

## A Prospective Analysis of Visual Outcomes and Complications of Sutured Scleral Fixated Posterior Chamber Intraocular Lens Implantation- 7 Years of Post-Operative Follow Up Study

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### Abstract

The aim of this study is to analyze the visual outcomes of 2 point Ab Externo technique of sutured scleral fixated Posterior chamber intra ocular lens (PCIOL) implantation in patients with surgical aphakia and in grossly subluxated cataractous lenses and the complications of the procedure both intra operatively and during the 7 years of post-operative period. The options for visual rehabilitation in aphakic patients can be in the form of spectacles, contact lenses or placement of intraocular lenses. Each of these has their own merits and demerits but the secondary placement of an intraocular lens is the most closest to the physiological correction of vision in these patients. In this study we have found that 80% of the operated patients maintained a best corrected visual acuity of 6/36 throughout the 7 years follow-up period. The most important complication to be taken care of is the prolene suture exposure by erosion over many years leading to vision threatening complication of endophthalmitis.

**Keywords:** Scleral Fixated Posterior Chamber Intraocular Lens; Aphakia; Secondary; Visual Outcomes; Complications

### Introduction

The literature supports the safe and effective use of open-loop anterior chamber, scleral-sutured posterior chamber, and iris-sutured posterior chamber IOLs for the correction of aphakia in eyes without adequate capsular support for placement of a posterior chamber lens in the capsular bag or ciliary sulcus [1]. In the absence of a posterior capsular support following a complicated cataract surgery there are various options to the placement of an intraocular lens (IOL) like Anterior chamber IOL (ACIOL), Scleral Fixated Intra Ocular Lens (SFIOL), Iris- Fixated IOL's rather than leaving the patient aphakia. These lenses can either be placed primarily during the first surgery itself or at a later date as a secondary implantation. Studies have shown that there are no significant differences in the visual outcomes when comparing ACIOLs to sutured PCIOLs in complicated cataract extraction with poor capsular support. Recent advances in ACIOL design have yielded lenses that provide a safe and effective alternative to sutured PCIOL's [2].

### Materials and Methods

All patients with surgical aphakia and grossly subluxated cataractous lens giving consent for surgery were included in the study and underwent the treatment with 7 years of follow up. Patients with identifiable posterior segment pathology, glaucoma and those in which potential for vision was minimal were excluded. Ethical committee approval was obtained and the study was done between February 2009 and January 2016.

**Technique:** All patients underwent ab externo 2 point fixation of scleral fixated PCIOL after a thorough manual anterior vitrectomy with the aid of preservative free intracameral triamcinolone injection under peribulbar anaesthesia using double armed 9-0 prolene suture.

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**Lens Specification**

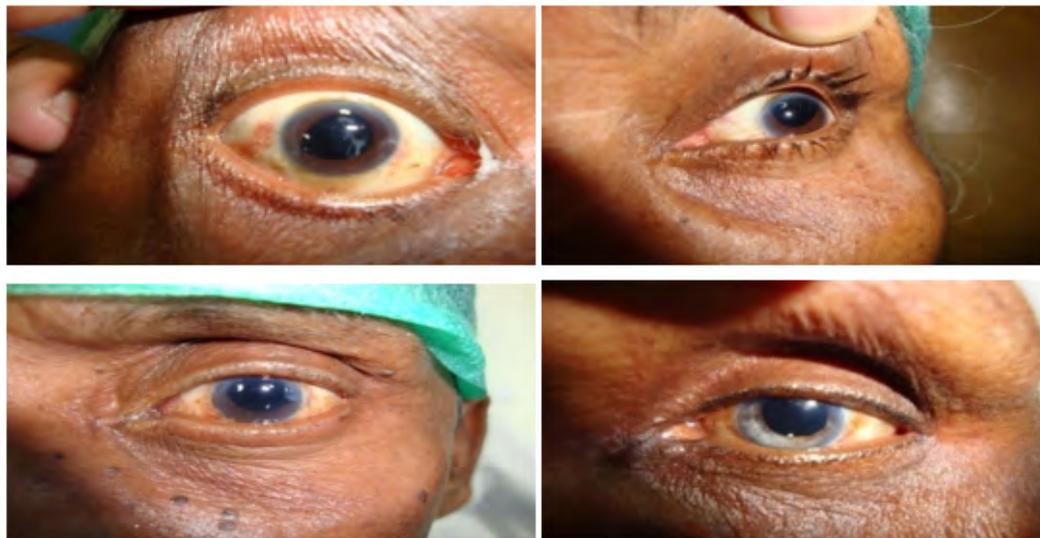
Optic- 6.5 mm, Length- 13 mm, Vault- 0.4 mm, Modified C loop model SC6530, Equiconvex, UV absorbing PC lens, A- constant- 118.5. The lens is from AUROLAB LTD.



**Figure 1**

**Steps of Surgery**

- Step 1: Creation of main scleral incisions and scleral pockets/flaps
- Step 2: Passing of 26g needle and 9-0 prolene suture needle at diagonally opposite poles
- Step 3: Bringing the suture out through the main scleral incision
- Step 4: Cutting the suture loop and tying them to the respective islets of the sfiol
- Step 5: sfiol implantation and suture pull through to stabilize the sfiol and anchoring of the sfiol
- Step 6: Checking the sfiol centration and suturing of the scleral flaps with 10-0 nylon and conjunctiva using 8-0 vicyrl sutures.



**Figure 2: Pre-operative photographs.**



*Figure 3: Post-operative (early and late, diffuse and slit-lamp) photographs.*

## Results

20 Eyes of 20 patients underwent the SFIOL fixation and were followed up from 1<sup>st</sup> post-operative day, 1 week post-operative, 1 month post-operative, 3 months post-operative, 1 year post-operative and every year or in between if patients had any issues till 7 years post-operative period. Among the operated 12 were right eyes and 8 were left eyes. 8 eyes underwent the procedure with temporal scleral incision with scleral flaps at 6 and 12 'o clock hours the remaining 12 eyes from a superior scleral incision with scleral flaps at 2:30 and 8:30 clock hours. Prior to the surgery 16 eyes (80%) had surgical aphakia, 3 eyes (15%) had traumatic subluxated cataracts and 1 eye (5%) had ACIOL with localized corneal decompensation whose specular microscopy showed 1850 cells/sq.mm endothelial cell count. The mean age of the patient was 63.95 and ranged from 35 to 84 years. There were 3 patients below 50 years, 11 patients between 50 and 70 years, and 6 patients above 70 years. There were 11 males and 9 female patients in the study.

Visual Acuity (V/A)	Before Surgery		After Surgery (1 <sup>st</sup> post-operative day)	
	Frequency	%	Frequency	%
6/6-6/12 (20/20-20/40)	-	-	1	5.0
6/18-6/36 (20/60-20/120)	-	-	12	60.0
≤ 6/60 (20/200)	20	100.0	7	35.0
Total	20	100.0	20	100.0

**Table 1:** Uncorrected visual acuities before and 1<sup>st</sup> post-operative day, McNemar chi square test.

Visual Acuity (V/A)	Before surgery	After surgery								
		4 wks	3 mths	1 yr	2 yrs	3 yrs	4 yrs	5 yrs	6 yrs	7 yrs
	Frequency (%)	Frequencies (%)								
6/6-6/12 (20/20-20/40)	4 (20.0)	12 (60.0)	12 (60.0)	11 (55.0)	10 (50.0)	10 (50.0)	10 (50.0)	10 (50.0)	10 (50.0)	10 (50.0)
6/18-6/36 (20/60-20/120)	6 (30.0)	5 (25.0)	5 (25.0)	5 (25.0)	5 (25.0)	6 (30.0)	6 (30.0)	6 (30.0)	6 (30.0)	6 (30.0)
≤6/60 (20/200)	10 (50.0)	3 (15.0)	3 (15.0)	4 (20.0)	5 (25.0)	4 (20.0)	4 (20.0)	4 (20.0)	4 (20.0)	4 (20.0)
Total	20 (100.0)	20 (100.0)	20 (100.0)	20 (100.0)	20 (100.0)	20 (100.0)	20 (100.0)	20 (100.0)	20 (100.0)	20 (100.0)
P-Value	-	< 0.001	< 0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001

**Table 2:** Best spectacle corrected visual acuities before and after surgery, McNemar chi square test.

S. No	Intra operative complications	No. of patients	%
1.	<b>Scleral flap related</b>	0	0
A.	Difficulty in creating the sclera flaps		
	Loss of sclera flaps		
2.	<b>Prolene suture related</b>		
A.	Suture breakage during the procedure	1	5
B.	Suture tangling and orientation confusion	1	5
3.	<b>SFIOL related</b>		
A.	Problem in positioning the lens	1	5

**Table 3:** Intra operative complications during the procedure.

S. No	Early post-operative complications (From day 1 to 3 weeks)	No. of eyes	%
1	Sub conjunctival haemorrhage	4	20
2	Corneal edema	2	10
3	Severe iridocyclitis	8	40
4	Fibrin reaction	2	10
5	Shallow anterior chamber	0	0
6	SFIOL malposition/subluxation	0	0

**Table 4:** Early post-operative complications.

S. No	Late post-operative complications (Anytime later than 3 weeks to 7 years)	No. of eyes	%
1	Astigmatism	20	100
2	Prolene suture exposure under the sclera flaps	2	10
3	Corneal decompensation	1	5
4	Cystoid macular edema	0	0
5	IOL dislocation/subluxation	0	0
6	Endophthalmitis	2	10
7	Vitreous haemorrhage/Retinal detachment	0	0
8	Suture breakage	0	0

**Table 5:** Late post-operative complications.

## Discussion

Ideally, the intraocular lens is placed in the capsular bag, which affords stable fixation at a position closest to the nodal point of the eye. However, there are instances where this might not be possible like in congenital weakness of the lens zonules or acquired following pseudo exfoliation syndrome or trauma, subluxated cataractous lens, and following surgical complications of cataract surgery are just some examples. Hence in patients with aphakia, if contact lens or spectacle correction is not viable, then secondary placement of an IOL is the choice in the absence of capsular support. The choice of IOL mainly depends on the preoperative status of the eye and the selected location for the implant. No consensus exists, however, on the indications as well as on the relative safety and efficacy of the different options available as previously mentioned. However, in the absence of capsular support, the trans-sclerally sutured PCIOLs offer numerous advantages. Because of its anatomic location, the sutured PCIOL is more appropriate for eyes with compromised cornea, peripheral anterior synechiae, shallow anterior chamber, or glaucoma. Moreover sutured PCIOLs are appropriate if the patient with aphakia is young or has a life expectancy of 10 years or more [3]. The sutured PCIOL procedure specifically, the trans-sclerally sutured PCIOL procedure is safe, however, surgical expertise is an important consideration. Recent surgical and technological advances, including the technique of burying the suture knot in sclera, use of an ab externo suturing approach have improved the accuracy of the trans-sclerally sutured PCIOL technique [4].

In this study the data support's that sutured sclera fixated PCIOL to be a good choice for a good visual outcome as well as maintenance of the same vision with least complications in the long follow up period except for 2 patients who developed endophthalmitis probably through the prolene suture exposure. The vitreous culture showed staphylococcus epidermidis in one patient who developed endophthalmitis at the end of 2 years and another patient at the end of 4 years. Both the patients recovered well and attained BCVA of 6/36 with a single intra vitreal injection of vancomycin, and ceftazidime. Both the patients who had suture exposure underwent suture burial over a scleral patch graft after the endophthalmitis resolved to avoid further recurrences of infection.

BCVA of 6/36 or better was maintained in 80% of the patients in the study at the end of 7 years. During the procedure suture breakage of the 9-0 prolene suture, suture orientation confusion and tangling during the SFIOL placement and positioning which were encountered in 2 eyes. The late post-operative complications included astigmatism in all the patients and 1of corneal decompensation (at the end of 1 year) in a patient who had a pre-operative low endothelial cell count. The patient who had corneal decompensation underwent penetrating keratoplasty to restore vision.

## **Conclusion**

Scleral fixated PCIOL implantation has good long term visual outcome and are a safe option as it has relatively few serious complications for patients with surgical aphakia and in patients with grossly subluxated cataractous lenses [5,6]. However the risk of vision threatening complications secondary to endophthalmitis due to suture erosion and exposure of the 9-0 prolene suture from under the sclera flaps does exists. Modifications in the technique of trans-scleral fixation of SFIOL to minimize the suture exposure have been in the literature [7,8]. Sutureless fixation of SFIOL has also been tried and has been successful [9,10]. Long term corneal endothelial cell loss have to be explained to the patients prior to the procedure and the need for long term follow up also has to be counseled to the patient and their family. There are studies which compares primary and secondary implantation of sclera fixated posterior chamber lenses in such patients [11,12].

The strength of the study was the long period of follow up, there was not a single patient drop out from the study and all were followed up for 7 years. There have been very few studies of such long term follow-up following SFIOL fixation [13-15]. Similar results of visual outcomes and complications were also found by other authors in the literature [16].

Suture-fixated PCIOLs can dislocate due to degradation of the suture material over time. The use of larger diameter (9-0 instead of 10-0) polypropylene suture material and placement of the haptic and sutures in the ciliary sulcus to promote attachment of scar tissue may enhance the long-term stability of scleral-fixated PCIOLs [17]. However no dislocation of these lenses was seen in any of the patients in this study till end of their 7 years of follow up which were seen in a study done by Price., *et al.* which showed late dislocation of the SFIOL [17].

Secondary implantation of SFIOL in patients with absent capsular support following a cataract extraction seems to have a lower early complication rate than primary implantation in complicated cataract extraction although the final visual acuity and late complication rate are not significantly different [18]. This study also had similar results of complications. The early post-operative complications were as similar to that of a routine cataract surgery. The most common complication was surgery induced astigmatism which probably is due the combined effect of main scleral incision and the possibility of SFIOL tilt. Even after 7 years there was no suture breakage/retinal detachment/IOL dislocation in any of the patients.

The drawback of this study are the sample size is less, the tilt of these lenses after surgery were not measured or documented post operatively using anterior segment optical coherence tomography (AS-OCT) or ultra sonic bio microscopy (UBM) which could have been done to know the position of these lenses over period of 7 years and also the amount of astigmatism this produces.

In conclusion there are methods that have been devised to allow placement of intraocular lens in the absence of capsular or zonular support. These include anterior chamber angle and iris-fixated lenses, as well as posterior chamber iris and sclera sutured lenses [19,20]. It is the convenience of the operating surgeon with the method and the secondary IOL he/she is familiar with to implement for the best possible visual outcome, the least complications and the safest possible choice for the patient given the many recent developments and refinements of methods in implanting intraocular lenses. This long term study shows that secondary SFIOL have good visual outcomes and low complication rates and should be a better option in patients with aphakia.

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