

Sutureless 27-gauge needle-assisted transconjunctival intrascleral intraocular lens fixation: Initial experience

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Purpose: The purpose of the study was to report our initial experience with the transconjunctival Intrascleral Intraocular Lens (SFIOL) fixation with modified Yamane's double-needle technique and flanged haptics. **Methods:** This was a prospective interventional study that enrolled 31 consecutive patients undergoing SFIOL with the modified Yamane's technique. All patients underwent comprehensive evaluation including uncorrected and best-corrected vision, intraocular pressure, ultrasound biomicroscopy, endothelial cell density, and macular thickness using optical coherence tomography (OCT). We excluded patients with visually significant coexistent pathology such as corneal scars, macular pathology, and glaucoma. **Results:** The mean age of subjects was 57 ± 16.9 years and 23 were men (74%). Surgery was performed for aphakia following complicated cataract surgery in 10 eyes (32%), with lensectomy for subluxated/dislocated cataract in 6 eyes (19%), and with IOL explantation for subluxated/dislocated IOL in 15 eyes (48%). There were no intraoperative complications. Uncorrected visual acuity improved from median of 1.48 logarithm of minimum angle of resolution (logMAR) units (interquartile range [IQR] = 1.3–2 logMAR) at baseline to 0.3 logMAR (IQR = 0.2–0.4 logMAR) at 6 weeks ($P < 0.001$) which was maintained at 6 months. There were no significant changes in endothelial cell density ($P = 0.34$) and OCT-based macular thickness ($P = 0.31$) at 6 months. Two eyes had slight IOL decentration. **Conclusion:** Our initial experience suggests that the Yamane's technique for SFIOL is a simple procedure with a short-learning curve and is independent of scleral flaps, tunnels, sutures, and fibrin glue. Using widely available 27-gauge needle instead of 30-gauge thin wall needle as originally described by Yamane makes it possible for the use of various three-piece IOLs available globally. Further studies are required for widespread acceptance of this technique.

Key words: Endothelial cell density, intraocular pressure, macular thickness, modified Yamane's double-needle technique and flanged haptics, transconjunctival intrascleral intraocular lens fixation, visual outcomes

The Yamane's technique of fixing a three-piece intraocular lens (IOL) to the sclera in a sutureless manner by creating flanges is a truly novel technique that has the potential to revolutionize aphakia management.^[1,2] This transconjunctival technique is independent from scleral flaps, tunnels, sutures, and fibrin glue and has short-learning curve and faster postoperative recovery. However, 30-gauge thin wall needle used to engage and exteriorize the haptic is not readily available across the world.^[1,2] Here, we report our initial experience of modified transconjunctival intrascleral IOL fixation technique using 27-gauge needle for the three-piece IOL options available in our country.

Methods

The study was approved by the Institutional Ethics Committee and adhered to the tenets of the Declaration of Helsinki. Informed consent was obtained from all patients. We performed a prospective interventional study of consecutive

eyes that received scleral fixation of a three-piece IOL in cases of aphakia due to PC Rent or Nucleus Drop and subluxated or dislocated IOL from September 2016 to December 2016. We proceeded with the SFIOL implantation as a secondary procedure, a minimum of 1 month after the previous cataract surgery. We excluded patients with visually significant coexistent pathology such as corneal scars, macular pathology, and glaucoma.

Before recruitment, all patients underwent comprehensive ophthalmic evaluation including uncorrected visual acuity (UCVA) and best-corrected visual acuity (BCVA), Goldmann applanation tonometry (GAT), and slit lamp examination (SLE) to determine adequacy of capsular and zonular support, corneal clarity, and vitreous in the anterior chamber, fundus examination to rule out peripheral retinal tears, specular microscopy (SP-1P Topcon, Japan), and optical coherence tomography (OCT) (DRI OCT-1 Topcon, Japan) of the macula. All IOL powers were calculated by SRK-T formula

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Manuscript received: 04.08.17; Revision accepted: 26.09.17

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DOI:
10.4103/ijo.IJO_659_17

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Cite this article as: Kelkar AS, Fogla R, Kelkar J, Kothari AA, Mehta H, Amoaku W. Sutureless 27-gauge needle-assisted transconjunctival intrascleral intraocular lens fixation: Initial experience. Indian J Ophthalmol 2017;65:1450-3.

using the IOL Master 700 apparatus (Carl Zeiss Meditec, XX, USA). The target refraction in all cases was -0.50 D.

Surgical technique

Under peribulbar anesthesia, conjunctival entry spots were marked 180° apart with a marker at 3'o clock and 9'o clock meridians, 2 mm from the limbus. All patients underwent anterior vitrectomy and those with significant subluxation or dislocation of the nucleus or IOL underwent complete pars plana vitrectomy before SFIOL implantation [Video 1]. Following adequate vitrectomy, the three-piece IOL was either injected with the cartridge and injector into the eye through the limbal incision or in cases with prior IOL explantation, directly with McPherson's forceps through a sclerocorneal tunnel. Using the previous marking, an angled sclerotomy was made with 27-gauge needle, 2 mm from the limbus to engage the leading haptic, keeping it tangential with the iris plane to avoid ciliary body injury. A 25-gauge end gripping forceps was introduced from a paracentesis to insert the tip of the leading haptic into the lumen of the 27-gauge needle. The haptic was externalized and the tip was heated with a thermal cautery to create a flange [Fig. 1], which was pushed back and fixed intrasclerally. The same technique was repeated 180° opposite to fixate the trailing haptic. In case of sclerocorneal tunnel, McPherson's forceps was used to insert the tip of the trailing haptic into the lumen of 27-gauge needle. Viscoelastic material was aspirated and anterior chamber was formed with balanced salt solution (BSS) [Video 2]. If a pars plana vitrectomy was performed, the trocars were removed at the end and integrity of the incisions ensured. Following surgery, the patients' eye was padded and shifted to the recovery room. The eye pad was removed after 6 hours and topical medication was started. Nepafenac eye drops three times a day for 2 weeks, moxifloxacin eye drops three times a day for 4 weeks, and topical prednisolone 1% eye drops in tapering dose for 6 weeks were given.

UCVA, BCVA, GAT, SLE, specular microscopy, OCT, serial digital slit lamp images of the eye with full pupillary dilatation [Fig. 2], and anterior segment OCT (RTVue-100, Optovue Inc., USA) to assess the position of the flange were done at 1 week [Fig. 3], 6 weeks, and 6 months. Descriptive data from patients who lost follow-up were utilized to report on the intraoperative experience but were excluded from the postoperative statistical analysis. All the data were entered in Microsoft Excel sheets and were analyzed using STATA 12.0 I/C (Fort worth, Texas). Continuous variables were described as means \pm standard deviation or median and interquartile range (IQR) and categorical variables were described as proportions. Visual acuity was converted to logarithm of minimum angle of resolution (logMAR) for analysis. Pre- and post-operative data were analyzed using the paired *t*-test. $P < 0.05$ was considered statistically significant.

Results

The study comprised of 31 eyes of 31 patients undergoing SFIOL by the modified Yamane's technique. Twenty-three (75%) patients returned for follow-up at 6 weeks and 21 (67%) visited at 6-month follow-up.

Demographics and indications

The mean age of subjects was 57 ± 16.9 years (media $n = 60$ years, IQR = 52–68 years) and 23 were men (74%). SFIOL was performed

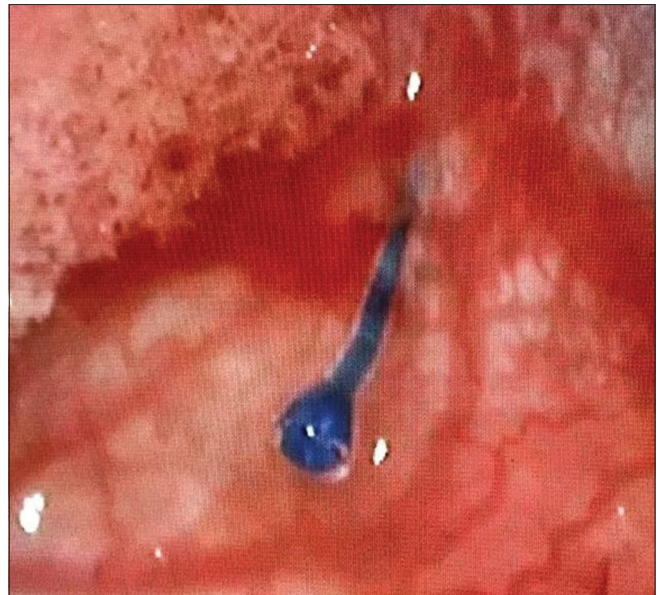


Figure 1: Flange of the externalized haptic

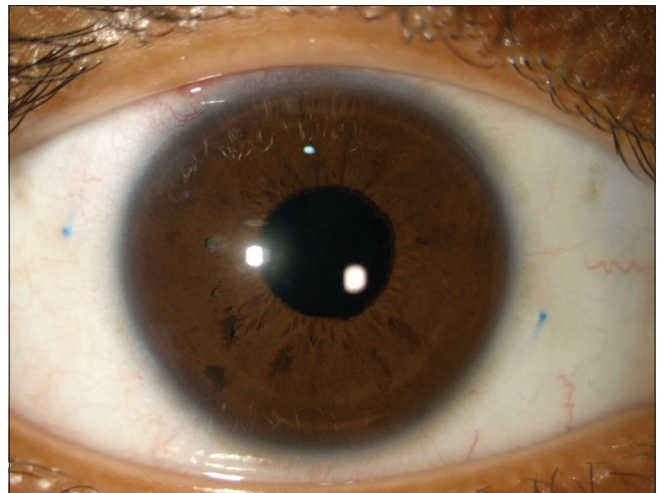


Figure 2: Postoperative picture at 1 week

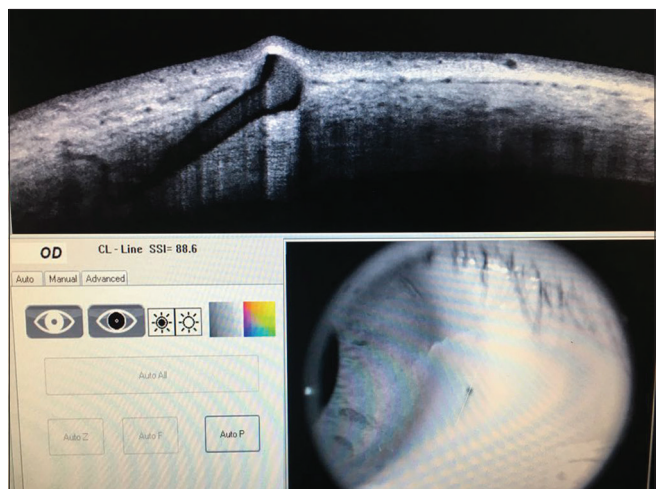


Figure 3: Anterior segment optical coherence tomography demonstrating intrascleral flange of the haptic

for aphakia following complicated cataract surgery in ten eyes (32%), along with lensectomy for subluxated/dislocated cataract in six eyes (19%) and along with IOL explantation for subluxated/dislocated IOL in 15 eyes (48%). Overall, 13 eyes (42%) underwent anterior vitrectomy at the time of SFIOL placement and the remaining 18 eyes (58%) underwent pars plana vitrectomy.

Outcome

UCVA improved from median of 1.48 logMAR units (IQR = 1.3–2 logMAR) at baseline to 0.6 logMAR (IQR=0.5–0.8 logMAR) at 1 week postoperative ($P < 0.001$) period and improved further to 0.3 logMAR (IQR = 0.2–0.4 logMAR) at 6 weeks ($P < 0.001$ compared to baseline and $P = 0.002$ compared to 1 week) and was maintained at 3- and 6-month follow up. The best-corrected vision was 0.3 logMAR (IQR = 0.2–0.6) preoperatively and was maintained at 6 weeks (median $n = 0.2$ logMAR, IQR = 0.2–0.4) and 6 months ($P = 0.83$).

Eyes with IOL explantation at time of SFIOL had greater refractive error (astigmatism), but this was not significantly different from those without IOL explantation ($P = 0.24$). These eyes had comparatively lower vision (0.6 ± 0.5 logMAR) at 6 weeks, 3 months, and 6 months compared to those without IOL explantation (0.33 ± 0.2 logMAR) though this difference was not statistically significant ($P = 0.08$). Overall, refractive median error at the end of 6 weeks was -0.75 D sphere (IQR = -0.5 to -1.00 D sphere) and median cylinder was -1.3 D sphere at 80° (IQR = -1.00 to -1.8 D). There was no appreciable change in spherical and cylindrical correction between 6 weeks and 6 months follow-up. Mean preoperative intraocular pressure (IOP) was $17.6 + 7.1$ mmHg and it rose to $21.2 + 9.1$ mmHg at 1 week ($P = 0.06$) but returned to normal levels at 6-week follow-up ($14.9 + 4.2$, $P = 0.16$). There was no significant change in endothelial cell density (preoperative = $2734 + 571$ cells/mm² vs. postoperative = $2491 + 904$ cells/mm², $P = 0.34$) and macular thickness on OCT (preoperative = $241 + 39 \mu$ vs. $248 + 46 \mu$, $P = 0.31$) at 6-month follow-up. None of the eyes developed clinical or OCT-based cystoid macular edema at 6 months.

Complications

None of the eyes experienced any intraoperative complications. Transient IOP rise above 21 mmHg was seen in 12 eyes (39%), but all these were managed conservatively with topical antiglaucoma medications. Two eyes had mildly decentred SFIOL but were managed with appropriate refractive correction. One eye had persistent postoperative vitreous hemorrhage and underwent pars plana vitrectomy at 6 weeks with excellent visual recovery.

Discussion

Many techniques have evolved over the decades ranging from anterior chamber IOL implantation, either supported on the anterior iris surface or the anterior chamber angle,^[3,4] scleral fixated IOLs (SFIOL) anchored either using sutures^[5-7] or by sutureless methods,^[8] and retropupillary iris claw IOL fixation.^[9] Each technique has its merits and demerits; however, scleral fixated IOL is the most preferred technique in view of their long-term safety and efficacy.^[10] Compared to sutured SFIOL, performing sutureless SFIOL fixation as described by Scharioth is relatively simple where the exteriorized haptics of a regular three-piece IOL are fixated into scleral pockets.^[11]

Sindal has shown comparable results using sutured SFIOL and sutureless SFIOL for postcataract and posttraumatic aphakia.^[12] Similarly, Agarwal's technique of glued SFIOL exteriorizes the IOL haptic under a partial thickness scleral flap, which is then secured using fibrin glue.^[13,14] Although technically less challenging than sutured SFIOL, these techniques of sutureless SFIOL involve conjunctival dissection and related patient discomfort. In addition, it is always challenging to ensure adequate length of haptic fixation inside the scleral tunnels or under scleral flaps. Long-term impact of the exteriorized IOL haptic and fibrin glue on the scleral integrity and stability of IOL fixation is unknown at present.

To address these concerns, Yamane described the elegant use of a 30-gauge thin wall needle to externalize the haptics of a three-piece haptic IOL before using heat from a cautery to create a flanged haptic tip that permits intrascleral fixation without slippage.^[12] He termed it the transconjunctival intrascleral IOL fixation with the double-needle technique using flanged haptics. Its ease of performance and many advantages over the conventional SFIOL techniques make it the most attractive choice for both, anterior and posterior segment surgeons. However, the haptics of routinely used lenses such as Tecnis ZA9003 (Abbott Medical Optics, Santa Ana, CA, USA) and Sensor AR40e (Abbott Medical Optics, Santa Ana, CA, USA) cannot be negotiated through routine 30-gauge needle. Since the thin walled 30-gauge needle is not freely available in our setting, we used 27-gauge needles to exteriorize the haptics of these IOLs. Even while using the 27-gauge needle, we found that it took efforts to thread the trailing haptic into the needle lumen. In view of this, we recommend using a 26-gauge needle for beginners so that the procedure is completed without haptic-related complications such as breakage and slippage in the initial cases. We did not encounter any intraoperative complications related to the surgical technique.

We modified the Yamane technique where we exteriorized and fixed the leading haptic entirely before manipulating the lagging haptic, contrary to Yamane's description of exteriorizing both haptics simultaneously because we believe that if the needle is made to hang inside after engaging the leading haptic, then there is a probable risk of iris, ciliary body, and retinal damage. IOP fluctuations, which are inevitable during insertion of the lagging haptic, enhance risk of intraocular tissue damage and disengagement. In our experience, though it is little difficult to manipulate the lagging haptic tip into the 27-gauge lumen once the leading haptic is outside the eye, we found that using an end gripping forceps and inserting the lagging haptic from the side port lead to successful completion of surgery without too much difficulty; one can use even a McPherson's forceps through the main incision to introduce the lagging haptic tip into the 27-gauge lumen if scleral tunnel is used. The drawback of fixing the leading haptic first is that it becomes difficult to explant the IOL in toto if the trailing haptic gets damaged. However, we did not experience this in our series of 31 cases. In an unlikely event of such a complication, the externalized haptic can be cut and the IOL should be explanted. Complications were comparable to the previously described techniques of SFIOL [Table 1] except transient IOP elevation (39%) which was possibly due to retained viscoelastic following inadequate AC wash. We had a significant number of eyes with IOL explantation coupled with the SFIOL procedure, leading to significant astigmatism after surgery and reduced

Table 1: Comparison of complication rates with other common techniques of sutureless scleral fixated intraocular lens

Complication	Scharioth <i>et al.</i> ^[11] (Sutureless SFIOL, n=63), n (%)	Kumar <i>et al.</i> ^[14] (glued SFIOL, n=53), n (%)	Yamane <i>et al.</i> ^[1] (flanged SFIOL, n=100), n (%)	Our study (modified Yamane, n=31), n (%)
Temporary corneal edema	5 (7.94)		1 (1)	Nil
IOP elevation	2 (3.17)	0	2 (2)	12 (39)
Hyphema		2 (3.7)		Nil
Hypotony	1 (1.59)		2 (2)	Nil
Pigment dispersion		2 (3.7)		
Cystoid macular edema	1 (1.59)	4 (7.5)	1 (1)	Nil
Vitreous hemorrhage	2 (3.17)	0	5 (8)	1 (3.2)
IOL decentration		3 (5.6)		2 (6.4)
Spontaneous IOL dislocation	2 (3.17)		Nil	Nil
Iris capture of IOL	1 (1.59)		8 (8)	Nil
Traumatic IOL subluxation	1 (1.59)			Nil

IOP: Intraocular pressure, IOL: Intraocular lens, SFIOL: Scleral fixated intraocular lens

vision due to scarring induced by two back-to-back surgeries. Despite this, there was excellent visual recovery at the end of 6 weeks, which was maintained at 6 months. Similarly, we did not see any significant reduction in endothelial cell count and none of the eyes developed cystoid macular edema.

The main drawback of our study is the lack of a conventional control group. Future studies are required with larger sample, longer duration of follow-up with a control group to understand the long-term implications, and stability of this surgical technique.

Conclusion

Our initial experience spanning the intraoperative and 6-month postoperative course suggests that this technique of SFIOL fixation is relatively easy to perform, is independent of scleral flaps, tunnels, sutures, and fibrin glue and has great potential in simplifying surgical correction of aphakia.

Acknowledgement

We acknowledge the assistance of Dr. Sabyasachi Sengupta from Sengupta's Research Academy in statistics and content editing for this manuscript. We also acknowledge Dr. Shrikant B. Kelkar for his guidance.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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