



Large capsulorhexis with implantation of a 7.0 mm optic intraocular lens during cataract surgery in patients with diabetes mellitus

Yoshihiro Takamura, MD, PhD, Takeshi Tomomatsu, MD, PhD, Satoshi Yokota, MD, Takehiro Matsumura, MD, PhD, Yuji Takihara, MD, PhD, Masaru Inatani, MD, PhD

PURPOSE: To evaluate the efficacy of a large capsulorhexis and intraocular lens (IOL) in obtaining a larger anterior capsule opening after cataract surgery in patients with diabetes mellitus (DM).

SETTING: Department of Ophthalmology, University of Fukui, Fukui, Japan.

DESIGN: Prospective clinical trial.

METHODS: Patients with DM had bilateral cataract surgery with a 2.8 or 3.0 mm scleral incision, a capsulorhexis with a diameter of approximately 5.0 or 6.0 mm, and implantation of a 6.0 mm optic (Eternity X-60) or 7.0 mm optic (Eternity X-70) IOL. The anterior capsule opening area, aqueous flare intensity, surgically induced astigmatism (SIA), corneal endothelial cell density (ECD), and central corneal thickness (CCT) were measured 1 day, 1 week, and 1, 3, and 6 months after surgery.

RESULTS: Thirty-one patients (62 eyes) with DM were enrolled. At all postoperative timepoints, the anterior capsule opening was significantly larger in eyes with the 7.0 mm optic IOL than in eyes with the 6.0 mm optic IOL ($P < .05$, Mann-Whitney U test). There were no significant differences in postoperative aqueous flare intensity, SIA, ECD, or CCT based on the size of the capsulorhexis and IOL.

CONCLUSION: A larger capsulorhexis and implantation of a 7.0 mm IOL resulted in a larger anterior capsule opening after cataract surgery in patients with DM.

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Contraction of the anterior capsule opening is one of the most common ocular complications associated with modern cataract surgery. Capsule opacification

occurs as a result of the proliferation, migration, and differentiation of residual lens epithelial cells (LECs),¹ and anterior capsule contraction results in a smaller optic zone area. The presence of diabetes mellitus (DM),^{2,3} uveitis,⁴ pseudoexfoliation syndrome,⁵ and pigmentary retinal degeneration⁶ are putative risk factors for the progression of anterior capsule contraction. From a clinical standpoint, poor pupil dilation and severe anterior capsule opening shrinkage are especially important in patients with DM because these factors can interfere with postoperative funduscopy, photocoagulation of the peripheral retina, and vitreous surgery. Capsule retraction can lead to decentration of the intraocular lens (IOL).

Several clinical trials have studied how to prevent postoperative progression of anterior capsule contraction. Hayashi et al.⁷ report that 3 neodymium:YAG

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From the Department of Ophthalmology (Takamura, Tomomatsu, Yokota, Matsumura, Takihara, Inatani), Faculty of Medical Sciences, University of Fukui, Fukui, and the Department of Ophthalmology and Visual Sciences (Yokota), Kyoto University Graduate School of Medicine, Kyoto, Japan.

Corresponding author: Yoshihiro Takamura, MD, PhD, Department of Ophthalmology, Faculty of Medical Sciences, University of Fukui, Eiheiji-cho, Yoshida-gun, Fukui-ken, 910-1193, Japan. E-mail: ytakamura@hotmail.com.

(Nd:YAG) relaxing incisions made in the anterior capsule rim were effective in preventing anterior capsule contraction after cataract surgery. However, this treatment can lead to complications, such as transient intraocular pressure elevation, iritis, corneal edema, and IOL pitting. Alternatively, because the remaining LECs may undergo fibrous metaplasia with capsule opacification, removal of residual LECs by polishing under the anterior capsule is effective in reducing postoperative anterior capsule contraction.⁸ However, in a study by Shah et al.,⁹ capsule polishing induced advanced inflammation; thus, the preventive effect may be temporary.

Continuous curvilinear capsulorhexis (CCC) is one of the most important techniques for minimizing the incidence of radial tear formation, maintaining the integrity of the central opening and centration of posterior chamber IOLs.^{10,11} Evidence suggests that posterior capsule opacification (PCO) is reduced when the CCC diameter is slightly smaller than that of the IOL optic so the edge of the anterior capsule rests on the IOL optic. It has been reported that the rate of the postoperative change in the anterior capsular opening is not related to the initial CCC size.¹² Therefore, it is possible that a smaller capsulorhexis results in greater loss of the anterior capsule opening area. The creation of a larger CCC may have the advantage of maintaining a wide anterior capsule opening after cataract surgery, even if anterior capsule contraction progresses in the eyes of patients with DM.

In this prospective study, we created a CCC with a diameter of 5.0 mm or 6.0 mm and implanted an IOL with an optic diameter of 6.0 mm or 7.0 mm. One eye of each patient received the smaller CCC and smaller IOL, and the contralateral eye received the larger CCC and larger IOL. We assessed the influence of CCC size and IOL optic diameter on the progression of anterior capsule opening shrinkage.

PATIENTS AND METHODS

This clinical trial was approved by the University of Fukui Institutional Review Board and complied with the tenets of the Declaration of Helsinki. The protocol and the possible risks and benefits of the interventions were explained to all participants before enrollment. All patients gave written informed consent. This study was registered with the University Hospital Medical Information Network Clinical Trials Registry of Japan.^A

Patients with noninsulin-dependent DM who were scheduled to have binocular cataract surgery were prospectively approached and invited to participate in the study. Diabetic retinopathy (DR) was diagnosed by specialists using fundoscopic images. Eyes with proliferative DR were excluded from the study. The grade of lens opacity was estimated using the Lens Opacities Classification System III.¹³ No eye had a history of ocular surgery. Eyes were excluded if they had pseudoexfoliation, pigmentary retinal degeneration,

high myopia, or uveitis, all of which are known risk factors for anterior capsule contraction.⁴⁻⁶

Randomization and Intraocular Lenses

A foldable IOL with a round 6.0 mm optic (Eternity X-60, Santen, Inc.) or a 7.0 mm optic (Eternity X-70, Santen, Inc.) was implanted in the first eye or the second eye to have surgery. Right eyes and left eyes were randomized as follows: The first patient had implantation of the 6.0 mm optic IOL in the right eye first and then of the 7.0 mm optic IOL in the left eye. The second patient had implantation of the 6.0 mm optic IOL in the left eye first and then of the 7.0 mm optic IOL in the right eye. This cycle was repeated throughout the study. Both IOLs are foldable, 3 piece, and hydrophobic acrylic with a 4% water content. They are made of hydroxyethyl methacrylate, polyethylene glycol phenyl ether acrylate, and styrene crosslinked with ethylene glycol dimethacrylate. Both have a square-edged design with an overall diameter of 12.75 mm (6.0 mm optic IOL) or 13.20 mm (7.0 mm optic IOL).

Surgical Technique

The same surgeon (T.T.) performed all cataract procedures at Fukui University Hospital between August 9, 2012, and March 4, 2013. During cataract surgery, a 2.4 mm scleral incision and a CCC approximately 5.0 mm or 6.0 mm in diameter for implantation of the 6.0 mm optic IOL or 7.0 mm optic IOL, respectively, were made. After hydrodissection, phacoemulsification of the nucleus and cortical aspiration were performed. The anterior chamber was filled with an ophthalmic viscosurgical device (OVD) and the incision enlarged to 2.8 (6.0 mm IOL group) or 3.0 mm (7.0 mm IOL group). One of the 2 IOL models was implanted in the capsular bag using a dedicated injector (XJ-60 or XJ-70, Santen, Inc.), and the OVD was washed out. If the CCC was too small, it was enlarged by creating a double CCC. One day after surgery, the CCC edge was confirmed to be completely covering the IOL optic; if not, the eye was excluded from analysis.

No patient was treated with an Nd:YAG laser posterior capsulotomy after cataract surgery. Postoperatively, all patients received diclofenac sodium, fluorometholone, and ofloxacin 3 times daily for 1 month.

Patient Assessment

The anterior capsule opening area was determined by diaphanoscopy using the EAS-1000 anterior eye segment analysis system (Nidek Co., Ltd.) 1 day, 1 week, and 1, 3, and 6 months postoperatively. The area was calculated from Scheimpflug images using software included in the system. The percentage reduction in the anterior capsule opening 3 months after surgery was calculated as follows: (anterior capsule opening 1 day after surgery – anterior capsule opening 3 months after surgery) × 100/anterior capsule opening 1 day after surgery. Anterior flare intensity was measured using a laser flare-cell meter (FC-1000, Kowa Co., Ltd.) before surgery and 1 day, 1 week, and 1, 3, and 6 months after surgery. Ten measurements were taken 30 minutes after the application of tropicamide 0.5%-phenylephrine hydrochloride 0.5% (Mydrin P) and averaged to obtain the final flare-intensity results. At the same timepoint, the central corneal thickness (CCT) and surgically induced astigmatism (SIA) were measured and calculated

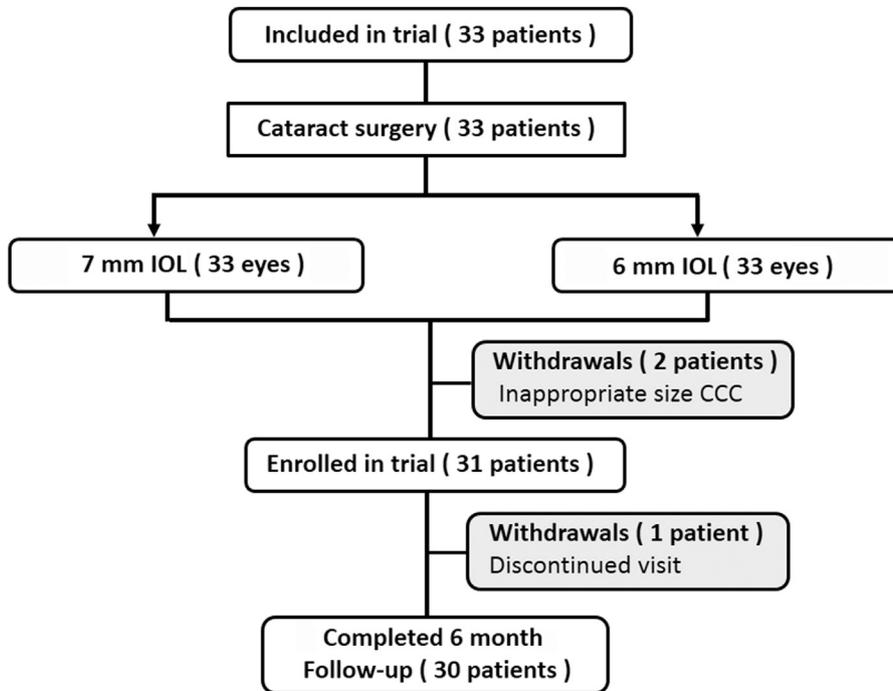


Figure 1. Study design and progression of patients through the trial (CCC = continuous curvilinear capsulorhexis, IOL = intraocular lens).

automatically by an anterior segment optical coherence tomography system (SS-1000, Casia, Tomey Corp.). To minimize measurement error, the same experienced examiner (S.A.) performed all tests. The examiner was masked to the treatment status, including to the random allocation of the 2 IOL models, and at what postoperative time the examiner performed the tests.

Statistical Analysis

Statistical analyses were performed using JMP 10 software (SAS Institute, Inc.). Data are expressed as means \pm standard deviations. Differences in the grading of the lens nucleus, surgical time, rate of anterior capsule contraction, and aqueous flare intensity between the eyes were analyzed using the Mann-Whitney *U* test. In each eye, the rate of anterior capsule contraction and aqueous flare intensity before surgery and 1 day and 1, 3, and 6 months after surgery were compared using the Wilcoxon signed rank test. Differences with a *P* value less than 0.05 were considered statistically significant.

RESULTS

Thirty-three patients with noninsulin-dependent DM had bilateral cataract surgery. **Figure 1** shows the study design and the progression of patients through the trial. **Table 1** shows the characteristics of the patients and the eyes. There were no statistically significant differences in lens nucleus grade or surgical time between the 6.0 mm IOL group and the 7.0 mm IOL group. In 2 eyes in the 7.0 mm IOL group, the CCC edge 1 day after surgery did not cover the entire

IOL optic; these patients were excluded from the study. The results in the remaining 31 patients (62 eyes) are reported. One patient did not attend the 6-month postoperative visit. A double CCC was

Table 1. Baseline patient demographics.

Parameter	Result	<i>P</i> Value*
Mean age (y) \pm SD	70.4 \pm 7.2	—
Male patients (%)	45.5	—
Mean duration of DM (y) \pm SD	11.4 \pm 3.5	—
Mean hemoglobin A1c (%) \pm SD	6.9 \pm 1.1	—
Diabetic retinopathy (%)		
6.0 mm optic IOL	48.4	.73
7.0 mm optic IOL	45.2	
Lens nucleus (%)		.65
Grade 2		
6.0 mm optic IOL	12.9	
7.0 mm optic IOL	9.7	
Grade 3		
6.0 mm optic IOL	67.7	
7.0 mm optic IOL	64.5	
Grade 4		
6.0 mm optic IOL	19.4	
7.0 mm optic IOL	25.8	
Mean surgical time (min)		.65
6.0 mm optic IOL	13.4 \pm 3.4	
7.0 mm optic IOL	14.1 \pm 3.9	

DM = diabetes mellitus; IOL = intraocular lens

*Mann-Whitney *U* test

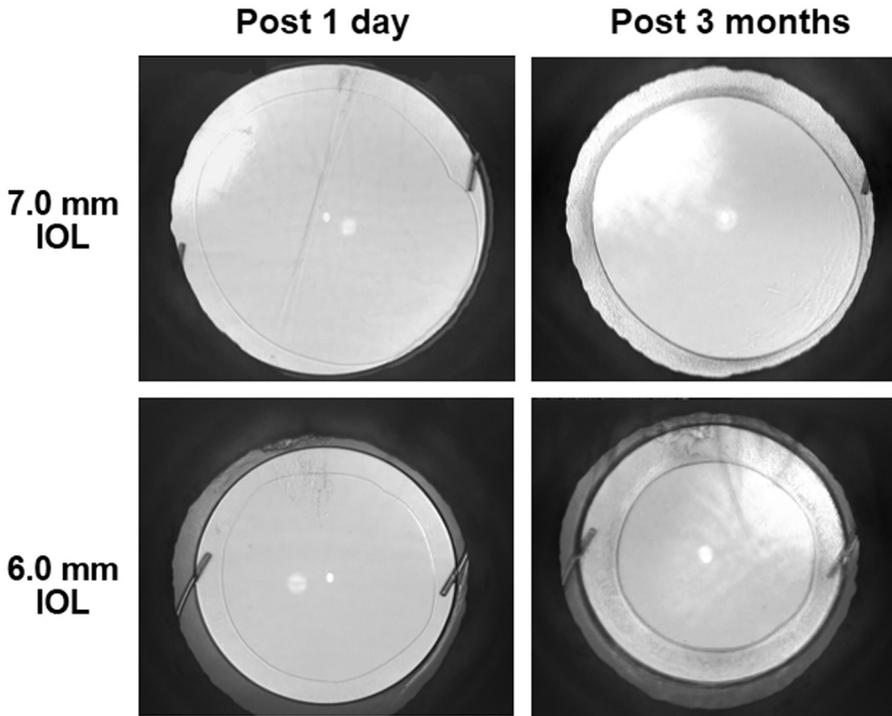


Figure 2. Representative images photographed by the EAS-1000 anterior eye segment analysis system at 1 day and 3 months (IOL = intraocular lens).

created in 7 eyes (22.6%) in the 6.0 mm IOL group and in 12 eyes (38.7%) in the 7.0 mm IOL group.

The mean anterior capsule opening area on the first postoperative day was statistically significantly larger in the 7.0 mm IOL group ($28.2 \pm 3.6 \text{ mm}^2$) than in the 6.0 mm IOL group ($20.3 \pm 1.9 \text{ mm}^2$) (Figures 2 and 3, A). One, 3, and 6 months after surgery, the anterior capsule opening area in all eyes in the 6.0 mm IOL

group and all eyes in the 7.0 mm IOL group was statistically significantly smaller than 1 day after surgery (1 day versus 1 month: $P = .028$ and $P = .027$, respectively; 1 day versus 3 months: $P = .024$ and $P = .025$, respectively; 1 day versus 6 months: $P = .022$ and $P = .026$, respectively; Wilcoxon signed rank test). The anterior capsule opening area was statistically significantly larger in the 7.0 mm IOL group than in

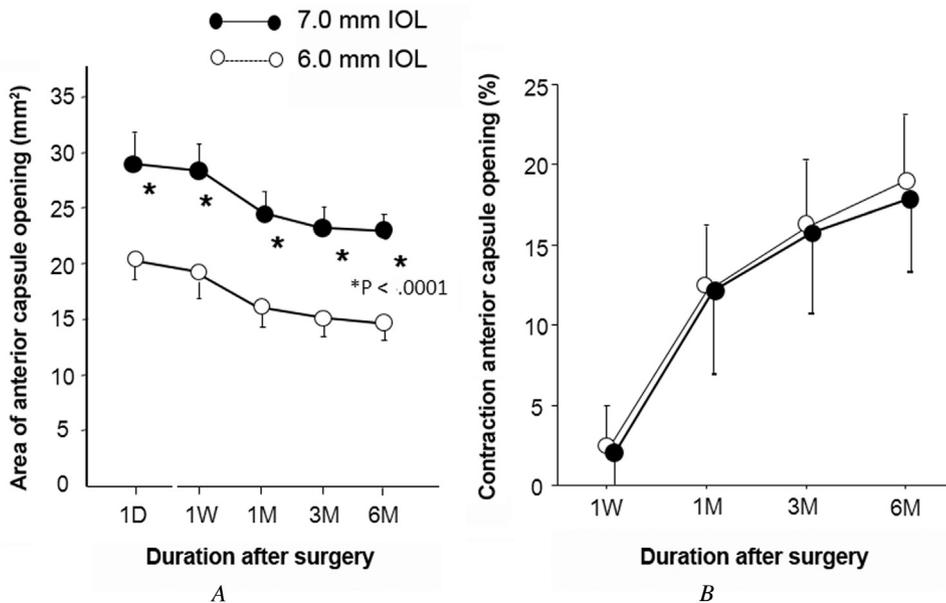


Figure 3. Changes in the anterior capsule opening (A) and its contraction rate (B) over time (IOL = intraocular lens).

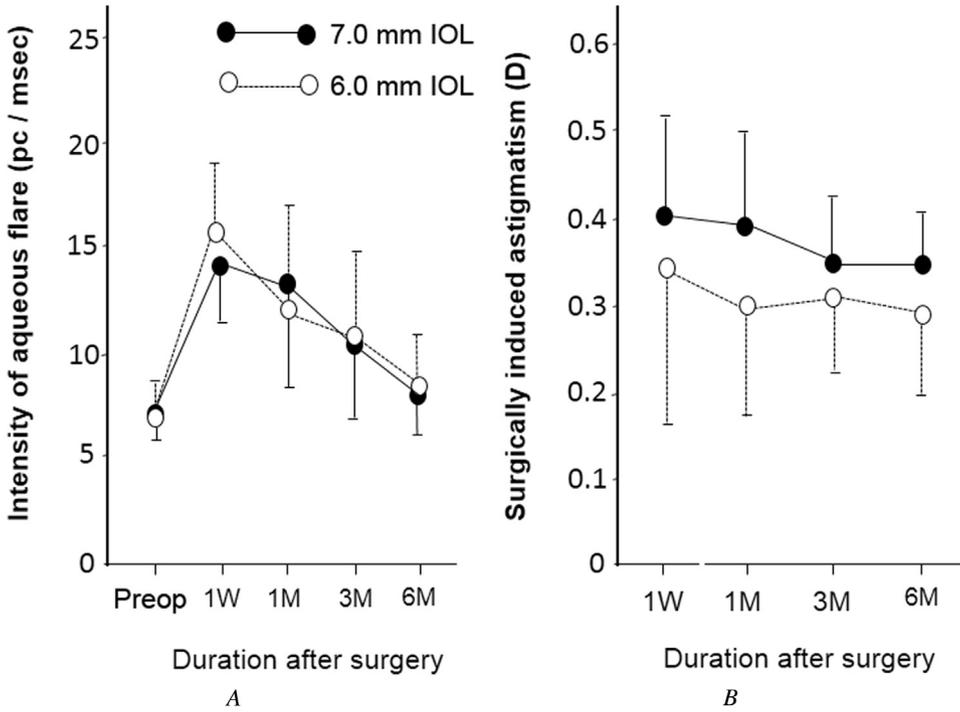


Figure 4. Changes in aqueous flare intensity (A) and SIA (B) (IOL = intraocular lens).

the 6.0 mm IOL group throughout the study ($P < .0001$, Mann-Whitney U test). The difference in the rate of anterior capsule opening contraction between the 2 IOL groups was not statistically significant at any timepoint (Figure 3, B).

Figure 4, A, shows the changes in aqueous flare intensity after surgery. Aqueous flare intensity values in both IOL groups were higher 1 week after surgery and lower thereafter. There were no statistically significant

differences in aqueous flare intensity levels between the eyes with the 6.0 mm optic IOL and eyes with the 7.0 mm optic IOL. Surgically induced astigmatism in the 7.0 mm IOL group tended to be greater than in the 6.0 mm IOL group; however, the difference was not statistically significant at any timepoint (Figure 4, B). Also, there were no statistically significant differences in the density of corneal endothelial cells or in the CCT between the 2 IOL groups (Figure 5).

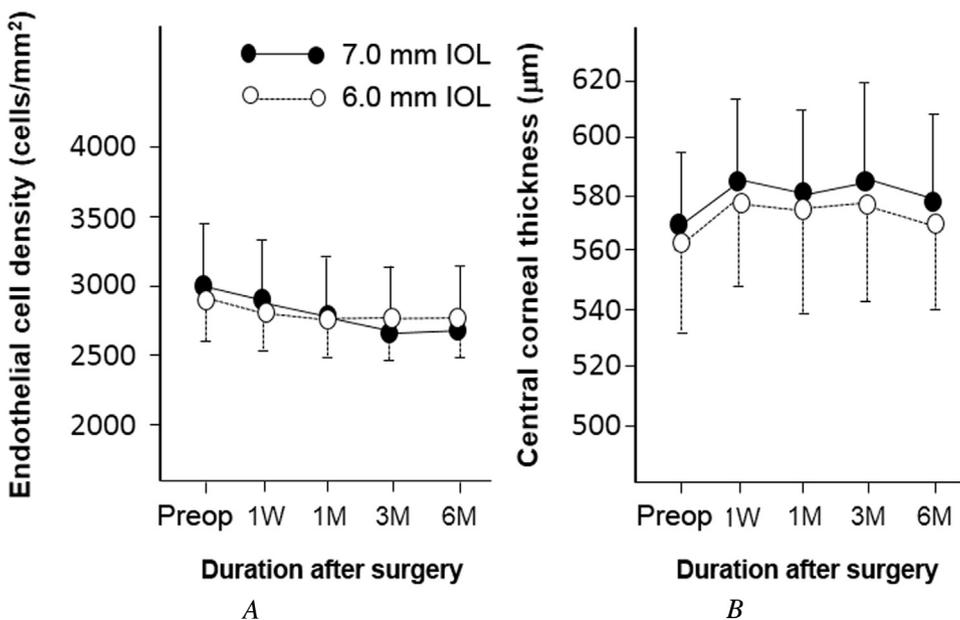


Figure 5. Changes in ECD (A) and CCT (B) (CCT = central corneal thickness; ECD = endothelial cell density; IOL = intraocular lens).

DISCUSSION

In this prospective study, we compared the postoperative temporal profile of the anterior capsule opening in eyes of patients with DM and found that a large capsulorhexis and implantation of a large-diameter IOL resulted in a larger anterior capsule opening. Because a wide scleral incision was required to insert the 7.0 mm optic IOL, this technique may be more surgically invasive. However, the difference in postoperative anterior inflammation, SIA, and loss of corneal endothelial cell density (ECD) were insignificant. Thus, this procedure seems to be safe and does not seem to contribute to surgical complications.

The progression of anterior capsule contraction, flare intensity, and corneal damage could be influenced by the presence and severity of DM or DR. We, along with several other investigators, showed that anterior capsule opening shrinkage and anterior inflammation after cataract surgery are associated with the severity of preoperative DR.¹⁴ Because the progression of DR is affected by the duration of diabetes and the adequacy of glycemic control, these factors probably influence the progression of anterior capsule opening shrinkage. Also, the presence of DM results in a significant delay in the postoperative recovery from corneal edema and loss of corneal ECD.¹⁵ Thus, direct comparisons between the eyes of individual patients are valid even if patients with varying degrees of DM and DR are recruited. In this study, we compared the anterior capsule opening in the left eye and right eye of the same patient. Therefore, despite the small scale of the study, our data can be considered reliable.

A CCC smaller than the diameter of the IOL optic is associated with less PCO and helps achieve good IOL fixation and centration. Thus, the use of a large-diameter IOL is reasonable when a larger CCC is created. In this study, CCCs were approximately 1.0 mm smaller than the IOL. To perform this procedure accurately, we used a 2-stage double CCC technique, which has several advantages. First, because the CCC is enlarged after the IOL is implanted in the capsular bag, the IOL edge helps guide CCC sizing and positioning. Second, this technique helps prevent tears from the anterior capsule edge to the zonular fibers. A more convex anterior lens surface is associated with more tearing during capsulorhexis creation.¹⁶ After lens extraction, the convexity of the anterior surface flattens, resulting in more resistance to radial tear formation.

A sharp optic edge plays an important role in preventing PCO.^{17,18} On the other hand, it remains controversial whether a sharp-edged IOL is associated with the progression of anterior capsule contraction. Sacu et al.^{19,20} report that sharp-edged IOLs led to more severe anterior capsule contraction than round-edged IOLs. In contrast, Miyata et al.²¹ found that sharp-

edged IOLs did not appear to be a risk factor for anterior capsule contraction. Moreover, severe anterior capsule contraction was found to be more likely with the use of silicone IOLs than with poly(methyl methacrylate) or foldable acrylic IOLs.²² These findings suggest that edge design and IOL material influence the progression of anterior capsule opening shrinkage. Because the Eternity X-60 IOL and Eternity X-70 IOL differ only in the size of the optic, the influence of optic-edge design and IOL material on the progression of anterior capsule opening shrinkage is insignificant.

Microincision cataract surgery can reduce SIA, the need for suturing, and the time required for recovery of visual function.^{23,24} Kim et al.²³ found that a 2.75 mm incision induced less incisional corneal edema at 1 week, but more astigmatism at 2 months, than a 1.80 mm or 2.20 mm incision. Berdahl et al.²⁵ also found that phacoemulsification using the torsional handpiece through a 2.2 mm incision was associated with less cumulative ultrasound energy and less endothelial cell loss than a 2.8 mm incision. In this study, we created 2.8 and 3.0 mm scleral incisions for implantation of a 6.0 mm optic IOL and a 7.0 mm optic IOL, respectively, and found no significant difference in the degree of complications, such as SIA, flare intensity, and corneal damage. However, a microincision that is 2.4 mm or smaller may provide more favorable clinical outcomes than a conventional 2.8 mm or 3.0 mm incision. It has been reported that the Eternity X-70 IOL can be inserted through a 2.45 mm incision using an IS injector and Type E-1 cartridge (Hoya Corp.).²⁶ Further studies are needed to confirm the safety and efficacy of implanting a large IOL through a microincision.

In conclusion, implantation of a 7.0 mm optic IOL using a larger CCC led to a larger anterior capsule opening, which may be advantageous for examination and photocoagulation of the peripheral retina. Based on our data, the double CCC contributed to the enlargement of the anterior capsule opening, indicating that this technique is beneficial because it allows the surgeon to adjust the size of the CCC during cataract surgery.

WHAT WAS KNOWN

- Eyes of patients with DM have significant shrinkage of the anterior capsule opening after cataract surgery.

WHAT THIS PAPER ADDS

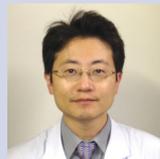
- The creation of a larger capsulorhexis with implantation of a 7.0 mm optic IOL contributed to a larger anterior capsule opening after cataract surgery in patients with DM.

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First author:

Yoshihiro Takamura, MD, PhD

Department of Ophthalmology, Faculty of Medical Sciences, University of Fukui, Fukui, Japan