



Cataract Surgery in Children from Birth to Less than 13 Years of Age

Baseline Characteristics of the Cohort

Michael X. Repka, MD, MBA,¹ Trevano W. Dean, MPH,² Elizabeth L. Lazar, MSPH,² Kimberly G. Yen, MD,³ Phoebe D. Lenhart, MD,⁴ Sharon F. Freedman, MD,⁵ Denise Hug, MD,⁶ Bahram Rahmani, MD,⁷ Serena X. Wang, MD,⁸ Raymond T. Kraker, MSPH,² David K. Wallace, MD, MPH,⁵ for the Pediatric Eye Disease Investigator Group*

Objective: To describe baseline characteristics, initial postoperative refractive errors, operative complications, and magnitude of the intraocular lens (IOL) prediction error for refractive outcome in children undergoing lensectomy largely in North America.

Design: Prospective registry study of children from birth to <13 years of age who underwent lensectomy for any reason within 45 days preceding enrollment.

Participants: Total of 1266 eyes of 994 children; 49% female and 59% white.

Methods: Measurement of refractive error, axial length, and complete ophthalmic examination.

Main Outcome Measures: Eye and systemic associated conditions, IOL style, refractive error, pseudophakic refraction prediction error, operative and perioperative complications.

Results: Mean age at first eligible lens surgery was 4.2 years; 337 (34%) were <1 year of age. Unilateral surgery was performed in 584 children (59%). Additional ocular abnormalities were noted in 301 eyes (24%). An IOL was placed in 35 of 460 eyes (8%) when surgery was performed before 1 year of age, in 70 of 90 eyes (78%) from 1 to <2 years of age, and in 645 of 716 eyes (90%) from 2 to <13 years of age. The odds of IOL implantation were greater in children ≥ 2 years of age than in those <2 years of age (odds ratio = 29.1; $P < 0.001$; 95% confidence interval: 19.6–43.3). Intraoperative complications were reported for 69 eyes (5%), with the most common being unplanned posterior capsule rupture in 14 eyes, 10 of which had an IOL placed. Prediction error of the implanted IOL was <1.00 diopter in 54% of eyes, but >2.00 diopters in 15% of eyes.

Conclusions: Lensectomy surgery was performed throughout childhood, with about two-thirds of cases performed after 1 year of age. Initial surgery seemed safe, with a low complication rate. IOL placement was nearly universal in children 2 years of age and older. The immediate postoperative refraction was within 1 diopter of the target for about one-half of eyes. *Ophthalmology* 2016;■:1–12 © 2016 by the American Academy of Ophthalmology



*Supplemental material is available at www.aaojournal.org.

Childhood cataract in the developed world is an uncommon, but important, cause of lifelong visual impairment. The prevalence of visually significant infantile cataract has been estimated to range from 3.0 to 4.5 per 10 000 live births, affecting up to 2000 infants annually in the United States.¹ These are about equally divided between bilateral and unilateral cases. There are limited data on the prevalence of acquired cataracts during childhood in the United States.

Most children in developed countries with visually significant cataract(s) undergo surgery. A number of ophthalmic sequelae may occur, including secondary opacification of the visual axis, contraction of the capsular openings, lens cellular Elschnig pearl formation, amblyopia, glaucoma, ametropia, anisometropia, strabismus, retinal detachment, additional ocular surgery, and failure of the

operated eye to emmetropize. The incidence, natural history, and risk factors for each of these adverse events, as well as the impact on visual acuity, have not been prospectively studied in a large cohort. The authors of a systematic review² of surgical interventions for bilateral congenital cataract recognized the need for ongoing research to identify risk factors, particularly for secondary glaucoma and retinal detachment. Few clinical trials have evaluated the management of childhood cataract, and most information on clinical outcomes is based on case series, with 2 notable exceptions.^{3–5}

The Pediatric Eye Disease Investigator Group (PEDIG) developed a cataract surgery registry to collect data on children undergoing lensectomy for any reason from birth to <13 years of age with 5 years of follow-up. There were 2

Table 1. Baseline Characteristics of Children Enrolled in the Pediatric Eye Disease Investigator Group Cataract Registry

Enrolled patients	994 (100)
Sex	
Female	490 (49)
Male	504 (51)
Laterality of surgery	
Bilateral	410 (41)
Unilateral*	584 (59)
Age at first eligible surgery [†]	
<6 months	269 (27)
6 months to <1 year	68 (7)
1 to <2 years	72 (7)
2 to <4 years	122 (12)
4 to <7 years	211 (21)
7 to <13 years	252 (25)
Mean (SD) years	4.17 (3.84)
Median (range) years	3.60 (0.04–12.98)
Race/ethnicity	
American Indian/Alaska native	5 (<1)
Asian	36 (4)
Black/African American	145 (15)
Hispanic	160 (16)
White	582 (59)
More than 1 race	42 (4)
Unknown/not reported	24 (2)

SD = standard deviation.

Data are n (%) unless otherwise indicated.

*Two patients had bilateral cataracts, but 1 eye was considered too abnormal for surgery.

[†]Patients who underwent surgery in both eyes may contribute 2 eyes to the study. Age at first eligible surgery refers to the child's age when surgery was performed on the first enrolled eye.

primary objectives for development of this registry: (1) to determine the occurrence and risk factors for complications following cataract surgery after a minimum of 5 years in a cohort of about 1000 children, and (2) to provide visual acuity outcome data for unilateral and bilateral cataract surgery, with and without intraocular lens (IOL) implantation.

Herein we describe the baseline characteristics of 994 children, birth to <13 years of age, who underwent lensectomy largely in North America. In addition, we describe initial postoperative refractive errors, operative complications, and magnitude of the prediction error for refractive outcome in children receiving IOLs.

Methods

This study, supported through a cooperative agreement with the National Eye Institute of the National Institutes of Health, was conducted by PEDIG. An Investigational Device Exemption (#G110149) was obtained from the United States Food and Drug Administration, Centers for Devices and Radiologic Health, Silver Spring, Maryland, because of the use of a medical device for an unapproved indication. The protocol and Health Insurance Portability and Accountability Act (HIPAA)—compliant informed consent forms were approved by each participating site's institutional review board. The parent or guardian of each child gave written informed consent.

Between June 2012 and July 2015, 61 centers (3 in Canada, 57 in the United States, and 1 in the United Kingdom) enrolled into a clinical research registry children from birth to <13 years of age who had undergone lensectomy for any reason during the preceding 45 days. Surgery was performed before consent and enrollment. Ophthalmic, systemic, and historical data were collected from medical record review for each child at the time of enrollment. Data from fellow eyes that had cataract surgery within 1 year following enrollment are included in this report. Bilateral cases were defined by performance of surgery in both eyes within 1 year after enrollment or by report of lensectomy in the fellow eye before enrollment.

Logistic regression with generalized estimating equations to adjust for intereye correlation was used to (1) estimate the odds of IOL implantation in children undergoing bilateral lensectomy compared with children undergoing unilateral lensectomy; (2) estimate the odds of IOL implantation in children ≥ 2 years of age compared with children <2 years of age, adjusting for laterality of surgery; and (3) compare the odds of IOL implantation between children undergoing unilateral surgery and those undergoing bilateral surgery separately in children <2 years of age and in those ≥ 2 years of age.

Descriptive statistics were calculated for postoperative spherical equivalent refractive error, measured 1 to 45 days after surgery, stratified by IOL placement; and for axial length, stratified by laterality of lens surgery and age group. The IOL prediction error was calculated as the difference between the target refractive error and the postoperative spherical equivalent refractive error. The absolute value of the prediction error was determined and descriptive statistics calculated.

Table 2. Medical History of Children Enrolled in the Pediatric Eye Disease Investigator Group Cataract Registry at Baseline, Stratified by Laterality of Surgery

	Laterality of Surgery			Overall
	Bilateral	Unilateral	Overall	
Enrolled patients	410 (100)	584 (100)	994 (100)	
Current medical conditions				
Yes	163 (40)	153 (26)	316 (32)	
No	245 (60)	430 (74)	675 (68)	
Unknown	2 (<1)	1 (<1)	3 (<1)	
Medical conditions reported				
Attention deficit hyperactivity disorder	3 (<1)	8 (1)	11 (1)	
Antenatal infection	3 (<1)	0 (0)	3 (<1)	
Asthma	14 (3)	14 (2)	28 (3)	
Congenital malformations	2 (<1)	5 (<1)	7 (<1)	
Diabetes	3 (<1)	1 (<1)	4 (<1)	
Developmental delay	35 (9)	14 (2)	49 (5)	
Down syndrome	20 (5)	11 (2)	31 (3)	
Galactosemia	0 (0)	0 (0)	0 (0)	
Genetic	17 (4)	14 (2)	31 (3)	
Heart/cardiac	15 (4)	5 (<1)	20 (2)	
Leukemia	4 (<1)	5 (<1)	9 (<1)	
JIA	5 (1)	10 (2)	15 (2)	
Marfan syndrome	9 (2)	3 (<1)	12 (1)	
Prematurity	3 (<1)	1 (<1)	4 (<1)	
Psychiatric/neurological	16 (4)	8 (1)	24 (2)	
Skin	3 (<1)	3 (<1)	6 (<1)	
Tumor	4 (<1)	9 (2)	13 (1)	
Other	39 (10)	30 (5)	69 (7)	

JIA = juvenile idiopathic arthritis.

Data are n (%).

Download English Version:

<https://daneshyari.com/en/article/5705520>

Download Persian Version:

<https://daneshyari.com/article/5705520>

[Daneshyari.com](https://daneshyari.com)