Central vault after phakic intraocular lens implantation: Correlation with anterior chamber depth, white-to-white distance, spherical equivalent, and patient age

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PURPOSE: To compare the central postoperative vault of a phakic intraocular lens (pIOL) to correct myopia, myopic astigmatism, and hyperopia and identify ocular and lens parameters that might predict the vault amount.

SETTING: Fernández-Vega Ophthalmological Institute, Oviedo, Spain.

DESIGN: Cohort study.

METHODS: Three months after implantation of Implantable Collamer Lens pIOLs to correct myopia, hyperopia, and myopic astigmatism, central vault was measured using optical coherence tomography. Patients were divided into groups according to the preoperative anterior chamber depth (ACD) to compare the effects of ACD, white-to-white (WTW) distance, and lens diameter on postoperative pIOL vault.

RESULTS: Hyperopic pIOLs had statistically significantly lower vault followed by myopic pIOLs and toric pIOLs, which had a higher mean value and narrower range (260 to 860 μm). Measured vaults had a positive correlation with preoperative ACD ($r = .32$, $P<.001$) and WTW ($r = .29$, $P<.001$) and a negative correlation with preoperative spherical equivalent (SE) ($r = -0.21$, $P<.001$) and patient age ($r = -0.12$, $P=.025$). Eyes with a vault of 250 μm or less had a shallower ACD than eyes with a vault between 250 μm and 750 μm (mean difference −0.11 mm; $P=.012$) and those with a vault greater than 750 μm (mean difference −0.25 mm; $P<.001$).

CONCLUSIONS: Central vaulting was lower in hyperopic eyes. Current nomograms for pIOL diameter selection based on ACD and WTW might yield ideal vault and may have to be adjusted for older patients, shallower ACD, lower WTW, and lower SE.

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In many cases, phakic intraocular lens (pIOL) implantation is a good alternative treatment for ametropia correction, and the technique has become an important refractive surgery option. The Visian Implantable Collamer Lens (Staar Surgical Co.) is a foldable pIOL designed to be placed in the posterior chamber behind the iris with the haptic zone resting on the ciliary sulcus. Studies have found this pIOL to be safe and effective in the refractive correction of myopia,[1] hyperopia,[2] and astigmatism[3–5] and in eyes that may not be appropriate for corneal reshaping procedures.[6–8] Results in long-term studies confirm these results.[9]

The most important way to avoid pIOL-induced complications, such as pupillary block[10] and cataract formation,[11] is to achieve the proper distance between the back pIOL surface and the anterior crystalline lens pole; this distance, called vault, is dependent on the chosen pIOL diameter. At present, the diameter of the pIOL is determined based on the horizontal white-to-white (WTW) distance, anterior chamber depth (ACD), and manufacturer's recommendations.

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The ideal vault is between 1.0 and 1.5 corneal thicknesses on slitlamp examination. However, choosing the pIOL diameter based on WTW has limitations; thus, it is not likely that conventional methods will give accurate vault values, specifically in eyes with a large WTW distance or a shallower ACD.[12]

The present study assessed the effects of ocular parameters (ACD and WTW values) and pIOL diameter on postoperative vault and evaluated the factors that affect central vault after pIOL implantation in eyes with myopia, hyperopia, or astigmatism.

PATIENTS AND METHODS

This study comprised patients having pIOL implantation at the Fernandez-Vega Ophthalmological Institute, Oviedo, Spain, from August 2006 to May 2009. After being fully informed of the details and possible risks of the surgical procedure, all patients provided written informed consent. The study followed the Declaration of Helsinki, and an institutional review board approved the study.

The inclusion criteria for pIOL implantation were a corrected distance visual acuity (CDVA) of 20/50 or better, a stable refraction, and a clear central cornea. The exclusion criteria were age over 22 years, an ACD less than 2.8 mm, an endothelial cell density (ECD) more than 2000 cells/mm^2, cataract, a history of glaucoma or retinal detachment, macular degeneration or retinopathy, neuro-ophthalmic disease, and a history of ocular inflammation.

Before pIOL implantation, patients had a complete ophthalmologic examination. The examination included the manifest and cycloplegic refractions, keratometry, corneal topography and pachymetry (Orbscan II, Bausch & Lomb), ECD measurement (SP 3000P, Topcon Europe BV), slitlamp evaluation, Goldmann applanation tonometry, and binocular indirect ophthalmoscopy through a dilated pupil.

Phakic Intraocular Lens Size and Power Calculation

A Visian Implantable Collamer Lens pIOL was used in all cases. The pIOL is rectangular, 7.0 mm wide, and available in 4 overall lengths: 11.5 mm, 12.0 mm, 12.5 mm, and 13 mm for the myopic model (ICMV4) and toric model (TICMV4) and 11.0 mm, 11.5 mm, 12.0 mm, and 12.5 mm for the hyperopic model (ICHV3). All eyes had implantation of the most recent pIOL model and, when possible, were targeted for emmetropia.

The pIOL diameter was individually determined based on the horizontal WTW distance and ACD, measured from the endothelium with the Orbscan II device and following the pIOL manufacturer's recommendations. For eyes with an ACD measurement of 3.5 mm or less, the IOL size was calculated by adding 0.5 mm to the horizontal WTW measurement. For eyes with an ACD measurement greater than 3.5 mm, up to 1.0 mm was added to the WTW measurement. Calculated IOL sizes between the available IOL diameters (in 0.5 mm steps) were usually rounded down if the ACD was 3.5 or less and rounded up if the ACD was greater than 3.5 mm. The pIOL power was calculated using the pIOL power table software provided by the manufacturer and a modified vertex formula. The pIOL implantation technique has been reported.[13,14]

Vault Assessment

The central separation between the anterior lens surface and the posterior pIOL surface (vault) was assessed using optical coherence tomography (OCT) (Visante, Carl Zeiss Meditec AG). The separation was measured perpendicular to the lens apex or at the narrowest space between the 2 surfaces. All vault measures were performed during the routine visit 3 months postoperatively.

All vault measures were taken under the same lighting conditions and with cycloplegia to avoid the potential influence of accommodation-induced changes in the position of the anterior surface of the crystalline lens or the pIOL, which could affect the estimation of the amount of vault. The same technician took multiple measurements and calculated the mean value.

To compare the effects of ACD, WTW, and pIOL diameter, patients were divided into several subgroups according to the preoperative ACD ($\leq$3.17 mm or $>$3.17 mm), WTW diameter ($\leq$11.7 mm or $>$11.7 mm), and the difference between the pIOL diameter and WTW ($\leq$0.5 mm or $>$0.5 mm). Cutoff values were arbitrarily set based on the median preoperative ACD (3.17 mm), median WTW diameter (11.7 mm), and median difference between WTW and the chosen pIOL diameter (0.5 mm).

As in previous studies,[15–17] the eyes were also divided into groups based on the vault value. Ideal vault was defined as 250 to 750 μm, excessive vault as more than 750 μm, and insufficient vault as less than 250 μm.

Statistical Analysis

Statistical analysis was performed using SPSS for Windows software (version 18.0, SPSS, Inc.). Descriptive statistics were obtained. The Kolmogorov-Smirnov test was used to evaluate the normality of the data distribution. The Kruskal-Wallis test was used to determine statistically significant differences in vault between the 3 pIOL models (ie, myopic, hyperopic, toric). The Mann-Whitney *U* test and analysis of variance (ANOVA), with multiple comparisons (with Bonferroni post hoc correction of *P* values) where appropriate, were used to determine statistically significant differences between the stratified subgroups. The

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Table 1. Patient demographics, pIOL characteristics, and postoperative visual and refractive outcomes.

	Myopic pIOL Group			Hyperopic pIOL Group		
Parameter			P Value*			P Value*
Eyes (n)	323	—	—	28	—	—
Age (y)	31.3 ± 7.0	21, 46	.001	30.2 ± 6.8	20, 47	.322
Sphere (D)	−8.40 ± 3.49	−19.00, −0.50	.002	4.71 ± 1.94	+1.00, +8.25	.825
Cylinder (D)	−1.20 ± 1.09	−2.50, 0.00	<.001	−1.46 ± 1.28	−4.00, 0.00	.159
ACD (mm)	3.28 ± 0.38	2.89, 4.03	.888	3.02 ± 0.23	2.83, 3.40	.749
WTW (mm)	11.8 ± 0.3	11.2, 12.5	.007	11.9 ± 0.3	11.3, 12.4	.424
pIOL diameter (mm)	12.2 ± 0.3	11.5, 12.5	<.001	11.9 ± 0.3	12.5, 11.5	.028
CDVA	0.88 ± 0.17	0.40, 1.00	<.001	0.92 ± 0.12	0.70, 1.00	.004
Postoperative						
SE (D)	−0.25 ± 0.61	−5.00, 1.50	<.001	−0.05 ± 0.57	−2.00, 1.25	.005
UDVA (Snellen lines)	0.83 ± 0.23	0.4, 1.0	<.001	0.87 ± 0.17	0.3, 1.0	.124
CDVA (Snellen lines)	0.92 ± 0.14	0.4, 1.0	<.001	0.92 ± 0.11	0.7, 1.0	.004

ACD = anterior chamber depth; CDVA = corrected distance visual acuity; pIOL = phakic intraocular lens; SE = spherical equivalent; UDVA = uncorrected distance visual acuity; WTW = white-to-white distance
*One-sample Kolmogorov-Smirnov test
†Between groups; Kruskal-Wallis test

correlations between pIOL vault and the preoperative ACD, the WTW diameters, and the differences in the pIOL and WTW diameters were analyzed using Spearman rank correlation coefficient (*r*) analysis. Differences were considered statistically significant when the *P* value was less than 0.05.

RESULTS

The study enrolled 371 eyes of 196 patients (116 women [59.2%]). Table 1 shows patients' demographics, pIOL characteristics, and postoperative visual and refractive outcomes by pIOL type (ie, myopic, hyperopic, toric). There was no statistically significant difference in the postoperative spherical equivalent (SE), uncorrected distance visual acuity ($P=.209$), or CDVA ($P=.342$) between the 3 pIOL groups.

The mean baseline postoperative vault was highest in the toric pIOL group (mean 493 μm ± 161 [SD]; range 260 to 860 μm) and lowest in the hyperopic pIOL group (mean 371 ± 183 μm; range 140 to 850 μm). The mean vault was 448 ± 22 μm in the myopic pIOL group, and this group had the lowest value and the highest value (range 100 to 1060 μm). The difference between the 3 pIOL groups was statistically significant ($P<.001$, Kruskal-Wallis test), as were the differences between the myopic pIOL group and the hyperopic pIOL group ($P=.04$, Mann-Whitney *U* test) and between the hyperopic pIOL group and the toric pIOL group ($P=.02$, Mann-Whitney *U* test). Measured vaults had a positive correlation with preoperative ACD ($r = 0.32$, $P<.001$) and WTW ($r = 0.29$, $P<.001$) (Figure 1, *A* and *B*) and a negative correlation with preoperative SE ($r = -0.21$, $P<.001$) and patient age ($r = -0.12$, $P=.025$) (Figure 1, *C* and *D*).

Table 2 compares the vault in the subgroups (ie, stratified by ACD, WTW, and difference between pIOL diameter and WTW). In the myopic pIOL group, the mean measured vault in the ACD ≤3.17 mm subgroup was significantly statistically lower than in the ACD >3.17 mm subgroup ($P=.011$); no significantly statistically difference was found between the 2 WTW subgroups. In the hyperopic pIOL group, the mean measured vault was significantly statistically lower in the ACD ≤3.17 mm subgroup than in the ACD >3.17 mm subgroup and significantly statistically lower in the WTW ≤11.7 mm subgroup than in the WTW >11.7 mm subgroup (both $P<.001$); no statistically significant difference was found between the 2 subgroups stratified by the difference between WTW and lens diameter ($P=.551$). In the toric pIOL group, there were no statistically significant differences in the mean vault between the 2 ACD groups ($P=.314$), the 2 WTW subgroups ($P=.275$), or the 2 subgroups stratified by the difference between WTW and lens diameter ($P=.615$).

Table 3 compares the ACD and WTW values in the myopic pIOL group stratified by the amount of postoperative vault. Eyes with a vault between 250 μm and 750 μm and eyes with a vault of more than 750 μm had a deeper ACD than eyes with a vault less than 250 μm by +0.11 mm ($P=.012$) and +0.25 mm ($P<.001$), respectively. In addition, eyes with a vault less than 250 μm had a significantly lower WTW diameter than eyes with a postoperative vault more than 750 μm (mean difference −0.22 mm) ($P=.011$).

Table 1. (Cont.)

Toric pIOL Group			
		P Value*	*P* Value†
20	—	—	—
31.9 ± 5.7	24, 42	.534	.563
−6.41 ± 3.06	−11.00, 0.00	.772	<.001
−2.89 ± 1.21	−5.00, −1.00	.910	<.001
3.37 ± 0.30	2.93, 3.99	.648	.001
12.0 ± 0.4	11.5, 12.9	.622	<.001
12.4 ± 0.3	13.0, 12.0	.008	<.001
0.82 ± 0.21	0.40, 1.00	.157	.342
−0.23 ± 0.38	−1.50, 0.00	.191	.100
0.75 ± 0.24	0.3, 1.0	.449	.209
0.87 ± 0.18	0.4, 1.0	.114	.342

DISCUSSION

The present study found that the mean central vault with the 3 types of Implantable Collamer Lens pIOLs was different. The hyperopic pIOLs had the lowest mean values and the toric pIOLs the highest mean values. This agrees with previous findings[18,19] and is the result of the inherent design of each pIOL type and of the different anatomy of hyperopic, myopic, and astigmatic eyes. The myopic pIOL is plano concave, with the plano surface facing anteriorly, and it has an optic diameter ranging from 4.65 to 5.50 mm. The toric pIOL for astigmatism has a similar design but incorporates cylinder in the posterior optic zone. The hyperopic pIOL is meniscus-shaped (concave–convex), with a convex anterior surface and a 5.5 mm optic diameter; the central thickness is much greater than that of the myopic pIOL. In addition, hyperopic eyes have a more crowded anterior segment than myopic eyes. These differences may explain the difference in the vault we observed.

We had observed that the ideal vault was not reached in some cases when we followed the recommendations of the Implantable Collamer Lens pIOL manufacturer. Thus, we focused on the effect of ACD and WTW, which were shown to have significant correlations with the amount of postoperative vault, and assessed the efficacy of the conventional method. For the hyperopic pIOL, ACD was the most significant parameter associated with vault; eyes with a lower ACD had significantly lower vault. For the myopic pIOL, significant differences were found between the ACD subgroups and between the WTW subgroups. Eyes with a shallower ACD and/or a lower WTW had significantly lower vault; conversely eyes with a deeper ACD and/or a higher WTW had significantly higher vault. This agrees with the findings of Seo et al.,[12] who report that a high WTW diameter or a deep ACD are likely to result in high vault, regardless of differences in pIOL diameter and sulcus diameter.

According to the manufacturer's recommendations, the pIOL diameter should be 0.5 to 1.0 mm larger than the WTW measurement in myopic eyes and the same as or 0.5 mm larger than the WTW in hyperopic eyes. In addition, the ideal postoperative vault must create space over the whole anterior crystalline lens surface, with the recommended amount of vault equal to 1.0 to 1.5 central corneal thicknesses on slitlamp examination,[20] which corresponds approximately to a value between 400 μm to 600 μm.[13] For this to be achieved, the appropriate pIOL must be selected. Underestimating the pIOL diameter is frequently associated with poor vault (<250 μm) immediately after surgery.[17] This increases the risk for cataract development, which is caused by pIOL–crystalline lens contact or by disturbances in aqueous flow, which interferes with lens nutrition and thus results in metabolic disturbances to the crystalline lens.[11,21,22] On the other hand, excessive vault (>750 μm)[17] can cause angle-closure, pupillary block glaucoma, or pigmentary-dispersion glaucoma and is often associated with an oversized pIOL.[23–25] Moreover, the anterior segment (including anterior chamber and posterior chamber) is a dynamic rather than static space. Thus, factors such as accommodation and biometric ocular changes

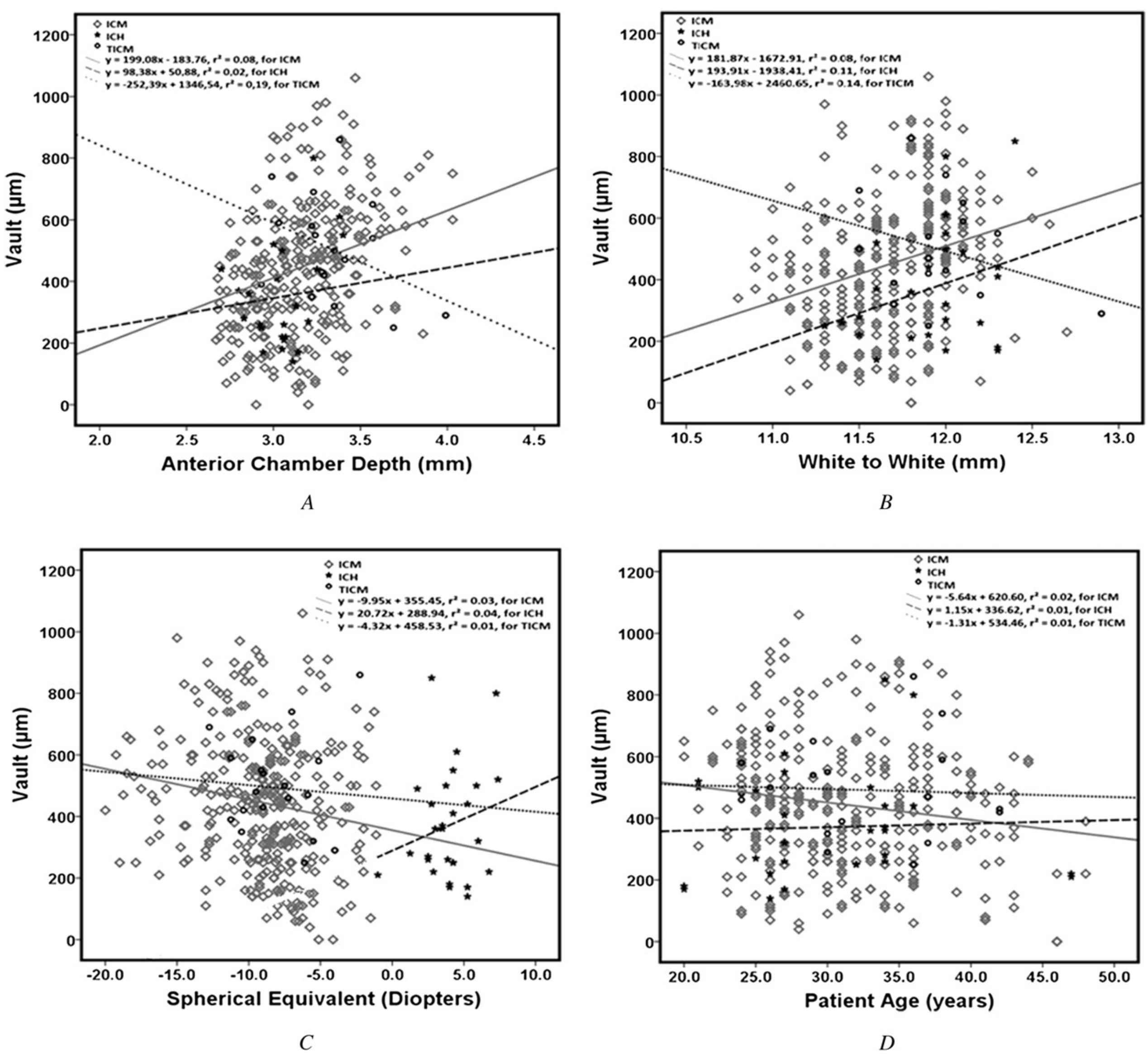

Figure 1. Correlations between vault and preoperative biometry (ICH = hyperopic pIOL group; ICM = myopic pIOL group; TICM = toric pIOL group).

Table 2. Subgroup comparisons of ACD, WTW, and difference between WTW and lens diameter.

Group/Parameter	ACD			WTW			WTW − LD		
	≤3.17 mm	>3.17 mm	*P* Value*	≤11.7 mm	>11.7 mm	*P* Value*	≤0.5 mm	>0.5 mm	*P* Value*
Myopic group									
pIOL diameter (mm)	11.88 ± 0.36	12.00 ± 0.00	.340	11.75 ± 0.42	12.06 ± 0.24	.016	11.90 ± 0.32	—	—
Vault (µm)	301 ± 119	534 ± 197	.011	315 ± 122	403 ± 205	.388	366 ± 188	—	—
Hyperopic group									
pIOL diameter (mm)	12.07 ± 0.29	12.29 ± 0.26	<.001	12.03 ± 0.24	12.36 ± 0.25	.000	12.14 ± 0.30	12.24 ± 0.27	.010
Vault (µm)	386 ± 189	507 ± 232	<.001	390 ± 187	512 ± 240	.000	440 ± 209	469 ± 242	.551
Toric group									
pIOL diameter (mm)	12.33 ± 0.29	12.47 ± 0.30	.477	12.20 ± 0.27	12.53 ± 0.23	.017	12.45 ± 0.35	12.50 ± 0.00	.707
Vault (µm)	573 ± 176	479 ± 171	.314	542 ± 94	476 ± 178	.275	497 ± 159	477 ± 214	.615

ACD = anterior chamber depth; pIOL = phakic intraocular lens; LD = lens diameter; WTW = white-to-white distance
*Mann-Whitney *U* test (in myopic group, no statistical analyses between WTW – LD because all myopic pIOL diameters chosen by adding ≤0.5 mm to WTW)

Table 3. Mean differences in preoperative ACD and WTW in the myopic pIOL group stratified by postoperative vault amount.

	Group 1: Vault ≤250 μm (n = 65)					
			Versus			
Parameter	Mean ± SD	95% CI	Group 2	*P* Value*	Group 3	*P* Value*
ACD (mm)	3.05 ± 0.23	2.99, 3.10	−0.11	0.012	−0.24	<.001
WTW (mm)	11.62 ± 0.33	11.54, 11.70	−0.09	0.206	−0.22	.011

ACD = anterior chamber depth; CI = confidence interval for mean; WTW = white-to-white distance
*Statistically significance for differences between stratified groups

related to aging affect the space available between the posterior cornea and anterior crystalline lens surface, which in turn affects the amount of vault.[14,19,26–30] Thus, achieving satisfactory vault is important for safe and successful pIOL implantation. In the U.S. Food and Drug Administration Implantable Collamer Lens study,[31] which implemented the WTW measurement protocol, the pIOL replacement rate because of clinically significant oversizing or undersizing was 1.5%. In the present study, although no pIOL was replaced, 70 eyes (18.9%) had a vault less than 250 μm and 32 eyes (8.6%) had a vault of more than 750 μm. Eyes with a lower vault had an ACD less than 3.10 mm, while eyes with vaults more than 750 μm had a WTW greater than 11.76 mm (Table 3).

Patient-dependent factors, such as age and higher myopia, were correlated with the amount of postoperative vault. Kamiya et al.[32] found patient age and WTW to be the most significant factors affecting vault; that is, eyes of younger patients and eyes with a greater WTW were more likely to have greater vault. In the present study, there was a statistically significant negative correlation between postoperative vault and age ($r = -0.12$, $P = .025$) and between postoperative vault and SE ($r = -0.21$, $P < .001$); older patients had lower vault, while patients with higher degrees of myopia tended to have higher vault. The reason is that the anterior chamber decreases in the aging eye because of the thickening of the aging crystalline lens.[33] This results in lower vault, and the thicker periphery of highly powered pIOLs causes anterior chamber narrowing because of an iris forward shift; these factors result in excessive vault.

Because the haptics of the Visian Implantable Collamer Lens pIOL rest in the ciliary sulcus, the ideal overall diameter of pIOL depends on the ciliary sulcus diameter. Thus, it is desirable to obtain a direct measurement of the sulcus-to-sulcus length using new imaging technologies such as ultrasound biomicroscopy (UBM).[34] However, regardless of the accuracy of the WTW measurement, recent studies[35–38] found no anatomic correlation between external measurements and internal dimensions. Therefore, WTW distance alone may not predict angle or sulcus size, and the horizontal diameter of the ciliary sulcus may not be accurately predicted, resulting in size mismatching. Moreover, it has been reported that UBM determination of pIOL length yields significantly better vault than the conventional WTW method.[16] Although using UBM might provide better outcomes than WTW measurements, there is still a risk for high or low vaulting resulting from incorrect positioning of the pIOL in the sulcus.[39] In the present study, the pIOL diameter was chosen according to the WTW diameter, and we could not accurately predict the exact position of the pIOL in the sulcus. However, the results in our study reflect the postoperative vault surgeons might expect when they use the current nomogram and select pIOL diameter based on WTW and ACD measurements. Our results suggest that in some cases, the current nomogram to select pIOL diameter might not yield ideal vault, particularly in eyes with a shallower ACD (≤3.1 mm) and lower WTW diameter (11.5 mm) and in eyes with a large WTW diameter (>11.8 mm).

A limitation of this study is the discrepancy in sample size. Despite the results of a power analysis that showed the sample size was not big enough to confirm statistically significant differences between the 3 pIOL models, the results in our study show the vault behavior with the myopic, hyperopic, and toric models and the correlation between vaulting and ocular parameters.

In conclusion, the results indicate that the current nomogram for pIOL sizing does not always yield ideal vault and that it requires adjustment in certain cases, in particular for older eyes, eyes with a shallow ACD, eyes with a lower WTW distance, and eyes with a lower SE. Additional studies using UBM to select the pIOL diameter may help to achieve uniform vault regardless of preoperative ocular dimensions and may prevent poor or excessive vault.

Table 3. (Cont.)

Group 2: Vault 250–750 μm (n = 227)				Group 3: Vault >750 μm (n = 31)	
		Versus			
Mean ± SD	95% CI	Group 3	*P* Value*	Mean ± SD	95% CI
3.16 ± 0.31	3.12, 3.20	−0.12	.111	3.28 ± 0.29	3.17, 3.39
11.71 ± 0.37	11.66, 11.76	−0.13	.145	11.84 ± 0.23	11.76, 11.92

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