

Long-term outcomes of transsclerally sutured intraocular lens correctly fixed in the ciliary sulcus

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ABSTRACT

Objective To report the long-term postoperative outcomes of transsclerally sutured intraocular lenses (IOLs), in which the haptics were correctly fixated into the ciliary sulcus using an auxiliary device and endoscope.

Methods and analysis Data were collected from eyes that were followed up for at least 12 months after ciliary sulcus suture fixation of an IOL using an auxiliary device for securely placing the IOL haptics to the ciliary sulcus, which was confirmed using intraoperative endoscopy in all cases. The corrected distance visual acuity (CDVA), refractive error, anterior chamber depth (ACD), IOL decentration and tilt, corneal endothelial cell density (CECD) and postoperative complications were recorded. ACD and IOL deviations were compared with those of normal controls after standard cataract surgery.

Results A total of 146 eyes of 142 patients were included, with a mean follow-up period of 56.0±35.3 (range 12–174) months. Postoperative CDVA from 1 month to 8 years and final CDVA were significantly better, and the mean refraction error, ACD and CECD decline rate were -0.71 ± 0.75 dioptre, 4.01 ± 0.37 mm and $-7.4\%\pm16.0\%$, respectively. Compared with normal controls, ACD was not significantly different but the tilt and decentration were significantly different. The main postoperative complications included vitreous haemorrhage (24.0%), suture thread exposure (19.2%) and corectopia (18.5%). There were no cases of IOL dislocation due to suture breakage or postoperative endophthalmitis.

Conclusion Long-term postoperative outcomes were favorable with good CDVA and without IOL dislocation and endophthalmitis. The significance and value of fixing haptics to the ciliary sulcus should be re-evaluated.

INTRODUCTION

In the absence of zonular support, the intraocular lens (IOL) is implanted by employing several techniques such as anterior chamber (AC) IOL, iris fixation IOL, transscleral suture fixation of posterior chamber IOL (PCIOL), and intrascleral fixation of PCIOL. These techniques have equivalent visual acuity outcomes and their own set of complications, and no single technique is superior to the others.¹

The site of transscleral suturing is either pars plana^{2 3} or ciliary sulcus.^{4–9} Although

Key messages

What is already known on this topic?

► In the transsclerally sutured intraocular lens (IOL), there was no report confirmed intraoperatively that the haptics were correctly fixed to the ciliary sulcus by endoscope and IOL dislocation due to suture breakage has become a problem in the late postoperative period.

What this study adds?

► We reported the long-term outcomes of transsclerally sutured IOLs which confirmed intraoperatively with an endoscope that the haptics were correctly fixed in the ciliary sulcus. The postoperative visual acuity was very good for a long time, IOL dislocation and endophthalmitis were not observed and there were fewer serious postoperative complications than previously reports. It is beneficial to fix haptics in the ciliary sulcus.

How this study might affect research, practice or policy?

► In the transsclerally sutured IOL, the significance and value of fixing haptics to the ciliary sulcus will be re-evaluated and using our technique will improve the long-term postoperative results.

pars plana suture fixation has been used pars plana is anatomically not an appropriate place to secure IOL haptics, because deterioration of suture materials can result in IOL dislocation. In addition, because the IOL is fixed at only two points, there may be always a risk of IOL tilting.

The ciliary sulcus seems more physiologically suitable than the pars plana as the site of suture fixation of IOL haptics,^{10 11} but it is not possible to perform needle penetration under direct visual guidance. Therefore, in many previous reports,^{4–9} it remained unclear whether the suture was placed correctly in the ciliary sulcus. Pavlin *et al*¹² reported successful haptic fixation to the ciliary sulcus in 38% of patients who underwent surgery with the intention of ciliary sulcus suture fixation. Kamal *et al*¹³ reported that successful haptic

fixation to the ciliary sulcus was achieved in 31% and 29% of patients who underwent surgery with the intention of ciliary sulcus suture fixation from outside and inside the eye, respectively.

By analysing the anatomical morphology of the ciliary sulcus in living eyes using ultrasound biomicroscopy and endoscopy,¹⁴ we developed an injector (Ciliary Sulcus Pad Injector; Duckworth & Kent, Baldock, UK,) to facilitate accurate suturing to the ciliary sulcus without direct observation.¹⁵ Using this device, the needle correctly pierced the ciliary sulcus in a single attempt in 91.4% of cases.^{15 16}

Considering that the indication for cataract surgery is expanding to younger patients and the patients' life expectancy is increasing, it is critical to learn the long-term outcomes of IOL implantation in eyes with deficient capsular support. Furthermore, in recent years, several long-term outcomes of more than 10 years after surgery have been reported,^{17–19} and IOL dislocation due to suture breakage has become a problem in the late postoperative period.¹⁷

In this study, we aimed to assess the long-term outcomes of transscleral suture fixation of IOLs, in which ciliary sulcus suturing was performed using a specialised injector and the site of fixation was confirmed intraoperatively with the endoscope.

METHODS

This study design is a retrospective, comparative, interventional case series. The inclusion criteria were aphakia with deficient capsular support, a dislocated IOL and a subluxated crystalline lens. We included patients who used the IOLs of NR81K (NIDEK, Gamagori, Japan) and CZ70BD (Alcon, Geneva, Switzerland) which were specialised for transscleral suture fixation and who had a minimum follow-up period of 12 months. The exclusion criteria were that the observation period was less than 12 months and that IOLs other than NR81K and CZ70BD were used.

The preoperative ocular pathologies of transsclerally sutured IOL group were examined. The eyes undergoing standard cataract surgery, without any ocular pathologies other than age-related cataracts, served as normal controls. As the IOL of controls, we selected AN6KA (KOWA Co, Nagoya, Japan) whose overall length is close to that of NR81K (NR81K: 12.75 mm, AN6KA: 13.0 mm).

All patients underwent the same procedure¹⁵ (online supplemental video S1) performed by the same surgeon (TS) at the Sugiura Eye Clinic between November 2006 and April 2020. The surgery^{15 16} was performed using the aforementioned injector, and accurate piercing of the ciliary sulcus and precise fixation of the haptics to the ciliary sulcus were confirmed intraoperatively in all cases using an endoscope (online supplemental figure S1). The needle was passed through the sclera in a half layer and the suture was ligated on the scleral surface. A suture thread of approximately 5 mm was left on the scleral surface and placed under the conjunctiva to prevent it

from penetrating the conjunctiva (online supplemental figure 2B).

In the control group, standard cataract surgery was performed by the same surgeon (TS) at the Sugiura Eye Clinic between January 2020 and April 2020 with a 2.65 mm temporal corneal incision and implantation of AN6KA. The control was used to compare AC depth (ACD), decentration, and tilt of IOLs.

Preoperative, postoperative and final follow-up corrected distance visual acuity (CDVA) were measured, and the transition of CDVA up to 10 years after surgery was examined in detail.

The axial length was measured using AL-4000 (TOMEY, Aichi, Japan) or OA-2000 (TOMEY), and IOL power was calculated using the SRK/T formula. The amount of refractive error (spherical equivalent at six postoperative months—target refraction) and decline rate of the corneal endothelial cell density (CECD) at six postoperative months were assessed. CECD was not available at 1 year after surgery. Anterior segment optical coherence tomography (AS-OCT, CASIA 2, TOMEY) was used to measure ACD from the posterior corneal surface to the IOL surface, IOL decentration and tilt. The IOL tilt was defined as the angle between the normal line of the corneal apex (vertex normal) and the optical axis of the IOL; decentration was defined as the distance between the vertex normal and the IOL centre. The directions were determined based on the results of the three-dimensional analysis.

We examined the detailed postoperative complications. The incidence of corectopia, which was defined as the major axis of the pupil being ≥ 1.5 times larger than the minor axis, was assessed. In this report, visual acuity is indicated by the logarithm of the minimum angle of the resolution (logMAR) units. Furthermore, We compared this report with the long-term observation reports^{17–19} of transsclerally sutured IOL.

Statistical analyses

The decimal CDVA was converted to logMAR units. The Wilcoxon signed-rank test was used for statistical comparison of preoperative and postoperative CDVA, and Welch's t-test was used for comparison of CECD and age. The Mann-Whitney U test and Welch's t test were used to compare the amount of IOL decentration and tilt. The Kruskal-Wallis and χ^2 tests were used to compare the ACD between the groups. The Mann-Whitney U test was used to compare refractive errors between IOLs. Fisher's exact test was used to compare sex and laterality, and the incidence of iris capture by the type of IOL. Statistical significance was set at $p < 0.05$. All statistical analyses were performed using Excel Statistics 2015 software (Social Survey Research Information, Tokyo, Japan) and EZR for medical statistics²⁰ (Saitama Medical Center, Jichi Medical University, Saitama, Japan).

RESULTS

We examined 146 eyes of 142 patients with aphakia without capsular support, marked deviated IOLs,

Table 1 Patient characteristics

Type of IOL	Ciliary sulcus suture fixation of IOL			Normal cataract surgery	P value
	All cases	NE81K	CZ70BD	AN6KA	
No of eyes	146	124	22	54	
Age (y.)	68.6±13.7 (23, 94)	68.6±13.9 (23, 94)	68.6±12.4 (46, 88)	73.2±9.0 (54, 87)	0.0372
Sex (M/F)	99/47	82/42	17/5	23/31	< 0.01
Right/left	75/71	59/65	16/6	32/22	0.568
Postoperative observation period (mon.)	56.0±35.3 (12, 174)	61.1±35.7 (12, 174)	27.0±10.5 (12, 55)	6.0±0 (6, 6)	< 0.01

Mean±SD (range).

A statistical study was conducted between all cases group and normal cataract surgery group.

Fisher's exact test was used for sex and right/left and Welch's test was used for age and postoperative observation period.

IOL, intraocular lens.

dislocated IOLs and subluxated crystalline lenses. The postoperative follow-up period was 56.0±35.3 months (mean±SD, range: 12–174 months). The control group included 54 eyes of 41 patients who underwent standard cataract surgery. **Table 1** summarises the characteristics of the participants. The ocular conditions that necessitated IOL suture fixation are summarised in **table 2**. The preoperative ocular pathologies other than aphakia were 12 eyes (8.2%) for eye trauma, 8 eyes (5.5%) for treated retinal detachment, 8 eyes (5.5%) for glaucoma and 7 eyes (4.8%) for pseudoexfoliation syndrome, 8 eyes (5.5%) for diabetic retinopathy, 3 eyes (2.0%) for age-related macular degeneration, 2 eyes (1.4%) for branch retinal vein occlusion after laser treatment was 2 eyes (1.4%) and 1 eye (0.7%) for corneal leukoma.

The mean preoperative CDVA was 0.30±0.45, and the mean postoperative CDVA decreased in 1 week after surgery but remained significantly better than the preoperative level from 1 month to 8 years (**figure 1**). The

mean final follow-up CDVA (n=146) was 0.15±0.43, which was significantly better than the preoperative level.

The mean refractive error at 6 months postoperatively was -0.712±0.749 dioptres (D), which was significantly more myopic than the preoperative target refraction (p<0.01) and the spherical equivalent of the normal controls (p<0.01) (**table 3**). There was a significant difference in the mean refractive error between the NR81K and CZ70BD IOLs (p<0.01) (**table 3**). There was no significant difference in the mean ACD between all eyes with sutured IOL, eyes with NR81K, eyes with CZ70BD, and the standard cataract surgery group (**table 3**). The preoperative and postoperative (6 months) CECD were 2105±631 cells/mm² and 1932±623 cells/mm², respectively, with a decline rate of -7.4±16.0%. The amounts of tilt and decentration of IOL are shown in online supplemental table 1.

Table 4 shows the incidence of postoperative complications and online supplemental table 2 shows a

Table 2 Causes of need for suture fixation

Causes	No of eyes	Rate (%)
IOL dislocation after cataract surgery	56	38.4
Inability to insert IOL due to complications during cataract surgery	40	27.4
Removal of IOL and lens by vitreous surgery	11	7.5
Aphakic eye with ECCE or ICCE	16	11.0
Trauma	12	8.2
Aphakic eye due to cataract surgery in children	5	3.4
Subluxated lens due to Marfan syndrome	4	2.7
Subluxated lens of unknown cause	1	0.7
Deterioration of IOL (subsurface nano glistening)	1	0.7

(Total no of eyes=146)

ECCE, extracapsular cataract extraction; ICCE, intracapsular cataract extraction; IOL, intraocular lens.

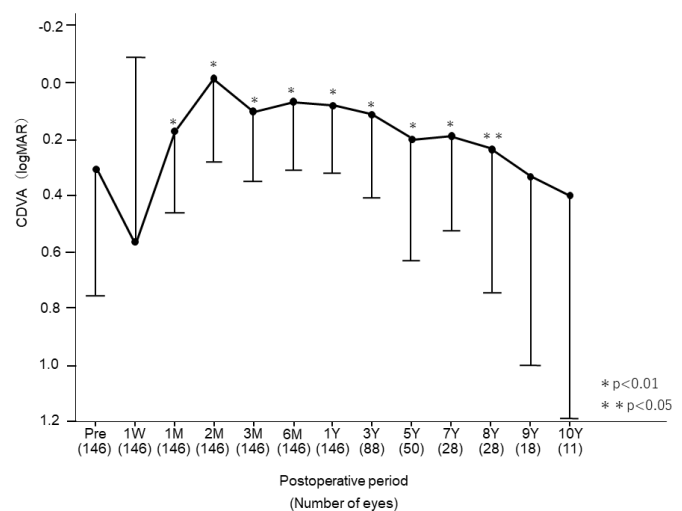


Figure 1 Time course of changes in corrected distance visual acuity. *P<0.01, **p<0.05, significantly better than the preoperative level. CDVA, corrected distance visual acuity; logMAR, logarithm of the minimum angle of the resolution; Pre, preoperative; W, week; M, month; Y, year.

Table 3 The refractive error and anterior chamber depth

Type of IOL	Ciliary sulcus suture fixation of IOL			Standard cataract surgery
	All IOLs for suture fixation	NR81K	CZ70BD	AN6KA
The preoperative target refraction (D)	0.143±0.738	0.155±0.679	0.146±0.960	-0.142±0.707
The spherical equivalent power at 6 m after surgery (D)	-0.559±1.07	-0.478±0.989	-1.01±13.0	-0.214±0.962
The refractive error (D)	-0.712±0.749**	-0.633±0.744*	-1.16±0.610*	-0.064±0.59**
n	146	124	22	54
The anterior chamber depth (mm)	4.01±0.37	4.03±0.40	3.94±0.25	3.93±0.29
n	77	57	20	54

The refractive error=postoperative spherical equivalent power – preoperative target refraction.

The refractive error was recorded at 6 months after surgery.

For the refractive error, the Mann-Whitney U test showed a significant difference between NR81K and CZ70BD groups and between All IOLs and AN6KA.

For the anterior chamber depth, Kruskal-Wallis test showed no significant difference between NR81K, CZ70BD and AN6KA groups.

Data are mean±SD.

* $p < 0.05$, ** $p < 0.01$.

D, dioptre; IOL, intraocular lens; m, month; n, number of cases.

comparison with the long-term follow-up reports^{17–19} of 10 years or more. There were no cases of suture thread breakage and subsequent IOL dislocation. Vitreous haemorrhage cleared in 1 month without vitrectomy in all cases, with a mean period of 14.7±6.7 days (range: 4–28 days). The suture thread exposure on the conjunctiva was recognised at 11.3±8.1 months (3–30 months). Exposure was observed in the nasal-superior and temporal-inferior sides in 32% and 68% of the cases, respectively. The exposed suture thread was cut immediately when it occurred (online supplemental figure 2C), and the thread was completely removed in 10 eyes (6.8%). However, there were no cases of IOL dislocation or deviation.

The mean CDVA of Corectopia was 0.07±0.27 at 12 months postoperatively and 0.15±0.42 at the final follow-up, which did not differ significantly from that

of all eyes (n=146) and was significantly better than the preoperative level. Seven eyes of postoperative glaucoma had normal intraocular pressure (IOP) but had pseudo-exfoliation syndrome preoperatively. Trabeculectomy was performed in one eye due to uncontrolled IOP. The incidence of iris capture was significantly higher with IOLs of 6.0 mm optic diameter (NR81K, n=8) than with IOLs of 7.0 mm optic diameter (CZ70BD, n=1) ($p < 0.01$). Iris capture was observed only in male patients, and none of them were taking α_1 -adrenergic receptor antagonists for prostatic hypertrophy. Retinal detachment developed at 27.4±35.0 months (1–101 months) postoperatively. Pars plana vitrectomy (PPV) was performed in these eyes. Cystoid macular oedema (CME) was found in one eye at 4 months and in another eye at 5 months after surgery. In ciliary dissociation ciliary body suturing was performed. There were no cases of postoperative endophthalmitis.

The number of eyes with at least one complication during the follow-up was 49 eyes (33.6%).

Postoperative reoperations for severe complications of retinal detachment, glaucoma and ciliary dissociation were performed in eight eyes (5.5%; PPV, six eyes; trabeculectomy, one eye; ciliary body suturing, one eye).

DISCUSSION

We have developed the technique to securely fix haptics in the ciliary sulcus to use the injector and an endoscope. The advantages of this technique are that haptics are securely fixed to the ciliary sulcus, so that IOL dislocation due to suture thread breakage does not occur, and there are few serious complications and reoperations (online supplemental table S2). Therefore, the postoperative visual acuity is also good.

Because life expectancy after cataract surgery is long, IOL dislocation due to rupture of the zonule of Zinn due to ageing deterioration after cataract surgery without complications is increasing even in the absence

Table 4 Postoperative complications

Postoperative complications	No of eyes	Rate (%)
Vitreous haemorrhage	35	24.0
Exposing the suture thread	28	19.2
Corectopia	27	18.5
Glaucoma	16	11.0
Iris capture	9	6.2
Retinal detachment	6	4.1
Bullous keratitis	3	2.1
CME related to this surgery	2	1.4
Ciliary dissociation	1	0.7
Suture breakage	0	0.0
Dislocation of IOL	0	0.0
Postoperative endophthalmitis	0	0.0
(Total no of eyes=146)		

CME, cystoid macula oedema; IOL, intraocular lens.

of serious pathological disease. In this study, 38.4% of the patients had IOL dislocation after cataract surgery, which was approximately twice of that (21%) reported by McAllister and Hirst¹⁹ in 2011. Therefore, in the secondary implantation of IOL, a surgical procedure with fewer complications and better postoperative CDVA is required. The results of CDVA and complications in this study are better than those in the previous reports (online supplemental table 2).

In previous reports in which ciliary sulcus suture fixation of IOLs was planned, correct placement of the haptics in the ciliary sulcus was achieved in approximately 30%–38% of the cases.^{12–13} This was because the ciliary sulcus cannot be observed directly under a microscope, making it difficult to confirm the exact location of the needle passage. This can cause damage to the blood-aqueous barrier, leading to a higher incidence of CME.

Previous studies on suture fixation of IOLs have reported CME as a major cause of deteriorated visual acuity.⁸ However, we observed CME in only two eyes (1.4%), which is very small compared with that (7.3%–19.6%) reported in previous reports.^{8–19}

Our technique using the specified injector¹⁵ enables accurate needle passage through the ciliary sulcus in 91.4% of cases in a single attempt, which would reduce postoperative inflammation and incidence of CME.

Using an endoscope to confirm secure haptic fixation in the ciliary sulcus allowed reliable results regarding ACD, which did not differ significantly from that in the standard cataract surgery group (table 3). This result indicates that the IOL was placed in nearly the same plane as in standard cataract surgery whose IOLs are fixed in the capsular bag. This is a new finding that has not been previously reported.

The ciliary process, which forms part of the ciliary sulcus, has a network of capillaries that originate from the major arterial circle of the iris and tend to bleed easily. Therefore, in our report, many cases of postoperative vitreous haemorrhage were observed (online supplemental figure S1), but it disappeared in all cases within 1 month, and no vitreous surgery was required to remove the bleeding. Therefore, we did not consider vitreous haemorrhage as a serious complication.

In IOL suture fixation, IOL dislocation due to suture breakage occurred in 27.9% of the cases, and have been a major problem.¹⁷ Moreover, IOL dislocation was more common in young patients.^{17–19}

Drews²¹ reported that the suture material rapidly deteriorated when buried in actively metabolising tissue. Price *et al*¹⁰ reported five cases in which 10–0 polypropylene sutures were broken after pars plana suture fixation. They recommended suturing haptics to the ciliary sulcus to avoid IOL dislocation, as well as the use of thicker 9–0 polypropylene threads to induce inflammation to cover the haptics with fibrous membranes. Holland *et al*¹¹ recommended haptic fixation in the ciliary sulcus based on their gonioscopy findings that showed fibrous membranes in 83% of the haptics fixed in the ciliary

sulcus; however, haptic fixation to the pars plana did not cause fibrosis. Kuchle *et al*²² reported that haptics fixed in the ciliary sulcus were buried within the superficial stroma of the ciliary body and were covered with fibrous membranes. Ishibashi observed that in cadaver eyes that underwent out-of-the-bag IOL fixation, the haptics were covered with granulation tissue containing multinucleated giant cells.²³ Inoue published photographs of out-of-the-bag IOL fixation in living eyes that showed that the haptics were buried in the granulation tissue of the ciliary sulcus (online supplemental figure S3). In our study, the suture threads were completely removed in 10 eyes, but there was no subsequent IOL dislocation. This is presumably attributed to haptics buried in the ciliary sulcus tissue and fixed with fibrous membranes. These findings indicate that in ciliary sulcus suture fixation, the risk of IOL deviation or dislocation is very low, even if the sutures are removed postoperatively. In our study, there were no cases of suture breakage, IOL deviation or dislocation. This is a major advantage of ciliary sulcus suture fixation.

Therefore, we do not think it is necessary to use thicker suture thread in our technique.

In our technique, the suture thread remained under the conjunctiva without any complications in 80.8% of the eyes (online supplemental figure 2A–D). But it is hard to say that even if the suture thread is left long, it will have a sufficient effect to prevent suture exposure. The role of the suture thread is to fix the haptics until they are buried and fixed in the ciliary sulcus. Therefore, Z suture^{24–25} is effective in overcoming this shortcoming, which we would like to adopt.

We did not employ the scleral flap method because there were reported cases of scleral flap thinning and suture thread exposure (online supplemental figure S4).

The mean amount of tilt and decentration in normal eyes was reported to be 4.6°, 0.30 mm respectively.²⁶ Hayashi *et al* reported 6.35°±3.09°, 0.62 mm ±0.31 mm, respectively, in the ciliary sulcus suture fixation of IOL,²⁷ and the tilt was similar and the decentration was larger compared with this study. As for decentration, when the IOL deviates from the centre by 1 mm, the line of sight is displaced by 2.2 ΔD.²⁸ Further, the tolerable threshold for fusion due to a change in the line of sight in the vertical direction is 2 ΔD. Therefore, it is reported that the tolerable range of decentration of IOL is within 1 mm. In this study, no laterality was observed except in the direction of decentration. From the above, IOL deviations in this study are considered to be small and within the permissible range.

Yamane *et al* technique and Flanged technique²⁹ are excellent techniques, but recently, endophthalmitis due to the exposure of the flange has become a problem.^{30–32} We also experienced a case of endophthalmitis due to a protrusion of the haptic flange. In our study, no endophthalmitis was found, which is a great advantage of our procedure.



The combination of various scleral fixation techniques and keratoplasty has been reported,^{33–36} but we have no experience in these. We would like to keep an eye on the long-term outcomes of these procedures.

The most important thing in secondary IOL implantation is good postoperative long-term results, not the convenience of surgery.

The postoperative reoperation rate in our study was 5.5%, which was much lower than that (15.8%–49.2%) in the previous reports^{17–19} (online supplemental table 2) and can be attributed to the progress of the surgical technique such as using the injector.

Shen *et al* have evaluated a large number of IOL implantation in the absence of zonular support studies, and their review is very important and helpful. We will compare the results of the review with the results of this study.

The postoperative visual acuity of Shen's review was 20/35–20/76 (Snellen), and the final average visual acuity (logMAR 0.15) in this study was superior to any of those reports. The incidence of pupillary capture ranges from 0% to 9.6%, which is within the range of this study. The highest ratio of exposure of suture thread was 11%. This study is more than it and is a drawback of this technique. The incidence of glaucoma ranges from 0% to 23%, and this study is also within that range. CME was observed in 2% to 28%, and the highest rate (28%) was reported for 10–0 polypropylene iris suture IOL. The incidence of CME in this study is very low. Vitreous haemorrhage was observed in 0% to 26%, and also in intrascleral fixation in 0%–22%. The results of this study are close to the highest value. Retinal detachment was reported in the 10–0 polypropylene scleral suture group in 4.2%–8.2%, and the incidence of this study is low. Regarding IOL dislocation, the incidence tended to increase as the postoperative observation period became longer, with a maximum of 28%. Intrascleral fixation was also found in 5.7% of studies. Although the observation period is 11 months, Shen *et al* noted that only the CV-8 polytetrafluoroethylene-sutured PCIOL study did not report IOL dislocation. But the fixation site has not been examined in the review of Shen *et al*.

In previous reports, the fixation site of haptics has not been sufficiently discussed. However, we believe that the fixation site is important, and it is highly beneficial to correctly fix the haptics in the ciliary sulcus. We should reaffirm the significance and value of fixing haptics to the ciliary sulcus. Our study showed that better long-term postoperative results may be obtained by our technique. Therefore, our technique can be recommended for young patients.

The limitation of this study is that the number of patients who were followed up for longer than 5 years after surgery was small because many of them were lost to follow-up due to age and other reasons.

In conclusion, we report excellent IOL positioning and stability with highly satisfactory clinical results in the long term when the haptics were correctly fixed in the ciliary

sulcus using the injector and an endoscope. The significance and value of fixing haptics to the ciliary sulcus should be re-evaluated.

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