

# Posterior sclera reinforcement and phakic intraocular lens implantation for highly myopic amblyopia in children: a 3-year follow-up

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## Abstract

**Purpose** To study the safety and efficacy of posterior scleral reinforcement (PSR) combined with phakic intraocular lens (PIOLs) implantation for highly myopic amblyopia in children.

**Methods** This study included eight highly myopic children (11 eyes) who failed in conventional therapy for amblyopia using various combination of spectacles, contact lenses, and intensive patching before enrollment into this study. They were treated sequentially with PSR and PIOL implantation, and were followed up for 3 years after surgery. Uncorrected visual acuity (UCVA) and best corrected visual acuity (BCVA) in LogMAR, spherical equivalent power (SE), and complications were evaluated.

**Results** Before surgery, the mean UCVA was  $1.59 \pm 0.33$ , BCVA,  $0.74 \pm 0.37$ , SE,  $-17.57 \pm 5.56$ D, the axial length (AL),  $30.09 \pm 2.18$  mm. After PSR, BCVA improved one line in three patients, the rest were unchanged, and AL was unchanged among all cases. Six eyes of three patients were implanted with an iris-claw PIOL and five eyes of five patients were implanted with a posterior PIOL. After completion of treatment, the mean UCVA was  $0.44 \pm 0.21$ , BCVA  $0.38 \pm 0.24$ , SE  $-0.54 \pm 0.74$  D, and AL  $30.35 \pm 2.29$  mm. No patient experienced complications.

**Conclusion** Combined PSR and PIOL implantation treatment for highly myopic amblyopia in children is safe and effective.

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## Introduction

Children with high myopia or severe anisometropia tend to develop amblyopia. Myopia is prone to progression, and its elongation of axial length (AL) may result into lesions in the fundus, eventually causing visual impairment. In children, high myopia or anisometropia is often difficult to correct because of noncompliance with spectacle or contact lens. Corneal refractive surgery is limited to patients with myopia of 10 D or less owing to the concern of ectasia secondary to a reduction in the residual stromal bed.<sup>1,2</sup> Reinforcement of the posterior sclera can control the progression of myopia. Phakic intraocular lens (PIOLs) implantation for children has been reported in the literature.<sup>3–7</sup> In the current study, posterior scleral reinforcement surgery (PSR) and PIOL implantation were performed in highly myopic amblyopic children. The safety and efficacy for 3 years of follow-up were analyzed.

## Materials and methods

This study enrolled highly myopic amblyopic children. All patients underwent conventional therapy for amblyopia using various combination of spectacles, contact lenses and intensive patching, and proved to be no improvement in their condition before enrollment into this study. Before PSR and PIOL implantation, the nature of both procedures and the expected results were explained to the parents and the children. Written informed consent was obtained from each patient.

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### Examinations

Patients were followed up at 1 day, 1 week, 1 month, 3 months, 6 months, and every 6 months after each of the intervention (ie, PSR, PIOL implantation, and patching therapy). Preoperative and postoperative examinations included manifest and cycloplegic refraction, uncorrected visual acuity (UCVA) and best corrected visual acuity (BCVA) in LogMAR, biomicroscopy, intraocular pressure, and dilated funduscopy. Eye position was measured by cover test. Postoperative stereopsis was measured by Randot Stereotest (Stereo Optical, Chicago, IL, USA) with refractive correction. Corneal curvature, anterior chamber depth and AL (IOLMaster, Zeiss, Jena, Germany), and corneal endothelium density (SP-8000, Konan, Nishinomiya, Japan) were also measured.

### Surgery procedure

Our surgical technique of PSR was published previously.<sup>8</sup> PSR was performed under general anesthesia. Human sclera was obtained from a local eye bank after the cornea had been removed for transplantation. The donors of the sclera all had negative serology for HIV and hepatitis B. A 210° peritomy of the conjunctiva was performed along the inferior-temporal axis of the limbus. A radial cut was made at each end of the peritomy to expose the inferior and external rectus muscles and traction sutures prepared for these muscles. With the assistance of the traction sutures and a muscle hook that lifted up the complete inferior oblique, the scleral flap that was to be used for reinforcement was sequentially passed underneath the inferior oblique, external rectus, and inferior rectus muscles. During this process, efforts were made to protect the orbital septum and vortex veins. One end of the reinforcing flap was fixed to the sclera 2 mm behind the insertion point of the inferior rectus muscle, and the other end was stretched around the posterior pole and fixed to the sclera 2 mm temporal to the insertion point of the superior oblique muscle by using 5-0 nylon sutures. The reinforcement flap was stretched into a U-shape to surround the posterior pole. Before the end of procedure, the flap was checked to assure that it was correctly positioned and oriented. Finally, the conjunctival incision was closed using 8-0 absorbable sutures. Postoperatively, dexamethasone (0.1%) and antibiotic eye drops were recommended for use 4 times daily for 3 weeks.

After PSR, if the follow-up results revealed that manifest refraction, BCVA, and AL were stable, the PIOL would be implanted. Our surgical technique of PIOL implantation was published previously.<sup>9</sup> An iris-fixated PIOL (Artisan, Ophtec, Groningen, The Netherlands) was implanted in

six eyes, and a posterior chamber PIOL (Visian ICL, STAAR Surgical, Nidau, Switzerland) was implanted in five eyes. One week after PIOL implantation, patients began patching therapy for 4 h per day, and continued for 3 months.

### Results

Eight highly myopic pediatric patients (11 eyes) were recruited at the Eye Hospital of Wenzhou Medical University from February 2007 to July 2009. The patient demographics are as described in Table 1. Among them, four were female (seven eyes) and four were male (four eyes). The mean age was  $13.25 \pm 3.69$  years (range: 9–17 years). The preoperative spherical equivalent power ranged from  $-11.5$  D to  $-26.5$  D. Three patients had bilateral high myopia and amblyopia, while 5 had severe anisometropia.

PSR and PIOL implantations were uneventful in all patients. The mean follow-up time was 38.25 months, and no postoperative complications occurred during whole follow-up period. Postoperative outcomes are presented in Tables 1–3. The mean spherical equivalent power improved from  $-17.57 \pm 5.56$  D preoperatively to  $-0.54 \pm 0.74$  D postoperatively ( $t = -10.33$ ,  $P < 0.01$ ). BCVA improved from  $0.74 \pm 0.37$  preoperatively to  $0.38 \pm 0.24$  postoperatively ( $t = 5.16$ ,  $P < 0.01$ ). The mean postoperative UCVA was  $0.44 \pm 0.21$ . The preoperative and postoperative AL were  $30.09 \pm 2.18$  and  $30.35 \pm 2.29$  mm, respectively ( $t = -3.19$ ,  $P = 0.01$ ).

All patients were orthophoria before and after the combined treatment. Patients with unilateral high myopia (patients 1, 2, 3, 4, and 8) did not undergo stereopsis test after surgery. Patients 3, 4, and 8 gained one line of BCVA after intensive patching.

### Discussion

After PSR, BCVA improved one line in three patients, the rest were unchanged, and AL was unchanged among all cases. The AL after PSR remained clinically stable during the 3 years of follow-up. In contrast, the AL increased significantly in eyes that did not receive PSR. High myopia occurs in children during a period of growth and development, and axial elongation occurs frequently, probably resulting to a series of fundus lesions such as choroidal atrophy, macular hemorrhage, choroidal neovascularization, and retinal holes. These lesions may ultimately lead to a serious decline in visual acuity. Many researches<sup>8,10,11</sup> indicate that reinforcement of the posterior sclera can allow the allogeneic scleral material place around the macular area to adhere to the host sclera, and promote the entry of new vessels, thicken the new sclera, and mechanical reinforcement of the wall of

**Table 1** Outcomes of posterior sclera reinforcement in eight children with high myopia

Patient no.	Sex	Age (years)	Eye	Operated	Preoperation			Postoperation				Follow-up (months)
					SE (D)	BCVA	AL (mm)	SE (D)	BCVA	Line change in BCVA	AL (mm)	
1	M	10	OD	Y	-11.5	0.82	27.52	-11.5	0.7	1	27.51	3
			OS	N	-2	0	23.62	-2	0		23.63	
2	M	8	OD	Y	-12	0.15	27.91	-12	0.15	0	27.91	3
			OS	N	-2.25	0	24.4	-2.25	0		24.4	
3	F	17	OD	Y	-13	0.82	26.99	-13	0.82	0	27.00	3
			OS	N	0	0	22.36	0	0		22.36	
4	M	15	OD	Y	-13.25	0.82	29.05	-13.25	0.82	0	29.05	6
			OS	N	-3.25	0	25.09	-3.25	0		25.09	
5	F	16	OD	Y	-17	0.52	32.41	-17	0.52	0	32.42	3
			OS	Y	-17.5	0.40	32.46	-17.5	0.40	0	32.46	
6	F	9	OD	Y	-26.25	1.30	31.38	-26.25	1.30	1	31.38	3
			OS	Y	-26.5	1.00	30.87	-26.5	1.00	1	30.88	
7	F	17	OD	Y	-23.75	0.80	33.1	-23.75	0.80	0	33.12	4
			OS	Y	-17.75	0.30	30.9	-17.75	0.30	0	30.88	
8	M	14	OD	N	-1.75	0	23.93	-1.75	0		23.93	3
			OS	Y	-14.75	1.30	28.42	-14.75	1.00	1	28.41	

Abbreviations: AL, axis length; BCVA, best corrected visual acuity in LogMAR; SE, spherical equivalent power.

**Table 2** Outcomes of PIOL implantation in eight children with high myopia

Patient no.	Eye	Preoperation							Postoperation					Follow-up (months)	
		SE (D)	UCVA	BCVA	ACD (mm)	AL (mm)	CED	PIOL	SE (D)	UCVA	BCVA	Line change in BCVA	AL (mm)		CED
1	OD	-11.5	1.3	0.7	3.2	27.51	3205	ICL-15.5	0	0.52	0.52	2	27.47	3121	46
	OS	-2	0.7	0		23.63			-6.75	1.30	0		26.53		
2	OD	-12	1.5	0.15	3.02	27.91	2923	ICL-17	-0.75	0.22	0.10	1	28.56	2860	42
	OS	-2.25	0.52	0		24.4			-6.75	1.00	0		26.49		
3	OD	-13	1.3	0.82	2.87	27.00	3076	ICL-19	0.5	0.30	0.22	5	26.92	2993	42
	OS	0	0	0		22.36			-1.25	0.30	0		22.93		
4	OD	-13.25	1.5	0.82	3.06	29.05	3158	ICL-19	-1.5	0.40	0.30	4	29.56	3058	39
	OS	-3.25	0.7	0		25.09			-6.25	1.00	0		26.49		
5	OD	-17	1.3	0.52	2.94	32.42	3401	Artisan-17	-0.5	0.22	0.15	3	32.77	2988	39
	OS	-17.5	1.3	0.40	2.96	32.46	3400	Artisan-17	-1	0.30	0.22	2	32.88	2933	
6	OD	-26.25	2	1.30	2.93	31.38	3058	Artisan-23.5	-0.5	0.70	0.70	3	31.48	2678	39
	OS	-26.5	2	1.00	2.97	30.88	2906	Artisan-23.5	0	0.70	0.70	2	30.91	2896	
7	OD	-23.75	2	0.80	3.20	33.12	3003	Artisan-23	-1.75	0.80	0.70	1	33.46	2604	31
	OS	-17.75	2	0.30	3.3	30.88	2801	Artisan-18.5	-1	0.22	0.10	2	31.46	2755	
8	OD	-1.75	0.7	0		23.93			-2.25	0.30	0		24.08	39	
	OS	-14.75	1.3	1.00	2.94	28.41	3169	ICL-20	0.5	0.52	0.52	3	28.38		3108

Abbreviations: ACD, anterior chamber depth; AL, axis length; BCVA, best corrected visual acuity in LogMAR; CED, corneal endothelium density (cells/mm<sup>2</sup>); PIOL, phakic intraocular lens; SE, spherical equivalent power; UCVA, uncorrected visual acuity in LogMAR.

eyeball. These changes can alleviate the pressure that extends back into the eye and maintain a stable refractive statue. At the same time, the biological effect of stimulating local allogeneic tissue leads to the dilation of the retinal vasculature and increased blood flow. The complications of PSR, particularly including optic nerve damage, muscle injury, retinal hemorrhage or ischemia, vortex vein damage, and globe distortion, has been reported in the literature. In the current study, PSR was

performed under microscope, all patients had regular postoperative follow-up, and no complication occurred during the whole follow-up period.

Although PIOL implantation for myopia correction in adults proved to be safe and effective,<sup>1,9,12</sup> performing surgery in pediatric patients may be somewhat controversial. People are concerned that PIOL implantation in children may cause complications such as acute or chronic inflammation, glaucoma, cataract, or a

**Table 3** Functional results after combined therapy in eight children with high myopia during a 3-year follow-up

Patient no.	Eye	Preoperation		Postoperation						
		Orthophoria	Stereopsis	Orthophoria	Stereopsis	BCVA 1 week	BCVA 3 months	BCVA 1 year	BCVA 2 years	BCVA 3 years
1	OD	Y	N	Y	N	0.52	0.52	0.52	0.52	0.52
	OS									
2	OD	Y	N	Y	N	0.1	0.1	0.1	0.1	0.10
	OS									
3	OD	Y	N	Y	N	0.52	0.4	0.22	0.22	0.22
	OS									
4	OD	Y	N	Y	N	0.52	0.4	0.3	0.3	0.30
	OS									
5	OD	Y	—	Y	—	0.22	0.22	0.22	0.15	0.15
	OS					0.22	0.22	0.22	0.22	0.22
6	OD	Y	—	Y	—	0.7	0.7	0.7	0.7	0.70
	OS					0.7	0.7	0.7	0.7	0.70
7	OD	Y	—	Y	—	0.7	0.7	0.7	0.7	0.70
	OS					0.1	0.1	0.1	0.1	0.10
8	OD									
	OS	Y	N	Y	N	0.7	0.52	0.52	0.52	0.52

Abbreviation: BCVA, best corrected visual acuity in LogMAR.

sustained loss of corneal endothelial cells. Patients were encouraged to maintain intensive patching therapy before they were enrolled into this study. However, visual acuity was not improved, and they were having difficulty in maintaining a normal daily life and learning due to poor vision during patching therapy. So PIOL implantation was considered as an alternative correction for high myopia in these children after fully communicating with patients' family members to ensure their understanding of the treatment. In this study, patients were followed up for 3 years after PIOL implantation, and no glaucoma, cataract, chronic inflammation, or other complications occurred. The rate of endothelial cell loss ranged from 1 to 13%. Our results are similar to previous studies<sup>13</sup> that revealed implantation with an iris-claw or posterior chamber intraocular PIOL in highly myopic children significantly improved visual acuity. For safety reasons, doctors must carefully weigh the risks and benefits of PIOL implantation in children, and patients must be followed up regularly for long periods of time.

After combined PSR and PIOL implantation, the spherical equivalent power and visual acuity improved significantly and remained stable for 3-year follow-up. The stable refractive status may be because of the enhanced mechanical resistance to axial growth after PSR. Visual acuity improvement after treatment is mainly due to the improvement of retinal image quality as a result of PIOL implantation. In addition, for highly anisometropic children, the refractive errors of the weak eye can be corrected after unilateral surgery. As visual stimulation improves, the pronounced inhibition can be

significantly reduced. In this way, visual acuity can be significantly improved in these anisometropic cases. After intensive patching, BCVA improved one line in three patients. All patients expressed satisfaction with the results of their treatment. However, patients had no stereopsis after surgery even though they were orthophoria and the visual acuity was improved.

In conclusion, combined PSR and PIOL implantation treatment for highly myopic amblyopia in children is safe and effective. It is a good alternative to treat highly myopic amblyopia in children who have failed in conventional therapy (ie, spectacle and/or contact lens, and intensive patching).

### Summary

#### What was known before

- Children with high myopia or severe anisometropia tend to develop amblyopia.
- Myopia tends to progress in children.
- Conventional therapy is performed using various combination of spectacles, contact lenses, and intensive patching.

#### What this study adds

- Children with severe anisometropic myopia or high ametropia can be treated by PIOL implantation if the conventional therapy (ie, spectacle and/or contact lens) proved to be unsuccessful.
- For extremely high myopia children, PSR can control progression of myopia.
- The combined PSR and PIOL therapy is a good alternative for the patients mentioned above.

### Conflict of interest

The authors declare no conflict of interest.

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