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CLINICAL STUDY

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### Abstract

Purpose Although pediatric cataract surgery has become standardized and safe, further surgical interventions are not uncommon. The purpose of this study was to analyze the incidence of complications in children who required an intraocular intervention. Methods A retrospective review of medical records of children (<7 years) with cataract who underwent cataract surgery with or without primary posterior chamber intraocular lens (IOL) placement between January 2006 and December 2014 was carried out. Data were collected regarding visual axis opacification (VAO), glaucoma, IOL decentration, intraocular infections, and other indications that required a second intraocular surgery. Results Out of 814 (570 pseudophakic and 244 aphakic) eyes of 620 operated children, 45 eyes of 40 children (5.5%, 45/814) needed a second surgery. The most common indication being VAO (2.9%, 24/814), followed by glaucoma (0.73%, 6/814). Incidence of complications was higher in children <1 year (VAO 6.1%, 19/308 and glaucoma 6%, 6/308). Among all children, repeat interventions and VAO were slightly less frequent in pseudophakics (4.91%, 28/570) vs aphakics (6.91%, 17/244) (P = 0.31). As VAO was more common in pseudophakic eyes in infants, glaucoma was equally common in both groups. Best-corrected visual acuity improved from 1.6 + 0.56 LogMAR preoperatively to  $0.80 \pm 0.50$  LogMAR postoperatively. Conclusions Our study suggests that overall incidence of second intraocular surgery is low after primary pediatric cataract surgery. VAO remains the most common indication

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followed by secondary glaucoma. Incidence of complications is higher in children <1 year of age at initial surgery. *Eye* (2016) **30**, 1260–1265; doi:10.1038/eye.2016.170; published online 29 July 2016

### Introduction

Developments of new microsurgical techniques and amblyopia management have improved the safety and effectiveness of pediatric cataract treatment.<sup>1,2</sup> However, owing to the inherent nature of growing eyes, marked inflammatory responses in pediatric eyes and inherent risks involved in surgery, management of congenital cataract remains a challenge in terms of preventing and managing complications.<sup>3,4</sup> The most commonly reported complications after pediatric cataract surgery with or without an intraocular lens (IOL) implantation are visual axis opacification (VAO), <sup>5,6</sup> heightened inflammatory response,7 secondary membranes,<sup>7</sup> IOL precipitates,<sup>8</sup> pupillary capture,<sup>8</sup> posterior synechiae,<sup>8</sup> uveitis,<sup>9</sup> iris prolapse, corectopia,<sup>10,11</sup> endothelial cell loss,<sup>12</sup> pupillary block and aphakic/ pseudophakic glaucoma,<sup>6,13,14</sup> retinal detachment,<sup>15</sup> and endophthalmitis.<sup>10,16</sup> Although some retrospective studies have reported prevalence of postoperative complications after pediatric cataract surgery, only a few studies have focused on complications that require intervention/ reoperation.<sup>9–11</sup> Wilson et al<sup>17</sup> reported a 22% reoperation rate over a 3-year follow-up most commonly for pupillary membranes. Lambert et al<sup>18</sup> reported a 72% reoperation rate

for glaucoma, pupillary membranes, VAO, and corectopia. These studies however had a very small sample size with a short follow-up. In addition, most of these studies reported VAO and secondary glaucoma as the most common complications requiring intervention after pediatric cataract surgery.<sup>5,8</sup> There are only a few reports suggesting other complications needing surgical intervention,<sup>9,10</sup> and only a few studies that reported complications both in aphakia and pseudophakia.

The current study reports the incidence of all the complications following lens aspiration with and without IOL implantation in children <7 years that necessitated a second intraocular surgery over a 5-year follow-up.

# Materials and methods

We conducted a retrospective chart review at our institute, after receiving institutional review board approval. A search of the pediatric cataract database and medical records of patients who underwent lens aspiration with/without primary IOL placement between January 2006 and December 2014 was performed. We reviewed records of all children aged <7 years who underwent lens aspiration with or without primary posterior capsulotomy, anterior vitrectomy, and primary posterior chamber IOL (LA  $\pm$  PPC  $\pm$  AV  $\pm$  PCIOL) implantation for congenital and developmental cataracts. We selected records of consecutive patients who underwent second intraocular procedure for complications (except secondary IOL implantation and strabismus surgery). Children with traumatic cataracts, complicated cataracts secondary to retinoblastoma, uveitis, and those who underwent extraocular surgery were excluded. All the selected patients underwent surgery using the standard surgical technique and postoperative medications were prescribed according to the regimen as described in the previous reports.<sup>19</sup> Preoperatively, biometry was performed either by partial coherence interferometry (IOL master, Carl Zeiss Meditec, Dublin, CA, USA) or applanation technique under general anesthesia depending on the age and cooperation of the child. Intraocular pressure (IOP) was measured with a Perkins MK2 handheld applanation tonometer (Belrose Refracting Equipment Co. Inc., Skokie, IL, USA). Keratometry was performed using a Nidek KM 500 handheld autokeratometer (Nidek Inc., Fremont, CA, USA) and axial length was measured with contact A-scan with OcuScan RxP (Alcon Laboratories, Inc., Fort Worth, TX, USA) in cataract mode. Sanders-Retzlaff-Kraff II formula was used to calculate the IOL power. IOL power was chosen according to Enyedi's rule of seven. The sutures were removed 4 weeks postoperatively. Retinoscopy readings after suture removal were taken into consideration for the purpose of analysis. A trained

optometrist who was unaware of the amount of under correction performed the retinoscopy. Postoperative evaluation was carried out at intervals during examination under anesthesia or outpatient visits, depending on the age of the patient. The interval between surgeries in bilateral cases ranged from 1 to 4 weeks.

# Data collection and analysis

Case records were analyzed and data were collected regarding the age at surgery, gender, cataract morphology, etiology, technique of biometry, and surgical technique. Postoperative data were used to look for the incidence of complications like corneal edema, increased postoperative inflammation, glaucoma, retinal detachment, secondary membrane formation, wound leak, strabismus, IOL decentration, and endophthalmitis, which if found, were duly noted.

VAO was defined as lens material regrowth extending across the pupil believed to be interfering with vision.

Glaucoma was defined as increase in the IOP (<22 mm Hg), with the presence of increased optic nerve cupping and/or myopic refractive shift.

IOL was recorded as decentered if the edge of the optic was seen in the pupillary area in undilated or dilated state.

Visual outcome was assessed by changes in bestcorrected visual acuity (BCVA), which was measured with appropriate optical correction during each postoperative follow-up visit.

## Outcome measures

- (1) Prevalence of all the complications that needed resurgery in eyes with or without IOLs.
- (2) Visual outcomes in the children with various indications for second surgery.

# Statistical analysis

Statistical analysis was performed using the R-software 3.1.2 (R-foundation for statistical computing, Vienna, Austria). Shapiro–Wilk test was used to assess the normal distribution of the data.

Descriptive analysis was performed. In addition, univariate and multivariate analysis were carried out to study the effect of various factors such as age, type of IOL, and surgical technique (aphakia *vs* pseudophakia) on the incidence of the complications.

# Results

During the period from 1 January 2006 to 31 December 2014, a total of 814 (570 pseudophakic with an IOL

implantation and 244 aphakic) eyes of 620 children <7 years underwent cataract surgery.

Of these, 45 eyes of 40 patients (5 bilateral) needed a second surgical intervention over a mean follow-up of 4.8 years (median 3 years: IQR 2–5.5 years). Of all the 40 patients, 39 patients had >1-year follow-up and 1 patient with only a 6-month follow-up.

Table 1 summarizes the clinical features of children who needed a second intraoperative surgical intervention. Out of 45 (5.53%) eyes, 28 were pseudophakic and 17 were aphakic. Out of 40 children, 22 were boys and 18 were girls. Out of 45 eyes, 3 had preexisting posterior lenticonus and 5 had microcornea (2 along with persistent fetal vasculature (PFV) and 1 had only PFV).

Table 2 shows the distribution of the second surgery for all children. Overall incidence of the second intraocular surgery was 5.53% (45/814 eyes: 95% CI: 3.96-7.1%). Most common indications were VAO (2.9%, 24/814), followed by glaucoma (0.73%, 6/814). The incidence of repeat surgery was slightly less in pseudophakics (4.91%, 28/570) vs aphakics (6.91%, 17/244), though not statistically significant (P = 0.31). The incidence of VAO was significantly less in pseudophakics (2.1%, 12/570)vs aphakics (4.9%, 12/244) (P=0.05). However, if we excluded eyes with microcornea and PHPV cases, incidence of repeat surgery and VAO in aphakic group lowers from 4.5% (12/244) to 2.86% (7/244), respectively. The overall prevalence of glaucoma was 3.4% (28 eyes of 24 patients). Most children were managed medically. The incidence of glaucoma necessitating surgery in pseudophakia was 0.35% (2/570) vs 1.6% (4/244) in aphakia (P = 0.12, 1.2% (3/244) if microcornea and PFV are excluded).

Heightened postoperative acute inflammation was seen in 24 eyes (2.9%; 24/814: 2 aphakic, 22 pseudophakic), however, only 7 eyes had sequelae of inflammation (IOL deposits and posterior synechiae) and only 1 eye underwent IOL exchange.

Out of 24 eyes with VAO, 18 eyes (75%) had their first surgery when they were <1 year old. The incidence of VAO was significantly higher in children <1 year of age. Out of 308 eyes operated at age <1 year, 19 had VAO

(6.1%) *vs* 5/506 eyes (1%) in children operated at age >1 year (P = 0.001). In addition, postoperative glaucoma developed exclusively in eyes operated at age <1 year, and of these, four eyes (66.6%) were operated at age <6 months (e-Supplementary Table 1). The incidence of postoperative uveitis was higher in pseudophakic infants 9.6% (10/104) *vs* 0.4% (1/204) aphakia, P = 0.0001, however, only one eye needed repeat intervention. Data of individual complications were summarized in e-Supplementary Table 2 and the distribution of various surgeries at each follow-up year is summarized in e-Supplementary Table 3.

Table 3 shows that mean BCVA improved postoperatively at last follow-up in children who underwent a second surgical procedure from  $1.16 \pm 0.56$ LogMAR preoperatively to  $0.80 \pm 0.50$  LogMAR. BCVA data were available for patients before and after the surgery. A total of 17 patients had vision <20/200 at last follow-up, even after appropriate intervention. Poor compliance to spectacles and patching in cases with dense amblyopia accounted for poor vision in majority of these cases. One child had poor vision following the intervention for endophthalmitis, 4 due to coexisting glaucoma, 10 due to coexisting amblyopia and poor compliance to glasses and patching, and 2 patients were lost to follow-up after 1 year.

### Discussion

In today's world, although pediatric cataract surgery has become standardized and simplified with the advent of fine microsurgical techniques and instrumentation, incidence of postoperative complications still remain of concern to all pediatric ophthalmologists especially in the infants. The infant aphakia treatment study (IATS) showed that at 4.5-year follow-up, infants who underwent primary IOL implantation or were aphakic and treated with contact lenses (CL) had similar visual outcomes, whereas children who were pseudophakic had a greater incidence of complications and second interventions than CL group (CL, 56%; IOL, 81%; P = 0.02).<sup>10</sup> Wilson *et al*<sup>17</sup> (22%) and Lambert *et al*<sup>18</sup> (72%)

Table 1 Clinical characteristics of patients in our study

Characteristic	Median (interquartile range)
1. Age at first surgery	0.5 years (IQR: 0.17–3 years)
2. Duration between first and second surgery	0.4 years (0.21–0.85 years)
3. Follow-up duration	Mean: $4.8 \pm 2.3$ years
1	Median: 3 years (IQR: 2–5.5 years)
4. Ratio Boys:girls	22:18
5. Distribution of the special cataract morphology (type: number of eyes)	Posterior lenticonus (3)
	Microcornea (5) PHPV (3)

also reported a significantly high number of reoperations in infants.

As the mean age of the children in the current study was more than in IATS and other studies, it might not be directly possible to compare the results with the older studies. However, as this is the largest study that reports the incidence of various complications in children who underwent primary surgery at <7 years of age, we attempt to compare outcomes in infants and older children with reported literature. As reported in previous studies, majority of the complications occurred in the age group <1 year. However, as compared with the previous studies, the overall incidence of second surgical interventions was relatively low (only 5.5%). The overall incidence in children <1 year was 5.5% (28/308 eyes), which was, still less when compared with the IATS (72%) and other studies. This may be attributable to age difference, genetic differences, surgical technique, difference in the selection of cases at the time of surgery, more intensive postoperative regimes, and the effect of surgery being performed at a single center by a single experienced surgeon.

In addition, unlike previous studies, incidence of complications was not higher in children who had an IOL implantation as against children who were left aphakic. This may be attributable to more intensive postoperative medication regimes followed at our center that lowers the incidence of severe inflammatory response.

As reported in previous studies,<sup>5,8,10,11,15,16</sup> VAO requiring surgical intervention is the most frequent complication in our study as well (Table 3). Membranectomy constituted 53.3% (24/45) of all the secondary interventions. Five cases with IOL in our series also required Nd: YAG capsulotomy. However, the overall incidence was low as compared with the previous studies; even in infants alone, the incidence of VAO needing a second surgery was 6.1% (19/308). The incidence was 7.7% (8/104 eyes) in pseudophakic and 5.4% (11/204 eyes) in aphakic infants. In a study by Lambert *et al*<sup>6</sup> in 2004, none of the 11 aphakic eyes required intervention for VAO and 70% (7/10) eyes with PCIOL required intervention for VAO. However, as compared with the previous reports, in our series, VAO was seen equally in both pseudophakic and aphakic eyes. This might be attributable to coexisting pathology in eyes left aphakic, such as microcornea and PHPV. If we excluded eyes with microcornea and PHPV cases, incidence of repeat surgery and VAO in aphakic group lowers to 4.5%.

As previously reported, relative risk of eyes needing secondary surgery for VAO is more, if surgery is performed before 6 months of age.<sup>18</sup> Similarly, in our series, children who underwent membranectomy had initial cataract surgery at the age of  $0.96 \pm 1.44$  range

**Table 3** Distribution of improvement in BCVA in the study cohort after surgical intervention

Type of surgery	Median pre op BCVA	Median post op BCVA		
	LogMAR	LogMAR		
Membranectomy	2.5 (1.07-3)	0.92 (0.72–1.22)		
Glaucoma surgery	3 (2.5–3)	3 (2.3–3)		
Yag capsulotomy	2 (0.8-2.17)	0.6 (0.36-0.96)		
Vitrectomy for VWS	1.3	0.3ª		
IOL repositioning	1.7	1.4 <sup>a</sup>		
IOL exchange	2.17	0.22		
Cortical aspiration	2	0.75 <sup>a</sup>		
Vitreous	1.25	0.8ª		
biopsy+IOAB for				
endophthalmitis				
Resuturing	1.6	_		
Total	2 (1.3–3)	0.92 (0.5–1.3)		

Abbreviations: IOAB, intraocular antibiotic; IOL, intraocular lens; VWS, vitreous wick syndrome. <sup>a</sup>Denotes the groups with 1–2 patients.

Table 2	Distribution of	of the various	reoperations i	n children	undergoing	primary	cataract surgery
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Type of surgery	Total number of eyes (number, percentage)	Psuedophakic eyes (number, percentage)	Incidence in aphakic eyes (number, percentage)	Overall incidence in the entire cohort (number, percentage)			
Membranectomy	24 (53.3)	12 (2.1)	12 (4.9)	24 (2.9 )			
Glaucoma surgery	6 (13.3)	2 (0.35)	4 (1.64)	6 (0.74)			
IOL exchange	3 (6.7)	3 (0.52)	NA	3 (0.36)			
Yag capsulotomy	5 (11.1)	5 (0.7)	0 (0)	5 (0.49)			
Residual cortical aspiration	2 (4.4)	0 (0.17)	2 (0.81)	2 (0.24)			
Vitrectomy for VWS	1 (2.2)	1 (0.35)	0 (0)	1 (0.12)			
Vitreous biopsy+IOAB for endophthalmitis	2 (4.4)	2 (0.17)	0 (0)	2 (0.24)			
Resuturing	1 (2.2)	1 (0.17)	0 (0)	1 (0.12)			
IOL repositioning	1 (2.2)	1 (0.17)	0 (NA)	1 (0.12)			

Abbreviations: IOAB, intraocular antibiotic; IOL, intraocular lens; VWS, vitreous wick syndrome.

(0.08–5 years), suggesting early age was a common risk factor for risk of VAO.

The reported incidence of secondary glaucoma after pediatric cataract surgery varies from 15 to 58%.<sup>14</sup> The highest incidence is reported when the surgery is performed early (below the age of 2 months) and in children left aphakic.<sup>20,21</sup>

In our study, the incidence of glaucoma was 3.4% (28/814) and glaucoma requiring surgical intervention was 0.73% (6/814) (13.3% of all the secondary interventions). As noted above, all our patients who developed glaucoma were operated at age <1 year. In this subgroup, the incidence of glaucoma was 6% (16/308) with a mean follow-up of  $4.8 \pm 2.3$  years. Average age of these children at the time of initial surgery was  $0.31 \pm 0.29$  (range 0.08–0.75) years. Average interval between primary cataract and glaucoma surgery was  $1.94 \pm 2.4$  years (range: 0.17–5 years). Unlike previous reports, the incidence of surgery for secondary glaucoma in these patients was similar in pseudophakic (1.9%, 2/104) and aphakic (2.0%, 4/2014) eyes. Out of these 6 cases, 3 cases had trabeculotomy and trabeculectomy, 2 had trabeculectomy with mitomycin-C, and 1 had transscleral cyclophotocoagulation.

Factors which have been reported to influence the risk of glaucoma in children include age at surgery, preexisting ocular abnormalities, type of cataract and the effect of lens particles, lens proteins, inflammatory cells, retained lens material, type of lensectomy, development of pupillary block, and duration of postoperative followup.<sup>21</sup> Our results are similar to those suggested by Rabiah<sup>13</sup> and Haargaard *et al*,<sup>22</sup> who suggested that the risk of glaucoma was higher in children operated before 9 months of age.

In our series, four eyes had IOL exchange for varied reasons: two for significant pigments on IOL, one for lens dislocation into vitreous and one for anterior subluxation of the IOL. Three children in our series had a significant IOL decentration or dislocation necessitating IOL exchange or repositioning. One child had IOL exchange for IOL drop through posterior capsulotomy and underwent *pars plana* vitrectomy and IOL exchange within a week of primary surgery.

Another child had IOL exchange as superior haptic had subluxated into anterior chamber after 5 years of surgery. A third child required IOL repositioning for significant decentration. This might be attributable to capsular bag instability from radial tears or poor construction capsulotomies,<sup>23</sup> vitreous prolapse, instability produced by a posterior capsulotomy, and significant growth of the eyes of younger children.<sup>24</sup>

A fourth child, operated at 4 months of age, with IOL in sulcus had significant deposits on IOL and underwent IOL exchange after 5 years. This might be seen secondary to fibrinoid uveitis in the early postoperative period or owing to the sulcus implantation of the IOL, and may result in the formation of posterior synechiae, pigment deposition on the IOL, pupil irregularity, and IOL decentration occasionally. Sharma *et al*<sup>8</sup> have reported that sequelae of uveitis were present in 30.8% of eyes in their series. Use of intraoperative heparin in the irrigating fluid might reduce the incidence of fibrinoid uveitis.<sup>25</sup> However, the incidence was reported less in our study (2.4%, 24/814 overall and 3.5%, 11/308 infants). In our opinion, atraumatic surgical techniques, in-the-bag fixation of IOLs, and intensive postoperative steroid treatment (prednisolone acetate 1% starting 12 times a day and slow taper over 6 weeks) are other contributing factors that help reduce inflammatory responses. It is mentioned that years after surgery, decentralization and iris chafing can occur with the single-piece AcrySof IOL (Alcon Laboratories, Inc.) implanted in the sulcus.<sup>22</sup> One child with posterior lenticonus had to undergo vitrectomy for vitreous wick syndrome within a month.

Endophthalmitis is one of the most serious complications after intraocular surgery in children, with an incidence similar to that observed following adult cataract surgery.<sup>16</sup> In our series, two children developed endophthalmitis after surgery via a scleral incision. The children underwent vitreous biopsy+intraocular antibiotic injection. However, biopsy showed inflammatory cells and no organisms were identified on culture. Even after surgery, BCVA did not improve significantly in these patients owing to possible macular damage.

In our series, we claim that low prevalence of complications leading to resurgery is owing to a thorough preoperative examination, good surgical technique with minimal intraoperative manipulation, optimal postoperative regimen, relatively older children, and long-term follow-up.<sup>26,27</sup>

Our study is limited by its retrospective nature, occasional ciliary sulcus placement of IOL, different IOL models being used over time, and loss of patients to follow-up. However, our study does suggest that the incidence of second surgery after primary IOL implantation in children, especially VAO- and IOLrelated complications, might be less frequent than previously reported. Further, the incidence of complications does not tend to be higher in pseudophakic children as compared with aphakic children. Our study however cautions that the incidence of glaucoma might be significantly higher especially in children operated at an early age.

#### What was known before

• Common complications after pediatric cataract surgery. Visual axis opacification and glaucoma are quite common. Incidence is high in infants.

#### What this study adds

• Incidence of complications needing second surgery. Incidence of complications is lower than reported. Membranectomy and glacuoma surgery are most common.

### Conflict of interest

The authors declare no conflict of interest.

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Supplementary Information accompanies this paper on Eye website (http://www.nature.com/eye)

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