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sutureless, scleral fixated intraocular lens

Complications and visual outcome of

in cases with traumatic aphakia

# Abstract

Purpose: The aim of this study is to describe the complications and outcome of sutureless scleral fixated intraocular lens (SFIOL) implantation in traumatic aphakia. Setting: The study was conducted in a tertiary eye care centre in South India. **Design:** The study involved a retrospective data analysis. Methods: Medical records of cases with traumatic aphakia who had undergone sutureless SFIOL implantation in the last 2 years were included in the study. Data on intraoperative and postoperative complications and visual outcome were collected and analysed. Results: In total, 45 cases were recruited. Mean logarithm of the minimum angle of resolution (logMAR) best-corrected visual acuity (BCVA) improved from preoperative  $1.64 \pm 0.45$  to  $0.63 \pm 0.36$  at last follow-up visit, and the difference was statistically significant (p < 0.0001). Final logMAR BCVA was worse than one in three patients who had associated posterior segment pathology. There was no incidence of intraoperative haptic rebound into the vitreous cavity or intraocular lens (IOL) drop. Four cases had hypotony, two cases had choroidal detachment, four cases had raised intraocular pressure (IOP), eight cases had transient corneal oedema and six patients had mild dispersed vitreous haemorrhage during immediate postoperative period. Six patients had postoperative cystoid macular oedema (CME). Two cases developed glaucoma. None of the patients had postoperative haptic exposure, retinal detachment (RD), iris capture of IOL or SFIOL dislocation till the last follow-up. **Conclusion:** Final visual outcome of sutureless SFIOL implantation in traumatic aphakia may be affected by concomitant posterior segment pathology. The immediate and late postoperative complications noted in our study were comparable with other similar studies. However, longer follow-up is needed to detect RD and angle recession glaucoma at the earliest and initiate therapy.

*Keywords:* haptic rebound, IOL drop, sutureless SFIOL, traumatic aphakia, traumatic glaucoma

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#### Introduction

Ocular trauma is one of the leading causes of visual impairment.<sup>1</sup> The annual incidence of eye trauma is more than 50 million globally, of which around 1.5% of the cases need hospitalization.<sup>2</sup> Ocular trauma can cause both anterior and posterior segment complications. Anterior segment complications can manifest as traumatic cataract, subluxated or dislocated lens/intraocular lens (IOL).<sup>3–5</sup> Management of these complications is often difficult, and visual outcomes may be suboptimal due to coexisting corneal injury, vitreous haemorrhage, retinal detachment (RD), choroidal rupture, traumatic optic neuropathy and so on.<sup>1,4</sup> Correspondence to: Sandip Sarkar Senior Resident, Department of Ophthalmology,

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Posterior chamber IOL (PCIOL) placement following cataract or lens removal is often difficult in these trauma cases due to the absence of adequate zonular or capsular support. Alternative options in traumatic aphakia include anterior chamber IOL (ACIOL), iris-fixated IOL and scleral fixated IOL (SFIOL). However, ACIOL or iris-fixated IOL is associated with increased risk of corneal endothelial decompensation, cystoid macular oedema (CME), postoperative uveitis, peripheral anterior synechiae, secondary glaucoma and so on. SFIOL implantation helps to overcome these drawbacks by positioning the IOL in a further posterior plane.<sup>3,6,7</sup>

SFIOL implantation techniques involve sutured SFIOLs and sutureless SFIOLs. Sutured SFIOLs may be associated with suture erosion/breakage, exposure of suture knot and so on in the postoperative period.<sup>3,8</sup> Sutureless SFIOL techniques were, thus, adopted to reduce suture-related complications. These techniques involve exteriorization of the haptics and embedding them in scleral tunnels,9-11 fixing the haptic with glue below scleral flaps<sup>12</sup> or flanging the haptic tips with cautery.13 Data on the outcomes of IOL implantation in cases of traumatic aphakia are limited in the existing literature. The primary objective of this retrospective analysis is to describe the outcomes and complications of sutureless SFIOL implantation in traumatic aphakias.

Various techniques have been described for exteriorization of the haptics<sup>10–16</sup> and to secure the haptics into the scleral pockets.<sup>9,10,14–17</sup> However, all the techniques described for haptic management have risk of accidental rebound of the haptics into vitreous cavity and intraoperative IOL drop, especially for the beginners. This intraoperative complication is undesirable for any surgeon and particularly for an anterior segment surgeon. The secondary objective of this study is to describe our experience in preventing this intraoperative complication of sutureless SFIOL implantation using a small modification in one of the steps of an already established technique.<sup>10</sup>

# Materials and methods

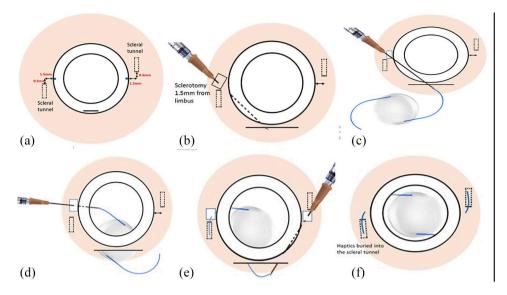
Our study was conducted in a tertiary eye care centre in South India and involved a retrospective data analysis of the hospital medical records of all patients with traumatic aphakia who underwent SFIOL implantation from June 2018 to June

2020. Inclusion criteria included the following: (1) traumatic aphakia due to posterior lens or IOL dislocation secondary to closed globe injury (CGI), and (2) traumatic aphakia due to posterior lens or IOL dislocation secondary to open globe injury (OGI). Parameters analysed included the following: (1) type of ocular injury, for example, OGI or CGI; (2) details of prior ocular surgery like globe repair, prior IOL surgery, prior RD surgery and so on; (3) preoperative ocular examination findings, including best-corrected visual acuity (BCVA), slit lamp evaluation, intraocular pressure (IOP), fundus evaluation and ocular ultrasound B scan when fundus was not visualized; (4) postoperative details like BCVA, months of follow-up, IOP, gonioscopy, fundus evaluation and so on; (5) presence of ocular comorbidities like vitreous haemorrhage, RD, choroidal rupture, glaucoma, traumatic optic neuropathy, corneal or scleral injury and so on; and (6) intraoperative, immediate and late postoperative complications of SFIOL.

Descriptive statistics were used to analyse the data obtained. All statistical analyses were done using Statistical Package for the Social Sciences (SPSS), version 20. Quantitative data such as age, months of follow-up and logarithm of the minimum angle of resolution (logMAR) BCVA were expressed as means with standard deviations. Paired *t*-test was used to compare preoperative and postoperative BCVA. The data on categorical variables were expressed as frequency and percentages. All statistical analyses were carried out at 5% level of significance and *p* value <0.05 was considered as significant.

# Surgical technique

All surgeries were performed under peribulbar anaesthesia by a single experienced surgeon (A.K.D.). For trans-scleral fixation of IOL, we had followed a haptic exteriorization technique similar to that described by Baskaran and colleagues:<sup>10</sup> 'Extraocular needle-guided haptic insertion technique of scleral fixation intraocular lens surgeries (X-NIT)'. However, the steps of scleral tunnel construction and haptic tucking were slightly modified as compared with the original X-NIT and other similar techniques.<sup>10,11,15</sup> Conjunctival peritomy was done from 3 to 9 o'clock superiorly followed by cauterization of the bleeders to achieve haemostasis. Two points were marked at limbus 180° apart with a marker pen, preferably at 3 and 9 o'clock positions (Figure



**Figure 1.** Schematic images showing (a) limbal markings 180° apart, site of sclerotomy (1.5 mm posterior to the limbal markings on both sides), commencement of the scleral tunnels (0.5 mm from the sclerotomy) and 3-mm long scleral tunnels on both sides parallel to the limbus; (b) silicone stopper, entry of the bent 26G needle through the sclerotomy and its exit through the corneoscleral tunnel to the extraocular space; (c) loading of the leading haptic into the lumen of the 26G needle in the extraocular space; (d) withdrawal of the bent needle gradually from the sclerotomy site and simultaneous gradual insertion of the IOL; (e) entry of the second bent needle through sclerotomy, exit of the needle into extraocular space through the sclerocorneal tunnel and loading of the trailing haptic; and (f) well-centred SFIOL with both the haptics tucked into the preformed scleral tunnels. IOL, intraocular lens; SFIOL, scleral fixated intraocular lens.

1(a)). These limbal markings were used as guides for subsequent sclerotomies. Either an infusion cannula via a 23G pars plana port or an anterior chamber (AC) maintainer was secured as per need. Two scleral tunnels (one on each side) were then fashioned starting 1.5 mm behind the limbus using a 23-gauge microvitreoretinal (MVR) blade or a 15-degree paracentesis blade (Figure 1(a)). Direction was parallel to limbus and in anticlockwise directions at both starting points of the tunnels. Scleral tunnels were 3-mm long and constructed with their starting points commencing 0.5 mm farther away from the future site of sclerotomy, that is, the entry point of the needle or exit point of the IOL haptic (Figure 1(a)). Two more 23G vitrectomy ports were then secured. Sclerocorneal tunnel (6-mm incision size) without entering the AC was constructed superiorly spanning 12 o'clock meridian. Pars plana vitrectomy (PPV) was then performed along with pars plana lensectomy (PPL) or PCIOL explantation based on the case. PPL was done with the 23G cutter or phacofragmatome (20G) based on hardness of the nucleus. In cases where fragmatome was required, one 23G port was converted to 20G after completion of vitrectomy. Triamcinolone acetonide (Aurocort 40 mg/ml, Aurolab, Chennai, India)-assisted posterior vitreous detachment (PVD) induction was done whenever needed. Retinal periphery was examined for retinal breaks with scleral indentation. Endolaser was performed, if needed. In case of silicone oil removal (SOR), as needed in one case, it was done prior to SFIOL implantation in the same sitting. Once vitrectomy had been completed, SFIOL implantation was performed next using X-NIT technique (as shown in schematic form in Figure 1(a)-(f)). AC entry was made through the sclerocorneal tunnel once all steps of PPV were completed. Three-piece PMMA aurolens (6-mm Polymethyl methacrylate haptic, prolene modified C loop haptics, overall diameter 13.5 mm; Aurolab) was used in all our cases.

*Modification used in our surgeries.* In all previous techniques,<sup>9,10,14–17</sup> sclerotomy for needle insertion was made flush to the commencement of the scleral tunnel. We modified this step by leaving 0.5-mm gap between the site of sclerotomy (i.e. point of exit of the haptics) and the point of commencement of the scleral tunnel for better manipulation of the haptics (Figure 1(a) and (f)).

Parameters				Values	
Number of eyes				45	
Gender		Male		30 (66.66%)	
		Female		15 (33.33%)	
Age		Mean		$57.84 \pm 10.82$ years	
Follow-up		Mean		13.75 $\pm$ 5.9 months (3–27 months)	
Type of trauma		Open globe	Corneal tear	3	10 (22.22%)
			Sclerocorneal tear	5	
			Scleral tear	2	
			Closed globe		35 (77.77%)
Cause of aphakia	Open globe	Anterior lens dislocation Anterior IOL dislocation Posterior IOL dislocation (single piece IOL)		3 (6.66%)	
				4 (8.88%)	
				3 (6.66%)	
	Closed globe	Posterior lens	dislocation	22 (48.88%)	
		Posterior IOL c piece IOL)	lislocation (single	13 (28.88%)	
Associated ocular comorbidities		Vitreous haemorrhage Retinal detachment Choroidal rupture Lamellar macular hole		2 (4.44 %)	
				1 (2.22%)	
				1 (2.22%)	
				1 (2.22%)	
		Glaucoma		1 (2.22%)	
		Traumatic opti	c neuropathy	1 (2.22%)	

 Table 1. Baseline demographic characters.

#### Results

In total, 45 eyes of 45 patients were included in our study. Mean age was  $57.84 \pm 10.82$  years, with minimum age of 39 years and maximum age of 75 years; 30 patients were males and 15 were females. Mean follow-up was  $13.75 \pm 5.9$  months. Demographic profiles of the patients are described in Table 1.

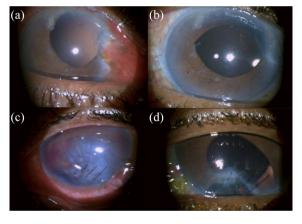
Thirty-five cases had CGI and 10 patients had OGI. Traumatic aniridia was not present in any of the cases. Superior and inferior iris defects with irregular pupil shape were present in three and two cases, respectively, in patients with OGI. Irregular pupils due to associated sphincter injury were present in five cases of CGI. Causes of aphakia included 22 cases of posterior lens dislocation, 16 PCIOL dislocation, three anterior lens dislocation and four anterior IOL dislocation. Prior to SFIOL implantation, PPV with PPL was done for all posterior lens dislocation cases, while PPV with IOL explantation was done for all IOL dislocation cases. IOL re-fixation using the same dislocated IOL could not be performed as they were single piece IOL (rigid or foldable) in all the 16 cases. Cases with anterior dislocation of lens

or IOL underwent lens or IOL explantation with anterior vitrectomy during primary globe repair. Trans-scleral fixation of three-piece IOL was done as a primary procedure in all 35 CGI cases after lensectomy or IOL explantation. In nine OGI cases, primary globe repair was done initially followed by PPV with SFIOL after a gap of minimum 8 weeks (range: 8-15 weeks). Two OGI cases with posterior IOL dislocation underwent IOL explantation during PPV. In one OGI case with rhegmatogenous retinal detachment (RRD) and posterior IOL dislocation, primary globe repair was followed by PPV, IOL explantation and silicone oil implantation (SOI) 2 weeks later. This was followed by SOR and SFIOL 4 months later (Table 2). Five patients had sclerocorneal tear and three had corneal tear. Corneal sutures were removed in four patients before biometry. In the remaining four patients, biometry values documented at the time of prior cataract surgery done at our centre were used for IOL power calculation. As our study was retrospective in nature, corneal sutures removal prior to biometry in all the patients could not be ensured. Images of two patients of our series post OGI repair and post SFIOL are shown in Figure 2.

Intraoperative retinal break was noted in the periphery in three cases; all three had CGI. There was no incidence of intraoperative IOL drop. There was no rebound of the haptics into the vitreous cavity. Immediate postoperative hypotony was noted in four cases of which two had associated choroidal detachment. Four patients had immediate postoperative raised IOP. Mean preoperative IOP was  $14.64 \pm 3.04$  mmHg, and mean IOP at last follow-up was  $14.44 \pm 2.08$ mmHg. Eight patients had transient postoperative corneal oedema, which resolved over next 2 weeks. Six patients had mild dispersed vitreous haemorrhage during immediate postoperative period, which resolved spontaneously over next 2 to 3 weeks of follow-up.

Mean LogMAR BCVA improved from preoperative  $1.64 \pm 0.45$  to  $0.63 \pm 0.36$  at last follow-up visit, and the difference was statistically significant (p < 0.0001). Final logMAR BCVA was 0.3 or better in eight patients, 0.4 to 1 in 34 patients and worse than 1 in three patients (Table 3). These three patients had associated posterior segment pathology. Mean postoperative spherical refraction was  $-0.56 \pm 1.05$  D and mean astigmatism was  $0.77 \pm 1.29$  D. Two patients had persistent rise in IOP and were started on topical 
 Table 2.
 Details of surgical procedures.

	5 1			
Parameters			Values	
Infusion system	Pars plana port		34 (75.55%)	
	Anterior chamber maintainer		11 (24.45%)	
Additional procedures	PPV + PPL	23-gauge cutter	18 (40%)	
		Phacofragmatome	4 (8.88%)	
	PPV + IOL expla	16 (35.55%)		
	SOR		1 (2.22%)	
Peripheral retinal breaks noted and endolaser done 3 (6.66%)				
IOL, intraocular lens; PPL, pars plana lensectomy; PPV, pars plana vitrectomy; SOR, silicone oil removal.				



**Figure 2.** Images of two patients with open globe injury showing (a) aphakia with irregular pupil post scleral tear repair, (b) well-centred SFIOL in patient 1, (c) corneal oedema and aphakia post corneal tear repair and (d) well-centred SFIOL in patient 2. SFIOL, scleral fixated intraocular lens.

antiglaucoma medications (AGMs). IOP was under control on AGM in both the patients at the last follow-up. Six patients had postoperative CME. Mean central macular thickness (CMT) at last visit was  $265.68 \pm 53.79$  microns. One patient had preexisting lamellar macular hole, which progressed to full thickness macular hole (FTMH) during the follow-up period (Table 4). None of our patients had postoperative haptic exposure. One patient with axial myopia had minimal IOL decentration. No patient developed RD, iris capture of IOL or SFIOL dislocation till the last follow-up.

Table 3. D	etails of visua	l acuity pre	operatively and	l at last	follow-up visit.
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	Preoperative		At last follow-up	Statistics
BCVA (logMAR)	Mean	$1.64\pm0.45$	$0.63\pm0.36$	<i>p</i> < 0.0001, <i>t</i> = 11.044
	0.3 or better	0 (0%)	8 (17.77%)	
	0.4-1	10 (22.22%)	34 (75.55%)	
	Worse than 1	35 (77.77%)	3 (6.66%)	
	Total	45 (100%)	45 (100%)	

 $\mathsf{BCVA},$  best-corrected visual acuity;  $\mathsf{logMAR},\mathsf{logarithm}$  of the minimum angle of resolution.

#### **Table 4.** Postoperative complications.

Parameters		Values
Immediate postoperative complications (within 1 month of surgery)	Transient corneal oedema	8 (17.77%)
	Rise in intraocular pressure	4 (8.88%)
	Hypotony	4 (8.88%)
	Choroidal detachment	2 (4.44%)
	Dispersed vitreous haemorrhage	6 (13.33%)
	IOL decentration	1 (2.22%)
Late postoperative complications (more than 1 month after surgery)	Persistent rise in intraocular pressure	2 (4.44%)
	Macular hole	1 (2.22%)
	Cystoid macular oedema	6 (13.33 %)

IOL, intraocular lens.

#### Discussion

Traumatic lens or IOL dislocations are common after ocular trauma and result in severe visual impairment. Surgery and visual rehabilitation are often challenging in these eyes due to the presence of associated anterior or posterior segment complications.<sup>1</sup> In this study, we describe the complications and visual outcome of sutureless SFIOL implantation in traumatic aphakia. We also describe a small modification of the X-NIT technique<sup>10</sup> to prevent intraoperative rebound of the haptics back inside the vitreous cavity.

Haptic rebound and IOL drop are important intraoperative complications of SFIOL implantation that can prolong the surgery time and can also lead to other subsequent iatrogenic complications. There are two instances where the leading IOL haptic can rebound or slip back into the vitreous cavity. The first instance is when the leading haptic is inadvertently pulled during manipulation and threading of the trailing haptic. Leading haptic rebound at this step can be prevented by using a silicone stopper, first introduced by Beiko and Steinert<sup>18</sup> and later modified by Baskaran and colleagues.<sup>10</sup> We also used silicone stopper in our surgeries.

The second common instance of haptic rebound is when the leading haptic is being tucked into the scleral tunnel after removing the stopper. The scleral tunnels in all the techniques that were described previously usually commence flush to the exit point of the haptic from the globe.<sup>10,11,15</sup> The haptic can accidentally slip from the forceps and slide back inside the vitreous cavity, especially at the hand of the beginners. Our modification makes the tucking of the haptics into the preformed scleral pockets easier. The 0.5-mm length of the haptic between the point of exit from the globe and the commencement of the scleral pocket provides a small working length which makes manipulation of the haptics easier while inserting them into the scleral pockets. It prevents intraoperative haptic rebound and IOL drop. Once the haptic slides back inside the globe, the tip of the haptic has to be grasped with micro forceps under wide angle viewing system and then exteriorized again. This prolongs the surgery time and may cause other intraoperative iatrogenic complications like retinal breaks, vitreous haemorrhage and so on. The 26G sclerotomy entry has to be enlarged to 25G or 23G to facilitate insertion of the micro forceps. This can cause subsequent sclerotomy site leakage and postoperative hypotony. Our modification prevents any such intraoperative complication. Prospective studies comparing the complication rates and duration of surgery using the conventional techniques<sup>10,11,15</sup> versus the modified technique are further needed to ascertain or establish the advantages of the modified technique. However, a definite advantage of our technique akin to X-NIT is that it is easier to perform in cases with small pupil or corneal scar or oedema as compared with the conventional handshake techniques.<sup>10</sup> This is particularly important in cases of globe injury where intraocular visualization of the haptics may be difficult due to associated posttrauma corneal oedema or opacity.

Another important intraoperative complication that can be expected during SFIOL implantation, especially in traumatic aphakias, is peripheral retinal break. Media haze in a trauma case often precludes preoperative identification of the breaks. Therefore, intraoperative thorough examination of the peripheral retina is mandatory to identify and treat any breaks. Intraoperative retinal break was noted in three cases in our series. Barrage endolaser was done and retina was attached in all cases till the last follow-up.

Mean preoperative logMAR BCVA in our study had improved from  $1.64 \pm 0.45$  to  $0.63 \pm 0.36$  at last follow-up visit. However, visual outcome in trauma cases can be confounded by various factors pertaining to the mode of injury, extent of injury, trauma-related anterior and posterior segment comorbidities and so on. Therefore, pupillary examination and detailed fundus evaluation are needed in all cases of traumatic aphakia to rule out any posterior segment pathology that can compromise the final visual outcome. Three cases in our study had postoperative BCVA of less than logMAR 1. They had associated preexisting macular hole, choroidal rupture at macula and traumatic optic neuropathy.

Postoperative complications reported with various SFIOL techniques include hypotony, choroidal detachment, corneal oedema, RD, suprachoroidal haemorrhage and glaucoma.<sup>1,8,10,11,19,20</sup> These complications are more likely to occur in traumatic aphakias due to coexistent ocular comorbidities in these eyes. In our case series, transient corneal oedema was noted in eight (17.77%) eyes, which resolved over the next 2 weeks. Previous studies have shown incidence of corneal oedema around 10% following SFIOL implantation.<sup>1,13,19,21</sup> Associated corneal endothelial injury secondary to ocular trauma may be responsible for slightly higher incidence of early postoperative transient corneal oedema in our study.

Immediate postoperative hypotony was noted in four (8.88%) cases of which two had associated choroidal detachment. All of them responded to a course of 1 week of oral and topical steroids. Four (8.88%) patients had immediate postoperative raised IOP of which two cases had persistent rise in IOP. Similar study by Zhao and colleagues1 on SFIOL implantation in traumatic aphakias has shown an incidence of glaucoma as 7.2%. Early rise in IOP following trauma can occur due to uveitis, hyphema and so on, which usually responds to topical steroids and AGMs. On the contrary, late onset glaucoma secondary to trabecular meshwork damage, angle recession or pigment recession may be refractory in nature and often imperceptible. Therefore, it is important to follow up the patients of traumatic aphakia with gonioscopy and IOP measurements.<sup>22</sup> None of our patients had angle recession on gonioscopy performed in the postoperative period. However, a close review is needed to diagnose late onset traumatic glaucoma and initiate appropriate treatment at the earliest.

Incidence of CME has been found to be around 1–2% following SFIOL implantation.<sup>1,13,20,21</sup> Our series had six (13.33%) cases with CME. This slightly higher incidence can be explained due to associated ocular traumatic uveitis. They were treated with topical nonsteroidal anti-inflammatory drug (NSAID) eye drops. Two patients received additional intravitreal triamcinolone acetonide (IVTA) 4 mg/0.1 ml two doses each till the last follow-up.

Postoperative IOL drop has been reported in around 3% of eyes after SFIOL fixation.<sup>21,23</sup> None of our patients had postoperative haptic exposure, postoperative IOL dislocation or iris capture of IOL till the last follow-up. One patient with axial myopia had minimal IOL decentration. However, mean follow-up is only  $13.75 \pm 5.9$  months. Longer follow-up is needed to comment on the IOL stability and dislocation rates of this technique.

There was no incidence of RD following SFIOL implantation in our case series. RD can be seen in around 30% cases with serious eye injuries.<sup>24</sup> All our cases had grievous eye injury with lens or IOL dislocation. However, thorough peripheral retinal examination was done in all the cases by intraoperative indentation. Retinal breaks were identified and treated with endolaser in three cases. Nevertheless, longer follow-up is needed in all the cases to detect and treat RD at the earliest.

SFIOL implantation can lead to endothelial cell loss in the postoperative period like any other intraocular surgery. However, endothelial cell count in the preoperative period could not be done in our cases due to coexistent ocular trauma. Another limitation of our study is that IOL tilt, preoperative corneal astigmatism and total astigmatism were not measured in all cases due to retrospective nature of the study. Future prospective studies can, therefore, be planned to address these limitations.

# Conclusion

To summarize, final visual outcome of sutureless SFIOL implantation in traumatic aphakia may be affected by concomitant posterior segment pathology. The immediate and late postoperative complications noted in our study were comparable with other similar studies. There was no evidence of any severe postoperative complications like RD in our study. However, in all cases of traumatic aphakias, longer follow-up is needed to detect RD and angle recession glaucoma at the earliest and initiate therapy.

#### **Conflict of interest statement**

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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# **Ethics statement**

The study was conducted after obtaining the approval from the Institutional Ethics Committee of Jawaharlal Institute of Post Graduate Medical Education & Research, Puducherry, India (approval number: JIP/IEC/2020/183) and it adhered to the tenets of the Declaration of Helsinki.

Informed consent was obtained from all individual participants included in the study. The authors certify that they have obtained all appropriate patient consent forms. In the form, the patients have given their consent for their images and other clinical information to be reported in the journal. The participants understand that their names and initials will not be published and due efforts will be made to conceal their identity.

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