Visual outcomes and complications in infantile cataract surgery: a real-world scenario

Goura Chattannavar, Akshay Badakere, Ashik Mohamed, Ramesh Kekunnaya

ABSTRACT

Objective To evaluate visual outcomes and complications of infantile cataract surgery through a 1-year follow-up period in a real-world scenario.

Methods and analysis Prospective observational study evaluating infants with cataract undergoing surgery.

Results We analysed 173 eyes of 97 infants (76 bilateral, median age 18.7 weeks, IQR: 11–33.9 weeks). Toxoplasmosis, rubella, cytomegalovirus and herpes infection was the most common aetiology in both unilateral (10.46%) and bilateral (35.11%) cases, followed by familial and syndromic cases. Fifty-four eyes (29.5%) received primary intraocular lens (IOL) implantation. Seventy-five infants (76%) were less than 6 months of age. At 1-year follow-up, mean log MAR best-corrected visual acuity was 1.00±0.08 and 1.21±0.30 in unilateral and bilateral cases respectively (p=0.012), which was not statistically significant. At 1-year follow-up, pseudophakic (1.09±0.05) eyes had a better mean log MAR visual acuity comparing aphakic (1.24±0.04) clinically but was not statistically significant after the application of Bonferroni correction (p=0.012). The mean myopic shift of -2.9 D±0.39 and -4.53 D±0.55 over 1 year was noted in aphakes and pseudophakes, respectively (p=0.016). Visual axis opacification and glaucoma were the most common complications noted in pseudophakes and aphakes, respectively.

Conclusion Primary IOL implantation in selected cases of infantile cataract is a feasible option, particularly in cases when optimal aftercare and refractive rehabilitation of aphakes are not possible.

INTRODUCTION

The first 2 years of a child’s life are critical in the development of vision. Lenticular opacities during this phase can suppress primary sensory development leading to amblyopia. As age at cataract surgery is an important factor influencing the visual outcome in children with both unilateral and bilateral cataracts, it is important to treat and visually rehabilitate these children as early as possible.

The intraocular lens (IOL) implantation in infants below the age of 7 months is controversial. Although several studies have shown varying results regarding the safety of early IOL implantation, the Infant Aphakia Treatment Study (IATS) suggested that, at 1 year of age, visual outcomes were similar among aphakes, in those who have been given early rehabilitation with contact lenses and pseudophakes. The IATS results also showed a higher complication rate in pseudophakes with a need for secondary intervention. Hence, IATS recommended early IOL implantation in those infants for whom cost and contact lens handling were challenges. Negalur and associates reported that the primary IOL implantation is safe in infants aged <6 months in the absence of conditions such as anterior segment dysgenesis, microcornea and glaucoma. With existing challenges due to economic constraints and
follow-up in developing nations and by weighing the risk–benefit ratio, there is an inclination towards primary IOL implantation.

Visual axis opacification (VAO), glaucoma, retinal detachment and, rarely, endophthalmitis are sight-threatening complications following an infantile cataract surgery.4 5 6 IATS has reported VAO as the most common complication in pseudophakia, whereas in aphakia, glaucoma is the most common complication.7 Overall, glaucoma is the second most commonly reported complication after an infantile cataract surgery. The various risk factors for the development of glaucoma are cataract surgery at a very early age, additional surgery for secondary membrane formation, presence of microcornea, type of cataract and phakic status.8 9 In several studies, presence of IOLs has been recognised as a protective factor against the development of glaucoma.10 11 The objective of our study was to prospectively evaluate visual outcomes and complications following infantile cataract surgery over a 1-year follow-up period.

MATERIALS AND METHODS

This was a prospective study conducted at L V Prasad Eye Institute, Hyderabad, India. A total of 173 eyes of 97 infants (age range, 4–46 weeks) operated for congenital cataract between June 2016 and June 2017 with a follow-up of 1-year postsurgery were included. A written informed consent explaining the details of evaluation, surgery performed and possible complications associated with surgery and general anaesthesia was obtained from the parents.

All patients were subjected to a comprehensive ocular examination after taking complete history from the parents. The preoperative visual status was recorded whenever possible and strabismus and nystagmus, if present, were noted in all eyes. An ultrasound B scan was performed in all cases. Under general anaesthesia, axial length (Tomey AL-100, Germany), corneal thickness (Tomey SP-100, Germany), keratometry (Nidek HandyReF-K, Japan) and corneal diameter (Castroviejo callipers) were measured. Gonioscopy (Volk 4 mirror indirect gonio lens) was performed under anaesthesia prior to surgery and anterior chamber angles were labelled as open when posterior pigmented trabecular meshwork was seen. The presence of abnormal iris processes, anterior insertion of iris and extent of peripheral anterior synchiae (PAS), if any, were noted in all eyes.

Lens aspiration with primary posterior capsulotomy and anterior vitrectomy with or without IOL implantation was performed. We did not randomise the patients into aphakia and pseudophakia groups as we wanted to study the real world scenario without any restricting factors. Only eyes which satisfied the criteria of an axial length ≥16.5 mm and a horizontal corneal diameter ≥10.5 mm were implanted with an IOL in the bag (Acrysof SA60AT, Alcon laboratories, Inc, Fort Worth, Tx USA).12 The IOL power was calculated using Sanders-Retzlaff-Kraff II/T formula with Enyedi’s guidelines for under-correction.13 14 All surgical wounds were sutured with non-absorbable 10–0 nylon sutures. Postoperatively, topical tobramycin 0.3% or moxifloxacin 0.5% four times a day for 1 week, atropine sulfate 1% twice daily for 1 week and a tapering dose of prednisolone acetate 1% 8–12 times daily with a gradual tapering over 6 weeks were prescribed to all infants.

The children were examined on first postoperative day and, under general anaesthesia, at 1 week during which sutures were removed and glasses or contact lenses were prescribed. The children were followed up at one, six and 12 months postsurgery. Age-appropriate visual acuity testing methods were followed. In children where visual acuity could not be estimated by these methods, visual behaviour and their ability to fix and follow light were assessed. Teller Acuity Charts (TAC, Stereo Optical Chicago, Illinois, USA) were used for assessing grating visual acuity at 1 year of age. When a child resisted occlusion during monocular vision recording, binocular grating acuity was recorded. Intraocular pressure (IOP) was measured with Perkins tonometer (Haag-Streit, UK) when under anaesthesia and Icare tonometer (TA01i, Finland) in the outpatient department. Retinoscopy was performed by a trained optometrist. All children operated for bilateral cataracts were rehabilitated with spectacles and children with unilateral aphakia were offered contact lenses. In cases of non-compliance to contact lens, spectacles were given for constant wear. Amblyopia therapy was initiated from 1 week after surgery. Additionally, gonioscopy, keratometry, corneal thickness, axial length and corneal diameter were also documented at 1 year follow-up.

Strabismus, if present, was measured using prism bar cover test (if the child allowed examination) or a modified Kreissig test. Nystagmus, if present, was also documented. In addition, VAO, signs of inflammation, position of IOL and posterior segment complication, if any, were noted in every visit. A diagnosis of glaucoma was made if IOP was ≥20 mm Hg with one or more of the following changes that is, increase in corneal diameter, asymmetric progressive myopic shift coupled with increase in corneal diameter and/or increase in axial length and an increased cup to disc ratio of the optic nerve head. A patient was designated as a glaucoma suspect if they had two consecutive IOP readings ≥20 mm Hg on two different visits without any other anatomical changes.

Statistical analysis was performed using STATA V.14.2 (StatCorp). A linear mixed effects model using maximum likelihood estimation with random intercepts at the subject level was used in the data analysis to account for the correlation between fellow eyes of the same subject. The comparisons between postoperative visits or groups (aphakic vs pseudophakic or unilateral vs bilateral) were evaluated by mixed effects regression analysis using marginal linear predictions. A p <0.05 was considered statistically significant. For multiple comparisons, a Bonferroni correction was made.
RESULTS

One hundred and twelve patients under the age of 12 months (median age: 14.5 weeks and IQR: 9.3–32.2 weeks) were enrolled in the study. Fifteen patients were excluded as they either did not undergo surgery at our centre or were lost to follow-up after surgery. Finally, a total of 173 eyes belonging to 97 patients (86.6%) were included. Fifty subjects (51.6%) were females and 76 (78.4%) had bilateral cataract.

TORCH infection (Toxoplasmosis, Rubella, Cytomegalovirus and Herpes virus infections) was the most common aetiology in both unilateral (n=10, 47.6%) and bilateral (n=43, 55.1%) cataracts, followed by familial and syndromic cases. Overall, cytomegalovirus infection was the predominant (n=21, 21%) TORCH infection, followed by mixed infection (n=19, 19%), rubella virus infection (n=8, 8%) and herpes virus infection (n=5, 5%). The number of patients with undetermined causes was 18 (23.1%) and 9 (11.5%) in bilateral and unilateral cataracts, respectively. Two eyes (9.5%) of 21 unilateral cataracts had persistent fetal vasculature. Of 26 infants diagnosed with rubella cataract, 7 (26.9%) infants underwent IOL implantation, while 24 of 71 (33.8%) non-rubella aetiology cataracts underwent IOL implantation.

The mean age at surgery was 23.7 weeks (median: 18.7 weeks and IQR: 11–33.9 weeks). Of 173 eyes that underwent surgery, 54 eyes (29.5%) were implanted with IOls. The IOL status in unilateral and bilateral cases is summarised in online supplemental table 1. Of 97 patients who were operated, 94 (96.9%), 91 (93.8%) and 65 (67.0%) followed up at 1 week, 1 month and 6 months, respectively. When there was a follow-up attrition, each patient was given a telephonic reminder call within a week of their missed follow-up and only patients who reviewed to clinic within 2 weeks of telephonic call were included in further analysis. At 1 year, the follow-up rate continued to drop to 53 patients (54.6%), but improved to 79 patients (81.4%) following a reminder telephone call after non-attendance.

Best-corrected visual acuity (BCVA) outcomes and myopic shift are tabulated in table 1. Grating acuity in LogMAR equivalents was achieved for 123 eyes, visual fixation behaviour was recorded in the remainder. Binocular measurements only were possible in 53 (43%) eyes but included in the analysis as most of these eyes were of bilateral cataract and had not resisted occlusion of either eye. When there was a resistance to occlusion of either eye, efforts were made to assess monocular visual acuity. There was no significant difference in mean LogMAR BCVA between unilateral and bilateral cases or aphakic and pseudophakic eyes (table 1). A myopic shift was recorded in all eyes, with no significant difference in dioptric power change between aphakic and pseudophakic eyes (table 1). Figure 1 shows mean spherical equivalent refraction at all postoperative visits.

The secondary outcomes such as corneal diameter, central corneal thickness, keratometry and axial length

<table>
<thead>
<tr>
<th>Variable</th>
<th>All eyes</th>
<th>Unilateral</th>
<th>Bilateral</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visual acuity FFL, FL, FNFL or NFL</td>
<td>18/141 (12.8%)</td>
<td>4/13 (30.8%)</td>
<td>14/128 (10.9%)</td>
<td>0.04</td>
</tr>
<tr>
<td>LogMAR, mean±SD</td>
<td>1.19±0.24, n=123</td>
<td>1.00±0.19, n=9</td>
<td>1.27±0.22, n=114</td>
<td>0.01</td>
</tr>
<tr>
<td>Myopic shift (D), mean±SD</td>
<td>−3.45±1.93</td>
<td>−3.96±2.73</td>
<td>−3.40±1.96</td>
<td>0.64</td>
</tr>
</tbody>
</table>

Table 1 Visual acuity and myopic shift in each group at 1-year follow-up

<table>
<thead>
<tr>
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</tr>
</tbody>
</table>

(Confidence correction was made and p<0.008, that is, 0.05/6, was considered statistically significant. FFL, fixing and following light; FL, fixing at light; FNFL, fixing at light but not following light; NFL, not following light.)
Of the two eyes (1%) that developed endophthalmitis, one eye presented immediately postoperatively and the other eye presented 1 month postoperatively. Both cases of chronic endophthalmitis occurred in babies who had been lost to routine follow-up.

Table 2. Preoperative and postoperative (1 year) corneal diameter, central corneal thickness, average keratometry and axial length.

<table>
<thead>
<tr>
<th>Variable, mean±SD</th>
<th>All eyes</th>
<th>Unilateral</th>
<th>Bilateral</th>
<th>P value</th>
<th>Aphakes</th>
<th>Pseudophakes</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corneal diameter (mm)</td>
<td>Preoperative (173 eyes of 97 patients)</td>
<td>9.98±1.02</td>
<td>9.91±1.21</td>
<td>10.00±0.97</td>
<td>0.73</td>
<td>9.50±0.80</td>
<td>11.06±0.50</td>
</tr>
<tr>
<td></td>
<td>Year 1 (139 eyes of 76 patients)</td>
<td>10.74±1.07</td>
<td>10.83±1.00</td>
<td>10.72±1.01</td>
<td>0.72</td>
<td>10.42±1.07</td>
<td>11.47±0.49</td>
</tr>
<tr>
<td></td>
<td>P value</td>
<td>&lt;0.0001</td>
<td>0.0001</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Central corneal thickness (µm)</td>
<td>Preoperative (117 eyes of 65 patients)</td>
<td>550.6±67.2</td>
<td>542.5±57.7</td>
<td>552.5±69.7</td>
<td>0.64</td>
<td>552.9±72.0</td>
<td>546.6±55.9</td>
</tr>
<tr>
<td></td>
<td>Year 1 (100 eyes of 55 patients)</td>
<td>571.1±46.4</td>
<td>589.9±34.8</td>
<td>568.1±47.8</td>
<td>0.25</td>
<td>581.4±46.4</td>
<td>549.7±38.8</td>
</tr>
<tr>
<td></td>
<td>P value</td>
<td>&lt;0.0001</td>
<td>0.005</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Axial length (mm)</td>
<td>Preoperative (173 eyes of 97 patients)</td>
<td>17.52±2.13</td>
<td>17.39±2.08</td>
<td>17.56±2.15</td>
<td>0.74</td>
<td>16.77±2.00</td>
<td>19.25±1.21</td>
</tr>
<tr>
<td></td>
<td>Year 1 (74 eyes of 40 patients)</td>
<td>20.28±2.20</td>
<td>21.90±3.27</td>
<td>20.01±1.87</td>
<td>0.05</td>
<td>20.00±2.44</td>
<td>21.13±0.69</td>
</tr>
<tr>
<td></td>
<td>P value</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Kavg (D)</td>
<td>Preoperative (125 eyes of 69 patients)</td>
<td>45.60±2.14</td>
<td>45.21±1.59</td>
<td>45.68±2.26</td>
<td>0.49</td>
<td>46.22±2.10</td>
<td>44.78±1.89</td>
</tr>
<tr>
<td></td>
<td>Year 1 (112 eyes of 61 patients)</td>
<td>45.36±2.29</td>
<td>43.96±2.75</td>
<td>45.59±2.19</td>
<td>0.06</td>
<td>45.64±2.37</td>
<td>44.84±2.04</td>
</tr>
<tr>
<td></td>
<td>P value</td>
<td>0.09</td>
<td>0.27</td>
<td>0.10</td>
<td>0.03</td>
<td>0.99</td>
<td>0.0001</td>
</tr>
</tbody>
</table>

Bonferroni correction was made and p<0.0014, that is, 0.05/36, was considered statistically significant.
DISCUSSION

This prospective study adds to existing literature, a large cohort of infants who underwent cataract surgery with a reasonably good follow up. The salient feature of our study was the congenital cataract cohort group was not randomised and were studied in a natural course as we wanted to prospectively look into the outcomes without any restrictive factors in a developing nation, unlike the existing literature on randomised studies in developed nations. Bilateral cataracts were predominant in our study in contrast to studies from developed nations where more unilateral infantile cataracts have been reported. The goal of this study was not to compare the complications between aphakes and pseudophakes, but rather to see the practical feasibility of IOL implantation, visual outcomes and report complications (if any) in both groups.

Majority of the infants in our study were females, unlike studies by Eckstein and associates, implying a shifting trend towards gender parity and an increase in awareness among the population. More than three-quarters of the patients in our study had presented before 6 months of age implying increasing awareness and regular screening of infants. While Foster et al and Eckstein et al reported most cataracts as idiopathic in aetiology, our study showed that TORCH infection was the most common in both unilateral and bilateral cases. One-third of the children presented, had high-risk systemic conditions such as congenital heart disease and seizure disorder.

The mean age at surgery in our study was 23.7 weeks which was higher compared with the study done by Autrata and associates, where it was 12.4 weeks. In IATS, the mean age at surgery was 7.2 weeks. The optimal method for visual rehabilitation for children following cataract surgery remains debatable. In recent years, there has been an increase in the use of IOLs to correct aphakia during infancy. One-third of the eyes in our study satisfied the criteria for IOL implantation and were successfully implanted with a posterior chamber IOL. The remaining two-thirds were prescribed either spectacles or contact lenses.

The study by Chougule and associates has reported a loss of follow-up from 85% at 1-month postsurgery to 52% at the end of 1 year. In our study, despite regular reminders for follow-ups through telephone calls and text messages, the rate of follow-ups dropped from almost 100% on the first postoperative day to 50% at 6 months. After persistent telephone calls and explaining the need for follow-up and examination, the rate of follow-up increased to 80% at 1 year.

At 1 year, there was no significant difference in mean BCVA in implanted eyes compared with non-implanted eyes. Unlike IATS and IOL under two study which strongly discourage IOL implantation in infants less than 6 months of age owing to higher adverse effect at 5 years, our study by Chougule and associates showed implantation of IOL in carefully selected cases as a viable option in developing countries. Chougule et al had shown in their studies that TORCH infection was the most common in both unilateral and bilateral cases. One-third of the children presented, had high-risk systemic conditions such as congenital heart disease and seizure disorder.

<table>
<thead>
<tr>
<th>Postoperative complication n, (%), 95% CI</th>
<th>Aphakes (119 eyes)</th>
<th>Pseudophakes (54 eyes)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visual axis opacification</td>
<td>5 (4.2%, 1.6% to 10%)</td>
<td>12 (22.2%, 12.5% to 35.9%)</td>
<td>0.0004</td>
</tr>
<tr>
<td>Secondary glaucoma</td>
<td>6 (5.0%, 2.1% to 11.1%)</td>
<td>1 (1.9%, 0.1% to 11.2%)</td>
<td>0.37</td>
</tr>
<tr>
<td>Endophthalmitis</td>
<td>1 (0.8%, 0.04% to 5.3%)</td>
<td>1 (1.9%, 0.1% to 11.2%)</td>
<td>0.56</td>
</tr>
<tr>
<td>Vitreous in anterior chamber</td>
<td>1 (0.8%, 0.04% to 5.3%)</td>
<td>0 (0%, 0% to 8.3%)</td>
<td>0.50</td>
</tr>
<tr>
<td>Corneal decompensation</td>
<td>0 (0%, 0% to 3.9%)</td>
<td>1 (1.0%, 0.1% to 11.2%)</td>
<td>0.13</td>
</tr>
<tr>
<td>Vitreous haemorrhage</td>
<td>2 (1.7%, 0.3% to 6.5%)</td>
<td>0 (0%, 0.1% to 11.2%)</td>
<td>0.34</td>
</tr>
<tr>
<td>Total</td>
<td>15 (12.6%, 7.5% to 20.3%)</td>
<td>14 (25.9%, 15.4% to 39.9%)</td>
<td>0.04</td>
</tr>
</tbody>
</table>

Bonferroni correction was made and p<0.007, that is, 0.05/7, was considered statistically significant.

<table>
<thead>
<tr>
<th>Secondary surgery n, (%), 95% CI</th>
<th>Aphakes (119 eyes)</th>
<th>Pseudophakes (54 eyes)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Membranectomy</td>
<td>3 (2.5%, 0.7% to 7.7%)</td>
<td>9 (16.7%, 8.4% to 29.8%)</td>
<td>0.001</td>
</tr>
<tr>
<td>Trabeculectomy + trabeculotomy</td>
<td>2 (1.7%, 0.3% to 6.5%)</td>
<td>0 (0%, 0% to 8.3%)</td>
<td>0.34</td>
</tr>
<tr>
<td>Vitrectomy</td>
<td>2 (1.7%, 0.3% to 6.5%)</td>
<td>0 (0%, 0% to 8.3%)</td>
<td>0.34</td>
</tr>
<tr>
<td>Vitrectomy + intraocular antibiotics</td>
<td>1 (0.8%, 0.04% to 5.3%)</td>
<td>1 (1.9%, 0.1% to 11.2%)</td>
<td>0.56</td>
</tr>
<tr>
<td>Intraocular lens explantation</td>
<td>N/A</td>
<td>1 (1.9%, 0.1% to 11.2%)</td>
<td>N/A</td>
</tr>
<tr>
<td>Total</td>
<td>8 (6.7%, 3.2% to 13.2%)</td>
<td>10 (18.5%, 9.7% to 31.9%)</td>
<td>0.02</td>
</tr>
</tbody>
</table>

Bonferroni correction was made and p<0.01, that is, 0.05/5, was considered statistically significant.

N/A, not available.
study of unilateral cataracts that the mean final visual of
the operated eye was 0.43±0.33 for the IOL group and
0.58±0.39 for the CL group (p=0.14) while the mean
interocular difference in visual acuity was 0.22±0.29
for the IOL group and 0.56±0.31 for the CL group
(p=0.042). Thus, they had concluded that the correc-
tion of aphakia after cataract surgery with primary IOL
implantation resulted in improved visual acuity.21 Similar
to our results, IATS had shown that the median visual
acuity at 12 months after cataract surgery was the same
for both aphakia and the IOL cohorts (aphakia group
0.80 Log MAR, IOL group 0.97 Log MAR; p=0.19).22 IOL
under-2 study had looked into the effectiveness of IOL
implantation in children less than 2 years of age and had
found that IOL implantation had significant better vision
compared with children who were left aphakic, but this
result was consistent only in bilateral cataracts and not in
unilateral cataracts.23

We found that the average myopic shift was similar in
both the groups and emmetropisation was faster in pseu-
dophakes compared with aphakes.

Among the secondary outcomes, the corneal diam-
eter increased significantly in both aphakes and
pseudophakes. There was an increase in central corneal
thicker order was 1-year post surgery compared with the
immediate postoperative period. These results are
consistent with the results of earlier studies.22–24 While
the myopic shift was significant in pseudophakes, a signif-
icant change in axial length was noted in both groups;
similar to the IATS study.23 Differing results have been
reported on the axial growth of the eye after cataract
surgery during infancy.25

The most common complication noted in our study
was VAO followed by secondary glaucoma. The rate of
complications and second surgery were more in pseu-
dophakes compared with aphakes. VAO following
cataract surgery can range from 40% to 95%. Trivedi
and associates reported that 25% of their cases with VAO
required a second surgery.26 However, in our study, VAO
was noted in 9.8% of patients and was predominant in
pseudophakes. More than 70% of the eyes that devel-
oped VAO underwent membrane surgery. In common with
the findings from other studies, VAO was significantly
more common in implanted eyes than aphakic eyes as
was the requirement for further surgery. This incidence
was much lower compared with the previous studies and
could be attributed to using a hydrophobic acrylic lens,
in the bag lens implantation, a thorough cortical clean
up and an intense postoperative topical steroid regimen.

In contrast to the IATS study, 3% of infants were
labelled as glaucoma suspects and 4% were treated for
glaucoma, and fewer pseudophakes developing glau-
coma, suggesting a possible protective role of the IOL as
has been suggested in some studies.9,27 Endophthalmitis
is rare after paediatric cataract surgery with an estimated
prevalence of 0.07%.28

Two babies who had been lost to follow-up returned with
endophthalmitis. While one developed endophthalmitis
1 month postoperatively and had a suture site infiltrate,
the other presented at 8 months postoperatively with
chronic endophthalmitis. Microbiological work up did
not reveal any organisms. Both the children were given
intravitreal antibiotics without any delay and followed up
subsequently.

The major limitation in our study was the follow-up
attrition and hence the parameters evaluated were
corrected for age and analysed. Due to high-risk systemic
conditions, the anaesthesia time had to be shortened
and in few cases the biometry readings were not available
during the follow-up period. We did not select unilateral
or bilateral cataracts in particular as cohort and also did
not randomise the patients for aphakia or pseudophakia
group as we wanted to study the real life scenario without
any restricting factors.

CONCLUSION
Unlike many other studies of infantile cataract surgery,
the most frequent aetiology of cataract in the studied
cohort in India was TORCH infection. While there is
debate regarding primary IOL implantation in infants
less than 6 months of age, our large cohort suggests that
it is feasible in nearly one third of infants: important
criteria being the absence of anterior segment pathol-
y, a minimum axial length of 16.5 mm and horizontal
corneal diameter of at least 10.5 mm. In this cohort,
eyes which had primary IOL implantation had compar-
able BCVA at 1 year to aphakic eyes, however, they had
a significantly increased incidence of complications and
subsequent surgery. Given these findings, the decision to
implant should be balanced against potential attendance
issues and compliance with optical correction of aphakia
in developing nations, the issues with attendance and
optical rehabilitation in low-income and middle-income
countries and may tip the balance in favour of early IOL
implantation.

Contributors Contributor ship statement: GC: planning, acquisition of data or
analysis and interpretation of data, AM: planning, acquisition of data or analysis
and interpretation of data, draft, revision: RK: conduct, reporting, conception and design,
AM: planning, acquisition of data or analysis and interpretation of data, draft, revision: AB acquisition of data or analysis
and interpretation of data, AM planning, acquisition of data or analysis
and interpretation of data, draft, revision: AM: planning, acquisition of data or analysis
and interpretation of data, draft, revision, supervision and guarantor.

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Patient consent for publication Not applicable.

Ethics approval The study was approved by the Institutional Ethics Committee and
adhered to the tenets of the Declaration of Helsinki (LEC 06-16-046).

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REFERENCES


<table>
<thead>
<tr>
<th>Post-operative complication</th>
<th>Unilateral (n= 21 eyes)</th>
<th>Bilateral (152 eyes)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visual Axis opacification</td>
<td>1 (4.8%, 0.3%-25.9%)</td>
<td>16 (10.5%, 6.3%-16.8%)</td>
<td>0.41</td>
</tr>
<tr>
<td>Secondary Glaucoma</td>
<td>1 (4.8%, 0.3%-25.9%)</td>
<td>6 (4.0%, 1.6%-8.8%)</td>
<td>0.86</td>
</tr>
<tr>
<td>Endophthalmitis</td>
<td>0 (0%, 0%-19.2%)</td>
<td>2 (1.3%, 0.2%-5.2%)</td>
<td>0.60</td>
</tr>
<tr>
<td>Vitreous in Anterior Chamber</td>
<td>0 (0%, 0%-19.2%)</td>
<td>1 (0.7%, 0.03%-4.2%)</td>
<td>0.71</td>
</tr>
<tr>
<td>Corneal Decompensation</td>
<td>1 (4.8%, 0.3%-25.9%)</td>
<td>0 (0%, 0%-3.1%)</td>
<td>0.006</td>
</tr>
</tbody>
</table>

**Supplemental Table 1 : Summary of lens status post-cataract surgery in both unilateral and bilateral cataract groups**
### Supplemental Table 2: Rate of complications in unilateral and bilateral cataract groups
(CI—Confidence interval)

<table>
<thead>
<tr>
<th>Secondary surgery</th>
<th>Unilateral (21 eyes)</th>
<th>Bilateral (152 eyes)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Membranectomy</td>
<td>1 (4.8%, 0.3%-25.9%)</td>
<td>11 (7.2%, 3.9%-12.9%)</td>
<td>0.68</td>
</tr>
<tr>
<td>N (%, 95%CI)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trabeculectomy</td>
<td>0 (0%, 0%-19.2%)</td>
<td>2 (1.3%, 0.2%-5.2%)</td>
<td>0.60</td>
</tr>
<tr>
<td>Trabeculotomy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N (%, 95%CI)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitrectomy</td>
<td>1 (4.8%, 0.3%-25.9%)</td>
<td>1 (0.7%, 0.03%-4.2%)</td>
<td>0.10</td>
</tr>
<tr>
<td>N (%, 95%CI)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitrectomy+IOAB</td>
<td>0 (0%, 0%-19.2%)</td>
<td>2 (1.3%, 0.2%-5.2%)</td>
<td>0.60</td>
</tr>
<tr>
<td>N (%, 95%CI)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IOL explantation</td>
<td>1 (4.8%, 0.3%-25.9%)</td>
<td>0 (0%, 0%-3.1%)</td>
<td>0.006</td>
</tr>
<tr>
<td>N (%, 95%CI)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>3 (14.3%, 3.8%-37.4%)</td>
<td>15 (9.9%, 5.8%-16%)</td>
<td>0.54</td>
</tr>
<tr>
<td>N (%)</td>
<td>95%CI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-------</td>
<td>-------</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Supplemental Table 3: Rate of second surgery in unilateral and bilateral cataract groups (CI-Confidence interval)**