm). To improve the accuracy of the measurement, the small absolute value of the CLR was calculated by subtracting the vertical central distance between the corneal endothelium and the anterior pole of the crystalline lens from the vertical central distance between the corneal endothelium and the horizontal line joining the two anterior chamber angle crypts. Each measurement was repeated three times by the same physician under the same mesopic conditions, and the average value was taken.

Surgical Procedure

After topical anesthesia, a 3.0-mm temporal corneal incision was made and an ophthalmic viscosurgical device (OVD) was injected into the anterior chamber. When the ICL was placed in the anterior chamber, a special crystalline tweezer was used to adjust the four haptics in the sulcus. The left OVD was completely removed from the anterior chamber using a balanced salt solution. Intraocular pressure was normal. Postoperatively, tobramycin and dexamethasone eye drops and antibiotics were administered topically.

Postoperative Follow-up

Postoperative measurements, including automated refraction, uncorrected distance visual acuity, intraocular pressure (IOP), slit-lamp microscopy, and AS-OCT, were performed 1 day, 3 months, and 6 months postoperatively. Symptomatic measures were provided during follow-up, as necessary, according to the patient's condition.

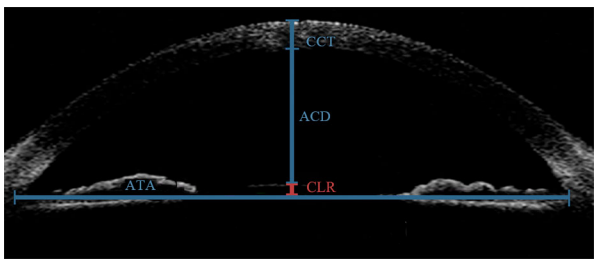

Fig. 1 Image of CLR, ATA, and ACD measured by AS-OCT. *CLR* crystalline lens rise, *ATA* angle-to-angle, *ACD* anterior chamber depth, *AS-OCT* anterior segment optical coherence tomography, *CCT* Central corneal thickness

Table 1 Preoperative characteristics

Characteristic	First part *N* = 298 eyes/298 patients	Second part *N* = 159 eyes/159 patients
Age (years)	24.73 ± 4.75 (18, 38)	24.70 ± 4.79 (18, 38)
Gender (M/F)	132/166	61/98
Sphere (D)	− 9.36 ± 2.53 (− 6.00, − 18.00)	− 9.60 ± 2.41 (− 6.00, − 17.00)
Cylinder (D)	− 1.18 ± 1.17 (0, − 5.75)	− 1.02 ± 1.00 (0, − 5.00)
SE (D)	− 9.95 ± 2.61 (− 6.00, − 18.00)	− 10.09 ± 2.53 (− 6.25, − 17.25)
WTW (mm)	11.53 ± 0.36 (10.78, 12.41)	11.52 ± 0.37 (10.89, 12.40)
CLR (μm)	67.93 ± 150.66 (− 350, 480)	68.52 ± 177.46 (− 320, 480)

SE spherical equivalent, *WTW* white-to-white, *CLR* crystalline lens rise

Statistical Analysis

All statistical analyses were performed using RStudio (Version 4.3.0), and the quantitative data were presented as mean ± standard deviation. Pearson's correlation analysis was performed to investigate the correlation between CLR and postoperative vault. Repeated-measures analysis of variance was performed to compare the vault at different postoperative time points (1 day, 3 months, and 6 months). A one-way analysis of variance was performed to compare vaults in the different groups (A–E). $P < 0.05$ was considered statistically significant.

RESULTS

Preoperative Baseline Data

In the first part, 298 patients (298 eyes) were included to investigate the characteristics of CLR in the high myopia population, including 132 men (44.30%) and 166 women (55.70%). The mean age was 24.73 ± 4.75 years (range 18–38 years), and the mean spherical equivalent (SE) was − 9.95 ± 2.61 D (range − 6.00 to − 18.00 D).

In the second part, 159 eyes (159 patients) were included to investigate the effect of CLR on vault in the high myopia population, which included 61 men (38.36%) and 98 women (61.64%). The mean age was 24.70 ± 4.79 years (range 18–38 years), and the mean SE was − 10.09 ± 2.53 D (range − 6.25 to − 17.25 D). Table 1 presents the descriptive data of the samples.

Distribution of CLR in High Myopia Population

In this part, we confirmed that the CLR had a normal distribution in the 298 eyes ($P = 0.345$) using the Shapiro–Wilk test (Fig. 2). The mean CLR value was 67.93 ± 150.66 μm (range − 350 to 480 μm; and 95% confidence interval 50.76–85.11 μm).

Further statistical tests revealed that of the 298 eyes, 20 (6.71%), 79 (26.51%), 108 (36.24%), 71 (23.83%), and 20 (6.71%) eyes had a CLR ≤ − 150, − 150 to 0, 0–150, 150–300, and ≥ 300 μm, respectively (Table 2).

Effect of CLR on Vault in High Myopia Population

In this part, the vault of the 159 eyes at postoperative 1 day, 3 months, and 6 months was 0.66 ± 0.23 mm, 0.58 ± 0.20 mm, and 0.56 ± 0.19 mm, respectively (Table 3, Fig. 3). The vault on postoperative 1 day was significantly different from that at 3 and 6 months (all $P < 0.05$). However, there were no statistically

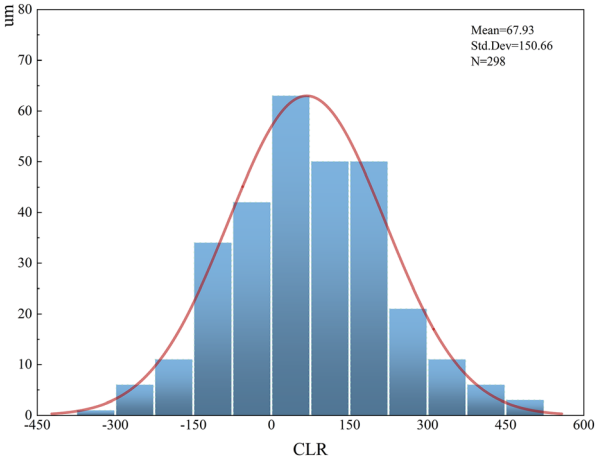

Fig. 2 The CLR had a normal distribution in the high myopia population. *CLR* crystalline lens rise

Table 2 Distribution of CLR in the high myopia population (298 eyes)

CLR (μm)	Eyes	Percentage (%)	Cumulative percentage (%)
Less than − 150	20	6.71	6.71
− 150 to 0	79	26.51	33.22
0–150	108	36.24	69.46
150–300	71	23.83	93.29
More than 300	20	6.71	100

CLR crystalline lens rise

significant differences between 3 and 6 months ($P = 0.71$).

CLR showed a negative correlation with postoperative vault at 1 day, 3 months, and 6 months after surgery, according to Pearson's correlation analysis, with a correlation coefficient of − 0.497 ($P < 0.001$), − 0.505 ($P < 0.001$), and − 0.505 ($P < 0.001$), respectively (Fig. 4).

The vault at 6 months postoperatively was selected to further analyze the differences between the different CLR groups (A–E). Table 4 and Fig. 5 show the vaults at 6 months postoperatively in the different CLR groups.

Table 3 Changes in the vault after ICL implantation (mean ± standard deviation, 159 eyes)

Time	Vault (mm)
1 day	0.66 ± 0.23
3 months	0.58 ± 0.20
6 months	0.56 ± 0.19
F	156.48
P	< 0.001

ICL implantable collamer lens

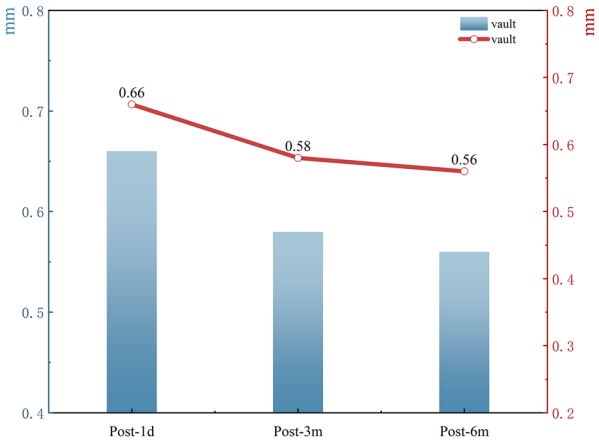

Fig. 3 Time course of vault changes in eyes undergoing ICL implantation. The vault decreased gradually with time and stabilized at 3 months after operation. *ICL* implantable collamer lens

Statistically significant differences were observed between the subgroups ($F = 24.00$; $P < 0.001$). After Bonferroni comparisons were performed, group A was significantly different from groups B–E (all $P < 0.05$), and group E was significantly different from groups A–D (all $P < 0.001$). However, there were no statistically significant differences between groups B, C, and D (all $P > 0.05$).

DISCUSSION

Studies have shown that approximately 20% of patients with ICL customization based on WTW

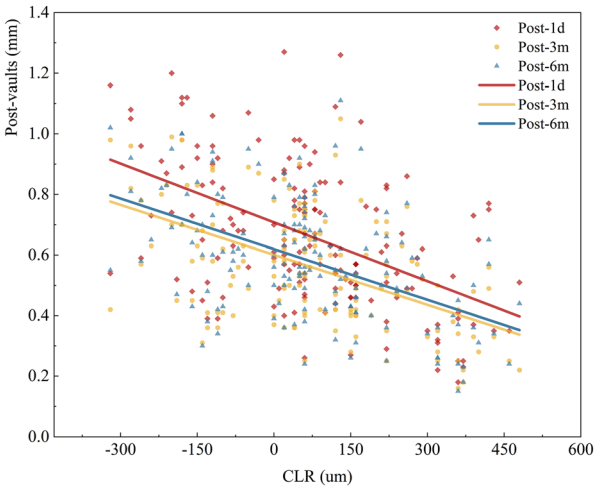

Fig. 4 The vault was negatively correlated with CLR at all time points of postoperative follow-up. *CLR* crystalline lens rise

Table 4 Comparison of the vault in different groups at 6 months ICL implantation (mean ± standard deviation, 159 eyes)

Group	Eyes	Vault (mm)	95% CI
A	20	0.75 ± 0.19	(0.66, 0.83)
B	29	0.58 ± 0.18	(0.51, 0.65)
C	64	0.59 ± 0.17	(0.55, 0.63)
D	26	0.52 ± 0.13	(0.47, 0.58)
E	20	0.33 ± 0.11	(0.28, 0.38)
F		24.00	
P		< 0.001	

A, CLR ≤ − 150 μm; B, − 150 < CLR ≤ 0 μm; C, 0 < CLR < 150 μm; D, 150 ≤ CLR < 300 μm; E, CLR ≥ 300 μm

CLR crystalline lens rise, *ICL* implantable collamer lens, *CI* confidence interval

and ACD cannot achieve a perfect vault after the operation [18]. Although the diameter of the sulcus is included as one of the criteria for selecting the ICL model, many patients still require secondary surgery for ICL replacement or even ICL removal [19]. In 2005, Baïkoff et al. proposed the use of CLR as a safety standard for crystalline surgery [17].

CLR was defined as the vertical distance between the anterior pole of the crystalline lens and the horizontal line joining the two anterior chamber angle crypts, which directly reflected the relationship between the anterior pole of the crystalline lens and the anterior chamber. CLR is negatively correlated with ACD [20, 21]. It is well understood that the more convex the crystalline is, the more space it occupies in the anterior chamber, which might result in a lower vault than predicted. Fully understanding the distribution characteristics of CLR in the high myopia population is of great significance for the preoperative selection of the ICL diameter and evaluation of the postoperative vault after ICL surgery. Therefore, as one of the factors that influence the postoperative vault, CLR should not be ignored in the selection of ICL.

In this study, we observed CLR in 298 patients with high myopia. The CLR was normally distributed, which is consistent with the findings of Gonzalez-Lopez et al. [22]. That study also showed most patients with high myopia had the anterior pole of the crystalline lens located above the line that joins the two anterior chamber angle crypts, but the corresponding proportion of this group of patients in this study (66.8%) was lower than that reported by Gonzalez-Lopez et al. (86.5%) [22]. First, the CLR values for the different lighting conditions were different. When the light intensity changed, the CLR value also changed. Second, it is also possible that the instruments used to measure the CLR values were different. The ability to recognize anatomical structures also differed for different instruments.

We know from our experiments that CLR is negatively correlated with the postoperative vault, which is consistent with previous studies [18, 23, 24]. The authors reported that the mean CLR of the low vault group (< 100 μm) was higher than that of the high vault group (> 750 μm) [23]. Wang et al. [25] found that the correlation coefficient between CLR and the 1-year postoperative vault was − 0.509, which was close to the correlation coefficient (− 0.505) between CLR and the 6-month postoperative vault in this study. The fact that crystalline lens could have a crucial influence on vault was also confirmed by Qi et al. [26]. On

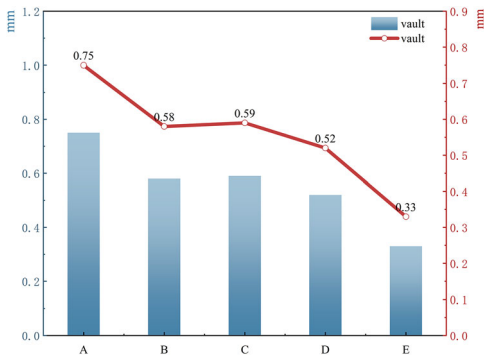

Fig. 5 The difference of vault at 6 months among different groups. *CLR* crystalline lens rise. A, CLR ≤ -150 μm; B, $-150 < \text{CLR} \leq 0$ μm; C, $0 < \text{CLR} < 150$ μm; D, $150 \leq \text{CLR} < 300$ μm; E, CLR ≥ 300 μm

the basis of the results of studies by Trancón et al. [18] and Nakamura et al. [4], it could be observed that for every 100-μm increase in CLR, the vault decreased by 37–40 μm.

Previous studies have shown that the vault stabilizes 3 months postoperatively [24, 27]. The results of our study also did not show changes in the vault between 3 and 6 months after surgery. Therefore, we chose the vault 6 months after surgery to analyze the relationship between the CLR and the vault. Given that there was no clear grouping standard for CLR measured by optical coherence tomography, to further study how CLR affected the postoperative vault, we exploratively divided the subjects into five groups according to CLR: A, CLR ≤ -150; B, $-150 < \text{CLR} \leq 0$; C, $0 < \text{CLR} < 150$; D, $150 \leq \text{CLR} < 300$; and E, CLR ≥ 300 μm. The results showed that group A was significantly different from groups B–E (all $P < 0.05$), and group E was significantly different from groups A–D (all $P < 0.001$). There were no statistically significant differences between groups B, C, and D (all $P > 0.05$). In other words, this further study found that when the CLR was from -150 to 300 μm, it had little effect on the postoperative vault. However, when the CLR was greater than 300 μm (CLR ≥ 300 μm), the distance between the intraocular lens and the crystalline lens decreased, and the postoperative vault was expected to be relatively lower; when the CLR was less than -150 μm (CLR ≤ -150 μm), the distance between the intraocular lens and the crystalline lens increased, and the postoperative vault was expected to be relatively higher.

A limitation of this study is the short follow-up period. In subsequent studies, we will further explore the relationship between the crystalline lens rise and the vault in the late postoperative period.

CONCLUSION

Our study groups the research data, for the first time, according to the CLR (A, CLR ≤ -150; B, $-150 < \text{CLR} \leq 0$; C, $0 < \text{CLR} < 150$; D, $150 \leq \text{CLR} < 300$; E, CLR ≥ 300 μm) to explore the effect of preoperative CLR on postoperative vault. The obtained results suggest the CLR was normally distributed. When the CLR was from -150 to 300 μm, it had little effect on the postoperative vault. However, when the CLR was greater than 300 μm (CLR ≥ 300 μm), the postoperative vault was expected to be relatively lower; when the CLR was less than -150 μm (CLR ≤ -150 μm), the postoperative vault was expected to be relatively higher. The extreme value of the CLR should be considered when calculating the required lens size for the ICL. If the CLR is ≥ 300 μm, a diameter of ICL larger than that recommended by the manufacturer should be considered, and if the CLR is ≤ -150 μm, a smaller diameter of ICL or an intraoperative ICL rotation at a certain angle may be good choices.

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or approval of manuscript (Ziyu Zhou); and responsibility for the integrity of the entire study and manuscript (Ziyu Zhou). All authors read and approved the final manuscript.

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Data Availability. The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Conflict of Interest. Ziyu Zhou, Xiaoyu Zhao, Xiaohang Jiao, Wenxin Xue, Jing Yang, Weiqun Wang, Yanhui Bai declare no conflicts of interests.

Ethical Approval. This study was conducted in compliance with the tenets of the Declaration of Helsinki, and the study protocol was approved by the Ethics Committee of the First Affiliated Hospital of Zhengzhou University (2023-KY-1354). All patients provided informed consent after receiving a detailed explanation of the surgical procedure before the operation.

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