

Clinical outcomes and patient satisfaction after Visian Implantable Collamer Lens removal and phacoemulsification with intraocular lens implantation in eyes with induced cataract

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Abstract

Purpose To assess the clinical outcomes and patient satisfaction after simultaneous Implantable Collamer Lens (ICL) removal and phacoemulsification with intraocular lens (IOL) implantation in ICL-implanted eyes with developing cataracts.

Methods We retrospectively reviewed the clinical charts of 10 eyes of eight patients who developed significant cataract after ICL implantation. Patient age was 47.2 ± 5.9 (mean \pm SD) years (range, 37–57 years). We determined visual acuity (log MAR), manifest refraction, endothelial cell density, and subjective satisfaction with visual outcomes measured using a visual analogue scale, that ranged from 0 (very dissatisfied) to 10 (very satisfied), before and 3 months after cataract surgery.

Results Log MAR best spectacle-corrected visual acuity was significantly improved from 0.19 ± 0.30 preoperatively to -0.06 ± 0.07 postoperatively ($P = 0.007$, Wilcoxon signed-rank test). Eight (80%) and nine (90%) of the 10 eyes were within 0.5 D (diopter) and 1.0 D of the targeted correction, respectively. The endothelial cell density was 2584.9 ± 266.2 cells/mm² preoperatively, and 2340.1 ± 269.7 cells/mm² postoperatively. The overall satisfaction with visual outcomes was scored 1.8 ± 1.1 (range: 0–3) preoperatively, and

7.9 ± 1.4 (range: 6–10) postoperatively. No vision-threatening complications were seen throughout the follow-up period.

Conclusions Simultaneous ICL removal and phacoemulsification with IOL implantation was safe and effective with predictable refractive results, and thus yielded a high level of patient satisfaction with ICL-induced cataract treatment.

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Keywords: ICL; safety; predictability; patient satisfaction; cataract

Introduction

Visian Implantable Collamer Lens (ICL, STAAR Surgical, Nidau, Switzerland), a posterior chamber phakic intraocular lens (IOL), has become widely accepted in the recent years as an effective method for the correction of moderate to high ametropia.^{1–9} This surgical procedure may have advantages over laser *in situ* keratomileusis (LASIK) because it is not only highly predictable but also reversible. It may also have advantages over refractive lens exchange because the crystalline lens, which plays a major role in accommodative function, especially in younger patients, remains untouched. On the other hand, there are

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ongoing concerns about one postoperative complication: the development of lens opacity after ICL implantation because of the close proximity of the ICL to the crystalline lens. In light of the prevalence of this surgical procedure, it is clinically important to assess the prognosis of patients with developing cataract after ICL implantation. However, there have been only a few studies on the prognosis of patients with developing cataract after ICL implantation.^{10,11} Moreover, patient subjective satisfaction and endothelial cell loss after these procedures, both of which are major concerns in the prognosis of such patients, still remain unclear. The aim of this study is retrospectively to assess the clinical outcomes, including endothelial cell density and patient satisfaction after ICL removal and phacoemulsification with IOL implantation in eyes with ICL-induced cataract.

Materials and methods

We retrospectively reviewed the clinical charts of 37 eyes of 22 patients who had undergone ICL implantation at Musashino Red Cross Hospital (Tokyo, Japan) from 1997 to 1998 with a minimal follow-up for 6 months after surgery. ICL models V2, V3, and V4 were implanted in 24 (65%), four (11%), and nine (24%) eyes of these patients, respectively. Sixteen eyes (43%) of 12 patients developed anterior subcapsular cataract, and of them, 10 eyes (six of men and four of women) of the eight patients who developed cataract with a significant loss of two or more lines of best spectacle-corrected visual acuity (BSCVA), after ICL implantation for the correction of myopia, were included in this study. The remaining six of the 16 eyes did not require cataract surgery because cataract formation was asymptomatic and they were not included in this study. Informed consent was obtained from all patients. The study adhered to the tenets of the Declaration of Helsinki. Institutional Review Board approval was not required for this retrospective study.

Implantable collamer lens power calculations were performed by the manufacturer (STAAR Surgical) using a modified vertex formula. The size of the ICL was also chosen by the manufacturer on the basis of the horizontal corneal diameter and anterior chamber depth with scanning-slit topography (Orbscan IIz, Bausch & Lomb, Rochester, NY, USA). IOL power calculations were performed by the SRK-T formula using the axial length measured by A-scan ultrasonography (US-800, Nidek, Aichi, Japan) without any correction for the ICL *in situ*, and keratometric readings measured with an autorefractometer (RK-5, Canon, Tokyo, Japan).

Before ICL implantation, the patients underwent two peripheral iridectomies with a neodymium-YAG laser. On the day of surgery, the patients were administered dilating and cycloplegic agents. After topical anaesthesia,

a model V2, V3, or V4 ICL was inserted through a 3-mm corneal incision with the use of an injector cartridge (STAAR Surgical) after the introduction of viscoelastic material (Opegan Santen, Osaka, Japan) into the anterior chamber. The ICL was placed in the posterior chamber, the remaining viscoelastic was completely washed out of the anterior chamber with balanced salt solution, and a miotic agent (acetylcholine chloride, Ovisort Daiichi-Sankyo, Tokyo, Japan) was instilled. After surgery, steroidal (0.1% betamethasone, Rinderon Shionogi, Osaka, Japan) and antibiotic (levofloxacin, Cravit Santen, Osaka, Japan) medications were topically administered four times daily for 2 weeks, with the dose being steadily reduced thereafter.

For ICL removal and phacoemulsification with monofocal IOL implantation, a 3.0-mm clear corneal incision at a site identical to the original incision, was created after topical anaesthesia. After the introduction of viscoelastic material (Opegan) into the anterior chamber, the proximal haptics of the ICL were dislocated, grasped with forceps, and extracted from the anterior chamber through the incision. Then, standard phacoemulsification was performed by capsulorrhexis, nuclear and cortex extraction, and IOL implantation (KS-3Ai, STAAR Surgical) using the same 3.0-mm incision. All surgeries were uneventfully performed by the same surgeon (KS) and no intraoperative complication was observed. After surgery, steroidal (0.1% betamethasone, Rinderon), antibiotic (levofloxacin, Cravit), diclofenac sodium (0.1% Diclod Wakamoto, Tokyo, Japan) medications were topically administered four times daily for 1 month, and then the dose was steadily reduced.

Before and 3 months after these combined surgeries, we performed the following examinations: uncorrected visual acuity (UCVA), BSCVA, manifest refraction, endothelial cell density measured with a non-contact specular microscope (SP-8800, Konan, Nishinomiya, Japan), and patient subjective satisfaction. The patient satisfaction was assessed according to the visual analog scale in a range from 0 (very dissatisfied) to 10 (very satisfied) by one of the authors who did not participate in the overall treatment or follow-up of the patients in the study.

All statistical analyses were performed using SPSS (SPSS Inc., Chicago, IL, USA). The results are expressed as mean \pm standard deviation (SD), and a value of $P < 0.05$ was considered statistically significant.

Results

Patient demographics

Preoperative and postoperative patient demographics are listed in Table 1. The patient age at the time of cataract surgery was 47.2 ± 5.9 years (range: from 37 to 57

Table 1 Patient demographics of 10 eyes that underwent ICL removal and phacoemulsification with intraocular lens implantation

No.	Age (years)	Gender	Eye	ICL versions	Manifest refraction D	BSCVA		ECD (cells/mm ²)		Intervals from ICL implantation to cataract surgery (years)	Follow-up (years)
						Preoperative	Postoperative (3 months)	Preoperative	Postoperative (3 months)		
1	53	M	L	II	-10.38	0.8	1.2	2700	2438	2.4	9.1
2	37	M	R	II	-10.75	0.8	1.2	2604	2344	7.4	7.7
3	44	M	R	II	-13.00	0.7	1.2	2915	2795	2.1	2.5
4	44	M	L	II	-12.00	0.7	1.2	2540	2336	2.2	2.5
5	42	M	R	II	-13.00	0.1	1.2	2603	2625	5.7	9.2
6	48	F	R	II	-17.75	0.6	1.2	2943	1956	2.8	10.0
7	48	F	L	II	-16.38	0.9	1.2	2703	2150	3.4	10.0
8	46	M	L	II	-14.38	1.2	1.2	2361	2227	1.6	9.2
9	53	F	R	II	-24.00	1.0	1.2	2037	1992	2.7	9.3
10	57	F	L	IV	-18.50	0.6	0.7	2443	2538	5.4	8.9

BSCVA, best spectacle-corrected visual acuity; ECD, endothelial cell density; ICL, implantable collamer lens; M, male; F, female; D, diopter.

years old). In six (60%) and four (40%) of the 10 eyes, the patients were men and women, respectively. The preoperative manifest refraction (spherical equivalent) before ICL implantation was -15.0 ± 4.2 diopters (D) (range: from -10.4 to -24.0 D). The preoperative astigmatism was 1.1 ± 1.2 D (range: from 0.0 to 3.5 D). The preoperative endothelial cell density was 2603.9 ± 213.4 cells/mm² (range: from 2239 to 2859 cells/mm²). The anterior chamber depth was 2.99 ± 0.23 mm (range: from 2.76 to 3.35 mm). In nine (90%) and one (10%) of the 10 eyes, we implanted a model V2 and a V4 ICL, respectively. Intervals from ICL implantation to cataract surgery were 3.6 ± 1.9 years (range: from 1.6 to 7.4 years). The follow-up duration was 7.8 ± 2.9 years (range: from 2.5 to 10.0 years). There were no concomitant eye diseases, except for lattice dystrophy in two eyes (in case 2 and case 9) and for one eye with macular atrophy (in case 10).

Safety outcomes

Log MAR BSCVA was significantly improved from 0.19 ± 0.30 preoperatively to -0.06 ± 0.07 postoperatively ($P = 0.008$, Wilcoxon signed-rank test). The safety index (mean postoperative BSCVA/mean preoperative BSCVA) was 2.51 ± 3.35 , 3 months postoperatively. One eye (10%) showed no change in BSCVA, two eyes (20%) gained one line, seven eyes (70%) gained two or more lines, and no eyes lost any lines (Figure 1).

Effectiveness outcomes

Log MAR UCVA was changed from 0.56 ± 0.28 preoperatively to 0.26 ± 0.30 postoperatively ($P = 0.09$, Wilcoxon signed-rank test). The targeted manifest refraction (spherical equivalent) was -2.34 ± 1.22 D

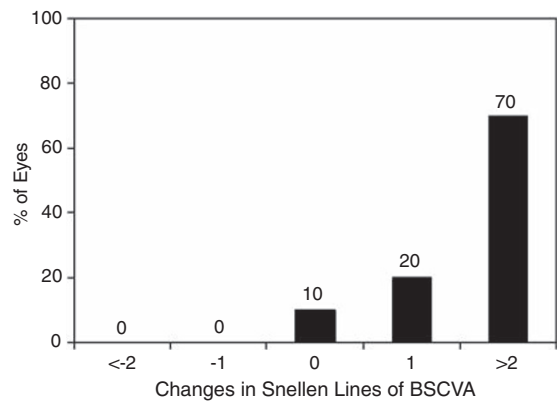


Figure 1 Changes in best spectacle-corrected visual acuity (BSCVA) after Implantable Collamer Lens (ICL) removal and phacoemulsification with intraocular lens (IOL) implantation.

(range: from -0.74 to -4.27 D) depending on the refraction of the fellow eye and the patient’s wish for near or far vision. Manifest refraction was -2.87 ± 2.06 D preoperatively, and -2.07 ± 1.56 D postoperatively. The efficacy index (mean postoperative UCVA/mean preoperative BSCVA) was 1.13 ± 1.05 , 3 months postoperatively. Seven (70%) of 10 eyes had UCVA of 0.5 or better 3 months after surgery.

Predictability

A scatter plot of the attempted versus the achieved refraction (manifest spherical equivalent) 3 months after surgery is shown in Figure 2. Eight (80%) and nine (90%) of the 10 eyes were within ± 0.5 D and 1.0 D, respectively, of the targeted correction.

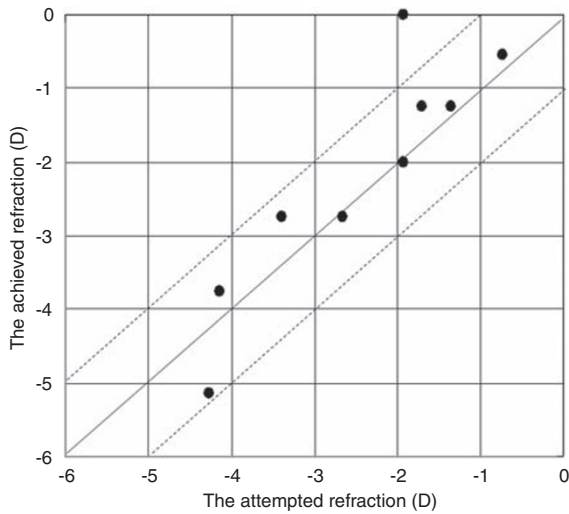


Figure 2 Scatter plot of attempted vs achieved refraction (manifest spherical equivalent) in Implantable Collamer Lens (ICL) removal and intraocular lens (IOL) implantation. Eight (80%) and nine (90%) of the 10 eyes were within ± 0.5 D and 1.0D, respectively, of the targeted refraction 3 months after surgery.

Patient satisfaction

The overall satisfaction score with visual outcomes using the visual analogue score was significantly improved from 1.8 ± 1.1 (range: 0–3) preoperatively to 7.9 ± 1.4 (range: 6–10) 3 months postoperatively ($P < 0.001$, Wilcoxon signed-rank test).

Adverse events

The endothelial cell density fell from 2584.9 ± 266.2 cells/ mm^2 preoperatively to 2340.1 ± 269.7 cells/ mm^2 , 3 months postoperatively. The percentage of endothelial cell loss was $8.9 \pm 11.0\%$. No vision-threatening complications including intraocular pressure rise, posterior capsular opacity, cystoids macular oedema, and retinal detachment were seen at any time during the follow-up period.

Discussion

In this study, we have shown that simultaneous ICL extraction and phacoemulsification with a monofocal IOL were safe, effective, and predictable surgical methods in eyes with developing ICL-induced cataract. Bleckmann *et al*¹⁰ first reported that the BSCVA after ICL removal and cataract extraction with monofocal IOL implantation improved 1.44 ± 1.33 lines more than that before ICL implantation. Morales *et al*¹¹ also reported that the mean BSCVA before ICL implantation, after ICL

implantation, and after cataract surgery were 0.31 ± 0.32 , 0.28 ± 0.19 , and 0.27 ± 0.21 , respectively. However, the endothelial cell loss after these surgical procedures, which is one of major concerns in the prognosis of these patients, was not investigated in these earlier articles. In this study, we observed a mean endothelial cell loss of $8.9 \pm 11.0\%$, which was considered to be clinically acceptable in such cases complicated by a developing significant ICL-induced cataract.

Concerns about the backgrounds of patients with developing ICL-induced cataract also exist. With regard to patient age, Gonvers *et al*¹² 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. Lackner *et al*¹³ and Sarikkola *et al*¹⁴ 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*¹⁵ stated that a decrease in accommodation with ageing may affect the continuous flow of the aqueous humour, resulting in a higher incidence of cataract development after ICL implantation. With regard to the ICL configuration, Sanders *et al*¹⁶ reported that the incidence of anterior subcapsular cataract with ICL V3 and V4 was 12.6 and 2.9%, respectively, probably because ICL V4 is designed to have a vaulting 0.13–0.21 mm higher than ICL V3, depending on dioptric power. Gonvers *et al*¹⁷ also stated that the central vaulting of ICL V3 was slightly less than that of ICL V4. Sarikkola *et al*¹⁴ reported the incidence of anterior subcapsular cataracts with ICL V4 in younger patients was 7.7%, whereas that with ICL V2, V3, or V4 in older patients was 47.7%. The US FDA trial showed that the incidence of anterior subcapsular cataract with ICL V4 was 2.7%.⁸ In this study, the patient age at the time of surgery was 47.2 ± 5.9 years (mean \pm SD), and model ICL V2, V3, and V4 were implanted through nine (38%) of 24 eyes, none (0%) of four eyes, and one (12%) of nine eyes in the cases complicated by cataract. Although we cannot refute the possibility that the early clinical results are influenced by the surgeon's learning curve, only two eyes (20%) developed cataract immediately after surgery, suggesting that the learning curve alone may not contribute to the higher rate of ICL V2-induced cataract. We assume that the higher rate of ICL V2-induced cataract was attributable to the higher patient age, as well as to the learning curve. In another study, we also compared the patient backgrounds of the group in which cataracts developed with those of the group in which they did not. The eyes with cataract were found in patients of significantly higher age (49.5 ± 6.0 years) than those without (42.2 ± 9.1 years), but the amounts of myopia did not differ significantly between the eyes with cataract (-14.3 ± 3.6 D) and those without (-13.9 ± 2.7 D).

The eyes with cataract (V2 69%, V3 13%, and V4 19%) were found to have ICLs with versions that were earlier than those in eyes without (V2 62%, V3 10%, and V4 29%). ICL V2 and V3 have now been withdrawn from the market, but our present findings are in good accordance with the earlier findings indicating that higher patient age and earlier versions of the ICL were risk factors for cataract development in ICL-implanted eyes. We assume that the rate of developing cataract with ICL V3 was higher than that with ICL V4 possibly because of a small sample size. The characteristics may also account for the higher incidence (43%) of developing cataracts in the overall population undergoing ICL implantation at that time than those in recent years.

With regard to the predictability of these combined procedures in eyes with ICL-induced cataract, Bleckmann *et al*¹⁰ stated that refractive error in no eyes ever exceeded the value of 1 D independent of the initial refraction or degree of hyperopia or myopia. Morales *et al*¹¹ reported that the percentage of eyes within ± 1.0 D of the targeted correction was 71.4%. In this study, we have shown that the percentage of eyes within ± 0.5 , and ± 1.0 D of the targeted correction after 3 months after surgery were 80, and 90%, respectively, which is in accordance with their earlier findings that the combined procedures offer high predictability of the intended correction. Hoffer *et al*¹⁸ reported that the greatest difference in A-scan axial length measurements will occur with a silicone IOL in an eye with very high hyperopia, and that the least difference will occur with a ICL in an eye with very high myopia. Morales *et al*¹¹ also stated that the difference between the axial length measurements before ICL implantation and those after was small. These findings may partly account for the higher predictability of these combined procedures.

Gimbel *et al*¹⁹ expressed the view that subjective patient information was as important as visual and refractive data because patient satisfaction would ultimately affect the future popularity of refractive surgery. Although patient satisfaction is known to be influenced by the status of the fellow eye, the UCVA of the fellow eye was excellent in six of these eight patients, because they had undergone bilateral ICL implantation. In this study, postoperative patient satisfaction, which was highly important for the future propagation of ICL implantation, was comparatively high, and no significant complications occurred during the observation period, supporting our view that these procedures are safe and effective for the treatment of ICL-induced cataract.

Nevertheless, the loss of accommodation in pseudophakic eyes was not negligible, especially for younger patients. It will be prominent in patients with a unilateral cataract, because there is little of depth of focus in the pseudophakic eye, but normal depth of focus in

the fellow eye. Interestingly, the mean age of the patients who developed ICL-induced cataract was 47.2 ± 5.9 (mean \pm SD) years, which is higher than that of the overall population who underwent ICL implantation. We have already shown that the accommodation of eyes with subcapsular cataracts was considerably lower than that of eyes without cataract even in ICL-implanted eyes.²⁰ We have also examined the amplitude of accommodation in patients aged 46–50 years old after ICL implantation, and found that it was 2.95 ± 1.88 D (mean \pm SD), which was not much different from that (apparent accommodation, 2.01 ± 0.92 D) in monofocal IOL-implanted eyes (unpublished data). As the higher patient age may lead to the lower amplitude of accommodation even in phakic eyes, the loss of accommodation in pseudophakic eyes may not be as severe as we presumed, and this may contribute to the high levels of subjective satisfaction.

It is known that the risk of retinal detachment after refractive lens exchange or cataract extraction has been increased in high myopic eyes. We found lattice degeneration without holes in two eyes, but did not perform any photocoagulation in these eyes during the follow-up period. Although we found no retinal detachment in this study, more prolonged observation is necessary.

In conclusion, our results support the view that simultaneous ICL removal and phacoemulsification with IOL implantation was safe and effective, and that the accuracy was predictable for the treatment of developing cataracts in ICL-implanted eyes. These combined surgical procedures also provided high levels of patient satisfaction. The results indicate that we had a viable surgical option even when a significant cataract occurred after ICL implantation, which was important for the prognosis of these complicated cases. A further study in a large series of patients is required to confirm these findings.

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