Changes in vaulting and the effect on refraction after phakic posterior chamber intraocular lens implantation

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PURPOSE: To assess the changes in vaulting over time after implantable Collamer lens (ICL) implantation and the effect of vaulting on refraction.

SETTING: Department of Ophthalmology, Kitasato University, Kanagawa, Japan.

METHODS: This retrospective study evaluated eyes of consecutive patients having ICL implantation. The postoperative changes in vaulting between the ICL and the crystalline at 1, 3, and 6 months and 1 year were quantitatively assessed. The relationship between the vaulting and refractive outcomes at 1 year was also evaluated.

RESULTS: Seventy-five eyes of 47 patients were evaluated. The mean vaulting was 0.61 mm $\pm$ 0.26 (SD), 0.59 $\pm$ 0.25 mm, 0.54 $\pm$ 0.25 mm, and 0.53 $\pm$ 0.24 mm at 1 month, 3 months, 6 months, and 1 year, respectively. The mean refractive error (difference between attempted and achieved manifest spherical equivalent refraction) was 0.01 $\pm$ 0.42 diopter (D) 1 year postoperatively. There was no significant association between the amount of vaulting and the refractive error ($r = 0.19$, $P = .11$).

CONCLUSIONS: Vaulting of the ICL over the crystalline lens decreased slightly with time, likely as a result of pupil movement, age-related increases in crystalline lens thickness, and the fixed position of the ICL haptics. The vaulting did not significantly affect refractive outcomes, suggesting that a precise effective lens position leads to higher predictability, largely as a result of the narrow fixated location of the ICL between the back surface of the iris and the ciliary sulcus.

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Although the most common refractive surgery technique has been laser in situ keratomileusis (LASIK), patients with high myopia or thin corneas face restrictions aimed at avoiding the risk for iatrogenic keratectasia. In addition, the deterioration in superior intrinsic corneal optical performance after LASIK cannot be ignored. Phakic intraocular lenses (pIOLs) were developed to address these disadvantages. One posterior chamber pIOL, the Visian implantable Collamer lens (ICL) (Staar Surgical Co.), has been studied extensively and found to be effective in correcting moderate to high ametropia.[1–10]

Implantation of an ICL is thought to have advantages over LASIK because it is safer, more effective, and provides highly predictable and stable results, especially in the correction of high myopia. Furthermore, the ICL is removable and can be replaced with another; this is not true of LASIK, even in cases of unexpected refractive outcomes. However, after ICL implantation, the crystalline lens can opacify as a result of its close proximity to the ICL. Eyes with lower vaulting (ie, distance between the posterior surface of the ICL and the anterior surface of the crystalline lens) are more

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predisposed to posterior capsule opacification.[11,12] Therefore, the amount of vaulting is an important factor in determining the safety of the surgical technique.

In view of chronic chafing of the ICL against the iris induced by physiologic or accommodative pupillary movement and age-related crystalline lens thickening,[13–17] it is likely that the amount of ICL vaulting after implantation changes over time. Moreover, the change in the ICL vaulting is a possible source of postoperative refractive error. However, the time course of the changes in vaulting has been not fully elucidated, and its effect on refractive outcomes remains unclear. The purpose of this study was to longitudinally assess the amount of vaulting over time and evaluate its relationship to postoperative refractive errors.

PATIENTS AND METHODS

This retrospective study evaluated eyes of consecutive patients who had implantation of an ICL for the correction of myopia and who returned regularly for postoperative examinations. All patients provided informed consent. The study adhered to the tenets of the Declaration of Helsinki. Institutional Review Board approval was not required.

Power calculations for the ICLs were performed by the manufacturer using a modified vertex formula. The size of the ICL was also chosen by the manufacturer based on the horizontal corneal diameter and anterior chamber depth (ACD) measured with a scanning-slit topographer (Orbscan IIz, Bausch & Lomb).

Preoperatively, the patients had peripheral iridectomies at 2 sites with a neodymium:YAG laser. On the day of surgery, dilating and cycloplegic agents were given. After topical anesthesia was administered, hyaluronic acid was placed in the anterior chamber. Next, a model V4 ICL was inserted through a 3.0 mm clear corneal incision with an injector cartridge. After the ICL was placed in the posterior chamber, the remaining ophthalmic viscosurgical device was completely washed out of the anterior chamber with a balanced salt solution and acetylcholine chloride was instilled into the eye. After surgery, betamethasone 0.1% and antibiotic levofloxacin were administered topically 4 times daily for 2 weeks, with a gradual taper thereafter.

One, 3, and 6 months and 1 year postoperatively, central vaulting of the ICL over the crystalline lens was evaluated on anterior segment images obtained by slitlamp microscopy using procedures reported by Gonvers et al.[11,18] and Kamiya et al.[19] In brief, digitized photographs were taken after pupil dilation using a slitlamp camera with the beam as thin as possible and focused on the center of the ICL. Using NIH Image software (National Institutes of Health), the amount of central vaulting of the ICL over the crystalline lens (distance between posterior surface of ICL and anterior surface of crystalline lens) was calculated and compared with the central thickness of the ICL provided by the manufacturer. The relationship between vaulting and refractive error (difference between attempted and achieved manifest spherical equivalent [SE] refraction) 1 year postoperatively was also assessed.

All statistical analyses were performed using StatView software (version 5.0, SAS Institute, Inc.). The results are expressed as means ± SD. A P value less than 0.05 was considered statistically significant.

RESULTS

Seventy-five eyes of 47 patients (21 men, 26 women) were evaluated. Table 1 shows the patients' demographics. All surgery was uneventful with no significant complications.

The mean postoperative ICL vaulting was 0.61 ± 0.26 mm (range 0.13 to 1.35 mm) at 1 month, 0.59 ± 0.25 mm (range 0.10 to 1.25 mm) at 3 months, 0.54 ± 0.25 mm (range 0.10 to 1.14 mm) at 6 months, and 0.53 ± 0.24 mm (range 0.10 to 1.14 mm) at 1 year. Multiple comparisons showed no statistically significant differences in vaulting between 1 month and 3 months (P = .94, Dunnett test), 1 month and 6 months (P = .23), or 1 month and 1 year (P = .09); however, there was a slight tendency for ICL vaulting to decrease with time.

The mean refractive error (manifest SE) was 0.01 ± 0.42 D (range −0.80 to 1.68 D) 1 year after surgery. Although there was a slight tendency toward a hyperopic shift in eyes with higher central vaulting, there was no statistically significant correlation between the amount of vaulting and the refractive error (Pearson correlation coefficient = 0.19, P = .11) (Figure 1).

No eye had pupillary block or contact between the ICL and the crystalline lens. Anterior subcapsular cataract developed in 3 eyes (4.0%); of these eyes, 2 (2.7%) had no change in corrected distance visual acuity (CDVA) and 1 (1.3%) lost 1 line of CDVA during the 1-year study. The ICL vaulting in the 3 eyes with cataract was 0.26 mm, 0.25 mm, and 0.41 mm, respectively.

Table 1. Patient demographic data.

Demographic	Result
Age (y)	
Mean ± SD	33.6 ± 8.9
Range	18 to 53
Sex (% female)	55
Manifest SE (D)	
Mean ± SD	−9.96 ± 3.95
Range	−4.00 to −22.7
Central cornea thickness (μm)	
Mean ± SD	531.5 ± 26.3
Range	467 to 586
Keratometry reading (D)	
Mean ± SD	44.3 ± 1.6
Range	40.4 to 47.1
White-to-white distance (mm)	
Mean ± SD	11.6 ± 0.4
Range	10.8 to 12.4
Anterior chamber depth (mm)	
Mean ± SD	3.28 ± 0.29
Range	2.81 to 4.12

SE = spherical equivalent

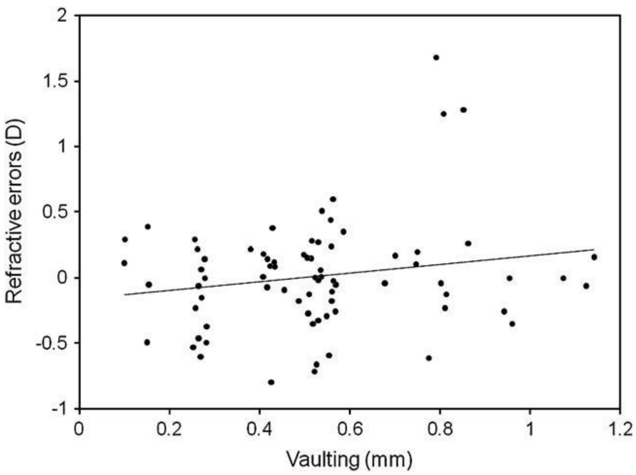

Figure 1. Correlation between the change in vaulting and refractive errors 1 year postoperatively.

DISCUSSION

In the current study, we found that the ICL vaulting over the crystalline lens decreased slightly over time. In a study by Gonvers et al.,[11] vaulting had a slight tendency to decrease between the 3-month visit and the last follow-up visit. This finding is in line with our results; however, the time course of changes in ICL vaulting remains unclear because the amount of vaulting was measured fewer times (2) in the Gonvers et al study. Because the ICL remains in contact with the back surface of the iris, there is a possibility that physiologic or accommodative pupillary movement will induce chronic chafing between the ICL and the iris, resulting in changes in ICL vaulting. In addition, the central thickness of the crystalline lens is reported to increase with age.[13–17] A thicker lens may contribute to anterior protrusion of the front surface of the crystalline lens. García-Feijoó et al.[20] found the location of the ICL haptic tip was at the sulcus or the ciliary body. Using 50 MHz ultrasound biomicroscopy, Choi et al.[21] found that the ICL haptics were placed ideally in the ciliary sulcus in 11 of 13 eyes. Given that the fixation location was changed from the ciliary body to the ciliary sulcus, the vaulting may have decreased with time. We assume that physiologic or accommodative pupillary movement, age-related increases in crystalline lens thickness, and the fixed position of the ICL haptics account for the slight decrease in the ICL vaulting over the crystalline lens with time. In recent studies, rotating Scheimpflug imaging[11,22] and anterior segment optical coherence tomography [23–25] provided highly accurate and reproducible measurements of anterior segment biometry; thus, these methods can improve the clinical evaluation of ICL vaulting.

We also found a slight tendency toward a hyperopic shift in eyes with high vaulting; however, there was no significant association between ICL vaulting and refractive error. Several studies report that ICL implantation provides excellent, predictable results in the correction of high myopia,[1–10] even though the preoperative refraction may be less reliable in these eyes.[26] Because the ICL was fixated in the narrow space between the back surface of the iris and the ciliary sulcus, the effective position of the ICL was more predictable than that of the aphakic IOL for cataract surgery. Although postoperative refraction is influenced by many clinical factors, ICL implantation, regardless of the amount of myopic correction, is less subject than keratorefractive surgical procedures (eg, LASIK) to the wound-healing processes of the cornea, especially in the correction of high myopia. Thus, ICL implantation is considered to have a negligible effect on refractive outcome. In addition, we believe that the precise effective lens position, resulting largely from the narrow fixated location of the ICL between the iris and the ciliary sulcus, adds to the predictability of the surgical procedure.

An important factor in predicting proper vaulting is selection of an appropriately sized ICL. Although the manufacturer has not disclosed the precise targeted amount of vaulting based on ICL size or dioptric power, the proper amount of vaulting is considered to be identical to the thickness of the central cornea (approximately 500 μm). We currently use ICL sizes from 11.5 to 13.0 mm in steps of 0.5 mm, 1 of which we select on the basis of horizontal corneal diameter and ACD only. In principle, the ICL diameter was chosen as the horizontal corneal diameter plus 0.5 mm for myopia. However, Pop et al.,[27] using ultrasound biomicroscopy, found no significant correlation between sulcus-to-sulcus measurements and white-to-white measurements. We previously found that patient age may also play a role in selecting an appropriate ICL size.[19] In the current study, no contact or high vaulting (>1.35 mm) between the ICL and the crystalline lens was observed in any case during a 1-year follow-up, suggesting that no extreme underestimation or overestimation of ICL size occurred.

Although the pathogenesis of cataract development has not been fully elucidated, it is suspected to involve direct physical contact between the ICL and the crystalline lens or malnutrition of the lens resulting from poor circulation of the aqueous humor. Gonvers et al.[11] report that central vaulting greater than 0.09 mm appears to protect the crystalline lens from cataract formation; they found that there was no contact between the ICL and the crystalline lens when the central vaulting was 0.15 mm or more. Lege et al.[12] also observed no contact when central vaulting was 0.135 mm or more. In contrast, Lackner et al.[28] found that ICL vaulting did not correlate with the risk for lens opacification. Although no contact between the ICL and the crystalline lens was observed under a slitlamp in any case in our study, 3 eyes (4.0%) developed anterior subcapsular cataract postoperatively. None of the eyes required lens extraction, however, because the cataract was not severe. In another study,[19] we found that the mean central vaulting tended to be lower in eyes with cataract than in eyes without cataract 3 months after ICL implantation. We therefore consider low vaulting to be a risk factor for anterior subcapsular cataract.

It is important to assess the repeatability of the measurements with slitlamp microscopy to confirm the authenticity of the results. We previously examined 26 eyes of 13 patients having ICL implantation and found that the mean difference between 2 consecutive measurements with slitlamp microscopy (±95% limits of agreement) was 3.2 ± 22.6 μm (range −19.4 to 25.8 μm).[19] Accordingly, we believe that digitized photography using a slitlamp camera offers reasonable repeatability in evaluating central ICL vaulting. Although the technique is considered inadequate for evaluation of peripheral vaulting beyond the optic–haptic junction of the ICL, it is an easy and reproducible method for routine examination.

A limitation of this study was that we measured central vaulting of the ICL when the pupil was dilated. Because the ICL optic remains in contact with the rear surface of the iris, the iris may push the ICL toward the crystalline lens before mydriasis. Moreover, the anterior surface of the crystalline lens was shifted posteriorly after mydriasis. Accordingly, pupil dilation appears to increase the amount of vaulting of the ICL. In our preliminary data, pupil dilation tended to increase the amount of vaulting slightly; however, the increase remained constant (unpublished data), suggesting that the changes in ICL vaulting after mydriasis mimic those before mydriasis.

In summary, ICL vaulting over the crystalline lens decreased slightly with time and did not significantly affect the refractive outcome 1 year after surgery. Further long-term observation is needed to confirm whether the tendency toward a slight decrease in vaulting remains in the late postoperative period.

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