

Long-term safety outcomes of posterior chamber phakic intraocular lens implantation for high myopia

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Objective: To assess the long-term safety outcomes of best-spectacle corrected visual acuity (BSCVA), intraocular pressure (IOP), and endothelial cell density (ECD), and the adverse events after implantable Collamer lens (Visian ICL™; STAAR Surgical) implantation for high myopia.

Methods: This study evaluated 12 eyes of 10 patients with myopic refractive errors of -13.96 to 2.62 diopters (D) who underwent ICL implantation and routine postoperative examinations. Before, and 1, 3, and 6 months and 1, 2, 3, 5, and 10 years after surgery, we assessed BSCVA (on a logMAR scale), IOP, ECD, and any adverse events of this surgery.

Results: BSCVA (on a logMAR scale) was 0.11 ± 0.13 , -0.04 ± 0.06 , -0.04 ± 0.10 , -0.03 ± 0.10 , -0.04 ± 0.08 , -0.04 ± 0.08 , -0.05 ± 0.08 , and -0.045 ± 0.09 , before surgery, and 1, 3 and 6 months, and 1, 3, 5 and 10 years after surgery, respectively. The IOP was 14.1 ± 3.3 , 14.3 ± 3.2 , 12.8 ± 2.2 , 13.5 ± 2.8 , 14.4 ± 3.7 , 14.2 ± 3.6 , 14.3 ± 3.8 , and 14.5 ± 3.1 mmHg, respectively. The ECD was 2381 ± 400 , $2,236 \pm 436$, $2,193 \pm 429$, $2,332 \pm 320$, $2,329 \pm 347$, $2,287 \pm 405$, and $2,303 \pm 302$ cells/mm², respectively. Although no eyes developed clinical significant symptomatic cataract, 11 eyes (92%) developed asymptomatic cataract formation 10 years postoperatively. No other vision-threatening complications occurred during the 10-year observation period.

Conclusions: ICL implantation was safe in terms of BSCVA, IOP, and ECD, in the treatment of high myopia throughout a 10-year observation period, suggesting its viability as a surgical option for the treatment of such eyes.

Key words: ICL implantation, safety, intraocular pressure, endothelial cell density, high myopia

Introduction

Laser 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. The Visian Implantable Collamer Lens (Visian ICL™ STAAR Surgical, Nidau, Switzerland), a posterior chamber phakic intraocular lens (ICL) that was developed to rectify such disadvantages has been reported to be effective for the correction of moderate to high ametropia.¹⁻¹¹ In addition, this surgical procedure is largely reversible and the lens exchangeable, unlike LASIK, even when unexpected refractive changes occur

after surgery. However, complications of ICL implantation, such as cataract formation, endothelial cell loss, pigment dispersion glaucoma, and pupillary block have been reported, and these complications are expected to increase with time.¹²⁻¹⁷ In consideration of the prevalence of this surgical procedure, it is essential to evaluate the long-term safety outcomes of ICL implantation. Nevertheless, there have only been a few studies on the long-term safety outcomes, including best spectacle-corrected visual acuity (BSCVA), intraocular pressure (IOP), and endothelial cell density (ECD) of ICL implantation. The aim of the current study is to investigate the long-term (10-year) safety outcomes of ICL implantation in the correction of high myopia.

Between September 1997 and December 1998, 39 eyes of 24 patients underwent implantation of the posterior

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phakic implantable collamer lens (Visian ICL™ STAAR Surgical) for the correction of high myopia at the Musashino Red Cross Hospital.

Twelve eyes (4 of men and 8 of women) of 10 patients, who underwent implantation of the ICL (V2, 6 eyes [50%], V3, 3 eyes [25%], and V4, 3 eyes [25%]) for the correction of high myopia, and who regularly returned for follow-up, postoperative examinations, were included in this retrospective study. The patients' mean age at the time of surgery was 49.4 ± 9.2 years (mean age \pm standard deviation [SD]; range, 28 to 65 years). The preoperative manifest spherical equivalent was -13.96 ± 2.62 diopters (D) (range, -9.75 to -19.00 D). The preoperative manifest refractive cylinder was 1.08 ± 1.28 D (range, 0.00 to 4.50 D). There were no concomitant eye diseases, except for macular atrophy in 1 eye (8%). Eyes with keratoconus were excluded from the study by using the keratoconus screening test of Placido disk videokeratography (TMS-2N, Tomey, Nagoya). Preoperatively, and 1, 3, and 6 months, and 1, 3, 5, and 10 years postoperatively, we determined the following: logarithm of the minimum angle of resolution (logMAR) of BSCVA, IOP, and ECD (except for 1 month postoperatively), and the adverse events, in addition to the usual slit-lamp biomicroscopic and funduscopic examinations. Before surgery, the horizontal white-to-white distance and anterior chamber depth were measured using a scanning-slit topograph (Orbscan IIz, Bausch & Lomb, Rochester, New York, USA), and the mean keratometric readings and the central corneal thickness were measured using an autorefractometer (ARK-700A, Nidek, Gamagori, Aichi) and an ultrasound pachymeter (DGH-500, DGH Technologies, Exton, PA, USA), respectively. The IOP was assessed with a noncontact tonometer (KT-500, Kowa, Tokyo). The endothelial cell density was determined with a noncontact specular microscope (SP-8800, Konan, Nishinomiya). We followed the tenets of the Declaration of Helsinki to perform this study. Informed consent was obtained from all the patients. The study was approved by the institutional review board at Musashino Red Cross Hospital.

ICL power calculation

ICL power calculation was performed by the manufacturer (STAAR Surgical) using a modified vertex formula. In 9 of 12 eyes, the preoperative manifest refraction was selected as the target myopic correction to reduce the preoperative refractive errors as much as possible. In the remaining 3 eyes, we intentionally selected undercorrection for near vision. 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 with scanning-slit topography (Orbscan IIz, Rochester, NY, USA).

ICL Surgical Procedure

To avoid a postoperative pupillary block, the patients underwent two peripheral iridectomies 70° and 110° in the upper quadrant with a Nd-YAG laser before surgery. On the day of surgery, dilating and cycloplegic agents were administered to the patients. After topical anesthesia, the 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) 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 miotic agent was instilled. All surgeries were uneventful and no intraoperative complications were observed. After surgery, steroidal (0.1% betamethasone; Rinderon; Shionogi, Osaka) and antibiotic (levofloxacin; Cravit; Santen, Osaka) medications were administered topically 4 times daily for 2 weeks, the dose being reduced gradually thereafter.

Statistical analyses

All statistical analyses were performed using StatView version 5.0 (SAS, Cary, NC, USA). The results were expressed as mean \pm SD, and a value of $P < 0.05$ was considered to indicate statistically significant differences.

Results

Patient population

Preoperative patient demographics are summarized in Tables 1 and 2. Uncorrected visual acuity (UCVA) and BSCVA (on a logMAR scale) were 1.62 ± 0.11 (range, 1.40 to 1.70) and 0.11 ± 0.13 (range, -0.08 to 0.40), respectively. Horizontal white-to-white distance was 11.7 ± 0.3 mm (range, 11.0 to 12.1 mm). Anterior chamber depth was 3.25 ± 0.28 mm (range, 2.82 to 3.60 mm). The mean keratometric reading was 44.0 ± 1.3 D (range, 42.0 to 45.9 D). Central corneal thickness was 549.7 ± 28.1 μ m (range, 494 to 595 μ m).

Best spectacle-corrected visual acuity

BSCVA (on a logMAR scale) was 0.11 ± 0.13 , -0.04 ± 0.06 , -0.04 ± 0.10 , -0.03 ± 0.10 , -0.04 ± 0.08 , -0.04 ± 0.08 , -0.05 ± 0.08 , and -0.04 ± 0.09 , before surgery, and 1, 3 and 6 months, and 1, 3, 5 and 10 years after

Table 1. Preoperative demographics of the study population

Characteristic	Mean ± Standard Deviation
Age (years)	49.4 ± 9.2 years (range, 28 to 65 years)
Gender (Male : Female)	M : F = 4 : 8
Manifest spherical equivalent (D)	-13.96 ± 2.62 D (range, -9.75 to -19.00 D)
Manifest cylinder (D)	1.08 ± 1.28 D (range, 0.00 to 4.50 D)
UCVA on a LogMAR scale	1.62 ± 0.11 (range, 1.40 to 1.70)
BSCVA on a LogMAR scale	0.11 ± 0.13 (range, -0.08 to 0.40)
White-to-white distance (mm)	11.7 ± 0.3 mm (range, 11.0 to 12.1 mm)
Anterior chamber depth (mm)	3.25 ± 0.28 mm (range, 2.82 to 3.60 mm)
Mean keratometric readings (D)	44.0 ± 1.3 D (range, 42.0 to 45.9 D)
Central cornea thickness (μm)	549.7 ± 28.1 μm (range, 494 to 595 μm)

D, diopter; logMAR, logarithm of the minimum angle of resolution; UCVA, uncorrected visual acuity; BSCVA, best spectacle-corrected visual acuity

Table 2. Preoperative data of the study population

Case No.	Age	Eye	Gender	Spherical (D)	Cylinder (D)	ICL version	ICL power (D)
1	42	L	M	-12.00	-1.50	V2	-16.0
2	46	R	M	-14.00	-0.75	V2	-17.0
3	51	R	F	-9.00	-1.50	V2	-12.0
4	51	L	F	-10.00	-1.00	V2	-13.0
5	53	R	F	-15.50	0.00	V2	-16.5
6	53	L	F	-15.00	-1.25	V2	-16.5
7	28	R	M	-12.00	-2.00	V3	-15.0
8	43	L	M	-19.00	0.00	V3	-21.0
9	49	R	F	-13.00	0.00	V3	-15.5
10	55	L	F	-13.50	-0.50	V4	-16.0
11	57	R	F	-13.75	-4.50	V4	-20.0
12	65	R	F	-13.00	0.00	V4	-15.0

R, Right eye; L, Left eye; M, Male; F, Female; D, diopter

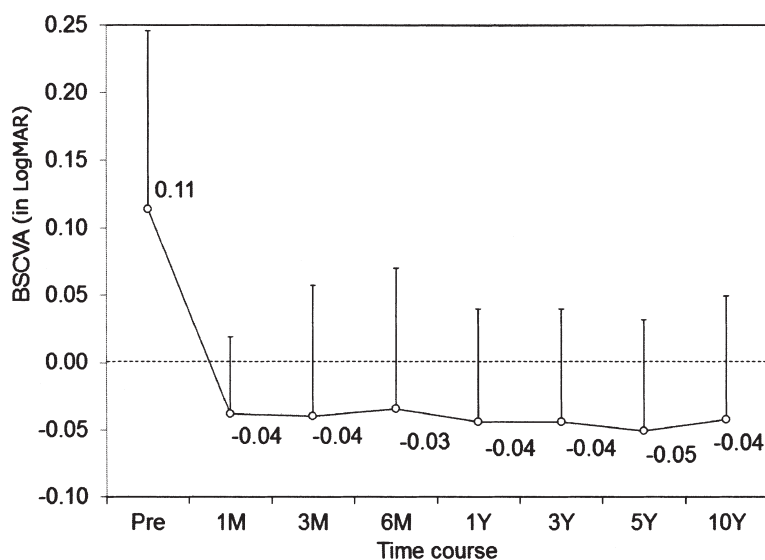


Figure 1. Time course of best spectacle-corrected visual acuity (BSCVA) in the logarithm of the minimum angle of resolution (logMAR) scale after implantable collamer lens (ICL) implantation
M, Month; Y, Year

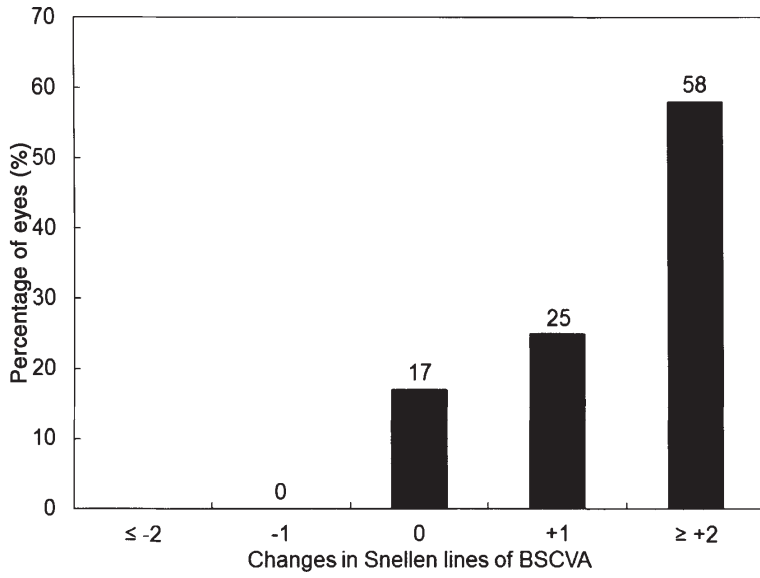


Figure 2. Changes in BSCVA 10 years after ICL implantation

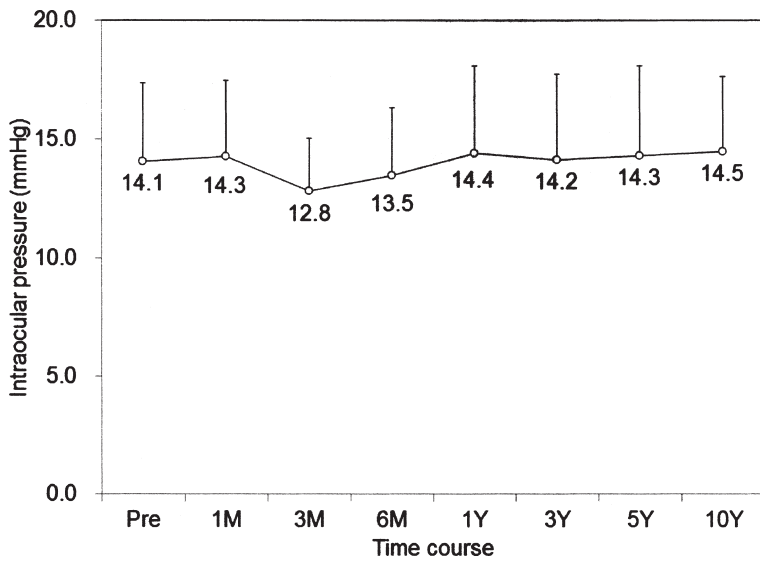


Figure 3. Time course of intraocular pressure (IOP) after ICL implantation

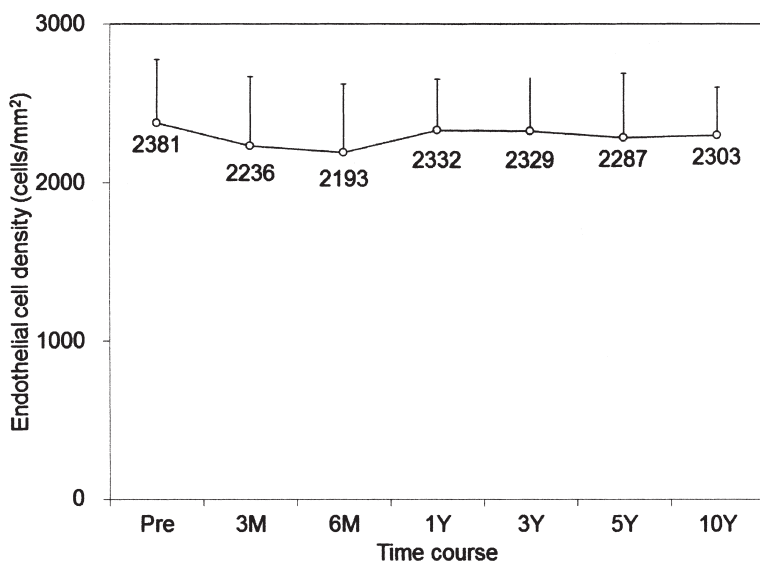


Figure 4. Time course of endothelial cell density (ECD) after ICL implantation

surgery, respectively (Figure 1). BSCVA (on a logMAR scale) was significantly improved 10 years after surgery ($P = 0.005$, Wilcoxon signed-rank test). Two eyes (17%) showed no changes in BSCVA, 3 eyes (25%) gained 1 line, and 7 eyes (58%) 2 lines or more, no eyes lost 1 or more lines 10 years after ICL implantation (Figure 2).

Intraocular pressure

The IOP was 14.1 ± 3.3 , 14.3 ± 3.2 , 12.8 ± 2.2 , 13.5 ± 2.8 , 14.4 ± 3.7 , 14.2 ± 3.6 , 14.3 ± 3.8 , and 14.5 ± 3.1 mmHg, before surgery, and 1 week, and 1, 3, and 6 months, and 1, 3, 5, and 10 years after surgery, respectively (Figure 3). There was no significant change in the IOP before and 10 years after surgery ($P = 0.95$, Wilcoxon signed-rank test). No significant increases in IOP occurred in any case during the observation period.

Endothelial cell density

The ECD was $2,381 \pm 400$, $2,236 \pm 436$, $2,193 \pm 429$, $2,332 \pm 320$, $2,329 \pm 347$, $2,287 \pm 405$, and $2,303 \pm 302$ cells/mm², before surgery, and 3 and 6 months, and 1, 3, 5, and 10 years after surgery, respectively (Figure 4). There were no significant changes in the ECD before or 10 years after surgery ($P = 0.56$, Wilcoxon signed-

rank test). The mean percentage of endothelial cell loss was 3.3% 10 years after surgery.

Adverse events

In 12 eyes, no eyes (0%) developed clinically significant symptomatic anterior subcapsular cataract, which lost 1 or more lines in BSCVA, or required simultaneous ICL extraction and phacoemulsification with IOL implantation, but 11 eyes (92%) developed asymptomatic anterior subcapsular cataract, in which no eyes lost 1 or more lines, 10 years postoperatively (Figure 5). Pigment dispersion glaucoma, pupillary block, or any other vision-threatening complications were not seen at any time during the 10-year follow-up period.

Discussion

In the present study, we demonstrated that ICL implantation was good in all measures of BSCVA, IOP, and ECD for the correction of high myopia throughout the 10-year follow-up period. It has been reported that ICL implantation may be effective for the correction of moderate to high ametropia.¹⁻¹¹ However, many studies have focused on the short-term clinical outcomes up to 2

Case No.	ICL	Age	Pre	1M	3M	6M	1Y	3Y	5Y	10Y
1	V2	42								
2	V2	46								
3	V2	51								
4	V2	51								
5	V2	53								
6	V2	53								
7	V3	28								
8	V3	43								
9	V3	49								
10	V4	55								
11	V4	57								
12	V4	65								

Figure 5. Postoperative changes of lens

■ = nuclear cataract
Case Nos. are used for the same Case Nos. as those in Table 2.

Case No.	ICL	Age	Pre	1M	3M	6M	1Y	3Y	5Y	10Y
1	V2	42								
2	V2	46								
3	V2	51								
4	V2	51								
5	V2	53								
6	V2	53								
7	V3	28								
8	V3	43								
9	V3	49								
10	V4	55								
11	V4	57								
12	V4	65								

Figure 6. Postoperative changes of lens

■ = anterior subcapsular cataract
Case Nos. are used for the same Case Nos. in Table 2.

years postoperatively, especially for refractive data; and, to our knowledge, there have only been a few studies spanning more than 3 years to examine the long-term results, including refractive data and adverse events, of this surgical technique. The U.S. 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 postoperatively.⁹ Sanders et al reported anterior subcapsular opacities and cataracts 5 years after ICL implantation, but their study focused on the incidence of anterior subcapsular cataract and clinically significant cataract in the U.S. FDA ICL clinical study.¹⁷ Lackner et al. 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 as well as those with lens opacification.¹⁴ Pesando et al. demonstrated that ICL implantation was safe and effective for the treatment of hyperopia up to 10 years, but did not investigate the clinical outcomes of ICL implantation for myopia.¹⁸

With regard to the safety of the procedures, ICL implantation was safe in terms of visual acuity for the correction of moderate to high myopia, a finding which was in line with previous studies.¹⁻¹¹ When discussing the visual acuity after myopic and hyperopic correction, cautions are required about retinal magnification. Magnification effects can be large, accounting for a visual acuity increase of 1 line or more.¹⁹ Kamiya et al. reported about the retinal magnification after myopic correction in a Gullstrand eye model, the retinal image was least affected by ICL implantation, more affected by LASIK, and most affected by spectacles.²⁰ The higher myopic was corrected by spectacles, the smaller the retinal

magnification became.

With regard to the adverse events of this surgery, there are ongoing concerns about the development of lens opacity because of the close proximity of the ICL to the crystalline lens, about the IOP, and about ECD after ICL implantation. Although no eyes developed clinical significant symptomatic cataract, 11 eyes (92%) developed asymptomatic cataract formation 10 years postoperatively in this study. The backgrounds of patients with developing ICL-induced cataract such as age, ICL power, and ICL configuration have been discussed so far. Regarding patient age, Gonvers et al. reported that ICL-induced cataracts develop more frequently in older patients than in younger patients; the incidences in those of 40 years of age or less and of 41 or over were 14% and 37%, respectively.¹³ Lackner et al.¹⁴ and Sarikkola et al.¹⁵ proposed ages of 50 years or older and 45 years or older, respectively, as risk factors for cataract development after ICL implantation. Fujisawa et al. stated that a decrease in accommodation with aging may affect the continuous flow of the aqueous humor, resulting in a higher incidence of cataract development after ICL implantation.²¹ Regarding the ICL power, Sanders et al. stated that preoperative myopia (>12.00 D) was a significant risk factor in the development of cataract.¹² Higher myopic eyes requires a thicker ICL optic and a lower ICL vault in the mid-peripheral area, which may contribute to the higher incidence of cataract formation.

The improving points of the Visian Implantable Collamer Lens (Visian ICL™) are shown in Figure 7. Regarding the ICL configuration, Sanders et al. also reported that the incidence of anterior subcapsular cataract with the ICL V3 and V4 was 12.6% and 2.9%, respectively, probably because ICL V4 is designed to

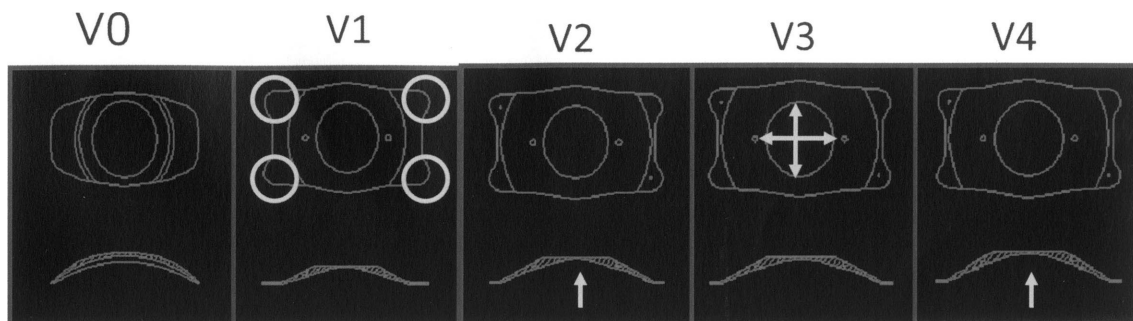


Figure 7. The model figure of the Visian Implantable Collamer Lens (Visian ICL™)

- V0: Version 0 was a curved plate haptic.
- V1: Version 1 was improved with footplates.
- V2: Version 2 was improved with orientation holes.
- V3: Version 3 was improved with a bigger optic.
- V4: Version 4 was improved with more vaulting.

have a vaulting 0.13 to 0.21 mm higher than ICL V3, depending on dioptric power.¹² Gonvers et al. also stated that the central vaulting of ICL V3 was slightly less than that of ICL V4.¹³ Sarikkola et al. reported the incidence of anterior subcapsular cataracts with ICL V4 in younger patients was 7.7%, while that with ICL V2, V3, or V4 in older patients was 47.7%.¹⁵ The U.S. FDA Trial demonstrated that the incidence of anterior subcapsular cataract with ICL V4 was 2.7%.⁹ Sanders reported that 31 (5.9%) of 526 eyes developed symptomatic and asymptomatic anterior subcapsular cataract.¹⁷ Although we cannot refute the possibility that the early clinical results are influenced by the surgeon's learning curve, only 1 eye (8%) developed cataract immediately after surgery, suggesting that the learning curve alone may not contribute to the higher rate of ICL-induced cataract. We assume that the higher rate of ICL-induced cataract was attributable to the older patient age (49.4 ± 9.2 years), higher myopic correction (-13.96 ± 2.62 D), the use of the older version of the ICL (V2 50% and V3 25%), as well as the learning curve in the present study. Accordingly, we should be aware that our findings do not reflect the current status of ICL V4 implantation, especially with regard to cataract formation, because ICL V2 and V3 have now been withdrawn from the market.

The IOP was highly stable, and no significant IOP rise was observed throughout the 10-year observation period, indicating that neither pupillary block, pigment dispersion syndrome, nor pigment glaucoma occurred in any case throughout the duration of the follow-up. In this study, neither contact nor high vault in excess of 1.25 mm between the ICL or the crystalline lens was observed under a slit lamp in any of these cases, suggesting that extreme underestimation or overestimation of ICL size did not occur. We assume that uncomplicated ICL implantation with appropriate ICL size selection did not significantly affect the IOP even 10 years after surgery.

The mean percentage of endothelial cell loss was 3.3% 10 years after surgery in the present study, which was low in comparison with that in other previous studies. Jiménez-Alfaro et al. reported that the percentage of endothelial cell loss was 6.6% 2 years after surgery.³ The U.S. FDA trial demonstrated that it was 8.4% to 9.7% 3 years postoperatively.⁹ Lackner et al. stated that the endothelial cell density was slightly decreased in eyes with a clear lens, but that the decrease was more pronounced in those that developed opacification.⁸ Pineda-Fernandez et al. reported that the percentage of endothelial cell loss was 6.1% 3 years after surgery.¹⁰ Bourne et al. demonstrated that the mean endothelial cell

density significantly decreased during the 10.6-year interval from $2,715 \pm 301$ cells/mm² to $2,539 \pm 284$ cells/mm², and that the calculated exponential cell loss rate over this interval was $0.6 \pm 0.5\%$ per year.²² At present, we cannot fully explain the discrepancy, but we assume that the differences of the surgeons' skills, sample sizes, or other patient background factors such as race, as well as the reproducibility of a noncontact specular microscope might play a role. We also believe that uncomplicated ICL implantation with appropriate ICL size selection did not significantly affect the ECD, even as long as 10 years after surgery.

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 gold standard for refractive surgical procedures. Sanders et al. reported that ICL had advantages over LASIK not only in eyes with moderate to high myopia but also in eyes with low myopia,^{23,24} and they also demonstrated that ICL was superior to LASIK for myopia of -3.00 to -7.88 D with matching preoperative data.²⁵ Wavefront-guided LASIK has been reported to be more effective for reducing the induction of higher-order aberrations than conventional LASIK.²⁶⁻²⁸ However, we previously showed that ICL implantation was superior to wavefront-guided LASIK in visual performance not only for the correction of high myopia,²⁹ but also for the correction of low to moderate myopia.³⁰ 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 the standard or wavefront-guided LASIK, and that this advantage is more prominent with higher myopic eyes requiring greater laser ablation.

The limitation to this study is that we present a small amount of sample data using the currently unavailable ICL V2 and V3. Thus, as mentioned above, our findings do not necessarily reflect the current status of ICL V4 implantation, especially with regard to cataract formation. However, we believe that two important clinical implications were obtained from this study. One is that ICL implantation was safe, in terms of visual acuity, even 10 years after surgery, despite the fact that cataract formation occurred in most eyes. The other is that we found neither significant endothelial cell loss nor significant IOP rise, during the 10-year observation period, when the appropriate ICL sizes were selected.

In summary, our long-term results indicate that ICL implantation is safe in terms of visual acuity, IOP, and

ECD in the correction of moderate to high myopia throughout a 10-year follow-up observation period. Although we found a high incidence of cataract formation, possibly resulting from the use of the old version of the ICL (V2 50% and V3 25%), from that of the high myopic correction (-13.96 ± 2.62 D), and from the older age of the patients (49.4 ± 9.2 years), no vision-threatening complications occurred throughout the 10-year follow-up period. Considering that the ICL V2 and V3 have been withdrawn from the market, a further longitudinal study with a larger number of patients using the current ICL V4 is warranted.

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