Original Article

A clinical trial on phakic intraocular lens for the treatment of refractive amblyopia in children and adolescents

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Purpose: To analyze the demographics and clinical outcomes of posterior chamber phakic intraocular (IOL) implantation for refractive amblyopia in children and adolescents. **Methods:** A prospective interventional study was performed on children and adolescents with amblyopia at a tertiary eye care center from January 2021 to August 2022. Twenty-three eyes of 21 anisomyopic and isomyopic amblyopia patients operated for posterior chamber phakic IOL (Eyecryl phakic IOL) as a treatment for amblyopia were included in the study. Patient demographics, pre- and postoperative visual acuity, cycloplegic refraction, anterior and posterior segment examination, intraocular pressure, pachymetry, contrast sensitivity, endothelial count, and patient satisfaction scores were evaluated. Patients were followed up at day 1, 6 weeks, 3 months, and 1 year after surgery, and visual outcomes and complications were documented. **Results:** The mean age of patients was 14.16 ± 3.49 years (range: 10–19 years). The mean intraocular lens power was − 12.20 diopter spherical (DS) in 23 eyes and − 2.25 diopter cylindrical (DC) in four patients. The mean unaided distant visual acuity (UDVA) and best-corrected visual acuity (BCVA) were 1.39 ± 0.25 and 0.40 ± 0.21 preoperatively on the log of minimum angle of resolution (logMAR) chart. Postoperatively, the visual acuity improved by 2.6 lines in 3 months period and maintained till 1 year. Postsurgery, contrast sensitivity in the amblyopic eyes significantly improved, and the average endothelial loss recorded was 5.78% at 1 year, which was statistically insignificant. Patient satisfaction score was statistically significant, with 4.736/5 recorded on the Likert scale. **Conclusion:** Posterior chamber phakic IOL is a safe, effective, and alternative method for treating amblyopia patients who are noncompliant with glasses, contact lenses, and keratorefractive procedures.

Access this article online

Website: www.ijo.in

DOI: 10.4103/IJO.IJO_2567_22

Quick Response Code:

Key words: Amblyopia, anisometropia, anisomyopic, isomyopic, phakic IOL

Amblyopia is a neurodevelopmental ocular disease manifested as monocular and binocular impairments, including vision reduction, contrast sensitivity, or even loss of stereoscopic vision.[1] Amblyopia is classified as refractive, strabismus, and visual deprivation subtypes. The reported prevalence of amblyopia globally is 1%–5%. Further, there are three types of refractive amblyopia – isometropia, anisometropic, and meridional. The most common type of amblyopia is anisometropic, followed by strabismus and mixed strabismus and anisometropic types. Refractive correction with spectacles and contact lenses and occlusion therapy are the traditional treatments for refractive amblyopia. However, these modes of treatment are associated with poorer compliance as children find it difficult to wear glasses and contact lenses because of foreign body sensations and chances of corneal infections.[2] Also, there are many psychosocial issues faced by children, like bullying and harassment associated with glass use, especially if these are thicker and associated with higher refractive errors. Therefore, there is a strong need for alternative treatment strategies to manage pediatric and adolescent patients with high myopic amblyopia. Photorefractive keratectomy (PRK), laser keratomileusis (LASIK), and laser-assisted subepithelial keratectomy (LASEK) have emerged as alternate corneal refractive surgery techniques that are effective as well as safe in children and young adults who are not compliant with the

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Received: 04-Oct-2022 Revision: 10-Dec-2022
Accepted: 14-Dec-2022 Published: 03-Mar-2023

Cite this article as: Morya AK, Kaur K, Gurnani B, Janti SS, Shrivastava AK, Tejaswini A, *et al*. A clinical trial on phakic intraocular lens for the treatment of refractive amblyopia in children and adolescents. Indian J Ophthalmol 2023;71:804-9.

conventional approaches.[3-8] For pediatric and young adults with refractive amblyopia who cannot undergo refractive laser surgery techniques, phakic intraocular lens (IOL) implantation is an effective surgical correction technique in managing amblyopia.[9-13] Althomali[12] reported toric phakic IOL implantation in six eyes of six amblyopic patients aged 5–15 years and proved that it is a viable therapeutic modality for treating children with anisometropic amblyopia. Zhang *et al*. observed no complications with posterior chamber implantable Collamer lens in adults with high myopia with anisometropic amblyopia. They also observed improved visual acuity, contrast sensitivity, and binocular vision.[14] However, there is limited literature on phakic IOL implantation in pediatric and adolescent patients in the Indian scenario. Keeping this in mind, through this study, we aimed to analyze the effectiveness and safety of posterior chamber phakic IOL (Eyecryl) implantation for the treatment of pediatric and adolescent Indian patients with unilateral and bilateral refractive amblyopia secondary to high myopia.

Methods

This was a prospective study performed on 23 eyes of 21 patients with refractive amblyopia due to myopia or myopic astigmatism from January 2021 to August 2022 at a tertiary care center. The study was conducted in accordance with the Declaration of Helsinki after obtaining approval from the Institutional Ethics Committee. Written informed consent was obtained from all the patients or parents/guardians in the case of minors. It is the first such registered clinical trial regarding phakic IOL as a treatment modality in amblyopes in India. The Clinical Trial Registry of India number is CTRI/2021/01/030394. The inclusion criteria were as follows: patients aged 10–19 years; corrected distance visual acuity (CDVA) recorded on the log of minimum angle of resolution (logMAR) chart in the amblyopic eye <0.2; patients having poor compliance with glasses or contact lenses, and occlusion therapy; anterior chamber depth of >2.8 mm; endothelial density more than 2700 cells/mm^2; and amblyopia due to myopia or myopic astigmatism. The exclusion criteria were patients with hypermetropic amblyopia, strabismic amblyopia, or with any history of glaucoma, active inflammation, cataract, previous intraocular surgery, or any other ocular disease.

A complete preoperative detailed ophthalmic evaluation was performed on all the patients. The detailed evaluation included noting the demographics, unaided distant visual acuity (UDVA), and best-corrected visual acuity (BCVA) by Early Treatment of Diabetic Retinopathy Study (ETDRS) chart, cycloplegic refraction, slit-lamp anterior and posterior segment examination, Hirschberg corneal reflex for ocular alignment, cover, uncover, and alternate cover test, applanation tonometry for measuring intraocular pressure (IOP), contrast sensitivity, corneal topography, pachymetry, and specular microscopy. Optical coherence tomography (OCT) was performed in selected patients as and when indicated. All patients were given a trial of patching for a minimum of 6 months before embarking onto the surgery. All patients underwent Phakic IOL implantation. The IOL size for implantation was measured with the help of calipers as horizontal white-to-white (WTW) distance with an addition of 1.5 mm to that value. In patients requiring cylindrical correction, the axis was marked under a slit lamp in a sitting position preoperatively.

Phakic IOL and surgical procedure

The same surgeon (AKM) operated on all cases under topical anesthesia with proparacaine 0.5% or under general anesthesia. Also, 1% cyclopentolate and 2.5% phenylephrine eye drops were applied to achieve pharmacological dilatation 60 min before surgery. A 2.8-mm temporal clear corneal incision was placed, and viscoelastic material was injected into the anterior chamber. Two side ports were fashioned, each being two clock hours away from the main incision, with a 15° blade for positioning the IOL. Eyecryl phakic IOL was injected through the main incision behind the iris, and all four haptics were positioned in the sulcus. After positioning the IOL with a Sinskey's hook, intracameral 1% pilocarpine was instilled for constricting the pupil. Then, the viscoelastic material was aspirated and the anterior chamber was washed thoroughly and formed with a basal salt solution. Topical 0.5% moxifloxacin and 0.1% dexamethasone, and carboxymethylcellulose 0.5% were prescribed four times per day for 6 weeks in tapering doses in the postoperative period. On follow-up, UDVA and BCVA, anterior segment and posterior segment details, IOP, endothelial cell count (ECD), pachymetry, and contrast sensitivity were recorded on day 1, 6 weeks, 3 months, and 1 year. Postoperatively, occlusion therapy was prescribed for the dominant eye for 3 months. The duration of occlusion therapy per day was based on the guidelines laid by the pediatric eye disease investigator group [Figs. 1 and 2]. We also assessed the patient satisfaction score using the Likert scale scoring at 12 weeks follow-up visit.

Statistical analysis

Data were entered into an Excel sheet and transferred to Statistical Package for the Social Sciences (SPSS) version 21 for analysis. Mean and standard deviation (SD) were calculated for all the parametric data. Paired *t*-test was used for before and after mean difference calculation, and the Kruskal–Wallis test was used for skewed visual acuity data. The patient satisfaction score was assessed using the Likert scale.

Results

Demographics – age and visual acuity

Twenty-three eyes of 21 patients were included in the study. The mean age (SD) of the patients was 14.16 (±3.49) years (range: 10–19 years). The mean preoperative logMAR UDVA and CDVA were 1.39 ± 0.25 (range: −1.10 to 1.80) and 0.40 ± 0.21 (range:

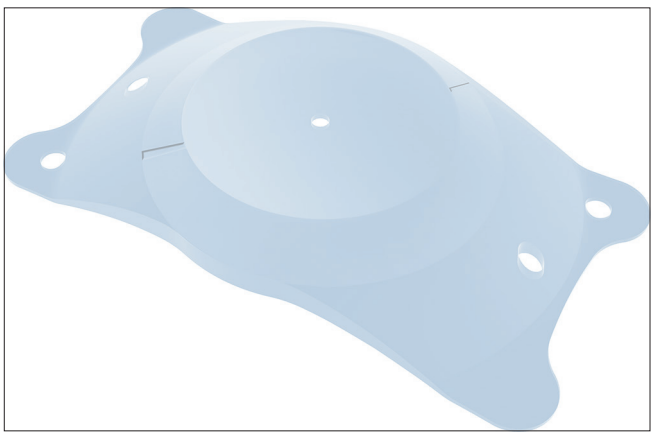

Figure 1: Eyecryl phakic toric IOL. IOL = intraocular lens

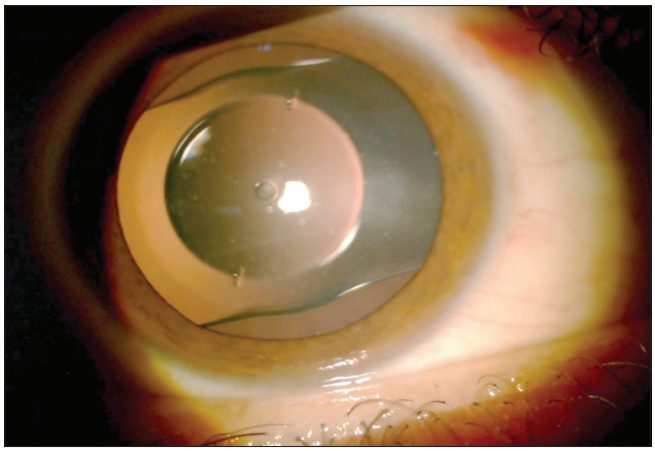

Figure 2: Postoperative image of the eye with phakic Eyecryl phakic toric IOL. IOL = intraocular lens

−0.20 to 0.80), respectively. All patients completed were followed up on day 1, 6 weeks, 3 months, and 1 year after surgery [Tables 1–3]. The mean postoperative logMAR UDVA of the amblyopic eye at 1 day, 6 weeks, 3 months, and 1 year was 0.27 ± 0.18, 0.21 ± 0.19,0.16 ± 0.18, and 0.17 ± 0.16, respectively. Similarly, the mean postoperative logMAR CDVA of the amblyopic eye at 1 day, 6 weeks, 3 months, and 1 year was 0.20 ± 0.11, 0.13 ± 0.12, 0.11 ± 0.13, and 0.11 ± 0.12, respectively. None of the patients lost any lines of visual acuity after surgery.

Contrast sensitivity

Preoperatively recorded contrast sensitivity was 1.0750 ± 0.2118, and it improved to 1.6500 ± 0.21669 at 3 months postoperatively and was the same up to 1 year. Contrast sensitivity significantly increased in the postoperative period and was significant. The average gain in the postoperative contrast sensitivity was 0.59 (SD: ±0.196), compared to pre-op contrast sensitivity with a *P* value of <0.001 [Table 4].

Intraocular pressure

The IOP for the amblyopic eye changed from 15.2 ± 2.52 mmHg preoperatively to 17.29 ± 5.0 mmHg at 3 months and 15.29 ± 0.34 at 1 year postsurgery, and the difference was not statistically significant as recorded till a year [Table 5].

Endothelial cell count

The mean ECD was 3131.33 ± 181.01 (range: 2832–3431) cells/mm^2 preoperatively and 2981 ± 171.62 (range: 2745–3265) cells/mm^2 at the last follow-up time postoperatively, without any significant endothelial cell loss. The mean difference between pre-op endothelial cell density and post-op endothelial cell density was149.70 (SD: ±35.033). The average endothelial cell loss was 5.78% at 1 year [Table 6].

Patient satisfaction score

The patient satisfaction score was assessed by the Likert scale (range: 0–5). Seventeen patients gave a score of 5, and six patients gave a score of 4. The mean patient satisfaction score was 4.736 ± 0.36 (range: 1–5) [Table 7].

IOL power

All patients underwent sulcus implantation of IOL with a mean phakic IOL power of –12.20 D spherical, with four patients having an added toricity of − 2.25 D cylindrical [Table 8].

Table 1: Age distribution of the study participants (*n*=23)

Age (years)	Frequency	Percentage
10	3	13.04
11	4	17.39
12	3	13.04
13	1	4.34
14	4	17.39
15	2	8.69
17	6	26.08
Total	23	100
Mean+SD	14.16±3.49	

SD=standard deviation

Table 2: Sex distribution of the study participants (*n*=23)

Sex	Frequency	Percentage
Male	12	52.17
Female	11	47.83
Total	23	100

Table 3a: Mean and standard deviation of preoperative vision uncorrected to the third visit after operation

Parameter	Mean	Standard deviation
Preoperative UDVA	1.39	0.25
Postoperative day 1 UDVA	0.27	0.18
Postoperative 1-week UDVA	0.21	0.19
Postoperative 3-month UDVA	0.16	0.18
Postoperative 1-year UDVA	0.17	0.16
Preoperative BCVA	0.40	0.21
Postoperative day 1 BCVA	0.20	0.11
Postoperative 1-week BCVA	0.13	0.12
Postoperative 3-month BCVA	0.11	0.13
Postoperative 1-year BCVA	0.11	0.12

BCVA=best-corrected visual acuity, UDVA=unaided distant visual acuity

Complications

Only two eyes had raised IOP at 1 day and 6 weeks. The IOP was 38 and 40 mmHg postoperatively, and these were successfully treated by short-term antiglaucoma medications in the form of topical timolol– brimonidine eye drops two times. Topical steroid were discontinued, and no other intraoperative or postoperative complications were noted. No general anesthesia complications were observed. No other complications like cataract, retinal detachment, IOL dislocation, pupillary block glaucoma, and pigmentary deposits were observed in a long follow-up period of 1 year. Not a single eye underwent phakic IOL explantation.

Discussion

Contact lenses and glasses are conventional methods of treatment of amblyopia, but the patients are not compliant with the above methods. Laser refractive methods such as LASIK or PRK have been the preferred alternative methods as they improve refractive amblyopia permanently. Complications

Table 3b: Uncorrected vision change from preoperative to third visit after operation

Patient visit	Mean difference	Standard deviation	Standard error mean	95% Confidence interval of the difference		*P*
				Lower	Upper	
Preoperative vision	1.11667	0.24613	-	-		-
Postoperative vision uncorrected Day 1	-	-	0.05024	1.01274	1.22060	0.0
Postoperative vision uncorrected first visit	0.05619	0.08990	0.01800	0.01900	0.09957	0.005
Postoperative vision uncorrected second visit	0.05417	0.08330	0.01700	0.01899	0.08934	0.004
Postoperative vision uncorrected third visit	0.05399	0.08110	0.01600	0.01869	0.08754	0.003

Table 3c: Postoperative average gain of visual acuity

Postoperative day	Uncorrected visual acuity gain	Best-corrected visual acuity gain
Day 1	11.3	1.3
First visit	11.7	2.6
Second visit	12.1	2.6
Third visit	12.1	2.6

Table 4: Comparison of contrast sensitivity between preoperative and postoperative periods

Patient visit	Contrast sensitivity mean	Mean difference with pre-op	*P*
Pre-op	1.07	-	-
Post-op first day	1.26	0.19	0.01
Post-op first visit	1.65	0.58	0.01
Post-op second visit	1.66	0.59	0.01
Post-op third visit	1.66	0.59	0.01

Table 5: Comparison of IOP between preoperative and postoperative periods

Patient visit	IOP mean	Mean difference with pre-op	*P*
Pre-op	15.25		-
Post-op first day	16.41	1.16	0.99
Post-op first visit	16.83	1.58	0.01
Post-op second visit	17.29	2.04	0.18
Post-op third visit	15.29	0.34	0.11

IOP=intraocular lens

Table 6: Preoperative and postoperative endothelial cell count

Patient visit	Mean	*n*	Standard deviation	Standard error mean
Preoperative endothelial cell count	3131.33	23	181.099	36.967
Postoperative endothelial cell count at 1 year	2981.63	23	171.627	35.033

such as corneal haze in PRK[7,8] and flap-related complications in LASIK were reported along with keratectasia and corneal thinning.[6] So, posterior chamber phakic IOL is the preferred procedure of treatment for refractive amblyopia[6,14,15] because of its advantages such as better contrast sensitivity, less high-order aberration,[16,17] and no flap-related complications as reported in LASIK and no incidence of corneal ectasia and thinning. Anterior chamber phakic IOL and posterior phakic IOL were approved by the US Food and Drug Administration to treat refractive amblyopia in adults.[9] Only a few case reports are available regarding the use of phakic IOL in treating amblyopia in children and young adults in the research literature.[10]

Lesueur and Arne[9] reported five eyes of four children in the age group of 3–16 years who underwent phakic IOL for anisometropic amblyopia. No complications were noted within the 11.80-month follow-up period, and visual acuity improved by three or more Snellen's lines. BenEzra *et al*.[11] conducted a study on three female patients (aged 9–18 years) with anisometropic amblyopia. The results showed that BCVA improved in all patients and stereopsis improved in two patients at 9 months of follow-up. Temporary pigmentary dispersion was reported in one case. Althomali[12] reported on six children with anisometropic amblyopia who underwent toric phakic IOL, and three lines of visual acuity improvement was noted in six eyes. All phakic IOLs were well centered at 24 months follow-up.

The disadvantages of corneal haze and flap-related complications in corneal refractive procedures have led to a search for a newer treatment modality for refractive amblyopia in children and young adults.

In our study, 23 anisomyopic and isomyopic amblyopic eyes were operated on with phakic posterior chamber IOL (PCIOL) implantation to correct refractive amblyopia in children and young adults. Postoperative contrast sensitivity improved significantly compared to the preoperative period at 1 year of follow-up. The visual acuity continued to improve considerably from 1 day to 3 months after phakic PCIOL implantation and maintained till 1 year without anyone losing one line of the logMAR chart, which was consistent with the study result of Lesueur and Arne,[9] wherein the preoperative spherical equivalent of − 12.8 D showed a postoperative gain of three or more Snellen's lines. The study by BenEzra *et al*.,[11] where anisometropic amblyopia and myopia of − 6 to − 16 D were operated, showed significant improvement in visual acuity and binocular function in the 9 months follow-up period. A study by Alio *et al*.,[20] with a follow-up period of 5 years, showed improvement in visual acuity of one logMAR line and no complications. Contrast sensitivities of amblyopic eyes in the low and mild

Table 7: Patient satisfaction rate (*n*=23)

Patient satisfaction score	Percentage (%)
1	0
2	0
3	0
4	26
5	74

Table 8: Descriptive statistics of IOL (*n*=23)

Variable	Mean	SD	Toricity (*n*=4)
IOL	−12.20 DS	1.531	−2.25 DC

DC=diopter cylindrical, DS=diopter spherical, IOP=intraocular lens, SD=standard deviation

spatial frequencies (0.5, one, two cycles per degree) were better postoperatively than the preoperative values and significantly increased with follow-up time postoperatively. However, there was no improvement in stereopsis at 1 year follow-up in our study.

Assil *et al*.[19] reported an endothelial loss of 6.5%–15.2% over 3 years of follow-up in patients who underwent iris-fixated phakic IOL for anisometropic amblyopia.[18] Alio *et al*., in their retrospective study of 10 children who underwent Phakic intraocular lens (PIOL) implantation (nine eyes with iris-fixated phakic IOL and one eye with aphakic PCIOL), showed that BCVA improved in all children.[19] Five years after surgery, the ECD was >2000 cells/mm^2 in eight (80%) patients. There was no significant endothelial cell loss in our study at 12 months after surgery (5.78%). However, regular long-term follow-ups will elucidate more intricate results.

In earlier studies, postoperative complications such as cataract, dislocation of phakic IOL, pupillary block glaucoma, and retinal detachment have been described.[20] FDA approved studies on Implantable Collamer Lens have stated that cataract was a significant complication with an incidence of 2.1% within 1 year and 2.7% within 3 years of postoperative follow-up.[21]

Only two cases of raised IOP were reported, and the IOP dropped generally after treatment with antiglaucoma medication and discontinuing steroid eye drops as raised IOP may be attributed to the use of steroids postoperatively. No other complications such as cataract, retinal detachment, IOL dislocation, pupillary block glaucoma, and pigmentary deposits were reported in our study. Not a single case of pupillary block glaucoma may be attributed to the unique design of this phakic IOL with three holes – one in the center and two in the peripheral haptics – for an uninterrupted passage of aqueous.

Translational Relevance: This study will pave way for a new and acceptable method for managing anisomyopic and isomyopic amblyopia in young and adolescent patients. This is the first such registered clinical trial from India reporting the application of phakic IOL as an alternative and effective treatment in amblyopia associated with anisomyopic and isomyopic patients.

Conclusion

Our study results revealed that phakic PCIOL is the preferred method of correction of refractive amblyopia in children and young adolescents who are intolerable to contact lenses and unsuitable or unwilling to go for LASIK-like procedures. The phakic IOLs provide advantages such as reversibility and ability to exchange IOL, predictability, high visual quality, preservation of accommodation, lack of regression, and retinal magnification in myopic eyes. However, complications such as endothelial cell loss, dislocation, pigment dispersion, and shallow anterior chamber can be encountered. More follow-ups are needed to assess the complication and safety in the long-term period.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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