SURGEON'S CORNER

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

Kazutaka Kamiya, MD, PhD; Kimiya Shimizu, MD; Akihito Igarashi, MD; Fumika Hikita, MD; Mari Komatsu, MD

Objective: To assess the long-term clinical outcomes of implantation of a lens consisting of a biocompatible collagen copolymer (Visian implantable Collamer lens [ICL]; STAAR Surgical, Nidau, Switzerland) for moderate to high myopia.

Methods: We evaluated 56 eyes of 34 patients with myopic refractive errors of –4.00 to –15.25 diopters (D) who underwent ICL implantation and routine postoperative examinations. Before and 1, 3, and 6 months and 1, 2, and 4 years after surgery, we assessed the safety, efficacy, predictability, stability, and adverse events of the surgery.

Results: Mean (SD) logMAR uncorrected and best spectacle-corrected visual acuities were –0.03 (0.23) and –0.21 (0.09), respectively, at 4 years after surgery. The mean (SD) safety and efficacy indexes were 1.19 (0.25) and 0.83 (0.29), respectively. At 4 years, 44 (79%) and 52 (93%) of the eyes were within ±0.5 and ±1.0 D, respectively, of the targeted correction. Mean (SD) manifest refraction changes of –0.24 (0.57) D occurred from 1 month to 4 years after surgery. No vision-threatening complications occurred during the observation period.

Conclusion: Implantation of ICLs is safe and effective and provides predictable and stable refractive results in the treatment of moderate to high myopia during a 4-year observation period, suggesting its viability as a surgical option for the treatment of such eyes.

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LASER-ASSISTED IN-SITU KERatomileusis (LASIK) has gained widespread popularity as a safe and effective surgical method for the correction of myopia, but patients with high myopia or thin corneas face some restrictions in avoiding the risk of developing keratectasia. Moreover, a large amount of laser ablation may lead to the deterioration of superior intrinsic corneal optical performance. An implantable lens consisting of a biocompatible collagen copolymer (Visian implantable Collamer lens [ICL]; STAAR Surgical, Nidau, Switzerland) was developed as a posterior chamber phakic intraocular lens to rectify such disadvantages, and implantation of the ICL has been reported to be effective for the correction of moderate to high ametropia.[1-10] In addition, this surgical procedure is largely reversible and the lens is exchangeable, unlike LASIK, even when unexpected refractive changes occur after surgery. However, complications of ICL implantation such as cataract formation, endothelial cell loss, pigmentary glaucoma, and pupillary block have been reported, and these complications are expected to increase with time.[11-16] In consideration of the prevalence of this surgical procedure, it is essential to evaluate the long-term clinical outcomes of ICL implantation. Nevertheless, only a few studies have examined the long-term clinical results, including refractive results and adverse events, of ICL implantation. The aim of the present study was to investigate the long-term (4-year) clinical outcomes of ICL implantation in the correction of moderate to high myopia.

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Author Affiliations: Departments of Ophthalmology, University of Kitasato School of Medicine, Kanagawa, Japan (Drs Kamiya, Shimizu, and Igarashi); and Sanno Hospital, Tokyo, Japan (Drs Hikita and Komatsu).

METHODS

Fifty-six eyes (20 from men and 36 from women) of 34 patients who underwent implantation of the posterior chamber phakic ICL for the correction of moderate to high myopia and who regularly returned for postoperative examination were included in this retrospective observational study.

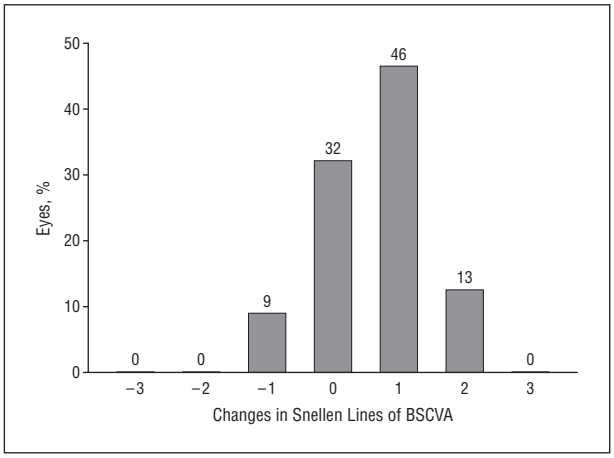

Figure 1. Changes in best spectacle-corrected visual acuity (BSCVA) after implantation with a lens consisting of a biocompatible collagen copolymer (Visian implantable Collamer lens; STAAR Surgical, Nidau, Switzerland).

(Unless otherwise indicated, data are expressed as mean [SD].) The patient age at the time of surgery was 37.0 (10.3) (range, 21-59) years. The preoperative manifest spherical equivalent was –9.83 (3.00) (range, –4.00 to –15.25) diopters (D). The preoperative manifest refractive cylinder was 1.16 (0.73) (range, 0.00-3.25) D. Eyes with keratoconus were excluded from the study by results of a keratoconus screening test using Placido disk videokeratography (TMS-2 system; Tomey Corp, Nagoya, Japan). Routine postoperative examinations were performed 1 day; 1 week; 1, 3, and 6 months; and 1, 2, and 4 years after surgery. Before surgery and 1, 3, and 6 months and 1, 2, and 4 years after surgery, we determined the following: logMAR of the uncorrected visual acuity (UCVA), logMAR of the best spectacle-corrected visual acuity (BSCVA), manifest refraction (spherical equivalent), intraocular pressure (IOP), and endothelial cell density (except for 1 month after surgery), in addition to the usual slitlamp biomicroscopic and funduscopic examination results. Before surgery, the horizontal white-to-white distance and anterior chamber depth were measured using a scanning-slit topography system (Orbscan IIz; Bausch & Lomb, Rochester, New York); the keratometric readings were measured using an autorefractometer (ARK-700A; Nidek, Gamagori, Japan); and the mean central corneal thickness was measured using an ultrasound pachymeter (model DGH-500; DGH Technologies, Exton, Pennsylvania). The IOP was assessed with a noncontact tonometer (KT-500; Kowa Co Ltd, Tokyo, Japan). The endothelial cell density was determined with the use of a noncontact specular microscope (SP-8800; Konan Medical Inc, Nishinomiya, Japan). The study was approved by the institutional review board at Kitasato University School of Medicine and followed the tenets of the Declaration of Helsinki. Informed consent was obtained from all patients.

ICL POWER CALCULATION

Calculation of ICL power was performed by the manufacturer using a modified vertex formula. In all eyes, emmetropia was selected as the target refraction 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 was measured with the scanning-slit topography system.

ICL SURGICAL PROCEDURE

The patients underwent 2 peripheral iridectomies with an Nd:YAG laser before surgery. On the day of surgery, the patients were administered dilating and cycloplegic agents. After topical anesthesia, the V4 model 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 (sodium hyaluronate, 1% [Opegan]; Santen Pharmaceuticals Co, Ltd, 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 balanced salt solution, and a myotic agent was instilled. All surgical procedures were uneventful and no intraoperative complication was observed. After surgery, betamethasone, 0.1% (Rinderon; Shionogi & Co, Ltd, Osaka, Japan) and levofloxacin (Cravit; Santen Pharmaceutical Co, Ltd, Osaka) were administered topically 4 times daily for 2 weeks, with the dose reduced gradually thereafter.

STATISTICAL ANALYSIS

All statistical analyses were performed using commercially available software (StatView, version 5.0; SAS Institute Inc, Cary, North Carolina). A value of $P < .05$ was considered statistically significant.

RESULTS

PATIENT POPULATION

We evaluated 56 eyes from 34 patients, of whom 22 were women (mean age of all patients, 37.0 [10.3] years; range, 21-59 years). The logMAR UCVA and BSCVA were 1.49 (0.22) (range, 1.05-2.00) and –0.15 (0.08) (range, –0.30 to 0.00), respectively. The horizontal white-to-white distance was 11.5 (0.3) (range, 10.9-12.1) mm, and the anterior chamber depth was 3.24 (0.32) (range, 2.81-4.12) mm. The keratometric reading was 44.2 (1.4) (range, 41.8-46.5) D. The central corneal thickness was 542.4 (27.2) (range, 485-639) μm. The IOP was 14.7 (2.1) (range, 10-20) mm Hg. The endothelial cell density was 2821 (276) (range, 2309-3533) cells/mm^2.

SAFETY OUTCOMES

The logMAR BSCVAs were –0.20 (0.09), –0.21 (0.09), –0.20 (0.09), –0.20 (0.10), –0.20 (0.11), and –0.21 (0.09) when measured 1, 3, and 6 months and 1, 2, and 4 years after surgery, respectively. The safety indexes (mean postoperative BSCVA divided by mean preoperative BSCVA) were 1.15 (0.23), 1.16 (0.23), 1.19 (0.27), 1.22 (0.26), 1.15 (0.26), and 1.19 (0.25) when determined 1, 3, and 6 months and 1, 2, and 4 years after surgery, respectively. Eighteen eyes (32%) showed no change in BSCVA, 26 eyes (46%) gained 1 line, 7 eyes (13%) gained 2 lines, 5 eyes (9%) lost 1 line, and no eyes lost 2 or more lines 4 years after ICL implantation (**Figure 1**).

EFFECTIVENESS OUTCOMES

Mean logMAR UCVAs were –0.04 (0.16), –0.09 (0.17), –0.07 (0.16), –0.03 (0.19), –0.08 (0.17), and –0.03 (0.23) when measured 1, 3, and 6 months and 1, 2, and 4 years after surgery, respectively. The mean efficacy indexes (mean postoperative UCVA divided by mean preoperative BSCVA) were 0.84 (0.27), 0.92 (0.30), 0.90 (0.28), 0.88 (0.32), 0.88 (0.28), and 0.83 (0.29) when deter-

mined 1, 3, and 6 months and 1, 2, and 4 years after surgery, respectively. One, 3, and 6 months and 1, 2, and 4 years after surgery, 56 (100%), 55 (98%), 55 (98%), 54 (96%), 54 (96%), and 53 (95%) of the eyes had a UCVA of 0.5, respectively, and 40 (71%), 44 (79%), 43 (77%), 35 (63%), 45 (80%), and 39 (70)% of the eyes had a UCVA of 1.0 or better, respectively (**Figure 2**).

PREDICTABILITY

One, 3, and 6 months and 1, 2, and 4 years after surgery, 51 (91%), 40 (71%), 45 (80%), 45 (80%), 45 (80%), and 44 (79%) of the eyes, respectively, were within ±0.5 D of the attempted correction, and 55 (98%), 54 (96%), 54 (96%), 52 (93%), 52 (93%), and 52 (93%) of the eyes, respectively, were within ±1.0 D of the attempted correction (**Figure 3**).

STABILITY

The change in the manifest spherical equivalent is shown in **Figure 4**. One, 3, and 6 months and 1, 2, and 4 years after surgery, the mean manifest spherical equivalents were –0.15 (0.40), –0.06 (0.50), –0.10 (0.37), –0.19 (0.49), –0.16 (0.27), and –0.38 (0.52) D, respectively. Mean changes in manifest refraction from 1 to 3 months, from 3 to 6 months, from 6 months to 1 year, from 1 to 2 years, and from 1 to 4 years were 0.09 (0.35), –0.04 (0.37), –0.08 (0.49), 0.04 (0.32), and –0.22 (0.43) D, respectively.

INTRAOCULAR PRESSURE

The mean IOPs were 14.5 (3.2), 13.7 (2.1), 13.3 (2.8), 12.7 (2.8), 13.3 (2.1), and 13.7 (2.4) mm Hg when measured 1, 3, and 6 months and 1, 2, and 4 years after surgery, respectively. No significant increase in IOP occurred in any eyes during the observation period.

ENDOTHELIAL CELL DENSITY

The mean endothelial cell densities fell from 2821 (276) cells/mm^2 preoperatively to 2764 (321), 2771 (205), 2764 (285), 2763 (314), and 2716 (224) cells/mm^2 when determined 3 and 6 months and 1, 2, and 4 years after surgery, respectively. The mean percentage of endothelial cell loss was 3.7% 4 years after surgery.

SECONDARY SURGICAL PROCEDURES AND ADVERSE EVENTS

There were no intraoperative complications, and all implantations were uneventful. In 56 eyes, only 1 eye (1.8%) developed a clinically significant symptomatic anterior subcapsular cataract 1 year after surgery and lost 3 lines in BSCVA (**Figure 5**). Another eye (1.8%) developed a cataract due to a traumatic event. Simultaneous lens extraction and phacoemulsification with intraocular lens implantation was successfully performed in both of these eyes. Six eyes (11%) also developed an asymptomatic anterior subcapsular cataract, in which 5 eyes (9%) showed no change in BSCVA and 1 eye (1.8%) lost 1 line. No pigmentary glaucoma, pupillary block, or other vision-

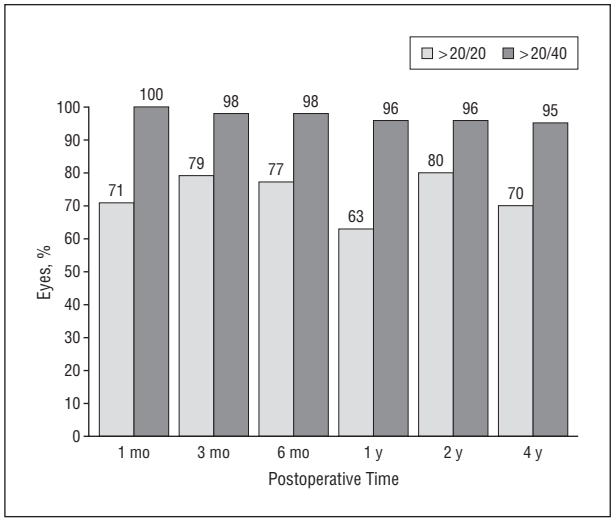

Figure 2. Changes in uncorrected visual acuity after implantation with a lens consisting of a biocompatible collagen copolymer (Visian implantable Collamer lens; STAAR Surgical, Nidau, Switzerland).

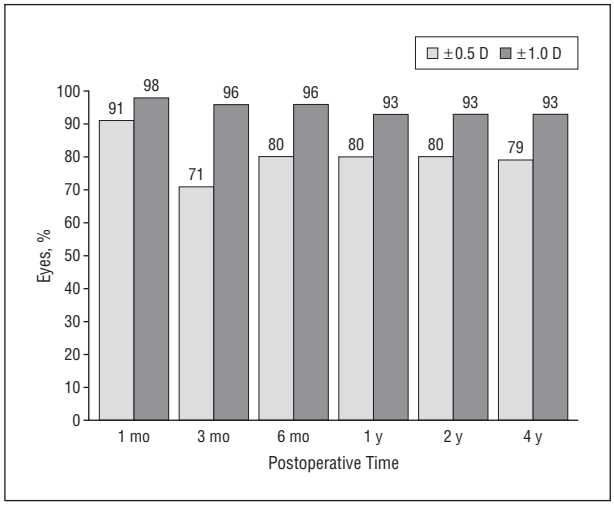

Figure 3. Percentages of eyes within ±0.5 and ±1.0 diopter (D) of the attempted correction (spherical equivalent) after implantation with a lens consisting of a biocompatible collagen copolymer (Visian implantable Collamer lens; STAAR Surgical, Nidau, Switzerland).

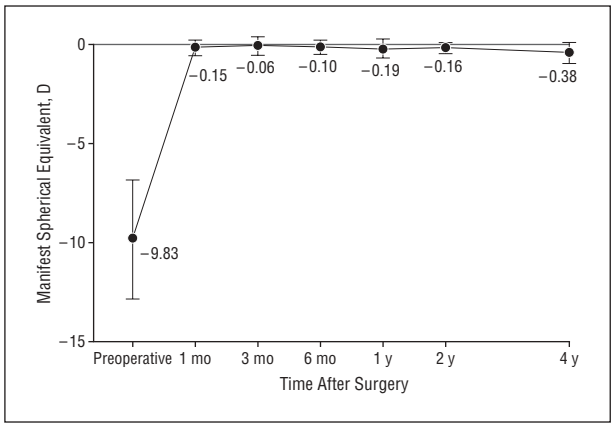

Figure 4. Time course of manifest spherical equivalent after implantation with a lens consisting of a biocompatible collagen copolymer (Visian implantable Collamer lens; STAAR Surgical, Nidau, Switzerland). D indicates diopter.

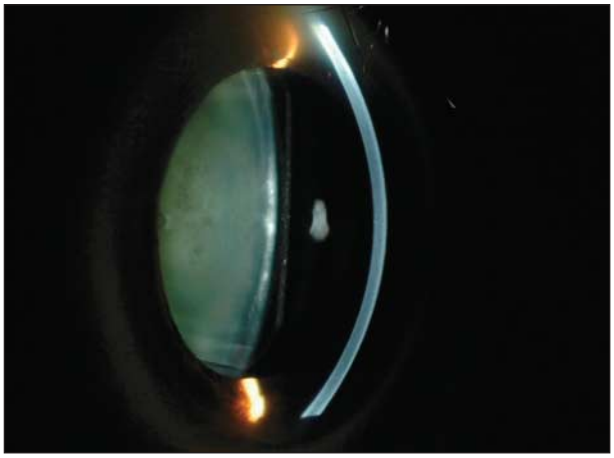

Figure 5. Slitlamp photograph of the eye that developed a symptomatic anterior subcapsular cataract after implantation with a lens consisting of a biocompatible collagen copolymer (Visian implantable Collamer lens; STAAR Surgical, Nidau, Switzerland).

threatening complications were seen at any time during the follow-up.

COMMENT

In the present study, we demonstrated that ICL implantation results were good in all measures of safety, efficacy, predictability, and stability for the correction of high myopia throughout the 4-year follow-up. It has been reported that ICL implantation may be effective for the correction of moderate to high ametropia.[1-10] However, many studies have focused on the short-term clinical outcomes after only 1 to 2 years, especially for refractive data, and only a few studies have spanned more than 3 years to examine the long-term results, including refractive data and adverse events, of this surgical technique. Considering that the numbers of the complications of ICL implantation, such as cataract formation, endothelial cell loss, pigment dispersion syndrome, pigmentary glaucoma, and pupillary block, are expected to increase with time,[11-16] the long-term clinical outcomes need to be elucidated. The US Food and Drug Administration (FDA) ICL clinical study demonstrated that ICL implantation was an effective and predictable method for treating moderate to high myopia up to 3 years after surgery.[9] Sanders[16] reported anterior subcapsular opacities and cataracts 5 years after ICL implantation, but that study focused on the incidence of anterior subcapsular cataract and clinically significant cataract in the US FDA ICL clinical study. Lackner et al[13] reported in a 3-year follow-up study of ICL implantation that lens opacification occurred in 11 eyes and that endothelial cell density was significantly decreased in eyes with clear lenses and in those with lens opacification. Pesando et al[17] demonstrated that ICL implantation was safe and effective for the treatment of hyperopia for up to 10 years but did not investigate the clinical outcomes of ICL implantation for myopia. To our knowledge, this is the longest study to assess the refractive outcomes and adverse events of ICL implantation for myopia. With regard to the safety and efficacy of the procedures, ICL implantation was safe and highly effective for the correction of moderate to high myopia, a finding that was in line with those of previous studies.[1-10] With regard to predictability and stability, ICL implantation is also excellent for the treatment of moderate to high myopia. It may be that ICL implantation through a 3-mm corneal incision, regardless of the amount of myopic correction, has a negligible effect on refractive outcome and that this surgical technique is less subject to the wound-healing responses of the cornea.

It is also important to compare the clinical outcomes of ICL implantation and keratorefractive surgery such as LASIK, which has become widely accepted as the criterion standard for refractive surgical procedures. Sanders and Vukich[18,19] reported that ICL had advantages over LASIK, not only in eyes with moderate to high myopia but also in eyes with low myopia. Recently, Sanders[20] also demonstrated that ICL was superior to LASIK for myopia of –3.00 to –7.88 D with matching preoperative data. A larger variation of wound-healing responses may occur after LASIK, especially when the amount of ablation is large, leading to refractive instability such as overshoot or regression. Hence, we believe that ICL implantation has advantages over keratorefractive surgical techniques such as standard LASIK and that these advantages are more prominent in eyes with higher myopia that require greater laser ablation. However, standard LASIK has been reported to be slightly inferior to wavefront-guided LASIK in visual performance, especially in the induction of high-order aberrations (HOAs).[21-23] Thus, at present, we cannot conclude that ICL implantation provides better clinical outcomes than even wavefront-guided LASIK. We await the results of a randomized, controlled, comparative study of these 2 surgical procedures. Moreover, it remains unclear whether ICL implantation has advantages over other keratorefractive surgical techniques such as laser-assisted subepithelial keratectomy, especially in eyes with high myopia or in those with a thin cornea.

Because LASIK requires more laser ablation in eyes with high myopia, the shape of the cornea becomes more oblate, resulting in more surgically induced HOAs.[24,25] In our preliminary data (not shown), LASIK significantly induced larger HOAs (especially spherical-like HOAs) than did ICL implantation in eyes with high myopia. Bühren et al[26] reported that HOAs increased slightly after implantation of the Artisan phakic intraocular lens. Both ICL implantation and Artisan intraocular lens implantation are considered to induce fewer HOAs than wavefront-guided LASIK, possibly because the prolate shape of the cornea is kept unchanged. Moreover, the retinal magnification of toric ICL implantation is decreased less than that of wavefront-guided LASIK.[27-29] Postoperative BSCVA was significantly improved after ICL implantation, as evidenced by the high safety index (1.19) in the present study. This may be attributed to the smaller increase in HOAs and the smaller decrease in retinal magnification after ICL implantation.

Pupil diameter plays an important role in determining the refractive outcomes of the surgical procedure. Because ICL implantation requires direct contact of the optic with the iris, it is possible that this surgical procedure may induce some changes in pupil diameter. Keuch and Bleckmann[30] reported that the rate of pupil contraction and

redilation, the pupil diameter, and the amplitude of pupil constriction were reduced after surgery, suggesting that ICL can cause mechanical interference with pupil constriction and redilation. Mechanical irritation of the uveal tissue may have played a role in the postoperative pupil reaction. In addition, the entrance pupil is magnified and displaced anteriorly by the corneal refractive power, and thus a reduction in the central corneal refractive power owing to myopic correction results in a decrease in clinically measured pupil diameter. In contrast, Chun et al[31] reported that the significantly smaller pupil diameter at 1 and 3 months after ICL implantation increased to the postoperative levels at 6 months and remained so at 12 months. Unfortunately, we did not measure pupil diameter in all eyes. However, in our preliminary data, ICL implantation did not induce a significant change in pupil diameter (data not shown). Further investigations of pupil diameter would be helpful for determining the exact effect on refractive outcomes after ICL implantation.

There are ongoing concerns about the development of lens opacity because of the close proximity of the ICL to the crystalline lens and about endothelial cell loss after ICL implantation. The incidence of development of clinically significant cataract formation with the model V4 ICL was 1.8% in this study if traumatic cataract formation was excluded. Sanders et al[11] reported that the incidence of anterior subcapsular cataract with the V3 and V4 model ICLs was 12.6% and 2.9%, respectively, probably because the V4 model is designed to have a vaulting 0.13 to 0.21 mm higher than the V3 model, depending on dioptric power. Gonvers et al[12] also stated that the central vaulting of the V3 model was slightly less than that of the V4 model. Sarikkola et al[14] reported that the incidence of anterior subcapsular cataracts with the V4 model in younger patients was 7.7%, whereas it was 47.7% with the V2, V3, or V4 model in older patients. The US FDA clinical study demonstrated that the incidence of anterior subcapsular cataract with the V4 model was 2.7%,[9] which was similar to our findings. More recently, Sanders[16] reported that 31 of 526 eyes (5.9%) developed symptomatic and asymptomatic anterior subcapsular cataract. Mean endothelial cell loss was 3.7% in the present study, which was low compared with that in previous studies. Jiménez-Alfaro et al[3] reported that the percentage of endothelial cell loss was 6.57% 2 years after surgery. The US FDA clinical study demonstrated that it was 8.4% to 9.7% 3 years after surgery.[9] Lackner et al[8] stated that the endothelial cell density was slightly decreased in eyes with a clear lens but that the decrease was more pronounced in the eyes that developed opacification. Pineda-Fernández et al[10] reported that the percentage of endothelial cell loss was 6.09% 3 years after surgery. At present, we cannot fully explain the discrepancy, but we assume that the differences of surgeon's skill, sample size, or other patient background factors such as race and the reproducibility of a noncontact specular microscope might play a role.

In recent years, the toric ICL has also been shown to be effective for the correction of high myopic astigmatism.[32-34] The US FDA clinical study of the toric ICL demonstrated that toric ICL implantation was an effective and predictable method for treating moderate to high myopic astigmatism.[32] Schallhorn et al[33] recently reported that the toric ICL performed better than photorefractive keratectomy in terms of safety, efficacy, predictability, and stability. In a previous report,[34] our group also demonstrated that, for the correction of high myopic astigmatism, toric ICL implantation was better than wavefront-guided LASIK, which appeared to be one of best surgical techniques in refractive surgery, in almost all measures of safety, efficacy, predictability, and stability. In addition, a toric ICL can be easily and safely repositioned, even if improper alignment of the axis occurs after surgery. These findings indicate that the toric ICL may hold promise for the treatment of high myopic astigmatism. A further long-term study is necessary to assess the clinical outcomes of toric ICL implantation.

In summary, our long-term results indicate that ICL implantation is safe and effective and provides predictable and stable refractive results in the correction of moderate to high myopia throughout a 4-year observation. In addition, no vision-threatening complications occurred throughout the follow-up period. These findings suggest that ICL implantation may be a good alternative for the treatment of moderate to high myopia. More prolonged careful observation for longer than 4 years is necessary to assess late-onset complications of this surgical technique.

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Correspondence: Kazutaka Kamiya, MD, PhD, Department of Ophthalmology, University of Kitasato School of Medicine, 1-15-1 Kitasato, Sagamihara, Kanagawa 228-8555, Japan (kamiyak-tky@umin.ac.jp).
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Additional Contributions: Christopher W. P. Reynolds provided careful linguistic assistance with this article.

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