

Short Research Article

Revised Technique of Four - Point Scleral Fixated Intraocular Lens: Visual Outcome and Complications

ABSTRACT:

Aims: To analyze the visual results and complications in sclera-fixated intraocular lenses with four point fixation technique.

Study design: Case series

Place and duration of study: Sarojini Devi Eye Hospital, a government medical college tertiary care eye hospital in south India. Study conducted between October 2013 and June 2016.

Methodology: This study was conducted on patients who have undergone a secondary SF IOL implantation in cases of aphakia with inadequate posterior capsular support with a modified four-point scleral fixation technique, comprising of scleral tunnels to bury the suture knots and fixing the IOL at four points on sclera.

Results:

Statistical analysis used: Student paired T - test for all continuous data using GraphPad software.

The study comprised 30 eyes of 30 patients (17 men, 13 women). The mean age at surgery was 46.6 years (range 8 - 83 years) and the mean follow-up was 19 months (range 15 months to 31 months). The corrected distance visual acuity was 6/24 (0.68 log mar units) preoperatively which improved to 6/18 (0.45 log mar units) postoperatively. The most common postoperative complication was raised intraocular pressure, seen in 13 eyes (43.6% P value <0.0001).

Conclusions: Aphakia with no capsular support is a challenge where SF IOL is a promising option with minimal complications, when done with proper care and good technique.

Key-words: *Aphakia, Capsular support, Scleral-fixated intraocular lens, sclera tunnel.*

Abbreviations:

SF IOL – sclera fixated intraocular lens, CDVA – Corrected distance visual acuity,

1. INTRODUCTION

The prevalence of senile cataract in people above 60 years in India varies from 53 to 58% [1]. In the event of a capsular rupture with vitreous disturbance during cataract surgery, an inadequate posterior capsular remnant would compromise the prospects of a routine IOL implantation. The other situation of inadequate capsular support is a capsular injury in ocular trauma.

Alternative options due to inadequate capsular support include scleral-fixation, iris-fixation or placement of the IOL in the anterior chamber [2]. Each of these methods offers definite advantages and

disadvantages on surgical intricacy, operative duration, and complications. There is no unanimity of opinion on the best choice in the presence of inadequate posterior capsular support.

The anatomic site of scleral-fixated intraocular lenses (SF IOL) puts them at an advantage over other IOLs in regard to complications, especially in young patients and in cases of trauma [3,4]. SF IOLs give a better visual outcome without the complications of AC IOLs [4,5]. Surgical technique of SF IOL is more difficult and takes longer than other IOLs and suture tracking inside the eye and manipulation in the ciliary region may cause vitreous hemorrhage [6]. Other well documented postoperative complications are suture exposure, suture erosion, IOL tilt, elevated intraocular pressure, retinal detachment, and endophthalmitis [7,8].

The present study has analyzed patients with a minimum of 15 months of follow-up to find the visual acuity outcomes and incidence of complications after scleral fixated PC IOL implantation with a modified four-point fixation technique.

2. MATERIAL AND METHODS:

This prospective interventional case series was conducted at Sarojini Devi Eye Hospital, a tertiary care government eye hospital from October 2013 to June 2016. The Institutional review board of the Hospital approved the study protocol, which was conducted following the tenets of the Declaration of Helsinki. All participants signed a written informed consent. Thirty aphakic patients (thirty eyes) were enrolled for four-point scleral fixation of IOL after meeting the inclusion and exclusion criteria.

Inclusion criteria included: Best-corrected visual acuity better than 6/60, no corneal pathology, normal posterior segment, no active uveitis.

Exclusion criteria included; patients with the only eye, active or old vitreoretinal pathology, diabetic retinopathy with CSME or proliferative retinopathy and cystoid macular edema.

The advantages and the potential risks of the procedure was explained to the patients and their relatives. A detailed medical history was taken to rule out uncontrolled diabetes, hypertension, asthma, orthopnea and any other systemic diseases. Comprehensive eye examination was done in all patients, at baseline, and at later follow-ups. The preoperative corrected distance visual acuity(CDVA) and post-operative CDVA and complications were analyzed on long-term follow-up. Postoperative complications were divided into early and late; late complications are those seen 2 weeks after surgery.

Ciprofloxacin eye drops were started one day before surgery. Biometry was performed using Alcon OcuScan RxP Ophthalmic Ultrasound System.(USA).The surgical procedures were performed by a single surgeon (SL)

Surgical Technique: Local anesthesia, used for performing surgical procedures, was composed of equal portions of Lignocaine 2% (Neon Laboratories Limited, India) and Bupivacaine 0.5%.(Neon Laboratories Limited, India) Patients were prepared and draped according to the standard protocol for cataract surgery affecting instillation of 5% Povidone Iodine in the eye. 23 G Pars plana partial anterior vitrectomy was performed to clear the vitreous from the anterior chamber, pupillary plane and the posterior chamber (place of SF IOL placement). Limited conjunctival peritomy was performed. Homeostasis on the scleral surface was achieved by wet field-bipolar cautery. Partial thickness (1/2 - 2/3 scleral depth) scleral tunnels were fashioned at 3 and 9 clock hours using a crescent knife, starting about 4 mm posterior to the limbus and advancing forward till 1.5 to 2 mm from limbus. A 10° bent tip 26 gauge hollow needle passed

from one edge of 9 clock hour scleral tunnel, placed perpendicular to the sclera wall and then parallel to the iris until the tip appeared in the pupillary plane. A 10-0 polypropylene suture on the straight needle was introduced from the edge of the opposite 3 clocks hour scleral tunnel to the posterior chamber, meeting the 26 gauge needle in the pupillary area. 10/0 proline suture needle was engaged in the lumen of 26 gauge needle and the needle was carefully withdrawn. Consequently, the strand of 10/0 proline suture was spanning just posterior to iris plane from 3 to 9 clock hours. Similar procedure was repeated from the other side of the tunnels from 9 clock hour to 3 clock hour resulting in two strands of 10-0 proline suture spanning behind the iris plane. After making a three-step 7 mm scleral tunnel at 12 clock hour, the two strands of proline suture were taken out. The exteriorized proline sutures were cut in the middle and the ends were fixed to the eyelets on the haptics of scleral fixated IOL. SC65430 lenses were used. (Aurolab, India) (These are specially designed, Modified 'C' Loop lenses, made of high quality PMMA material, with holes in the haptic and optic diameter 6.5 mm.) IOL was inserted in the anterior chamber and positioned behind the iris while executing controlled traction on the exposed ends of the 10 / 0 proline. Knots were tied resulting in the burial of 10 / 0 proline knots in the scleral tunnels. Peritomies were closed using 8/0 Vicryl. (Figures 1 and 2) All the patients were given postoperative topical steroids. Patients were seen on the 1st postoperative day and then after one week, one month and three months.

Statistical analysis: The recorded Snellen visual acuity was converted to log mar units (logarithm of minimum angle of resolution units). The data were recorded and presented as mean with standard deviation. Student paired T- test was used to see the statistically significant difference between the preoperative and postoperative values using GraphPad software. The statistical significance was taken with P - value < 0.05.

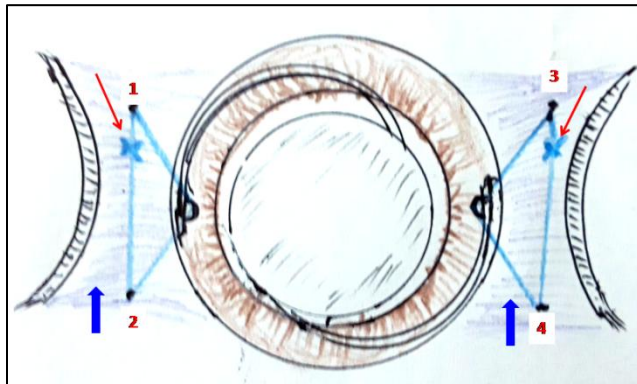


Figure 1. Red arrows point to the buried knots in the sclera tunnels. Blue arrows point towards the sclera tunnels.

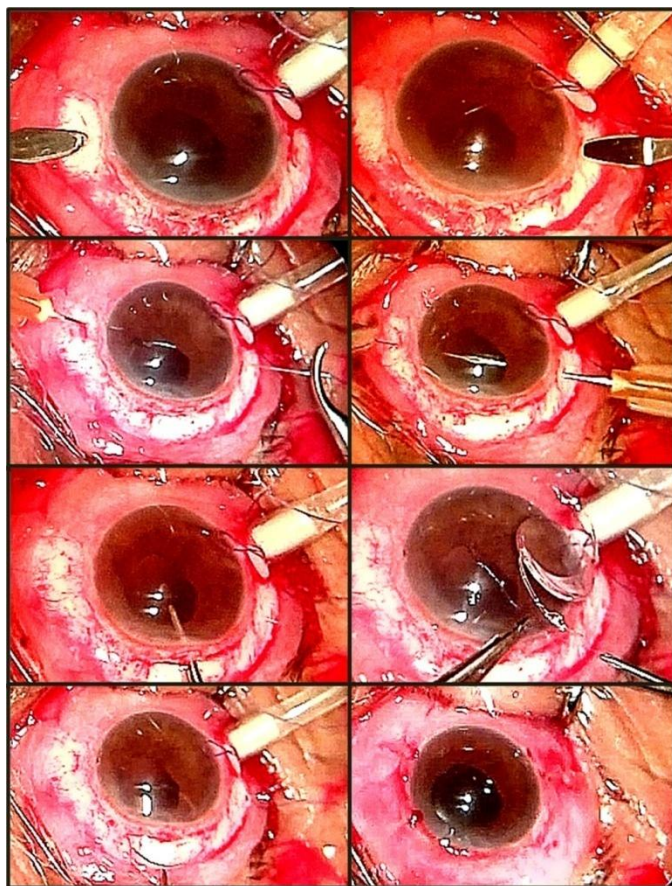


Figure 2. Surgical steps: Top row: Scleral tunnels at 3 and 9 clock hours. Second row: 10/0 Prolene suture on straight needle passed from one side of tunnel negotiated out with 26 number needle on the other side, leaving two strands of proline. Third row: Suture strands took out and cut in the middle and tied to the holes in the haptics. Bottom row: Intraocular lens introduced in the posterior chamber and suture pulled out from scleral tunnels tied; with the knot remaining in the tunnel.

3. RESULTS:

The present study included 30 eyes of 30 patients who have undergone SFIOL implantation by four point fixation technique by a single surgeon.(SL) The mean age group of the patients who have undergone surgery was 46.6 years (range 8 years – 83 years).Out of 30 patients studied, 17 patients (56.6%) were men and 13 patients (43.3%) were women. Almost three-fourths of the cases were due to cataract surgery-related complications leaving inadequate capsular support, and the remaining cases were trauma-related dislocation of crystalline lens (Table 1).

Table 1: Indications for Scleral-fixated Intraocular Lens (SFIOL) implantation

Causes of Aphakia	Number of patients (%)
Complications during cataract surgery	15 (50)
Postoperative displacement (subluxation or dislocation) of Intraocular lens	7 (23)
Traumatic dislocation of crystalline lens	8 (26.6)

All the patients were followed for variable periods ranging from 15 months to 31 months with a mean follow-up period of 19 months. Preoperative CDVA and the most recent postoperative CDVA were measured for all the patients. The mean of preoperative CDVA and postoperative CDVA was compared and statistically analyzed. The mean of CDVA preoperatively was 6/24 (0.689 log MAR units). The mean of CDVA postoperatively was 6/18 (0.456 log MAR units). The improvement in vision post-operatively, when compared with pre-operative mean CDVA calculated by using paired t-test, is statistically significant. ($P=0.0002$). (95% CI: 0.1204 - 0.3449). Out of 30 patients studied, when compared to preoperative CDVA the post-operative CDVA improved in 24 patients (80%) (95% CI: 65.69%-94.31%), same in 4 patients (13.3%) (95% CI: 1.15%- 25.45%), deteriorated in 2 patients (6.6%) (95% CI: -2.28% - 15.48%). The cause for deterioration was retinal detachment in one patient and the cause in the other patient was unknown. The change in the K values calculated from pre and postoperative keratometry values was not statistically significant ($P = 0.688$). Mean astigmatism from preoperative K – values was 0.1333 (SD 1.2641) and the postoperative value was 0.3333. (SD 1.812). Astigmatism of +/- 2.00D to +/- 4.00D were present in about 8 patients.

3.1 Early complications: (Table 2): The most common complication that occurred after surgery was ocular hypertension (IOP > 20mmhg), seen within first 24 hr postoperatively in 13 patients (43.6%) (95% CI: 25.57% - 61.03%) The other complication was vitreous hemorrhage (mild vitreous haem) in 3 patients (10%). (95% CI: 0.74% – 9. 69%). All the patients with the ocular hypertension were treated by antiglaucoma medications. The IOP levels came to normal with medications. None of the patients developed chronic glaucoma. Patients with vitreous hemorrhage were observed without any treatment. Vitreous hemorrhage resolved spontaneously in all the 3 patients without any need for re-vitrectomy.

3.2 Late complications: (Table 2): There was cystoid macular edema in two patients (6.6%) (95% CI:- 2.28%- 15.48%), retinal detachment in one patient (3.3%)(95% CI: -3.09%- 9. 69%), IOL tilt in one patient (3.3%)(95% CI: -3.09%- 9. 69%). The patient who suffered retinal detachment underwent vitreo-retinal surgery and the last CDVA was counting fingers at 2 meters. The cause for retinal detachment was a retinal dialysis in a patient of traumatic dislocation of crystalline lens. Patients with CME were treated with intravitreal triamcinolone acetonide. CME subsided and there was an improvement in vision to 6/18 in both these patients. The cause for IOL tilt was inadequate anterior vitrectomy.

Table 2 Post-operative complications			
	No.of patients	%	P-value
Early Complications:			
Ocular hypertension	13	43.6	0.0001
Vitreous hemorrhage	3	10	0.2089
Late Complications:			
Cystoid macular edema	2	6.6	0.6876
Retinal detachment	1	3.3	0.6692
IOL Tilt	1	3.3	0.6692

4. DISCUSSION:

SF IOL can be used to recuperate the visual status of aphakic eyes in both adults and children. There are different techniques of performing SFIOL; sutured and sutureless fixation with a range of possible complications like lens tilt, lens decentration and dislocation, exposed sutures, glaucoma, macular edema and transient vitreous hemorrhage[7,9]. Intraocular lens can be fixed to the sclera at two points or at 4 points; the two-point suture fixation may carry a higher risk of axial IOL tilt. In sutureless scleral fixation, the IOL haptics are brought out externally and negotiated into intrascleral passages without the use of sutures. In a study on "Comparison of sutured versus sutureless scleral-fixated intraocular lenses", Sindal et al have concluded that both the sutured and the sutureless techniques appear to be equally good in eyes with aphakia after cataract surgery or trauma [10].

With the reduced risk for corneal endothelial damage and secondary glaucoma, scleral-fixated IOL is a preferred choice over other options like iris-fixated IOL and AC IOL [11].

In the present study, we have studied the visual outcome and complications with a modified 4-point fixation technique in postoperative and post-traumatic cases after more than 15 months of follow-up. In this study, out of 30 patients studied, the post-SF IOL CDVA improved in 24 patients (80%). This is better compared to the study by Andrew et al, where the CDVA was improved or unchanged in 59 eyes (71.9%) [9]. This is due to a large amount of cataract surgery-related cases in our present study and trauma related cases being only 25%. The main advantages of this modified technique are the stability of the IOL and non-exposure and non-erosion of the proline suture knot. The final proline knot remains within the scleral tunnel without any exposure or erosion. It is a common practice to cover the suture ends with a triangular flap of the sclera. These triangular flaps atrophy over a period and leave the suture ends exposed causing erosion. We did not see any case of suture exposure and suture erosion in the follow-up of our cases. For the same reason, the risk of endophthalmitis is also reduced. In the study by Andrew S. McAllister et al, there were 11% cases of suture exposure [9]. The most common early complication that we have seen in this series was ocular hypertension. All the 13 patients were managed by anti-glaucoma medications with no case going into chronic glaucoma. Other studies have also reported early complications. Long and colleagues in a study of transscleral fixation in 48 patients, reported post-

operative complications like transient corneal edema (77.1 %), temporary hypotony (22.9 %), vitreous hemorrhage in (8.3 %), temporary intraocular pressure elevation (16.7 %), and cystoid macular edema (10.4 %) [12]. All these complications resolved within 4 weeks. All the aphakic cases in our series were managed by a secondary scleral-fixated IOL. When a posterior capsular rupture occurs leaving an inadequate capsular support, the surgeon has to decide whether to do a primary or a secondary implantation. The factors that affect the decision-making process are the type of anesthesia, the general condition of the patient and his compliance, the time spent in managing the complication. The technique of scleral-fixated IOL requires good surgical skills and meticulous maneuvering which are quite challenging in a stressful situation of capsular rupture and poor patient compliance. Scleral-fixated IOL is a prolonged procedure requiring some time in creating scleral tunnels, tying the prolene suture to the haptics, maneuvering and positioning the IOL before tying the knot. Added to this; the time spent in managing the cataract surgery and its complication makes it quite prolonged increasing the possibilities of postoperative inflammation and cystoid macular edema. Lee et al reported higher early postoperative complications and less favorable visual outcome in primary scleral fixated IOLs [13]. Suture rupture is reported after many years of SF IOL implantation, particularly in young people [3]. We have not seen any case with this complication in our follow-up of cases.

In the absence of an adequate capsular support, different IOL implantation options are pursued. SF IOL, AC IOL, and iris-fixated IOLs have all been found to be effective and safe in this setting.⁴

5. CONCLUSION:

Scleral-fixated PC IOL insertion can offer favorable visual outcomes, as shown in this study using four-point fixation technique, in cases of aphakia with inadequate capsular support. Open-loop AC IOLs or iris-claw lenses may also offer good visual outcome when there are no contraindications to their use. This technique allows stable placement of PC IOLs in cases of post-operative and post trauma aphakic eyes. According to our data, parsplana anterior vitrectomy, four-point fixation of the IOL and placement of the knots inside the scleral tunnels give a satisfactory and stable outcome. The limitations of this study are its single surgeon, heterogenous pre-operative indications and variable durations of follow-up. We need a randomized study with a longer follow-up to show the safety and efficacy of this procedure.

CONSENT:

The authors declare that 'written informed consent was obtained from the patients for publication of this case series.

ETHICAL APPROVAL:

As per international standard or university standard, written approval of Ethics committee has been collected and preserved by the authors.

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Conflicts of interest: There are no conflicts of interest

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