Preoperative Biometric Parameters Predict the Vault after ICL Implantation: A Retrospective Clinical Study

Qian-Yin Zheng^a Wen Xu^a Guan-Lu Liang^b Jing Wu^d Jun-Ting Shi^c

^aEye Center, 2nd Affiliated Hospital of Zhejiang University College of Medicine, ^bDepartment of Ophthalmology, Zhejiang Hospital, and ^cDepartment of Ophthalmology, 1st Affiliated Hospital of Zhejiang University College of Medicine, Hangzhou, and ^dDepartment of Ophthalmology, Xi'an No. 4 Hospital, Guanren Hospital of Xi'an Jiaotong University, Xi'an, China

Key Words

Vault · Eye · Crystalline lens · Intraocular lens · Lens implantation · Biometry

Abstract

Purpose: To investigate the correlation between the preoperative biometric parameters of the anterior segment and the vault after implantable Collamer lens (ICL) implantation via this retrospective study. **Design:** Retrospective clinical study. **Methods:** A total of 78 eyes from 41 patients who underwent ICL implantation surgery were included in this study. Preoperative biometric parameters, including white-to-white (WTW) diameter, central corneal thickness, keratometer, pupil diameter, anterior chamber depth, sulcus-to-sulcus diameter, anterior chamber area (ACA) and central curvature radius of the anterior surface of the lens (Lenscur), were measured. Lenscur and ACA were measured with Rhinoceros 5.0 software on the image scanned with ultrasound biomicroscopy (UBM). The vault was assessed by UBM 3 months after surgery. Multiple stepwise regression analysis was employed to identify the variables that were correlated with the vault. **Results:** The results showed that the vault was correlated with 3 variables: ACA ($22.4 \pm 4.25 \text{ mm}^2$), WTW ($11.36 \pm 0.29 \text{ mm}$) and Lenscur ($9.15 \pm 1.21 \text{ mm}$). The regres-

sive equation was: vault (mm) = $1.785 + 0.017 \times \text{ACA} + 0.051 \times \text{Lenscur} - 0.203 \times \text{WTW}$. **Conclusions:** Biometric parameters of the anterior segment (ACA, WTW and Lenscur) can predict the vault after ICL implantation using a new regression equation.

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Introduction

The implantable Collamer lens (ICL; Staar Surgical) is a sulcus-placed posterior-chamber phakic intraocular lens. Compared with clear lens extraction surgery and corneal laser refractive techniques [1, 2], the ICL has many potential advantages including the possibility of correction of high refractive errors, maintaining the integrity of the corneal structure and accommodation of the lens, and the reversibility [3, 4]. However, ICL implantation also has some potential disadvantages. The distance between the center of the posterior artificial lens surface and the center of the anterior crystalline lens surface (referenced as vault) [5] plays an important role in the occurrence of complications after ICL implantation surgery. If the vault value is insufficient or the separation between the intraocular and the human lens is short, the risks of

Fig. 1. UBM image showing the postoperative vault. The line between the center of the posterior artificial lens surface and the center of the anterior crystalline lens surface represents the postoperative vault, and the value is 0.46 mm.

anterior subcapsular cataract would be high [6–8]. On the other hand, an excessive vault will cause pupillary block and/or anterior angle closure that may result in secondary glaucoma [9–11]. Therefore, predicting the vault value precisely and choosing the appropriate ICL size [12, 13] before surgery are crucial. Studies have shown that the anterior segment of biometric parameters, e.g. horizontal corneal diameter (white-to-white, WTW), anterior chamber depth (ACD) [14] and ciliary sulcus-to-sulcus (STS) diameter [15, 16], were correlated with the vault value. Kojima et al. [17] reported that the distance between STS plane and anterior crystalline lens surface (STSL) was relevant to the vault value as well. In the present study, the lens surface curvature radius (Lenscur) and anterior chamber area (ACA) were introduced and considered to be correlated with the vault; these biometric parameters could be obtained preoperatively by ophthalmologic examination instruments.

The purpose of the present study was to create a new multiple stepwise regression equation to predict the postoperative vault precisely and to make a correct decision before ICL implantation. Our results demonstrated that WTW, Lenscur and ACA could contribute to the prediction of the vault with the new regression equation.

Methods

Design

This retrospective study was carried out in the Eye Center of the Second Affiliated Hospital of Zhejiang University School of Medicine. A total of 78 eyes from 41 patients (22 males and 19 females) who underwent ICL implantation were enrolled in this study. Preoperative ophthalmologic examinations included visual

acuity, slitlamp microscopic examination, subjective and cycloplegic refraction, intraocular pressure (ophthalmotonometer, NT-510; Nidek, Gamagori, Japan), ophthalmoscopic examination, corneal topography (Orbscan II; Bausch & Lomb, Germany) and ultrasound biomicroscopy (UBM, Vumax II; Sonomed Inc., USA).

Patient Data

The following criteria of patients were included: the age is between 21 and 45 years; the ACD is no less than 2.80 mm; the corneal endothelial cell count is no less than 2,000 cells/mm²; the refractive error is stable for at least 1 year, and the spectacle spherical power ranges from −2.50 to −20.00 dpt; the cylindrical power is less than 5.00 dpt; there was no previous history of a recurrent or active ocular disease, Fuchs' corneal dystrophy, synechia, uveitis, pigment dispersion syndrome, glaucoma, lens dislocation, retinopathy or macular degeneration (nonpathologic myopia), keratoconus, or a diagnosed autoimmune disease, connective tissue disease, systemic disease and no duration of lactation or pregnancy. Before the surgery, patients meeting the requirements were asked to undergo Nd:YAG laser peripheral iridotomy to prevent pupillary-blocking glaucoma.

Measurement

The preoperative WTW diameter, central corneal thickness, keratometer and pupil diameter were measured by a corneal topographer. The preoperative ACD, STS and STSL were measured by UBM. The distance between the center of the posterior artificial lens surface and the center of the anterior crystalline lens surface is referenced as vault. The vault value was assessed 3 months postoperatively by UBM as well, using high-frequency ultrasound (50 MHz) as the detection energy (fig. 1). Both vertical and horizontal biometric parameters were measured, and the calculated value was the average of the vertical and horizontal sections. Topical anesthesia (oxybuprocaine hydrochloride, 0.4%, Santen, Osaka, Japan) was administered in the supine position. A right size eyecup (20–26 mm diameter) filled up with buffer solution (normal saline) was fixed between the eyeball and the eyelids. The patient was asked to keep the fellow eye on a fixation point. Subsequently, high-quality images of the anterior segment were obtained by an experienced examiner.

Fig. 2. UBM image displayed with Rhino 5.0 software showing preoperative biometric parameters of the anterior segment. (1) The line represents the preoperative ACD, and the value is 3.12 mm. (2) The curve represents the preoperative Lenscur, and the value is 8.43 mm. (3) The line represents the STSL (the distance from STS plane to anterior lens surface), and the value is 0.59 mm. (4) The line represents the preoperative STS, and the value is 12.81 mm.

Fig. 3. UBM image displayed with Rhino 5.0 software showing the ACA, circled by a closed curve. The closed curve was delineated following the corneal endothelium, the anterior surface of the iris and the anterior surface of the crystalline lens. The ACA value is 25.55 mm².

Rhinoceros 5.0 (Rhino 5.0, Robert McNeel & Associates, USA), a professional 3-dimensional modeling software, was employed to build up a simulation model by means of straight line, circle and arc. UBM images were imported to Rhino 5.0 software, and the parameters were adjusted to the actual size. Then, a curve along the anterior lens surface was made by the curve drawing function in Rhino 5.0. The starting point and the end point fell on the junction of the iris and anterior lens surface. Furthermore, the central curvature radius of the anterior lens surface (Lenscur) was obtained by means of the function of measuring the radius of the curve. Finally, measurements were repeated 5 times to get the average value (fig. 2).

The ACA value was measured with Rhino 5.0 software on the image scanned with UBM as well. After adjusting the parameters

to the actual value, a closed curve along the corneal endothelium, the anterior surface of the iris and the anterior surface of the crystalline lens was made. The starting point and the end point converged at the junction of the corneal endothelium and the iris root. Then, the ACA value was measured by means of the function of measuring area in Rhino 5.0. Similarly, measurements were repeated 5 times to get the average value (fig. 3).

Surgery Procedure

Before surgery, Nd:YAG laser peripheral iridotomy was carried out to prevent pupillary-blocking glaucoma. All of the eyes to be treated were then operated on under topical anesthesia (oxybuprocaine hydrochloride, 0.4%, Santen). A 3-mm temporal clear corneal incision and a side hole were made by special diamond knives,

Table 1. Descriptive data of patient demographics, ICL characteristics and biometric parameters of the anterior segment

Factors	Mean $\pm$ SD	Min.	Max.
Number of patients (eyes)	41 (78)		
Sex (male/female)	22/19		
Age, years	31.21 $\pm$ 7.48	21	45
Sphere optical power, dpt	-14.78 $\pm$ 3.47	-20.00	-5.50
Cylindrical optical power, dpt	-1.43 $\pm$ 1.10	-5.00	0.00
Sphere equivalent, dpt	-15.53 $\pm$ 3.64	-22.50	-5.63
ACD, mm	3.22 $\pm$ 0.33	2.80	4.00
ACA, mm ²	22.43 $\pm$ 4.25	15.67	35.05
WTW, mm	11.36 $\pm$ 0.29	10.70	12.00
Lenscur, mm	9.15 $\pm$ 1.21	6.72	12.88
STS (horizontal), mm	11.55 $\pm$ 0.61	10.07	12.87
STS (vertical), mm	11.71 $\pm$ 0.63	10.48	13.06
STSL, mm	0.47 $\pm$ 0.16	0.12	0.72
CCT, mm	0.52 $\pm$ 0.04	0.40	0.61
K (horizontal), dpt	43.78 $\pm$ 1.36	40.70	47.30
K (vertical), dpt	45.05 $\pm$ 1.42	42.60	48.30
PD, mm	4.57 $\pm$ 0.68	2.40	5.9
ICL diameter, mm	11.80 $\pm$ 0.30	11.50	12.50
ICL optical power, dpt	-19.33 $\pm$ 3.58	-23.00	-8.50
Vault, mm	0.33 $\pm$ 0.19	0.10	0.95

CCT = Central corneal thickness; K = keratometer; PD = pupil diameter; SD = standard deviation.

followed by filling of the anterior chamber with the viscoelastic material (Hairont; Gallop Biological Products, Hangzhou, China). The ICL was subsequently inserted through the incision by an injector cartridge (Microstair Injector System, Staar Surgical Company). A modified intraocular spatula was applied to ensure that the ICL was placed entirely within the posterior chamber directly behind the iris and in front of the anterior capsule of the human crystalline lens with the feet of the haptics in the sulcus. Any remaining viscoelastic materials were completely removed and replaced with a balanced salt solution. Then a myotic was applied to the operated eye in order to open the iridotomy iris hole. The corneal wound was automatically sealed without stitches. Pranopropfen and Pred Forte eyedrops were used 4 times daily for 2 weeks postoperatively.

Calculation of Lens Power and Determination of Lens Diameter

The lens power was calculated and the lens diameter was determined using Staar ICL calculation software. The preoperative parameters measured in this study were keratometer, central corneal thickness, ACD, WTW and refraction.

Statistical Analysis

Statistical analysis was carried out by IBM SPSS Statistics 21.0 (IBM, Armonk, N.Y., USA). The data were analyzed using multiple stepwise regression analysis to identify the explanatory variables that were correlated with the vault value. A p value of <0.05 was considered statistically significant.

Table 2. Analysis of the linear relationship of the parameters with the vault

Parameters	R ²	p value
ACD	0.163	<0.001
ACA	0.196	<0.001
Lenscur	0.159	<0.001
STSL	0.137	0.001
WTW	0.061	0.029
ICL optical power	0.040	0.079
STS (horizontal)	0.027	0.151
PD	0.023	0.182
STS (vertical)	0.018	0.236
Sphere equivalent	0.016	0.273
K (horizontal)	0.006	0.519
CCT	0.005	0.544
ICL diameter	0.004	0.602
K (vertical)	0.003	0.655

Dependent variables: vault; ACD; ACA; WTW; STS; STSL; Lenscur; CCT = central corneal thickness; PD = pupil diameter; K = keratometer; ICL.

Results

Descriptive Statistics

A total of 78 eyes from 41 patients (22 males and 19 females) were enrolled in this study. The follow-up for these patients was at least 3 months. The patients' demographics, ICL characteristics and biometric parameters of the anterior segment are shown in table 1. The mean vault value which was measured 3 months after ICL implantation was 0.33 $\pm$ 0.19 mm ranging from 0.10 to 0.95 mm.

Regression Analysis

According to the p value shown in table 2, there was a linear relationship between vault and preoperative parameters: ACD (p < 0.001), ACA (p < 0.001), Lenscur (p < 0.001), STSL (p = 0.001) and WTW (p = 0.029). Therefore, the multiple stepwise regression equation for prediction of the vault was used for 5 explanatory variables including ACD, ACA, WTW, Lenscur and STSL. After statistical analysis, ACD (p = 0.570) and STSL (p = 0.127) were removed, while the remaining 3 variables ACA, Lenscur and WTW (all p < 0.001) were accepted to determine the following regressive equation: vault (mm) = 1.785 + 0.017 $\times$ ACA + 0.051 $\times$ Lenscur - 0.203 $\times$ WTW. The R² value of the regression equation was

Fig. 4. Correlation of STSL with Lenscur. The scatter diagram shows that there is a linear correlation between STSL and Lenscur ($p = 0.004$).

Fig. 5. Correlation of ACA with ACD. The scatter diagram shows that there is a linear correlation between ACA and ACD ($p < 0.001$).

0.383, and the adjusted R^2 value was 0.358. The mean values of these 3 parameters are shown in table 1. The partial regression coefficients of the parameters are shown in table 3. The tolerance indicated that there was no correlation among the 3 variables (table 3).

Discussion

In the present study, we showed that Lenscur is a new parameter that played a considerable role in predicting the vault value. Subsequently, Lenscur combined with ACA and WTW was applied in the regression equation as explanatory variables. The mean Lenscur value was 9.15 ± 1.21 mm (ranging from 6.72 to 12.88 mm). Kojima et al. [17] reported a different regression equation established with 3 different variables including STSL, ACD and STS. In this study, the mean STSL value was 0.47 ± 0.16 mm (range from 0.12 to 0.72 mm), which was significantly correlated with Lenscur (fig. 4). Such a relationship may be due to the fact that the accuracy of the STSL value depends on the accurate measurement of STS which was reported to be quite poor [18]. Lenscur was more reliable and more accurate than STSL because it was measured directly depending on the image scanned with UBM rath-

Table 3. Result of multiple stepwise regression analysis for prediction of the vault

Predictive variable	Unstandardized coefficients	Standardized coefficients	p value	Tolerance
Constant	1.785		0.01	
ACA	0.017	0.390	<0.001	0.939
Lenscur	0.051	0.335	0.001	0.937
WTW	-0.203	-0.313	0.001	0.987
STSL			0.189	
ACD			0.570	

Dependent variable: vault; predictors: constant, ACA, Lenscur, WTW; excluded variables: STSL, ACD.

er than depending on the calculation from other variables. Alternatively, the linear relationship between Lenscur and STSL could be due to the fact that Lenscur is one of the key factors that determine the STSL value. Therefore, the Lenscur value could be better than STSL to predict the postoperative vault.

Yokoyama et al. [18] measured STS 10 times per eye for 15 volunteers by 2 examiners and found that the variance of interexaminer measurement of STS using tradi-

tional UBM was relatively high. In the present study, no significant correlation between horizontal STS and the vault value was found ($p = 0.710$). In contrast, WTW was significantly correlated with vault ($p = 0.029$) (table 3). WTW may be more accurate and reliable than STS in predicting the vault when considering the measurements.

ACA, another new variable, made a nonignorable contribution to the prediction of ICL size. The mean ACA value was $22.43 \pm 4.25 \text{ mm}^2$ (ranging from 15.67 to 35.5 mm^2). Previously published work [14, 17] showed that ACD was one of the variables to predict the vault value. In the present study, the mean ACD value was $3.22 \pm 0.33 \text{ mm}$ (ranging from 2.80 to 4.00 mm). Guzman et al. [19] reported that anterior chamber volume and ACA performed better than ACD as a screening parameter for narrow angles. In this study, there was a linear relationship between ACA and ACD (fig. 5). Besides, ACA was encircled by the corneal endothelium, anterior surface of the iris and the anterior surface of the crystalline lens. The value of ACA was the combined effect of the value of these biometry parameters. The multiple stepwise regression analysis employed ACA, Lenscur and WTW as explanatory variables to the prediction of the vault while ACD and STSL were removed. Based on the analysis above, the measurement of ACA was more comprehensive and accurate than that of ACD in predicting the optimal ICL size.

In the study, the mean value of the ICL diameter was $11.80 \pm 0.30 \text{ mm}$ (ranging from 11.50 to 12.50 mm). No linear correlation between ICL diameter and the vault value was found ($p = 0.602$) so that the ICL diameter did not play a part in the stepwise regression analysis.

In the present study, the variables of Lenscur and ACA were measured using UBM images and Rhino 5.0 software. As Lenscur plays a nonignorable role in predicting the vault, it is worth developing a new device that can measure the Lenscur value directly and conveniently in future studies, and we would like to work towards releasing a clinical version of the software available for other researchers to use. Tassignon et al. [20] developed an algorithm to assess the postoperative centration and bending in the ICL and to better understand the patients' complaints after ICL implantation. In the present study, we measured the center distance between the posterior artificial lens surface and anterior crystalline lens as vault value while the peripheral vault value was neglected. In a future study, the peripheral vault, peripheral curvature radius of the anterior surface of the crystalline lens and lens thickness would be considered and analyzed. The postoperative bending and centration in the ICL and related complications would be taken into consideration.

In conclusion, this study found that in addition to WTW, the new biometric parameters (Lenscur and ACA) were linearly correlated with the postoperative vault and established a new regression equation for predicting the vault.

Disclosure Statement

No author has a financial or proprietary interest in any material or method mentioned.

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