ARTICLE

Determining vault size in implantable collamer lenses: preoperative anatomy and lens parameters

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Purpose: To determine patient preoperative anatomical features and the parameters of implantable collamer lenses (ICLs) relevant in explaining vault variability.

Setting: Ophthalmology Clinic Vista Sánchez Trancón, Badajoz, Spain.

Design: Retrospective case series.

Methods: This study comprised 360 eyes of 360 patients implanted with myopic or toric ICLs. Pentacam imaging was used for assessing white-to-white (WTW) diameter, central keratometry, and central corneal thickness. Anterior-segment optical coherence tomography was used to measure the horizontal anterior chamber angle distance (ATA), internal anterior chamber (ACQ), crystalline lens rise (CLR), anterior chamber angle (ACA), and vault. The sample was divided according to the implanted lens size (12.6 mm, 13.2 mm, and 13.7 mm). Vault predictors were identified from the variables above using multivariate regression analysis.

Results: The groups showed significant statistical differences for WTW, ATA, ACQ, ACA, and vault ($P < .007$ for all). In general, bigger lenses were implanted in eyes with larger transverse sizes (WTW and ATA) and deeper ACQ. Also, larger ICL diameters were associated with higher vaults. Multivariate regression analysis identified the lens size (13.2 mm as reference; 12.6 mm: β [standardized coefficients] = −0.33; 13.7 mm: β = 0.42), ATA (β = −0.42), and CLR (β = −0.25), ICL spherical equivalent (β = −0.22) and patient age (β = −0.12) as predictors of the vault size (adjusted-R^2 = 0.34 $P < .001$).

Conclusions: The multivariate model explained 34% of vault variability. The predictors indicated the presence of different mechanisms regulating the vault. These involved the difference between the transverse size of the eye and the ICL, the crystalline lens protrusion, and the ICL properties, such as power and size.

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The implantable collamer lens (ICL) is an established alternative in the field of refractive surgery. The ICL was initially recommended for the correction of moderate to high myopia and over the years its use has expanded to the correction of astigmatism, low myopia, and hyperopia.[1] A recent review argued that the ICL is an effective and safe method with a low rate of postoperative complications.[2] Despite the reduced number of complications reported, the distance between the ICL and the anterior crystalline lens surface, namely the vault, remains a critical parameter in classifying the surgery's success. The presence of a low vault may contribute to crystalline lens trauma, whereas a high vault may produce anterior chamber angle (ACA) closure, increased iris pigment dispersion with propensity to develop ocular hypertension, and changes in pupil dynamics, and increases the incidence of halos.[3] The rate of a second surgery to correct the vault size, either by ICL rotation or lens exchange, are approximately 0.8%.[2]

In ICLs, the main principle regulating the vault is the difference between the size of the ICL and the transverse size of the eye, for example, the sulcus-to-sulcus distance (STS).[4] The oversized ICL rests in the ciliary–sulcus complex under a compression force, producing an anterior bulging of the lens.[5,6] The manufacturer (STAAR Surgical Co.) has an online calculation and ordering system that uses the horizontal visible iris diameter, known as the white-to-white (WTW) diameter, and the internal anterior chamber (ACQ) for determining the size of the ICL to be implanted. This methodology leads to approximately 20% of cases outside the accepted vault range (<250 μm and >1000 μm).[6,7] Alternative

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methods have been proposed aiming to optimize the ICL size calculation, for instance, based on STS measurements.[4,6,8–10]

On one hand, the WTW has the advantage of being an easily measurable parameter. On the other hand, it is an anatomical landmark poorly correlated with the STS distance, with the agreement between WTW and STS being affected by the increasing ACQ and the level of myopia.[11–16] In contrast, the ciliary–sulcus complex is a more challenging structure to visualize, requiring the use of ultrasound biomicroscopy (UBM), which has low repeatability and has considerable operator dependency.[17] The horizontal anterior chamber angle distance (ATA), measured using anterior segment optical coherence tomography (AS-OCT), is an alternative technique for assessing the transverse size of the eye and is proven to be well correlated to the STS.[9,12,13] The ATA is an accessible structure, which can be measured with a repeatability of ±0.26 mm using AS-OCT.[18] Also, its assessment is more convenient for the patient and less operator-dependent compared to UBM. Recently, the AS-OCT has been used to assess the transverse size of the eye using the ATA, scleral-spur to scleral-spur distance and applied to estimate the optimal ICL size.[19,20]

The vault is a parameter varying on the anterior–posterior axis of the eye, and it is therefore plausible to argue that anatomical and lens properties varying along the same axis may play a role in vault variability. One of these parameters is the crystalline lens rise (CLR), indicative of the crystalline lens anterior surface protrusion. It has been demonstrated that patients presenting with a higher CLR (protruded crystalline anterior surfaces) tend to have lower vaults.[10,20–23] Also, from the geometric design of the lens, the intrinsic sagittal depth of the ICL is regulated by its dioptric power and overall size, with more myopic ICL and larger diameter ICL presenting deeper sagittal depths.[6] An additional factor that has remained overlooked is the compression's force effect on the different ICL sizes. The effect of a similar compression, that is an equal difference between the ICL size and the transverse size of the eye, for ICLs with different sizes may differ. This may result in a higher effect of the compression in the largest lens, producing more bulging of the lens and therefore higher vaults.

This study retrospectively analyzed a series of cases implanted with myopic ICLs aiming to determine the preoperative anatomic parameters and lens properties, which are predictive of the vault. Ultimately a series of equations predictive of the vault are presented.

METHODS

Study Design

This retrospective study analyzed the biometric parameters of patients operated with ICLs for the correction of myopia and astigmatism (EVO-V4c, STAAR Surgical AG). The patients were operated between December 2012 and December 2017 in the Ophthalmology Clinic Vista Sánchez Trancón (Badajoz, Spain) by 2 senior surgeons. The patients were considered for the analysis if they presented a manifest myopia between −3.00 diopter sphere (DS) and −20.00 DS, had a refractive astigmatism lower than −5.00 diopter cylinder (DC), an ACQ ≥ 2.8 mm, and an endothelial cell count >2000 cells/mm^2. From the eligible patients, those presenting any type of corneal ectasia, previous corneal refractive surgery, corneal dystrophy, ICL haptics oriented vertically, and those having missing data or nonsuitable for preoperative or postoperative examinations were excluded. For the analysis, only 1 eye (the first operated eye) was selected per patient, resulting in 217 and 143 eyes implanted with spherical and toric ICLs, respectively. The size and power of the ICL were selected following manufacturer recommendations most of the time. This research was in accordance with the principles of the Declaration of Helsinki and ethical clearance was obtained by the local ethics committee (Comité Ético de Investigación Clínica de Badajoz).

Preoperative and Postoperative Protocol

Prior to surgery, all patients underwent a complete ophthalmologic examination, including presenting visual acuity (VA), subjective dry refraction, and cycloplegic objective refraction and corrected distance VA. Anterior segment anatomy was assessed with slitlamp, intraocular pressure using Goldman tonometry, and the fundus observation by indirect ophthalmoscopy. AS-OCT (Visante, Carl Zeiss Meditec AG) was used for measuring the ATA, CLR, ACQ, and the nasal and temporal ACA. The AS-OCT scans were performed along the horizontal meridian using a single-scan centered on the pupil. All scans used in this study were retrospectively reviewed by 1 operator where the scan centration was rechecked and measurements redone. The ATA, CLR, and ACQ were measured using the inbuilt "chamber" caliper and the ACA (in degrees) using the "angle" caliper (Figure 1, *A*). The ATA (mm) refers to the distance measured along the horizontal meridian between the nasal and temporal anterior chamber recess angle, the ACQ (mm) was defined as the distance between the corneal endothelium and the crystalline lens apex, and the CLR (μm) was measured as the distance between the ATA line and the

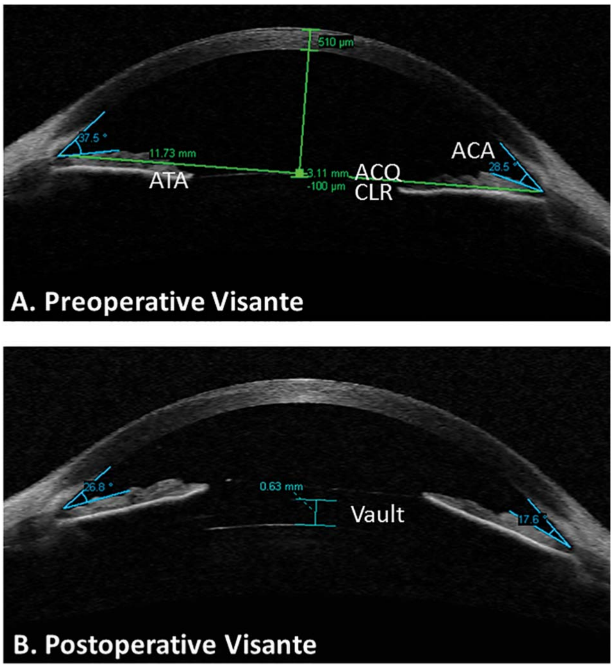

Figure 1. *A*: Preoperative measurements of the anterior chamber angle distance, internal anterior chamber, crystalline lens rise, and anterior chamber angle using the anterior-segment optical coherence tomography chamber and angle caliper. (*B*) Postoperative measurements using the vault linear caliper.

crystalline lens apex.[18] The CLR was defined as positive for a crystalline lens apex anterior to the ATA line and negative for a crystalline lens apex posterior to the ATA line.[24] Scheimpflug-based optical tomography (Pentacam HR, Oculus Optikgeräte GmbH) was used for quantifying the WTW (mm), central keratometry (KC) (D), and the central corneal thickness (CCT) (μm). Endothelial cell count was performed using noncontact specular microscopy (Topcon SP-2000P, Topcon Corp.) using a standard sample of 12 points. Measurements were performed in a room with dim light conditions, and the patients were instructed to look at the fixation systems of each instrument.

Post-surgery, the central vault was measured using the AS-OCT Visante. The measurement followed the same protocol as the one followed preoperatively. The central vault (μm) was measured using the "vault" caliper and was defined as the difference between the apex of the crystalline lens and the central most anterior point of the ICL posterior surface (Figure 1, *B*).

Surgical Protocol

The surgery was performed under local anesthesia using 2% intracameral lidocaine (B.Braun 20 mg/mL) diluted with saline solution, and the anterior chamber was filled with 2% methycellulose (Medicontur) as ophthalmic viscosurgical device, introduced through an anterior chamber paracentesis. The ICL was introduced in the anterior chamber through a 3.2 mm clear corneal incision using the manufacturer injector cartridge (STAAR Surgical Co.) and moved to the posterior chamber through the pupil. On positioning the lens the ophthalmic viscosurgical device was removed using a balanced saline solution and aspirated from the anterior chamber. Finally, a diluted antibiotic solution (ceftazidime, vancomicine and hydrocorticoid sodium phosphate) was injected into the anterior chamber via the paracentesis. After surgery, antibiotic (oftacilox ciprofloxacin 3 mg/mL), corticosteroid (Predforte prednisolone acetate 10 mg/mL), and antiinflammatory (Voltaren diclofenac sodium 1 mg/mL) drugs were applied topically 4 times a day for 3 weeks.

Statistical Analysis

The vault was used as the dependent variable. Preoperative anatomical parameters, namely ATA, WTW, CCT, ACQ, KC, CLR, ACA (average nasal and temporal), and horizontal compression (HC), defined as the difference between the ICL size and ATA; lens parameters, namely the ICL size and ICL spherical equivalent (SE); and age were tested as predictor variables.[6] Initially, multivariate analysis of variance (MANOVA) was applied to test the hypothesis of whether the parameters of eyes implanted with spherical and toric lenses differed, since differences between spherical and toric lenses had been reported.[25] Since there was no statistical difference between both groups, these were merged into a single group. For the toric lenses, the ICL refractive power was computed as SE. Patients implanted with 12.1 mm ICL were removed from analysis because of the small (3) number of cases.

Assuming each lens size as an individual identity, the group was divided into 3 subgroups corresponding to the size of the lens implanted (ie, 12.6 mm, 13.2 mm, and 13.7 mm, respectively). MANOVA was used to test the hypothesis of whether the variables differed among the 3 groups. Pairwise post hoc analysis was adjusted for multiple corrections (Bonferroni criterion). The relationship between the vault and the predictor variables was initially investigated using an exploratory bivariate correlation analysis. This was done independently for the 3 lens groups. The parameters showing significant relationships were combined into a model using the forward method in the multivariate linear regression analysis (MLR). The effect of the lens size was considered in the model by defining 2 indicator variables (12.6 mm and 13.7 mm), keeping 13.2 mm lens as the reference. The collinearity of the predictors was assessed using the Durbin-Watson test and the plot of the standardized residuals used for checking the homoscedasticity and normality of the residuals.

RESULTS

Comparison of preoperative and postoperative parameters between the spherical and toric ICL groups showed no significant statistical differences between groups for all parameters (Pillai's Trace: F = 1.6 $P = .110$). Table 1 summarizes the demographic characteristics for the 2 lens groups.

Preoperative Parameters and Vault by Lens Size

Table 2, shows the mean and the 95th percentile of the preoperative parameters and the vault of the 3 lens groups.

MANOVA showed significant statistical differences between the 3 lens groups (Pillai's Trace: F = 19.1 $P < .0001$). The variables differing between groups were age (F = 3.7, $P = .026$), vault (F = 18.4 $P < .0001$), WTW (F = 138.2 $P < .0001$), ATA (F = 158.3 $P < .0001$), ACQ (F = 43.1 $P < .0001$), KC (F = 29.1 $P < .0001$), and ACA (F = 5.1 $P = .007$). The remaining parameters—CCT, CLR, ICL SE, and HC—did not differ among the 3 groups (for all $P > .078$).

Table 3 summarizes the pairwise comparisons between the variables presenting significant statistical differences. Eyes implanted with the 13.7 mm lenses had higher vaults. As expected, eyes with smaller transverse sizes (WTW or ATA) were implanted with smaller lenses similarly to eyes with shallower ACQ and narrower ACA. KC was steeper in eyes implanted with smaller lenses.

Table 1. Sample demographic summary for groups implanted with spherical and toric ICLs.

Parameter	Spherical Mean	Spherical 95th Percentile	Toric Mean	Toric 95th Percentile
N	220		140	
Gender (M/F)	77/143		59/81	
Age (y)	32.7, 21.0: 48.0		31.6, 21.0: 48.0	
Sphere (D)	−9.88, −20.00: 4.00		−8.20, −15.94: 3.00	
Cylinder (D)	−0.84, −2.00: ±0.00		−2.71, −5.00: 1.27	
Preoperative CDVA (decimal VA)	0.78, 0.3: 1		0.76, 0.3: 1.0	
ECC (cells/mm^2)	2955, 2310: 3850		2892, 2376: 4000	
Postoperative follow-up (wk)	14, 8: 25		16, 9: 27	

CDVA = corrected distance visual acuity; ECC = endothelial cell count; ICLs = implantable collamer lenses; VA = visual acuity

Table 2. Descriptive statistics for the preoperative parameters and vault for the 3 lens groups.

	Lens 12.6 (n = 70)		Lens 13.2 (n = 218)		Lens 13.7 (n = 72)	
Parameter	Mean	95th Percentile	Mean	95th Percentile	Mean	95th Percentile
Vault (μm)	546.6	95.0: 1192.5	639.2	119.0: 1250.1	839.0	230.6: 1580.0
Age (y/o)	32.2	21.5: 46.5	33.0	21.0: 50.0	30.3	21.0: 46.0
WTW (mm)	11.39	10.90: 12.00	11.89	11.30: 12.51	12.32	11.63: 13.00
ATA (mm)	11.72	11.13: 12.27	12.22	11.61: 12.95	12.72	12.03: 13.36
HC* (mm)	0.89	0.33: 1.48	0.98	0.25: 1.60	0.98	0.34: 1.68
CCT (μm)	538.6	455.0: 610.0	535.9	469.0: 611.0	529.7	473.0: 590.0
ACQ (mm)	3.15	2.81: 3.54	3.28	2.85: 3.84	3.51	2.97: 3.98
CLR (μm)	79.0	−365.0: +365.0	126.7	−280.5: +531.0	72.6	−350.0: +478.0
KC (D)	45.03	42.18: 48.60	43.85	40.88: 46.80	42.98	39.99: 46.18
ACA (°)	24.30	13.85: 27.7	41.33	26.70: 58.01	44.21	30.78: 59.60
ICL SE (D)	−11.09	−18.00: −4.63	−11.05	−18.00: −5.49	−10.10	−15.60: −5.15

ACA = anterior chamber angle; ACQ = internal anterior chamber; ATA = anterior chamber angle distance; CCT = central corneal thickness; CLR = crystalline lens rise; HC = horizontal compression; ICLs = Implantable collamer lenses; KC = central keratometry; SE = spherical equivalent; WTW = white-to-white
*Compression = ICL size–ATA.[6]

An analysis of the number of cases per vault range showed that the 13.7 mm lens group had more cases in the higher vault range when compared to the remaining 2 groups (Figure 2).

Correlation Analysis: Vault vs Preoperative Parameters

A bivariate correlation analysis per group of lens was performed using the vault as the dependent variable and preoperative parameters as independent variables (Figure 3).

For the 12.6 mm lens group, the vault was negatively correlated with ATA ($R = -0.30$), indicating that eyes with smaller transverse sizes present higher vaults; negatively correlated with the CLR ($R = -0.36$) informing that the protrusion of crystalline lenses contributes to a lower vault; and positively correlated with ACQ ($R = 0.24$) indicating that larger ACQ allow for higher vaults.

For the 13.2 mm lens group, the number of parameters correlated with the vault increased. Vault was negatively correlated with ATA and WTW ($R = -0.39$ and $R = -0.21$); negatively correlated with CLR ($R = -0.39$), and positively correlated with ACQ ($R = 0.21$). In addition, the vault was negatively correlated with the ICL SE ($R = -0.25$) indirectly, suggesting that sagittal depth variation associated with the lens power influences the vault size. Also, the vault was positively correlated with KC (R = 0.24), indicating that eyes with flatter corneas had lower vaults.

For the 13.7 mm lens group, the results resemble those of the 12.6 mm lens, with stronger correlations though (ATA: R = −0.45; CLR: $R = -0.45$; and ACQ: $R = 0.37$).

Influence of Horizontal Compression on the Vault

The effect of the ICL oversize (HC) in relation to the vault was compared with the 3 lens groups (Figure 4). The HC was positively correlated with the vault (slope with the same magnitude as the relationship between ATA and vault but with opposite sign) for the 3 lens sizes. The hypothesis advanced that larger diameter lenses may be additionally affected by the HC, which is graphically observed by the higher slope of the 13.7 mm lens when compared to the slopes of the 12.6 mm and 13.2 mm lenses. Nevertheless, the slopes of the 3 groups did not differ statistically (interaction effects, ANOVA univariate analysis $F = 1.5$, $P = .213$).

Multivariate Correlation Analysis

The preoperative parameters correlated with the vault in the bivariate correlation analysis, namely age, WTW, ATA, ACQ, CLR, ICL SE, KC, and ICL size, were used as predictors in the MLR. The vault was significantly predicted by the ICL size, ATA, CLR, ICL SE, and age $F(3, 214) = 31.9$, $P < .0001$ (Table 4).

Table 3. Pairwise comparisons between the 12.6 mm, 13.2 mm and 13.7 mm lens groups.

	Difference of the Means, P Value*		
Parameter Difference	12.6 to 13.2 mm	12.6 to 13.7 mm	13.2 to 13.7 mm
Vault (μm)	−93.6, P = .072	−293.5, P < .001	−199.9, P < .001
Age (y/o)	−0.8, P = .999	1.9, P = .389	2.7, P = .022
WTW (mm)	−0.50, P < .001	−0.94, P < .001	−0.43, P < .001
ATA (mm)	−0.50, P < .001	−1.00, P < .001	−0.50, P < .001
ACQ (mm)	−0.13, P < .001	−0.36, P < .001	−0.23, P < .001
ACA (°)	−1.18, P = .885	−4.06, P = .008	−2.89, P = .025
KC (D)	1.12, P < .001	2.06, P < .001	0.88, P < .001

ACA = anterior chamber angle; ATA = anterior chamber angle distance; KC = central keratometry; WTW = white-to-white
*Statistical significance for multiple comparisons was accounted by applying Bonferroni correction (P = .05/21 = .0024).

The general multiple regression model can be defined as:

$$\text{Dependent Variable} = B0 + B1 \times X1 + B2. \times X2 + B3. \times X3 + \ldots + Bn. \times Xn + \varepsilon \quad (1)$$

where B represents the MLR coefficients and X the predictor variables. The indicator variables X_1 and X_2 are implemented in the model as follows:

For a 12.6 mm lens	For a 13.2 mm lens	For a 13.7 mm lens
$X_1 = 1$ and $X_2 = 0$	$X_1 = 0$ and $X_2 = 0$	$X_1 = 0$ and $X_2 = 1$

The predicted vaults for the 12.6 mm and 13.7 mm lens size are expressed by equations 3 and 4, respectively.

The equation for the predicted vault in the 13.2 mm lens size can be written as:

$$\text{Central vault}_{13.2\ mm}\ (\mu m) = 4132.04 + (-287.45 \times ATA) + (-0.37 \times CLR) + (-20.39 \times ICL\ SE) + (-4.82 \times Age) \quad (2)$$

$$\text{Central vault}_{12.6\ mm}\ (\mu m) = \text{Central vault}_{13.2\ mm}\ (\mu m) - 260.99 \quad (3)$$

$$\text{Central vault}_{13.7\ mm}\ (\mu m) = \text{Central vault}_{13.2\ mm}\ (\mu m) + 330.19 \quad (4)$$

Using the above equations, for the average ICL SE (−10.50 DS) and age (32 years), a two-dimensional matrix using ATA and CLR as variables can be used as an estimator of the vault. Figure 5 represents the areas where a vault between 250 μm and 1000 μm (white, light and dark gray areas) is expected and the areas where a non-optimal vault is expected (black areas).

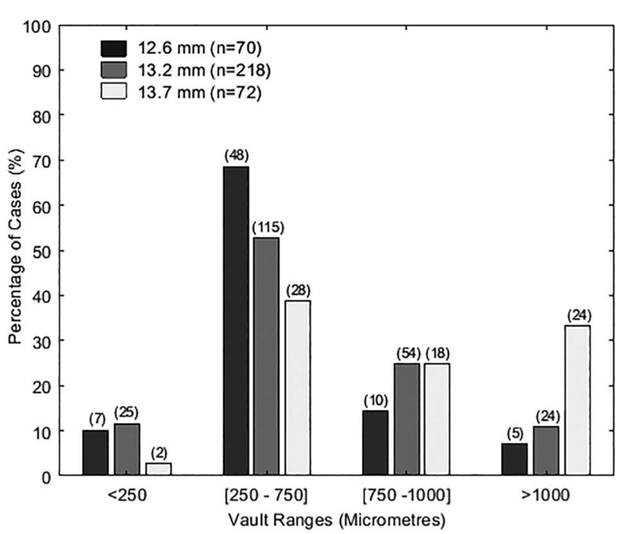

Figure 2. Distribution of the number of cases (percentage and the number of cases in parenthesis) for the 12.6 mm, 13.2 mm and 13.7 mm lens groups, respectively.

DISCUSSION

Predicting the postoperative vault to select the most suitable ICL size is a challenging process depending on a series of mechanisms related to the anatomy of the eye, ICL geometry, and the interaction between these two. In this case series, approximately 23% of the eyes showed a vault outside the vault range <250 μm and >1000 μm; thus, a percentage of these patients require careful and frequent follow-up. Among the various preoperative anatomical and lens parameters measured, the multiple regression analysis identified the ATA, CLR, ICL size, ICL power, and age as relevant predictors of the vault, explaining 34% of the vault variance. This compares with the 37% found by Lee et al., 36% reported by Zheng et al., and more recently 41% by Igarashi et al.[6,19,26]

The MLR identified the transverse size of the eye (given by the ATA) as the main predictor (β = −0.42) of the vault size. Previously, Malyugin et al., Nakamura et al., and Igarashi et al. using AS-OCT showed significant relationships between the vault and the transverse size of the eye determined by iris–pigment-end to iris–pigment-end, scleral-spur to scleral-spur distance, and ATA, respectively.[19,20,27] This finding supports the theoretical concept that the vault produced by an ICL is primarily driven by the compression force created by the oversized ICL resting on a narrower STS space.[4] As previously described in Lee et al., the compression force measured in vitro is linearly related to the vault with a gradient of 1.0, that is 1.0 mm of compression producing a 1000 μm vault.[6] In vivo, this relationship has a much lower magnitude. The regression formulas based on STS measurements indicate on average a 48 μm variation in vault size for each 0.1 mm of compression.[6,8,9] Nakamura et al. using the scleral-spur to scleral-spur distance reported a variation of 72 μm for 0.1 mm.[20] In the present study when analyzed individually by lens size the HC influence on the vault is stronger on the 13.7 mm lens with 53 μm for each 0.1 mm compression, compared with the 32 μm variation on the 12.6 mm and 13.2 mm lenses (Figure 3). Although the difference in slope variation among the three lenses did not reach statistical difference, it suggests that the effect of compression has a stronger effect in lenses with larger sizes compared with those of smaller sizes. This could be when a similar compression force is applied to 2 lenses of different sizes, the resulting bending force on the center of the lens, which is the product of the compression force by the lens half diameter, is stronger in the largest diameter lens. This finding has clinical implications, suggesting that the 13.7 mm lens may produce unexpected high vaults for similar levels of compression.

Regarding the WTW, although used to determine the size of the implanted lenses in the vast majority of cases, the WTW was not identified as a predictor of the vault in the final model, which concurs with a previous report.[19] This agrees with studies that found STS as being a better predictor of the vault compared to the WTW.[6] Studies comparing STS, WTW, and ATA distances showed similar average differences (0.20 mm) between STS and WTW or

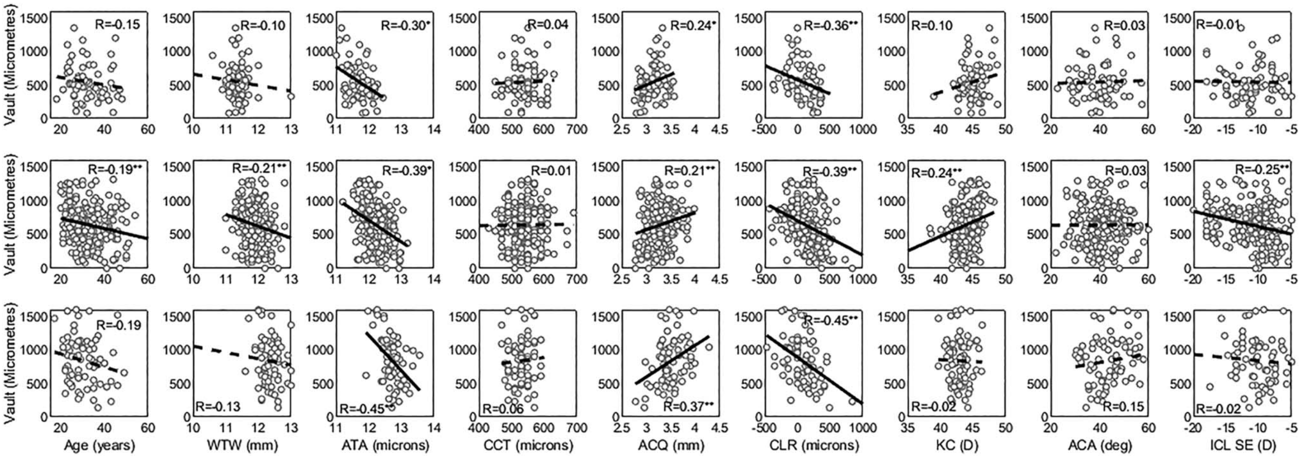

Figure 3. Bivariate correlation analysis for the 3 lens groups, using vault as the dependent variable and age, WTW, ATA, CCT, ACQ, CLR, KC, ACA, and ICL SE as independent variables. The lines in the plot represent the best linear square fit, with *continuous lines* representing a statistical significant correlation and *dashed lines* a non-statistical correlation. Horizontal compression was not included in the plot since its correlation is similar to the ATA correlation with the vault. *Top* figures represent 12.6 mm ICL and *bottom* 13.7 mm ICL (ACA = anterior chamber angle; ACQ = internal anterior chamber; ATA = anterior chamber angle distance; CCT = central corneal thickness; CLR = crystalline lens rise; ICL = implantable collamer lens; ICL SE = ICL spherical equivalent; and KC = central keratometry; WTW = white-to-white).

between STS and ATA, but the levels of agreement between WTW and STS (R^2 range: 0.00 to 0.59) were poorer compared to those between ATA and STS (R^2 range: 0.68 to 0.92).[9,11–13] The relationship between WTW and STS is weakened in the presence of higher anterior chamber depths and higher levels of myopia.[15,16] In this study, the WTW was on average 0.3 mm smaller than the ATA, in accordance with previous reports, also indicating that the measurements are not interchangeable.[28] This added to the evidence of a weak correlation between WTW and ATA (12.6 mm: R = 0.50; 13.2 mm: R = 0.48; and 13.7 mm: R = 0.16, data not shown in the present study, R = 0.45 in [Nemeth et al.]), suggesting that the actual manufacturer nomogram should not be used with transverse eye estimators other than the WTW. The present findings support that for the purpose of vault prediction in the absence of STS measurement, the ATA is a more robust predictor of the vault when compared to the WTW.

The protrusion of the anterior surface of the CLR was negatively correlated with the vault and identified as the predictor of the vault. The mean CLR found in this sample of myopes was close to those previously reported, range +60 to +140 μm.[20,24] The bulging of the ICL produced by the compression forces and its intrinsic lens vault produces a space that is partially used by the anterior hemisphere of the crystalline lens; thus, eyes with higher crystalline lens protrusion will show a reduced vault.[23] The vault prediction formula presented by Nakamura et al. is somehow more dependent on the CLR value compared to the regression analysis presented here (NK-partial coefficient = −0.72 vs this study = −0.37); in practical terms the formula presented in this report is less affected or more tolerable to CLR variation.[20] In this case series, ACQ was not a significant predictor of the vault size, similar to what other studies have reported using multiple regression models, despite the fact that when analyzed individually per lens ACQ positively correlated with the vault size.[6,8,9,20,26] The ACQ was negatively correlated with the CLR (R range: −0.59, to −0.74, data not shown) but CLR showed a stronger correlation with the vault than did the ACQ; therefore, the main variations in the vault size associated with axial parameters are related to CLR rather than ACQ. The manufacturer's calculator uses ACQ as a safety indicator, that is in the presence of insufficient compression, when the ICL size is close to the transverse size of the eye, the ICL size is increased to maintain an optimal vault. Including the CLR in the lens sizing protocol will inform the surgeon on how the lens bulging space is occupied by the crystalline lens. The ACQ in conjunction with the ACA

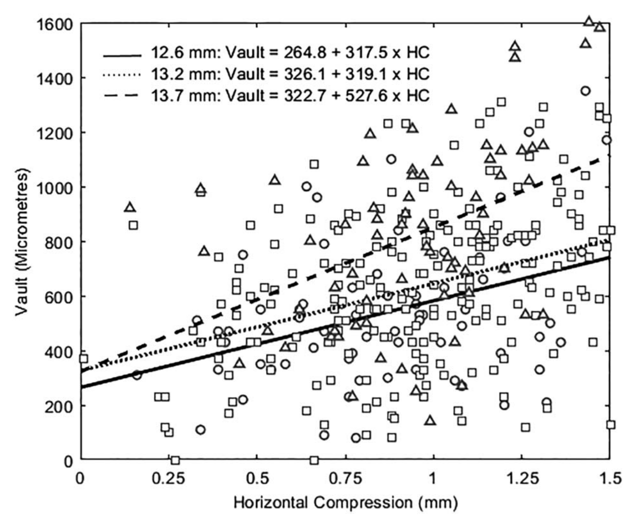

Figure 4. Horizontal compression vs vault for the 3 lens groups. Group (12.6 mm): *Circles* and *continuous regression line*; group (13.2 mm): *squares* and *dotted regression line*; and group (13.7 mm): *triangle* and *continuous regression curve*.

Table 4. Summary of the multivariate linear regression.

Predictors	Coefficients				
	B	Standard Error	β	Significance	Adjusted-R^2
0 Constant (13.2 mm)	4132.04	527.60		<0.001	R^2 = 0.34
1 Indicator variable (12.6 mm)	-260.99	40.77	−0.33	<0.001	
2 Indicator variable (13.7 mm)	330.19	41.85	0.42	<0.001	
3 ATA (mm)	−287.45	42.69	−0.42	<0.001	
4 CLR (μm)	−0.37	0.07	−0.25	<0.001	
5 SE (D)	−20.39	4.11	−0.22	<0.001	
6 Age (y)	−4.82	1.86	−0.12	= 0.010	

ATA = anterior chamber angle distance; CLR = crystalline lens rise; SE = spherical equivalent; β = standardized partial regression coefficient

should be accounted for, as safety parameters for predicting the vault influence in the proximity to the endothelium and angle closure.[29,30]

Age was an additional predictor of the vault variability. Increasing age induces physiological changes in the anterior pole of the eye such as the increase in crystalline lens thickness, which leads to an increase in CLR and anterior chamber narrowing thickness.[31,32] The present results reflect these changes through the moderate correlation between age, CLR (*R* range: 0.23 to 0.29), and ACQ (*R* range: −0.20 to 0.22). Despite the relationship between age and CLR, which do not present significant collinearity, both were included in the model. Another aspect of the influence of age on the vault is the reduction in pupil size observed with age increase, with an expected reduction in pupil size of 0.9 mm between the third and fifth decade of life.[33,34] This long-term effect may have a similar effect to the variation in vault created by light-induced myosis; however, this argument requires further analysis.[35,36]

Lens geometry, represented by the lens size and power, was a significant predictor for the vault. The size of the ICL has a close association with its intrinsic sagittal depth, that is bigger lenses have higher sagittal depths for similar dioptric powers. This effect is observed by the differences in vault size among the 3 lens groups, when the compression and dioptric power did not show significant statistical differences. A higher intrinsic sagittal depth associated with a bigger lens will allow implanting bigger lenses with lesser HC. Likewise, the association between the ICL power and vault indicates that lenses with more negative dioptric power show higher vaults. This may be explained through the decrease in the radius of curvature in the posterior surface of the ICL, which is necessary to increase the dioptric power, thereby contributing to an increase in the sagittal depth of the lens.[6]

The multivariate regression analysis using preoperative anatomy and lens parameters, developed in previous and in the current study, point out to similar levels of predictability and show the influence of additional factors in the vault size.[6,26] One such factor is the dampening effect of the haptics landing zone, and eyes presenting higher anatomical rigidity might have a stronger effect of the HC.[6] The landing position of the ICL haptics is a relevant factor affecting the vault, as lenses resting in different planes will show variation in the vault. Using UBM, Zhang et al. reported that 32.1% and 21.6% of the cases had the haptics positioned in the ciliary body and ciliary sulcus respectively.[37] Elshafei et al. reported 79% of their series of cases with the haptics on ciliary sulcus and 21% on the zonules.[38] Using AS-OCT, the landing zone of the ICL was not observable; therefore, it is not possible to ensure that all lenses rested in the same position and this

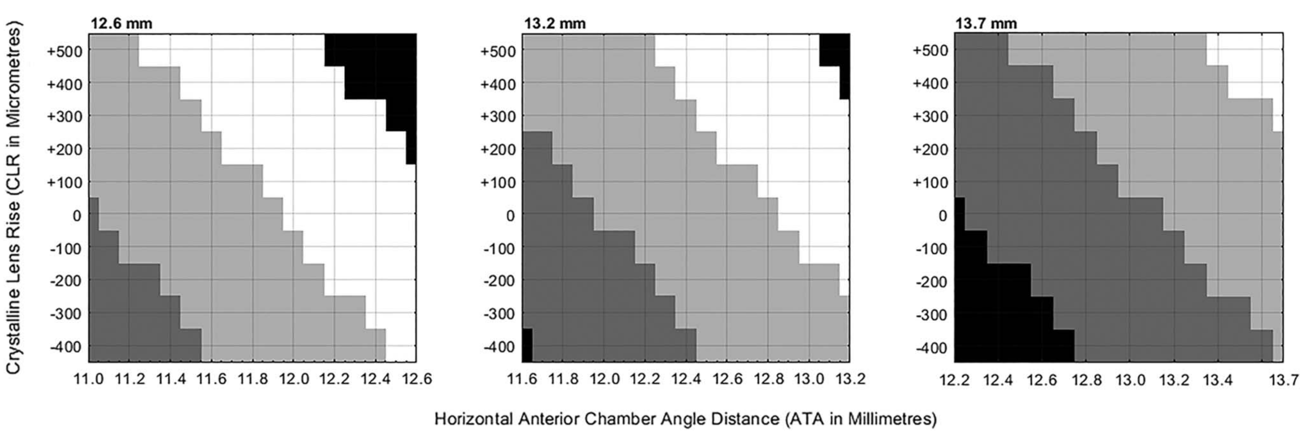

Figure 5. Vault estimation matrices for the 3 lens sizes. *x*-axis correspond to the anterior chamber angle distance values and *y*-axis to the crystalline lens rise values. Gray levels indicate: black, vault >1000 μm or vault <250 μm; dark gray, vault (1000, 750) μm; light gray, vault (750, 500) μm; and white, vault (500, 250) μm.

fact remains a limitation when assessing ICL with the AS-OCT. Another factor is the effect of postoperative pupil size on the vault. The influence of pupil can only be assessed postoperatively and depends on the average vault size; studies aiming to predict the influence of preoperative pupil on vault size show a weak association.[36,39] This study did not control the preoperative and postoperative pupil size.

The retrospective analysis of preoperative parameters for the prediction of the vault resulted in approximately one third of the vault variability explained, limiting the ability of accurately predicting the vault. However, the multivariate regression analysis evidenced 3 main mechanisms regulating the vault size, namely the effect of the HC (given by the ATA), the crystalline lens protrusion, and the ICL sagittal depth dictated by the power and size. Taking into account these mechanisms may provide the surgeon with a more comprehensive understanding of the effect of the ICL size on the vault in a particular eye. In practical terms the vault prediction methodology developed in the present study (ICL Vault Estimator accessed at http://bit.ly/ICLVAULTESTIMATOR) can be used to estimate the vault magnitude for the ICL suggested by the manufacturer and how the novel predictor variables of the vault will affect it.

WHAT WAS KNOWN

- The ability to predict the vault in implantable collamer lenses (ICLs) is still one of the major challenges in ICL implantation.
- The manufacturer sizing protocol leaves approximately one fifth of the patients with a nonoptimal vault.

WHAT THIS PAPER ADDS

- A vault prediction model based on preoperative anatomic and ICL parameters, which uses new variables in the context of vault prediction.
- Traditional parameters used for the ICL sizing, such as the white-to-white and ACQ can be substituted by others showing stronger associations with the vault.

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