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Original Article

# Long-term clinical results of posterior chamber phakic intraocular lens implantation to correct myopia

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## Abstract

**Background:** The aim of this study was to determine whether implantable collamer lens (ICL) implantation to correct myopia is an effective and safe surgical option even after long-term follow up.

**Design:** A retrospective observational study was carried out.

**Participants:** A total of 281 eyes of 145 myopic patients were included in the study.

**Methods:** Patients underwent ICL implantation and had the follow-up period of at least 5 years (87 ± 18.9 months).

**Main Outcome Measures:** Outcome measures included uncorrected and corrected distance visual acuities, refraction for the evaluation of efficacy, safety, stability and predictability, ICL vault and adverse events.

**Results:** The final mean logMAR uncorrected and corrected distance visual acuities were 0.02 ± 0.19 and −0.12 ± 0.13, respectively. The mean efficacy and safety indices were 1.04 ± 0.32 and 1.20 ± 0.26. The mean spherical equivalent decreased from −8.74 ± 2.27 diopter (D) to −0.58 ± 0.72 D, and there was high predictability with 69.8% and 87.2% having a postoperative refraction within 0.5 D and 1.0 D, respectively. The mean postoperative vault was changed from 2.53 ± 0.6 to 2.00 ± 0.7. Six (2.1%) eyes developed cataract, and the mean endothelial cell loss was 7.8 ± 8.3%. Increased intraocular pressure was found in two (0.7%) eyes that required the exchange of lenses with different sizes.

**Conclusions:** Implantable collamer lens implantation to correct myopia was an effective and safe surgery with high predictability and stability during long-term follow up. Slight myopic shift and cataract formation related with change in vault should be further evaluated.

**Key words:** implantable collamer lens (ICL), myopia, phakic intraocular lens (IOL).

## Introduction

Phakic intraocular lens (IOL) implantation to correct moderate to high myopia is a surgical option in the field of refractive surgery for the treatment of hyperopia and myopia.[1–3] The implantation of phakic IOL is a reversible refractive procedure that preserves the accommodative function with minimal induction of higher-order aberrations compared with keratorefractive procedures.[4] The implantable collamer lens (ICL; STAAR Surgical Co., Monrovia, CA, USA), a posterior chamber phakic IOL, has been reported to be effective for the correction of moderate to high ametropia.[1,5–16] Despite this, as an intraocular procedure, it has potential complications such as cataract, chronic uveitis, pupil ovalization, corneal

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endothelial loss, pigmentary dispersion syndrome, pupillary block glaucoma, astigmatism or endophthalmitis.[17] It is appropriate to investigate the long-term clinical results of ICL implantation, but there have been only a few long-term studies (more than 3 years) of the visual and refractive outcomes of ICL implantation for myopia with small number of patients.[13,15,16] This study aimed to evaluate the long-term (more than 5 years) clinical outcomes of ICL implantation for moderate to high myopia with large number of patients.

## Methods

This retrospective observational study included the medical records of 281 eyes of 145 patients who underwent implantation of the posterior phakic ICL for the correction of moderate to high myopia at the BalGunNun Eye Clinic and Pusan National University Yangsan Hospital and regularly returned for postoperative examination for at least 5 years. Thirty-eight eyes (11.9%) were excluded because of not attending the examinations. All patients provided informed written consent in accordance with the tenets of the Declaration of Helsinki, and an institutional review board approved the study. The inclusion criteria for this surgical technique were 20 years of age or older, corrected distance visual acuity (CDVA) of 6/9 or better, stable refraction, anterior chamber depth more than 2.8 mm, endothelial cell density more than 2000 cells/mm$^2$ and no history of ocular surgery, progressive corneal degeneration, cataract, glaucoma, uveitis, retinal disease or neuro-ophthalmic disease. Before surgery, patients had a complete ophthalmic examination including uncorrected distance visual acuity (UDVA), CDVA, mean keratometric readings with autorefractometer (RK-F1, Canon, Tokyo, Japan), manifest refraction (spherical equivalent), intraocular pressure (IOP) with noncontact tonometer (TX-F, Canon, Tokyo, Japan), endothelial cell density with noncontact specular microscope (EM-3000, Tomey, Nagoya, Japan), slit lamp biomicroscopic and funduscopic examination, and corneal topography, anterior chamber depths and pachymetry (Orbscan II, Bausch & Lomb, Rochester, NY, USA).

### Implantable collamer lens size and power calculation

The size of the ICL was performed based on the horizontal white-to-white distance and anterior chamber depth measured by Orbscan II following the manufacturer's recommendations. We calculated the size of the ICL by adding 0.5 mm to the horizontal white-to-white measurement for eyes with anterior chamber depth $\leq$3.0 mm and adding 1.0 mm for anterior chamber depth $>$3.0 mm.[18] ICL power calculation was chosen using the modified vertex formula provided by the manufacturer. In all cases, a model V4 ICL was implanted, and the target was emmetropia. In the market of South Korea, V4 models were used to treat refractive errors at the time of surgery, not the V4b and V4c ICL models.

### Implantable collamer lens surgical procedure

Before surgery, all patients underwent neodymium: YAG laser treatment to create two peripheral iridotomies. On the day of surgery, the patients were administered dilating and cycloplegic agents. After topical anesthesia, an ICL was inserted through a 3-mm clear corneal incision with the use of an injector cartridge (STAAR Surgical Co.) after the anterior chamber was filled with 1.0% sodium hyaluronate. The ICL was placed in the posterior chamber achieving a horizontal orientation, the viscoelastic material was completely removed out of the anterior chamber using irrigation/aspiration system, and the pupil was constricted with 0.01% acethylcholine. After surgery, topical 0.3% levofloxacin and 0.1% fluorometholone eye drops were administered four times a day for 2 weeks and tapered gradually.

### Follow up

Postoperative follow-up visits were at 1 day, 1 week, 1, 3 and 6 months, 1 year and yearly thereafter. We determined UDVA, CDVA, refraction, subjective vault, slit lamp biomicroscopic and funduscopic examination, endothelial cell density, and IOP. For averaging, visual acuities were converted to logMAR values. The vault was classified 5 levels by the separation between anterior surface of the crystalline lens and the posterior surface of the ICL to the corneal thickness using an optical section during routine slit-lamp examination, as described by Alfonso and associates.[19] The following criteria were used to rate ICL vault value: vault 0, ICL apparently touches the anterior capsule of the lens; vault 1, separation lower than half of corneal thickness; vault 2, separation equal to corneal thickness; vault 3, separation larger than corneal thickness; or vault 4, separation about twice the corneal thickness. All measurements were performed under the same light conditions in order to avoid the potential influence of accommodation-induced changes in the estimation of the ICL vault.

### Statistical analysis

All statistical analyses were performed using Prism (GraphPad Software Inc., CA, USA). Normality of data was checked by the Kolmogorov–Smirnov test and analyzed using one-way analysis of variance

(ANOVA) for the time course of changes, Tukey's test for multiple comparisons, paired *t*-test for comparison between pre-surgical and post-surgical data, Pearson correlation coefficient for correlation between the changes in spherical equivalent and Cox proportional hazard regression analysis for the development of cataract over time. A value of *P* less than 0.05 was considered statistically significant.

## Results

Preoperative demographic data of the patients and the ICL characteristics are demonstrated in Table 1.

### Efficacy and safety of visual acuity

Table 2 shows the visual acuity over time. There were significant improvements in logMAR UDVA and CDVA 1 month after surgery (paired *t*-test, $P < 0.0001$ for both), with no significant changes afterward (ANOVA, $P = 0.17$ and $P = 0.14$, respectively; Tukey's test, $P > 0.05$ for both at each visit).

At the end of follow up, the postoperative logMAR UDVA was 0.30 (approximately 6/12) or better in 254 eyes (90.4%), 0.10 (approximately 6/7.5) or better in 238 eyes (84.7%) and 0.00 (6/6) or better in 170 eyes (60.5%). At last visit, 141 eyes (50.2%) had no change in CDVA, 73 eyes (26.0%) gained one line, 50 eyes (17.7%) gained two or more lines, 12 eyes (4.3%) lost one line, and 5 eyes (1.8%) lost two or more lines (Fig. 1).

The efficacy index (ratio of postoperative UDVA/mean preoperative CDVA) and safety index (ratio of postoperative CDVA/preoperative CDVA) at the last follow-up visit were 1.04 ± 0.32 and 1.20 ± 0.26, respectively.

### Stability and predictability of manifest refraction

The change of mean spherical equivalent over time is shown in Figure 2. The mean spherical equivalent was −0.28 ± 0.23, −0.30 ± 0.33, −0.29 ± 0.34, −0.43 ± 0.55, −0.59 ± 0.51 and −0.58 ± 0.72 at 1 and 6 months, at 1, 3 and 5 years, and at last visit postoperatively, respectively (ANOVA, $P = 0.001$). Multiple comparisons demonstrated significant differences between measurements made at 1 month and at last visit ($P = 0.004$), at 6 months and at last visit ($P = 0.005$), and at 1 year and at last visit after surgery ($P = 0.017$).

High levels of predictability were achieved early after surgery; 78.7% of eyes were within ± 0.5 D and 94.9% of eyes were within ± 1.0 D of the attempted correction at 1 month (Fig. 3), and this improvement was maintained over the postoperative follow up ($r^2 = 0.959$ at last visit; Fig. 4).

**Table 1.** Preoperative demographics of the patients and the implantable collamer lens characteristics

| Parameters | Mean ± standard deviation (range) |
|---|---|
| Age (years) | 30.31 ± 4.5 (22 to 41) |
| Gender (male:female) | 39 (27%):106 (73%) |
| Manifest spherical equivalent (D) | −8.74 ± 2.27 (−4.00 to −15.25) |
| Manifest cylinder (D) | 1.47 ± 0.85 (0.00 to 3.75) |
| Uncorrected distance visual acuity (logMAR) | 1.52 ± 0.32 (1.10 to 2.00) |
| Corrected distance visual acuity (logMAR) | 0.02 ± 0.04 (−0.18 to 0.19) |
| Mean keratometric readings (D) | 43.82 ± 1.39 (40.3 to 46.4) |
| Anterior chamber depth (mm) | 3.26 ± 0.20 (2.9 to 3.94) |
| Intraocular pressure (mmHg) | 15.3 ± 3.0 (9 to 22) |
| Endothelial cell density (cells/mm$^2$) | 2898 ± 404 (2432 to 3120) |
| White to white distance (mm) | 11.58 ± 0.72 (11.10 to 13.00) |
| Implantable collamer lens | |
| Size (mm) | 12.08 ± 0.40 (11.5 to 13.0) |
| Power (D) | −12.48 ± 2.25 (−5.50 to −20.50) |

**Table 2.** Visual and vault changes during the follow up

| | Mean ± standard deviation | | | | |
|---|---|---|---|---|---|
| Parameters | 1 month | 1 year | 3 years | 5 years | Last visit |
| LogMAR UDVA | −0.04 ± 0.17 | −0.07 ± 0.16 | −0.06 ± 0.18 | −0.04 ± 0.14 | 0.02 ± 0.19 |
| LogMAR CDVA | −0.14 ± 0.10 | −0.15 ± 0.10 | −0.15 ± 0.09 | −0.14 ± 0.07 | −0.12 ± 0.13 |
| Vault | 2.53 ± 0.6 | 2.36 ± 0.6 | 2.25 ± 0.8 | 2.19 ± 1.0 | 2.00 ± 0.7 |

CDVA, corrected distance visual acuity; UDVA, uncorrected distance visual acuity.

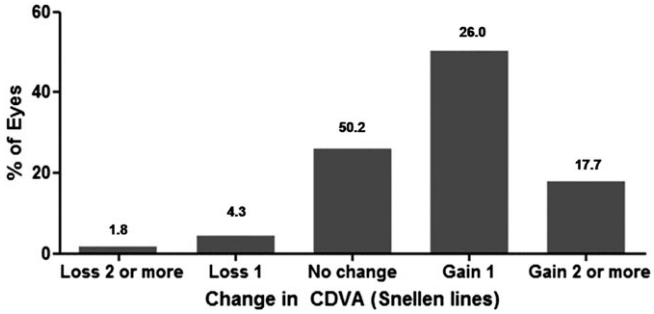


**Figure 1.** Changes in corrected distance visual acuity (CDVA) from preoperatively to postoperatively.

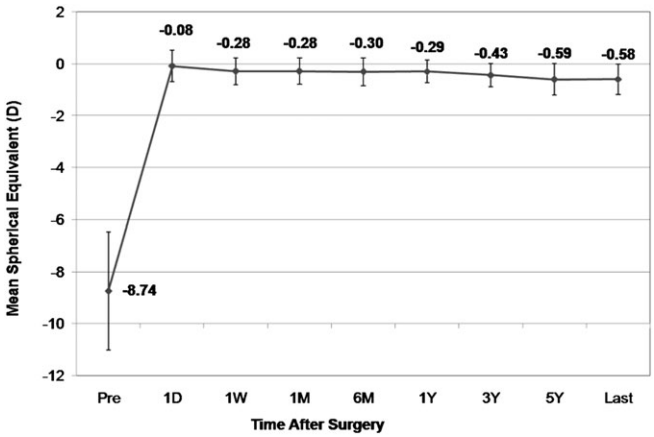


**Figure 2.** The mean spherical equivalent over time.

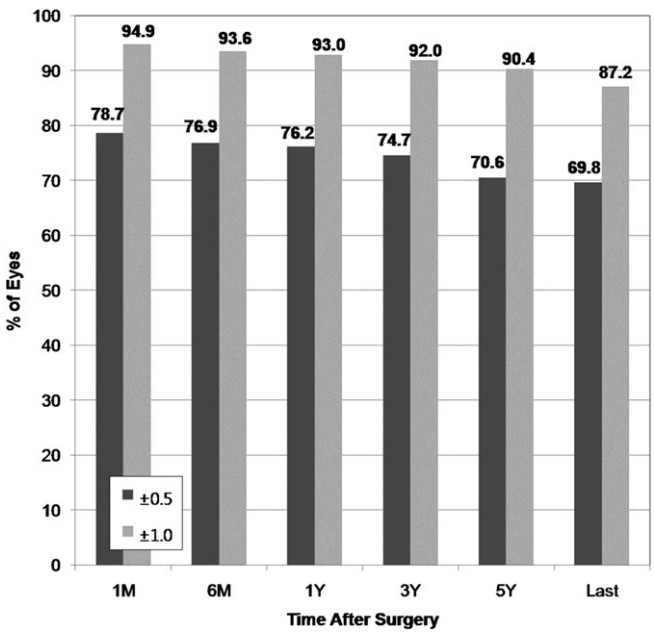


**Figure 3.** Percentage of eyes within ±0.5 and ±1.0 D of the attempted correction (spherical equivalent) after implantable collamer lens implantation.

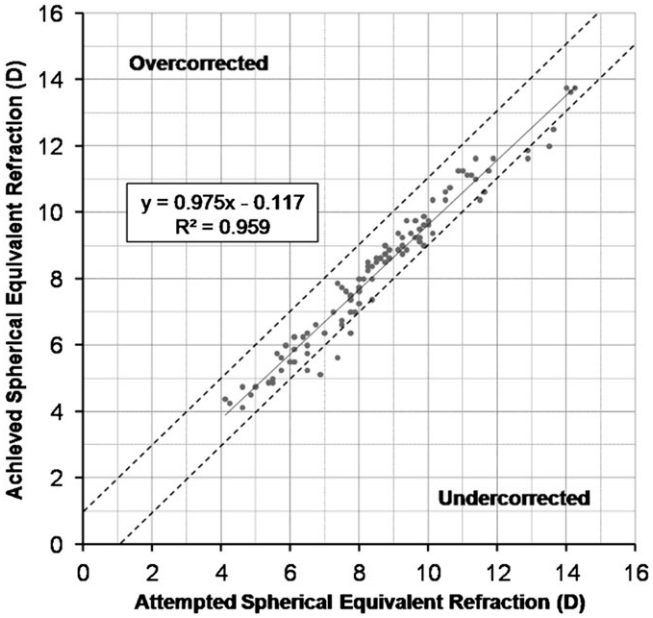


**Figure 4.** Spherical equivalent attempted *versus* achieved at last visit after implantable collamer lens implantation.

## Vault

The mean vaults over time are shown in Table 2 (ANOVA, $P=0.004$). Multiple comparisons demonstrated significant differences between measurements made at 1 month and at 5 years ($P=0.038$), and at 1 month and at last visit after surgery ($P=0.015$).

## Adverse events

Six eyes (2.1%) developed asymptomatic anterior subcapsular cataracts that had not required cataract surgery by the last visit, in which one eye (0.3%) showed no change in CDVA and five eyes (1.8%) lost two lines. Although neither eye required cataract surgery, the patients were scheduled for closer follow up. The development of cataract was not statistically related to patient age at the time of the implantation ($P=0.37$), anterior chamber depth before implantation ($P=0.56$), preoperative spherical equivalent ($P=0.25$) or vaulting ($P=0.49$).

The mean endothelial cell density decreased significantly from $2898 \pm 404$ cells/mm$^2$ preoperatively to $2814 \pm 354$, $2835 \pm 337$, $2794 \pm 245$, $2726 \pm 227$ and $2712 \pm 369$ cells/mm$^2$ at 6 months, at 1, 3 and 5 years and at last visit postoperatively (ANOVA, $P=0.02$). Multiple comparisons demonstrated significant differences between measurements made preoperatively and at last visit postoperatively ($P=0.015$). The mean percentage of endothelial loss was $7.8 \pm 8.3$% at last visit postoperatively.

The mean IOP was $15.3 \pm 3.0$ mmHg preoperatively and $16.0 \pm 3.3$, $15.8 \pm 2.4$, $15.9 \pm 2.3$, $16.3 \pm 2.6$, $16.1 \pm 2.7$ and $15.9 \pm 2.6$ mmHg at 1 and 6 months, at 1, 3 and 5 years and at last visit postoperatively,

**Table 3.** Long-term clinical outcomes of posterior chamber phakic IOL implantation

| Author | Phakic IOL | Eyes | Follow up (years) | Mean age (years) | Mean spherical equivalent (D) | Efficacy index | Safety index | Predictability within ±1.0 D (%) | Mean endothelial cell loss (%) | Cataract (%) |
|---|---|---|---|---|---|---|---|---|---|---|
| Alfonso et al.[15] | Visian ICL | 180/50 | 3/5 | 33.55 | −11.17 | 0.89 | 1.27 | 62.0 | 7.5 | 1.6 |
| Igarashi et al. [16] | Visian ICL | 41 | 8 | 37.3 | −10.19 | 0.83 | 1.13 | 85.4 | 6.2 | 4.9 |
| Current | Visian ICL | 281 | 7.3 (5–9) | 30.3 | −8.74 | 1.04 | 1.20 | 87.2 | 7.8 | 2.1 |

ICL, implantable collamer lens; IOL, intraocular lens.

respectively (ANOVA, $P=0.14$), except in two cases which had high IOP over 50 mmHg due to pupillary block induced by high vault (separation about three times the corneal thickness) and underwent lens exchanges at postoperative day 6. We had advised and planned removal of the ICL because of potential risk of pupillary block. No other vision-threatening complications were seen at any time during the follow up.

## Discussion

This study showed good results in all measures of efficacy, safety, stability and predictability of ICL implantation to correct moderate to high myopia throughout the mean follow up of 87 ± 18.9 months (61–110 months) with large number of patients, which are comparable with those previously reported (Table 3).

Although the prevalence of myopia is significantly different among racial groups, extremely high prevalence of myopia (96.5%) and high myopia (20.6%) has been reported in 19-year-olds ($n=23\,616$) in urban areas of Korea.[20] Therefore, refractive surgeries are popular, and a huge number of surgeries have been undergone in young myopic Korean patients, which explains much younger patients' average age and much less preoperative spherical equivalent of this study. In our study, 87.5% (238/281) of eyes achieved a UDVA of 6/7.5 or better at last visit with higher efficacy index. The greatest loss of CDVA was two lines in 1.8% (5/281) eyes that developed asymptomatic anterior subcapsular cataracts and did not require cataract surgery. The spherical equivalent showed a slight tendency toward a myopic shift throughout the follow up. The biometric changes such as axial elongation that occurs in myopic patients or the decrease in vault that leads to narrowing the gap between the phakic IOL and the crystalline lens and increasing the effective power of the optical system are suggested to be possible mechanisms of this myopic regression.[16,21,22] However, the correlation between the attempted refraction and the achieved refractions was high with 87.2% (245/281) of eyes and 69.8% (196/281) of eyes being within ±1.00 D and ±0.50 D of the desired refraction at last visit, respectively.

In case of developing complications related with ICL implantation, most patients have a tendency to visit the eye clinic they have been operated on in Korea. The most significant concern about posterior chamber IOL implantation is cataract formation. The rate of cataract formation has been reported as between 1.6%[18] and 14.5%.[23] The U.S. FDA trial demonstrated that the incidence of anterior subcapsular cataracts was 2.7% at 3 years postoperatively.[14] In a 5-year follow-up study by Sanders,[24] anterior subcapsular opacities occurred in 5.9% with 1.3% progressing to clinically significant cataract, which generally occurred in patients with very high myopia or in older patients. Alfonso and associates[15] stated that 1.6% developed anterior subcapsular cataract during the 5-year follow up, indicating that patient age and low vault are the most important factors in phakic IOL-induced cataract. Igarashi and associates[16] reported that 14.7% developed symptomatic and asymptomatic cataracts 8 years postoperatively related with older patient age and longer axial length. In the present study, the incidence of cataract formation appears to be lower (2.1%) than that in previous studies, possibly due to younger patient age (30.31 ± 4.5 years) and less preoperative spherical equivalent (−8.74 ± 2.27 D) despite long-term observation. Even though we did not find any significant correlation between the variables analyzed in this study and the incidence of cataract, this lack of statistical significance can be due to an insufficient power, taking into account the small number of eyes that developed cataract.

The main theories of the cause are absent or lower vault and the tendency of the vault to decrease slightly over time, causing constant or intermittent phakic IOL-crystalline lens contact.[25–28] With an agreement, we also found that the vault assessed with slit lamp decreased slightly over time. It has been reported 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.[29] With respect to cataract development, Gonvers and associates suggested that a central vault of more than 0.09 mm seems to protect the crystalline lens from cataract formation, and Maeng and associates

proposed 0.052 mm as the minimum cut-off below which there is a high probability of cataract formation.[30,31] Therefore, close follow up should be considered in cases of low vaulting.

Regarding the endothelial cell loss, we found that the mean endothelial cell loss was 7.8% at last visit postoperatively. The rate of postoperative endothelial cell loss has been reported to be 6.57% at 2 years[6] and 6.09% at 3 years.[12] The U.S. FDA Trial demonstrated that the endothelial cell loss was between 8.4% and 8.9% over the first 3 years and between 8.4% and 9.5% over the first 4 years.[32] Others report a mean endothelial cell loss of 3.7% at 4 years, 7.7% at 5 years and 6.2% at 8 years.[13,15,16] Our study showed similar results with the findings in previous studies, and differences may be due to follow-up time, sample size, surgeon's skill or other patient background factors, such as age and race, as well as the reproducibility obtained with a noncontact specular microscope.

Another important concern after phakic IOL implantation is increased IOP, which in most cases is associated with significant angle narrowing by forward iris displacement[33] or with chronic pigment dispersion.[34] In our study, two (0.7%) eyes had increased IOP due to larger size of IOL and needed IOL exchanges. Although the lower limit of vault has been reported by other authors,[30,31] there is no evidence on how high a vault is acceptable.[35,36] Because a high vault can cause angle closure like our cases, the association between ICL vault and iridocorneal angle should be evaluated in future studies.

There are limitations to this study in the aspect of its retrospective nature. It was not possible to measure the changes in vault objectively with optical coherence tomography over time. However, the mean vault assessed at the slit lamp and compared with corneal thickness decreased slightly over time, which was similar with other reports using optical coherence tomography.[25,26] Recently, V4c ICL (CentraFLOW technology, STAAR Surgical Co., CA, USA) was designed with a 360 um central hole to allow for the natural flow of aqueous humor without the need for iridotomy. The V4c ICL has shown a clinical outcome comparable with those of the conventional V4 ICL.[37,38] However, we could state that the longer-term follow up suggests that those who have V4 ICL do not need to have them replaced with V4c ICL.

In summary, our results suggest that ICL implantation is an effective and safe surgical option for correcting moderate to high myopia with stable and predictable refractive results over the long term (maximum 9 years). Slight myopic shift was observed possibly because of the biometric changes in myopia or the decrease in vault, which should be assessed as future studies with a longer follow up. Although there were no vision-threatening complications, the change in vault related with the development of anterior subcapsular cataract also should be further evaluated in the future.

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