

Bilateral implantation of multifocal versus monofocal intraocular lens in children above 5 years of age

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Abstract

Purpose To evaluate visual results and complications after bilateral implantation of multifocal versus monofocal intraocular lens (IOL) in children above five years of age.

Methods In this prospective non-randomized controlled trial, children with bilateral developmental cataract above five years of age were divided into two groups – Group A implanted with multifocal IOL (both refractive and diffractive) and Group B implanted with monofocal IOL in both eyes. Outcome measures of best corrected visual acuity (BCVA) for distance, distance-corrected near visual acuity (DCNVA), mean refractive spherical equivalent (MRSE), contrast sensitivity, stereopsis and complications such as posterior capsular opacification (PCO) and glare were analyzed using the Mann–Whitney U and the Wilcoxon Signed Rank tests.

Results Forty-two eyes of 21 children (mean age: 7.19 years, range: 5–12 years) were included in the study. Group A included 14 eyes (seven children) Group B included 28 eyes (14 children). Both groups showed significant improvement in BCVA at one year follow-up, but no significant difference was found on comparing contrast sensitivity. Stereopsis was slightly better in Group A (125.71 arc-sec) as compared to Group B (140 arc-sec) ($p=0.280$). Most patients in Group A were spectacle-independent for near (71.4 %) versus Group B. MRSE at one year was 0.21 in Group A and 0.5 in Group B. Incidence of PCO was similar in either groups (35.7 %). No intraoperative complication was noted in any child.

Conclusion Multifocal IOL implantation is a viable option in children above five years of age with bilateral cataract.

Keywords Pediatric cataract surgery · Multifocal intraocular lens · Phacoemulsification · Childhood cataract · Contrast sensitivity · Stereopsis

Introduction

Intraocular lens implantation (IOL) is an optimal method of visual rehabilitation in children with cataracts [1–4]. Visual rehabilitation in younger children poses a challenge due to the difficulty in evaluating visual acuity, binocularity and the problem of amblyopia associated with pediatric cataract [5].

Presently, the focus of pediatric cataract surgery is the choice of IOL to be implanted after removal of cataractous lens to aid in achieving the highest grade of binocular single vision. Pediatric ophthalmologists prefer to implant monofocal IOL in children as it can provide excellent distance vision correction [1–4]. Presently, the concept of bag-in-the-lens intraocular lens to prevent development of posterior capsular opacification is gaining popularity [6, 7].

With the removal of the crystalline lens, accommodative properties of the eye are lost and, thus, the near vision is affected. This problem was dealt with the introduction of multifocal IOL for the correction of presbyopia in adults [8–11]. However, some problems of contrast sensitivity, halos and glare exist in these patients postoperatively [10–14].

Evaluation of performance of multifocal IOLs in the pediatric age group has shown favorable outcomes making multifocal lenses a viable alternative to monofocal lenses [15]. Another study evaluated the results of multifocal IOLs in unilateral cataract in children in the age group of four to six years where apodized multifocal IOL has been shown to be a satisfactory alternative to monofocal Pseudophakia [16].

More experience is required to clarify the role of this IOL in children, especially in cases with bilateral cataracts and comparing its performance to monofocal IOLs. A head-to-head

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comparison may possibly help pediatric ophthalmologists to assess outcomes in terms of stereopsis and binocularity. It would also enable evaluation of undesirable side-effects like including glare, haloes and decreased contrast sensitivity.

In this study, we evaluated the visual performance including visual acuity, stereopsis, contrast sensitivity and complications after selecting children with bilateral developmental cataracts non-randomly based on the choice exercised by parents/guardians largely determined by affordability.

Materials and methods

Prospective enrollment was done for children with bilateral cataracts attending the pediatric lens clinic at our tertiary eye care centre from April 2010 to October 2011. Institutional Ethics Committee clearance (NK/G/767 dated April 16, 2010) was obtained and the study adhered to the tenets of declaration of Helsinki. Clinical trial registration was done at Clinical Trial Registry – India, <http://ctri.nic.in> (Identifier – CTRI/2012/05/002642, available publicly).

Children with bilateral visually significant developmental cataract planned for surgery in both eyes above five years of age were enrolled (visual acuity of 20/50 or worse). The key exclusion criteria were recurrent chronic uveitis leading to complicated cataracts, trauma, preoperative nystagmus, corneal pathologies impeding anterior chamber visualization, corneal astigmatism ≥ 1.5 D, retinal disorders and children with global developmental delay responsible for poor preoperative assessment. Children uncooperative for slit-lamp examination or for reading visual acuity charts for distance and near, microphthalmos or gross genetic defects were excluded.

Before surgery, a complete ophthalmological and systemic examination was performed which included Snellen's visual acuity assessment for distance and near vision, intraocular pressure (IOP) measurement by Goldmann Applanation Tonometry (GAT), assessment for ocular deviations, slit-lamp biomicroscopy and fundus evaluation under dilation with binocular indirect ophthalmoscopy. Manifest and cycloplegic refraction assessment were performed preoperatively. Recording of visual acuity was performed using Snellen's charts conforming to guidelines of British Standards Institution at 20 ft with uniform illumination more than 120 cd/m². The results analyzed using LogMAR units. Measurement of axial length using ultrasound technique (OcuScan A-scan, Alcon, Fort Worth, TX, USA) and keratometry by manual technique (Reichert B & L type, Depew, NY, USA) was performed. In uncooperative children, examination under anesthesia was performed preoperatively.

Preoperative counseling of the parents/guardians was done for the type of IOL to be implanted in all cases. Detailed information regarding the surgical technique, types of IOLs available, available knowledge of visual performance of

multifocal and monofocal IOLs was conveyed. IOL implantation was non-randomised and decided on the basis of choice exercised by the parents or guardians largely determined by their affordability. Written informed consent was obtained from all patients and the children were divided into two groups – Group A included children planned for bilateral multifocal IOL implantation and Group B included those planned for monofocal IOLs. IOL power calculation was performed using SRK II formula [17].

All the surgeries were performed under general anesthesia by a single surgeon (J.R). Cataract surgery was performed using the Alcon Infiniti System (Alcon Labs Inc. Fort Worth, TX, USA). Preoperative pupillary dilation was achieved with cyclopentolate 1 %, phenylephrine 5 % and tropicamide 0.8 %. Limbal or a clear corneal valvular incision was followed by continuous curvilinear capsulorhexis (CCC). Primary posterior capsulotomy measuring approximately 4 mm was created and anterior vitrectomy was performed in children less than eight years of age. The IOL was implanted in the capsular bag. A sub-conjunctival injection of gentamicin 20 mg and dexamethasone 4 mg was given at the end of surgery. Postoperatively, all the patients received topical betamethasone (0.1 %) instilled eight times a day; moxifloxacin 0.5 % four times and homatropine 1 % twice daily and titrated further according to the level of ocular inflammation over a period of six weeks. Both the eyes of these children were operated within a period of ten days. Occlusion therapy was started in the postoperative period depending on the presence or absence of amblyopia.

We used two types of multifocal IOLs, i.e., AcrySof[®] IQ ReSTOR[®] SN6AD1 IOL (Alcon Labs Inc. Fort Worth, TX, USA) with +3 D add for near and Preziol with +4 D add (Care group, Baroda, India) in patients of Group A. Both these IOLs have an optic size of 6 mm and overall diameter of 12.5 mm. AcrySof IQ ReSTOR has a central 3.6 mm of apodized diffractive optics with nine concentric rings of gradually decreasing step heights. Preziol is an aspheric refractive IOL, which has three optical zones with the central zone for distance vision and diameter of 1.5 mm, a second zone for near vision with a diameter of 2.5 mm and a peripheral zone for intermediate vision and added 1 D over the central zone. Patients of Group B were implanted monofocal hydrophobic acrylic IOL, i.e., Sensar OptiEdge (AMO, Abbott labs, Illinois, USA) and Alcon MA60AC or SA60AT IOLs. The same type of IOL was implanted in both eyes of a patient to enable comparison of binocular parameters.

Postoperatively, the children were assessed for their best corrected distance visual acuity (BCVA), distance-corrected near visual acuity (DCNVA), IOP, fusional status and detailed slit lamp examination was performed as a routine. Testing for refraction was performed by a single experienced pediatric optometrist. Contrast sensitivity was measured with the help of the Pelli-Robson chart (Haag-Streit UK, Essex, UK) at 1 m

distance with luminance of white areas of 90 cd/min in logarithmic units. Stereopsis was tested by use of the Stereo Butterfly chart SO-005 (Stereo Optical Co., Inc., IL, USA) with polarized glasses measured in seconds of an arc. Mean spherical equivalent (MRSE) was obtained by retinoscopy which was performed at each postoperative visit. Complications including posterior capsular opacification, posterior synechiae, IOL decentration, inflammatory reaction, glaucoma were looked for. Children were interrogated for the presence of visual symptoms including glare or haloes and spectacle dependency. For the purpose of the study, data obtained at a one year postoperative visit was used in the analysis.

Statistical analysis was performed using IBM SPSS software version 20.0. The data was tested for normality by the Kolmogorov Smirnov test and the value of significance was set at 5 %. When parametric analysis was possible, Students *t* test was used to analyze the data. The *t*-test for unpaired data was used for comparison between the groups. Data not normally distributed was analyzed using the Mann–Whitney *U* test to compare the two groups and analysis comparing preoperative and postoperative values within a group was performed using the Wilcoxon Signed Rank test. Improvement in BCVA, DCNVA, MRSE, Pelli-Robson contrast sensitivity values and stereopsis measured by the Stereo butterfly card test in both groups were compared. All tests were performed using 2-tailed analysis.

Results

Forty-two eyes of 21 children with bilateral developmental cataract were included in our study. Group A included 14 eyes of seven children (four males) and Group B included 28 eyes of 14 children (11 males).

Mean age of children in Group A was 7.43 years (5–10 years). Mean preoperative distance visual acuity was 1.57 and axial length was 22.67 mm. Mean age of children in Group B was 7.07 years (5–12 years). Mean axial length was 21.99 mm and preoperative distance visual acuity was 1.40. Both the groups did not statistically differ from each other in terms of age, visual acuity and other preoperative parameters at baseline ($p>0.131$) (Table 1).

All children in either group underwent successful cataract surgery and in-the-bag implantation of IOL. No major intraoperative difficulties were encountered in any patient. Primary posterior capsulotomy combined with anterior vitrectomy was performed in six eyes (42.85 %) in Group A and 14 eyes (50 %) in Group B. No intraoperative complications occurred in either group.

In Group A, apodized diffractive IOL (AcrySof IQ ReSTOR) was implanted in six eyes of three patients (42.85 %), while the refractive IOL (Preziol) was placed in the remaining eight eyes of four patients (57.14 %). In Group

Table 1 Comparison of preoperative and demographic data of the two groups

Parameter (Mean ± SD)	Group A Multifocal IOL	Group B Monofocal IOL	<i>P</i> value
Age (years)	7.43±1.71	7.07±2.93	0.770
Axial length (mm)	22.67±1.21	21.99±1.42	0.131
BCVA (LogMAR)	1.57±0.79	1.40±0.62	0.352*
Mean Keratometry (D)	43.29±1.04	43.70±0.69	0.154
Mean IOP (mm Hg)	13.29±1.43	13.70±1.98	0.514
IOL power (D)	23.21±3.21	23.64±2.57	0.642

BCVA best corrected visual acuity for distance; IOP intraocular pressure; IOL intraocular lens

*Mann–Whitney *U* test for non-parametric data

B, Sensor OptiEdge was implanted in eight eyes of four patients (28.57 %), Alcon SA60AT in 16 eyes of eight patients (60.71 %) and Alcon MA60AC in four eyes of two patients (10.71 %).

BCVA at one year postoperative follow up visit in Group A was 0.40±0.25 LogMAR units. Nine eyes (64.28 %) achieved BCVA of 20/40 or better and the remaining five eyes (35.71 %) had BCVA in the range of 20/50–20/200. This improvement was significantly better compared to the preoperative BCVA ($p=0.005$, Wilcoxon Signed Rank test). MRSE was 0.27±0.81 and 0.21±0.85 at six months and one year postoperative visits respectively. The DCNVA at one year for patients of Group A was 0.2±0.13 LogMAR units (20/32 in terms of Snellen's Equivalent). The measured DCNVA was N6 in seven eyes, N12 in four eyes and N8 in three eyes in terms of Roman test types. BCVA of children in Group B was 0.43±0.2. Fourteen eyes (50 %) achieved a BCVA of 20/40 or better and 11 eyes (39.2 %) had a BCVA ranging from 20/50–20/80. Postoperative improvement in visual acuity for distance was significantly better compared to the preoperative BCVA ($p<0.0001$, Wilcoxon Signed Rank test). The BCVA was not significantly different between the two groups one year postoperatively ($p=0.528$, Mann–Whitney *U* test). At the one year postoperative visit, the DCVNA for patients belonging to Group B was 0.58±0.15 LogMAR units (approximately 20/80 in terms of Snellen's Equivalent). The DCNVA was significantly superior in patients belonging to Group A as compared to Group B ($p<0.002$, Mann–Whitney *U* test) with 33 eyes in Group B (78.57 %) having DCNVA worse than 20/50 Snellen's equivalent. MRSE values for Group B were 0.73±1.6 and 0.5±1.62 at six months and one year postoperative visits, respectively. At the end of one year, the mean MRSE values were lower in Group A versus Group B but not statistically significant ($p=0.528$). Five eyes of Group A and eight eyes of Group B received occlusion therapy for postoperative amblyopia. Details of the visual performance in the two groups are summarized in Table 2.

Table 2 Comparison of postoperative performance in the two groups at one year follow-up visit

Parameter (Mean ± SD)	Group A Multifocal IOL	Group B Monofocal IOL	P value
BCVA (LogMAR)	0.40±0.25	0.43±0.29	0.528*
DCNVA (LogMAR)	0.2±0.13	0.58±0.15	<0.002*
MRSE (D)	0.21±0.85	0.5±1.62	0.528*
Contrast Sensitivity (Pelli-Robson)	1.57±0.16	1.60±0.21	0.794
Stereopsis (arc-sec)	125.71±37.80	140±30.38	0.280
PCO (% of patients)	35.7 %	35.7 %	–

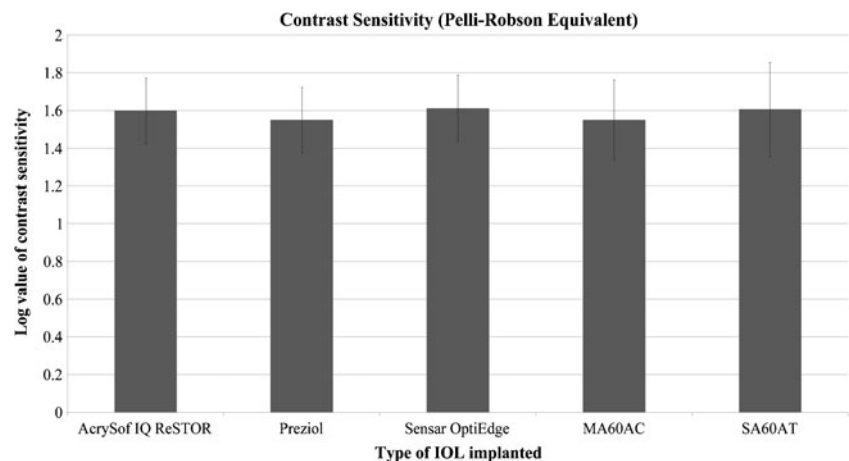
BCVA best corrected visual acuity for distance; DCNVA distance corrected near visual acuity; MRSE mean refractive spherical equivalent; PCO posterior capsular opacification

*Mann–Whitney *U* test for non-parametric data

Contrast sensitivity as measured by Pelli-Robson's equivalent was 1.57 ± 0.16 in Group A and 1.60 ± 0.21 in Group B at one year follow-up visit. There was no statistical difference between the two groups for the measured contrast sensitivity ($p=0.794$). Mean value of stereopsis as measured by the Stereo Butterfly Card test was 125.71 ± 37.80 s of arc in Group A and 140 ± 30.38 s of arc in Group B. There was no statistical difference in the stereopsis values between the two groups ($p=0.28$). Analysis of contrast sensitivity and stereopsis values based on the type of multifocal or monofocal IOLs used in the study are depicted in Figs. 1 and 2.

At the one year follow up visit, five patients (71.4 %) in Group A were spectacle independent for near. Appropriate near correction was prescribed for all children in Group B. On interrogation, three children of Group A noticed mild glare/halos; two of these children belonged to the refractive IOL (Preziol) group. Postoperatively, fusion was maintained in all eyes of Group A and two eyes of Group B had manifest esodeviation.

Fig. 1 Graph showing logarithmic values of contrast sensitivity obtained in all the patients tested by the Pelli-Robson chart. Although the limited number of patients did not allow statistical analysis, patients with apodized diffractive multifocal intraocular lens (AcrySof® IQ ReSTOR®) performed at par with aspheric hydrophobic acrylic monofocal lenses as compared to the refractive multifocal intraocular lens, Preziol



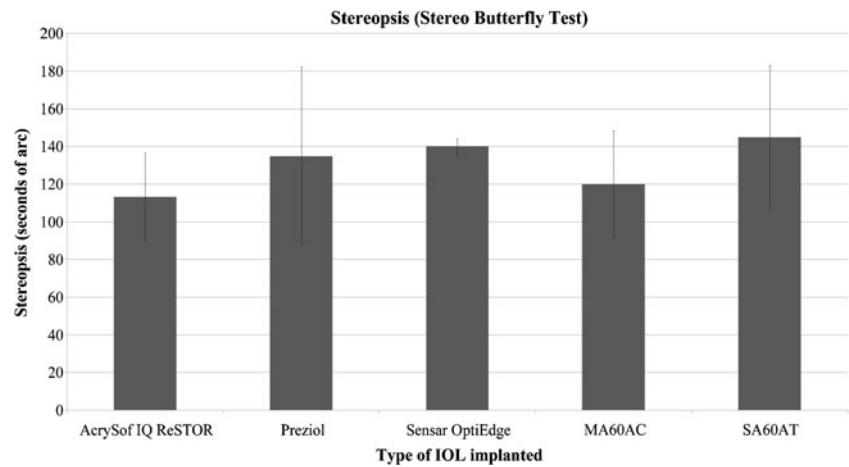
Visually significant posterior capsular opacification (PCO) developed in five eyes (35.7 %) in Group A and ten eyes (35.7 %) in Group B. Nd: YAG capsulotomy/surgical capsulotomy was performed in two eyes of Group A and four eyes of Group B, which developed visually significant PCO. No other serious complication in the form of glaucoma, endophthalmitis or retinal detachment was noted in any child of either group at the end of one year.

Discussion

With advanced techniques and improved surgical instruments, implantation of monofocal IOLs has become the most common mode of visual rehabilitation after pediatric cataract surgery [1–4]. This study was undertaken to compare visual performance of monofocal versus multifocal IOLs, which are not used as often due to various concerns raised by pediatric cataract surgeons [15, 16, 18]. Although many controversies surround the use of multifocal IOLs, there is a paucity in the literature clarifying their role and visual performance in children with cataract.

Performance of multifocal IOLs has been tested in assorted cohorts of children with both, unilateral and bilateral cataracts due to various etiologies [15, 16, 18]. Cristobal et al. [16] have shown satisfactory results using multifocal IOLs in children with unilateral cataract. Jacobi et al. [15] evaluated the performance of multifocal IOLs in children with both unilateral and bilateral cataract without comparing them with monofocal IOLs. Multifocal IOLs were shown to result in acceptable outcomes in their study. Another recent study by Abouzeid et al. [18] has evaluated outcome of multifocal IOL implantation in both unilateral and bilateral pediatric cataracts and obtained encouraging results. However, children with bilateral cataracts are a unique subset of patients who may not have normal youthful accommodative ability unlike those with unilateral cataract. This subgroup of patients needs to be

Fig. 2 Graph showing results obtained on testing stereopsis using the Stereo Butterfly Card test in all the patients included in the study. Amongst the various types of intraocular lenses used in the study, apodized diffractive multifocal lens (AcrySof® IQ ReSTOR®) subgroup appeared to perform better than the refractive multifocal or aspheric hydrophobic acrylic monofocal lenses



carefully analyzed separately and the results must be compared to those obtained by implanting monofocal IOLs in pediatric population.

In the present study, children above five years of age were selected so that the growth of the eye has been largely completed [3, 4, 19]. In our study, children planned for bilateral multifocal IOL implantation belonged to Group A and those for monofocal IOLs belonged to group B. The dioptric power selection of multifocal IOLs in children is a challenge as one should not aim for emmetropia to take care of the myopic shift [15, 16, 18]. In our patients, the SRK II formula was used based on a study by Wilson et al. [17] comparing the results obtained using theoretical and regression formulae. IOL power was under corrected by 10 % depending on the age of the child. Mean age of children belonging to the multifocal group was 7.43 years and their mean MRSE value was 0.21 diopters at the end of one year. On the other hand, children in the multifocal group were 7.07 years old and had a mean MRSE of 0.5 diopters at one year follow-up. These values indicate slight hypermetropia. However, it is possible that minor myopic shift with further growth of the eye [20], though not regarded as important, may correct this error. The other advantage of including ‘older’ children in the study is to obtain more reliable results with subjective testing like contrast sensitivity and stereopsis [15].

The results of our study indicate that children who underwent multifocal IOL implantation performed well for near vision. In patients with monofocal IOLs, prescription for near vision of approximately +3 D add was provided. Unlike the study by Jacobi et al. [15], since the majority of baseline characters in our study including cause and duration of cataract, laterality, age of the patient and postoperative amblyopia therapy were similar in the two groups, meaningful comparison of the final visual result between the two groups was possible. BCVA was not statistically different between the two groups for distance acuity ($p=0.718$).

There was no statistical difference in the contrast sensitivity between the two groups. According to the published literature,

multifocal IOLs allow multiple focal points for the incident beam, possibly degrading the image quality [12, 21]. However, newer IOL designs such as apodized diffractive IOLs may not be associated with a drop in contrast sensitivity to the extent as the older designs (Fig. 1) [9, 10, 16, 22, 23]. This may be the reason for better results in our patients receiving multifocal IOLs compared to the study by Jacobi et al. [15] in which a significant drop in contrast was noted after implantation of refractive multifocal IOLs. Our results compare well with those obtained by Cristobal et al. [16].

Recent reports suggest that implantation of multifocal IOLs bilaterally may benefit binocularity with an improvement in stereo-acuity [15, 16, 18]. Stereopsis being the highest form of binocularity, a gain in stereo-acuity may be considered as one of the most desirable goals of pediatric cataract surgery. Stereo-acuity measurements were performed only postoperatively. Three patients in Group A (42.85 %) achieved stereo-acuity value of 100 s of arc compared to five patients in Group B (35.71 %). All the three patients in Group A were implanted with apodized diffractive IOL (Fig. 2). In our study, though the results of stereo-acuity analysis revealed better outcomes for patients with multifocal IOLs, this did not reach significant levels on comparison with monofocal IOLs. In addition to the type of IOL implanted, various factors may have unpredictable net effect on stereo-acuity such as age and amblyopia [24].

Results of subjective questioning for visual symptoms including glare and haloes must be interpreted carefully in children [15]. On enquiry, three children of the multifocal group complained of mild glare most of which (two patients) belonged to the refractive IOL group. The newer design of apodized diffractive optics multifocal IOLs like AcrySof IQ ReSTOR may be responsible for fewer subjective complaints. Detailed statistical analysis comparing the various types of multifocal IOLs within Group A was not possible in our study due to a smaller sample size. Most patients with multifocal IOLs were spectacle independent (71.4 %). This may be an advantage because faulty spectacle design and cost of

spectacles especially in developing countries may lead to poor compliance as noted by various studies done in different populations [25–27]. These factors may seriously hinder the visual rehabilitation of children with monofocal IOLs possibly rendering them amblyopic.

Surgical factors and postoperative complications most closely associated with poor performance of multifocal IOLs include IOL tilt, decentration and PCO [15, 28–30]. The incidence of IOL tilt and decentration is directly related to the intraoperative factors such as poor capsulorhexis design [15, 16]. In a previously published study [15], nearly one-fifth of the patients (17 %) developed tilt which was attributed mainly to preoperative history of trauma and postoperative inflammation. In the absence of these factors in our study, none of the patients experienced deterioration of vision due to tilt or decentration. Securing the haptics of the multifocal IOL well within the capsular bag is the sine qua non of achieving adequate IOL centration. The concept of bag-in-the-lens implantation also avoids this major complication of PCO without the need for anterior vitrectomy. Long term follow-up of these patients is available and the technique has been used in pediatric eyes with success [6, 7]. The rate of development of PCO was nearly 35 % in either group in our study. These were eyes of children more than eight years of age who were not subjected to primary posterior capsulotomy with anterior vitrectomy. Development of PCO may seriously hinder optical performance of any IOL type [28, 29, 31, 32]. Nd: YAG capsulotomy was required in two eyes in the multifocal group and three eyes of the monofocal group. One eye of a patient with monofocal IOL required surgical capsulotomy. Laser and surgical capsulotomies were uneventful and no major post-procedure complications were noted in either group.

Moderate postoperative inflammation was noted in nearly one-third eyes in either group during the first week after surgery. This was managed by intensive topical therapy including topical betamethasone (0.1 %) or prednisolone (0.1 %) frequently. There were no cases with endophthalmitis or any patient requiring surgical procedures like pupiloplasty or iridectomy till the one year follow-up visit.

Obtaining satisfactory long-term optimal visual results is the most challenging task for a pediatric cataract surgeon. Limitations of our study underline this fact and point towards the need for more research in this direction. Our study included a smaller number of patients with follow-up analysis up to one year. Comparison of monofocal and multifocal IOLs revealed a high rate of satisfaction amongst the multifocal group, however, affordability remains one of the major concerns in a developing country. Non-randomization of study subjects into two groups was a limitation in our study. The current trend is the use of formulae like SRK/T and Hoffer Q for IOL calculation rather than SRK II, which has been used in this study. Various brands of monofocal IOL used in the study may have a bearing on some of the measured parameters.

Binocularity was not measured preoperatively in our patients. Probably the postoperative manifest esodeviation in two eyes of Group B may reflect a problem of preoperative binocularity. In the future, we may expect better results with multifocal IOLs in pediatric cataract surgery with introduction of newer designs like apodized diffractive IOLs. More studies discussing the outcomes in terms of contrast, near vision, depth of focus and binocularity with superior stereopsis will enable pediatric cataract surgeons to incorporate multifocal IOLs in their armamentarium. We can conclude by stating that multifocal IOLs are a viable option in children above five years of age provided the decision to implant is backed by thorough preoperative counseling, appropriate case-selection and postoperative amblyopia therapy.

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Conflict of interest No conflict of interests exists for any author

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