

A comparative study of transscleral suture-fixated and scleral-fixated intraocular lens implantation

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Abstract

Purpose To compare short-term clinical outcomes between scleral-fixated and transscleral suture-fixated intraocular lens (IOL) implantation.

Setting Hiroshima Prefectural Hospital, Japan.

Design A retrospective, nonrandomized, comparative case series.

Methods Eighty-nine eyes of 87 patients were included in this study; 45 eyes underwent transscleral suture-fixated IOL implantation (group 1), and 44 eyes underwent scleral-fixated IOL implantation (group 2) between February 2009 and June 2017 in the department of Ophthalmology, Hiroshima Prefectural Hospital, Japan. The postoperative best corrected visual acuity (BCVA), degree of astigmatism, IOL astigmatism (total astigmatism–corneal astigmatism), and refractive error were all measured at 1-week and 1-month intervals.

Results The mean preoperative BCVA in logarithm of minimum angle of resolution (log MAR) was 0.39 ± 0.56 and 0.46 ± 0.51 in groups 1 and 2, respectively, and the mean postoperative BCVA was 0.25 ± 0.41 and 0.34 ± 0.49 at 1 month. The postoperative degree of astigmatism in group 2 was significantly less than that in group 1 at 1 week and

1 month ($p = 0.0046$ and $p = 0.021$, respectively). The postoperative IOL astigmatism in group 2 was significantly less than that in group 1 at 1 week ($p = 0.021$), while the refractive error between the two groups was not significantly different at 1 week or 1 month.

Conclusions Scleral-fixated IOL implantation has equivalent BCVA and refractive error outcomes as transscleral suture-fixated IOL implantation during the early postoperative period without serious complications. Scleral-fixated IOL implantation appears to provide more stable fixation than suture-fixated IOL implantation.

Keywords Secondary IOL implantation · Transscleral suture-fixated IOL implantation · Scleral-fixated IOL implantation · Double-needle technique

Introduction

There are several surgical techniques for intraocular lens (IOL) implantation in the absence of capsular support. When endocapsular IOL placement is not possible, transscleral suture-fixated IOL implantation is an effective method for avoiding aphakia. However, suture degradation remains a potential problem with a high probability (6–27%) [1, 2]. Recently, scleral-fixated IOL implantation, a new surgical technique, has been reported. It provides good flap wound

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adaptation, IOL centration, and stability without suture-related complications.

The aim of this retrospective study was to report the demographic characteristics, postoperative complications, visual outcomes, and IOL stability during the early postoperative period of two secondary IOL implantation methods, transscleral suture-fixated IOL and scleral-fixated IOL implantation, using foldable IOL.

Methods

This retrospective study included patients who underwent secondary IOL implantation surgery between February 2009 and June 2017 at the department of Ophthalmology, Hiroshima Prefectural Hospital, Japan. The study received approval from the institutional ethics committee, and the research adhered to the tenets of the Declaration of Helsinki.

This study included 89 eyes of 87 patients who were followed for at least 1 month after the secondary IOL implantation surgery; 45 eyes underwent transscleral suture-fixated IOL implantation (group 1) from February 2009 to February 2015, which was performed by 5 surgeons, and 44 eyes underwent scleral-fixated IOL implantation (group 2) from March 2016 to June 2017, which was performed by 3 surgeons. Patients with incomplete operative or postoperative medical records and a postoperative follow-up of < 1 month were excluded. All patients underwent complete preoperative ophthalmologic evaluation including best corrected visual acuity (BCVA) and objective and subjective refraction. Measurements recorded were keratometry and IOL master or A scan; a constant and SRK/T formula used for calculating the IOL power. Three-piece IOL was used in all patients. BCVA, degree of astigmatism, IOL astigmatism (total astigmatism – corneal astigmatism), and refractive error (postoperative spherical equivalent – refraction prediction) were all measured postoperatively at 1 week and 1 month.

Surgical techniques

Transscleral suture-fixated IOL implantation

All eyes were operated under local anesthesia using a sub-Tenon injection of 0.2% ropivacaine. An infusion cannula was inserted, and 25-gauge vitrectomy was performed. A 3.5- or 5.5-mm corneoscleral incision was made at the 11 o'clock position to remove the subluxated IOL. In cases of lens subluxation, 2.4-mm small-incision cataract surgery for phacoemulsification and aspiration (PEA) or 8.0-mm corneoscleral incision for extracapsular cataract extraction was made to remove the lens. Two diametrically opposed limbal-based partial-thickness quadrangle scleral flaps were then prepared at the 3–4 and 9–10 o'clock positions. A straight 10-0 polypropylene suture needle was passed via a paracentesis through the eye under the scleral flap. On the opposite side, a 27-gauge needle carrying the suture was inserted into the limbus under the scleral flap and pulled out through the corneal incision, which was made at 11 o'clock for lens implantation. The loops of the 10-0 polypropylene were sutured to the haptics, and the sutures outgoing through the sclera were drawn out through the incisions in scleral pockets and tied. IOL was implanted into the posterior chamber and fixed by the suture.

Scleral-fixated IOL implantation

Under a sub-Tenon injection of 2% mepivacaine anesthesia, an infusion cannula or anterior chamber maintainer was inserted, and 25-gauge vitrectomy was performed. A 3.5- or 5.5-mm corneoscleral incision was made at the 1 o'clock position; removal of a subluxated IOL was performed using a method similar to that used for transscleral suture-fixated IOL implantation described above. A 2.4-mm small-incision cataract surgery for PEA or 8.0-mm corneoscleral incision for extracapsular cataract extraction was made to remove the lens. An acrylic foldable three-piece IOL was placed in the anterior chamber with an injector via the corneal incision, and trailing haptic was kept outside to prevent the IOL from falling into the vitreous cavity. A 30-gauge thin needle (Scarlet needle; Tochigi Seiko, Tochigi, Japan) with an internal diameter of 0.16 mm, which is large enough to insert the haptics of commonly used three-piece

foldable IOLs (0.14–0.15 mm), was used for a paracentesis, the leading haptic 2 mm posterior to the limbus at the 4 o'clock position. The tip of the leading haptic was grasped and inserted into the lumen of the needle. The IOL was rotated, and the trailing haptic was inserted into the anterior chamber. A second 30-gauge thin needle was used for a paracentesis at the 10 o'clock position. On the opposite end, the second haptic was inserted into another 30-gauge thin needle. Then, the haptics were pulled out, guided by the needles. The haptic was cauterized using an Accu-Temp (Beaver Visitec Inc.), and the IOL position was centered.

Statistical analysis

Data were entered in an Excel spreadsheet (Microsoft Corp.) and analyzed using JMP software (version 9, SAS, Inc., Cary, NC). Measurement data were expressed as the mean \pm standard deviation, and the Student's *t* test was used to compare the two groups. BCVA was converted into logMAR units for analysis. Differences were considered to be statistically significant when the *p* value was < 0.05 .

Results

The 89 eyes of 87 patients fulfilled the inclusion and exclusion criteria. Group 1 comprised 45 eyes (45 patients: 29 males and 16 females) with a mean age of 68.73 ± 11.74 years (range 47–89 years) who underwent transscleral suture-fixated IOL implantation. Twenty-five eyes in 25 patients had IOL subluxation, 1 eye had iris capture, 5 eyes had lens subluxation, and 14 eyes had left aphakia after cataract extraction. Group 2 comprised 44 eyes (42 patients: 28 males and 14 females) with a mean age of 68.00 ± 16.05 years (range 17–94 years) who underwent scleral-fixated IOL implantation. In group 2, 26 eyes had IOL subluxation, 14 eyes had lens subluxation, and 4 eyes had left aphakia after cataract extraction. There was no significant difference in age, gender, and preoperative BCVA between the two groups (Table 1).

The mean preoperative BCVA in logMAR was 0.39 ± 0.56 and 0.44 ± 0.51 in groups 1 and 2, respectively ($p = 0.55$). The mean postoperative BCVA for groups 1 and 2 at 1 week was

0.37 ± 0.50 and 0.45 ± 0.49 ($p = 0.51$) and at 1 month was 0.25 ± 0.41 and 0.34 ± 0.49 ($p = 0.37$), respectively. Changes in the mean postoperative BCVA between the two groups were not statistically significant at 1 week and 1 month postoperatively (Table 2). The mean preoperative and postoperative BCVA at 1 week and 1 month did not show any change in group 1 ($p = 0.87$ and $p = 0.17$, respectively) and group 2 ($p = 0.88$ and $p = 0.26$, respectively).

Postoperative IOL astigmatisms at 1 week were significantly lower in group 2 ($p = 0.021$), whereas the mean refractive error was not significantly different between the two groups at both 1 week and 1 month ($p = 0.47$ and $p = 0.96$, respectively). The postoperative degree of astigmatism was greater in group 1 than in group 2 at 1 week and 1 month ($p = 0.046$ and $p = 0.021$, respectively; Table 3).

All complications are shown in Table 4. Ocular hypotension was observed in eight eyes that underwent transscleral suture-fixated IOL implantation, whereas none of the eyes that underwent scleral-fixated IOL implantation demonstrated this complication. Vitreous hemorrhage was observed in four eyes in the transscleral suture-fixated IOL implantation group and two eyes in the scleral-fixated IOL implantation group, which resolved spontaneously. There was no case of suture erosion or retinal detachment in either group at the 1-month follow-up.

There were no differences in the mean preoperative BCVA, refractive error, degree of astigmatism, and IOL astigmatism based on the type of lens.

Discussion

Modern cataract surgery requires retaining an intact posterior capsule and implanting the posterior chamber IOL inside the capsular bag. Some patients without capsular support may carry a risk of serious complications, such as lens subluxation and IOL dislocation, spontaneously or secondary to trauma. Various surgical procedures for IOL implantation in the absence of capsular support have been reported, such as anterior chamber IOL, iris-fixated IOL, and transscleral suture-fixated IOL. Anterior chamber IOL and iris-fixated IOL have rarely been used because of endothelial loss due to bullous keratopathy, peripheral anterior synechiae, fibrosis of haptic into the angle, pupillary block

Table 1 Preoperative data of all patients

	Group 1	Group 2	<i>p</i>
No. of eyes	45	44	
Mean age (range), years	68.73 ± 11.74 (47–89)	68.00 ± 16.05 <i>p</i> (17–94)	0.81
Sex			0.93
Male	29 (64.4%)	28 (66.7%)	
Female	16 (35.6%)	14 (33.3%)	
Eye			0.23
Right	24 (53.3%)	29 (65.9%)	
Left	21 (46.7%)	15 (34.1%)	
Preoperative pathology			
IOL subluxation	25 (55.6%)	26 (59.1%)	
Lens subluxation	5 (11.1%)	14 (31.8%)	
Left aphakia after cataract extraction	14 (31.1%)	4 (9.1%)	
Iris capture	1 (2.2%)	0 (0%)	
Other	0 (%)	0 (0%)	
Type of implanted IOL			
NR-81 K (NIDEK)	22 (48.9%)	0 (0%)	
Avansee PN6A (KOWA)	17 (37.8%)	16 (36.4%)	
AF-1 YA-60BBR (HOYA)	6 (13.3%)	0 (0%)	
Eternity natural NX-70 (Santen)	0 (0%)	28 (63.6%)	

Table 2 Visual outcomes

	Group 1	Group 2	<i>p</i>
Preoperative	0.39 ± 0.56	0.44 ± 0.51	0.55
1 week	0.37 ± 0.50	0.45 ± 0.49	0.51
1 month	0.25 ± 0.41	0.34 ± 0.49	0.37

is frequently used because of fewer reported complications [4–7]. However, it is a more difficult technique that requires a longer surgical time than other secondary IOL implantation methods despite anatomical safety compared with anterior chamber IOL and iris-fixated IOL implantation. However, the transscleral suture-fixated IOL technique may have suture-associated problems, such as suture-induced inflam-

Table 3 Postoperative astigmatism and IOL tilt

Parameter 1 week	Group 1: mean (SD)	Group 2: mean (SD)	<i>p</i>
Refractive error	0.92 ± 0.78	1.08 ± 0.94	0.47
Degree of astigmatism	2.51 ± 1.48	1.58 ± 1.33	0.0046
IOL astigmatism	0.083 ± 1.45	− 0.79 ± 1.87	0.021
Parameter 1 month	Group 1: mean (SD)	Group 2: mean (SD)	<i>p</i>
Refractive error	1.09 ± 0.88	1.08 ± 1.10	0.96
Degree of astigmatism	2.30 ± 1.31	1.47 ± 1.45	0.021
IOL astigmatism	− 0.17 ± 1.08	− 0.69 ± 1.59	0.12

with increased intraocular pressure, iris chaffing, and hyphema. The technique of transscleral suture-fixated IOL, which was first described in 1986 by Malbran [3],

is frequently used because of fewer reported complications [4–7]. However, it is a more difficult technique that requires a longer surgical time than other secondary IOL implantation methods despite anatomical safety compared with anterior chamber IOL and iris-fixated IOL implantation. However, the transscleral suture-fixated IOL technique may have suture-associated problems, such as suture-induced inflam-

Table 4 Early postoperative complications in the two groups

Complications	Group 1	Group 2
Iris capture	1 (2.2%)	3 (6.9%)
Lens tilt	4 (8.9%)	2 (4.5%)
Ocular hypertension	4 (9.1%)	4 (9.1%)
Ocular hypotension	8 (18.1%)	0 (0%)
Vitreous hemorrhage	4 (9.1%)	2 (2.5%)
Vitreous incarceration	1 (2.2%)	0 (0%)
Corneal ulcer	0 (0%)	1 (2.3%)
Retinal detachment	0 (0%)	0 (0%)
Suture knot exposure	0 (0%)	0 (0%)

sutureless scleral-fixated IOL technique was first reported by Gabor and Pavlidis et al. [12] in 2007 in which a 24-gauge cannula was implanted for creating a scleral tunnel for hepatics. Agarwal et al. [13] described IOL fixation achieved using fibrin glue in 2008, which can completely block the sclerotomy. However, fibrin glue is a blood product, and problems of viral infection or allergic reaction cannot be completely excluded. In 2014, Yamane et al. [14] described the double-needle technique, whereby the hepatics of IOL are externalized using a 27-gauge needle passed through the ciliary sulcus and fixed in a scleral tunnel made using a lamellar scleral dissection without a scleral flap. This technique provides good IOL fixation with reliable wound closure without the use of any sutures or fibrin glue and has a very low risk of ocular hypotension.

In the present study, the mean BCVA was better or similar following fibrin glue-assisted scleral-fixated IOL implantation than that following suture-assisted scleral-fixated IOL implantation. The IOL tilt is reportedly greater with transscleral suture-assisted scleral fixation [12, 15], which was also observed in our study during the early postoperative period. Although changes in the mean BCVA between the two groups were not statistically significant, the degree of astigmatism in the scleral-fixated group was less than that in the transscleral suture-fixated group during the early follow-up period, suggesting that the IOL tilt was less in the scleral-fixated group. We hypothesize that in the transscleral suture-fixated group there is only hepatic fixation point, while in the scleral-fixated group, the hepatic tip is tucked into the

scleral wall via the tunnel. IOL is, therefore, more stable for preventing movement of the hepatic along the transverse axis. There is evidence that IOL tilt and decentration could cause lens-induced astigmatism [16, 17], which is inconsistent with our study; IOL astigmatism was significantly less in the scleral-fixated group at 1 week postoperatively. Moreover, obvious IOL tilt was seen in four eyes (8.9%) in the transscleral suture-fixated group and only seen in two eyes (4.5%) in the scleral-fixated group.

With regard to the complications observed in our study, postoperative complications occurred less frequently in the scleral-fixated group. In particular, ocular hypotension occurred in eight eyes (18.1%) in the transscleral suture-fixated group, but was not noted in any eyes in the scleral-fixated group. This may be explained by the larger incision wound and increased surgical manipulation in the transscleral suture-fixated group than in the scleral-fixated group using the double-needle technique.

Suture-related complications reported in the literature [4, 5, 8, 18, 19] include suture-induced inflammation, suture erosion, and suture degradation. In our study, there were no suture-induced complications. Uthoff et al. [19] reported that vitreous loss at the time of cataract surgery increases the incidence of retinal detachment (1.4%) in scleral-fixated patients. In our study, no patient experienced retinal detachment. This may be attributed to performing not only anterior but also complete vitrectomy in most patients in the scleral-fixated group, which decreases vitreous traction and retinal detachment.

In our study, specular microscopy was not routinely measured in the transscleral suture-fixated group; hence, we were unable to compare endothelial cells within two groups. However, in the scleral-fixated group, the loss of endothelial cells was $13.6 \pm 14.0\%$ compared with the reported endothelial cell loss in transscleral suture-fixated IOL implantation of 5–11% [20, 21]. We hypothesize that this outcome depends on the progress of the surgical procedure. According to our main operator (Y.S.), the learning curve of the scleral-fixated IOL implantation technique is 20 cases, after which the surgical time is considerably shortened to less than 10 min (from IOL insertion to fixed center position; Fig. 1). Compared with initially learning the technique, the loss of endothelial cells decreased from $17.14 \pm 15.24\%$ to $6.40 \pm 4.63\%$ when > 20 cases had been performed ($p = 0.027$; Fig. 2).

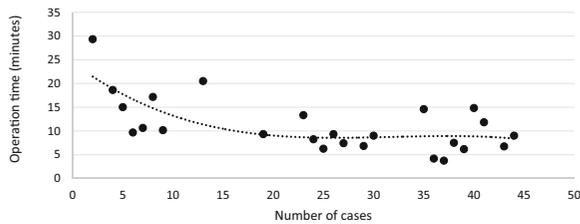


Fig. 1 Learning curve for the scleral-fixed IOL implantation technique. When > 20 cases were performed, the surgical time was considerably shortened

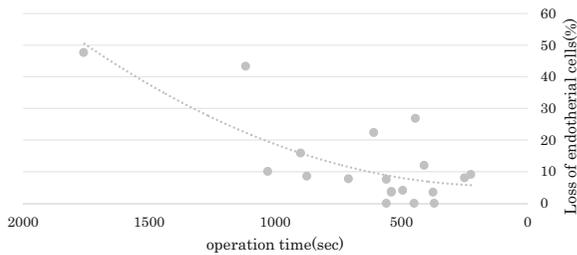


Fig. 2 Association between loss of endothelial cells and surgical time for scleral-fixed IOL implantation. The shorter the operation time, the lower the endothelial cell reduction rate

In the scleral-fixed group, BCVA did not show statistically significant difference between 1 week postoperatively and 12 months ($p = 0.20$). Degree of astigmatism, IOL astigmatism, and refractive error were also comparable between 1 week and 12 months ($p = 0.78$, $p = 0.21$, and $p = 0.14$, respectively). In the literature, no statistically significant difference was found between BCVA at 1 month and BCVA at 12 months in transscleral suture-fixed IOL implantation [22]. Edward [23] reported that final refraction cylinder was not different from the 3-month value in transscleral suture-fixed IOL implantation. This result indicates that scleral-fixed IOL implantation has the possibility of long-term visual outcomes and IOL stability during the early postoperative period.

Based on the findings of our study, scleral-fixed IOL implantation using the double-needle technique is difficult to learn, particularly the procedure of passing the haptic into the lumen of the needle. When we punctured the needle to sclera, we made the needle to be as parallel as possible as to the iris of the needle penetration angle. But once learnt, it is possible to achieve better visual outcomes and is associated with increased safety during the early postoperative period.

There are some limitations in our study. First, the sample size was small and follow-up for

complications was short; therefore, late complications such as suture degradation, hepatic exposure, or endothelial cell loss, which markedly increased according to the 6–12-month follow-up values, were not measured, and further studies are needed to confirm the results. Second, the operator and the type of IOL differed. Third, the incision for removal of lens or IOL was different for the primary inserted lens, such that variation in corneal astigmatism may have affected total and IOL astigmatism.

In conclusion, the scleral-fixed IOL implantation using the double-needle technique provides more stable fixation during the early postoperative period and less complications compared with transscleral suture-fixed IOL implantation. Further studies with more patients and long-term follow-up are needed to determine the safety and effectiveness of these procedures.

Compliance with ethical standards

Conflict of interest The authors declared that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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