• Clinical Research •

Evaluation of functional outcome and stability of sutureless scleral tunnel fixated IOLs in children with ectopia lentis

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Abstract

● **AIM:** To evaluate functional outcome of sutureless scleral tunnel intraocular lens (SSTIOL) in children with crystalline lens subluxation of more than 7 clock hours.

● **METHODS:** A prospective interventional study was conducted consisting of 45 eyes of 44 children in age group 6-18y having >7 clock hours of lens subluxation who underwent lensectomy-vitrectomy followed by SSTIOL implantation. Primary outcome was improvement in best corrected visual acuity (BCVA) and secondary outcomes were assessment of intraocular lens (IOL) tilt using ultrasound biomicroscopy (UBM), mean change in astigmatism at last follow-up of 1y and associated complications.

● **RESULTS:** The mean preoperative and postoperative BCVA was 1.05±0.28 and 0.64±0.45 (logMAR) respectively (P=0.001) at last follow-up. The mean astigmatism preoperatively and postoperatively was -4.17±2.69 D and -1.86±1.25 D respectively (P=0.011). Significant IOL tilt (>5 degrees) was present in 5 cases. The mean percentage endothelial loss was 3.65%±1.92%. The most serious complication encountered was retinal detachment seen in 2 cases.

● **CONCLUSION:** SSTIOL implantation provides efficient visual rehabilitation in children provided there is stringent case selection. We recommend caution in children having white-to-white distance >12 mm and presence of peripheral retinal degenerations.

● **KEYWORDS:** ectopia lentis; subluxated lens; sutureless scleral tunnel fixated intraocular lens

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INTRODUCTION

Lens subluxation in children is a frequently encountered challenging problem. It can induce significant oblique astigmatism and high refractive errors which can lead to amblyopia, thereby hindering early visual rehabilitation.

Management of subluxated lenses ranges from conservative techniques like optical correction in mild cases to in-the-bag intraocular lens (IOL) implantation with modified capsular tension ring (mCTR) in moderate subluxations. In severe lens subluxations, lensectomy can be done with management of the resultant aphakia. The options available are anterior chamber IOLs (ACIOLs), iris fixated IOL (anterior and retropupillary) and scleral fixated IOLs (sutured and sutureless)[1-2].

The modern day open loop ACIOLs have potential complications of corneal decompensation, uveitis, glaucoma, hyphaema and peripheral anterior synechiae in children[3-4].

Sutured scleral fixated IOLs (SFIOLs) are a popular option. The technique is surgically demanding and has suture related complications like suture degradation, IOL dislocations due to suture breakage and endophthalmitis[5-6].

In recent years, sutureless scleral tunnel IOLs (SSTIOLs) have gained popularity. This technique eliminates the suture related complications of SFIOLs while maintaining advantages over ACIOLs. It has shown high success rates in adults but there is paucity of literature on their functional outcome and safety in children[7-8]. We evaluated the stability, functional outcome and complications of SSTIOLs in children between 6-18 years of age.

SUBJECTS AND METHODS

Ethical Approval Approval was taken from the Institutional Ethics Committee and research adhered to the tenets of the Declaration of Helsinki. We conducted a prospective interventional study in a tertiary eye care centre. Totally 45 eyes of 44 children in age group 6-18y with crystalline lens subluxation >7 clock hours (ectopia lentis) were enrolled in the study after taking informed consent.

Patients with pre-existing corneal pathology, uveitis, glaucoma, optic nerve pathology and posterior segment abnormalities were excluded. A thorough preoperative ophthalmic evaluation was performed including best corrected visual acuity (BCVA) using Snellen chart, retinoscopy (wherever possible), endothelial cell count (SP-200P), intraocular pressure (IOP)

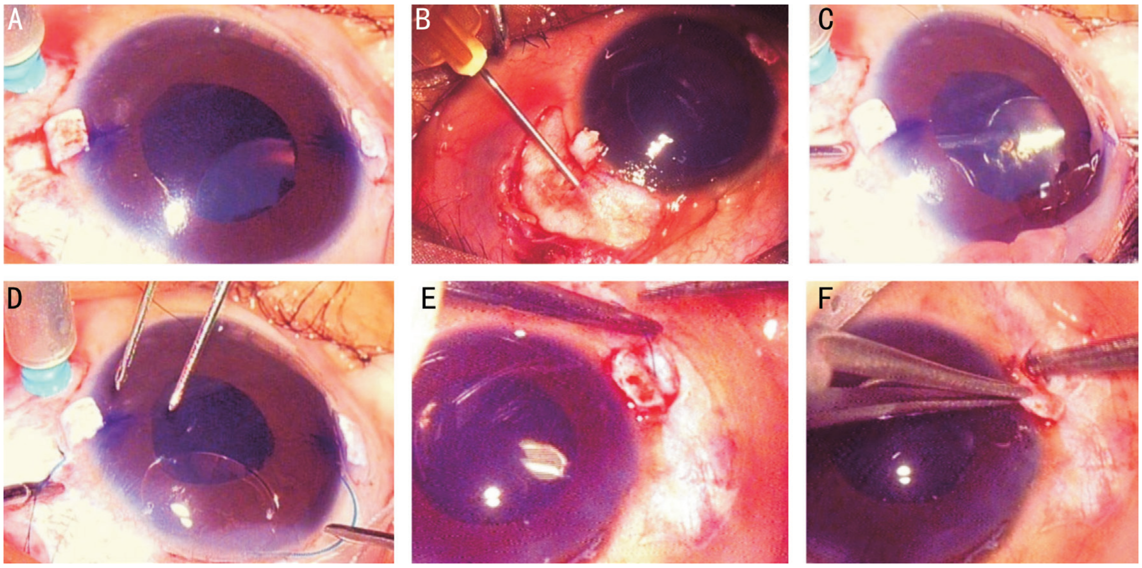

Figure 1 Surgical steps of sutureless scleral tunnel IOL fixation A: Creation of scleral flaps exactly 180° apart; B: Creation of scleral tunnel under scleral flaps; C: Lensectomy-vitrectomy being done; D: Leading haptic externalized; E: Trailing haptic externalized; F: Tucking of haptics in scleral tunnel.

measurement (SHIN-NIPPON NCT-10) and dilated posterior segment assessment. Ultrasound B scan (APPASWAMY MARVELL-II) was done wherever fundus evaluation could not be performed. All the patients underwent lensectomy-vitrectomy followed by SSTIOL implantation. Postoperative assessment was done at 1wk, 1, 3 and 6mo and final outcome was assessed at 1y follow-up. Ultrasound biomicroscopy (UBM) was used to assess IOL tilt (>5° tilt with reference to iris plane was considered as significant). Pseudophacodonesis was evaluated on slit lamp as demonstrated by Möonestam[9] [after pupillary dilatation, patients were asked to look in upward direction for 5s followed by quick downgaze to induce IOL movement which was classified as none (0), minor (1), moderate (2), and severe (3)].

Surgical Technique All surgeries were performed by same surgeon under general or peribulbar anesthesia. Two limbus based partial thickness scleral flaps of approximately 3×3 mm^2 were made exactly 180° apart at 3 and 9 o'clock positions. Under the scleral flap, a 26 G needle was used to create the scleral tunnels approximately 3 mm long and parallel to the limbus adjacent to the planned sclerotomy sites in opposing directions. Two straight sclerotomies were made 1-1.5 mm away from limbus under the scleral flaps using 22 G needle. An infusion cannula (23 G) was introduced 3 mm from the limbus inferotemporally. Vitrectomy probe (23 G) was inserted from one of the sclerotomy sites and lensectomy was done followed by a thorough vitrectomy. After creation of main section (2.8 mm) and side port, a foldable three piece IOL (Abbot AR40e IOL) was injected through the main section. A 23 G intravitreal forceps was used to externalize haptics using the hand shake technique. The haptics were tucked in the previously created scleral tunnels. At this point IOL centeration was checked and if required, was corrected by varying the amount of tuck of either haptic (Figure 1). Fibrin glue was applied to appose the scleral flaps. The main corneal wound was sutured with 10-0 nylon.

Postoperative Period All patients received a 5-day course of systemic antibiotics *i.e.* syrup amoxicillin (250 mg/5mL) 20 mg/kg in divided doses and capsule amoxicillin 500 mg according to age along with topical prednisolone 1% eye drops, topical antibiotics and oral steroids (1 mg/kg) tapered for 6wk. Amblyopia therapy was initiated 1mo after the surgery wherever necessary.

Data Analysis Data was analysed using SPSS version 21.0. Normality of data was tested by Kolmogorov-Smirnov test. If the normality was rejected then non parametric test was used. Quantitative variables were compared using Mann-Whitney test/independent *t* test between the two groups and Paired *t* test/Wilcoxon signed rank test was used across follow up comparison. *P* value of <0.05 was considered statistically significant.

RESULTS

Mean age was 10.86±3.26y (6-17y). Totally 80% cases were males and 20% were females. Marfan's syndrome accounted for 85% and Homocystinuria for 15% of all subluxations.

The mean preoperative and postoperative BCVA was 1.05±0.28 and 0.64±0.45 logMAR respectively at 1y follow-up (*P*=0.001) which was statistically significant. Amblyopia was an important vision limiting factor observed in 18 eyes.

The mean preoperative and postoperative spherical equivalent was -10.91±4.03 D and -0.42±0.91 D respectively at 1y follow-up (*P*<0.001) which was statistically significant. The mean preoperative and postoperative astigmatism was

Table 1 Comparison of preoperative and postoperative (at 1y follow-up) parameters

Parameters	Preoperative	Postoperative			*P*
		3mo	6mo	1y	
Mean BCVA (logMAR)	1.05±0.28	0.68±0.43	0.64±0.45	0.64±0.45	0.001
Mean spherical equivalent (D)	-10.91±4.03	0.41±0.91	-0.42±0.91	-0.42±0.91	<0.001
Mean astigmatism (D)	-4.17±2.69	-1.87±1.24	-1.86±1.25	-1.86±1.25	0.011
Mean IOP (mm Hg)	15.75±2.37	14.7±2.63	14.8±2.64	14.8±2.64	0.60
Mean endothelial count (cells/mm^2)	2882±149.5	2778.16±162.5	2777.18±159.9	2777.17±159.9	<0.001

BCVA: Best corrected visual acuity; IOP: Intraocular pressure.

-4.17±2.69 D and -1.86±1.25 D respectively at 1y follow-up (*P*=0.013) which was statistically significant. Table 1 shows comparison of preoperative and postoperative parameters.

IOL tilt was analyzed using UBM (Figure 2) and angular tilt >5° in either axis was considered to be significant. The mean BCVA in eyes with tilt was 1.13±0.49 D and in eyes without tilt was 0.59±0.45 D. Although the mean BCVA was better in eyes without significant tilt, this difference was not statistically significant (*P*=0.139). The mean astigmatism in eyes with significant tilt was -2.88±0.18 D and in eyes without significant tilt was -1.71±1.27 D. Although the mean astigmatism was less in eyes without significant tilt, this difference was not statistically significant (*P*=0.23). None of the patients had clinically evident decentration in a mesopic pupil. In our study, none of the eyes had significant pseudophacodonesis on slit lamp examination.

The mean preoperative and postoperative IOP was 15.75±2.37 and 14.8±2.64 mm Hg respectively at 1y follow-up (*P*=0.60) which was not statistically significant. The mean preoperative and postoperative specular count was 2882±149.5 cells/mm^2 and 2777.17±159.9 cells/mm^2 respectively at 1y follow-up. This decrease was statistically significant (*P*<0.001; paired *t*-test). The mean endothelial cell loss was 3.65%±1.92%.

Complications were classified as intraoperative, early postoperative (≤1mo) and late postoperative (>1mo; Table 2). In one case during manipulation, one haptic was deformed and broke. The defective IOL was immediately explanted and replaced with another IOL. There were no complications like iridodialysis, IOL drop or hyphaema.

In early postoperative period, transient anterior uveitis and transient IOP rise was seen in 5 and 4 eyes respectively. Early complications included sclerotomy leak which was seen in 1 eye for which the patient was reoperated and the scleral flap was sutured. There were no cases of corneal edema, hypotony, IOL decentration, IOL dislocation, vitreous hemorrhage, macular edema and endophthalmitis in early postoperative period.

Amongst the late complications, the most serious complication encountered was rhegmatogenous retinal detachment (RRD)

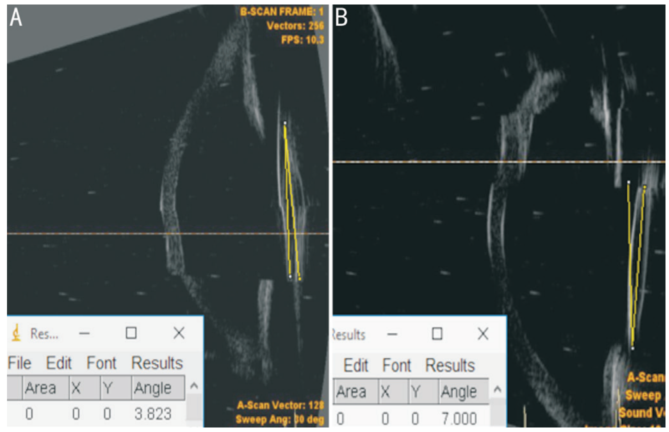

Figure 2 IOL tilt assessments using Imege J on UBM image A: IOL without significant tilt; B: IOL with significant tilt.

Table 2 Intraoperative and postoperative complications

Complications	No. of eyes
Intraoperative	
Haptic breakage	1
Early postoperative period (<1mo)	
Sclerotomy leak	1
Late postoperative period (>1mo)	
Rhegmatogenous retinal detachment	2
Subconjunctival haptic	3
Haptic extrusion	1

in 2 patients of Marfan's syndrome. Other late complications included subconjunctival haptic in 3 eyes and haptic extrusion in 1 eye. The patient with haptic extrusion was reoperated for haptic repositioning.

DISCUSSION

Management of large (>7 clock hours) lens subluxations in children continues to be a perplexing problem for pediatric ophthalmologists. Despite maximum conservative management, Romano *et al*[10] reported ametropic amblyopia in 50% children with ectopia lentis.

Wherever feasible, in-the-bag placement of IOL with the aid of mCTR remains most acceptable option. The cases where it is not feasible, lens extraction can be done with management of resultant aphakia. Over the years, there has been much discussion on the most acceptable management option for secondary IOL implantation in children that offers visual rehabilitation with minimal complications.

The flexible open loop ACIOLs are technically easier to implant but they are not free of complications[3-4]. Iris claw lenses avoid potential complications of ACIOLs and SFIOLs. However, they may be associated with spontaneous disenclavation, pigment dispersion, hyphaema and pupil ovalization[2,11]. SFIOLs is a time tested option for eyes with inadequate capsular support. Numerous modifications of this technique have been described. This method is surgically demanding and involves intra operative manipulation of vitreous base with potential risk for retinal detachment and suture related complications[5-6].

SSTIOLs popularized by Gabor and Pavlidis[12] have the advantage of avoiding complications of ACIOLs. Many studies have shown SSTIOLs to be a simple, safe and effective technique in adults but there is paucity of literature on use of this technique in children.

In our study, there was significant improvement in the mean BCVA, spherical equivalent and a significant reduction in mean astigmatism was seen with SSTIOL implantation which is comparable to similar studies[13-15]. In children with immature visual system, amblyopia is a common obstacle for early visual rehabilitation. In our study, 18 eyes were amblyopic. We chose foldable 3 piece IOL (Abbot AR40e IOL) for implantation in our study which allowed IOL implantation with a small incision. In our experience this IOL has sturdy haptics enabling easier manipulation. Smaller incision provided advantage of lesser astigmatism, globe stability and less frequent globe collapse.

In addition to visual rehabilitation, postoperative IOL stability is an important concern in management of large lens subluxations in children. IOL stability depends on positioning of scleral flaps exactly 180° apart, equidistant sclerotomies from the limbus and adequate tucking of haptics in scleral tunnels. The main stabilizing factor is the fibrosis taking place around the haptic tucked in scleral tunnels. Tsai and Tseng[16] demonstrated that IOL tilt >5° can cause significant oblique astigmatism which is difficult to correct with spectacles. In our study 5 eyes had IOL tilt >5°. However there was no statistically significant difference between eyes with and without significant tilt in terms of BCVA and postoperative astigmatism.

Eyes with pseudophacodonesis, due to oscillations in fluid in anterior and posterior segment, are prone to develop endothelial damage and macular edema. Theoretically SSTIOL decrease the risk of pseudophacodonesis as compared to SFIOLs since stability is provided by an intrascleral segment of haptic as opposed to point fixation in SFIOLs. In our study, none of the eyes had pseudophacodonesis on the final follow-up. There was significant reduction in endothelial cell count postoperatively with mean percentage cell loss of 3.65%±1.92%. The reason of endothelial cell loss in our study could be intraoperative manipulation in few cases. None of the eyes developed corneal decompensation or corneal edema postoperatively. Both findings correlated well with other studies on glued IOL implantation in children[7,17-18].

It is difficult to create scleral tunnel due to low scleral rigidity and lack of counterforce in pediatric eyes especially after thorough vitrectomy where globe hypotony makes haptic externalization and intrascleral haptic placement very challenging. In our opinion, patients with horizontal limbus-limbus diameter >12 mm are less suitable candidates for SSTIOL implantation since the length of exteriorized haptic is likely to be inadequate leading to complications like haptic extrusion.

The fundus examination is of utmost importance in cases of ectopia lentis as they are predisposed to retinal detachment. The incidence of retinal detatchment in eyes undergoing SFIOL implantation has been reported between 0-9.5% in literature[19]. In our study, 2 eyes developed RRD. On retrospective analysis, both patients were diagnosed cases of Marfan's syndrome. There were no cases of IOL dislocation, cystoid macular edema, pseudophacodonesis, IOL dislocation, vitreous hemorrhage, pigment dispersion and endophthalmitis in our study.

We conclude, SSTIOL implantation provides efficient visual rehabilitation in children provided there is stringent case selection. We recommend a thorough preoperative screening and caution in children having white-to-white distance >12 mm and presence of peripheral retinal degenerations as large subluxations in Marfan's patients are prone to retinal detachments. Long term studies with larger sample size are required to validate the efficacy and safety profile of this procedure in children.

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