Original Article

A new formula based on new parameters for predicting postoperative vault after posterior chamber intraocular lens implantation: a retrospective study

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Background: To investigate the parameters influencing vault after posterior chamber intraocular lens implantation, thereby establishing a formula to predict the vault after operation.

Methods: In this retrospective study, 61 patients (122 eyes) who underwent implantable collamer lens (ICL) implantation were enrolled consecutively from the Qingdao Eye Hospital of Shandong First Medical University, China, between August 2020 and October 2021. Comprehensive optometry, axial length, curvature, anterior chamber depth (ACD), lens thickness (LT), white-to-white distance (WTW), corneal thickness, sulcus-to-sulcus distance (STS), the distance between the sulcus-to-sulcus plane and the anterior crystalline lens surface (STSL), ciliary-to-ciliary distance (CTC) and the distance between the ciliary-to-ciliary plane and the anterior crystalline lens surface (CTCL) were recorded preoperatively. The vault was measured by ultrasound biomicroscopy at 1 month after operation. The correlation among vault, preoperative parameters and ICL size was analyzed. The accuracy and reliability of the prediction formula were verified by analyzing the postoperative correlation coefficient of actual and predicted vaults of the contralateral eye and through the Bland-Altman consistency test.

Results: Parameters significantly influencing the vault at 1 month after operation are ACD (r=0.260, P=0.004), LT (r=–0.338, P<0.001), WTW (r=0.240, P=0.03), STSL (r=–0.394, P<0.001), CTC (r=–0.199, P=0.03), CTCL (r=–0.328, P<0.001), ICL size (r=0.224, P=0.01) and ICL power (r=–0.231, P=0.01). The regression formula was as follows: vault (mm) = –2.179 – 0.227 * CTC (vertical) – 0.783 * CTCL (mean) + 0.472 * ICL size (fitting R=0.853, R2=0.727, adjusted R2=0.705). The predicted vault was 0.50±0.18 mm, and the actual vault was 0.56±0.24 mm. The Bland-Altman scatter plot showed a satisfactory agreement between actual and predicted vaults (–0.06 mm, 95% limits of agreement: –0.45 to 0.32 mm).

Conclusions: ACD, LT, WTW, STSL, CTC, CTCL, ICL size and ICL power were the factors affecting vault after ICL implantation. The prediction formula with the new parameter CTCL was accurate and reliable.

Keywords: Ciliary; formula; implantable collamer lens (ICL); vault

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Submitted Dec 31, 2022. Accepted for publication Jul 10, 2023. Published online Jul 28, 2023.
doi: 10.21037/qims-22-1425
View this article at: https://dx.doi.org/10.21037/qims-22-1425

Introduction

Implantable collamer lenses (ICL) are new intraocular lenses being surgically implanted into the eye as a long-term solution for refractive errors (1). However, the size of ICL affects the occurrence of intraoperative and postoperative complications. Oversized ICL can produce a shallow anterior chamber, which would progress into a closed chamber angle, pupil block and glaucoma. Small ICL have been associated with a higher risk of cataract (2-6). An optimal vault, defined as the distance between the posterior surface of ICL and the anterior surface of the crystalline lens, is critical in determining the safety of the operation. Considering ICL implantation with and without central hole, the most common complications due to an abnormal vault were corneal endothelial damage (52% and 31%, respectively), high intraocular pressure with secondary glaucoma (22% and 26%, respectively), halos, night glows and dysphotopsia (11% and 6%, respectively), and cataract (15% and 37%, respectively) (7). Packer (8) determined the range of a safe vault between 50–250 and 1,000 μm, provided that the structure and function of the anterior chamber angle remain normal. In order to minimize the occurrence of complications, an appropriate vault has been suggested to be between 250 and 750 μm (9-11).

The size of ICL was initially determined based on the horizontal corneal (white-to-white distance, or WTW) diameter and the anterior chamber depth (ACD). The official online calculator is available at https://evo-ocos.staarag.ch. Considering that the haptics of ICL are fixed in the sulcus, it may be more desirable to calculate the size of ICL based on the sulcus to sulcus (STS) diameter (12). Several studies have found a poor correlation between WTW and STS, with the use of devices directly measuring the parameters of the posterior chamber providing a unique opportunity to improve the predictability of ICL size (13-17). Dougherty *et al.* (18) retrospectively analyzed preoperative STS and postoperative vault by ultrasonic biomicroscopy (UBM), determining an optimal ICL size between 90 and 1,000 μm. Kojima *et al.* (19) used the same technique to measure the distance between the STS plane and the anterior surface of the lens, showing that 88.9% of the postoperative vaults were between 0.15 and 1.00 mm.

Proper UBM measurements require direct/indirect contact between the probe and the eye, long inspection time and trained personnel. In addition, UBM is an operator-dependent procedure. Although unable to probe the posterior structure of the iris, the optical coherence tomography (OCT) is easy to perform and does not require a direct contact with the eyes. Nakamura *et al.* (20) used the anterior segment OCT to measure the horizontal distance between the angle recesses, the distance between the scleral processes, the distance between the anterior pole of the crystalline lens, a line joining the 2 opposite iridocorneal angles, the perpendicular distance between the anterior pole of the crystalline lens and the horizontal line joining the two scleral spurs. The ideal vault was calculated to be around 500 μm, while the formula calculating the ICL size was optimized to reduce the prediction error (21). Igarashi *et al.* (22) optimized the KS formula using the same instruments, reducing the error of vault prediction. More recently, Reinstein *et al.* (23) used a robotic digital ultrasound device to discover new parameters: the ciliary body diameter and the pupil diameter in a dark environment. Although the optical instrument was used accurately, the structural image of the posterior chamber at which the ICL was located was ignored in previous studies. The predicted results were not accurate because only a few parameters were considered by the ultrasound probe.

The aim of this study was to investigate the parameters influencing the vault after posterior chamber intraocular lens implantation, thereby establishing a formula to predict the vault after operation. In this study, we found a new parameter that indirectly quantified ciliary groove morphology and was related to the vault after ICL implantation. At the same time, the new formula provides an important reference for the selection of ICL diameter. We present this article in accordance with the STARD reporting checklist (available at https://qims.amegroups.com/article/view/10.21037/qims-22-1425/rc).

Methods

A total of 61 patients (122 eyes) who underwent ICL implantation in the Qingdao Eye Hospital of Shandong First Medical University, China, from August 2020 to October 2021 were enrolled in this continuous sequence

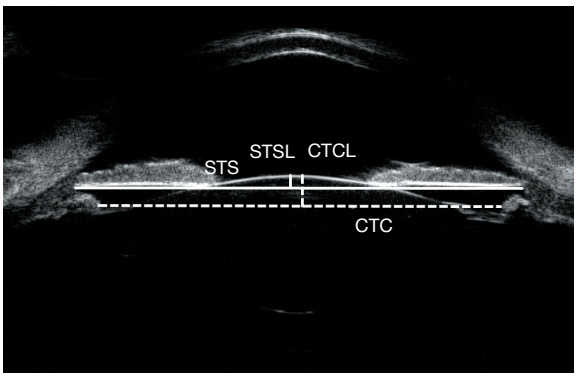

Figure 1 Several parameters marking. STS, sulcus-to-sulcus distance; STSL, the distance between the sulcus-to-sulcus plane and the anterior crystalline lens surface; CTCL, the distance between the ciliary-to-ciliary plane and the anterior crystalline lens surface; CTC, ciliary-to-ciliary distance.

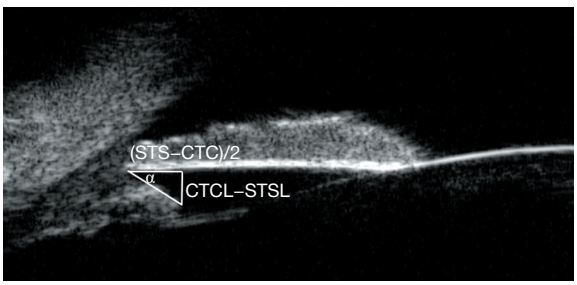

Figure 2 The ciliary body angle (α) marking. STS, sulcus-to-sulcus distance; CTC, ciliary-to-ciliary distance; CTCL, the distance between the ciliary-to-ciliary plane and the anterior crystalline lens surface; STSL, the distance between the sulcus-to-sulcus plane and the anterior crystalline lens surface.

review study. The surgical operation was performed by the same experienced physician. Inclusion criteria were as follows: age ≥18 years old, myopia diopter ≤–18.0 D, astigmatism ≤6.0 D, stable diopter in the past two years with changing within ±0.50 D every year, central ACD ≥2.80 mm and corneal endothelial cell count ≥2,000/mm^2. Exclusion criteria were as follows: cataract, uncontrolled glaucoma, advanced keratoconus, uveitis, retinal detachment, optic neuritis, severe congenital fundus lesions (such as familial exudative vitreoretinopathy) and/or other eye diseases, a previous eye surgery and concomitant systemic diseases including diabetes, hypertension and autoimmune disorders. The study was conducted according to the Declaration of Helsinki (as revised in 2013). This study was reviewed and approved by the Ethics Committee of Qingdao Eye Hospital of Shandong First Medical University [approval number QYLS 2023(30)]. A waiver of written informed consent for use of data was granted due to the retrospective nature of the study.

Preoperative examination

Before operation, mydriatic optometry and refraction were recorded. The curvature (K), axial length (AL), ACD, lens thickness (LT) and corneal diameter (WTW) were measured by using OA-2000 biometrics (Tomey, Nagoya, Japan). The corneal thickness (CT), K, ACD and WTW were measured by Pentacam Anterior Segment Analyzer (OCULUS, Wetzlar, Germany). The UBM (SW-3200L, SUOER, Tianjin, China) (frequency: 50-MHz, resolution: 50 μm) measured the STS diameter, the distance between the crystallin lens and the ciliary sulcus line (STSL), the ciliary-to-ciliary (CTC) diameter and the distance between the crystallin lens and the ciliary process line (CTCL) by horizontal and vertical directions (*Figure 1*). All measures were performed on the same magnification and probe frequency.

UBM was performed by a single investigator in a lighting environment. Each eye was scanned in eight positions (superior, inferior, nasal, temporal, superior nasal, inferior nasal, superior temporal and inferior temporal images). Three horizontal and three vertical axial images were obtained from each eye, then the biological parameters were measured three times and averaged. The ciliary body angle (α) was calculated as the angle between the anterior surface of the ciliary process and the ciliary sulcus line (*Figure 2*).

$$\alpha = \arctan 2 * (CTCL - STSL) / (STS - CTC) \quad [1]$$

For each eye, the tilt angles of upper, lower, nasal, and temporal directions were calculated and then averaged. The ICL size was selected using the STAAR's official online calculator combined with the UBM evaluations of the anterior and posterior chambers and ciliary processes.

ICL implantation

The patients were routinely disinfected and anesthetized with topical alcaine (0.5%). A three-plane corneoscleral incision (length, 3.0 mm) was performed temporally. The ICL (model V4c, STAAR Surgical, Monrovia, CA, USA) was implanted into the anterior chamber. Then, the high elastic viscoelastic agent (Healon) (Qisheng Biological Preparation Co. Ltd. Shanghai, China) was injected into the anterior chamber. The ICL haptics were placed in

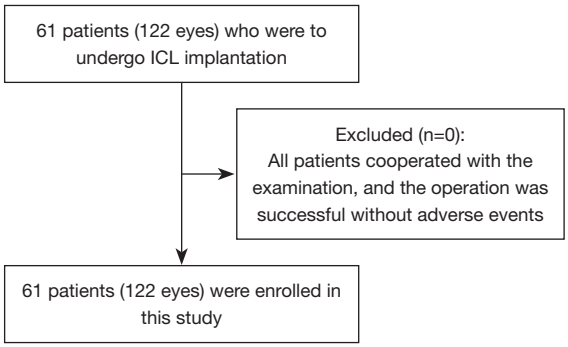

Figure 3 Patient selection flowchart. ICL, implantable collamer lens.

the ciliary sulcus and a balanced saline solution was used to replace the viscoelastic agent in the anterior chamber. The lenses were placed within 10° of horizontal deviation in all patients. The manual injection and suction system adequately displaced the intraocular viscoelastic agent. Topical tobramycin-dexamethasone was later applied to the eyes. After operation, 1% prednisolone eye drops was applied 4 times a day. The dose was reduced to a single administration every 3 days, for 12 days in total. Topical gatifloxacin (0.3%) was applied 4 times daily, for a week. In addition, 1% sodium hyaluronate eye drops was instilled 4 times daily. All implantations were performed by the same physician without any intraoperative complications.

Postoperative examination

One month after operation, UBM was used to measure the vault by axial scanning and to observe the position of haptics. During axial scanning, the UBM probe was perpendicular to the center of the cornea. We collected images when the echo arcs of corneal surfaces (front and back) and the front and back surfaces of the lens were displayed in the same straight line. The mean value was measured 2–3 times, then the vertical distance between the center of the face of the back surface of the ICL and the front surface of the lens was measured with the measuring tool of the device. The positions of the four haptics were scored: the ciliary sulcus was scored 1 point, the ciliary body was scored 2 points, and the position behind the ciliary body was scored 3 points. For each eye, the haptics scores were added and divided by four. The final result was considered as the haptics' score of the eye. The correlation among preoperative biological parameters, implanted ICL size and postoperative vault was analyzed.

Statistical analysis

The statistical analysis was performed with the SPSS software, version 23.0. Collected data were analyzed by the Kolmogorov-Smirnov test. Normally distributed data were expressed as mean ± standard deviation and compared with the Pearson correlation test. Non-normally distributed data were expressed as medians and interquartile and compared with the Spearman correlation test. According to the random number method, a single eye from each patient was randomly selected as the test eye. Multiple linear regression analyses were performed to calculate the prediction formula and the vault, with the vault being the dependent variable while preoperative parameters and ICL diameter being the independent variables. A tolerance less than 0.1 or a variance inflation factor more than 10 was used to indicate the presence of collinearity. The predicted vault was calculated by substituting the relative parameters of the contralateral eye into the formula, then the predicted vault was compared with the actual vault by the Bland-Altman test. A two-sided P value <0.05 was considered statistically significant. No missing data were reported in this study.

Results

There were 61 patients (122 eyes) with myopia who met the criteria for ICL implantation (*Figure 3*) and were included in the study. The demographics, preoperative and postoperative data of patients are presented in *Table 1*. Vaults between 0.25 and 0.75 mm accounted for 71.08% (87 eyes) of the total vaults. Vaults higher than 0.75 mm accounted for 19.67% (24 eyes) of the total vaults, while vaults lower than 0.25 mm accounted for 9.02% (11 eyes) of the total vaults. The results of analysis of factors related to the vault are displayed in *Table 2*.

The prediction formula:

$$vault = -2.179 - 0.227 * CTC(vertical) - 0.783 * CTCL(mean) + 0.472 * ICLsize \quad [2]$$

In this formula, R=0.853, R^2=0.727, adjusted R^2=0.705. No collinearity was found, the statistical significance of the three independent variables was <0.001. The normalized residuals of regression are shown in *Figure 4*. The predicted vault was 0.50±0.18 mm (0.10–0.88), while the actual vault was 0.56±0.24 mm (0.10–1.13). The Bland-Altman scatter plot was used to analyze the consistency between the predicted vault and the actual vault (*Figure 5*). The 95% limits of agreement (LoA) between predicted and

Table 1 Demographics, preoperative and postoperative data of included 61 patients (122 eyes)

Characteristics	Values	Range
Gender (men/women)	17 (27.87)/44 (72.13)	–
Age (years)	27.51±5.81	19 to 40
K1 of OA2000 (diopter)	42.81±1.40	39.57 to 45.79
K2 of OA2000 (diopter)	44.26±1.44	40.27 to 48.01
K1 of Pentacam (diopter)	42.61±1.36	39.30 to 45.50
K2 of Pentacam (diopter)	44.01±1.40	40.00 to 47.60
AL (mm)	27.52±1.43	23.67 to 31.64
ACD of OA2000 (mm)	3.72±0.23	3.31 to 4.31
ACD of Pentacam (mm)	3.21±0.23	2.76 to 3.71
LT (mm)	3.73±0.26	2.84 to 4.25
WTW of OA2000 (mm)	11.89±0.48	11.01 to 13.45
WTW of Pentacam (mm)	11.50 (11.30, 11.90)	10.80 to 13.20
CT (μm)	517.16±32.77	448.00 to 495.00
SEQ (D)	–9.76±3.00	–19.50 to –3.88
STS (horizontal) (mm)	11.67±0.55	10.58 to 13.18
STSL (horizontal) (mm)	0.48±0.18	0.00 to 1.12
CTC (horizontal) (mm)	10.69±0.56	9.38 to 11.96
CTCL (horizontal) (mm)	0.94±0.16	0.59 to 1.35
STS (vertical) (mm)	12.29±0.60	10.97 to 13.78
STSL (vertical) (mm)	0.69±0.18	0.16 to 1.18
CTC (vertical) (mm)	11.18±0.65	9.93 to 12.78
CTCL (vertical) (mm)	1.13 (1.03, 1.27)	0.74 to 1.62
STS (mean) (mm)	11.98±0.54	10.93 to 13.45
STSL (mean) (mm)	0.58±0.16	0.15 to 1.06
CTC (mean) (mm)	10.94±0.57	9.83 to 12.06
CTCL (mean) (mm)	1.04±0.15	0.70 to 1.38
Angle α	41.92°±10.25°	20.77° to 74.52°
ICL power (diopter)	–11.08±2.81	–18.00 to –4.50
ICL size (12.1/12.6/13.2/13.7 mm) (case)	12/63/45/2	–
Vault (mm)	0.55±0.23	0.10 to 1.13
Haptics	1.67 (1.50, 2.00)	1.00 to 2.50

Data are shown as n (%) or mean ± standard deviation or medians (quartiles). The mean values of STS, STSL, CTC and CTCL were considered as the mean values of horizontal and vertical directions. K, curvature; AL, axial length; ACD, anterior chamber depth; LT, lens thickness; WTW, corneal diameter; CT, corneal thickness; SEQ, spherical equivalent; CTC, ciliary-to-ciliary distance; CTCL, the distance between the ciliary-to-ciliary plane and the anterior crystalline lens surface; STS, sulcus-to-sulcus distance; STSL, the distance between the sulcus-to-sulcus plane and the anterior crystalline lens surface.

Table 2 Analysis of factors related to the vault

Factors	r	P value	95% CI
ACD of OA2000	0.259	0.005*	0.082 to 0.42
ACD of Pentacam	0.260	0.004*	0.084 to 0.42
LT	−0.338	<0.001*	−0.489 to −0.166
WTW of OA2000	0.240	0.03*	0.024 to 0.434
STSL (horizontal)	−0.394	<0.001*	−0.536 to −0.231
CTC (horizontal)	−0.199	0.03*	−0.365 to −0.021
CTCL (horizontal)	−0.328	<0.001*	−0.479 to −0.158
STSL (vertical)	−0.362	<0.001*	−0.508 to −0.196
CTC (vertical)	−0.253	0.005*	−0.414 to −0.078
CTCL (vertical)	−0.378	<0.001*	−0.526 to −0.209
STSL (mean)	−0.414	<0.001*	−0.552 to −0.253
CTC (mean)	−0.244	0.007*	−0.405 to −0.068
CTCL (mean)	−0.357	<0.001*	−0.504 to −0.190
ICL size	0.224	0.01*	0.042 to 0.392
ICL power	−0.231	0.01*	−0.394 to −0.054

The mean values of STSL, CTC and CTCL were considered as the mean values of horizontal and vertical directions. *, P<0.05. CI, confidence interval; ACD, anterior chamber depth; LT, lens thickness; WTW, corneal diameter; CTC, ciliary-to-ciliary distance; CTCL, the distance between the ciliary-to-ciliary plane and the anterior crystalline lens surface; STSL, the distance between the sulcus-to-sulcus plane and the anterior crystalline lens surface; ICL, implantable collamer lens.

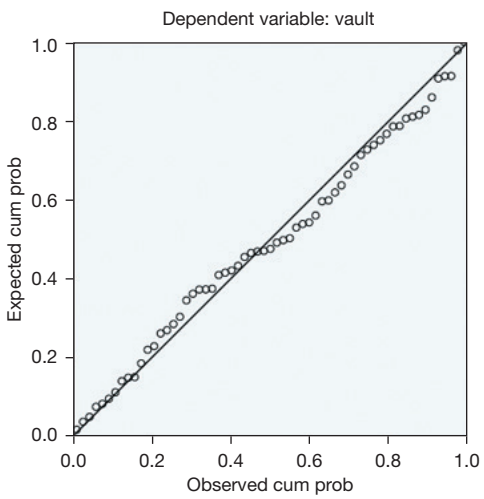

Figure 4 Normal P-P plot of the regression standardized residual of the prediction formula. P-P, probability-probability.

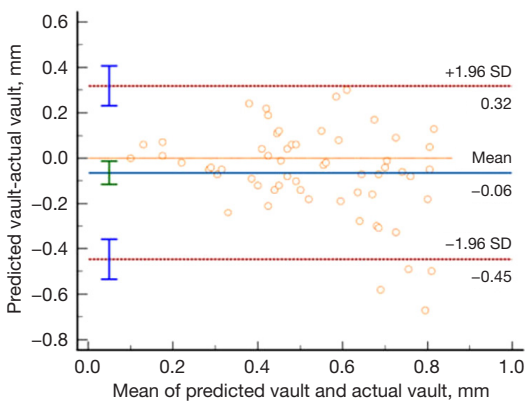

Figure 5 Bland-Altman test of predicted vault and actual vault. SD, standard deviation.

actual vault was −0.45 to 0.32 mm. Four points (6.56%) were outside the 95% LoA, which was within the clinically acceptable range.

After operation, the UBM was used to observe the location of ICL haptics. A total of 37.09% (181 haptics) of ICL haptics were located in the ciliary sulcus, 61.27% (299 haptics) of them were embedded in the ciliary body and 1.64% (181 haptics) of ICL haptics were located behind

the ciliary body. The angle of inclination was positively correlated with the haptics' score (r=0.319, P<0.001).

There were no intraoperative or postoperative complications, all IOL implantations were successfully performed.

Discussion

Selecting the appropriate size of ICL is still a challenge for implantation. An inappropriate vault should be replaced, or otherwise with consequences on patient's physical and mental health. The anterior segment OCT and UBM are the most utilized instruments to predict a correct vault by measuring the intraocular parameters. The OCT is accurate, quick and requires low cooperation from patients. However, the OCT is unable to explore the structures behind the iris. The main structures of the eye in close proximity to ICL are all located behind the iris, such as the posterior surface of the iris, the ciliary sulcus and the ciliary body. Therefore, UBM examination might be more accurate and reliable. The UBM requires a skilled examinator and a high level of cooperation from patients. In addition, the UBM is operator-dependent and not accurately reproducible.

In this study, we measured several parameters before and after surgery by combining UBM with biometrics and corneal topography. We found that the postoperative vault was positively associated with ACD, WTW, ICL size and myopia degree of ICL, but negatively associated with LT and STSL. These findings were consistent with previously published studies (18,24-27). In contrast to the study of Zhu *et al.* (24), we did not confirm a significant correlation between the vault and STS, possibly due to the wide ciliary sulcus observed in some eyes and the STS measurement placed at the ciliary sulcus rather than the angle between the iris root and ciliary body. The purpose of our study was to predict the position of ICL haptics, resulting in a poor consistency of STS. In accordance with a previous study, the vault was found to be negatively correlated with CTC (23). Reinstein *et al.* showed that a small CTC resulted in a small rear room space. When the ICL is inserted into a smaller space, the compression is higher and the vault increases. However, the decrease of CTC could reduce the slip of the haptics to a certain extent. We showed that the haptics' score was positively associated with CTC, resulting in more inclined haptics in the ciliary groove. If the haptics are easy to slide to or behind the ciliary body, the vault reduces. When the CTC is constant, the posterior chamber space is affected by the tilt angle of the posterior chamber and by the shape of the iris root. We also found that the inclination of the posterior chamber was positively associated with the haptics' integral. However, the correlation and significance of the vault with the haptics' integral and the inclination angle were not significant (–0.166, 0.070 and –0.162, 0.078, respectively). Although there was no significant correlation, the P value was close to 0.05, possibly related to the measurement error.

The CTCL, a new parameter developed during this study, was negatively correlated with the vault. Although the correlation among the horizontal direction, vertical direction and average value of the vault was not significantly higher compared to that of the STSL, the CTCL was selected as an independent variable in the prediction formula after multiple regression analyses. The regression coefficient of CTCL was –0.539, while the regression coefficients of the ICL size and the vertical CTC were 0.860 and –0.714, respectively. The degree of fit was high. The regression formula, with a fitting degree R=0.853, R^2=0.727 and adjusted R^2=0.705, was more accurate than that reported in many other studies (21,26-28). However, the overall predicted value was smaller than the actual value, possibly due to the fact that UBM did not measure the most convex part of ciliary processes, resulting in a larger CTC value. The CTC coefficient in the formula was negative, thus the obtained vault was smaller than the actual value.

Zhang *et al.* (29) examined 134 eyes with UBM after ICL implantation. Only 21.6% of the haptics were located in the ciliary sulcus, while most of the haptics were located outside. Different positions of the haptics could affect the vault. For example, the vault may be higher when the haptics are located in the ciliary sulcus. Or, the vault may be lower when the haptics are located in the ciliary process and the ciliary body. UBM examinations of the haptics after surgery revealed that 37.00% of them were located in the ciliary sulcus, 61.23% were embedded in the ciliary body and 1.76% were located behind the ciliary body. We did not find any correlation between the position of the haptics and the vault.

This study was a single-center study with a small sample size, possibly impairing the generalizability of the results. In addition, the study was limited by the presence of errors during UBM measurements. Due to the lack of clear regularities in the ciliary body structure, UBM findings varied widely. When more accurate instruments for measuring the posterior chamber parameters is available, the prediction of the vault will be more accurate. The

selection of ICL size did not follow a specific formula, while the orientation of ICL was not grouped and summarized. The CTC was smaller in the horizontal direction than in the vertical direction, affecting the vault with the orientation of ICL. Thirdly, the pressure of iris with different shapes on ICL was not recorded during the study. The UBM examination was performed under the same light illumination before and after surgery, thus we considered the parameters such as pupil diameter, ciliary process and LT were not potentially affected by light.

Conclusions

In conclusion, this study identified a new parameter (CTCL) which was negatively correlated with the vault. A more accurate prediction formula of the vault was established, which could help to select the optimal ICL size. Additional measurements of CTCL can be made before surgery and the formulas can be used to calculate the type of diameter ICL needed, thus avoiding complications caused by an abnormal arch height. Due to the great variation of the anatomy of the ciliary body, it is necessary to increase the sample size and optimize the measurements, as well as including more factors to improve the accuracy and feasibility of the formula.

Acknowledgments

We acknowledge TopEdit LLC for the linguistic editing and proofreading during the preparation of this manuscript. *Funding:* None.

Footnote

Reporting Checklist: The authors have completed the STARD reporting checklist. Available at https://qims.amegroups.com/article/view/10.21037/qims-22-1425/rc

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://qims.amegroups.com/article/view/10.21037/qims-22-1425/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted according to the Declaration of Helsinki (as revised in 2013). This study was reviewed and approved by the Ethics Committee of Qingdao Eye Hospital of Shandong First Medical University [approval number QYLS 2023(30)]. A waiver of written informed consent for use of data was granted due to the retrospective nature of the study.

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Cite this article as: Cui W, Wu X, Ren Q, Liu K, Kong F, Wu J. A new formula based on new parameters for predicting postoperative vault after posterior chamber intraocular lens implantation: a retrospective study. Quant Imaging Med Surg 2023;13(9):5502-5510. doi: 10.21037/qims-22-1425

