

Outcome of primary intraocular lens implantation in infants: Complications and rates of additional surgery

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PURPOSE: To study the requirement of additional surgery and adverse events in infants having primary intraocular lens (IOL) implantation.

SETTING: Tertiary care institute, Chandigarh, India.

DESIGN: Prospective observational noncomparative case series.

METHODS: Infants who had phacoaspiration, primary posterior capsulotomy, anterior vitrectomy, and primary IOL implantation were evaluated for complications and the need for additional surgery over a 3-year period. The main outcome measures were the rate of complications, adverse events, and need for additional surgery.

RESULTS: Sixty infants (100 eyes) with a mean age of 7.13 months \pm 2.32 (SD) (range 3 to 12 months) were studied. The mean follow-up was 41.2 \pm 3.5 months. Indication of additional surgery included visual axis opacification in 13 eyes, pupillary membrane/IOL decentration in 4 eyes, and iris prolapse in 4 eyes. Adverse events included pigment on the IOL in 14 eyes and iridolenticular adhesions in 9 eyes. Ocular hypertension was observed in 2 eyes. The IOL was placed in sulcus or by optic capture in 14 eyes. There was no difference in additional surgery and adverse events between infants aged 6 months or younger versus those older than 6 months (P = .734).

CONCLUSION: There was a low incidence of adverse events and additional surgery requirement in infants who had cataract surgery with primary IOL implantation.

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Although there is growing consensus for primary intraocular lens (IOL) implantation in children at the time of congenital cataract surgery, controversy remains concerning IOL implantation in children

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younger than 1 year.^{1–8} Results of the Infant Aphakia Treatment Study (IATS) do not favor IOL implantation in infants younger than 7 months.⁶ The authors report a high incidence of adverse events and rates of repeat surgeries in infants who had congenital cataract surgery with IOL implantation as opposed to those who were left aphakic and subsequently treated with contact lens placement.

On the other hand, few case studies^{2,7,8} describe the outcomes of primary IOL implantation in infants as being safe, effective, and advantageous; however, the feasibility of using this strategy in the developing world has not been established. In the developing world, compliance with contact lens use, proper follow-up, and hygiene are poor. In such cases,

primary IOL implantation could be beneficial. We report the outcomes of primary IOL implantation in infants younger than 1 year in this prospective study.

PATIENTS AND METHODS

All infants attending the pediatric ophthalmology clinic who had cataract surgery with primary IOL implantation were prospectively evaluated over a 3-year period. Informed consent was obtained from the parent or guardian of the infant after institutional review board approval. The study conformed to the tenets of the Declaration of Helsinki. Eyes with traumatic cataract were excluded.

The parameters evaluated included age at surgery, laterality, sex of the infant, significant family history, type of cataract, axial length preoperatively, type of IOL, power of the IOL, intraoperative and postoperative complications, indications for an additional surgical procedure, and postoperative retinoscopy/refraction. The IOL power was calculated using the SRK II formula with a postoperative refractive error target of +4.0 diopters (D) in infants younger than 6 months and +3.0 D in infants aged 6 months to 1 year. Objective streak retinoscopy was initially performed after surgery at an interval of 2 weeks when no inflammation was documented and then repeated at 6 weeks by the same optometrist. Spectacles were prescribed based on the retinoscopy value with additional addition up to 2.5 years, after which bifocal spectacles were prescribed. Intraocular pressure (IOP) was measured with the Perkins handheld applanation tonometer preoperatively as well postoperatively. B-scan ultrasonography was performed in eyes in which a dense cataract precluded the view of the fundus.

Surgical Technique

All surgeries were performed by the same surgeon (J.S.) under general anesthesia using the standard technique. Two limbal side-port tunnels were made at 3 o'clock and 9 o'clock using a 15-degree paracentesis knife. Trypan blue was injected to aid visualization of the anterior capsule in all cases.

After the anterior chamber was formed with sodium hyaluronate 1.4% (Healon GV), a posterior limbal incision was made with a 2.8 mm keratome knife and a continuous anterior capsulorhexis of approximately 5.0 mm diameter was created with a Utrata forceps. The aspiration of the lens was accomplished using an automated handpiece. A primary posterior capsulotomy of approximately 3.0 to 3.5 mm and an anterior vitrectomy were performed by the anterior route through the same limbal side ports. Thereafter, in-the-bag IOL implantation of a hydrophobic acrylic IOL (Tecnis Sensar AR40e, Abbott Medical Optics, Inc.) was attempted. Sulcus implantation was performed in cases in which there was anterior and posterior capsulorhexis extension, and optic capture was performed in cases with large posterior capsule tears. The residual ophthalmic viscosurgical device was removed, and the incisions were closed with 10-0 polyglactin (Vicryl).

Subconjunctival dexamethasone was administered in all eyes at the end of surgery. All patients were treated postoperatively with betamethasone eyedrops every hour for the first week, followed by a slow taper over the next 4 weeks. Topical moxifloxacin was given 4 times a day for 1 week postoperatively. Homatropine drops were given for 2 weeks.

Postoperative Assessment

At follow-up visits, patients were examined under anesthesia and a slitlamp evaluation was performed when possible. A record of all postoperative findings as well as complications was taken at every visit. The infants were prescribed spectacles and patching as needed. In cases of unilateral cataract, the parents were instructed to cover the phakic eye for 50% of waking hours per day if the infant was older than 6 months. If the infant was younger than 6 months, the number of hours was the age (eg, 4 hours patching if the infant was 5-months old). In cases of bilateral cataract, the infant received patching only if there was fixation preference in 1 eye. The refractive error was calculated as the spherical equivalent (SE), defined as the algebraic power of the sphere plus one half of the cylindrical power.

Intraoperative complications included unexpected difficulty or events occurring during the surgery and hampering adequate surgical maneuverability, namely iris prolapse, a pupil that would not dilate, hyphema, and corneal clouding or haze.

Visual axis opacification (VAO) was defined as significant if there was lens epithelial cell (LEC) regrowth extending into the pupillary area and interfering with vision and/or an inability to perform retinoscopy in that eye. The proliferation was further defined as being behind the lens (posterior capsule opacification [PCO]) or over the lens (membrane over IOL). Pupillary membrane was defined as fibrous tissue extending across the pupil and obscuring the visual axis.

Additional intraocular surgery was defined as a return to the operating room for intraocular surgery because of a complication. The above-mentioned complications were reviewed for every patient and analyzed.

Statistical Analysis

Statistical analyses were performed using SPSS software (version 20, SPSS, Inc.). A *P* value less than 0.05 was considered statistically significant. A descriptive analysis was performed on all patients, and a record of both eyes was kept. The rates of complications were evaluated in all patients as well as separately in infants younger than 7 months. The chi-square test was used to compare these rates between the 2 age groups for categorical data and the Mann-Whitney test was used for continuous data. Binary logistic regression analysis was used to determine factors associated with VAO.

RESULTS

One hundred eyes of 60 infants (25 girls, 35 boys) had cataract surgery within the first year of life. The mean age at surgery was 7.13 months \pm 2.32 (SD) (median 8; range 3 to 12 months). The mean postoperative follow-up was 41.2 \pm 3.5 months (range 38 to 47 months). Table 1 shows the demographic profile of the patients. Twenty-one infants (34 eyes) were younger than 6 months and 39 infants (66 eyes) were older than 6 months. Three patients had positive titers for toxoplasmosis, rubella, cytomegalovirus, and herpes simplex virus. One of them had a positive family history for congenital cataract. Eleven patients had nystagmus and 22 had strabismus preoperatively.

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