# Retropupillary iris claw lens versus Gore-Tex assisted scleral fixated intraocular lens in children with large lens subluxations

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**Purpose:** To compare the functional outcome of retropupillary iris claw lenses (RPIC-IOL) and scleral fixated intraocular lenses (SFIOL) in children with large lens subluxations. **Methods:** Sixty eyes of patients between 6 and 18 years of age having >7 clock hour lens subluxation were included and equally divided into group A (RPIC-IOL implantation) and group B (Gore-Tex sutured SFIOL implantation). Cases with anterior and posterior segment abnormalities, trauma and glaucoma were excluded. Primary outcome was improvement in best-corrected visual acuity (BCVA) at 1.5 years. Secondary outcomes were assessment of intraocular lens (IOL) tilt, mean change in astigmatism at 1.5 years, and median operating time. All surgeries were performed by the same surgeon. **Results:** The mean improvement in BCVA in group A was  $0.28 \pm 0.41$  logMAR and group B was  $0.44 \pm 0.45$  logMAR (P = 0.3). Significant IOL tilt was seen in 4 eyes in group A (13.33%) and 5 eyes in group B (16.66%) (P = 0.120). Mean change in astigmatism was  $4.38 \pm 5.9D$  in group A and  $4.91 \pm 4.4D$  in group B (P = 0.299). The median operating time was 40 min in group A and 90 min in group B (P < 0.001). No significant posterior segment complications were seen in either technique. **Conclusion:** Both procedures had comparable visual outcomes. RPIC-IOL implantation was relatively quick and comparatively easier; it may be preferred in cases with high risk of retinal detachment.



Key words: Ectopia lentis, retropupillary, scleral fixated, subluxation

Lens subluxation in children is a challenging problem. Management varies from optical correction using spectacles/ contact lenses in low grades of subluxation to lens removal and intraocular lens (IOL) implantation in higher grades. Wherever feasible, in-the-bag placement of IOL with the aid of modified CTR remains the most acceptable option. However, in cases with large subluxations, a pars plana lensectomy-vitrectomy followed by the management of resultant aphakia is recommended. The treatment options available are scleral fixated IOLs (SFIOLs) – sutured or sutureless, anterior chamber IOLs (ACIOLs), and iris claw IOLs, which can be placed in the posterior chamber (retropupillary) or in the anterior chamber.

Even though ACIOLs are surgically easier to implant and modern-day open loop ACIOLs have proved to be safe in few studies in children, their use may be complicated by uveitis, hyphaema, glaucoma, and corneal decompensation over long term.<sup>[1,2]</sup> Therefore, they are not widely accepted in children.

SFIOLs have the advantage of the lens being placed in a more physiological position. The technique of sutured SFIOL has evolved over time, beginning with the use of 10-0 prolene which was complicated by suture degradation and breakage<sup>[3]</sup> followed by use of 9-0 prolene which has a better safety

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Received: 15-Oct-2021 Accepted: 14-Feb-2022 Revision: 25-Nov-2021 Published: 31-May-2022 profile. Currently, 8-0 Gore-Tex (polytetrafluoroethylene) which has greater tensile strength is being used and has shown relatively good results in adult eyes.<sup>[4-6]</sup> However, there is a paucity of studies documenting its safety profile in pediatric eyes.

In recent years, sutureless scleral tunnel IOLs have gained popularity. This technique eliminates the suture-related complications of SFIOLs while maintaining advantages over ACIOLs. However, low scleral rigidity in pediatric eyes makes this surgery more difficult and challenging.

Retropupillary iris claw IOLs (RPIC-IOLs) are technically simpler than SFIOLs and avoid corneal complications of ACIOLs. However, they may be associated with problems like spontaneous disenclavation and pupil ovalization.<sup>[7,8]</sup>

Currently, there is no consensus as to which of these techniques is best for management of large subluxations in children. Hence, we carried out this study to assess and compare the visual outcomes and stability of RPIC-IOL and sutured SFIOL (using Gore-Tex) in children. We have also addressed the short-term safety profile of Gore-Tex-assisted SFIOL in pediatric eyes as there is a paucity of similar studies in literature.

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**Cite this article as:** Rastogi A, Gaonker T, Dhiman S, Singh KJ, Anand K, Suresh P. Retropupillary iris claw lens versus Gore-Tex assisted scleral fixated intraocular lens in children with large lens subluxations. Indian J Ophthalmol 2022;70:2002-9.

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# Methods

We conducted a randomized comparative interventional study in a tertiary eye care centre, registered with Clinical trial registry – India (CTRI/2020/02/023156) [Table 1]. Approval was obtained from the Institutional Ethics Committee. Research adhered to the tenets of the Declaration of Helsinki. Sixty eyes of children in the age group 6–18 years with crystalline lens subluxation >7 clock hours (ectopia lentis) were enrolled in the study after obtaining informed consent and were divided in two groups of 30 eyes each [Fig. 1].

Surgical outcomes and complications of sutured scleral fixated intraocular lenses in paediatric eyes were observed by Parveen Sen, *et al.*<sup>[9]</sup> The study observed mean values of postoperative BCVA after 6 weeks as  $0.66 \pm 0.59$ . Taking these values as reference and assuming mean difference of 0.5 in BCVA between two groups with an effect size of 0.85, the minimum required sample size with 80% power of study and 5% level of significance was 22 eyes in each study group. Taking attrition rate as 25%, total sample size was calculated to be 60 (30 eyes per group).

Calculation was done using the formula:

 $N = \frac{2(\text{standard deviation})^2 \times (Z_{\alpha} + Z_{\beta})^2}{(\text{Mean difference})^2}$ 

where  $Z_{\alpha}$  is the value of Z at two-sided alpha error of 5%

 $Z_{\rm B}$  is the value of Z at power of 80%

Mean difference is the difference in the mean values of two groups.

Standard deviation = 0.59

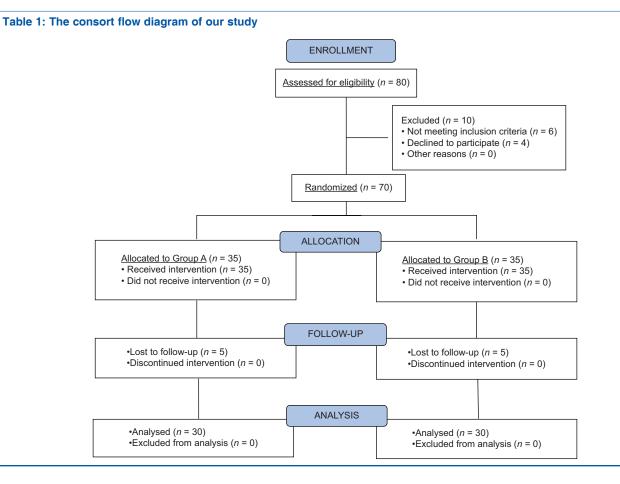
$$Z_{\alpha} = 1.96$$

$$Z_{\rho} = 0.84$$

Mean difference = 0.5

Group A underwent retropupillary iris claw lens implantation (RPIC-IOL group) and group B underwent sutured scleral fixated intraocular lens implantation using 8-0 Gore-Tex (SFIOL group). For allocation of the participants, a computer-generated list of random numbers was used. To randomly select among two groups, random number generating function RANDBETWEEN was used with lower limit as 1 and upper limit as 2. If 1 was generated, group A was allocated and if 2 was generated, group B was allocated. Once either of the groups got 30 samples, the others were allocated to the other group to make 30 samples in that group.

A thorough preoperative ophthalmic evaluation was performed including best-corrected visual acuity (BCVA) using the Snellen chart, retinoscopy (wherever possible), slit-lamp examination, automated keratometry, endothelial cell count, intraocular pressure (IOP) measurement and dilated posterior segment assessment. Contact biometry was done using the SRK-T formula, since the mean axial length in both



the groups was above 24 mm. Few patients had an axial length below 22 mm, in which case we used the Hoffer-Q formula. The use of optical biometers was not possible in our patients since most of them had very poor unaided visual acuity due to large lenticular myopia and astigmatism and were unable to fixate. Some patients had associated cataract. For the purpose of uniformity, we used contact biometry in all our patients. Ultrasound B scan was done wherever fundus evaluation could not be performed. Patients were examined by a pediatrician to rule out associated syndromes.

The IOL used in the RPIC-IOL group was an iris claw lens [Irifix, Model No J-IF54, overall diameter of 8.50 mm, optic diameter of 5.40 mm with an estimated A constant of 117.4 for posterior chamber]. In the SFIOL group, Akreos A060 [(Bausch and Lomb), overall diameter of 11 mm, optic diameter of 6 mm with an estimated A constant of 118.0] was used. The target refraction was emmetropia. In patients with unilateral subluxations, IOL power was calculated to match the other eye so as to avoid anisometropia. In some unilateral subluxation cases, slight overcorrection was done to avoid a high near add postoperatively in one eye.

## Surgical technique

All surgeries were performed by the same surgeon using Alcon Centurion machine under general anesthesia in younger children and local anesthesia in older children.

### Group A (Retropupillary iris claw lens)

Pars plana lensectomy-vitrectomy was done using 23 G vitrectomy cutter. A clear corneal incision of 4.5 mm was created. The iris claw lens was inserted vertically in the anterior chamber and was nudged to horizontal position. It was slipped posteriorly with a lens holding forcep. The midperipheral iris was enclaved at 3 o'clock and 9 o'clock positions 180° apart using a Sinskey hook one after the other. Peripheral iridectomy was done and the incision was closed with 10-0 vicryl followed by sclerostomy closure with 8-0 vicryl [Fig. 2].

## Group B (Sutured scleral fixated intraocular lens)<sup>[5]</sup>

Four sclerotomies were made (two on each side) 3 mm behind the limbus and 5 mm apart using 23 G trocar. Pars plana lensectomy-vitrectomy was done. A clear corneal incision of 3.2 mm was made. The Gore-Tex suture was cut into half, and each end was threaded through the two eyelets of the SFIOL on either side. The suture ends were then passed into the anterior chamber and pulled out of the corresponding sclerotomy using 23 G intravitreal forceps. The IOL was folded and introduced into the anterior chamber using Kelman–McPherson forceps. The sutures were tied using a 3-1-1 technique after ensuring IOL centration by adjusting the tension of sutures on either side. The

# Table 2: Comparison of demographic data between the two groups

Demographic data	Group A	Group B
Total eyes	30	30
Laterality		
Unilateral subluxations	16	14
Bilateral subluxations	7	8
Age (years)		
Mean±SD	9.57±4.13	9.64±4.09
Range	6-18	6-18
Gender		
Male	19 (63.3%)	24 (80%)
Female	11 (36.7%)	6 (20%)
Etiology of subluxation		
Муоріа	7 (23.33%)	6 (20%)
Marfan's	2 (6.66%)	3 (10%)
Homocystinuria	2 (6.66%)	3 (10%)
Idiopathic	19 (63.33%)	18 (60%)
Axial length (mm)		
Mean	25.25±2.44	24.21±2.27
Range	21.6-28.8	20.75-27.64
Association with cataract <sup>1</sup>	8 (26.66%)	6 (20%)

<sup>1</sup>fundus evaluation could not be done preoperatively; however, ultrasound B scan was normal

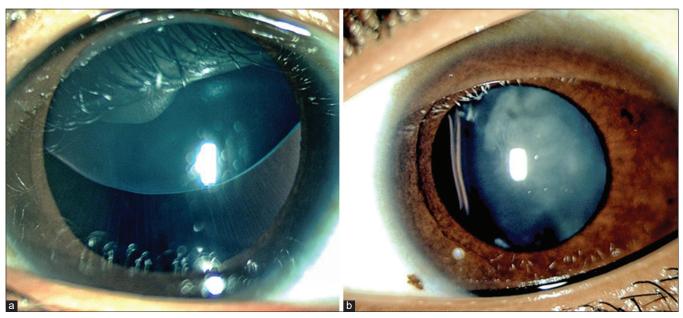
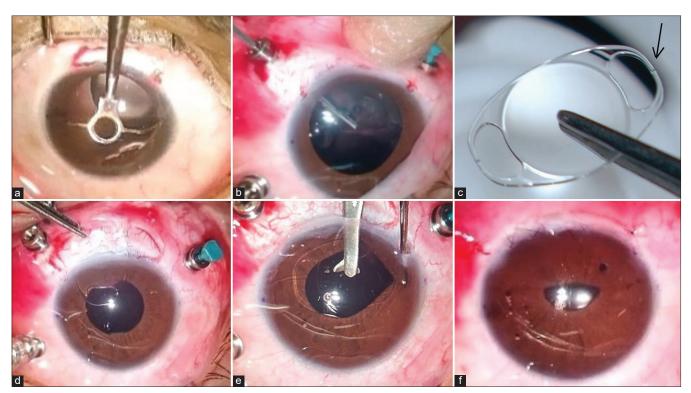
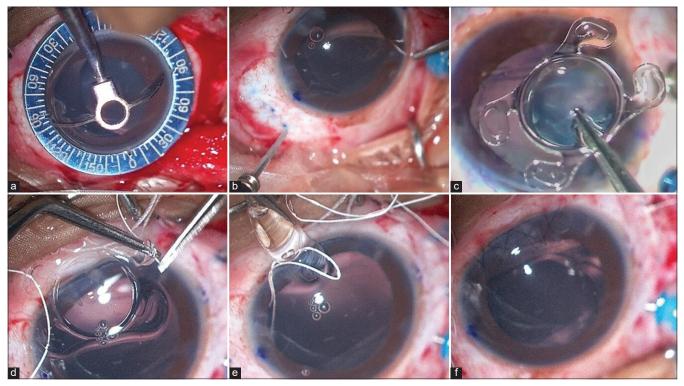


Figure 1: Preoperative photographs (a) clear lens subluxation from 2 to 8 clock hours in a patient with Marfan's syndrome who subsequently underwent RPIC-IOL implantation. (b) temporal subluxation of a cataractous lens with a poorly dilating pupil in a patient with homocystinuria who subsequently underwent SFIOL implantation



**Figure 2:** Surgical steps of RPIC-IOL Implantation (a) corneal markings being made 180° apart; (b) pars-plana lensectomy-vitrectomy being done; (c) RPIC-IOL showing claw (black arrow) for iris tissue enclavation; (d) insertion of IOL into anterior chamber; (e) IOL being slipped into posterior chamber and enclaved in mid-peripheral iris; (f) well-centered IOL with patent peripheral iridectomy at the end of surgery



**Figure 3:** Surgical steps of SFIOL implantation (a) corneal markings being made 180° apart; (b) creation of sclerotomies 3 mm from limbus and 5 mm apart followed by pars-plana lensectomy-vitrectomy; (c) SFIOL with four eyelets; (d) Gore-Tex being threaded through IOL eyelets; (e) insertion of SFIOL into an anterior chamber after pulling out Gore-Tex threads through corresponding sclerotomies; (f) well-centered IOL after surgery

Table 3: Age distribution of patients in both the groups					
Age (in years)	6-9	10-12	13-15	16-18	Total
A n (%)	16 (53.34%)	6 (20.0%)	3 (10.0%)	5 (16.67%)	30 (100%)
B n (%)	16 (53.34%)	8 (26.67%)	2 (6.67%)	4 (13.33%)	30 (100%)
Total	32 (53.33%)	14 (23.33%)	5 (8.33%)	9 (15.0%)	60 (100%)

knots were trimmed and buried into one of the sclerotomies. The sclerotomies were sutured with 8-0 vicryl and the corneal incision with 10-0 vicryl [Fig. 3].

Postoperative analysis was done at day 1, 1 week, 6 weeks, 3 months, 1 year, and 1.5 years. IOL tilt was assessed by UBM by the method described by Loya *et al*.<sup>[10]</sup> (>100  $\mu$  tilt with reference to iris plane was considered as significant).

### Data analysis

The data was entered in an MS EXCEL spreadsheet and analysis was done using Statistical Package for Social Sciences version 25.0. Statistical tests were applied as follows:

- 1. Quantitative variables were compared using the independent *t*-test/Mann–Whitney test (when the data sets were not normally distributed) between the two groups and paired *t*-test/Wilcoxon test within groups across follow-ups.
- 2. Qualitative variables were correlated using the Chi-square test/Fisher's exact test.

A *P* value of <0.05 was considered statistically significant.

# Results

The mean age was  $9.5 \pm 4.1$  years in the RPIC-IOL group and  $9.6 \pm 4.1$  years in the SFIOL group. Table 2 shows the demographic profile of patients in our study, and Table 3 shows the age distribution of patients in both the groups. The cause of subluxation in the RPIC-IOL group was high myopia in 7 cases (23.33%), homocystinuria in 2 cases (6.66%), Marfan's syndrome in 2 cases (6.66%), and idiopathic in 19 cases (63.33%). In the SFIOL group, it was high myopia in 6 cases (20%), homocystinuria in 3 cases (10%), Marfan's syndrome in 3 cases (10%), and idiopathic in 18 cases (60%).

Both the groups showed a significant change in BCVA postoperatively at 1.5 years. In the RPIC-IOL group, the mean preoperative BCVA was  $0.91 \pm 0.42 \log$ MAR and mean postoperative BCVA at 1.5 years was  $0.63 \pm 0.28 \log$ MAR (P = 0.025). In the SFIOL group, the mean preoperative BCVA was  $0.98 \pm 0.38 \log$ MAR and mean postoperative BCVA at 1.5 years was  $0.54 \pm 0.29 \log$ MAR (P = 0.003). In our study, the mean improvement in BCVA at 1.5 years was  $0.44 \pm 0.45 \log$ MAR in the SFIOL group and  $0.28 \pm 0.41 \log$ MAR in the RPIC-IOL group. The difference was not statistically significant (P = 0.322).

There was a marked change in postoperative spherical equivalent (SE) in both the groups. The mean preoperative (SE) was -18.4  $\pm$  5.26 D in the RPIC-IOL group and -16.25  $\pm$  5.15 D in the SFIOL group (P = 0.356). The mean postoperative SE at 1.5 years was 0.89  $\pm$  1.5 D in the RPIC-IOL group (P = < 0.001) and -0.61  $\pm$  1.89 D in the SFIOL group (P < 0.001). Ten eyes in the RPIC-IOL group and six eyes in the SFIOL group had amblyopia in our study. We did not have any postoperative surprises.

In the RPIC-IOL group, the mean preoperative keratometric reading was  $42.5 \pm 1.5$  D and mean postoperative keratometric reading was  $43.25 \pm 1.0$  D. The mean preoperative astigmatism was  $-5.85 \pm 5.38$  D and mean postoperative astigmatism at 1.5 years was  $-1.38 \pm 1.65$  D (*P* = 0.044).

In the SFIOL group, the mean preoperative keratometric reading was  $43.25 \pm 1.5$  D and mean postoperative keratometric reading was  $44.00 \pm 1.0$  D. The mean preoperative astigmatism was  $-7.05 \pm 4.13$  D and mean postoperative astigmatism at 1.5 years was  $-2.11 \pm 1.99$  D (P = 0.004). However, the difference between the two groups at 1.5 years postoperatively was not statistically significant (P = 0.300), as shown in Table 4.

The median operating time was 40 min in the RPIC-IOL group and 90 min in the SFIOL group. The surgeon experienced suture entanglement after passing the four ends through the sclerotomies, thus prolonging the duration of the surgery to 100 min in one patient in group B. The difference in the two groups was statistically significant ( $P \approx 0.001$ ).

IOL centration was evaluated in all patients by slit-lamp examination at every visit. The decentration was measured in millimeters from the margin of the pupil in the undilated state. At 3 months follow-up, IOL decentration was seen in one eye in the RPIC-IOL group (1 mm) and in three eyes in the SFIOL group (1, 1.2, 1.5 mm). Since the visual acuity was good and it was evident only on pupillary dilatation, no surgical intervention was done. At 1.5 years follow-up, there was no further increase in decentration in the above eyes or in the eyes which had no decentration at 3 months.

A significant IOL tilt was seen in 4 eyes (13.33%) of the RPIC-IOL group and in 5 eyes (16.66%) of the SFIOL group. The difference was not statistically significant between the groups (P = 0.12). Overall, the mean BCVA in eyes with significant tilt was  $0.53 \pm 0.32$  logMAR and in eyes without significant tilt was  $0.65 \pm 0.26$  logMAR. This difference was not statistically significant (P = 0.3).

Overall, the mean postoperative astigmatism in eyes with significant tilt in both the groups was  $-2.33 \pm 2.37$  D and in eyes without significant tilt was  $-1.56 \pm 1.57$  D. This difference was not statistically significant (*P* = 0.3).

The mean preoperative endothelial count was  $2782.5 \pm 494.86/\text{mm}^2$  in the RPIC-IOL group and  $2966.36 \pm 542.46/\text{mm}^2$  in the SFIOL group. The mean postoperative endothelial count at 1.5 years was  $2429.57 \pm 496.34/\text{mm}^2$  in the RPIC-IOL group (P < 0.001) and  $2553.14 \pm 665.55/\text{mm}^2$  in the SFIOL group (P < 0.001).

The postoperative IOP was measured at 1 week, 1 month, and 3 months. The difference between the two groups at each visit was not statistically significant. One eye in the RPIC-IOL group and 3 eyes in the SFIOL group developed immediate postoperative hypotony, which resolved by 2 weeks on medical

# Table 4: Comparison of visual acuity, spherical equivalent, and astigmatism between two groups preoperatively and postoperatively (1.5 year)

Parameter	Group A	Group B	Р
UDVA			
Preoperative	1.6±0.34	1.58±0.34	0.870
Postoperative	0.74±0.41	0.75±0.35	0.960
BCVA			
Preoperative	0.91±0.42	0.98±0.38	0.641
Postoperative	0.63±0.28	0.54±0.29	0.399
S.E			
Preoperative	-18.4±5.26	-16.25±5.15	0.356
Postoperative	0.89±1.5	-0.61±1.89 D	0.270
Astigmatism			
Preoperative	-5.85±5.38	-7.05±4.130	0.572
Postoperative	-1.38±1.65	2.11±1.99	0.300

UDVA=uncorrected distance visual acuity; BCVA=best-corrected visual acuity; SE=spherical equivalent

Table 5: Summary of complications seen in Group A and Group B

Complications Nur		nber of eyes (%)	
	Group A	Group B	
Anterior Segment			
High IOP <sup>a</sup>	3 (10%)	1 (7%)	
Hypotony <sup>b1</sup>	1 (7%)	3 (10%)	
Anterior uveitis <sup>c</sup>	3 (10%)	4 (13.33%)	
Corneal edemad	4 (13.33%)	4 (13.33%)	
IOL tilt	4 (13.33%)	5 (16.66%)	
IOL decentration <sup>e</sup>	1 (7%)	3 (10%)	
Pupil ovalization	18 (60%)	-	
POSTERIOR SEGMENT			
Choroidal detachment <sup>b2</sup>	1 (7%)	0	
Vitreous hemorrhage <sup>f</sup>	0	2 (6.66%)	
Cystoid macular edema <sup>9</sup>	4 (13.33%)	3 (10%)	

<sup>a</sup>Three eyes in group A had transient increase in IOP which normalized in 2 weeks. One eye in group B had lens droppings which led to high IOP, which was normalized after complete vitrectomy. <sup>b1,b2</sup>We consider this to be an expected observation of adequate vitrectomy in pediatric eyes with low scleral rigidity, one case in group A had choroidal detachment (CD) which led to low IOP and was normalized with resolution of CD. <sup>c,d</sup>All were transient and resolved in 2 weeks on topical drugs. <sup>e</sup>None of the eyes had significant decentration. <sup>f</sup>Mild vitreous hemorrhage which resolved by 3 weeks on medical management. <sup>g</sup>Resolved by 2 weeks follow-up.

management. We consider this to be an expected observation of adequate vitrectomy in pediatric eyes with low scleral rigidity No wound leaks were noted postsurgery in either of the groups. One eye in the RPIC-IOL group had a small lens fragment drop and developed a high IOP, which required surgical removal of lens material. Table 5 shows the list of complications seen in both the groups.

# Discussion

Management of large lens subluxation in children continues to be a perplexing problem for pediatric ophthalmologists. In-the-bag placement of an IOL with the aid of Cionni ring remains an acceptable option, but this surgery is technically challenging.<sup>[11]</sup> In cases where it is not feasible, lens extraction can be done with the management of resultant aphakia. The choice of IOL to be implanted is the next challenge as early visual rehabilitation with minimal complications is the ultimate goal in children.

ACIOLs are technically easier to implant, but they are not free of complications.<sup>[1,2]</sup> SFIOL is a time-tested option for eyes with inadequate capsular support due to their placement in a more physiological position. However, complications like retinal detachment, IOL tilt, vitreous or suprachoroidal hemorrhage, endophthalmitis, and suture erosion/breakage have all been reported.<sup>[12-14]</sup> Iris claw lenses avoid potential complications of ACIOLs and SFIOLs. However, they may be associated with spontaneous disenclavation, iris chaffing/ atrophy, pigment dispersion, hyphaema, and pupil ovalization.

Many studies have evaluated 10-0 polypropylene for SFIOL in children and have reported IOL dislocation secondary to suture breakage.<sup>[3]</sup> Use of thicker sutures like 9-0 prolene is considered a better alternative for scleral fixation in children due to its better safety profile.<sup>[12,15]</sup> Current literature supports the superiority of 8-0 Gore-Tex over 9-0 prolene for suturing SFIOL because of its greater tensile strength, high visibility due to its white color, minimal inflammatory response, minimal memory, and easy manipulation. Khan et al.<sup>[4]</sup> did SFIOL (Akreos) implantation using 7-0 Gore-Tex suture in 85 eyes, and there was no reported case of suture breakage during follow-up. Other studies have shown a similar safety profile in adult eyes.<sup>[16,17]</sup> However, there is a lack of documentation of its safety profile and outcomes in pediatric eyes. This study highlights the comparison of functional outcomes in both the procedures and addresses the technical and safety concerns of Gore-Tex-assisted SFIOL in children.

In our study, there was a statistically significant improvement in the mean BCVA in both the groups postoperatively; however, it was not statistically significant in between the groups. Rashad *et al.*<sup>[18]</sup> reported a mean BCVA of 0.51 ± 0.25 logMAR in the RPIC-IOL group and 0.42 ± 0.16 logMAR in the SFIOL group at last follow-up (P = 0.152) in aphakic patients. Their mean BCVA at all postoperative visits was better in the SFIOL group. Han Zhang *et al.*<sup>[19]</sup> compared the two techniques in aphakic patients and reported a mean BCVA of 0.55 ± 0.22 logMAR in the suture fixated RPIC-IOL group and 0.53 ± 0.19 logMAR in the SFIOL group (P = 0.249). However, both these studies have been done in adult eyes.

Visual recovery was found to be earlier in the RPIC-IOL group (mean UCVA was better in the RPIC-IOL group when compared to the SFIOL group at postoperative day 1). This could be attributed to a shorter median operating time as implantation of an iris claw lens is comparatively simpler with fewer steps as compared to the SFIOL group, where the surgeon faced more difficulty due to low scleral rigidity. In addition, since there were four suture ends, suture orientation and entanglement during SFIOL placement was encountered in a few cases. The sclerotomies were created using 23 G trocars, and thus, they all had to be sutured at the end of the surgery. This also contributed to a longer operating time in the SFIOL group. Rashad *et al.*<sup>[18]</sup> have also reported an early

visual recovery in their RPIC-IOL group, which they attributed to the uncomplicated nature of the surgery and a shorter operating time.

The mean postoperative SE showed a hypermetropic trend in the RPIC-IOL group and myopic trend in the SFIOL group. This difference was not statistically significant; it can be explained by the presence of certain outliers in each group. The mean SE in group A was  $0.89 \pm 1.5D$ . One patient in this group had a SE of +4.25 D. The mean SE in group B was  $-0.61 \pm 1.89$  D. The mean SE in two patients in this group was -4.25D and -4.5D. Our study correlates well with a study by Botsford *et al.*<sup>[6]</sup> who did SFIOL implantation using Gore-Tex in 31 eyes and reported a postoperative myopic trend. Rastogi *et al.*<sup>[20]</sup> reported mean postoperative SE  $-2.07 \pm 0.91$  with an iris claw lens. However, the technique used to insert the IOL in the study was through a corneo-scleral tunnel. Also, there is no mention of preoperative and postoperative keratometric data.

In our study, four patients in the RPIC-IOL group and five patients in the SFIOL group were noted to have a significant IOL tilt. However, the difference was not statistically significant (P = 0.12). Mahajan *et al.*<sup>[21]</sup> reported two cases of IOL tilt in the RPIC-IOL group and four cases in the SFIOL group. However, the method for IOL tilt measurement and its statistical significance value is not described. Additionally, they did not compare the BCVA or astigmatism in eyes with and without significant tilt.

In our study, the mean change in astigmatism was statistically significant in each group (due to the elimination of lenticular astigmatism) and was comparable in between the groups at the last follow-up. A smaller incision helps limit the postoperative astigmatism to an acceptable range. The incision required to insert the nonfoldable RPIC-IOL is 4.5 mm, which is larger than that required for foldable SFIOL (4.0 mm). However, postoperatively, eyes with IOL tilt were more in the SFIOL group compared to the RPIC-IOL group resulting in higher astigmatism in the former and negating the benefit of a small incision. Since there is a paucity of literature on Gore-Tex-sutured SFIOL implantation in children, this data needs more documentation in future studies.

One case in the RPIC-IOL group had an intraoperative small lens fragment drop with high IOP uncontrolled with topical and oral antiglaucoma medications on follow-up, for which pars plana vitrectomy was done in a second stage. None of our cases had retinal detachment, pseudophacodonesis, or IOL dislocation. No sclerotomy-related complications were seen. The most common postoperative complication in the RPIC-IOL group was pupil ovalization, which had no effect on the final BCVA or pupillary dilation. The most common postoperative complication in the SFIOL group was IOL tilt. This could be attributed to not so precise markings in these eyes. The authors would like to highlight that meticulous marking is of utmost importance in achieving good IOL centration and stability. This especially becomes challenging in eyes under general anesthesia, where the globe tends to diverge.<sup>[22]</sup> This coupled with multiple sclerotomies and postvitrectomy hypotony makes globe handling difficult. We recommend use of smaller gauge instruments to reduce the need for additional suturing and to minimize sclerotomy site leakage and thus hypotony. For the ease of instrument transfer and suture passage, valved cannulas can also be used. Gore-Tex could possibly be a stronger and safer option in pediatric eyes especially in non-Marfanoid cases. The limitation of this study is the relatively short duration of follow-up. More studies with larger sample size and longer duration of follow-up are needed to support this.

# Conclusion

Both RPIC-IOL and SFIOL respect the anterior segment anatomy and corneal endothelium as they are placed behind the iris plane. We conclude that both techniques provide good visual rehabilitation and IOL stability in children with large lens subluxations. RPIC-IOL implantation is comparatively easier and needs significantly lesser intraoperative manipulation. Hence, we recommend it in subjects with high risk of retinal detachment like Marfan's syndrome, high myopia and presence of peripheral retinal degenerations.

#### Disclosures

Nil.

### What was known

- Children with large lens subluxations usually undergo lens extraction with management of aphakia with secondary IOLs like ACIOLS, sutured SFIOLs (with prolene), sutureless SFIOLs (with/without glue). However, the best way of management is still controversial as each technique carry its own advantage and disadvantage.
- No prior study in literature documents the outcome of Gore-Tex-assisted scleral fixated IOL in children

### What this paper adds

- Goretex-assisted scleral fixated IOL gives good surgical outcome and can be considered as an alternative to RPIC-IOL in cases where bag stabilization techniques with IOL implantation are not possible.
- In the available duration of the study (1.5 years), no untoward side effects of Gore-Tex suture were noted. Also, in the current follow-up of this study, Gore-Tex continues to show promising results.

# Financial support and sponsorship Nil.

#### **Conflicts of interest**

There are no conflicts of interest.

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