Original Article

Novel technique of sutureless glueless scleral fixated intraocular lens (SFIOL)

Shweta Walia, Santosh Kashyap, V Bhaisare, P Rawat, N Kori

Purpose: To report results of a novel technique for sutureless, glueless intrascleral fixation of three-piece posterior chamber intraocular lens (IOL) using 26-G needle for management of aphakia. **Methods:** In this prospective series, 30 eyes of 20 patients with aphakia, subluxated IOL, or crystalline lens were included. 26-G-needle-guided intrascleral fixation of three-piece posterior chamber IOL was performed according to the described technique. The patients were evaluated on day 2, 1 week, 6 weeks, and 3 months postoperatively for change in best-corrected visual acuity (BCVA), intraocular pressure (IOP), IOL centration, and any other complications. The postoperative tilt of the IOL was indirectly measured by determining the lenticular astigmatism which in turn was calculated by the difference between net corneal astigmatism and refractive astigmatism. Paired *t*-test was used to determine the significance of any association between the preoperative and postoperative BCVA and IOP. $P < 0.05$ was considered significant. **Results:** Of 30 eyes ($n = 30$ patients), 18 were surgical aphakia, 6 traumatic aphakia, 5 subluxated IOL, and 1 ectopia lentis (Marfan syndrome). The mean preoperative BCVA was 1.37 ± 0.37 (logMAR) and postoperative BCVA at 3 months was 0.37 ± 0.29 (logMAR). A significant improvement in the mean BCVA ($P < 0.05$) was observed after the procedure. The mean IOP preoperatively was 13.33 ± 4.18 and postoperatively at 3 months was 12.82 ± 3.97 ($P > 0.05$), which was not significant. None of the eyes developed any intraoperative and postoperative complications. The IOLs had appropriate centration and stability. **Conclusion:** We have developed this new technique for intrascleral IOL fixation which is quite simple, cost-effective, minimally invasive, neither requires glue nor suture and gives consistent outcome.

Key words: Aphakia, glueless, intrascleral fixation of three-piece posterior chamber intraocular lens, 26-G needle, sutureless

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Optical rehabilitation in patients with aphakia presents a unique surgical challenge. The choice of intraocular lens (IOL) implantation includes anterior chamber (AC) IOL, iris-fixated IOL, iris claw IOL, sutured sclera-fixated IOL, and sutureless sclera-fixated IOL (SFIOL).[1] Each of these IOL has its own merits and demerits. ACIOL is technically less demanding but has potential for increased damage to the corneal endothelium and angle structures.[1,2] Iris claw and iris-fixated IOLs have increased chances of pigment release and intraocular inflammation.[2] SFIOL has the advantage of more physiological position near the nodal point of eye and greater distance from the cornea. Sutured SFIOL implantation is technically more demanding and can have problems such as pseudophacodonesis and suture-related complications such as suture knot exposure, suture breakage, and IOL subluxation.[3] However, to avoid suture-related intraoperative and postoperative problems, Gabor *et al*. introduced a new technique wherein sutureless technique for sulcus fixation of a posterior chamber IOL was done using permanent incarceration of the haptics in a scleral tunnel parallel to the limbus.[4] This method combines the control of a closed-eye system with the postoperative axial stability of the posterior chamber IOL while avoiding suture-related problems. In their technique, Gabor *et al*. used cannulas to create a limbus-parallel tunnel at approximately 50% scleral thickness, starting from the ciliary sulcus sclerotomies and ending with externalization of the cannula after 2 or 3 mm. The 25-G forceps was used for haptic externalization and introduced into the intrascleral tunnel. Amar Agarwal devised a technique of tucking IOL in the intrascleral tunnel and used a biological glue for the scleral flap.[5] We describe a much simpler technique which is a modification of the above-mentioned Gabor's technique. It also avoids the use of a specialized forceps for the haptic insertion and also does not require any suture or glue. In our technique, we used 26-G needle to exteriorize haptic which is far more finer than 25-G forceps.

Methods

All patients who had undergone sutureless, glueless intrascleral IOL fixation using 26-G needles between December 2016 and December 2017 were studied. All surgeries were performed by a single surgeon. The study protocol was approved by the institutional review committee, and the study was performed

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in accordance to the tenets of Declaration of Helsinki. A written informed voluntary consent was taken from all the study subjects. All patients underwent standard ocular examination protocol which includes preoperative IOL power calculation and measurements of best-corrected visual acuity (BCVA) with a LogMAR chart, slit-lamp examination, keratometry (K-vertical, K-horizontal), measurement of the intraocular pressure (IOP), and dilated retinal examination at all pre- and postoperative visits. Bausch and Lomb keratometer was used to measure the corneal curvature in vertical and horizontal meridian, and the difference in the power between the two principal meridian gives the total corneal astigmatism in dioptre. Postoperative retinoscopy and refraction was performed and correlated with corneal astigmatism measured by manual keratometer to calculate IOL-related astigmatism.

Operative procedure

Preoperative pupil centration marking was done under topical anesthesia. The surgery was performed under peribulbar anesthesia. The peripheral cornea was marked with a tissue pen at two points 180° apart using Osher-Neumann corneal marker [Fig. 1a]. To understand, we describe herein markings made at 4 and 10O'clock positions. Localized 5-mm conjunctival peritomy at these two sites was done and adequate cautery applied. Two side port entries were made at 3 and 9O' clock using 15° side port blade, and 23-G vitrectomy was performed through anterior route to remove all vitreous traction (None of the patient underwent pars plana vitrectomy). The AC was formed with viscoelastic material. A fornix-based conjunctival peritomy was performed from 11 to 1O' clock meridian, and a self-sealing three planar corneoscleral tunnel of size 6 mm spanning the 12O' clock meridian was made [Fig. 1b]. Many of our patients were recently operated post small incision cataract surgery. The same sclerocorneal tunnel was opened and used for IOL insertion. A three-piece IOL [polymethyl methacrylate (PMMA) optic and prolene haptics, Aurolens (Aurolab, model number B3602 India) of 6-mm optic diameter, overall size 13.5 mm, A constant 118.5, modified C loops haptics] was preferred (no financial interest) because it is very economic and affordable to the patients. Standard 26-G needles that are readily available were used to exteriorize the haptics. This reduced dependency on 23-G micro rhexis forceps. Two standard 26-G needles (13 mm) were bent to 60° about 1 mm from the hub. The first bent 26-G needle was introduced into the ciliary sulcus 1.5 mm behind the limbus at 4O' clock position [Fig. 1c]. Once the needle was visible within the pupillary margin, it was redirected and brought out through the corneoscleral tunnel wound; 4 mm of the leading haptic of a three-piece PMMA IOL was threaded into the lumen of the needle using McPherson forceps [Fig. 1d]. The 26-G needle was then withdrawn out of the sclerotomy along with the leading haptic following the curve of the haptic. The second bent 26-G needle was inserted through the sclera at the 10O'clock position and the trailing haptic was exteriorized in a similar way as the leading haptic [Fig. 1e and f]. The intrascleral tunnel of about 4 mm length (1.5 mm behind and parallel to the limbus) was made with the bent 26-G needle by starting 5 mm from the exit point of haptics, going intrasclerally and bringing needle near the exit site of haptic at 4O' clock position. The leading haptic was threaded into the lumen of 26-G needle and tucked into the scleral tunnel by gently withdrawing the 26-G needle out through the tunnel [Fig. 1g]. The 26-G needle acts as docking guide for intrascleral tucking of haptics. Similarly, trailing haptic was tucked into the intrascleral tunnel [Fig. 1h]. The conjunctival flaps were repositioned, edges were stuck using wet field cautery, and AC was washed and formed with air or normal saline.

IOL tilt estimation

The vector difference between the net corneal astigmatism (front and back corneal surface) and the refractive astigmatism at the corneal plane is the lenticular (phakic or pseudophakic) astigmatism at the corneal plane, described in mathematical form as follows: lenticular astigmatism = refractive astigmatism − net corneal astigmatism. Net corneal astigmatism and refractive astigmatism were calculated, and lenticular astigmatism at the corneal plane was determined. The lenticular astigmatism needed to be converted from the corneal plane to the IOL plane. The conversion depends on the effective lens position and the power of the IOL. Using the actual effective lens position and the actual IOL power, the exact conversion ratio was calculated using the vergence formula by Holladay.[6] Finally, the lenticular astigmatism at the IOL plane was used along with the IOL power to estimate the tilt angle of the IOL. Serial digital slit-lamp images of postoperative eyes with full pupillary dilatation showed good IOL centration [Fig. 2].

Paired *t*-test was used to determine the significance of any association between the preoperative and postoperative BCVA and IOP. Since data were compared before and after surgery within a group. Hence, the statistical test of significance, namely, paired *t*-test was applicable for interpretation of results, and $P < 0.05$ was considered significant. Statistical analyses were performed using SPSS software version 20.0.

Results

Thirty eyes of 30 patients completed the study (18 men and 12 women; mean age 54.20 ± 16.67 years) with a mean follow-up of 3 months. The mean BCVA preoperatively was 1.37 ± 0.37 and postoperatively at 3 months was 0.37 ± 0.29 [Table 1]. About 28 (93.33%) eyes showed improvement of three or more lines of logMAR BCVA and 2 (6.66%) eyes showed improvement of two lines of logMAR BCVA postoperatively [Table 2]. On applying paired *t*-test on pre- and postoperative BCVA, we obtained a significant P value <0.05. The mean IOP preoperatively was 13.33 ± 4.18 and postoperatively at 3 months was 12.82 ± 3.97 ($P > 0.05$), which was not significant. One patient had raised IOP which was attributed to preoperative posttraumatic glaucoma which was medically controlled. None of the patients had any intraoperative complications such as vitreous hemorrhage, IOL drop, and haptic breakage, and none of the patient had any postoperative complications such as haptic exposure, optic capture of lens, IOL tilt or decentralization, glaucoma, macular edema, vitreous hemorrhage, postoperative endophthalmitis, and retinal detachment.

Refractive characteristics

In patients (n = 30) included in the study, the preoperative mean ± standard deviation (SD) spherical refraction was +10.4 ± 1.56 D (range −3.00 to +13.00 D). The preoperative mean ± SD total astigmatism was +0.60 ± 1.04 D (range −2.5 to +3.00 D), and the mean ± SD corneal astigmatism was −0.38 ± 1.61D (range −2.50 to + 2.50 D). Posterior chamber IOL power was 17–27 D (mean 21.30 D). Postoperatively, the

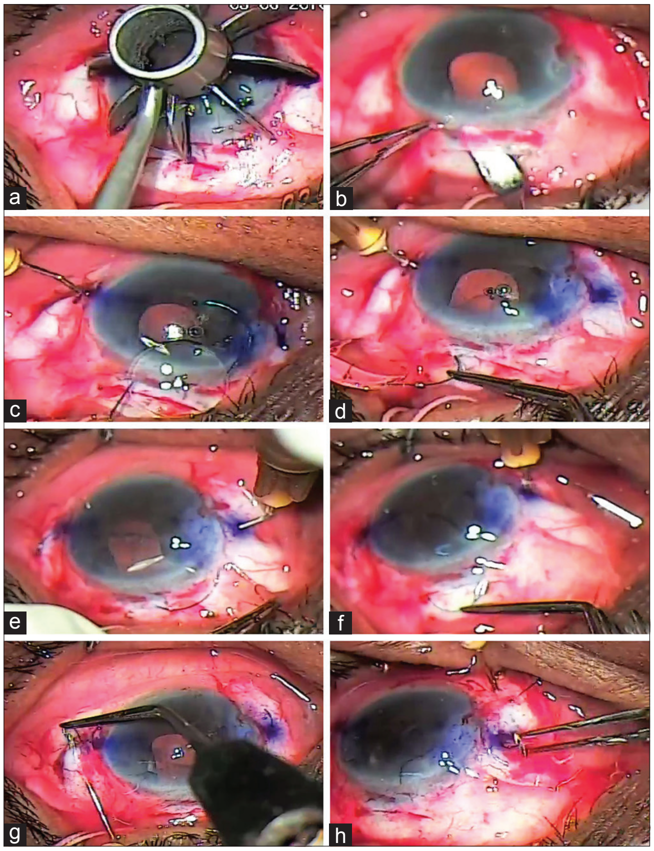

Figure 1: (a) Peripheral corneal marking at 4 and 10o'clock 180° apart. (b) Corneoscleral tunnel of 6 mm at 12 o'clock. (c) Introduction of 1st bent 26G needle into ciliary sulcus 1.5 mm behind limbus at 4 O'clock. (d) Threading of 4 mm of leading haptic of 3 piece IOL into lumen of needle using McPherson forcep and externalization. (e) Insertion of 2nd bent 26G needle at 10 O'clock. (f) Threading of trailing haptic into needle and exteriorization. (g) Threading of leading haptic into lumen of 26G needle and tucking into scleral tunnel. (h) Tucking of trailing haptic into intrascleral tunnel with 26G needle

mean ± SD spherical refraction was −0.042 ± 1.09D (range–-2.5 D to +1.75 D), with a mean ± SD total astigmatism of −0.46 ± 1.28 D (range −2.50 to +2.50 D), a mean ± SD corneal astigmatism of −0.16 ± 1.20 D (range −2.0 to +2.25 D), and a mean ± SD spherical refractive equivalent of −0.33 ± 1.39 D. The mean ± SD difference between total and corneal astigmatism in these eyes was −0.08 ± 0.87 D (range −1.75 to +2.00 D), which may indicate that the IOL-induced astigmatism was minimal.

Discussion

Sutureless techniques for an intrascleral fixation of PCIOLs in the management of aphakia have been reported by several investigators.[7-14] This type of surgery is used because it has some advantages over conventional trans-scleral suturing of the IOL.[10-13] Agarwal *et al*. achieved sutureless implantation using fibrin glue to close the scleral flaps without suture-related complications.[5] This technique uses a 22-G needle to make sclerotomies under the existing sclera flaps, about 1.5 mm from the limbus. The haptics were exteriorized with the end – gripping 23-G micro rhexis forceps.[5] The tunnels created by these gauge needles were too large for the externalization of the haptics of the IOLs. A mismatch between the diameters of

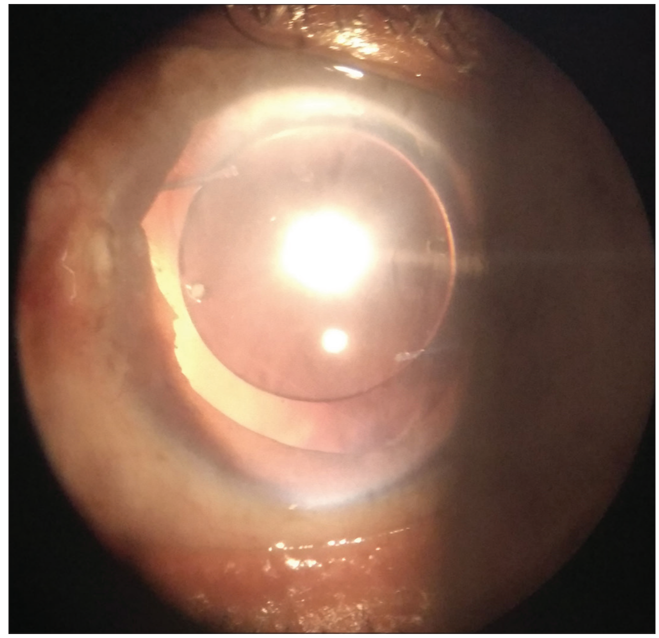

Figure 2: Postoperative photograph showing the perfect centralization and stability achieved after sutureless glueless scleral fixation of 3 piece intraocular lens in a patient with traumatic mydriasis

Table 1: Baseline characteristics and postoperative data

Characteristics	Value
Number of eyes (patients)	30 (30)
Age, years (mean±SD)	54.20±16.67
Sex (male/female)	18/12
Distribution of cases (of 30 eyes of 30 patients)	
Post complicated SICS	29
Post complicated phacoemulsification	1
Post ECCE	-
Post ICCE	-
Diagnosis	
Surgical aphakia	18
Traumatic aphakia	6
Subluxated IOL	5
Ectopia lentis (Marfan syndrome)	1
Follow-up	3 months
Baseline logMAR BCVA (mean±SD)	(1.37±0.37)
LogMAR BCVA at 3 months (mean±SD)	(0.37±0.29)
Baseline IOP (mean±SD)	(13.33±4.18)
IOP at 3 months (mean±SD)	(12.82±3.97)

SD: Standard deviation; SICS: Small incision cataract surgery; IOL: Intraocular lens; BCVA: Best-corrected visual acuity; IOP: Intraocular pressure; Post ECCE: Extracapsular cataract extraction; Post ICCE: Intracapsular cataract extraction

the sclerotomy and haptic of the IOL results in wound leakage and postoperative hypotony, and hence the need of glue to seal the scleral flaps and intrascleral tunnels. In this technique, there is dependency on 23- or 25-G micro rhexis forceps to exteriorize haptics. Second, fibrin glue might be not available everywhere and is costly too. Wilgucki *et al*. created ciliary sulcus-based sclerotomies using 20-G blades to facilitate passing the

Table 2: Visual outcome of the patients

	Preoperative (%)	Postoperative (%)
BCVA (LogMAR)		
Worse than 1.0	21 (70%)	-
1.0-0.5	9 (30%)	-
0.5 or better	-	30 (100%)
Change in BCVA (logMAR)		
Gained three or more lines or attained 0 logMAR	-	28 (93.33%)
Gained two lines	-	2 (6.66%)
Gained one line	-	-
Lost two lines	-	-

BCVA: Best-corrected visual acuity

haptics through the sclera.[12] The potential for vitreous hemorrhage and hypotony is very much in this technique because of large sclerotomies. A larger incision can lead to a decrease in IOP, choroidal hemorrhage, and postoperative corneal astigmatism. Three of the 12 cases in Wilgucki *et al*.'s series had IOL dislocation 1 year after surgery. Zhang *et al*. used a small-diameter scleral tunnel, which reduced scleral manipulation and surgical trauma. A small-diameter scleral tunnel can provide leak-free closure.[13]

In previous techniques of sutureless scleral fixation of IOL, it is not easy to insert the IOL haptic into a scleral tunnel because the sclerotomy and scleral tunnel are close to each other. To overcome the problems in intrascleral tucking of haptics, Yamane *et al.* made vertical dissection so that the sclerotomy for haptic externalization is further apart from the scleral tunnel and haptics can be grasped and inserted easily.[8]

In all the techniques described till date, the intrascleral tunnels are made before exteriorizing haptics. We observed that these tunnels many times get lost to sight by the end of surgery or one has to premark these tunnels by staining tip of 26-G needle which is used to make tunnel. In addition, haptic tips get distorted by the end of surgery because of various manipulations and it becomes difficult to traverse them into preformed tunnels.

Therefore, we modified the technique of sutureless SFIOL. In our technique, we use 26-G needle for exteriorization and tucking of haptics into scleral tunnel. This tunnel holds the IOL haptics adequately and is good for the organization and encapsulation of the haptics in the scleral tunnel. The intrascleral tunnels were made after exteriorizing haptics. A tunnel of approx 4 mm length (1.5 mm behind and parallel to the limbus) was made with the bent 26-G needle by starting 5 mm from the exit point of haptics, going intrasclerally and bringing the needle near the exit site of haptic at 4O′ clock position. The leading haptic was threaded into the lumen of 26-G needle. The haptic gets tucked into the sclera while the 26-G needle is gently withdrawn. The 26-G needle acts as docking guide for intrascleral tucking of haptics and there is no need for vertical dissection as described in Yamane *et al*.'s technique. The conventional handshake technique requires a pair of intraocular forceps, longer intraocular maneuvers, and skill to learn. The probable complications during this step include IOL drop, haptic slippage, globe collapse, and haptic deformation as they exit the sclerotomy which are overcome in our technique. 26-G needles are very fine needles, thus entry ports are also very fine and small. Hence, there is no leakage and also early postoperative recovery. The haptics fit snugly in 26-G needle, thus there is no chance of longitudinal displacement even if we do not use glue. The inside diameter of a 26-G needle is 0.26 mm, which is large enough to insert the haptics of the commonly used three-piece IOLs (0.14 mm). In addition, the IOL haptic is locked in the needle because the haptic is curved and is passed into a straight lumen. The outer diameter of a 26-G needle is 0.46 mm, which is small enough for the self-sealing of the angled sclerotomy. The minimum invasiveness is compatible with good operability using a 26-G needle.

In Shin Yamane *et al*.'s technique, the mean preoperative BCVA was 0.48 logMAR units, and the mean postoperative BCVA improved significantly to 0.17 logMAR units at 3 months (P = 0.002).[8] While comparing with it, in our technique the mean BCVA preoperatively was 1.37 ± 0.37 and postoperatively at 3 months was 0.37 ± 0.29. The mean BCVA significantly improved at 3 months after surgery in our series ($P < 0.05$).

Baskaran *et al*. reported the mean BCVA of patients at 1-month follow-up as 0.5 ± 0.3 logMAR with 18 of 19 eyes showing one or more lines of improvement in BCVA.[14] In our technique, of 30 eyes, 28 eyes showed improvement of three or more lines of logMAR and 2 eyes showed improvement of two lines of logMAR with a mean BCVA of 0.37 ± 0.29 postoperatively at 3-month follow-up without any significant complications.

Our sutureless, glueless technique was intended to improve visual acuity outcomes, shorten the operation time, reduce the complications, and provide good IOL centration. This procedure requires fewer corneal and trans-scleral penetrations, which can cause complications such as vitreous hemorrhage, postoperative inflammation, retinal detachment, uveitis–glaucoma–hyphema syndrome, and irregular astigmatism. During the follow-up, there was no evidence of haptic erosion, and the majority of the IOLs remained well-centered. Analysis over a 3-month period demonstrated good IOL positioning with no significant tilt. However, to assess complications such as IOL tilt, IOL decentration, and haptic loosening, a long-term follow-up is required.

The procedure does not require special forceps, trocars, or fibrin glue; the only requirement is 26-G needles. The aid of an assistant was not required to support the IOL haptic. The procedure is easy to learn and very safe even for beginners. The technique without a scleral flap has an advantage of being simple and requiring less time.[4]

The limitations of this study are its shorter duration of follow-up, lack of control group, and unavailability of imaging techniques such as ultrasound biomicroscopy, anterior segment optical coherence tomography, and Scheimpflug imaging system to measure IOL tilt. Longer follow-up is needed for further assessment of anatomic and functional outcomes.

Conclusion

Our technique of sutureless, glueless intrascleral fixation of a three-piece posterior chamber IOL is very economical, provides more stable fixation, and showed better visual outcome in the absence of serious complications.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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