Long-term In Vivo Stability of Posterior Chamber Phakic Intraocular Lens: Properties and Light Transmission Characteristics of Explants

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• PURPOSE: To evaluate the in vivo durability of the surface and optical properties of the implantable Collamer lens (ICL).
• DESIGN: Retrospective case series.
• METHODS: We included patients who developed cataracts after having undergone ICL implantation from March 2003 to May 2014 and underwent ICL explantation followed by cataract surgery from March 2017 to December 2019 at the Nagoya Eye Clinic. ICL explants were submitted to Chukyo Medical Co, Ltd (Nagoya City, Japan) for laboratory analysis using ultraviolet-visible light spectroscopy, light microscopy (LM), and scanning electron microscopy. Patients' demographic and clinical data were collected and reviewed.
• RESULTS: Thirteen eyes from 10 patients were studied. The average age at ICL explantation was 50.5 ± 8.5 years (range, 34.5-66.3 years). The average length of ICL stay in the eye (from implantation to explantation) was 10.5 ± 2.7 years (range, 4.4-13.7 years). No opacification or coloring of the ICL explants was observed by LM. The ICL explants showed almost the same light transmittance as that of unused ICLs. Scanning electron microscopy revealed no irregularities at the surface of the center and periphery of the optic and haptic footplate. The positioning holes did not show any deposition.
• CONCLUSION: The ICLs remained in-eye for >10 years without any deterioration in the surface and optical properties of the ICL, despite their contact with the ciliary body and iris tissues and the continuous interaction with the aqueous humor components. The present study shows long-term in vivo stability of the ICL. (Am J Ophthalmol 2020;219:295–302. © 2020 Elsevier Inc. All rights reserved.)

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PHAKIC INTRAOCULAR LENSES (PIOLS) HAVE BEEN widely accepted worldwide as an effective treatment for correction of refractive errors.[1,2] Historically, the Chiron-Adatomed (Munich, Germany) lens[3,4] and phakic refractive lens (PRL; Zeiss Meditec, Jena, Germany),[5,6] which are posterior chamber pIOLs made of silicon, were first introduced on the market. Although their efficacy and safety were relatively good with respect to the clinical outcomes after implantation,[3–6] these lenses are not currently available on the market,[7] probably because of low usage. In contrast, the Visian implantable Collamer lens (ICL),[8] a posterior chamber pIOL, was introduced by STAAR Surgical (Monrovia, California, USA) in 1998 as the current version of V4, and has been accepted by many surgeons for over 20 years. As a result, STAAR Surgical announced in April 2019 that 1 million Visian ICLs had been implanted globally.[9] In 2005, the ICL became only foldable posterior pIOL that received approval by the US Food and Drug Administration,[10] and short-to long-term follow-up studies have reported good outcomes regarding its safety and stability.[11–14] However, complications requiring postoperative explantation have occurred in <2% of patients.[1,2] In a recent report investigating the causes of ICL explantation, the major cause was anterior subcapsular cataract (ASC) formation (36/52 eyes, 66%).[15] With recent device advancement—namely the introduction of ICLs with central holes (model V4c)—the incidence of ASC has been reduced to almost 0.[2] Therefore, the reliability of the device has been improved.

In the case of aphakic IOLs (apIOLs) used for cataract surgery, several manufacturers currently offer models with different designs and materials, such as acrylate and silicon. apIOLs have been explanted in <1% of patients after normal cataract surgery, mainly because of dislocation because of zonular fiber weakness.[16] In addition, because of manufacturing problems, such as inadequate formulation of the polymer, opacification (primary calcification) frequently occurs in apIOLs made of hydrophilic acrylic materials.[17] It has also been reported that opacification (secondary calcification) can occur because of patient-related causes, such as changes in the aqueous milieu surrounding the implanted apIOL associated with pre-existing or concurrent diseases.[17] Opacification after

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cataract surgery has been observed in apIOLs from several manufacturers, but it has also been reported to occur frequently in certain models.[18] In contrast, to date, there has been no report of ICL explantation because of deterioration of the material itself or opacification of explanted ICLs.

In the present laboratory study we investigated the surface and optical properties of ICLs explanted because of cataract development after long-term implantation. In addition, the durability and biocompatibility of the device are discussed.

METHODS

IN THIS RETROSPECTIVE CASE SERIES WE PERFORMED A LABoratory study on optical devices after long-term clinical use. The patients were recruited at the Nagoya Eye Clinic, while the laboratory analysis was performed at Chukyo Medical Co, Ltd (Nagoya, Japan). The study adhered to the tenets of the Declaration of Helsinki and was approved by the institutional review board of Nagoya Eye Clinic. Informed consent was obtained from all patients.

The study included patients who developed cataracts after having undergone ICL implantation for myopia and astigmatism correction from August 2003 to May 2014 and underwent ICL explantation followed by cataract surgery from March 2017 to December 2019 at the Nagoya Eye Clinic. Cataract type (ASC, posterior subcapsular cataract, or nuclear cataract [NC]) was evaluated by slit lamp examination (30SL-M; Carl Zeiss Meditec AG, Jena, Germany). Surgery for ICL explantation was indicated in patients with a decrease in corrected distance visual acuity (CDVA) to Snellen 20/28.6 or less. In addition, symptoms of blurred vision caused by the cataract were also an indication for surgery, even if visual function was not significantly impaired.

Patients' demographic and clinical data were collected. Clinical data included the following: date of ICL implantation, cause and date of explantation, ICL model, uncorrected DVA, CDVA, manifest spherical equivalent refraction, intraocular pressure, and endothelial cell density. In addition, the horizontal white-to-white distance, and anterior chamber depth were measured preoperatively using scanning-slit topography (OrbscanIIz; Bausch & Lomb, Rochester, New York, USA), and the mean keratometric readings and central corneal thickness were measured using an autorefractometer (ARK-700A; Nidek, Gamagori, Japan) and a pachymeter, respectively. Intraocular pressure was assessed using a noncontact tonometer (KT-500; Kowa, Tokyo, Japan). Endothelial cell density was determined by a noncontact specular microscope (SP-8800; Konan, Nishinomiya, Japan). The vault between the anterior surface of the crystalline lens and the posterior surface of the ICL was measured by anterior segment optical coherence tomography (CASIA2; Tomey Corp, Nagoya, Japan).

For the ICL implantation surgery, the appropriate power and size of the ICL was selected. The ICL power calculation was performed by STAAR Surgical based on subjective refraction, keratometry, and anterior chamber depth. In all eyes, emmetropia was targeted to correct the refraction error. The ICL size was also selected by the manufacturer. Specifically, we sent the anterior chamber depth and white-to-white distance measurements to STAAR Surgical, who then provided information regarding the recommended ICL size. The lens models used were the ICL V4, the Toric ICL V4, and the ICL V4c.

For the ICL explantation surgery, a 3-mm clear corneal incision was made first, and 2 types of ophthalmic viscosurgical devices (Opegan High, Santen Pharmaceutical Co, Ltd, Osaka, Japan; Healon V, Johnson & Johnson, New Brunswick, New Jersey, USA) were injected into the anterior chamber. The peripheral part of the optic was grasped so as not to damage it using ICL extraction forceps (ICL-Fcps AE-4447, Asico LLC, Westmont, Illinois, USA), and the ICL was removed via the incision. Next, the ICL explant was stored at room temperature in a small bottle containing sterilized buffered salt solution (BSS plus500, Alcon Japan Ltd, Tokyo, Japan), and was submitted to Chukyo Medical Co, Ltd, for laboratory analysis within 3 days.

The light transmission in the ultraviolet-visible region was measured using a ultraviolet-visible/NIR Spectrophotometer U-4100 (Hitachi Co, Tokyo, Japan). ICLs were evaluated microscopically and photographed under a stereo microscope (SZX-10, Olympus Co, Tokyo, Japan), and were subsequently examined using scanning electron microscopy (SEM). For electron microscopic fixation and observation, samples were chemically fixed with 2.5% glutaraldehyde, followed by dehydration with ethanol and drying by t-butanol freeze-drying method with a freeze dryer (VA-140S, Taitec, Koshigaya, Japan). Dried ICLs were sputter-coated with gold in an ion sputter MC1000 (Hitachi Co). SEM was performed with a Hitachi FlexSEM 1000 (Hitachi Co).

RESULTS

THIRTEEN EYES FROM 10 PATIENTS WERE INCLUDED IN THIS study. The patients' characteristics are summarized in Table 1. Of the extracted ICLs, 11 were model V4 and 2 were model V4c. The average age at ICL explantation was 50.5 ± 8.5 years (range, 34.5-66.3 years). The average period of ICL stay in the eye (from implantation to explantation) was 10.5 ± 2.7 years (range, 4.4-13.7 years). In all patients, the cause for ICL explantation was cataract; ASC and posterior subcapsular cataract in 5 eyes, ASC in 5 eyes, and NC in 3 eyes. Although 7 eyes had good CDVA (>20/

TABLE 1. Characteristics of the Patients and Eyes from Which Implantable Collamer Lenses Were Explanted

ICL Sample No.	Age at Explantation (Years)	Date of Implantation	Date of Explantation	Intraocular Stay Period (Years)	ICL Type	UDVA at Explantation (Decimal)	UDVA at Explantation (logMAR)	CDVA at Explantation (Decimal)	CDVA at Explantation (logMAR)	Cataract Type	Vault at Explantation
1	66.3	08/04/2003	03/08/2017	13.7	ICM-V4	0.6	0.221849	0.8	0.09691	ASC	0.292
2	50.3	05/28/2008	08/03/2018	10.3	ICM-V4	0.9	0.045757	1.2	−0.07918	ASC + PSC	0.191
3	50.3	05/29/2008	08/04/2018	10.3	ICM-V4	1	0	1.2	−0.07918	ASC + PSC	0.176
4	51.4	05/30/2014	09/07/2018	4.4	VICMO-V4c	1.2	−0.07918	1.2	−0.07918	NC	0.335
5	55.7	10/04/2006	12/11/2018	12.2	ICM-V4	1.5	−0.17609	1.5	−0.17609	ASC + PSC	0.157
6	55.7	07/05/2006	12/12/2018	12.5	ICM-V4	1.2	−0.07918	1.5	−0.17609	ASC + PSC	0.197
7	35.7	02/16/2006	12/21/2018	12.9	TICM-V4	0.7	0.154902	1.5	−0.17609	ASC + PSC	0.275
8	46.9	04/29/2007	03/01/2019	11.8	TICM-V4	0.6	0.221849	0.7	0.154902	ASC	0.261
9	46.9	05/03/2007	03/01/2019	11.8	TICM-V4	0.6	0.221849	0.7	0.154902	ASC	0.287
10	51.7	10/22/2010	06/12/2019	8.5	ICM-V4	0.5	0.30103	0.6	0.221849	ASC	0.3
11	56.6	03/27/2009	09/04/2019	10.5	ICM-V4	0.3	0.522879	0.7	0.154902	NC	0.574
12	54.2	07/24/2013	11/29/2019	6.4	VICMO-V4c	0.3	0.522879	0.8	0.09691	NC	0.536
13	34.5	05/03/2008	12/02/2019	11.7	TICM-V4	0.9	0.045757	1.5	−0.17609	ASC	0.583

ASC = anterior subcapsular cataract; CDVA = corrected distance visual acuity; ICL = implantable Collamer lens; logMAR = logarithm of minimal angle of resolution; NC = nuclear cataract; PSC = posterior subcapsular cataract; UDVA = uncorrected distance visual acuity.

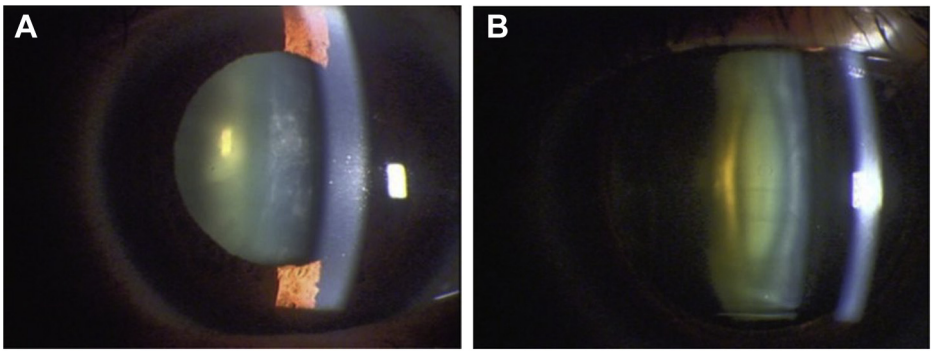

FIGURE 1. Slit lamp photographs of representative samples taken before cataract surgery. (A) A 51-year-old woman (sample 10) with anterior subcapsular cataract observed as white spot-type opacification. (B) A 51-year-old man (sample 4) with nuclear cataract, observed as white band-type opacification.

20), the ICLs were explanted because of patient complaints, such as problems with their daily life related to blurred vision or photophobia. The average vault at the time of ICL explantation was 0.32 ± 0.15 mm. Four eyes showed a low vault (<0.25 mm) and 9 eyes showed a moderate vault (0.25-1.0 mm). In 1 case (sample 5 in Table 1), the peripheral vault was almost 0 mm. When comparing V4 and V4c cases, V4c cases (samples 4 and 12 in Table 1) were explanted sooner (4-6 years) than those of V4 (≥10 years). Only 1 V4 case developed NC, whereas all V4c cases developed them. All cataracts in this study were associated with high myopia, and the direct effect of the implanted ICL was thought to be small. The cause of NC in V4c cases was unknown but may have been age-related.

In the slit lamp examination of the crystalline lens (Figure 1), no opacification of the lens was observed. No deposits could be confirmed for any of the cases. Laboratory examination by light microscopy showed no opacification or coloring of the explanted ICLs (Figure 2).

The optical transmission spectra of explanted ICLs and unused ICLs are shown in superposition in Figure 3A. All ICLs showed a transmittance of approximately 100% in the 400-800 nm wavelength range, and the transmittance dropped sharply in the wavelength region <400 nm. This indicated that the optical performance of the explanted ICL in terms of light transmission and the ultraviolet cut filter was unimpaired after long-term implantation. There was no difference in the transmission spectrum between ICL models V4 (Figure 3B) and V4c (Figure 3C) in the 360-800 nm wavelength range; however, in model V4c, a slight transmission (1%-2%) was observed in the range of 200-360 nm. This can be explained by the existence of a central hole in V4c. The diameter of this central hole was 0.36 mm, and the diameter of the light beam used to measure the transmittance of the ICL was 3 mm. Therefore, the area of the central hole was theoretically 1.44% of that of the measuring light beam, which corresponded to the actual transmittance because the measuring light beam passed through the central hole without being absorbed in any wavelength range. This meant that the central hole did not shrink or block because of deposition after long-term implantation.

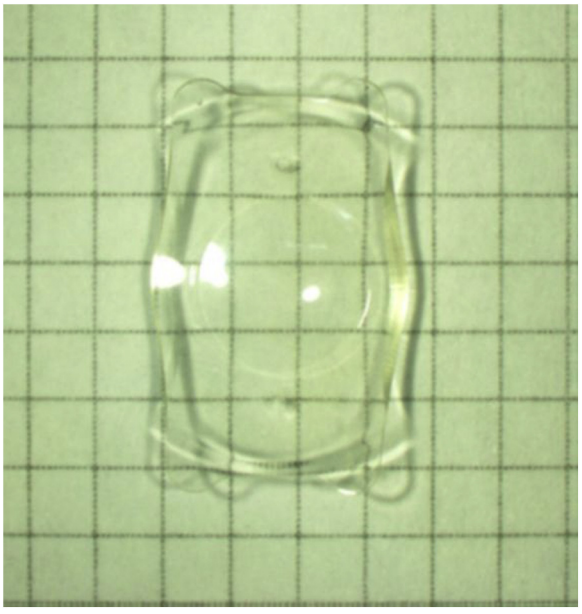

FIGURE 2. A light microscope image of the explanted implantable Collamer lenses (sample 7; intraocular stay, 12.9 years) showing no opacification.

The SEM examination revealed that the center of the optic (Figure 4A), the periphery of the optic (Figure 4B), and the haptic footplate (Figure 4C) demonstrated no irregularity. The positioning holes (Figure 4D) did not show any deposition. Even a high magnification of each position did not reveal any irregularities. Overall, no adhesion of proteins or other wastes or irregularities (changes in

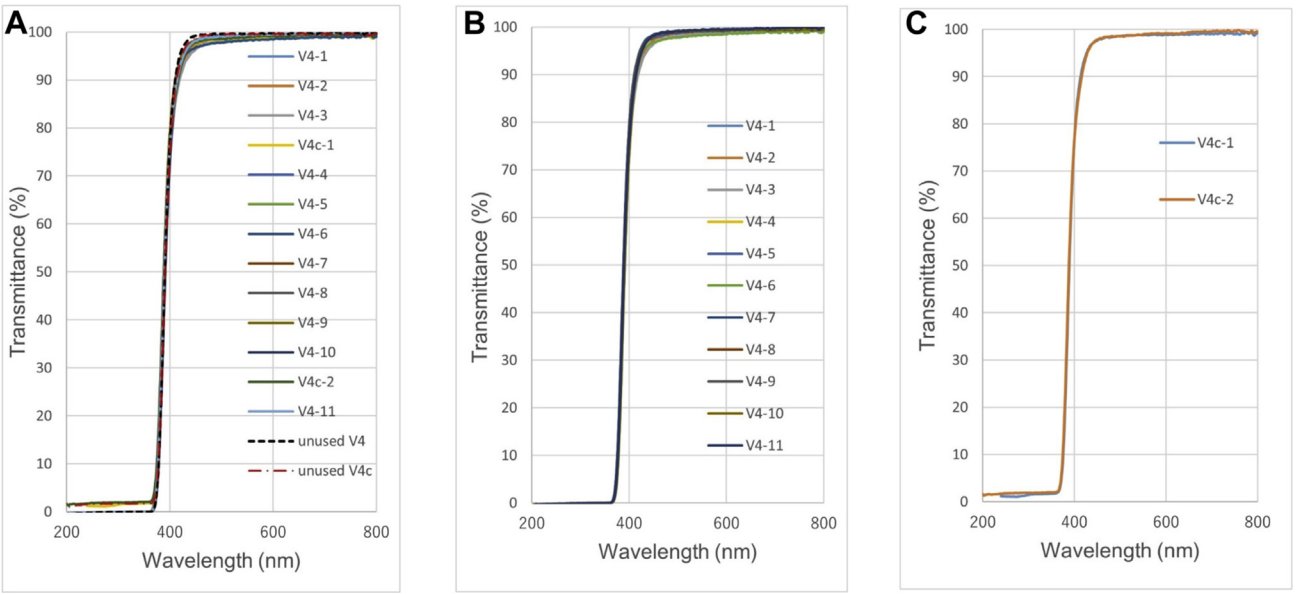

FIGURE 3. The transmission spectra (wavelength region, 200-800 nm) of the explanted implantable Collamer lenses (ICLs). (A) The spectra of the total ICL explants from 13 eyes (11 V4 and 2 V4c) are superimposed. The spectra of unused lenses (model V4 and V4c) are also shown as a control (broken line and chain line, respectively). (B) The spectra of ICL model V4 explanted from 11 eyes are superimposed. (C) The spectra of ICL model V4c explanted from 2 eyes are superimposed.

shape) could be attributed to deterioration of the lens surface layer.

DISCUSSION

IOLS IMPLANTED FOR CATARACT AND REFRACTIVE SURgery must be made of biomaterials that are easy to handle during surgery, have excellent biocompatibility, and have few postoperative complications. Seventy years have passed since apIOLs made of poly (methyl methacrylate) were used for cataract surgery. At present, with the improvement of lens designs and surgical methods, silicone, hydrophobic acrylate, and hydrophilic acrylate are mainly used as lens materials. These are well-known materials to which the immune system of the living host hardly reacts. In the 1980s, it was determined that coating the surface of a lens with another substance reduced the host's response to apIOLs.[19] Furthermore, a soft contact lens made by copolymerizing methacrylate with collagen was commercially available. Under these circumstances, in the 1990s, a foldable apIOL of a new material, termed Collamer, was introduced by STAAR Surgical. Collamer is a hydrophilic 2-hydroxyethyl methacrylate (HEMA)–based copolymer into which porcine collagen and chromophore are bonded.[20] The clinical results indicated that Collamer was safe and effective for apIOLs used in small-incision cataract surgery.[20] Sanders and associates[21] assessed the short-term safety, efficacy, and predictability of the ICL to treat moderate to high myopia. After the US Food and Drug Administration approved the ICL from clinical trials with a 3-year follow-up,[22,23] many researchers reported long-term clinical outcomes.[11–13] In a study with a long-term follow-up of >10 years, we have recently shown that ICL implantation offered good overall outcomes in all measures of safety, efficacy, predictability, and stability for correction of myopia and myopic astigmatism.[14] These follow-up studies certainly evaluated the in vivo functional stability of the ICL from the perspective of maintaining visual and refractive acuity; however, they did not directly evaluate the durability of the surface and optical properties of the ICL as a device in vivo. The present laboratory study on explanted ICLs showed for the first time that ICLs have long-term (≤13 years) in vivo durability.

Nonclinical studies conducted under investigational device exemption for US Food and Drug Administration submission by STAAR Surgical demonstrated acceptable biologic, toxicologic, engineering, and manufacturing results for the ICL and the Collamer apIOL.[10,20] However, these biocompatibility tests mainly focused on the effects of the IOL on the host and had a short-term follow-up. To the best of our knowledge, few clinical studies have investigated the effects of the host on the ICL, such as in vivo acceleration of degradation, breakage, and deformation of ICL materials. One of the reasons for the lack of such reports is that the evaluation methods of the in vivo durability of ICLs are not as defined as those for other

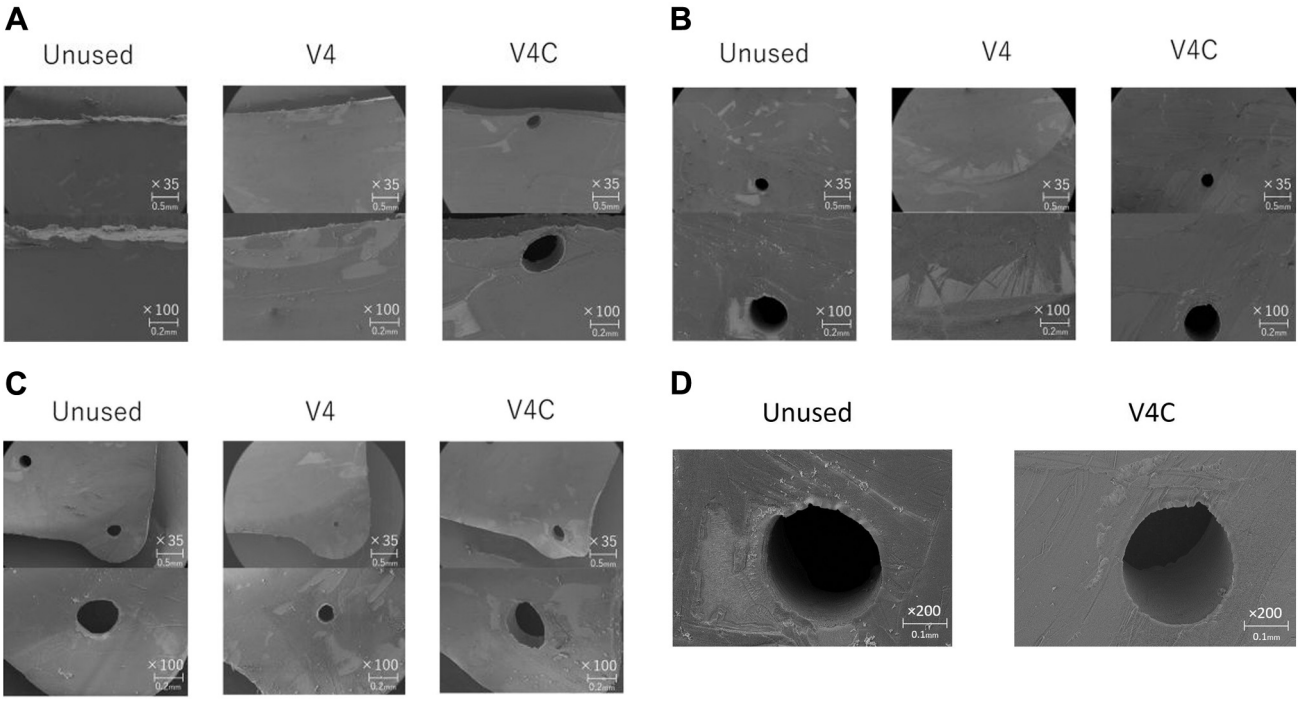

FIGURE 4. A scanning electron microscope image of explanted ICL V4 (sample 11; intraocular stay, 10.5 years), V4c (sample 12; intraocular stay, 6.4 years), and unused ICL. (A) The center of the optic. (B) The periphery of the optic. (C) The haptic footplate. (D) The positioning holes.

biomaterials and devices are. In addition, the main reason seems to be that most researchers are interested in the effect of the device on the host, although the durability of the device is recognized as being important.

Regarding in vitro ICL studies, Kohnen and associates[24] analyzed the surface quality of the ICL before implantation using light microscopy and SEM and determined that the surface was smooth, regular, and of excellent quality. Regarding explanted ICLs, Khalifa and associates[25] reported that pigment depositions were observed on the anterior surface of the ICL by light microscopy in ICLs explanted within 2 years after surgery from patients who developed ASC because of low vault. They suspected excessive interaction between the anterior surface of the ICL and the posterior surface of the iris, perhaps because of anterior displacement of the ICL haptics as a result of undersizing.[25] However, their study looked at the relationship between ASC and low vault rather than focusing on examining the degradation of ICL during implantation in vivo. In contrast to the cases described by Khalifa and associates,[25] where ASC developed relatively early after surgery, in our study cataract progressed slowly over a long period of approximately 10 years, and the surface of the explanted ICLs showed no damage or depositions. Thus, it was presumed that the contact between the ICLs and tissues such as the iris and crystalline lens was minimal. In addition, only model V4 and not model V4c ICLs were explanted because of ASC, and the average vault at the time of explantation was in the moderate range. In 1 case that had a slightly low central vault and scarce peripheral vault, the development of ASC may have been caused by poor aqueous humor circulation. In the remaining 9 cases, long-term metabolic deficiency, which was not identified, may have caused ASC generation. These findings were consistent with the results of our 10-year follow-up study, in which metabolism abnormality was postulated as the underlying mechanism of ASC.[14]

In contrast to the ICL, postoperative opacification associated with calcification has been observed on the surface of the optic, haptic, both, or the interior of the apIOL for cataract surgery, particularly in the case of hydrophilic acrylic apIOLs. Neuhann and associates[17] classified the pathologic calcification as primary calcification inherent to the apIOL itself and secondary calcification resulting from other circumstances. In addition, glistenings have been mainly associated with hydrophobic acrylic apIOLs. They are fluid-filled microvacuoles that form within the apIOL optic when the apIOL is in an aqueous environment, and factors influencing glistening formation include apIOL material composition, manufacturing technique, packaging, comorbidities, such as glaucoma or those leading to breakdown of the blood–aqueous barrier, and the concurrent use of ocular medications.[26] However, to date, there are no reports of calcification and glistening (or

whitening) by intraocular observation with a slit lamp in the case of ICLs. In fact, at our clinic, slit lamp observations of 2300 eyes with ICLs implanted since 2006 showed no signs of glistening, whitening, calcification, or change in color tone. In addition, there is no report of calcification in the case of nanoFLEXIOL (STAAR Surgical), which is an apIOL for cataract made of Collamer. Whether the absence of calcification and glistenings is specific to the Collamer material has not yet been considered. This is probably related to the fact that device manufacturing methods vary from manufacturer to manufacturer. This should be investigated in future studies.

Regarding biocompatibility, Schild and associates[27,28] reported that the absence of inflammatory cells 1 year after implantation and the minimal ongrowth of lens epithelial cells on the anterior surface from 1 day until 1 year postoperatively indicated good uveal and capsular biocompatibility of the Collamer apIOL, respectively. The small amount of collagen contained in the Collamer material seems to play an important role in biocompatibility. Linnola and associates[29] showed that fibronectin adhered well to hydrophobic apIOLs, such as AcrySof composed of poly (2-phenethy (meth) acrylate), whereas the amount of binding to hydrophilic apIOLs, such as hydrogel composed of HEMA, was reduced by half. Fibronectin is known to have a collagen-binding domain,[30,31] and therefore it can be predicted that Collamer material comprising HEMA and collagen binds more fibronectin than apIOLs made of HEMA. Furthermore, fibronectin is negatively charged (pI = 5.5-5.6) under physiologic conditions, and the Collamer covered with fibronectin carries enough negative charges to reduce protein adsorption in the aqueous humor and cell adhesion. Therefore it was expected that the adhesion of inflammatory cells and proliferation of lens epithelial cells on the anterior surface of Collamer apIOLs were suppressed. These findings were obtained for the Collamer apIOL, which was implanted in the lens capsule for cataract surgery; thus, similar or better biocompatibility could be expected for ICLs placed in the posterior chamber, anterior to the crystalline lens, whose optic surface was exposed to the aqueous humor.

Finally, because ICLs are usually implanted in young patients between 20-30 years of age, they remain in the eye for about 30 years before explantation because of cataract development. Therefore, to ensure long-term safety and visual efficacy for patients who have implanted ICLs, it is important to guarantee the safety, stability, and durability of ICLs by further examination of isolated ICLs and follow-up observation of implanted ICLs. Like the acrylic apIOL that is the current mainstream, we think that the properties of the ICL will be maintained for a long time in vivo, confirming its durability.

This study was limited by the small number of explanted ICLs that could be tested in the laboratory. In the future, it is necessary to investigate a greater number of explanted model V4 ICLs, which would also enable including a greater number of patients with longer in-eye lens stay periods, to verify the durability up to 20 years.

In conclusion, we showed for the first time that implanted ICLs V4 remained in the eye for >10 years without any deterioration in the surface and optical properties of the Collamer, despite the contact with the ciliary body and iris tissues and the continuous interaction with the aqueous humor components. Furthermore, the present results guarantee the long-term stability of the ICL, which is one of the requirements of biomaterials in refractive surgery.

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