

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

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Authors' contributions

This work was carried out in collaboration between both authors. Author SAKL designed the study, performed the statistical analysis, wrote the protocol, and wrote the first draft of the manuscript. Authors SAKL and GS managed the analyses and literature searches. Both authors read and approved the final manuscript.

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ABSTRACT

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

Study Design: Case series

Place and Duration of Study: The study was conducted at Sarojini Devi Eye Hospital, which is a government medical college and tertiary eye care hospital in South India. The study was conducted between October 2013 and June 2016.

Methodology: A consecutive series of patients who had undergone secondary scleral-fixated intraocular lens (SF IOL) implantation in cases of aphakia with inadequate posterior capsular support was analysed. This is a modified four-point scleral fixation technique that is comprised of scleral tunnels to bury the suture knots and fix the IOL at four points on the sclera.

Results: The study was comprised of 30 eyes of 30 patients (17 men, 13 women). The mean age at surgery was 46.6 years (range of 8–83 years), and the mean follow-up was 19 months (range of 15–31 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

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was raised intraocular pressure, which was seen in 13 eyes (43.6% P value <0.0001).

Conclusions: The results of the study indicate that SF IOL is a promising option in cases of aphakia with no capsular support, as the technique has minimal complications when conducted properly.

Keywords: Aphakia; capsular support; scleral-fixated intraocular lens; sclera tunnel.

ABBREVIATIONS

SF IOL : Scleral fixated intraocular lens,
CDVA : Corrected distance visual acuity,
LogMAR: logarithm of the minimal angle of resolution units.

1. INTRODUCTION

The prevalence of senile cataracts in people above 60 years of age in India ranges from 53 to 58% [1]. In the event of a capsular rupture with vitreous disturbance during cataract surgery, an inadequate posterior capsular remnant compromises the prospects of a routine IOL implantation. A capsular injury in ocular trauma also causes inadequate capsular support. 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 advantages and disadvantages regarding surgical intricacy, operative duration, and complications. There is no unanimity of opinion regarding the best choice in the presence of inadequate posterior capsular support.

The anatomic site of scleral-fixated intraocular lenses (SF IOL) puts these lenses at an advantage over other IOLs regarding complications, especially in young patients and in cases of trauma [3,4]. SF IOLs provide a better visual outcome without the complications of AC IOLs [4,5]. The 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 haemorrhage [6]. Other well-documented postoperative complications are suture exposure, suture erosion, IOL tilt, elevated intraocular pressure, retinal detachment, and endophthalmitis [7,8].

This study analyses patients with a minimum of 15 months of follow-up to determine the visual acuity outcomes and incidence of complications after scleral-fixated PC IOL implantation with a modified four-point fixation technique.

2. MATERIALS AND METHODS

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

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

Exclusion criteria included the following: 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 were explained to the patients and their relatives. A detailed medical history was taken to rule out uncontrolled diabetes, hypertension, asthma, orthopnoea, and any other systemic diseases. A 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 analysed on long-term follow-up. Postoperative complications were divided into early and late; late complications are those seen two weeks after surgery.

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

Surgical Technique: Local peribulbar anaesthesia, which is 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. Twenty-three G Pars plana partial anterior vitrectomy was performed to clear the vitreous from the anterior chamber, pupillary plane, and 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 three and nine clock hours using a crescent knife, starting about 4 mm posterior to the limbus and advancing forward till 1.5 to 2 mm from the limbus. A 10°-bent tip and 26-gauge hollow needle passed from one edge of the nine-clock hour scleral tunnel, was placed perpendicular to the sclera wall, and was then placed 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 three-clock hour scleral tunnel to the posterior chamber, meeting the 26-gauge needle in the pupillary area. The 10/0 prolene suture needle was engaged in the lumen of the 26-gauge needle, and the needle was carefully withdrawn.

Consequently, the strand of the 10/0 prolene suture was spanned just posterior to the iris plane from three to nine clock hours. A similar procedure was repeated from the other side of the tunnels from the nine-clock hour to the three-clock hour, thus resulting in two strands of the 10/0 prolene suture spanning behind the iris plane. After making a three-step, 7 mm scleral tunnel at the 12-clock hour, the two strands of prolene suture were removed. The exteriorized prolene sutures were cut in the middle, and the ends were fixed to the eyelets on the haptics of the 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 an optic diameter of 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 prolene. Knots were tied resulting in the burial of 10/0 prolene knots in the scleral tunnels. Peritomies were closed using 8/0 Vicryl (Figs. 1 and 2). All the patients were given postoperative topical steroids. Patients were seen on the first postoperative day and then after one week, one month, and three months.

Statistical analysis: The recorded Snellen CDVA was converted into a logarithm with a minimal angle of resolution (logMAR) units for analysis. The data were recorded and presented as a mean with a standard deviation. A student paired T- test was used to see the statistically significant difference between the preoperative and postoperative values using GraphPad software. A *P* - value of < 0.05 was considered statistically significant.

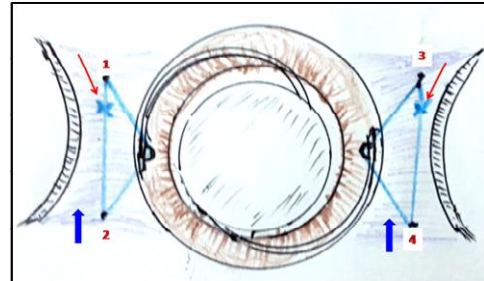


Fig. 1. Red arrows point to the buried knots in the scleral tunnels. Blue arrows point towards the sclera tunnels

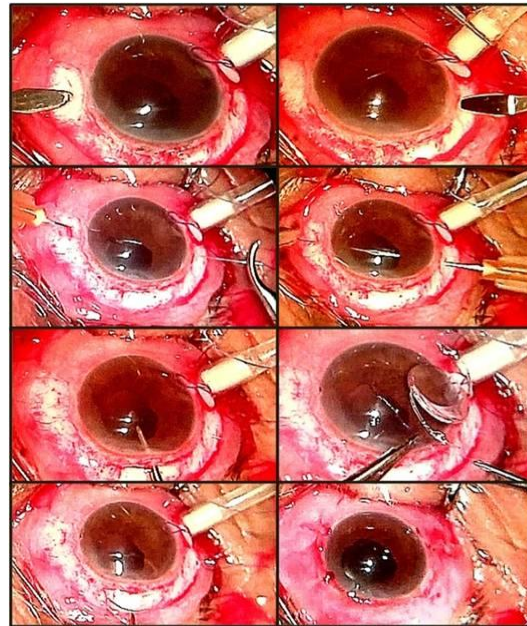


Fig. 2. Surgical steps

Top row: Scleral tunnels at three and nine clock hours, Second row: 10/0 prolene suture on the straight needle passed from one side of the tunnel negotiated out with 26 number needle on the other side, leaving two strands of prolene, Third row: Suture strands were removed, cut in the middle, and tied to the holes in the haptics, Bottom row: Intraocular lens introduced in the posterior chamber and sutures pulled out from the scleral tunnels were 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 the 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 lenses (Table 1).

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 the preoperative CDVA and postoperative CDVA was compared and statistically analysed. The mean preoperative logMAR CDVA was 0.689, and the mean postoperative logMAR CDVA was 0.456. The postoperative improvement in vision, when compared with the preoperative mean CDVA calculated by using the paired t-test, is statistically significant ($P = 0.0002$) (95% CI: 0.1204–0.3449). Out of the 30 patients studied, when compared to the preoperative CDVA, the postoperative CDVA improved in 24 patients (80%) (95% CI: 65.69%–94.31%), remained the same in four patients (13.3%) (95% CI: 1.15%–25.45%), and deteriorated in two 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 ($P = 0.688$). The 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 eight patients.

3.1 Early Complications

(Table 2): The most common complication that occurred after surgery was ocular hypertension (IOP > 20mmhg), which was seen within the first twenty-four hours postoperatively in 13 patients (43.6%) (95% CI: 25.57%–61.03%) The other complication was vitreous haemorrhage (mild vitreous haem) in three patients (10%). (95% CI:

0.74%–9.69%). All the patients with ocular hypertension were treated with antiglaucoma medications. The IOP levels became normal with medications. None of the patients developed chronic glaucoma. Patients with vitreous haemorrhage were observed without any treatment. Vitreous haemorrhage resolved spontaneously in all the three patients without any need for re-vitreotomy.

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%), and 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 retinal dialysis in a patient with traumatic dislocation of the 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 of these patients. The cause for IOL tilt was inadequate anterior vitrectomy.

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. Both techniques have a range of possible complications, including lens tilt, lens decentration and dislocation, exposed sutures, glaucoma, macular edema, and transient vitreous haemorrhage [7,9]. Intraocular lens can be fixed to the sclera at two points or at four 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 their study, Sindal et al. compared the sutured and sutureless scleral-fixed intraocular lenses and found that the sutured and sutureless techniques are equally effective for eyes with aphakia after cataract surgery or trauma [10].

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

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)

Table 2. Post-operative complications

	No.of patients	%	P-value
Early Complications:			
Ocular hypertension	13	43.6	0.0001
Vitreous haemorrhage	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

In the present study, we have studied the visual outcomes and complications with a modified four-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 result is better than that of Andrew et al.'s study, in which 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 the prevalence of trauma-related cases being only 25%. The main advantages of this modified technique are the stability of the IOL as well as 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, thus 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. McAllister et al. found that 11% of the cases included in their study were cases of suture exposure [9]. The most common early complication that we have seen in this series was ocular hypertension. All 13 patients were managed with anti-glaucoma medications, and no patient developed chronic glaucoma. Other studies have also reported early complications. In their study of transscleral fixation in 48 patients, Long et al. reported postoperative

complications such as transient corneal edema (77.1%), temporary hypotony (22.9%), vitreous haemorrhage in (8.3%), temporary intraocular pressure elevation (16.7%), and cystoid macular edema (10.4%) [12]. All these complications resolved within four weeks. All the aphakic cases in our series were managed by a secondary scleral-fixated IOL. When a posterior capsular rupture occurs and causes inadequate capsular support, the surgeon must decide whether to conduct primary or secondary implantation. The factors that affect the decision-making process are the type of anaesthesia, the general condition of the patient and his compliance, and the time spent managing the complication. The technique of scleral-fixated IOL requires good surgical skills and meticulous manoeuvring, which are quite challenging in a stressful situation of capsular rupture and poor patient compliance. Scleral-fixated IOL is a prolonged procedure, as much time is required to create the scleral tunnels, tie the proline suture to the haptics, and manoeuvre and position the IOL before tying the knot. Moreover, the time spent in managing the cataract surgery and its complications makes IOL even more prolonged, thus increasing the possibilities of postoperative inflammation and cystoid macular edema. Lee et al. reported higher early postoperative complications and less favourable visual outcomes in primary scleral-fixated IOLs [13]. Suture rupture is reported after many years of SF IOL implantation, particularly in young people [3]. There was no case with this complication in our follow-up of cases.

In the absence of 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 context [4].

5. CONCLUSION

Scleral-fixated PC IOL insertion can offer favourable visual outcomes, as shown in this study using the 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 outcomes 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. However, a randomized study with a longer follow-up is needed to determine 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.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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