Retropupillary Fixation of Iris-claw Intraocular Lens Versus Transscleral Suturing Fixation for Aphakic Eyes Without Capsular Support

Shuya Hara, MD; Andreas F.M. Borkenstein, MD; Angela Ehmer, MSc; Gerd U. Auffarth, MD

ABSTRACT

PURPOSE: Retropupillary fixation of an iris-claw intraocular lens (IOL) (Verisyse, Abbott Medical Optics) was performed for aphakic eyes without sufficient capsular support, and safety and recovery of the procedure were compared with transscleral suturing fixation.

METHODS: This interventional case series comprised 11 eyes of 10 aphakic patients without capsular support undergoing retropupillary fixation of the Verisyse, and 21 eyes of 20 patients undergoing transscleral suturing fixation of foldable acrylic IOLs (15 eyes of 14 patients, SuperFlex620H [Rayner Intraocular Lenses Ltd]) and polymethylmethacrylate IOLs (6 eyes of 6 patients, CP60NS [CORNEAL Laboratoire]). Surgical time was measured. Corrected distance visual acuity (CDVA) and intraocular pressure (IOP) were examined preoperatively and 1 day, 1 and 2 weeks, and 1 and 6 months postoperatively.

RESULTS: No complications occurred in the Verisyse group, whereas complications were reported in seven eyes in the transscleral suturing fixation group throughout follow-up. Mean CDVA (logMAR) in the transscleral suturing group 1 day after surgery was significantly worse than preoperative CDVA ($P<.05$). In the Verisyse group, no significant changes in CDVA were noted at any time point. Mean IOP at postoperative day 1 in the transscleral suturing fixation group was significantly higher than that in the Verisyse group ($P=.0126$). Mean surgical time of Verisyse implantation (20.0±8.9 min) was significantly shorter than transscleral suturing fixation (49.7±18.9 min) ($P<.0001$).

CONCLUSIONS: Retropupillary fixation of an iris-claw IOL provides early visual recovery, has a low risk of postoperative increase in IOP, and is a time-saving method compared with transscleral suturing fixation for aphakic eyes without sufficient capsular support. [*J Refract Surg*. 2011;xx(x):xxx-xxx.]

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Several surgical methods of intraocular lens (IOL) implantation for eyes without sufficient capsular support have been developed. Angle-fixated anterior chamber IOL implantation is one therapeutic option and has technical advantages such as ease and minimal invasion during the surgery. However, several complications such as progressive damage of corneal endothelial cells, decompensation, chronic inflammation in the anterior chamber, secondary glaucoma, and cystoid macular edema have been reported.[1-6] Implantation of an iris-claw–fixated anterior chamber IOL is another method. Early generations of iris-claw anterior chamber IOLs lacked adequate space between the IOL and iris or corneal endothelial cells, which can lead to damage to the iris or corneal endothelial cells.[7-9] Later generations of iris-claw–fixated anterior chamber IOLs (Verisyse; Abbott Medical Optics, Santa Ana, California) were developed with a vaulted optic design, which can provide enough space for aqueous flow between the IOL and iris to avoid iris chafing. Because the Verisyse lens was originally designed for surgical correction of phakic myopic eyes and the haptics are enclavated to the mid-peripheral iris stroma, it barely interferes with physiological movement of the pupil. This new design can reduce dispersion of iris pigment epithelium that can cause chronic ocular inflammation.

Previous studies have reported the efficacy of Verisyse IOL implantation in the anterior chamber for correction of refractive error in aphakic eyes without adequate capsular support.[10-13] However, Verisyse IOL implantation in the anterior

From International Vision Correction Research Center, Department of Ophthalmology, University of Heidelberg, Heidelberg, Germany (Hara, Borkenstein, Ehmer, Auffarth); and the Department of Ophthalmology, Social Insurance Chukyo Hospital, Aichi, Japan (Hara).

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Correspondence: Shuya Hara, MD, Social Insurance Chukyo Hospital, Dept of Ophthalmology, Sanjo 1-1-10, Minami-ku, Nagoya, Aichi, Japan. Tel: 81 52 691 7151; Fax: 81 52 692 1273; E-mail: hara@chukyogroup.jp

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TABLE 1

Causes of Insufficient Capsular Support in 32 Aphakic Eyes That Underwent IOL Implantation

	Retropupillary Fixation	Transscleral Suturing Fixation		
Cause	Verisyse IOL (n=11)	SuperFlex620H IOL (n=15)	CP60NS IOL (n=6)	Total
Marfan syndrome	2	1	1	4
Trauma	2	3	2	7
Iatrogenic	4	6	2	12
Unknown	3	5	1	9
Total	11	15	6	32

IOL = intraocular lens
Verisyse IOL (Abbott Medical Optics, Santa Ana, California); SuperFlex620H IOL (Rayner Intraocular Lenses Ltd, East Sussex, United Kingdom); CP60NS IOL (CORNEAL Laboratoire, Paris, France)

chamber may cause damage to the corneal endothelial cells. Güell et al[12] reported a mean 10.9% endothelial cell loss during the first 36 months after Verisyse implantation in the anterior chamber. Furthermore, to maintain the physiological features of an open-angled anterior chamber, it is desirable to implant the IOL in the posterior chamber with adequate distance from the corneal endothelium to avoid progressive corneal endothelial cell loss. For these reasons, the transscleral posterior chamber IOL suturing technique is favored by many surgeons as a method of posterior chamber IOL fixation at the ciliary sulcus for eyes without sufficient capsular support.[14-17]

In contrast, there have been various reports regarding the complications associated with transscleral suturing fixation, such as ciliary choroidal body hemorrhage, vitreous prolapse into the anterior chamber, retinal detachment, IOL dislocation, uveitis, cystoid macular edema, and conjunctival erosion.[18-21] Although the technique of transscleral suturing fixation has been improved to reduce those risks associated with the surgery, most of these techniques are still complex and invasive and require extensive experience to be performed safely and in a short time period.[14-17,22]

Retropupillary fixation of a Verisyse IOL in the posterior chamber is expected to be a less invasive and safer method of posterior chamber IOL implantation for aphakic eyes without sufficient capsular support.[23-27] Although Menezo et al[21] previously compared the visual outcomes and complications between implantation of an iris-fixated anterior chamber IOL (Worst-type) and transscleral suturing fixation of a posterior chamber IOL for aphakic eyes without sufficient capsular support, the present study is the first report to compare the safety and visual recovery between retropupillary fixation of a Verisyse IOL in the posterior chamber and transscleral suturing fixation of a posterior chamber IOL for aphakic eyes with insufficient capsular support.

PATIENTS AND METHODS

This prospective, interventional case series comprised 32 eyes of 30 patients with ages ranging from 18 to 88 years who presented at the International Vision Correction Research Centre, University of Heidelberg for secondary IOL implantation. Inclusion criteria were eyes that had already undergone lens extraction and resulted in aphakia with absence of sufficient capsular support.

The secondary IOL implantation was performed by a single surgeon (G.U.A.) in all eyes. Eleven eyes of 10 patients (mean age: 62.2±25.5 years; range: 18 to 88 years) underwent retropupillary fixation of the Verisyse lens, which is an iris-claw, biconvex, polymethylmethacrylate (PMMA) IOL with an 8.5-mm length, 0.95-mm maximum height, and 5.0-mm optical zone. Fifteen eyes of 14 patients (mean age: 63.9±18.1 years; range: 18 to 86 years) underwent implantation of a foldable hydrophilic acrylic posterior chamber IOL (SuperFlex620H; Rayner Intraocular Lenses Ltd, East Sussex, United Kingdom) with an optic diameter of 6.25 mm and overall length of 12.5 mm by transscleral suturing fixation. Six eyes of 6 patients (mean age: 60.7±24.0 years; range: 18 to 86 years) underwent implantation of an unfoldable PMMA posterior chamber IOL (CP60NS; CORNEAL Laboratoire, Paris, France) with an optic diameter of 6.0 mm and overall length of 13.5 mm by transscleral suturing fixation. The surgical methods and IOLs were chosen randomly according to a computer-generated list.

Before the present study was started, the surgeon had performed both procedures more than 20 times

and was therefore familiar with both retropupillary fixation and the transscleral suturing technique. Backgrounds of the absent sufficient capsular support are shown in Table 1. The study protocol adhered to the tenets of the Declaration of Helsinki, and full written informed consent was obtained from all patients. Corrected distance visual acuity (CDVA) as well as intraocular pressure (IOP) were examined preoperatively and at 1 day, 1 and 2 weeks, and 1 and 6 months postoperatively. Postoperative complications and replacement of IOLs due to dislocations were also investigated. The difference in mean surgical time between the two procedures was analyzed statistically.

Statistical Analysis

StatView software (Windows 2000; SAS Institute Inc, Cary, North Carolina) was used for statistical analysis. One-way analysis of variance (ANOVA) was performed to study the statistical significance of the differences in CDVA preoperatively and at each postoperative follow-up. Non-paired *t* tests were used to study the statistical significance of the differences in mean IOP at each measurement period between the two methods of IOL implantation. Non-paired *t* tests were applied to evaluate the differences in the surgical time between the two methods of IOL implantation. *P* values $<.05$ were considered statistically significant.

Surgical Procedure

Retropupillary Fixation of the Verisyse IOL. Two vertical paracentral paracenteses at the 3- and 9-o'clock positions were performed followed by an injection of cohesive viscoelastic material (sodium hyaluronate 1%) into the anterior chamber to protect the corneal endothelium and behind the iris plane to obtain and maintain enough space to manipulate the IOL. Scleral tunnel incisions of 5- to 6-mm widths at the 12-o'clock position were created. Bimanual anterior vitrectomy through the paracentesis and the scleral tunnel incision was performed only when vitreous prolapse into the anterior chamber was observed. A Verisyse IOL was inserted through the scleral tunnel into the anterior chamber with the vaulting optic leading posteriorly. The iris-claw haptics were rotated with a hook, keeping a horizontal position until at the 3–9-o'clock position. After aiming at a fixating position, a lens fixation forceps was introduced through the scleral tunnel to grasp the center of the optic tightly and horizontally, remaining centered to the pupil. One of two haptics was placed behind the iris through the pupil and was enclaved at the aimed retropupillary position by pushing the iris with a phacoemulsification spatula from the anterior chamber, entrapping the iris through the slotted center of the haptic. The other haptic was also enclaved in the same way, and the proper IOL position could be recognized during surgery by confirming the round shape of the pupil and the proper enclavation sites of both haptics, which could be seen anteriorly. Finally, the viscoelastic device was completely removed and sutures with 10-0 nylon were placed close to the scleral incision.

Transscleral Suturing Fixation of the SuperFlex620H. Before a 3.5- to 4.0-mm–wide clear corneal incision at the 12-o'clock position was created, vertical paracentral paracenteses at the 4- and 10-o'clock positions were performed. An additional conjunctival peritomy around the 4- and 10-o'clock quadrants was performed. After blunt dissection of the episcleral tissue and slight cauterization of the surgical field, two triangular scleral flaps were constructed at positions 180° apart. Bimanual anterior vitrectomy was performed for all transscleral IOL fixation cases. Polypropylene suture (10-0) was introduced through the scleral flaps into the anterior chamber and guided outside through the clear corneal incision at the 12-o'clock position. Both haptics of the IOL were tied with 10-0 polypropylene suture, and the IOL was folded with lens forceps and inserted into the posterior chamber through the clear corneal incision. The 10-0 polypropylene suturing was performed tightly enough not to loosen under the scleral flaps. The clear corneal incision was closed without sutures by stromal hydration. Finally, the scleral flaps were closed with 10-0 nylon and interrupted sutures with 8-0 bicryl were used to close the conjunctival peritomy.

Transscleral Suturing Fixation of the CP60NS. A 5.0- to 6.0-mm scleral tunnel incision at the 12-o'clock position was performed along with the methods of retropupillary fixation. The remaining procedures were performed in the same way as the method of SuperFlex620H IOL suturing fixation. After insertion of the CP60NS IOL through the scleral tunnel incision, sutures with 10-0 nylon were used to close the scleral tunnel incision.

RESULTS

No significant differences between the two procedures in mean age and preoperative CDVA (logMAR) (Verisyse: 0.49 ± 0.46, transscleral suturing group: 0.41 ± 0.41) were noted. No intraoperative complications occurred in any eyes. Postoperatively, five eyes in the transscleral suturing fixation group had ciliary choroidal body hemorrhage during follow-up. One eye was diagnosed with cystoid macular edema using fluorescein angiography, and another eye showed postoperative IOL dislocation resulting in replacement

TABLE 2

Postoperative Complications of 32 Aphakic Eyes With Insuffient Capsular Support That Underwent IOL Implantation

	Retropupillary Fixation	Transscleral Suturing Fixation		
Complications	**Verisyse IOL (n=11)**	**SuperFlex620H IOL (n=15)**	**CP60NS IOL (n=6)**	**Total**
Ciliary choroidal body hemorrhage	0	3	2	5
Cystoid macular edema	0	0	1	1
IOL dislocation	0	0	1	1
Total	0	3	4	7

IOL = intraocular lens
Verisyse IOL (Abbott Medical Optics, Santa Ana, California); SuperFlex620H IOL (Rayner Intraocular Lenses Ltd, East Sussex, United Kingdom); CP60NS IOL (CORNEAL Laboratoire, Paris, France)

of the IOL by resuturing. In the Verisyse IOL implantation group, no postoperative complications were noted during the observation period (Table 2).

Visual Recovery

No statistically significant changes in CDVA (logMAR) were noted in the Verisyse IOL group at each examination point before and after surgery (preoperative 0.49±0.46, 1 day 0.61±0.39, 1 week 0.41±0.21, 2 weeks 0.32±0.21, 1 month 0.35±0.26, and 6 months 0.28±0.28). In the transscleral suturing fixation group, CDVA at postoperative day 1 (0.97±0.84) was statistically significantly worse than preoperative CDVA (0.41±0.41) ($P<.05$) and recovered at postoperative week 1 (0.59±0.33) compared to the preoperative level (Fig 1A). In the SuperFlex620H IOL implantation subgroup, mean CDVA at postoperative day 1 (0.93±0.80) was statistically significantly worse than preoperative CDVA (0.43±0.40) ($P<.05$) and recovered to the preoperative level 1 week postoperatively (0.55±0.26). In the CP60NS IOL implantation subgroup, mean CDVA at 1 day and 1 week after surgery (1.06±1.06 and 0.63±0.42, respectively) were statistically significantly worse than preoperative CDVA (0.35±0.48) ($P<.05$) and recovered to the preoperative level 2 weeks postoperatively (0.53±0.52) (Fig 1B).

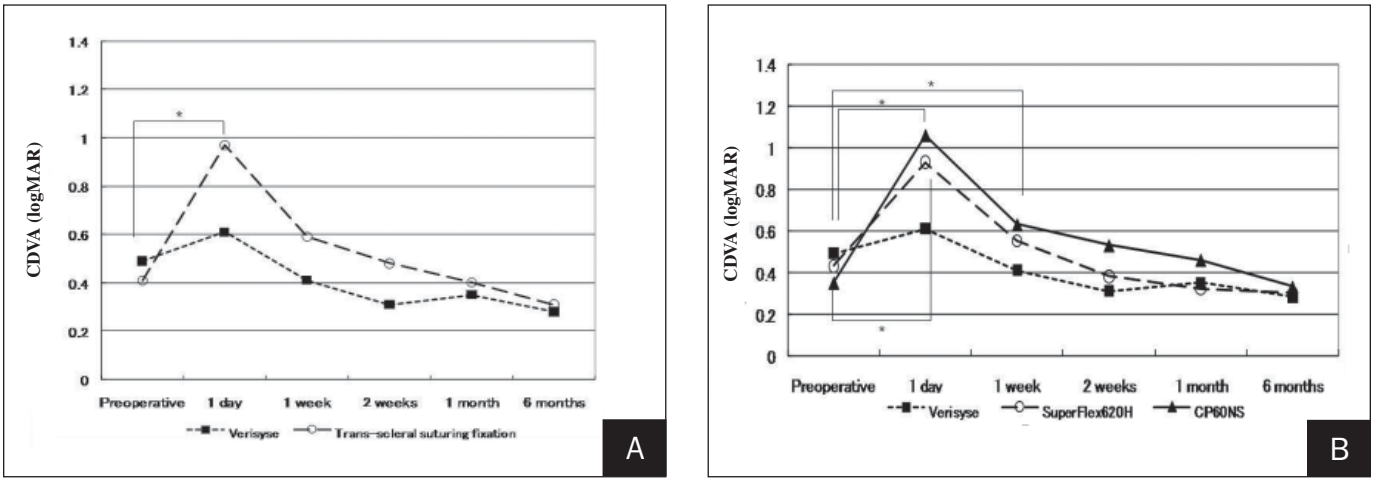

Figure 1. A) Changes in mean logMAR corrected distance visual acuity (CDVA) over time in the retropupillary fixation and transscleral suturing fixation groups. In the retropupillary fixation of Verisyse IOL (Abbott Medical Optics) group, mean CDVA showed no significant changes even 1 day postoperatively. In the transscleral suturing IOL group, mean CDVA at postoperative day 1 was significantly worse than preoperative CDVA ($P<.05$). **B)** Changes in mean CDVA (logMAR) over time for the two subgroups of transscleral suturing fixation. In the SuperFlex620H IOL (Rayner Intraocular Lenses Ltd) subgroup, mean CDVA at postoperative day 1 was statistically significantly worse than preoperative CDVA ($P<.05$) and recovered to the preoperative level at postoperative week 1. In the CP60NS IOL (CORNEAL Laboratoire) subgroup, mean CDVA at 1 day and 1 week after surgery were statistically significantly worse than preoperative CDVA ($P<.05$) and recovered to the preoperative level at postoperative week 2. *$P<.05$ (one-way analysis of variance).

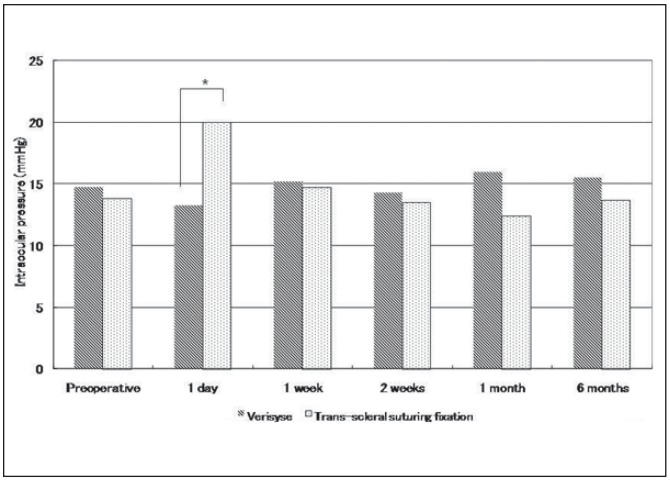

Figure 2. Changes in intraocular pressure over time. Mean intraocular pressure in the transscleral fixation group was significantly higher than that in the Verisyse IOL (Abbott Medical Optics) group at postoperative day 1. *P=.0126 (non-paired t test).

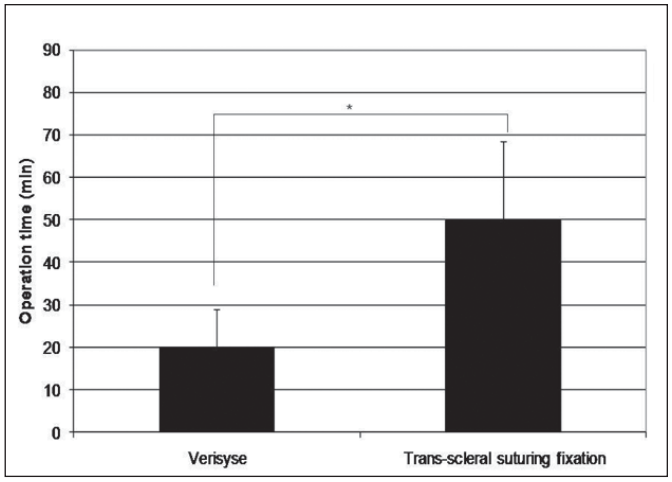

Figure 3. Mean surgical time in the two procedure groups of intraocular lens implantation. Mean surgical time in the Verisyse IOL (Abbott Medical Optics) group was significantly shorter than that in the transscleral suturing fixation group. *P<.0001 (non-paired t test).

INTRAOCULAR PRESSURE

Although mean preoperative IOP showed no significant differences between groups (Verisyse IOL 14.8±2.2 mmHg and transscleral suturing group 13.9±3.5 mmHg), IOP at postoperative day 1 in the transscleral suturing fixation group (20.2±7.4 mmHg) was statistically significantly higher than the Verisyse IOL group at the same time period (13.3±3.9 mmHg) (P=.0126) (Fig 2). No significant differences were noted in mean IOP between the Verisyse IOL and transscleral suturing fixation groups at 1 week (15.2±5.8 and 14.7±7.7 mmHg), 2 weeks (14.3±4.9 and 13.5±3.7 mmHg), 1 month (16.0±2.8 and 12.4±3.4 mmHg), and 6 months (15.5±2.1 and 13.7±1.9 mmHg), respectively.

SURGICAL TIME

The mean surgical time in the Verisyse IOL group (20.0±8.9 min) was significantly shorter than that in the transscleral suturing fixation group (49.7±18.9 min) (P<.0001) (Fig 3).

DISCUSSION

Retropupillary fixation of the Verisyse IOL has been reported to be a promising option for IOL implantation in the posterior chamber without sufficient capsular support.[23-27] Baykara et al[24] described that after retropupillary fixation of the Verisyse IOL, none of 32 eyes showed decompensation, clinically significant pigment dispersion, or secondary glaucoma requiring additional postoperative treatment. In the present study, no postoperative complications occurred in the Verisyse IOL group, whereas ciliary choroidal body hemorrhage was seen in 20% of eyes in the SuperFlex620H IOL and 33% of eyes in the CP60NS IOL implantation groups. Cystoid macular edema and IOL dislocation were seen in 17% of eyes in the CP60NS IOL group. We speculated that the difference between the two types of transscleral suturing IOL was that implantation of the SuperFlex620H IOL was more recently developed as a less invasive transscleral suturing fixation technique in which the posterior chamber IOL can be implanted in a foldable fashion through a 3.5-mm corneal incision, whereas implantation of the CP60NS IOL requires a 5.5-mm scleral tunnel incision.

Mean CDVA significantly deteriorated 1 day after surgery in the transscleral suturing fixation group compared with preoperative CDVA. This presumably occurred due to hyphema and ciliary choroidal body hemorrhage that resulted from invasive manipulation around the ciliary choroidal body. Perforation of the ciliary choroidal body, even by needles, can cause considerable stress to the eye. Eyes undergoing retropupillary fixation of the Verisyse IOL showed no decrease in CDVA 1 day postoperatively. In eyes undergoing implantation of the SuperFlex620H IOL, mean postoperative CDVA recovered to the preoperative level in 1 week. The retropupillary fixation of the Verisyse IOL showed earlier visual recovery and fewer complications than transscleral suturing fixation of the posterior chamber IOL.

Mean IOP was higher in the transscleral suturing fixation group than in the Verisyse IOL group 1 day postoperatively. We suggest that retropupillary fixation of the Verisyse IOL is not likely to cause secondary glaucoma after surgery, presumably due to the reduced invasion and rare occurrences of hyphema.

Mean surgical time in the Verisyse IOL implantation group was significantly shorter than in the trans-

scleral suturing fixation groups. In transscleral suturing fixation, surgeons often struggle while searching for adequate fixation positions for the haptics, scleral flaps are constructed to hide the knots, and proper vitrectomy is performed to avoid undesirable retinal detachment and ciliary choroidal hemorrhage. Because surgeons can omit these procedures in the retropupillary fixation of the Verisyse IOL, surgical time could be shortened in comparison with transscleral suturing fixation.

The present study has several limitations. Intraocular lens position and chronic damage to the iris at fixation points should be observed for a longer period of time. Although obvious dislocation of the Verisyse IOL and collapse into the vitreous cavity were not observed during a 6-month period in the present study, all patients should be informed of the possibility of dislocation, which can cause deterioration of vision and requires emergency replacement. It is also possible that the iris-claw haptic might release the chronically damaged iris and cause dislocation of the IOL for a long period after surgery. Although there were no eyes with significant corneal endothelial cells loss, dispersion of the iris epithelial pigment, or secondary glaucoma following retropupillary fixation of the Verisyse IOL in the present study, long-term observation and comparison of corneal endothelial cell density and IOP between two surgical methods with a larger series of cases is necessary.

Because claw-shaped haptics are directly enclaved at the iris plane in the posterior chamber, the Verisyse IOL is fixated behind the iris with the optic plane parallel to the iris plane. Therefore, theoretically, tilt of the IOL hardly occurs, whereas the sutured fixation easily causes the IOL to tilt due to a loosened knot. For this reason, evaluation of visual function such as higher order aberration and contrast sensitivity measurements should reveal the effects of tilting.

Retropupillary iris-claw fixation of the Verisyse IOL at the posterior chamber can be performed less invasively and in a shorter surgical time period with earlier visual recovery after surgery compared to transscleral suturing fixation of an IOL. This technique is a promising option for posterior chamber IOL implantation for aphakic eyes in the absence of sufficient capsular support.

AUTHOR CONTRIBUTIONS

Study concept and design (S.H., G.U.A.); data collection (S.H., A.F.M.B., A.E., G.U.A.); analysis and interpretation of data (S.H., A.E., G.U.A.); drafting of the manuscript (S.H.); critical revision of the manuscript (S.H., A.F.M.B., G.U.A.); statistical expertise (S.H.); supervision (G.U.A.)

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