

Primary Intraocular Lens Insertion in Infants Under 6 Months of Age: A Retrospective Cohort Study

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Background/Aims: Pediatric cataracts are considered a leading cause of visual impairment. While intraocular lens (IOL) implantation is mostly performed for children >2 years, its use in younger children remains contentious. This study assessed primary IOL in a unique pediatric population characterized by limited adherence to postoperative care, where primary IOL implantation was favored to minimize the risk of prolonged uncorrected aphakia.

Methods: This retrospective study examined primary IOL implantation outcomes in children across three age brackets: below 6 months, 6–12 months, and 1–18 years, focusing on best-corrected visual acuity (BCVA) and complications including glaucoma, toxic anterior segment syndrome (TASS), retinal detachment (RD), and yttrium-aluminum-garnet (YAG)/membranectomy.

Results: 169 eyes from 119 patients were evaluated over a median follow-up period of 6.4 years. No significant differences were observed between age groups in terms of LogMAR visual acuity ($p = 0.344$) or the incidence of postoperative complications such as glaucoma ($p = 0.244$), retinal detachment ($p = 0.244$), or TASS ($p = 0.960$). The incidence of YAG capsulotomy/membranectomy was highest in the <6 months group (36%), compared to 22% in the 6–12 months group and 13% in the >1 year group ($p = 0.020$). Among unilateral cases, all 3 patients diagnosed before 6 months required YAG/membranectomy.

Conclusion: Primary IOL implantation for pediatric cataracts resulted in comparable visual acuity and overall complication rates across all age groups. Although a higher incidence of YAG/membranectomy was observed in children under 6 months, particularly among unilateral cases, most patients still avoided the need for additional surgical intervention. These findings support primary IOL implantation as a valid option for selected patients.

Keywords: pediatric cataract, primary intraocular lens implantation, infant cataract surgery, congenital cataract, visual acuity, glaucoma, retinal detachment, aphakia vs. pseudophakia

Introduction

Pediatric cataracts are considered a leading cause of preventable, severe visual impairment in children. Optimal visual outcomes are determined by the timing of the intervention, the surgical procedure, and optical correction options.^{1–3}

Cataract extraction paired with intraocular lens (IOL) implantation has become the gold standard for children age two years or older.^{4–6} However, the application of this approach in younger infants remains controversial. The Infant Aphakia Treatment Study (IATS) recommended that infants younger than 6 months of age undergo cataract extraction followed by aphakia correction with contact lenses and secondary IOL implantation at a later age.

Primary IOL implantation was reserved for exceptional cases in which, according to the surgeon's judgment, contact lens management would likely result in significant periods of uncorrected aphakia.^{7–15} Nonetheless, some studies have suggested that primary IOL implantation in this age group results in visual outcomes and complications comparable to those achieved with secondary IOL implantation ([Supplemental Table 1](#)).^{16–21}

Soroka University Medical Center (SUMC), located in the Negev desert, provides care to a diverse population, including a substantial proportion from socioeconomically disadvantaged communities living in remote and underserved areas. In particular, the local Bedouin population often faces barriers to obtaining consistent medical care, including limited access to utilities, transportation challenges, and reduced adherence to long-term follow-up.²² In light of these unique circumstances, and recognizing the critical need to minimize the risk of prolonged uncorrected aphakia, over the past two decades, SUMC has adopted a clinical approach favoring primary IOL implantation for infants younger than 6 months of age.

Considering the unique circumstances and the choice to perform primary IOL implantation at all pediatric ages, this study provides an opportunity to evaluate the outcomes of this approach within this specific clinical setting. The study evaluates the long-term outcomes of primary IOL implantation in pediatric cataract patients, stratified into three age groups: younger than 6 months, 6 to 12 months, and 1–18 years at the time of surgery.

Materials and Methods

Study Design and Patient Selection

A retrospective review of medical records from 2000 to 2020 was conducted. The study was approved by the Soroka University Medical Center (SUMC) Ethics Committee (IOL-2000-2020). Children who underwent cataract extraction surgery with primary IOL implantation at the SUMC Ophthalmology Department within this timeframe were included. Subjects were stratified into three groups based on age at the time of surgery: under 6 months, 6–12 months, and 1–18 years,²³ to enable comprehensive analysis of outcomes across the full pediatric age range.

Inclusion and Exclusion Criteria

The inclusion criteria encompassed children under the age of 18 years who underwent cataract extraction surgery with IOL implantation. Exclusion criteria were patients without available postoperative follow-up data and patients with severe systemic comorbidities that could independently affect visual outcomes.

Data Collection

Electronic medical records were comprehensively reviewed, encompassing demographic information (age, sex, ethnicity), detailed ophthalmic medical history, surgical records, complication reports, and postoperative follow-up data. Biometric measurements were obtained using an Echoscan US-400 (NIDEK, Inc., San Jose, CA) for axial length and a Righton Retinomax K plus 3 Autorefractor Keratometer (Right Mfg. Co., Ltd. Tokyo, Japan) for keratometry. Surgical reports were meticulously examined, and patient follow-up data were thoroughly analyzed to assess postoperative outcomes and complications.

Surgical Methods

Two surgical methods were employed in this study: (1) lensectomy with posterior chamber IOL implantation - in the bag- with anterior vitrectomy (the anterior vitrectomy technique), (2) lensectomy with posterior chamber IOL implantation - in the bag- and posterior capsulorhexis, with posterior optic capture (the optic capture technique). The SRK/T formula was primarily used to calculate IOL power. Either 3-piece or 1-piece AcrySof IOLs were used across the study groups. The selection of IOL type was based on the surgical technique used; only three 3-piece IOLs were used in the optic capture technique. Whereas in the anterior vitrectomy technique, the IOL choice was based on the surgeon's preference.

When implanting IOLs in infants under 6 months of age, the refractive target was set to achieve postoperative hyperopia of +6.0 to +8.0 diopters, adjusted according to the infant's age at the time of surgery, to account for anticipated axial elongation and ocular growth.²⁴

Throughout the study period (2000–2020), all surgeries were performed by two experienced pediatric cataract surgeons using a consistent manual lens washout technique. An AcrySof IOL was implanted in all patients.

Follow-up and Complications

For unilateral cataract cases, postoperative amblyopia therapy was prescribed according to the severity-based guidelines established by the Pediatric Eye Disease Investigator Group (PEDIG). Amblyopia severity was categorized as mild (visual acuity better than 6/12), moderate (6/12–6/24), or severe (worse than 6/24). All visual acuity assessments which were conducted using age-appropriate tools, were converted to Snellen-equivalent values. Patients with mild or moderate amblyopia underwent patching therapy of the fellow eye for two hours daily, while those with severe amblyopia received 6 hours of daily patching. Regular follow-up visits were conducted with a pediatric ophthalmologist and orthoptist to assess visual development and adjust the treatment as necessary.^{25,26}

Surgical complications were defined as intraoperative, early postoperative (toxic anterior segment syndrome (TASS) or ophthalmic diseases such as IOL decentration, wound leakage, or corneal edema) and late-onset complications (yttrium-aluminum-garnet (YAG)/membranectomy indicating visual axis opacification, retinal detachment, or glaucoma). Metrics indicative of glaucoma, such as maximum intraocular pressure (IOP) and cup-to-disc ratio, were collected. Additionally, any medications prescribed and previous glaucoma surgeries performed were examined.

Best corrected visual acuity (BCVA) measurements were converted to logMAR for statistical analysis. Visual acuity was assessed according to the child's age and developmental stage at the time of follow-up. Pre-verbal children were evaluated using age-appropriate methods such as Teller Acuity Cards or Cardiff Cards, while verbal and cooperative children were tested with HOTV matching tests or the Snellen chart.

Statistical Analysis

Categorical covariates are presented as frequencies and percentages, while parametric variables are represented as means $\pm$ standard deviations (SD). Data analysis employed various statistical methods depending on the type of variable. ANOVA was applied for normal variable distribution, Kruskal–Wallis for quantitative variables that were not normally distributed, and chi-square for categorical variables. In cases with bilateral cataracts, the patient was defined as a cluster to account for repeated measures. Statistical analyses were performed using R Studio software, version 2021.09.2 Build 382. Results were considered significant at p-values < 0.05 .

Results

Patient Characteristics

The study included 169 eyes of 119 pediatric patients diagnosed with cataracts. Three patients were excluded from the analysis: two with a unilateral cataracts who lacked postoperative follow-up data, and one bilateral case due to severe neurodevelopmental delay and severe systemic comorbidities. All excluded patients were in the >12 months age group. No patients were excluded due to IOL explantation secondary to severe complications.

The study population consisted of 134 (79.3%) patients of Arab descent (Table 1). A familial incidence of pediatric cataracts was observed in approximately one-third of the patients. Parental consanguinity was noted in 37.8% of cases, with a notable prevalence in the 6–12-month age group (66.7%, $p = 0.022$). Concurrent systemic diseases accompanied cataract diagnoses in 13 patients, particularly prominent in the 6–12-month age group (33.3%, $p = 0.012$).

Table 1 Patient Characteristics

N = 119 (%)		0-6 mo. N = 17 (14.3%)	6-12 mo. N = 15 (12.6%)	>12 mo. N = 87 (73.1%)	P-value
Female	53 (44.5)	8 (47.1)	8 (53.3)	37 (42.5)	0.720
Arab descent	97 (79.3)	10 (58.8)	13 (86.7)	74 (85.1)	0.033
Family history	37 (31)	6 (35.3)	6 (40)	25 (28.7)	0.631
Parent kinship	45 (37.8)	8 (47.1)	10 (66.7)	27 (31.0)	0.022
Comorbidities, n (%)					
Systemic disease	13 (10.9)	1 (5.9)	5 (33.3)	7 (8.0)	0.012

Notes: Bold text, Statistical significance.

As detailed in Table 2, bilateral cataracts were present in 138 (81.7%) cases, including all patients in the 6–12-month group. Strabismus was the most common pre-surgery ocular comorbidity, present in 19 (11.2%) cases, with 2 (8.0%) in the 0–6 month group, 2 (9.1%) in the 6–12 month group, and 15 (12.3%) in the >12 month group ($p=0.778$).

Operative Details and Complications

The mean age at surgery was 2.7 (± 1.7), 8.3 (± 1.8), and 69.5 (± 53.8) months for the 0–6, 6–12, and > 12-month groups, respectively ($p<0.001$) (Table 3). The median (IQR) time from diagnosis to surgery was 15.0 (5.0, 35.0) months with the longest period of 24 (13.0, 48.0) months in children older than 12 months ($p = 0.001$).

Lens types, either 3p AcrySof and 1p AcrySof, were used. Regarding operative method, vitrectomy rates were 56.0%, 68.2%, and 63.1% for the 0–6, 6–12, and > 12-month groups, respectively, with no significant difference between groups ($p = 0.17$). Intraoperative complications between age groups were also not statistically different groups. Primarily subluxation occurred in 12.0%, 4.5%, and 5.7% of cases in the 0–6, 6–12, and >12 month groups, respectively ($p=0.352$). No significant differences were observed in other surgical parameters and complications across age groups ($p>0.5$ for all comparisons).

Post-Operative Follow-up

The median (IQR) follow-up period was 77 (31, 144) months: 85 (58, 202) for the 0–6 month group, 76 (44.50, 152.75) for the 6–12 month group, and 69.5 (18.25, 133) months for the > 12-month group ($p = 0.181$). The mean $\pm$ SD BCVA score as presented by logMAR was 0.56 ± 0.55 in the 0-6-month group, 0.28 ± 0.16 in the 6–12-month group, and 0.41 ± 0.58 in the >12 months group ($p = 0.344$) (Table 4).

Additional ocular parameters, including maximum IOP and cup-to-disc ratio, were uniform across the age groups. The outcome of objective refraction testing revealed consistent mean values across age groups: -0.70 ± 4.82 D for the sphere and -1.66 ± 1.44 D for the cylinder. Furthermore, the average axis measurement was 108 ± 56.35 mm, with no notable differences across age groups.

Axial length measurements were performed preoperatively and at the end of follow-up. Before surgery, the mean axial length was 20.67 ± 1.94 mm. It increased significantly with age ($p = 0.001$). Despite these preoperative differences, post-follow-up axial length measurements averaged 22.57 ± 2.00 mm and displayed no significant differences among age groups ($p = 0.12$). However, when considering the change in axial length, the degree of alteration decreased significantly with increasing age ($p = 0.001$).

Table 2 Eye Characteristics

N=169 (%)		0-6 mo N = 25 (14.8%)	6-12 mo N = 22 (13.0%)	>12 mo N = 122 (72.2%)	P value
Bilateral	138 (81.7)	22 (88.0)	22 (100.0)	94 (77.0)	0.025
Cataract type, n (%)					<0.001
Nuclear	95 (56.2)	11 (44.0)	12 (54.5)	72 (59.0)	
Mature	20 (11.8)	6 (24.0)	4 (18.2)	10 (8.2)	
PSC or POLAR	44 (26.0)	2 (8.0)	5 (22.7)	37 (30.3)	
Other	10 (5.9)	6 (24.0)	1 (4.5)	3 (2.5)	
Ophthalmic disease, n (%)					0.053 0.778
Strabismus	19 (11.2)	2 (8.0)	2 (9.1)	15 (12.3)	
Refractive error	3 (1.8)	1 (4.0)	0 (0.0)	2 (1.6)	
Nystagmus	4 (2.4)	0 (0.0)	2 (9.1)	2 (1.6)	
Strabismus and nystagmus	3 (1.8)	2 (8.0)	1 (4.5)	0 (0.0)	

Note: Bold text, Statistical significance.

Abbreviations: N, number of eyes; PSC, posterior subcapsular cataract.

Table 3 Operative Details and Complications

N=169 (%)		0-6 mo. N = 25 (14.8%)	6-12 mo. N = 22 (13.0%)	>12 mo. N = 122 (72.2%)	P value
Age at detection, months (mean (SD))	17.6 (31.3)	1.5 (1.6)	2.5 (2.3)	23.6 (35.0)	<0.001
Age at operation, months (mean (SD))	51.7 (54.0)	2.7 (1.7)	8.3 (1.8)	69.5 (53.8)	<0.001
Time until the operation, months (median (IQR))	15.0 (5.0, 35.0)	1.0 (0.0, 2.0)	5.0 (4.3, 7.8)	24.0 (13.0, 48.0)	<0.001
IOL, n (%)					
3p AcrySof	100 (59.2)	18 (72.0)	17 (77.3)	65 (53.3)	0.140
1p AcrySof	60 (35.5)	6 (24.0)	5 (22.7)	49 (40.2)	
Other	9 (5.3)	1 (4.0)	0 (0.0)	8 (6.6)	
Operative method, n (%)					
Optic capture	13 (7.7)	3 (12.0)	4 (18.2)	6 (4.9)	0.170
Vitrectomy	106 (62.7)	14 (56.0)	15 (68.2)	77 (63.1)	
Other	28 (16.6)	6 (24.0)	1 (4.5)	21 (17.2)	
Operative complications, n (%)					0.352
Subluxation	11 (6.5)	3 (12.0)	1 (4.5)	7 (5.7)	
Capsular tear	2 (1.2)	0 (0.0)	0 (0.0)	2 (1.6)	
Iris prolapse	2 (1.2)	0 (0.0)	0 (0.0)	2 (1.6)	
Subluxation and iris prolapse	1 (0.6)	1 (4.0)	0 (0.0)	0 (0.0)	

Note: Bold text, Statistical significance.

Table 4 Post-Operative Follow-up and Outcomes

N=169 (%)		0-6 mo. N = 25 (14.8%)	6-12 mo. N = 22 (13.0%)	>12 mo. N = 122 (72.2%)	P value
Follow-up, months (median (IQR))	77.00 (31.00, 144.00)	85.00 (58.00, 202.00)	76.00 (44.50, 152.75)	69.50 (18.25, 133.00)	0.181
Age at final follow-up months (median (IQR))	88.00 (48.00, 162.00)	86.00 (56.00, 208.00)	78.50 (43.00, 161.00)	91.00 (48.75, 163.00)	0.974
Eye parameters, mean (SD)					
LogMAR	0.42 (0.55)	0.56 (0.55)	0.28 (0.16)	0.41 (0.58)	0.344
Maximal IOP, mm Hg	14.19 (4.09)	14.48 (3.82)	14.87 (6.24)	14.00 (3.75)	0.702
CDR	0.23 (0.13)	0.21 (0.09)	0.26 (0.15)	0.23 (0.13)	0.582
Objective refraction, D (mean (SD))					
Sphere	-0.70 (4.82)	-1.75 (7.96)	-0.31 (5.04)	-0.51 (3.63)	0.497
Cylinder	-1.66 (1.44)	-1.43 (1.62)	-1.74 (2.04)	-1.70 (1.26)	0.719
Axis and axial length, mm (mean (SD))					
Axis	108.45 (56.35)	112.05 (44.63)	96.88 (62.49)	109.74 (57.99)	0.656
Preoperative axial length	20.67 (1.94)	18.29 (1.36)	19.00 (0.60)	21.50 (1.56)	<0.001
Post-operative axial length	22.57 (2.11)	23.30 (3.06)	21.17 (2.78)	22.65 (1.65)	0.120
Delta axial length	2.23 (2.13)	6.128 (2.69)	2.9 (0.8)	1.339 (1.1)	<0.001
Post-operative complications, n (%)					
Glaucoma (%)					
No Glaucoma	99 (97.1)	14 (100.0)	10 (76.9)	75 (100.0)	<0.001
Suspected glaucoma	2 (1.9)	0 (0.0)	2 (9.0)	0 (0.0)	
Glaucoma	1 (1.0)	0 (0.0)	1 (4.5)	0 (0.0)	
Retinal detachment	3 (1.77)	1 (4.0)	1 (4.54)	1 (0.81)	0.244
TASS	19 (11.3)	3 (12.0)	2 (9.5)	14 (11.5)	0.960
YAG/Membranectomy	30 (17.8)	9 (36.0)	5 (22.7)	16 (13.1)	0.020
Membranectomy	25 (14.8)	8 (32.0)	3 (13.7)	14 (14.5)	

Note: Bold text, Statistical significance.

Abbreviations: N, number of eyes; CDR, cup-to-disc ratio; TASS, toxic anterior syndrome; YAG, yttrium-aluminum-garnet.

Potential secondary outcomes were monitored during the follow-up period. Glaucoma was diagnosed in only one case, accounting for 0.6% of the study population. This patient was in the 6–12-month age group. Two other individuals in the same group were suspected of having glaucoma.

One patient from each of the three age groups had retinal detachment (1.8%). The rates were 4% for the 0–6-month-old age group, 4.5% for the 6–12-month-old group, and 0.8% for ages 12 and above ($p = 0.244$). TASS was identified in 19 patients (11.3%); 3 (12.0%) from the 0–6-month age group, 2 (9.5%) from the 6–12-month group, and 14 (11.5%) in the >12 months group ($p = 0.960$).

The incidence of YAG/membranectomy varied significantly among the age groups. As shown in Table 4, 9 cases (36%) were observed in the infant group, 5 cases (22%) in the 6–12-month group, and 16 (13%) in the 1-year or older group ($p = 0.020$).

Stratification of Outcomes by Laterality

Given the known differences in visual outcomes, amblyopia risk, and surgical prognosis between unilateral and bilateral cataracts, outcomes were analyzed separately for these cases (Table 5).

Among unilateral cases, 28 patients (90.3%) were observed in the >12 months group, while only 3 (9.7%) were in the <6 months age group. Visual outcomes, as measured by mean logMAR $\pm$ SD, were 1.60 ± 0.37 in the <6 months group and 0.65 ± 0.74 in the >12 months group, with no significant difference ($p = 0.253$). All three patients in the <6 months group underwent YAG/membranectomy (100%), compared to 17.9% in the >12 months group ($p = 0.012$). No cases of glaucoma, suspected glaucoma, or retinal detachment were observed in the unilateral cataract cohort.

Table 5 Long-Term Postoperative Outcomes Stratified by Laterality and Age at Surgery

Unilateral cases					
N=31 (18.3%)		0-6 mo. N = 3 (9.7%)	6-12 mo. N = 0 (0.0%)	>12 mo. N = 28 (90.3%)	P value
Eye parameters, mean (SD)					
LogMAR	0.75 (0.76)	1.6 (0.37)		0.65 (0.74)	0.253
Post-operative complications, n (%)					
Glaucoma	0 (0.0)	0 (0.0)		0 (0.0)	-
Retinal detachment	0 (0.0)	0 (0.0)		0 (0.0)	-
TASS	4 (12.9)	0 (0.0)		4 (12.9)	0.651
YAG/Membranectomy	8 (25.8)	3 (100.0)		5 (17.9)	0.012
Bilateral cases					
N=138 (81.7%)		0-6 mo. N = 22 (15.9%)	6-12 mo. N = 22 (15.9%)	>12 mo. N = 94 (68.2%)	P value
Eye parameters, mean (SD)					
LogMAR	0.26 (0.41)	0.27 (0.30)	0.16 (0.18)	0.28 (0.47)	0.496
Post-operative complications, n (%)					
Glaucoma (%)					0.003
Suspected glaucoma	2 (1.4)	0 (0.0)	2 (9.0)	0 (0.0)	
Glaucoma	1 (0.1)	0 (0.0)	1 (4.5)	0 (0.0)	
Retinal detachment	3 (2.2)	1 (4.5)	1 (4.5)	1 (1.1)	0.390
TASS	15 (10.9)	3 (13.6)	2 (9.5)	10 (10.6)	0.898
YAG/Membranectomy	22 (15.9)	6 (27.3)	5 (22.7)	11 (11.7)	0.127

Note: Bold text, Statistical significance.

Abbreviations: N, number of eyes; TASS, toxic anterior syndrome; YAG, yttrium-aluminum-garnet.

Among bilateral cases, 22 (15.9%) were observed in the <6 months of age, 22 (15.9%) in the 6–12 months group, and 94 patients (68.2%) in the >12 months group. Visual outcomes were 0.26 ± 0.41 in the <6 months group, 0.27 ± 0.30 in the 6–12 months group, and 0.16 ± 0.18 in the >12 months group, with no significant difference between groups ($p = 0.496$). Suspected glaucoma was observed in two patients (9.0%) in the 6–12 months group, and confirmed glaucoma was diagnosed in one patient (4.5%) in the same group ($p = 0.003$). Retinal detachment occurred in 1 patient (4.5%) in the <6 months group, 1 (4.5%) in the 6–12 months group, and 1 (1.1%) in the >12 months group ($p = 0.390$).

YAG/membranectomy was performed in 6 eyes (27.3%) in the <6 months group, 5 (22.7%) in the 6–12 months group, and 11 (11.7%) in the >12 months group, with no significant difference between age groups ($p = 0.127$).

In contrast to the unilateral cohort, no significant association was found between age at surgery and the need for YAG/membranectomy in bilateral cases.

Discussion

The present study explored the use of primary IOL implantation for pediatric cataract management across various age groups, incorporating a population of mixed ethnicities in the southern region of Israel. Given the limited adherence to postoperative care and the clinical concern for prolonged periods of uncorrected aphakia, primary IOL implantation was selected for all patients, including those younger than 6 months of age. This allowed for evaluation of this approach and its outcomes across different age groups. The results indicated no significant differences between age groups in visual acuity or intraoperative and postoperative complications, such as glaucoma, TASS, or retinal detachment, except for an increased rate of YAG/membranectomy in younger patients, predominantly unilateral cases, necessitating further surgical intervention.

In our study, the median follow-up period was 77 months (6.4 years), providing a long-term assessment of outcomes. The primary outcome, BCVA measured in logMAR units, did not differ significantly across age groups (<6 months, 6–12 months, >12 months), with mean logMAR $\pm$ SD values of 0.56 ± 0.55 , 0.28 ± 0.16 , and 0.41 ± 0.58 , respectively ($p = 0.344$). The relatively better BCVA observed in the 6–12-month group may, in part, reflect that this group included only bilateral cases. Those findings are similar to previous research, including the IATS, which reported comparable visual acuity outcomes between different age groups. Studies by Poole et al, Tadros et al, and Negalur et al similarly demonstrated that early primary IOL implantation in infancy can achieve visual outcomes comparable to those achieved with alternative approaches.^{7,8,10,15,17–20} In addition, The Toddler Aphakia and Pseudophakia Treatment Study Registry, evaluating patients ages 1 to 7 months with bilateral cataracts, reported a median logMAR of 0.35 in both aphakic and pseudophakic children.¹³ This underscores the broad consistency of visual acuity outcomes, regardless of the treatment modality or age group.

In the current study, objective refraction, as denoted by sphere values, revealed a median value of $-0.70 \text{ D} \pm 4.82 \text{ D}$ across the study population. Upon closer examination of the 0–6 month age group, the median was slightly higher at $-1.75 \pm 7.96 \text{ D}$. Despite this, the variation was not statistically significant, indicating a general uniformity in objective refraction across the age groups in our study. In our surgical protocol, the refractive target for infants under 6 months was set at $+6.0$ to $+8.0$ diopters of hyperopia, adjusted according to the infant's age at surgery to account for expected axial elongation. Thus, the mild myopic shift observed at long-term follow-up among the youngest age group likely reflects anticipated refractive changes associated with ocular growth.²⁴

Previous reports from the IATS described an overall intraoperative complication rate of 28% during the first postoperative year following primary IOL implantation. Additionally, adverse events were reported in 77% of patients in the IOL group compared to 25% in the contact lens group ($p < 0.0001$), and additional intraocular surgeries were required in 63% of the IOL group versus 12% in the contact lens group during the same period ($p < 0.0001$).⁹ During the longer-term follow-up of 5 years, the incidence of adverse events increased slightly in the contact lens group but decreased in the IOL group.¹¹ The IATS reported a 16% incidence of glaucoma or suspected glaucoma in the IOL group and 9% in the contact lens group at one year postoperatively, increasing to 28% and 35%, respectively, after five years of follow-up.^{10,27} In addition, high rates of visual axis opacification were also observed: 81% in the IOL group and 56% in the contact lens group at 5 years, with YAG/membranectomy required in 72% and 16% of these groups, respectively.⁹

In our cohort of patients who underwent primary IOL implantation, postoperative complications such as TASS, retinal detachment and glaucoma were not statistically different across the different age groups; consistent with findings from previous studies.^{17–20,28,29} These complications remained non-significant even when analyzed separately for unilateral

and bilateral cases. However, the increased incidence of YAG/membranectomy observed in the <6 months age group is primarily attributable to unilateral cases ($p=0.012$), as bilateral cases were not significantly different for this complication ($p=0.127$). This supports findings from the IATS, which included only unilateral cases and similarly reported higher rates of visual axis opacification requiring YAG or membranectomy interventions among infants operated on before 6 months of age.⁹ Nevertheless, within the <6 months group 64% of patients in our cohort who underwent primary IOL implantation without any complications did not require any further surgical interventions. Thus, for these infants, the cataract was effectively managed through a single surgical procedure.

Some studies have highlighted the cost and burden associated with contact lens use and secondary IOL implantation, suggesting that socioeconomic factors and parental involvement are important in determining treatment in pediatric cataracts.^{30,31} In line with these observations, and consistent with the findings of the IATS, we believe that primary IOL implantation could be considered a valid strategy for selected children younger than 6 months of age, particularly in populations characterized by low socioeconomic status, high birth rates, and limited compliance with contact lens management. In such settings, primary IOL implantation may help reduce the risk of prolonged uncorrected aphakia, and infections related to improper contact lens use, while providing visual outcomes comparable to those achieved with secondary IOL implantation, with a similar overall complication rate. The only notable difference observed was a higher incidence of YAG/Membranectomy among unilateral cases operated before 6 months of age. In these unilateral cases, surgeons should carefully weigh the risk-benefit ratio, specifically evaluating the potential risk of requiring additional interventions due to postoperative complications against the risk of poor optical correction.

This study was limited by its retrospective nature. In addition, the absence of a control group limited direct comparison between treatments, particularly with prospective studies such as the IATS, which included a larger sample size and a standardized study protocol. The study sample was primarily composed of Arab and Bedouin children, which could limit the applicability of the results to a broader, more diverse population. In addition, the relatively small sample size in the <6 months age group may limit the robustness of statistical comparisons. Most of the cases in our cohort were bilateral, which may further influence the generalizability of the findings, particularly in comparison to studies involving mostly unilateral cases. Furthermore, the absence of a control group limited direct comparison between treatments. Although substantial, the follow-up duration may not capture the full spectrum of long-term complications or the impact of primary IOL implantation on visual outcomes as patients age.

In conclusion, our findings suggest that primary IOL implantation for pediatric cataracts resulted in comparable visual acuity and overall complication rates across all age groups. However, we observed a higher incidence of YAG/membranectomy in the 0–6-month age group, mainly in unilateral cases. It is important to note that 64% of patients in this group still avoided additional surgery. We suggest that IOL implantation could be considered in children under 6 months of age, especially those with low compliance with contact lens use or when caregivers prefer alternatives to contact lens management.

Summary

This study revealed that primary intraocular lens implantation effectively treated pediatric cataracts across various age groups, with consistent outcomes; although, children <6 months had elevated YAG/membranectomy rates.

Data Sharing Statement

The datasets used and/or analyzed during the current retrospective study are available from the corresponding author upon reasonable request.

Ethics Statement

This retrospective study was conducted in accordance with the ethical standards of the Soroka University Medical Center Ethics Committee (IOL-2000-2020) and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Given the retrospective nature of the study, formal consent was not required. All patient data were anonymized and handled in accordance with institutional and national guidelines to ensure confidentiality.

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Disclosure

The authors declare that there is no conflict of interest in this work.

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