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Pupil Diameter Changes in High Myopes after Collamer Lens Implantation

Dan Li*, Yabo Yang†, Caipei Su‡, Houfa Yin*, and Xue Liu§

ABSTRACT

Purpose. To observe the changes in pupil size under photopic and scotopic conditions after Implantable Collamer Lens (ICL) implantations in eyes with high myopia.

Methods. The ICL was implanted in 90 eyes belonging to 45 patients with high myopia. Photopic pupil diameters, scotopic pupil diameters, anterior chamber depths, and ICL vaults were examined at the preoperative, postoperative 1-month, and postoperative 3-month stages. The preoperative and postoperative photopic pupil diameters and scotopic pupil diameters were also compared with each other to note the differences between them. The correlations between preoperative and postoperative pupil diameter changes under different light conditions and presurgical refractive error were analyzed alongside patient's age and ICL vault.

Results. Pupil diameters at both postoperative 1-month and postoperative 3-month stages were smaller than those before operation in distinct light environments, as well as pupil constriction amplitude. Correlation analysis showed that there was a statistically significant correlation between pupil diameter changes under different light conditions and presurgical refractive error at 1 month and 3 months after ICL implantation; pupil diameter decreased more when presurgical refractive error powers were less myopic. Statistically significant correlations were not found, however, with patient's age and ICL vault. Postoperative 1-month and mean postoperative 3-month anterior chamber depths were decreased when compared with preoperative anterior chamber depths. Statistically significant correlations were found in change in preoperative and postoperative anterior chamber depth and ICL vault. No statistically significant difference was found between ICL vault at the postoperative 1-month and postoperative 3-month stages.

Conclusions. Pupil diameter may decrease at the 1- and 3-month stages after ICL implantation under both photopic and scotopic conditions. This indicates that reduction of pupil diameter may be caused by mechanical contact between the ICL and the posterior iris surface.

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Key Words: Implantable Collamer Lens (ICL), pupil diameter, anterior chamber depth, ICL vault

In recent years, Implantable Collamer Lens (ICL) implantation has become an alternative refractive surgery for the correction of myopia and astigmatism, used alongside the more widely accepted methods of photorefractive keratectomy, laser-assisted subepithelial keratomileusis, and laser *in situ* keratomileusis. Although these procedures are the most common surgical methods used to treat low-to-moderate levels of myopia, it may not be the best option, particularly for patients who have high levels of myopia or who have thin corneas. Moreover, the ICL can be removed and replaced with a new one if unexpected refractive outcomes or other complications occur after surgery. The results of existing published studies support the safety, efficacy, and predictability of ICL implantation in treating moderate to high myopia and astigmatism.[1–5] In recent years, quality of vision has become an important factor in patient satisfaction.[6,7] The size of the pupil has a significant effect on the optical quality of the retinal image.[8–11] There had been some studies on pupil diameter changes after intraocular refractive surgery. Keuch and Bleckmann[12] found reductions of scotopic pupil size and amplitude of constriction 2 weeks after ICL implantation. Chun et al.[13] believed that photopic pupil diameter decreased 1 month and 3 months postoperatively. In Lee's et al.[14] study, scotopic pupil diameter decreased after V4 and

*MD
†PhD, MD
‡MMS
§PhD
Department of Ophthalmology, Second Affiliated Hospital, College of Medicine, Zhejiang University, Hangzhou, China (all authors).

TABLE 1.

Patient demographics: preoperative and postoperative patient baseline characteristics

Demographic	Result
Patients, n	45
Eyes, n	90
Sex, n	
Male	15
Female	30
Age, mean ± SD, y	26.56 ± 6.44
Preoperative spherical equivalent, mean ± SD, D	−12.50 ± 4.28
Preoperative sphere, mean ± SD, D	−11.33 ± 3.96
Preoperative cylinder, mean ± SD, D	−1.39 ± 1.15
Postoperative 1 mo spherical equivalent, mean ± SD, D	−0.31 ± 1.34
Postoperative 1 mo sphere, mean ± SD, D	0.02 ± 1.22
Postoperative 1 mo cylinder, mean ± SD, D	−0.58 ± 0.54
Postoperative 1 mo spherical equivalent correction, mean ± SD, D	−12.19 ± 3.51
Postoperative 3 mo spherical equivalent, mean ± SD, D	−0.33 ± 1.27
Postoperative 3 mo sphere, mean ± SD, D	−0.04 ± 1.16
Postoperative 3 mo cylinder, mean ± SD, D	−0.48 ± 0.57
Postoperative 3 mo spherical equivalent correction, mean ± SD, D	−12.17 ± 3.61
Preoperative anterior depth, mean ± SD, mm	3.18 ± 0.22
Postoperative 1 mo anterior depth, mean ± SD, mm	2.29 ± 0.29
Postoperative 3 mo anterior depth, mean ± SD, mm	2.27 ± 0.30
Postoperative 1 mo ICL vault, mean ± SD, mm	0.56 ± 0.30
Postoperative 3 mo ICL vault, mean ± SD, mm	0.55 ± 0.33

V4c ICLs were implanted. Considering that the ICL (ICMV4 or ICHV3, Staar Surgical Co), which has an anterior vault design, is placed directly behind the iris and may keep in contact with the iris, it is possible that the implantation of an ICL will affect pupil dynamics under scotopic conditions or photopic conditions and could even change pupil size.

This study was designed to estimate the change in pupil diameter under different light conditions after ICL implantation. Furthermore, we sought to determine the correlation between changes in pupil diameter with the spherical equivalent correction, the patient's age, and the ICL vault, which was defined as the distance between the posterior surface of the ICL and the anterior crystalline lens surface.

METHODS

This study included 90 eyes belonging to 45 patients who underwent ICL (ICMV4, STAAR) implantation for the correction of high myopia. The patients' characteristics are shown in Table 1. All operations were performed by the same surgeon (YY).

Appropriate written informed consent in accordance with the Declaration of Helsinki and the Zhejiang Institutional Review Board was obtained from all participants.

Key exclusion criteria for ICL implantation included anterior segment disease, retinal detachment, other serious macular degeneration related to myopia or otherwise, systemic diseases that may affect the pupil reaction, a central anterior chamber depth less than 2.8 mm (measured from the endothelium to the anterior surface of the crystalline lens), and a central endothelial cell count less than 2500 cells/mm^2.

All patients had comprehensive ocular examinations before and after surgery, including subjective refraction, slit-lamp biomicroscopy, noncontact tonometry (NT-510, Nidek, Japan), endothelial cell count (specular microscope EM-3000, TOMEY, Japan), ultrasound biomicroscopy (SUOER UBMScan SW3200, Suowei, Tianjin, China), corneal topography (OrbscanII topography, Bausch & Lomb, Germany), WASCA Analyzer (Asclepion-Meditec-Zeiss, Germany), and indirect ophthalmoscopy fundus examinations. We measured pupil sizes using corneal topography (OrbscanII topography, Bausch & Lomb) under photopic conditions and the WASCA Analyzer (Asclepion-Meditec-Zeiss) under scotopic conditions. The luminance of the OrbscanII topography was about 28.2 to 480 lux, which showed high reproducibility for measuring photopic pupil size.[15] The WASCA Analyzer measurements during wavefront capture revealed a luminance of 0.51 lux, and it

TABLE 2.

Preoperative and postoperative 1-month pupil diameters under different light conditions

	Photopic pupil diameters, mm	Scotopic pupil diameters, mm	Pupil constriction amplitude, mm
Preoperative	4.65 ± 0.67	6.22 ± 0.61	1.58 ± 0.53
Postoperative 1 mo	4.32 ± 0.66	5.50 ± 0.54	1.17 ± 0.49
F	11.34	67.96	29.79
p	<0.01*	<0.001†	<0.001†

*Significant difference ($p < 0.01$).
†Significant difference ($p < 0.001$).

TABLE 3.
Preoperative and postoperative 3-month pupil diameters under different light conditions

	Photopic pupil diameters, mm	Scotopic pupil diameters, mm	Pupil constriction amplitude, mm
Preoperative	4.65 ± 0.67	6.22 ± 0.61	1.58 ± 0.53
Postoperative 3 mo	4.45 ± 0.65	5.47 ± 0.45	1.19 ± 0.55
F	16.54	87.17	24.15
p	<0.001*	<0.001*	<0.001*

*Significant difference ($p < 0.001$).

was an ideal method for obtaining scotopic pupil size.[16] Anterior chamber depth and vault were measured by ultrasound biomicroscopy. A central anterior chamber depth was measured from the endothelium to the anterior surface of the crystalline lens before the ICL implantation, and it was measured from the endothelium to the anterior portion of the ICL postoperatively. Vault was measured from the posterior surface of ICL to the anterior surface of the crystalline lens. All measurements were repeated three times.

Implantable Collamer Lens power calculations were performed by the manufacturer (STAAR Surgical) using a modified vertex formula, based on horizontal white-to-white distance, corneal thickness, anterior chamber depth from the corneal endothelium measured with corneal topography, and cycloplegic refraction.

Before ICL implantation, the patients underwent peripheral iridectomies at two sites with a neodymium:YAG laser. On the day of the surgery, the patients were administered with tropicamide 0.1% to induce preoperative mydriasis. After topical anesthesia, a model V4 ICL was inserted with an injector (STAAR Surgical Co) through a 3-mm temporal clear corneal incision after placement of viscoelastic solution (Haironț, Hangzhou, China) into the anterior chamber. The ICL haptics were placed behind the iris. After the ICL had been verified as placed in the center of the pupillary zone, the remaining viscoelastic solution was irrigated completely from the anterior chamber with a balanced salt solution. Pupil contraction was then induced via acetylcholine chloride. All the surgeries were uneventful and no intraoperative complications were observed. After surgery, steroidal medications were administered topically four times daily for 2 weeks, after which the dose was reduced steadily.

Statistical analyses were performed using SPSS 20.0. The results were expressed as mean (±SD), and a p value of less than 0.05 was considered statistically significant.

RESULTS

Baseline Characteristics

Forty-five patients had bilateral implantation. Patient baseline characteristics are summarized in Table 1. It is worth noting that both the mean postoperative 1-month anterior depth and mean postoperative 3-month anterior depth were decreased compared with the preoperative anterior depth, and that the difference between mean preoperative anterior depth and mean postoperative 1-month anterior depth was statistically significant (F = 532.29,

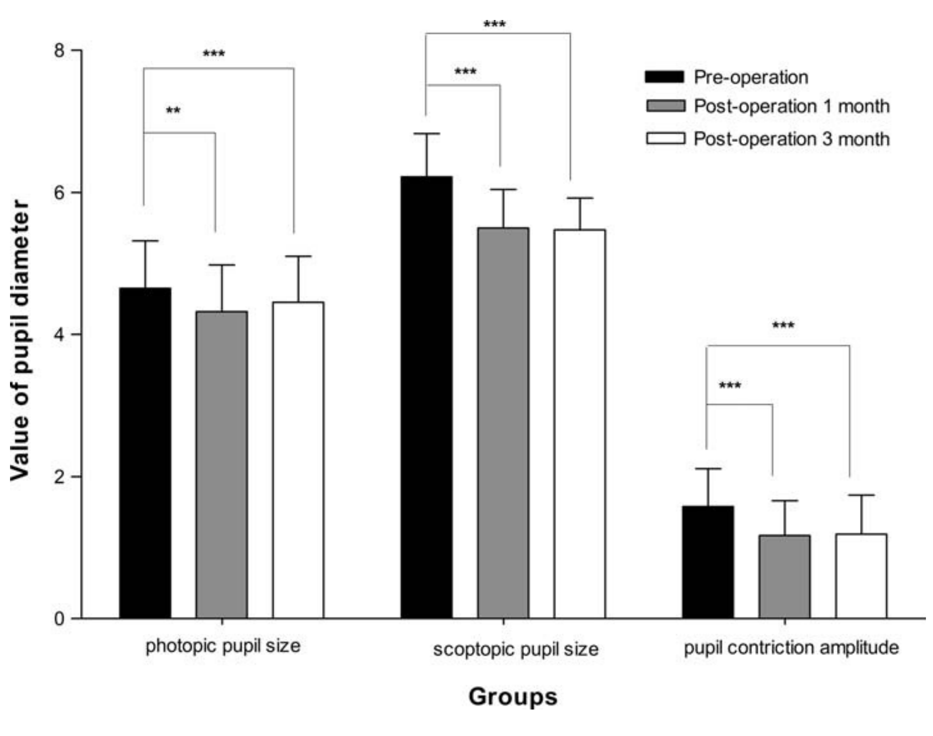

FIGURE 1.
Comparisons of preoperative and postoperative pupil diameters under different light conditions, as well as pupil constriction amplitude. Error bars represent the range of the SD of the mean. The significant differences were marked with ** ($p < 0.01$) and *** ($p < 0.001$).

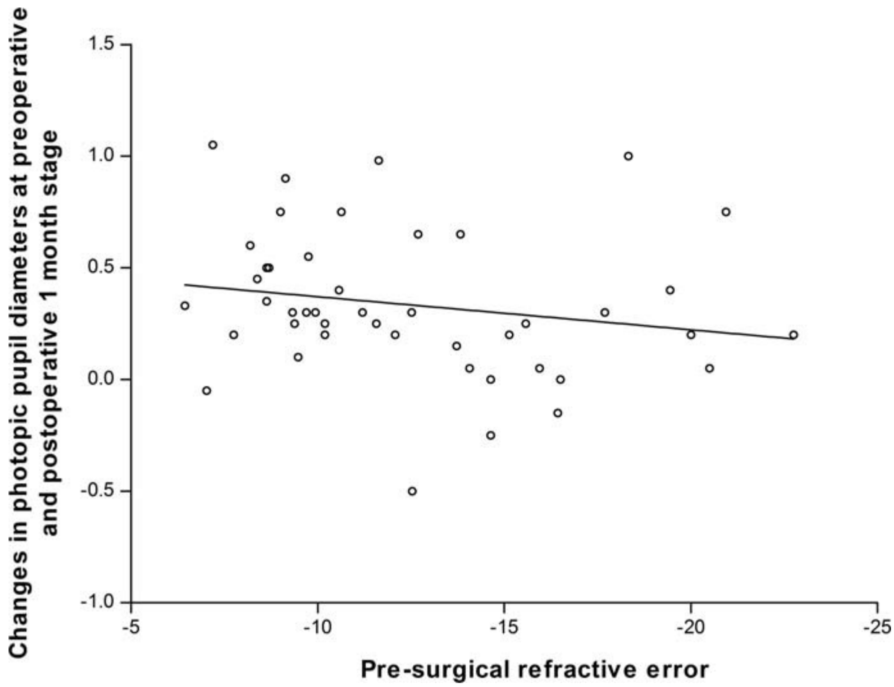

FIGURE 2.

A scatterplot showing a statistically significant correlation between changes in photopic pupil diameters and presurgical refractive error at the postoperative 1-month stage (Spearman correlation coefficient *r* = 0.299, p = 0.046).

p < 0.001). A similar situation was seen in the difference between the mean preoperative anterior depth and mean postoperative 3-month anterior depth (F = 530.54, p < 0.001). No statistically significant difference was found, however, in mean postoperative 1-month ICL vault and mean postoperative 3-month ICL vault (F = 0.061, p = 0.81).

Pupil Diameter

Tables 2 and 3 show preoperative, postoperative 1-month, and postoperative 3-month pupil diameters under different light conditions. Fig. 1 demonstrates a general condition that both postoperative 1-month and postoperative 3-month pupil diameters were significantly smaller than before operation in various light

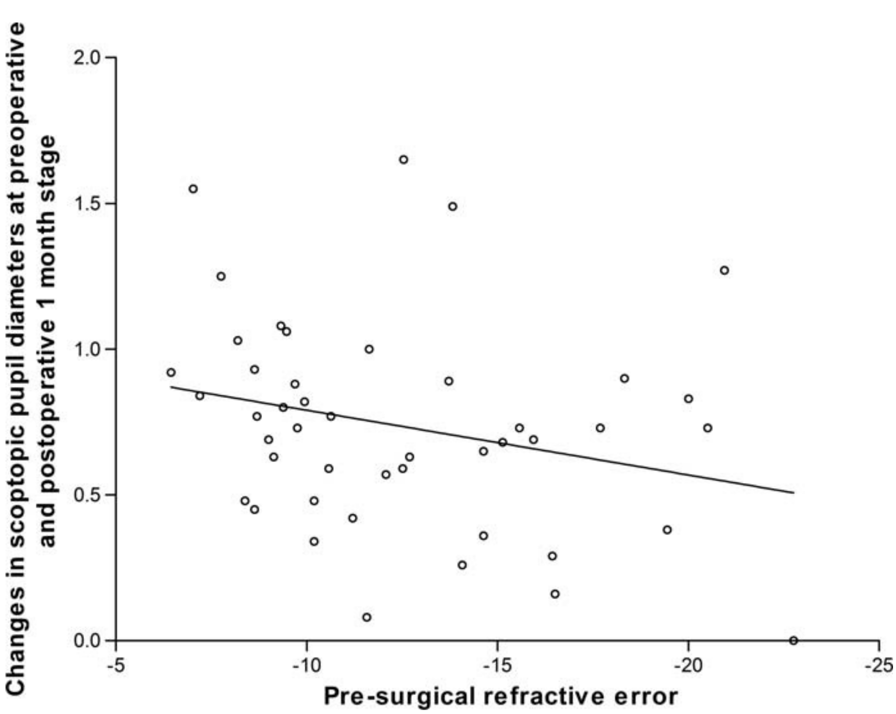

FIGURE 3.

A scatterplot showing a statistically significant correlation between changes in scotopic pupil diameters and presurgical refractive error at the postoperative 1-month stage (Spearman correlation coefficient *r* = 0.301, p = 0.044).

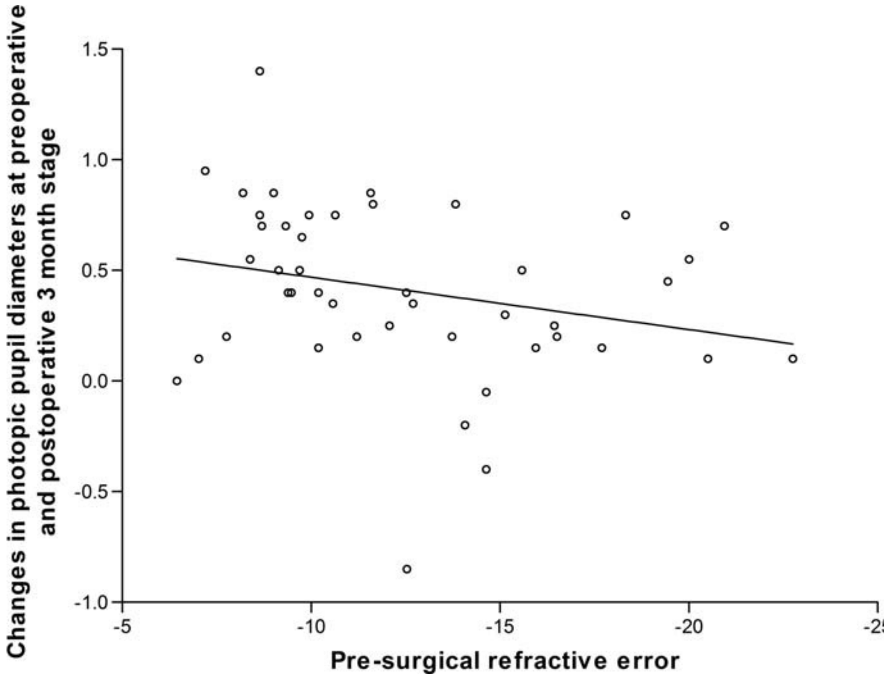

FIGURE 4.

A scatterplot showing a significant correlation between the change in photopic pupil diameter and presurgical refractive error at the postoperative 3-month stage (Spearman correlation coefficient $r = 0.322$, p = 0.031).

environments. To clarify whether pupil constriction amplitude had been changed after the implantation, we compared the difference of scotopic and photopic pupil diameters preoperatively and postoperatively. The results showed that pupil constriction amplitude decreased at both postoperative 1-month and postoperative 3-month stages.

Correlation Analysis

Figs. 2 to 5 demonstrate a correlation between pupil diameter changes under photopic and scotopic conditions and presurgical refractive error at 1 month and 3 months after ICL implantation. Significant correlations can be found between the reduction

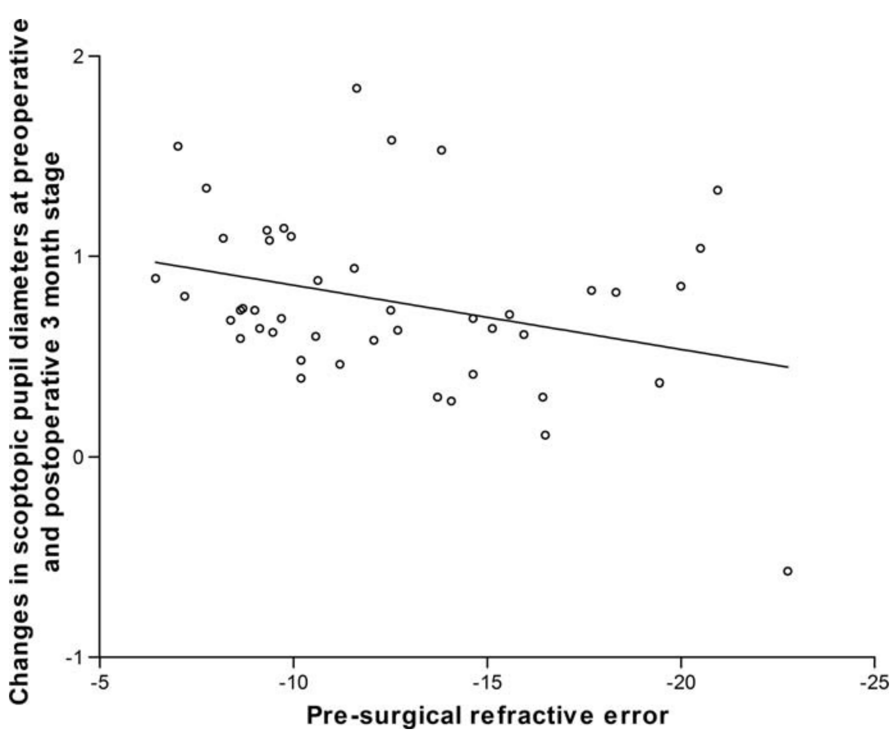

FIGURE 5.

A scatterplot showing a significant correlation between the change in scotopic pupil diameter and presurgical refractive error at the postoperative 3-month stage (Spearman correlation coefficient $r = 0.203$, p = 0.049).

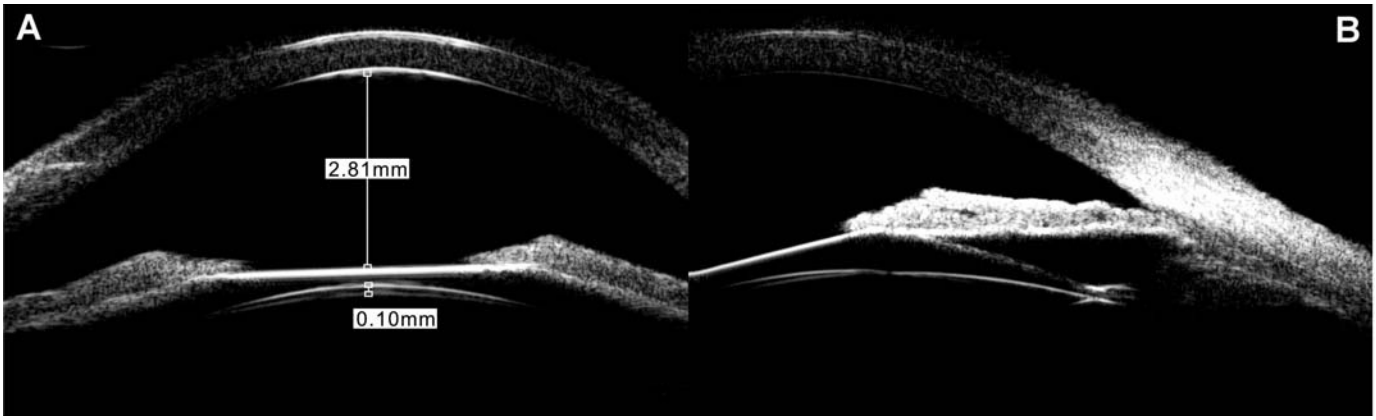

FIGURE 6.

Images with ultrasound biomicroscopy for patient A whose presurgical refractive error was −18.50 D. (A) Anterior chamber depth was 2.81 mm and ICL vault was 0.10 mm. (B) A representative quadrant.

of both photopic and scotopic pupil size postoperation and presurgical refractive error (Figs. 2 and 3 for 1 month postoperatively; Figs. 4 and 5 for 3 months postoperatively).

There was no significant correlation between pupil diameter changes under different light conditions, the ICL vault, and patients' age, after ICL implantation.

Considering the significant difference between preoperative and postoperative anterior chamber depth, we analyzed the correlation between change in preoperative and postoperative anterior chamber depth and ICL vault, as well as preoperative mean spherical equivalent. Figs. 8 and 9 show that there is a positive correlation between changes in preoperative and postoperative anterior chamber depth and the ICL vault at 1 month and 3 months postoperatively. No significant correlation was found between changes in preoperative and postoperative anterior chamber depth and preoperative mean spherical equivalent.

DISCUSSION

In this study, the diminutions of photopic pupil diameters and scotopic pupil diameters and the difference between photopic and scotopic pupil diameters at 1 month and 3 months after ICL insertions were observed. The results were in line with the research of Chun et al.,[13] in which a significant decrease in pupil diameter was reported 1 month and 3 months postoperatively. Our results were also consistent with Keuch and Bleckmann's research,[12] in which they found that the postoperative pupil diameter was smaller and the amplitude of constriction was reduced after implantation of a phakic posterior chamber ICL. We suggest that there might be mechanical contact (Figs. 6A and 7A) between the ICL and the posterior iris surface, and thus the mechanical irritation caused by the anterior vault design of the lens may play a vital role in decreasing pupil diameters. The postoperative reduction in pupil diameters may be beneficial to some extent because halos, which are produced by a pupil diameter exceeding the edges of the optical zone of ICL, are less frequent. However, aqueous humor circulation may be affected because of the flow resistance of aqueous humor lodged behind the V4 ICL[14]; a permanent reduction in pupil size may aggravate the resistance to intraocular fluid circulation or even induce the reduction of muscular tension of the dilator muscle of the pupil.

Correlation analysis showed (Figs. 2 to 5) that there was a statistically significant correlation between pupil diameter changes under different light conditions and presurgical refractive error at both 1 month and 3 months after ICL implantation. Pupil diameter changes were negatively correlated with preoperative

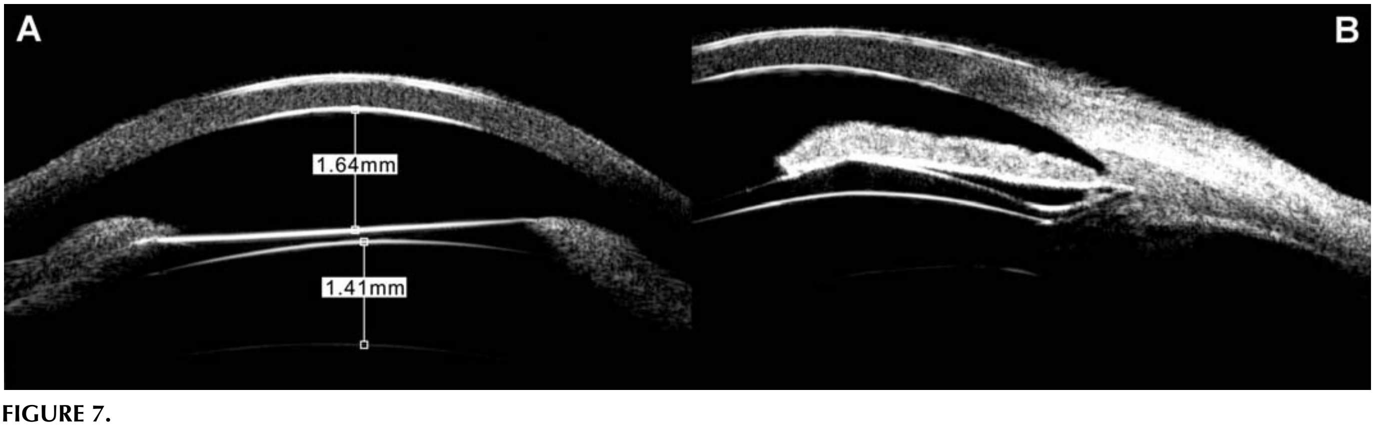

FIGURE 7.

Images with ultrasound biomicroscopy for patient B whose presurgical refractive error was −6.75 D. (A) Anterior chamber depth was 1.64 mm and ICL vault was 1.41 mm. (B) A representative quadrant.

TABLE 4.
Implantable Collamer Lens refractive error and thickness

Refractive error, D	Peripheral thickness, mm	Central thickness, mm
−6.00	0.38	0.116
−8.00	0.47	0.116
−10.00	0.52	0.116
−12.00	0.56	0.116
−14.00	0.57	0.116
−16.00	0.64	0.116
−18.00	0.71	0.116

refractive error; that is, larger decreases in pupil size postoperatively were seen in patients with the lowest amounts of preoperative myopia. It is worth noting that there are different peripheral thicknesses but the same central thickness in various refractive error ICLs. Moreover, peripheral thickness increases as refractive error increases (Table 4, provided by STAAR Surgical Co). According to general opinion, that would mean the higher ICL refractive errors are, the more limitations for pupil movements will be, and the more changes in postoperative pupil size will be. Interestingly, we obtained opposite results; that is, larger decreases in pupil diameter postoperatively were seen in patients with lower amounts of preoperative myopia. There is a larger degree of curvature at the peripheral part in higher refractive error ICLs than that in lower refractive error ICLs (Figs. 6B and 7B). In other words, a flatter curvature at the peripheral part in lower refractive error ICLs leads to increased contact area of iris and ICL, which limits postoperative pupil movements. From another perspective, there is an obvious difference in the amount of space between the edge of the optic zone and the ciliary body, with more space for the higher myope (Fig. 6B) and less space for the lower myope (Fig. 7B). Flowing aqueous humor in such a small space of lower myope may increase pressure to the posterior surface of the iris and affect pupil movements.

As expected, mean postoperative anterior chamber depths were decreased significantly more than preoperative anterior chamber depths at both postoperative 1-month and 3-month stages, as was the case in Ju et al.'s study.[5] On analyzing the correlation between changes in preoperative and postoperative anterior chamber depths and ICL vault, we found that there were statistically significant positive correlations at both postoperative 1-month and 3-month stages (Figs. 8 and 9). A possible explanation is that the postoperative anterior chamber depth is from the corneal to the anterior surface of ICL not the anterior portion of the crystalline lens; therefore, this decrease in postoperative anterior chamber depth, which was related with ICL vault, is expected. No statistically significant difference was found in the correlation analysis between changes in preoperative and postoperative anterior chamber depths and the preoperative mean spherical equivalent ($r = 0.216$, $p = 0.153$ for 1 month postoperatively; $r = 0.218$, $p = 0.150$ for 3 months postoperatively).

Studies have found that both pupil size and the amplitude of variation decrease with a patient's age.[17–21] Our results showed, however, that there was no significant correlation between pupil diameter changes and a patient's age ($r = 0.02$, $p = 0.89$ for 1 month postoperatively under photopic condition; $r = -0.16$, $p = 0.30$ for 1 month postoperatively under scotopic condition; $r = -0.03$, $p = 0.85$ for 3 months postoperatively under photopic condition; $r = -0.13$, $p = 0.40$ for 3 months postoperatively under scotopic condition). In this study, the mean (±SD) age of the

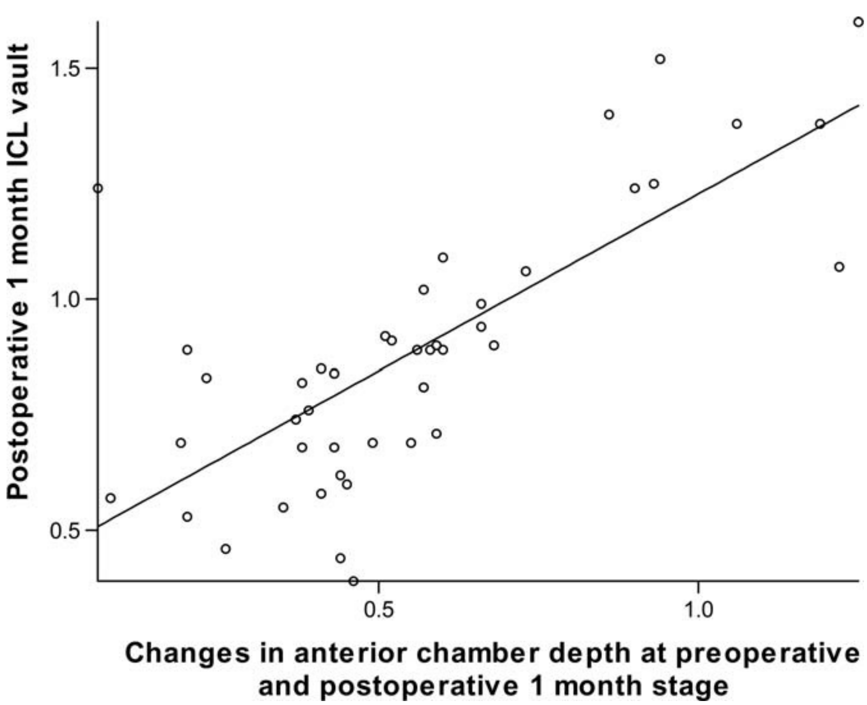

FIGURE 8.
A scatterplot showing a statistically significant correlation between change in preoperative and postoperative anterior chamber depths and ICL vault at the postoperative 1-month stage (Spearman correlation coefficient $r = 0.726$, $p < 0.001$).

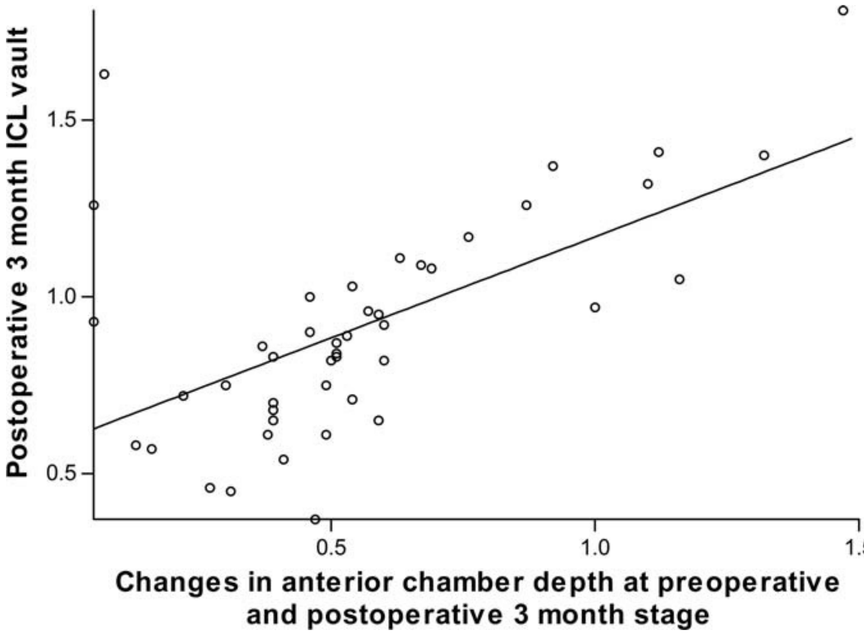

FIGURE 9.

A scatterplot showing a statistically significant correlation between change in preoperative and postoperative anterior chamber depths and ICL vault at the postoperative 3-month stage (Spearman correlation coefficient $r = 0.591$, $p < 0.001$).

45 patients was 26.56 (±6.44) years (range, 18 to 44 years). We hypothesize, therefore, that the range of patient ages here was not wide enough to show a correlation between pupil size changes and age.

In our study, there was no statistically significant difference between mean postoperative 1-month ICL vault and mean postoperative 3-month ICL vault ($F = 0.06$, $p = 0.81$), results that are in opposition to some other studies.[14,22] It was shown that there was also no significant correlation between pupil diameter changes and the ICL vault. This finding is in accordance with Kamiya et al.'s study,[23] whose results showed no significant correlation between the entrance pupil diameter and the amount of vaulting after ICL implantation.

There were some limitations to our study, such as the small number of patients. Moreover, pupil diameter can be affected by different measurement conditions, patient's psychological and emotional conditions,[24] the brightness of the measurement room, and so on. More comprehensive studies might, therefore, extend the results of our research into pupil size changes after ICL implantations.

In conclusion, our results support the view that pupil diameter may decrease 1 month and 3 months after ICL implantation under both photopic and scotopic conditions. The reduction of pupil diameter may be caused by mechanical contact between the ICL and the posterior iris surface. To investigate this issue further, both a longer follow-up and careful observations of a large number of patients are required.

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Yabo Yang
Department of Ophthalmology
Second Affiliated Hospital
College of Medicine
Zhejiang University
Hangzhou 310009, China
e-mail: yabyangz2@163.com