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No Suture No Glue Technique of Scleral Fixated IOL (SFIOL) Implantation for Management of Aphakia

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Abstract
Purpose: *To report results of a new technique for sutureless glueless intrascleral fixation of three piece posterior chamber intraocular lens (IOL) using 26-gauge needle for management of aphakia.*
Design: *Prospective, non-comparative, interventional case series.*
Participants: *30 eyes of 30 consecutive patients with aphakia, dislocated IOL or subluxated crystalline lens who underwent3-piece posterior chamber sutureless glueless implantation of an IOL were studied.*
Material and Methods: *26-gauge 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, IOL centration and any other complications.*
Result: *None of the eyes developed any intraoperative and postoperative complications. The IOLs had appropriate centration and stability. A significant improvement in mean BCVA ($P < 0.05$) was observed after the procedure.*
Conclusion: *We have developed this new technique for intrascleral IOL fixation which is quite simple, minimally invasive, neither requires glue nor suture and gives consistent outcome.*
Keywords: *aphakia, sutureless, glueless, intrascleral fixation of three piece posterior chamber intraocular lens, 26-G needle.*

Introduction

Optical rehabilitation in patients with aphakia presents a unique surgical challenge. Intraocular lens (IOL) is the best alternative for treating aphakia when spectacle or contact lens correction is not acceptable.[1],[2]The choice of IOL implantation include anterior chamber (AC) IOL, iris fixated IOL, iris claw IOL, sutured sclera fixated IOL and sutureless sclera fixated IOL (SFIOL). Each of these IOL has its own advantages and disadvantages. ACIOL is technically less demanding but has potential for increased damage to the corneal endothelium and the angle structures.[3]Iris claw and iris fixated

IOLs have increased chances of pigment release and intraocular inflammation.[3] 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 like pseudophacodonesis and suture related complications like suture knot exposure, suture breakage and IOL subluxation.[4] However, To avoid the suture related intraoperative and postoperative problems, Gabor and authors, 2007[5] introduced a new technique wherein they developed a sutureless technique for sulcus fixation of a posterior chamber IOL using permanent incarceration of the haptics in a scleral tunnel parallel to the limbus. 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 his 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. 25-gauge forceps was used for haptic externalization and introduced into the intrascleral tunnel. Amar Agarwal, (2008)[6] devised a technique of tucking IOL in intrascleral tunnel and used a biological glue for the scleral flap. 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 used26G needle to exteriorize haptic which is far more finer than 25G forceps.

Material and Methods

All patients who had undergone sutureless glueless intrascleral IOL fixation using 26-gauge needles between December 2016 and December 2017 were studied. The study protocol was approved by the institutional review committee and study was performed in accordance to the tenets of the Helsinki Declaration. 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 LOG-MAR chart, slit-lamp examination, keratometry (K-vertical, K-horizontal), measurement of the intraocular pressure and dilated retinal examination at all pre- and postoperative visits.

Operative Procedure

Pre-operative pupil centration marking was done under topical anesthesia. The surgery was performed under peribulbar anesthesia. The peripheral cornea was marked with tissue pen at two points 180° apart using Osher Neumann corneal marker (figure 1a). In order to understand, we describe herein, markings made at 4 and 10o'clock positions. Localized 5mm conjunctival peritomy at these two sites was done and adequate cautery applied. Two side port entries were made at 3 and 9 O' clock using 15 degree side port blade and 23 gauge vitrectomy was performed via anterior route to remove all vitreous traction. The anterior chamber was formed with viscoelastic material. A fornix‑based conjunctival peritomy was performed from 11 to 1 O' clock meridian and a self-sealing 3 planar corneoscleral tunnel of size 6 mm spanning the 12 o' clock meridian was made (figure 1b).A three piece PMMA IOL (aurolens, aurolab, India of 6mm optic diameter, overall size 13.5mm size, A constant 118.5, modified C loops haptics) was preferred. Two standard 26gauge needles (13 mm) were bent to 60 degree about 1mm from the hub. The first bent 26gauge needle was introduced into the ciliary sulcus 1.5 mm behind the limbusat 4 O' clock position (figure 1c). Once the needle was visible within the pupillary margin, it was redirected and brought out through the pupil and the corneoscleral tunnel wound.4 mm of the leading haptic of a three‑piece PMMA IOL was threaded intolumen of the needle using McPherson forceps (figure 1d). The 26‑gauge needle was then

withdrawn out of the sclerotomy along with the leading haptic following the curve of the haptic (figure 1e). The second bent 26‑gauge needle was inserted through the sclera at the 10 O'clock position and the trailing haptic was exteriorized in a similar way as the leading haptic (figure 1f-g). Intrascleral tunnel of about 4mm length (1.5mm behind and parallel to the limbus) was made with the bent26-gauge needle by starting 5 mm from exit point of haptics, going intrasclerally and bringing needle near the exitsite of haptic at 4 O' clock position. The leading haptic was threaded into the lumen of 26-gauge needle and tucked into the scleral tunnel by gently withdrawing the 26-gauge needle out through the tunnel (figure 1h). The 26 G needle act as docking guide for intrascleral tucking of haptics. Similarly trailing haptic was tucked into intrascleral tunnel (figure 1i).The conjunctival flaps were repositioned and anterior chamber washed and formed with air or normal saline.

Results

The 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. The statistical analyses were performed using the SPSS software. Thirty eyes of 30 patients completed the study(18 men, 12 women; mean age 54.20±16.67 year)with a mean follow-up of 3 months. Mean BCVA preoperatively was 1.37±0.37 and postoperatively at 3 months was 0.37 ± 0.29. On applying paired t-test on pre- and post-operative BCVA, we got a significant P value < 0.05. Mean IOP preoperatively was 13.33 ± 4.18and postoperatively at 3 month was 12.82 ± 3.97 (p value> 0.05), which was not significant. One patient was having raised IOP which was attributed to preoperative post traumatic glaucoma (medically controlled).None of the patients had any intraoperative complications such as vitreous hemorrhage, 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.

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
Diagnosis	
surgicalaphakia (consequence of ICCE or ECCE)	18
Traumatic aphakia	6
SubluxatedIOL	5
Marfans	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)

Table 2: Outlines the 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 3 or more lines or attained0 logMAR	-	28(93.33)%
Gained 2 line	-	2(6.66)%
Gained 1 line	-	-
Lost 2 lines	-	-

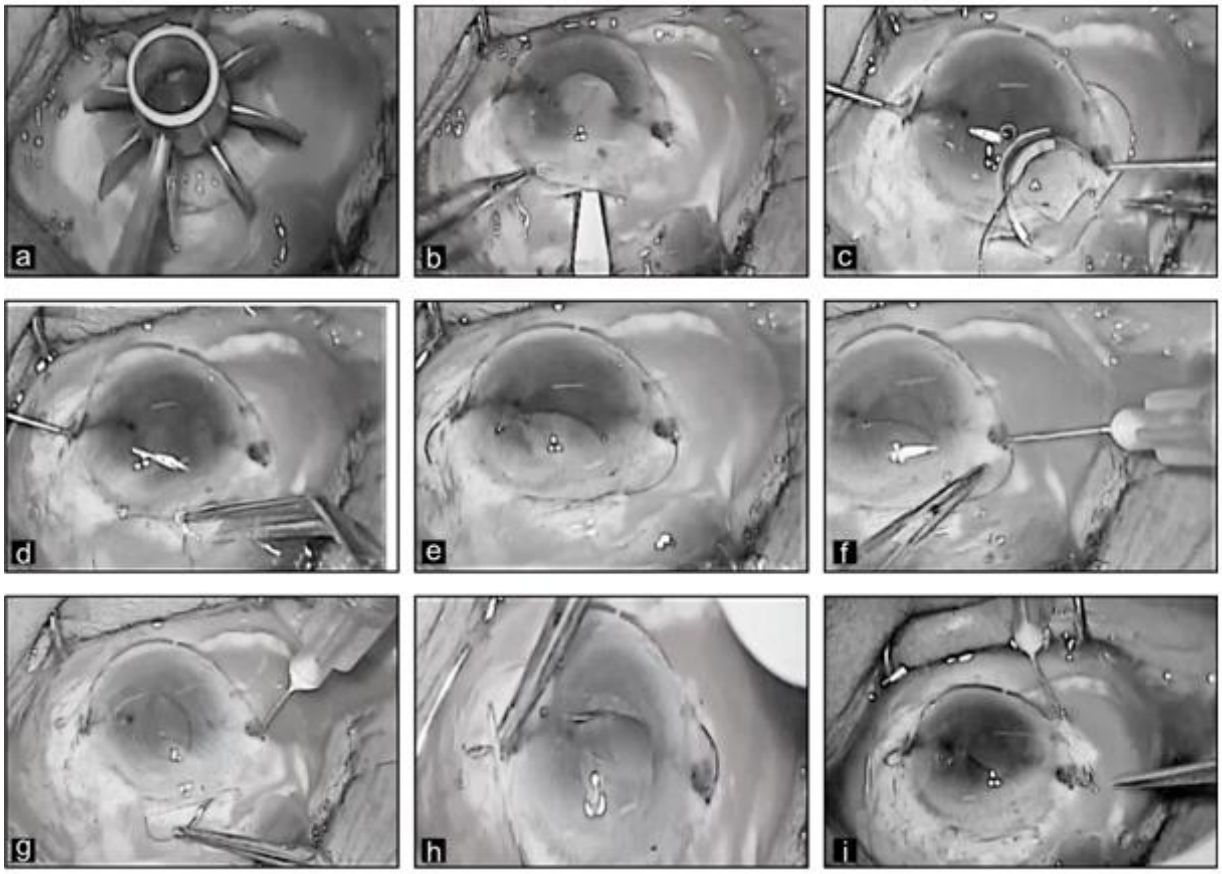

Fig. 1

a. Peripheral corneal marking with tissue pen at 4 and 10 o' clock position 180° apart using Osher Neumann corneal marker
b. Self sealing 3 planar corneoscleral tunnel of size 6 mm spanning the 12 o' clock meridian
c. Introduction of the first bent 26 gauge needle into the ciliary sulcus 1.5 mm behind the limbus at 4 O' clock position.(the needle visible within the pupillary margin)
d. Threading of 4 mm of the leading haptic of a three‑piece PMMA IOL into lumen of the needle using McPherson forceps
e. Externalization of the leading haptic (The aid of an assistant was not required to support the IOL haptic)
f. Similarly insertion of the second bent 26‑gauge needle through the sclera at the 10 O'clock position
g. Threading of the trailing haptic into needle and exteriorization in a similar way as the leading haptic
h. Threading of the leading haptic into the lumen of 26-gauge needle and tucking into the scleral tunnel by gently withdrawing the 26-gauge needle out through the tunnel. The 26 G needle act as docking guide for intrascleral tucking of haptics
i. Similarly tucking of the trailing haptic into intrascleral tunnel with the help of 26 G needle

Discussion

Sutureless techniques for an intrascleral fixation of PCIOLs in the management of aphakia have been reported by several investigators[5]-[11].This type of surgery is used because it has some advantages over conventional trans scleral suturing of the IOL[8]-[11]. Agarwal et al achieved sutureless implantation using fibrin glue to close the scleral flaps without suture-related complications[6]. However, there is dependency on23 or 25 G micro rhexis forceps to exteriorize haptics. Also fibrin glue might be not available everywhere and is costly too. Amar Agrawal et al in 2008,[6]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 25 G microrhexis forceps. 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 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. Wilgucki et al[12] created ciliary sulcus-based sclerotomies using 20G blades to facilitate passing the haptics through the sclera. The potential for vitreous hemorrhage and hypotony is very much in this technique because of large sclerotomies. A larger incision can lead to low IOP, choroidal hemorrhage, and postoperative corneal astigmatism. Three of the 12 cases in the Wilgucki et al series had IOL dislocation 1 year after surgery. Zhang Y., He F. et al[13]uses a small-diameter scleral tunnel, which reduces scleral manipulation and surgical trauma. A small-diameter scleral tunnel can provide leak-free closure.

In our technique we use 26-gauge 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. In all of the techniques described till date the intrascleral tunnels are made before exteriorizing haptics in which case these tunnels might be lost to sight by the end of surgery or one has to premark these tunnel by staining tip of 26 G needle which is used to make tunnel. Also these tunnels are made starting at the exit point of haptics. However we observed that while advancing 26 G needle into scleral to form these tunnels, there is always a chance of sideways movement and size of actual tunnel is not 26 G but a larger than it. Thus there is a chance for longitudinal displacement of IOL haptic and hence need of glue. Also we observed that haptic tips get distorted by the end of surgery because of various manipulations and it becomes difficult to traverse them into preformed tunnels. So we modified the method of making tunnel. In our technique, intrascleral tunnel was made after exteriorizing haptics. Tunnel of approx 4mm length (1.5mm behind and parallel to the limbus) was made with the bent26-gauge needle by starting at 5mm from exit point of haptics, going intrasclerally and bringing needle near the exitsite of haptic at 4 O' clock position. The leading haptic was threaded into the lumen of 26-gauge needle. Haptic gets tucked into the sclera while the 26-gauge needle is gentle withdrawn. The 26 G needle act as docking guide for intrascleral tucking of haptics.

26 gauge needles are very fine needles, thus entry ports are also very fine and small. So, there is no leakage and also early postoperative recovery. And the haptics fit snugly in 26G needle thus no chance of longitudinal displacement even if we don't use glue. The inside diameter of a 26-gauge needle is 0.26 mm, which is large enough to insert the haptics of commonly used 3-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-gauge needle is 0.46mm, which is small enough for the self-sealing of the angled sclerotomy. The minimum invasiveness is compatible with good operability by using a 26-gauge needle.

While comparing with Gabor and Pavlidis' technique[5], our method has fewer incisions. It can be performed on secondary IOL implantation with fewer scleral incisions, which could minimize intraoperative maneuvers and reduce the risk for intraoperative trauma.

In Gabor and Pavlidis' method[5], a 25-gauge forceps was used to grasp the haptics. Holding the haptics with 25-gauge forceps might be difficult. It is easy to break the IOL haptics and the forceps used to pull the haptics out through the scleral tunnel can cause breakage of the haptics. In our method, we used a 26-gauge needle to pull the haptics out through the scleral tunnel which provides better control and there is no chance of haptic breakage.

Our sutureless 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 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.

The procedure does not require special forceps, trocars or fibrin glue, only requirement is 26-gauge 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.[5]

Conclusion

Our technique of sutureless, glueless intrascleral fixation of a 3- piece posterior chamber IOL provides more stable fixation and showed better visual outcome in the absence of serious complications. We believe this technique is better than those previously reported because the sclerotomy is small and the IOL haptic is easily threaded and stably fixated in the intrascleral tunnels.

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