Eight-Year Follow-up of Posterior Chamber Phakic Intraocular Lens Implantation for Moderate to High Myopia

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• PURPOSE: **To assess the long-term clinical outcomes of Implantable Collamer Lens (Visian ICL; STAAR Surgical) implantation for moderate to high myopia.**
• DESIGN: **Retrospective observational case series.**
• METHODS: **This study evaluated 41 eyes of 41 patients with myopic refractive errors of −4.00 to −15.25 diopters (D) who underwent ICL implantation and routine postoperative examinations. Before surgery, and 1 and 6 months and 1, 4 and 8 years after surgery, we assessed the safety, efficacy, predictability, stability, and adverse events of the surgery.**
• RESULTS: **The safety and efficacy indices were 1.13 ± 0.27 and 0.83 ± 0.36. At 8 years, 68.3% and 85.4% of the eyes were within 0.5 and 1.0 D, respectively, of the targeted correction. Manifest refraction changes of −0.32 ± 0.73 D occurred between 1 month and 8 years. The mean endothelial cell loss from preoperative levels was 6.2% at 8 years. Two eyes (4.9%) developed clinically significant symptomatic cataract during the follow-up period. Simultaneous lens extraction and phacoemulsification with IOL implantation was successfully performed in these 2 eyes.**
• CONCLUSIONS: **According to our experience, ICL implantation was overall good in measures of safety, efficacy, predictability, and stability for the correction of moderate to high myopia during the 8-year observation period, suggesting its long-term viability as a surgical option for the treatment of such eyes. (Am J Ophthalmol 2014;157:532–539. © 2014 by Elsevier Inc. All rights reserved.)**

THE VISIAN IMPLANTABLE COLLAMER LENS (ICL) (STAAR Surgical, Nidau, Switzerland), a posterior chamber phakic intraocular lens (IOL) has been reported to be effective for the correction of moderate to high ametropia.[1–12] This surgical technique induces significantly fewer ocular higher order aberrations than does wavefront-guided laser in situ keratomileusis (LASIK) and significantly increases contrast sensitivity in the treatment not only of high myopia[13] but also in that of low to moderate myopia.[14] Moreover, its implantation is largely reversible and the lens is replaceable with another lens when unexpected refractive changes occur after surgery, which is not possible with LASIK. Several previous studies of the long-term outcomes of LASIK have been published,[15–20] but there have been only a few long-term studies (spanning more than 3 years) of the visual and refractive outcomes of ICL implantation.[10,12,21] In view of the prevalence of this surgical procedure, it is essential to evaluate the long-term clinical outcomes of ICL implantation. We have previously showed that such implantation was good in all measures of safety, efficacy, predictability, and stability for the correction of high myopia throughout the 4-year follow-up period.[10] In the current study, we proceeded further in order to investigate the long-term (8-year) clinical outcomes of ICL implantation in the correction of moderate to high myopia.

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PATIENTS AND METHODS

FORTY ONE EYES OF 41 CONSECUTIVE PATIENTS (16 MEN AND 25 women) who underwent implantation of the posterior phakic ICL (STAAR Surgical) for the correction of moderate to high myopia, and who regularly returned for postoperative examination, were included in this retrospective observational study. Using the envelope technique, only 1 eye per subject was selected randomly for statistical analysis. The inclusion criteria for this surgical technique were as follows: unsatisfactory correction with spectacles or contact lenses; 20years of age or younger; 55 years of age or younger; stable refraction for at least 6 months; −4.0 to −20.0 diopters (D) of myopia; anterior chamber depth ≥2.8 mm; endothelial cell density ≥1800 cells/mm^2; no history of ocular surgery; progressive corneal degeneration, cataract, glaucoma, or uveitis. Eyes with keratoconus were excluded from the study by using the keratoconus screening test of Placido disc videokeratography (TMS-2; Tomey, Nagoya, Japan). Before surgery, and 1 and 6 months, and 1, 4, and 8 years after surgery, we determined the following: logarithm of the minimal angle of resolution (logMAR) of uncorrected distance visual acuity (UDVA); logMAR of corrected distance visual acuity (CDVA); manifest refraction (spherical equivalent); intraocular pressure

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(IOP); and endothelial cell density, mean keratometric readings, and axial length (except for 1 and 6 months postoperatively), in addition to the usual slit-lamp biomicroscopic and funduscopic examinations. Before surgery, the horizontal white-to-white distance and anterior chamber depths were measured using a scanning-slit topograph (Orbscan IIz; Bausch & Lomb, Rochester, NY, USA), and the mean keratometric readings and the central corneal thicknesses were measured using an autorefractometer (ARK-700A; Nidek, Gamagori, Japan) and an ultrasound pachymeter (DGH-500; DGH Technologies, Exton, PA, USA), respectively. The IOP was assessed by a noncontact tonometer (KT-500; Kowa, Tokyo, Japan). The endothelial cell density was determined by a noncontact specular microscope (SP-8800; Konan, Nishinomiya, Japan). The axial length was measured using partial coherence laser interferometry (IOL Master; Carl Zeiss AG, Oberkochen, Germany). This retrospective review of data was approved by the Institutional Review Board at Kitasato University and followed the tenets of the Declaration of Helsinki. Informed written consent for the surgery was obtained from all patients.

• **IMPLANTABLE COLLAMER LENS POWER CALCULATION:** ICL power calculation was performed by the manufacturer (STAAR Surgical) using a modified vertex formula. In all eyes, emmetropia was selected as the target refraction in order to reduce the preoperative refractive errors as much as possible. The size of the ICL was also chosen by the manufacturer on the basis of the horizontal corneal diameter and the anterior chamber depth measured by scanning-slit topography (Orbscan IIz).

• **IMPLANTABLE COLLAMER LENS SURGICAL PROCEDURE:** The patients underwent 2 peripheral iridotomies with a neodymium:YAG laser before surgery. On the day of surgery, the patients were administered dilating and cycloplegic agents. After topical anesthesia, a model V4 ICL was inserted through a 3-mm clear corneal incision with the use of an injector cartridge (STAAR Surgical) after placement of a viscosurgical device (Opegan; Santen, Osaka, Japan) into the anterior chamber. The ICL was placed in the posterior chamber, the viscosurgical device was completely washed out of the anterior chamber with a balanced salt solution, and a myotic agent was instilled. All surgeries were uneventful and no intraoperative complications were observed. After surgery, steroidal (0.1% betamethasone; Rinderon; Shionogi, Osaka, Japan) and antibiotic (0.3% levofloxacin; Cravit; Santen, Osaka, Japan) medications were administered topically 4 times daily for 2 weeks, the dose being reduced gradually thereafter.

• **VAULT ASSESSMENT:** One and 6 months, and 1, 4, and 8 years after surgery, we also assessed the subjective vault of the ICL. The vault was classified in 5 levels by comparing the separation between the 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.[22] 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 StatView v 5.0 (SAS, Cary, NC, USA). One-way analysis of variance (ANOVA) was used for the analysis of the time course of changes, and the Dunnett test was used for multiple comparisons. The Wilcoxon signed-rank test was used for statistical analysis to compare the pre- and postsurgical data. The Pearson correlation coefficient was used to assess the correlation between the changes in spherical equivalent and axial length. The results are expressed as mean ± standard deviation (SD), and a value of $P < 0.05$ was considered statistically significant.

RESULTS

• **STUDY POPULATION:** Preoperative patient demographics are summarized in Table 1. The patient ages were 37.3 ± 10.2 years (mean age ± SD; range, 21 to 55 years). The preoperative manifest spherical equivalent was −10.19 ± 2.86 D (range, −4.00 to −15.25 D). The preoperative manifest refractive cylinder was 1.51 ± 0.91 D (range, 0.00 to 4.00 D). LogMAR UDVA and CDVA were 1.50 ± 0.23 (range, 1.10 to 2.00) and −0.13 ± 0.07 (range, −0.30 to 0.00), respectively. Horizontal white-to-white distance was 11.6 ± 0.4 mm (range, 10.9 to 12.6 mm). Anterior chamber depth was 3.24 ± 0.31 mm (range, 2.80 to 4.12 mm). The mean keratometric reading was 44.0 ± 1.5 D (range, 40.4 to 46.5 D). Central corneal thickness was 543.6 ± 31.0 μm (range, 480 to 639 μm). The IOP was 14.5 ± 2.1 mm Hg (range, 10 to 19 mm Hg). The endothelial cell density was 2819 ± 295 cells/mm^2 (range, 1912 to 3312 cells/mm^2). Finally, the axial length was 27.52 ± 1.25 mm (range, 24.40 to 30.08 mm).

• **SAFETY OUTCOMES:** LogMAR CDVAs were −0.19 ± 0.10; −0.20 ± 0.09; −0.20 ± 0.10; −0.21 ± 0.10; and −0.17 ± 0.11 at 1 and 6 months, and at 1, 4, and 8 years after surgery, respectively. The safety indexes (mean