

Visual Acuity and Ophthalmic Outcomes 5 Years After Cataract Surgery Among Children Younger Than 13 Years

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IMPORTANCE Cataract is an important cause of visual impairment in children. Data from a large pediatric cataract surgery registry can provide real-world estimates of visual outcomes and the 5-year cumulative incidence of adverse events.

OBJECTIVE To assess visual acuity (VA), incidence of complications and additional eye operations, and refractive error outcomes 5 years after pediatric lensectomy among children younger than 13 years.

DESIGN, SETTING, AND PARTICIPANTS This prospective cohort study used data from the Pediatric Eye Disease Investigator Group clinical research registry. From June 2012 to July 2015, 61 eye care practices in the US, Canada, and the UK enrolled children from birth to less than 13 years of age who had undergone lensectomy for any reason during the preceding 45 days. Data were collected from medical record reviews annually thereafter for 5 years until September 28, 2020.

EXPOSURES Lensectomy with or without implantation of an intraocular lens (IOL).

MAIN OUTCOMES AND MEASURES Best-corrected VA and refractive error were measured from 4 to 6 years after the initial lensectomy. Cox proportional hazards regression was used to assess the 5-year incidence of glaucoma or glaucoma suspect and additional eye operations. Factors were evaluated separately for unilateral and bilateral aphakia and pseudophakia.

RESULTS A total of 994 children (1268 eyes) undergoing bilateral or unilateral lensectomy were included (504 [51%] male; median age, 3.6 years; range, 2 weeks to 12.9 years). Five years after the initial lensectomy, the median VA among 701 eyes with available VA data (55%) was 20/63 (range, 20/40 to 20/100) in 182 of 316 bilateral aphakic eyes (58%), 20/32 (range, 20/25 to 20/50) in 209 of 386 bilateral pseudophakic eyes (54%), 20/200 (range, 20/50 to 20/618) in 124 of 202 unilateral aphakic eyes (61%), and 20/65 (range, 20/32 to 20/230) in 186 of 364 unilateral pseudophakic eyes (51%). The 5-year cumulative incidence of glaucoma or glaucoma suspect was 46% (95% CI, 28%-59%) in participants with bilateral aphakia, 7% (95% CI, 1%-12%) in those with bilateral pseudophakia, 25% (95% CI, 15%-34%) in those with unilateral aphakia, and 17% (95% CI, 5%-28%) in those with unilateral pseudophakia. The most common additional eye surgery was clearing the visual axis, with a 5-year cumulative incidence of 13% (95% CI, 8%-17%) in participants with bilateral aphakia, 33% (95% CI, 26%-39%) in those with bilateral pseudophakia, 11% (95% CI, 6%-15%) in those with unilateral aphakia, and 34% (95% CI, 28%-39%) in those with unilateral pseudophakia. The median 5-year change in spherical equivalent refractive error was -8.38 D (IQR, -11.38 D to -2.75 D) among 89 bilateral aphakic eyes, -1.63 D (IQR, -3.13 D to -0.25 D) among 130 bilateral pseudophakic eyes, -10.75 D (IQR, -20.50 D to -4.50 D) among 43 unilateral aphakic eyes, and -1.94 D (IQR, -3.25 D to -0.69 D) among 112 unilateral pseudophakic eyes.

CONCLUSIONS AND RELEVANCE In this cohort study, development of glaucoma or glaucoma suspect was common in children 5 years after lensectomy. Myopic shift was modest during the 5 years after placement of an intraocular lens, which should be factored into implant power selection. These results support frequent monitoring after pediatric cataract surgery to detect glaucoma, visual axis obscuration causing reduced vision, and refractive error.

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Childhood cataract is a cause of visual impairment requiring surgery and intensive follow-up. The eyes undergoing surgery may develop amblyopia, secondary opacification of the visual axis, glaucoma, anisometropia, strabismus, or retinal detachment or they may require additional surgery.¹ To our knowledge, the incidence of these adverse events and visual outcomes 5 years after surgery have not been prospectively studied in a large cohort of infants and children.

To characterize management and outcomes of cataract surgery in children, the Pediatric Eye Disease Investigator Group developed a data registry for children from birth to less than 13 years of age who underwent lensectomy for any reason. Data collection was performed annually for 5 years. We assessed visual outcomes, complications, and additional eye operations performed within the first 5 years after cataract surgery in children.

Methods

For this cohort study, the study protocol and informed consent forms compliant with the Health Insurance Portability and Accountability Act were approved by each participating site's institutional review board. The parent or guardian of each child provided written informed consent for data collection, and assent was obtained from children aged 7 years or older. Participants received no incentives or compensation. This study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guideline.

Data Collection

Between June 2012 and July 2015, 61 eye care practices (57 in the US, 3 in Canada, and 1 in the UK) prospectively enrolled children from birth to less than 13 years of age who had undergone lensectomy for any reason during the preceding 45 days into the Pediatric Eye Disease Investigator Group's clinical research registry. Surgery was performed before enrollment. Each year thereafter for 5 years until September 28, 2020, data were collected from medical record reviews. Data for fellow eyes were included if they underwent surgery.

Study-Specific Definitions

Participants were classified as having unilateral or bilateral lensectomy. Bilateral surgery was defined as surgery in both eyes by the last completed annual data collection or by lensectomy in the fellow eye before study enrollment.

Glaucoma and glaucoma suspect are defined in eTable 1 in Supplement 1. When the 2 diagnoses were combined for reporting, we use the term *glaucoma-related adverse event*. Additional diagnoses and complications including amblyopia and intraocular lens (IOL) centration were reported based on the investigator's diagnosis given on the case report forms.

Statistical Analysis

For analysis, the best-corrected monocular optotype visual acuity (VA) was converted to logMAR (−0.2 to 1.7 by 0.1 logMAR across the Snellen equivalent range of 20/12 to

Key Points

Question What are the visual outcomes and complications within 5 years after pediatric cataract surgery among children younger than 13 years?

Findings In this cohort study of 994 children (1268 eyes) undergoing lensectomy, the median refractive error in pseudophakic eyes at 5 years after surgery was minimally myopic, and age-normal visual acuity was uncommon. The 5-year cumulative incidence of glaucoma or glaucoma suspect was 46% among children with bilateral aphakia and 25% among children with unilateral aphakia, and surgery to clear the visual axis was performed in 1 of 3 pseudophakic eyes.

Meaning These results support frequent monitoring after pediatric cataract surgery to detect glaucoma and visual axis obscuration causing reduced vision and for management of refractive error.

<20/800). Visual acuity scores worse than the quantifiable range of the VA testing method were assigned logMAR values of 1.8 (20/1262) for counting fingers and 1.9 (20/1589) for hand motion, light perception, no light perception, or prosthesis. Visual acuity and refractive error were included in the analysis if testing was performed between 4 years (≥ 48 months) and 6 years (≤ 72 months) after the initial lensectomy. Visual acuity outcomes for traumatic cataract were excluded. Eyes were considered to have age-normal VA if the best-corrected VA was 20/40 or better at 4 years of age, 20/32 or better at 5 or 6 years of age, and 20/25 or better at 7 years or older.^{2,3} The proportion of eyes with age-normal VA was tabulated, and generalized estimating equations were used to account for the correlation between eyes of participants who underwent bilateral lensectomy.

A Cox proportional hazards regression model was used to estimate the 5-year cumulative incidence and corresponding 95% CI for each complication and additional surgery (Table). The date of a complication's onset was not collected; thus, the date of the most recent office visit at which the complication was reported was used to estimate the cumulative incidence for each complication. Complications were included in the analysis if reported up to 5.5 years after lensectomy to estimate the cumulative incidence. The actual date of surgery was used to document the timing of additional surgery, and operations were included in the analysis if performed within 5 years after lensectomy. Cox proportional hazards regression models were used to evaluate whether the following factors reported at the initial lensectomy were associated with surgery to clear the visual axis: age at lensectomy, performance of anterior vitrectomy, performance of other concomitant ocular surgical procedures, whether surgical complications were reported, presence of anterior segment abnormalities, self-identified race and ethnicity (non-Hispanic White vs Black or African American, Hispanic, or other), and sex. Factors were evaluated separately for eyes with aphakia and pseudophakia. The robust sandwich variance estimator was used to adjust for the correlation between eyes of participants who underwent bilateral lensectomy. Factors were considered

Table. Five-Year Cumulative Incidence of Complications and Surgical Procedures

Complication	Bilateral aphakia			Bilateral pseudophakia			Unilateral aphakia			Unilateral pseudophakia		
	Eyes, No.	Events, No.	5-y Incidence, % (95% CI) ^a	Eyes, No.	Events, No.	5-y Incidence, % (95% CI) ^a	Eyes, No.	Events, No.	5-y Incidence, % (95% CI) ^a	Eyes, No.	Events, No.	5-y Incidence, % (95% CI) ^a
Intraocular complications												
Corneal calcification	305	7	3 (1-5)	378	7	2 (0-4)	199	7	4 (1-7)	345	15	10 (0-18)
Endophthalmitis	305	1	0 (0-1)	378	0	0	199	0	0	345	1	0 (0-1)
Glaucoma-related adverse events ^b	276	84	46 (28-59)	345	14	7 (1-12)	169	30	25 (15-34)	265	20	17 (5-28)
Glaucoma ^b	276	67	39 (21-52)	345	11	5 (1-8)	169	22	17 (9-24)	265	9	8 (1-14)
Glaucoma suspect ^b	276	17	8 (3-13)	345	3	3 (0-8)	169	8	8 (2-13)	265	11	10 (0-19)
Iris-posterior synechiae	305	11	4 (1-7)	378	5	1 (0-3)	199	14	8 (4-12)	345	8	3 (1-5)
Peripheral anterior synechiae	305	8	3 (1-5)	378	3	1 (0-2)	199	5	3 (0-5)	345	1	0 (0-1)
Persistent intraocular inflammation	305	5	2 (0-3)	378	3	1 (0-3)	199	7	5 (1-8)	345	10	3 (1-5)
Retinal detachment	305	2	1 (0-2)	378	5	2 (0-3)	199	4	2 (0-4)	345	8	4 (0-7)
Surgically caused iris abnormalities	305	22	9 (4-13)	378	8	4 (0-9)	199	11	6 (3-10)	345	6	2 (0-4)
Visual axis opacification	305	37	13 (8-18)	378	122	40 (32-47)	199	23	13 (8-18)	345	123	42 (36-47)
Intraocular surgery not at time of lensectomy												
Secondary IOL implant	305	66	27 (18-34)	378	2	1 (0-2)	199	54	32 (24-38)	345	0	0
Glaucoma surgery ^b	276	25	10 (6-14)	345	2	1 (0-2)	169	8	5 (2-9)	265	1	1 (0-2)
Retinal detachment surgery	305	2	1 (0-2)	378	4	1 (0-3)	199	2	1 (0-2)	345	4	1 (0-2)
Surgery to clear the visual axis	305	37	13 (8-17)	378	105	33 (26-39)	199	21	11 (6-15)	345	102	34 (28-39)
Age at lensectomy, y												
≤7	292	37	13 (8-18)	255	51	22 (15-28)	185	21	12 (7-16)	209	58	32 (25-39)
>7	13	0	0	123	54	55 (41-65)	14	0	0	136	44	37 (28-45)
Type of surgery performed to clear the visual axis ^c												
Laser only	37	1	3	105	85	81	21	1	5	102	80	78
Membranectomy only	37	29	78	105	19	18	21	20	95	102	19	19
Both	37	4	11	105	1	<1	21	0	0	102	3	3
Not reported	37	3	8	105	0	0	21	0	0	102	0	0
Extraocular complications and surgical procedures												
Amblyopia	171	82	60 (48-69)	246	70	53 (21-72)	199	128	91 (35-99)	345	163	59 (51-65)
Nystagmus ^d	135	72	60 (49-68)	224	21	12 (7-16)	191	42	26 (18-33)	335	22	18 (7-28)
Strabismus	171	117	79 (69-86)	246	98	50 (37-60)	199	165	94 (85-97)	345	164	75 (50-88)
Strabismus surgery ^e	171	11	7 (3-11)	246	20	9 (5-13)	199	27	17 (10-22)	345	21	8 (4-11)

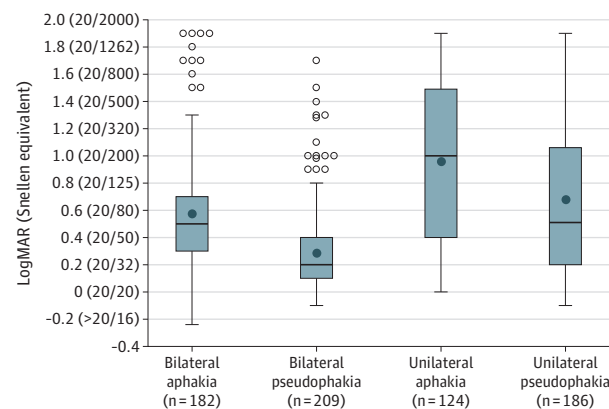
Abbreviation: IOL, intraocular lens.

^a Details on the Cox proportional hazards regression model are given in the Statistical Analysis subsection of the Methods section. A 95% CI was not reported when the cumulative incidence was 0%.^b Eyes with ocular trauma and eyes with preexisting glaucoma were excluded from analyses.^c The proportion was calculated by dividing the number of eyes in which

surgery was performed by the number of eyes in which surgery was performed to clear the visual axis; 95% CIs were not calculated.

^d Eyes with nystagmus at enrollment were excluded from analyses.^e The median age at lensectomy for participants who underwent strabismus surgery was 3 months in the bilateral aphakia group, 3 years in the bilateral pseudophakia group, 4 months in the unilateral aphakia group, and 3 years in the unilateral pseudophakia group.

Figure 1. Visual Acuity 5 Years After Lensectomy by Laterality of Surgery and Primary Intraocular Lens Implantation



Monocular visual acuity was converted to logMAR. Three ordinal categories were defined for visual acuities beyond the range of the testing method, and each was assigned an incremental logMAR value, starting 0.1 logMAR increment worse than 20/800: (1) worse than 20/800 = 1.7 logMAR, (2) counting fingers = 1.8 logMAR (20/1262), and (3) hand motions, light perception, no light perception, or prosthesis = 1.9 logMAR (20/1589). The top of each box represents the 75th percentile of the data and the bottom, the 25th percentile. Horizontal lines indicate group medians; filled circles, group means; and open circles, statistical outliers. The bars extending above and below each box represent 1.5 times the IQR or the maximum and minimum observed values within the range if not as extreme as the calculated value.

significant if the *P* value was <.01; 99% CIs were calculated for hazard ratios (HRs) to adjust for multiple testing.

Analyses and tabulations were stratified by whether (1) an IOL was implanted at the initial lensectomy and (2) the eye belonged to a participant who underwent bilateral or unilateral lensectomy. Analyses were performed using SAS, version 9.4 (SAS Institute). All CIs and *P* values are 2-sided.

Results

The Pediatric Eye Disease Investigator Group cataract surgery registry enrolled 994 children (1268 eyes) undergoing bilateral or unilateral lensectomy (504 [51%] male; median age, 3.6 years; range, 2 weeks to 12.9 years). Bilateral surgery was performed in 428 participants (43%) (eTable 2 in Supplement 1). An IOL was implanted in 750 eyes (59%) (eTable 3 in Supplement 1). There were 120 secondary IOL insertions into aphakic eyes and 2 IOL exchanges during the 5 years of follow-up.

Of the 994 enrolled participants, 33 (3%) did not return after enrollment. Eighty-two participants (8%) were last seen in the first year of follow-up, 62 (6%) in the second year of follow-up, 82 (8%) in the third year of follow-up, and 78 (8%) in the fourth year of follow-up. A total of 657 participants (66%) were last seen in the fifth year of follow-up, including 131 (20%) with bilateral aphakia, 158 (24%) with bilateral pseudophakia, 142 (22%) with unilateral aphakia, and 226 (34%) with unilateral pseudophakia. Baseline characteristics for participants seen in the fifth year of follow-up were similar to those of participants last seen before the fifth year.

Visual Acuity and Amblyopia

After excluding 86 eyes in which lensectomy was performed to remove traumatic cataract, the best-corrected letter optotype VA was reported at 5 years in 701 of 1182 eyes (59%). Visual acuity worse than 20/800 was reported for 48 eyes (7%), including 28 (4%) with quantifiable VA worse than 20/800, 7 (1%) with counting fingers, and 13 (2%) with hand motions, light perception, or no light perception. Baseline characteristics were similar between eyes with and without VA measurements at 5 years (eTable 4 in Supplement 1).

The median VA among 701 eyes with available VA data was 20/63 (range, 20/40 to 20/100) in 182 of 316 bilateral aphakic eyes (58%), 20/32 (range, 20/25 to 20/50) in 209 of 386 bilateral pseudophakic eyes (54%), 20/200 (range, 20/50 to 20/618) in 124 of 202 unilateral aphakic eyes (61%), and 20/65 (range, 20/32 to 20/230) in 186 of 364 unilateral pseudophakic eyes (51%) (Figure 1). Age-normal VA was achieved in 37 bilateral aphakic eyes (20%; 95% CI, 13%-27%), 88 bilateral pseudophakic eyes (42%; 95% CI, 34%-50%), 15 unilateral aphakic eyes (12%; 95% CI, 7%-19%), and 34 unilateral pseudophakic eyes (18%; 95% CI, 13%-25%). The 5-year cumulative incidence of amblyopia by group is reported in the Table.

Among 376 eyes in children without traumatic cataract who were younger than 6 months at lensectomy, VA data were reported for 237 eyes: 231 (61%) had aphakia and 6 (2%) had pseudophakia. In bilateral aphakic eyes, logMAR VA ranged from -0.24 to 1.9, with a median VA of 20/63 (range, 20/40 to 20/100). In unilateral aphakic eyes, logMAR VA ranged from 0 to 1.9, with a median VA of 20/200 (range, 20/50 to 20/632). For infants with bilateral cataracts, there were no differences in VA at 5 years between those who underwent surgery before 6 weeks of age, from 6 weeks to less than 3 months of age, and from 3 to 6 months of age. However, in infants with unilateral cataracts, better VA was observed when lensectomy was performed at a younger age (eFigure 1 in Supplement 1).

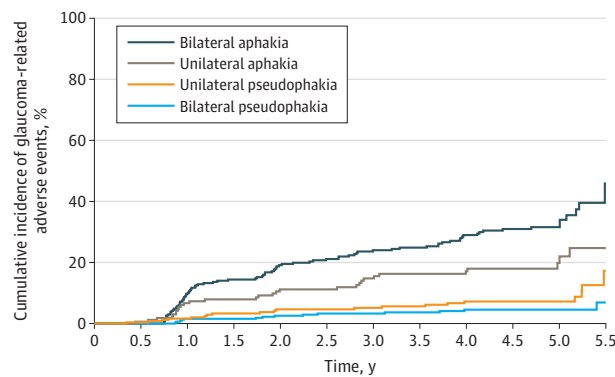
Glaucoma-Related Adverse Events

Glaucoma-related adverse events were reported in 148 of the 1055 eyes (14%) in children who did not have a preoperative diagnosis of glaucoma or ocular trauma. The incidence increased throughout the 5-year period (Figure 2). The 5-year cumulative incidence was 46% (95% CI, 28%-59%) in participants with bilateral aphakia, 7% (95% CI, 1%-12%) in those with bilateral pseudophakia, 25% (95% CI, 15%-34%) in those with unilateral aphakia, and 17% (95% CI, 5%-28%) in those with unilateral pseudophakia. The 5-year cumulative incidence is reported in eTable 5 in Supplement 1 for children younger than 6 months at lensectomy and in eTable 6 in Supplement 1 for children aged 6 months to less than 2 years at lensectomy.

Surgery to Clear the Visual Axis

The 5-year cumulative incidence of surgery to clear the visual axis was 13% (95% CI, 8%-17%) in bilateral aphakic eyes, 33% (95% CI, 26%-39%) in bilateral pseudophakic eyes, 11% (95% CI, 6%-15%) in unilateral aphakic eyes, and 34% (95% CI, 28%-39%) in unilateral pseudophakic eyes (Figure 3). Out of

Figure 2. Cumulative Incidence of Glaucoma-Related Adverse Events



A Cox proportional hazards regression model was used to estimate the 5-year cumulative incidence of glaucoma-related adverse events. The robust sandwich variance estimator was used to adjust for the correlation between eyes of participants who contributed data from both eyes to the analysis. The date of onset for glaucoma-related adverse events was not collected; thus, the date of the most recent office visit at which they were reported was used to estimate the 5-year cumulative incidence. Glaucoma-related adverse events reported up to 5.5 years after lensectomy were included in the analysis.

262 eyes that received surgery to clear the visual axis, anterior vitrectomy or membranectomy was performed in 87 (33%), Nd:YAG laser in 167 (64%), and both procedures in 8 (3%). The type of surgery performed to clear the visual axis was not reported for 3 eyes (1%).

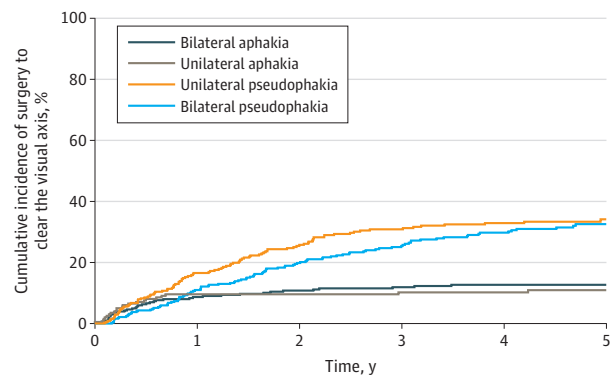
Among pseudophakic eyes, the rate of surgery to clear the visual axis was lower when anterior vitrectomy was performed during lensectomy (HR, 0.14; 99% CI, 0.08-0.24; $P < .001$) and higher when ocular trauma was the cause of lensectomy (HR, 2.11; 99% CI, 1.04-4.28; $P = .007$). Other factors associated with surgery to clear the visual axis were not evaluated in aphakic eyes because few events were reported.

In children younger than 6 months at lensectomy, the 5-year cumulative incidence of surgery to clear the visual axis was 14% (95% CI, 8%-20%) in 232 bilateral aphakic eyes and 12% (95% CI, 6%-17%) in 131 unilateral aphakic eyes. In children aged 6 months to younger than 2 years at lensectomy, the 5-year cumulative incidence of surgery to clear the visual axis was 10% (95% CI, 0%-19%) in 35 bilateral aphakic eyes, 12% (95% CI, 0%-23%) in 42 bilateral pseudophakic eyes, 10% (95% CI, 0%-19%) in 39 unilateral aphakic eyes, and 26% (95% CI, 12%-38%) in 47 unilateral pseudophakic eyes.

Other Findings and Eye Operations

The IOL was centered in 148 of 158 bilateral pseudophakic eyes (94%) and in 158 of 170 unilateral pseudophakic eyes (93%) 5 years after lensectomy. Intraocular surgery was performed in 406 eyes (33%), most often to clear the visual axis (membranectomy and laser capsulotomy in 207 pseudophakic eyes [29%]) or to implant a secondary IOL (120 of 504 eyes [24%]). The 5-year cumulative incidence of other complications and eye operations in the cohort is reported in the Table. Retinal detachment was reported in 19 of 1227 eyes (2%). Glaucoma surgery was performed in 36 of 1055 eyes

Figure 3. Cumulative Incidence of Surgery to Clear the Visual Axis



A Cox proportional hazards regression model was used to estimate the 5-year cumulative incidence of surgery to clear the visual axis. The robust sandwich variance estimator was used to adjust for the correlation between outcomes collected for participants who underwent bilateral lensectomy by the last documented office visit. The actual date of surgery was known and was used to document the timing of the surgery.

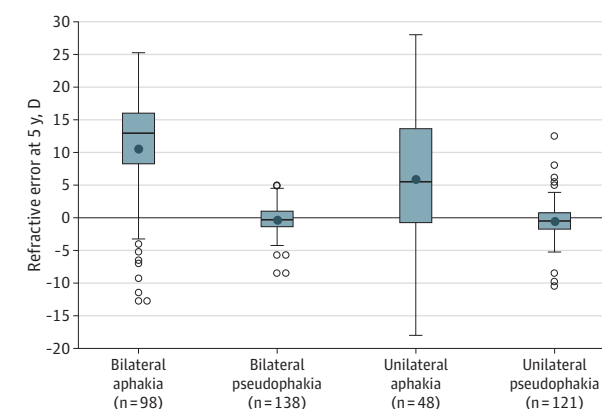
(3%), of which 33 were aphakic (92%). Two IOLs were exchanged owing to dislocation. The 5-year cumulative incidence of complications and additional eye operations is reported in eTable 5 in Supplement 1 for children younger than 6 months at the time of lensectomy and in eTable 6 in Supplement 1 for children aged 6 months to less than 2 years at the time of lensectomy. In children with aphakia, the 5-year cumulative incidence of strabismus was 79% among those with bilateral aphakia and 94% among those with unilateral aphakia. The 5-year cumulative incidence was slightly less among children with pseudophakia (50% among those with bilateral pseudophakia and 75% among those with unilateral pseudophakia). Few of these children had strabismus surgery within 5 years (Table).

Refractive Error

The median 5-year change in spherical equivalent refractive error was -8.38 D (IQR, -11.38 D to -2.75 D) in 89 bilateral aphakic eyes, -1.63 D (IQR, -3.13 D to -0.25 D) in 130 bilateral pseudophakic eyes, -10.75 D (IQR, -20.50 D to -4.50 D) in 43 unilateral aphakic eyes, and -1.94 D (IQR, -3.25 D to -0.69 D) in 112 unilateral pseudophakic eyes. Refractive error in pseudophakic eyes was clustered around emmetropia (Figure 4). A myopic shift in spherical equivalent refractive error from the refraction performed within 45 days of surgery was observed in all 4 subgroups, although the magnitude of change in pseudophakic eyes was small (eTable 7 in Supplement 1).

The median absolute value of spherical equivalent anisometropia in unilateral pseudophakia was 3.38 D (IQR, 1.75-10.25 D); out of 114 unilateral pseudophakic eyes with non-missing anisometropia data, 79 (69%) had anisometropia of 2.00 D or less (eFigure 2 in Supplement 1). Compared with the fellow eye that did not undergo surgery, 67 pseudophakic eyes (59%) were more myopic or less hyperopic, and 39 (34%) were more hyperopic or less myopic.

Figure 4. Refractive Error at 5 Years by Laterality of Surgery and Primary Intraocular Lens Implantation



The top of each box represents the 75th percentile of the data and the bottom, the 25th percentile. Horizontal lines indicate group medians; filled circles, group means; and open circles, statistical outliers. The bars extending above and below each box represent 1.5 times the IQR, or the maximum or minimum observed value within the range if not as extreme as the calculated value.

Discussion

This prospective cohort study using data from a cataract registry provides estimates of the 5-year cumulative incidences of outcomes among children younger than age 13 years at the time of lensectomy. We included eyes of children with systemic and ocular comorbidities and eyes with structural damage, which would be expected to have a worse prognosis for VA, strabismus, and development of glaucoma. Because VA outcomes are known to differ based on laterality of the disease, primary IOL placement may be confounded by age,¹ and IOL implantation in this study occurred rarely in children younger than 1 year and frequently in children older than 2 years, the study findings were presented for 4 analysis groups (unilateral aphakia, bilateral aphakia, unilateral pseudophakia, and bilateral pseudophakia) based on whether an IOL was placed at initial surgery.

Complications within 5 years of pediatric lensectomy were common, with 148 eyes (14%) experiencing a glaucoma-related adverse event and 19 eyes (2%) experiencing a retinal detachment. Additional intraocular surgery was performed in 406 eyes (33%), most often to clear the visual axis (membranectomy and laser capsulotomy in 207 pseudophakic eyes [29%]) or to implant a secondary IOL (122 of 1227 eyes [10%]). There were no unexpected adverse events (ie, events not included on IOL package warnings).

Although some children had excellent visual outcomes at 5 years after lensectomy, age-normal VA was achieved by fewer children, ranging from 12% in the unilateral aphakia group to 42% in the bilateral pseudophakia group. The 5-year median VA outcome in the unilateral aphakia group (20/200) was worse than the median VA of 20/159 reported in the Infant Aphakia Treatment Study (IATS),⁴ possibly because of measurement error or because we did not exclude eyes with structural ab-

normalities and patients with systemic comorbidities. For infants in the present study, VA outcomes for bilateral cases did not differ with the timing of surgery between 6 weeks and 6 months of age, whereas for unilateral cataracts, better visual outcomes were achieved when surgery was performed before 3 months of age.

The development of glaucoma-related adverse events is perhaps the most important long-term complication of childhood lensectomy. At 1 year after lensectomy, an overall rate of 6% was previously reported.¹ As found in the current study, the cumulative incidence continued to increase each year in all 4 analysis groups, reaching 46% in the bilateral aphakia group and 25% in the unilateral aphakia group after 5 years, with lower incidences of 7% in the bilateral pseudophakia group and 17% in the unilateral pseudophakia group. The 5-year cumulative incidence of glaucoma-related adverse events for aphakic eyes in this registry was higher than in 2 prospective randomized clinical trials at 5 years. In the IATS,^{5,6} which included infants younger than 6 months with unilateral cataract, the incidence was 31%,⁶ and in a trial by Vasavada et al⁷ of bilateral cataracts in children from birth to 24 months of age, the incidence was 15%. The cumulative incidence of glaucoma-related adverse events in the current study was similar to the incidence of 17% in the IoL-under2 prospective cohort study,⁸ which included children at 5 years who had undergone unilateral or bilateral cataract surgery before 2 years of age but was higher than the incidence of 2.5% to 30% reported in the retrospective Toddler Aphakia and Pseudophakia Study,⁹⁻¹¹ which included children 1 to 24 months of age who underwent unilateral or bilateral surgery. These estimates of the cumulative incidence of glaucoma-related adverse events likely vary owing to differing eligibility criteria. We enrolled all children with eyes with cataract, whereas the IATS, the Toddler Aphakia and Pseudophakia Study, and the trial by Vasavada et al⁷ enrolled children with structurally normal eyes and the IoL-under2 study excluded children with eyes with structural anomalies from some analyses including glaucoma.

Although not as serious to long-term eye health as glaucoma, secondary optical axis opacification was the most common reason for additional intraocular surgery in this study. Surgery was not performed in all eyes with this diagnosis; it is possible that some cases were not judged to be sufficiently severe. When there was no IOL placement at the initial cataract surgery, the 5-year cumulative incidence of surgery to clear the visual axis was 13%, and nearly all procedures occurred in the first year after cataract surgery. When there was primary IOL placement, the incidence of surgery to clear the visual axis was higher after 1 year¹ and continued to increase to approximately 1 in 3 pseudophakic eyes by 5 years. The incidence of surgery to clear the visual axis in pseudophakic eyes was significantly reduced when an anterior vitrectomy was performed at the time of cataract surgery.

Abnormal sensorimotor function after lensectomy was common. The 5-year cumulative incidence of strabismus among children with aphakia (79% among those with bilateral aphakia and 94% among those with unilateral aphakia) was similar to the finding of 81% in the IATS⁴ among children with

unilateral aphakia. Few of these children had strabismus surgery within 5 years. We suspect that variability of strabismic angle, unstable measured deviations, and poor visual prognosis may have caused surgeons to delay strabismus surgery until an older age.

Between the time of the 1-year study¹ and the present study, the number of secondary IOL procedures increased from 22 (2%) to 122 (10%). This would be expected because as children with aphakia approached school age, contact lens management may have become more difficult and the child's refractive error may have stabilized. However, only 24% of aphakic eyes had received a secondary IOL within 5 years after lensectomy, possibly because some parents were satisfied with their child's current spectacle or contact lens correction for aphakia or no clinical benefit was anticipated. A secondary IOL implant rate of 44% was reported in the IATS for unilateral cataract at 10 years¹²; thus, the rate in the group in the present study is likely to increase.

Accurately anticipating the change in refractive error during childhood and adolescence is important when choosing the power of the IOL for implant. Our 5-year data showed a clustering of refractive error around emmetropia despite the large variability observed between the actual postoperative refractive error and the target refractive error.¹³ We speculate that the image focus provided by the IOL encouraged emmetropization, thereby reducing the need for the precision of IOL calculations required for adults. Future analyses of refractive outcomes by age at surgery and VA are planned.

One related refractive error concern has been the possibility of substantial anisometropia occurring after unilateral IOL implantation in children. This was not a common problem in this study; 69% of unilateral pseudophakic eyes were within 2 D of the fellow eye, and only rare instances of anisometropia greater than 4 D occurred.

Strengths and Limitations

Strengths of our registry include its large sample size, large number of surgeons, wide age range of enrolled children, in-

clusion of bilateral and unilateral cases, multiple ocular conditions and systemic comorbidities, and prospective data collection. The outcomes represent real-world experience because the surgery and the postoperative management were at investigator discretion rather than following a protocol. We also included children with poor prognoses owing to anatomic abnormalities, trauma, and medical comorbidities, which improved generalizability.

This study has limitations. In accordance with our protocol, we enrolled participants within 45 days of surgery. It is possible that some clinicians might not have enrolled children with surgical complications. The sample sizes for some tabulations were small. There was substantial loss to follow-up, with 66% of patients last seen during the fifth year of follow-up. However, participants who did and did not complete the full length of the study did not appear to differ in any important baseline characteristics. For our VA outcomes, we included values for children able to perform letter optotypes; however, not all children were able to complete this test. Although the study protocol stated that the preferred VA measure 5 years after surgery was to use the standardized Amblyopia Treatment Study HOTV¹⁴ or Electronic Early Treatment of Diabetic Retinopathy Study¹⁵ protocol, some of our sites were not able to conduct that method of VA testing; thus, we included any VA testing that used line or surrounded single-letter optotypes. The diagnosis of amblyopia was by investigator report.

Conclusions

This cohort study found that although good VA was possible after cataract surgery in children from birth to less than 13 years of age, age-normal vision was uncommon. Amblyopia was frequent, and the risk for development of glaucoma increased during the first 5 years after cataract surgery. Refractive error after primary IOL implantation was tightly clustered around emmetropia.

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Invited Commentary

Challenges in Management of Pediatric Cataract

Jeff Yunglam Hui, MB, ChB, MPH

Although pediatric cataract is rare, it remains one of the leading causes of blindness in children. The worldwide prevalence varies between 2.2 and 13.6 per 10 000 children.¹

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Clinically, any lens opacification detected among children is defined as pediatric cataract. These cataracts are often associated with systemic and ocular comorbidities.

The management of pediatric cataract can be challenging not only because of the special surgical techniques that are sometimes needed but also because of the special postoperative considerations that can occur, which may be associated with visual acuity and other ophthalmic outcomes. Some special considerations include the timing of surgery, whether to leave the eye aphakic or to implant an intraocular lens, and postoperatively, how to manage posterior capsular opacification,² glaucoma that develops after surgery, and amblyopia and refractive errors.^{3,4}

The prospective cohort study by Repka et al⁵ provides estimates of the 5-year cumulative incidences of various outcomes after cataract surgery in children younger than 13 years.

The authors separated the findings into the following 4 analysis groups: unilateral aphakia, bilateral aphakia, unilateral pseudophakia, and bilateral pseudophakia. This subgrouping provided information regarding associations of laterality of disease and primary intraocular lens placement with visual and ophthalmic outcomes.

The study by Repka et al⁵ involved multiple centers and a large number of surgeons. It provided good generalizability for a mostly White population. However, it provided relatively little information regarding possible racial and ethnic disparities.

In the study by Repka et al,⁵ the refractive error observed at 5 years in the groups with pseudophakia was clustered around emmetropia. Although one might expect increasing myopia to be associated with increasing axial length, the magnitude of the myopic shift was relatively small. Some authors^{6,7} suggest an undercorrection of intraocular lens power at initial implantation to correct for the myopic shift associated with increasing age. However, the observed myopic shift in the study by Repka et al⁵ was relatively small in pseudophakic eyes, suggesting that aiming for emmetropia or only a small undercorrection would be reasonable.