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Cataract Surgery in Children from Birth to Less than 13 Years of Age: Baseline Characteristics of the Cohort

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Abstract

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 having undergone lensectomy for any reason within 45 days preceding enrollment.

Participants—1,266 eyes of 994 children; 49% female and 59% white

Testing—Measurement of refractive error, axial length, and complete ophthalmic examination

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This article contains online-only material. The following should appear online-only: Figure 10, Figure 11.

FDA Disclaimer: The study was conducted under an Investigational Device Exemption (#G110149) from the United States Food and Drug Administration.

Conflict of Interest: No conflicting relationships exist for any author.

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%) from birth to <1 year of age. Unilateral surgery was performed in 584 (59%) children. Additional ocular abnormalities were noted in 301 (24%) eyes. An IOL was placed in 35 of 460 (8%) eyes when surgery was performed prior to 1 year of age, in 70 of 90 (78%) eyes 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 those <2 years of age (odds ratio=29.1; p<0.001; 95% confidence interval: 19.6 to 43.3). Intraoperative complications were reported for 69 (5%) eyes, 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 D in 54% of eyes, but >2.00 D in 15% of eyes.

Conclusions—Lensectomy surgery was performed throughout childhood, with about two-thirds of cases performed after one year of age. Initial surgery appeared 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.

Precis

Children <13 years of age undergoing lensectomy, rarely had a medical abnormality known to be associated with cataract; however, one in five had a positive family history of early cataract. Intraocular lenses were used in nearly all children after two years of age.

Introduction

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 US.

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 review[2] 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 upon case series, with two 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 two 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 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 a medical device for an unapproved indication. The protocol and 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 US, and 1 in the UK) enrolled children from birth to <13 years of age who had undergone lensectomy for any reason during the preceding 45 days into a clinical research registry. Surgery was performed prior to consent and enrollment. Ophthalmic, systemic and historical data were collected for each child at the time of enrollment from medical record review. Data from fellow eyes that had cataract surgery within one year following enrollment are included in this report. Bilateral cases were defined by performance of surgery in both eyes within one year after enrollment or by report of lensectomy in the fellow eye prior to enrollment.

Logistic regression with generalized estimating equations to adjust for inter-eye 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.

Results

The PEDIG registry included 1,266 eyes of 994 children undergoing a lensectomy (Table 1): 69 children in Canada, 914 children in the US, and 11 in the UK. Forty-nine percent were female; 59% were white. Unilateral surgery was performed in 584 (59%) children. Bilateral surgery was performed in 410 (41%) children (141 of 410 had undergone lensectomy in one of their eyes more than 45 days prior to study enrollment and those eyes were not included in these analyses).

Mean age at first eligible surgery was 4.2 ± 3.8 years (median=3.6 years, interquartile range=5 months to 7.1 years). Seventy-three percent of children were of normal birth weight (>2500 g) and 80% of normal post-menstrual age (37 to 42 weeks) (Table 2a). Additional characteristics are provided in Tables 2a and 2b. Table 3 lists ocular conditions other than an abnormal crystalline lens found in the enrolled eyes prior to surgery; an ocular abnormality was present in 301 (24%) of 1266 enrolled eyes. Persistent fetal vasculature was reported for 63 (5%) eyes. Trauma was the cause of cataract in 86 eyes.

Axial length, reported for 373 (64%) unilateral and 419 (62%) bilateral surgical eyes, was not different between unilateral and bilateral cases when assessed by age (Table 4). Axial length increased with age, ranging from 17.3 mm in eyes of children <3 months of age to 23.0 mm in children 7 to <13 years of age (Figure 1).

An IOL was placed in 59% of all eyes in the study; in 35 of 460 (8%) when surgery was performed prior to 1 year of age, in 70 of 90 (78%) children from 1 to <2 years of age, and in 645 of 716 (90%) children from 2 to <13 years of age. The odds of IOL implantation were greater in children ≥2 years of age than those <2 years of age (odds ratio (OR)=29.1; p<0.001; 95% CI=19.6 to 43.3) and were lower in children undergoing bilateral surgery compared with unilateral surgery (OR=0.74; p=0.02; 95% CI=0.57 to 0.96). In children <2 years of age, the odds of IOL implantation were lower in children undergoing bilateral surgery compared with those undergoing unilateral surgery (OR=0.58; p=0.03; 95% CI=0.35 to 0.95), however there did not appear to be a difference in children ≥2 years of age (OR=0.92; p=0.77; 95% CI=0.53 to 1.59). With unilateral lens surgery, IOL implantation increased from <1% when <3 months of age to 90% when 7 to <13 years of age (Figure 2). With bilateral lens surgery, IOL implantation increased from 3% when younger than three months to 91% when 7 to <13 years of age (Figure 2, Figure 3). Of the 71 eyes left aphakic after 2 years of age, 13 (18%) were related to traumatic cataract.

The most common implant was a foldable acrylic lens from a variety of manufacturers (Table 5). The implant was placed in the posterior chamber in 715 (95%) of 750 eyes. Fixation was reported in the capsular bag for 85% of eyes and in the ciliary sulcus for 14% of eyes. For eyes receiving an IOL, management of the posterior capsule included no capsulotomy in 34%, a limbus approach capsulotomy in 43%, and a pars plana/plicata approach in 19% (Table 6). A trend to preservation of the posterior capsule with increasing age was seen, with no capsulotomy performed in 55% of eyes of children after 7 years of age. Anterior vitrectomy was performed in 59% of eyes receiving an IOL. The IOL power ranged from +2.00D to +39.00D, with most IOLs between +20.00D and +26.00D (Figure 4).

Intraoperative complications were reported for 69 (5%) eyes. The most common complication was an unplanned posterior capsule rupture in 10 (1%) of 750 eyes having primary IOL placement (Table 7). Complication rates did not differ between eyes receiving a primary IOL (pseudophakic eyes) and eyes without an IOL (aphakic eyes). Postoperative complications between 1 and 45 days after surgery were reported for 197 (16%) of 1266 eyes: 14% with pseudophakia and 17% with aphakia. Acute elevation of intraocular pressure and cloudy cornea were the most prevalent, each reported for 2% of eyes.

Immediate postoperative refractive errors were determined within 45 days of surgery (Figures 5, 6). The mean spherical equivalent refraction was +1.36 diopters (D) (SD = 2.37, median = +1.13 D, range = −10.00 D to +14.50 D) among pseudophakic eyes and +17.65 D (SD = 7.80, median = +19.00 D, range = −12.00 D to +35.00 D) among aphakic eyes. As evident in Figures 5 and 6, a wide range of postoperative *spherical equivalent* refractive errors were reported, with a few outliers responsible for the large ranges. Ninety percent of pseudophakic eyes were between −2.00 D and +5.25 D, while 90% of aphakic eyes were between 0.00 D and +29.00 D.

The IOL calculation formulae were chosen by each investigator. For 92% of pseudophakic eyes, a target refractive error was reported. On average, low hyperopia was the target for the immediate postoperative refractive error (mean = +1.45 D, SD = 1.88, median = +1.00 D, range = −8.50 D to +8.00 D; Figure 7). More hyperopia was planned for younger children, with a mean of +4.52 D for children 6 months to <1 year of age and +0.32 D for children 7 to <13 years of age (Figure 8).

Of the 750 eyes receiving an IOL, there were sufficient data (target refraction and immediate postoperative refraction) to calculate the prediction error for 599 (80%) eyes (Figure 9). Prediction error was <1.00 D in 54% of eyes, but >2.00 D in 15% of eyes. The mean of the absolute value of the prediction error was 1.11 D ± 1.14 (median = 0.75 D, range = 0 to 9.13 D). Prediction error did not vary by laterality within subgroups of age at time of surgery (Figure 10 – Online only).

Analyses after exclusion of traumatic cataract surgery found glaucoma at baseline, postoperative ocular hypertension, and prediction error (Figure 11 – Online only) to be unchanged.

Discussion

We enrolled 994 children from birth to <13 years of age undergoing lensectomy in one or both eyes to participate in a prospective 5-year observational study of childhood lensectomy, greater than 99% performed for cataract. The race/ethnicity of our cohort is similar to that of the overall population of the United States in 2014,[6] with nearly 40% of the children from minority groups. About one in four children had additional ocular abnormalities. Only one-third of children were younger than one year of age at time of their first eligible surgery. Lens surgery was performed throughout childhood up to 12 years of age.

There are two recent large prospective studies of childhood cataract surgery. IATS reported results of a randomized trial of 114 infants with unilateral infantile cataract with surgery

between 1 month and 6 months of age with 5 years of follow up.[3, 4] IATS included only children with a normal fellow eye and no major structural abnormalities in the operated eye. Median visual acuity at 5 years did not differ between the IOL and no IOL treatment groups, although additional surgery to clear the visual axis was more common in the IOL group.

The British Isles Congenital Cataract Interest Group (BCCIG) enrolled a prospective national inception cohort of 221 children younger than 2 years of age undergoing cataract surgery in the United Kingdom and Northern Ireland between January 2009 and December 2010.[5] BCCIG investigators felt they had near complete ascertainment of eligible children birth to less than two years of age. Each of these studies will serve as important comparisons for subgroups in our future reports, although such comparisons will be limited by differences in the populations and years of recruitment.

In our study the presence of a medical condition known to be associated with early cataract or lens abnormality was rare; Down syndrome accounted for 3% and Marfan syndrome for 1%. There were no cases associated with galactosemia. More common was a family history of infantile cataract (18%). These data support the value of a thorough medical evaluation and family history. However, given the low incidence of associated medical conditions detected through standard of care clinical testing, reevaluation of the recommended testing suggested for bilateral cataracts, including assessments of galactose metabolism, infectious disease, and metabolic disorders, would seem warranted.[7] It is possible that a thorough family history, pediatric medical history, assessment of medication use, and physical exam could eliminate the need for many of these tests.

While IOLs were implanted in 59% of all enrolled eyes, there was a significant effect of age on the decision to implant, with 8% of eyes implanted before 1 year of age and 90% of eyes implanted after 2 years of age. This finding demonstrates the continuing widespread use of IOLs in children in North America. A survey in 2001 of pediatric ophthalmologists found that between 1 and 2 years of age was the minimum age felt reasonable for implantation of an IOL.[8] A survey of practice patterns from 2008–2009 in the UK and Ireland found most surgeons performed IOL implantation in children younger than 2 years of age, but 25% would not place an IOL in children younger than one year of age.[9] However, the use of IOLs in children younger than one year of age may have been slowed during our recruitment period by publication of the 1- and 5-year IATS results,[3, 4] which failed to demonstrate an advantage to implantation of IOLs in infants younger than 7 months of age and urged caution in their use. In the more recent cohort study in the UK and Ireland of actual surgical cases, BCCIG investigators reported on the surgery for 221 children younger than 2 years of age with 1 year of follow-up; they placed implants in 44% (40% of bilateral and 53% of unilateral cases).[5] In the PEDIG registry, investigators implanted IOLs in only 19% of eyes in this same age range, suggesting a more cautious approach or differing referral patterns. In the present study, posterior capsulotomies were performed in most cases until about 7 years of age after which fewer than 50% of eyes had a primary capsulotomy performed. Presumably this was the time point when the majority of investigators assumed they could do an office-based laser capsulotomy if necessary.

The IOL calculation formula used was chosen and adjusted at the discretion of the surgeon along with the selection of the power of the particular IOL. While the range of chosen target refractive errors was large, the majority of cases were targeted to low hyperopia. As expected, more hyperopia was chosen at younger ages, while emmetropia was chosen for children 7 to <13 years of age (Figure 8). The mean power chosen between 6 months and 1 year of age by our investigators was +4.52 D, much less than the +6.00 D targeted for infants 6 weeks to 6 months of age in the IATS protocol.[10] In addition, the targets our investigators chose for children <3 years of age were generally less hyperopic than the myopic shifts that would be anticipated from earlier studies of refractive error change after cataract surgery.[11] This could mean that our registry participants may be more myopic than intended when reviewed in 5 years.

IOL power selection was fairly accurate with the absolute prediction error <1.00 D in 54%, but >2.00 D in 15%. Interestingly, the prediction error did not vary by age. In IATS the best prediction error when using the Holladay 1 formula was <1.00 D in 45%, but IATS included only infant eyes.[12] While the IOL power accuracy is better in our study, we included older children, which should make precision of preoperative measurements easier and perhaps more precise. The long term significance of the early prediction error in IOL power selection is uncertain at this early stage, but longitudinal follow-up of refractive progression over 5 years will provide more information regarding the significance of choice of IOL power.

Intraoperative complications were reported in 5% of eyes with the most common being unplanned posterior capsular rupture in 1%. An additional 16% of eyes were reported to have an adverse event during the 45-day postoperative period, most commonly an episode of ocular hypertension in 2%, with no newly diagnosed cases of glaucoma. IATS reported an intraoperative complication rate of about 20% among infants, most commonly iris prolapse.[13] BCCIG's cohort of children under 2 years of age reported a perioperative complication rate of 10%, most commonly iris prolapse.[5] Iris prolapse occurred at a much lower rate in the current study, which may again be due to our inclusion of older children.

There are several strengths to our study. This is a large, multicenter, prospective cohort study of 994 children undergoing lensectomy in a real-world setting (337 children were younger than one year of age) of a race/ethnicity distribution similar to that of the United States.[6] The large sample size should help establish tighter confidence intervals on rates of important clinical outcomes such as glaucoma. The data collection forms we used forced clinicians to report key data elements such as complications and medical history, which should be relatively complete. This lens surgery registry also includes outcomes for high-risk patients (eg. glaucoma, retinopathy of prematurity, persistent fetal vasculature), often excluded in clinical trials or case series, thus making the results more generalizable. Each of these factors will allow use of these pooled registry data as benchmarks for an individual physician's performance in the future.

There are limitations to our research registry. Although we recruited a large sample from an ethnically and socially diverse population, our study is not population-based. Furthermore, with the cohort limited mainly to North America, the data on associations with cataract reflects that of developed countries and would differ dramatically from the developing

world. We did not have a specific protocol so there are missing data elements, but we did request specific data on the collection forms, which were completed at the time of surgery and the two immediate postoperative visits. This should reduce the potential for data collection inaccuracies compared with routine reporting from medical records, a concern previously expressed and studied by BCCIG.[14] Children were managed at investigator discretion, so there is the potential for treatment bias at enrollment such as implanting an IOL in otherwise normal eyes undergoing uneventful surgery and using a contact lens or eyeglasses for other children.

In summary, lens surgery reported to the registry was performed throughout childhood, with about two-thirds of cases performed after one year of age. Initial surgery had a low complication rate in the 45 days following surgery. IOL placement was nearly universal in children >2 years of age. Future reports will focus on clinical outcomes after 5 years such as visual acuity, development of complications, and refractive error.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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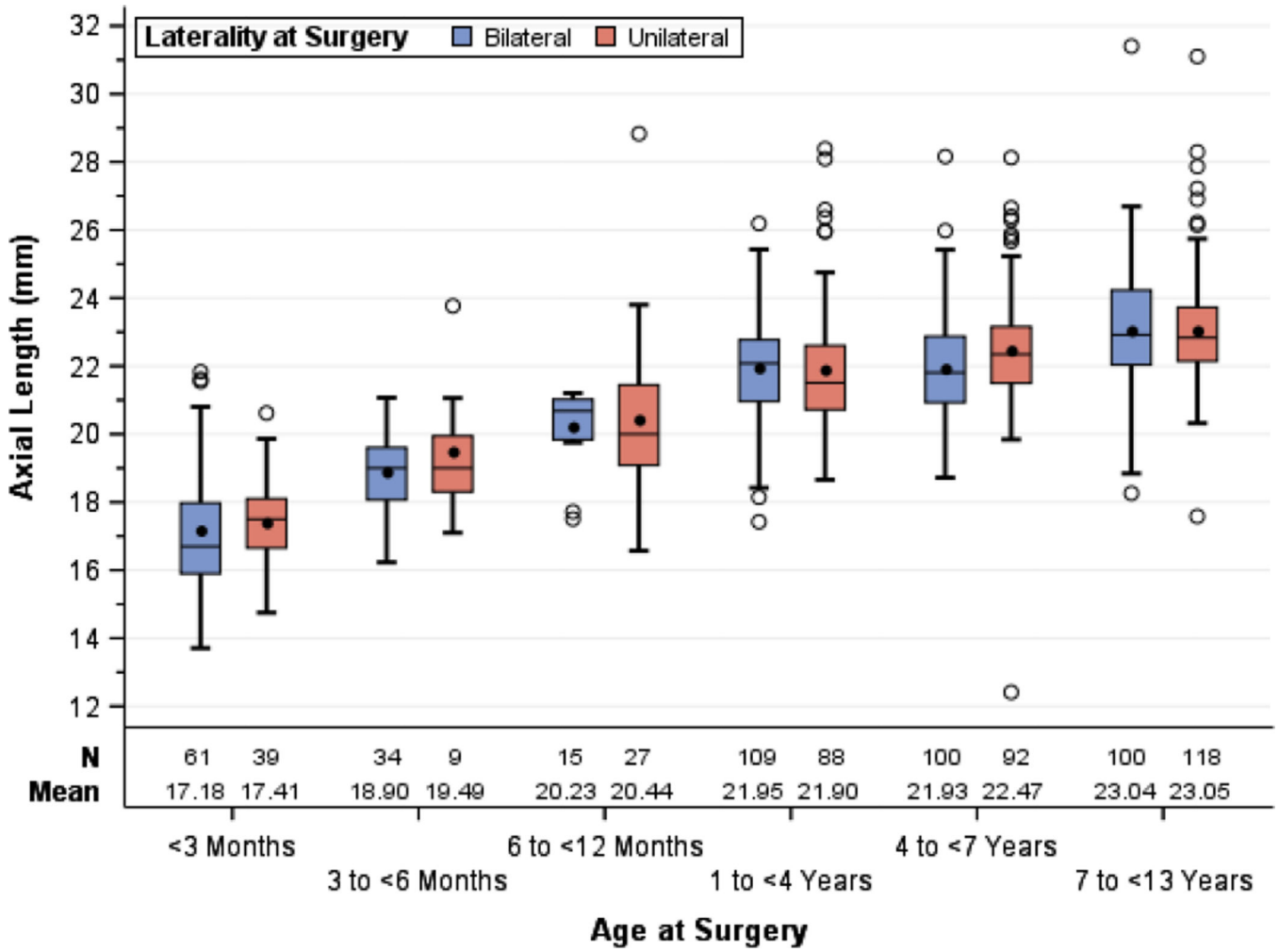

Figure 1.

Distribution of Axial Length for Bilateral and Unilateral Cataract Surgery Stratified by Age at Surgery. Axial length increased with age, regardless of laterality of cataract surgery. The top and bottom of each box represents the 75th and 25th percentiles of the data, respectively. Group medians are represented by the horizontal line in each box and group means by filled circles. The bars extending above and below each box represent 1.5 times the interquartile range (difference between the 75th and 25th percentiles), or the maximum (or minimum) observed value within the range if not as extreme as the calculated value. The open circles represent statistical outliers.

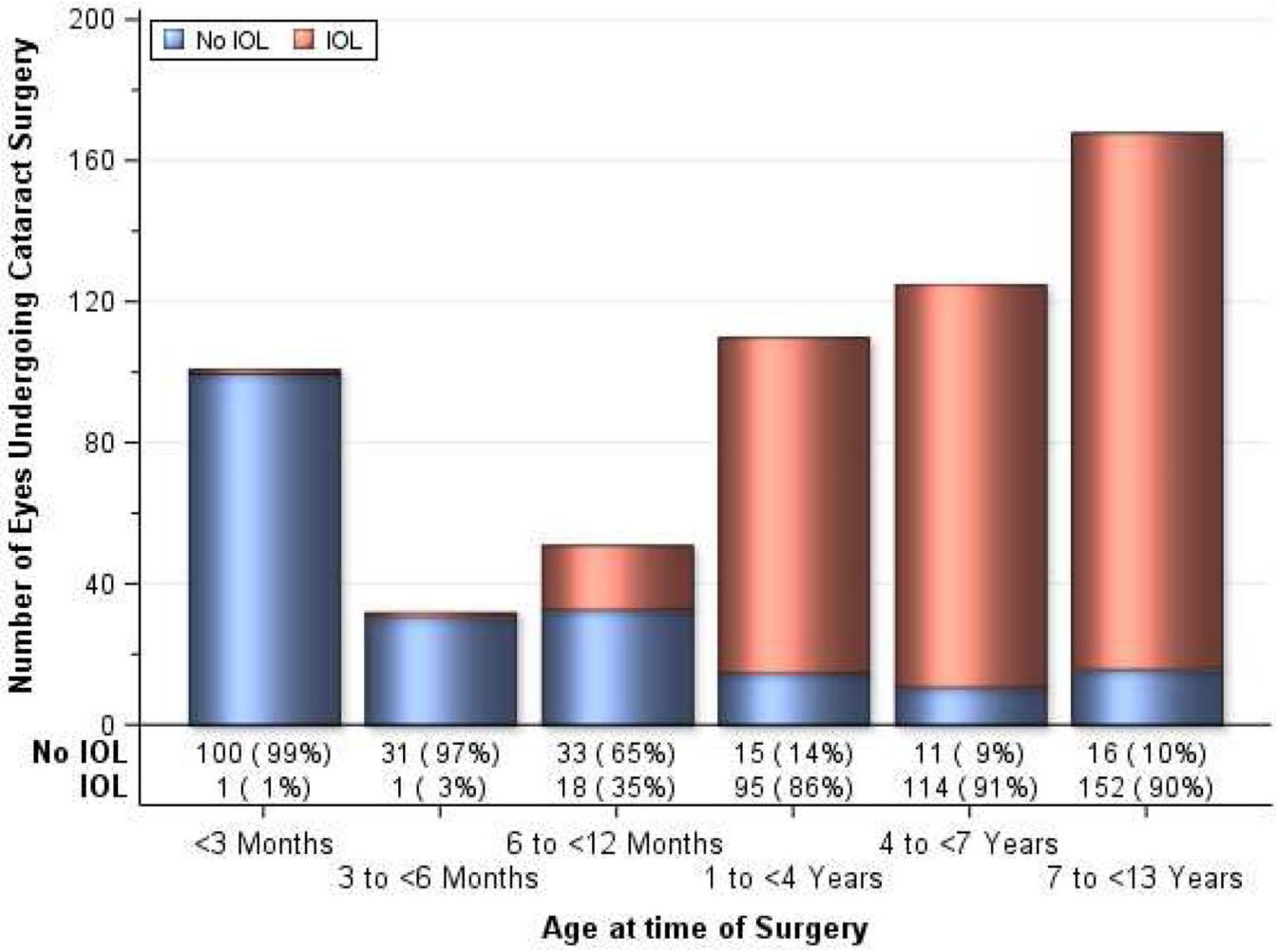

Figure 2.

Intraocular Lens (IOL) Implantation for Children with Unilateral Cataract Surgery Stratified by Age at Surgery. The percentage of IOL implantation increased with age in children undergoing unilateral surgery. Each column displays the number of eyes with cataract surgery within each age group. Columns are divided into two categories, representing the percentage of eyes within that age group that received IOL implant at the time of surgery (light grey) and those that did not (dark grey).

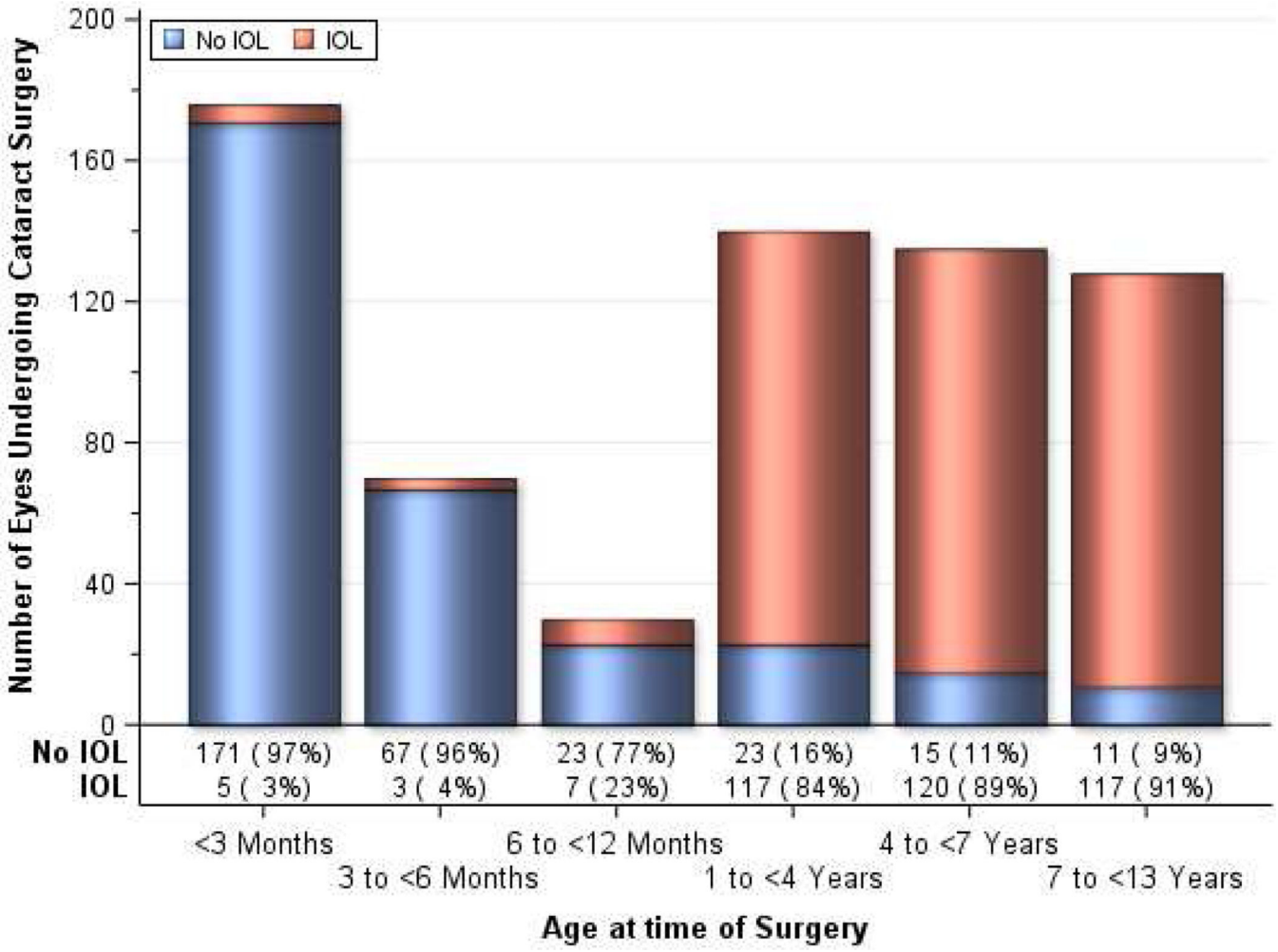

Figure 3.

Intraocular Lens (IOL) Implantation for Children with Bilateral Cataract Surgery Stratified by Age at Surgery. The percentage of IOL implantation increased with age in children undergoing bilateral surgery. Each column displays the number of eyes with cataract surgery within each age group. Columns are divided into two categories, representing the percentage of eyes within that age group that received an IOL implant at the time of surgery (light grey) and those that did not (dark grey).

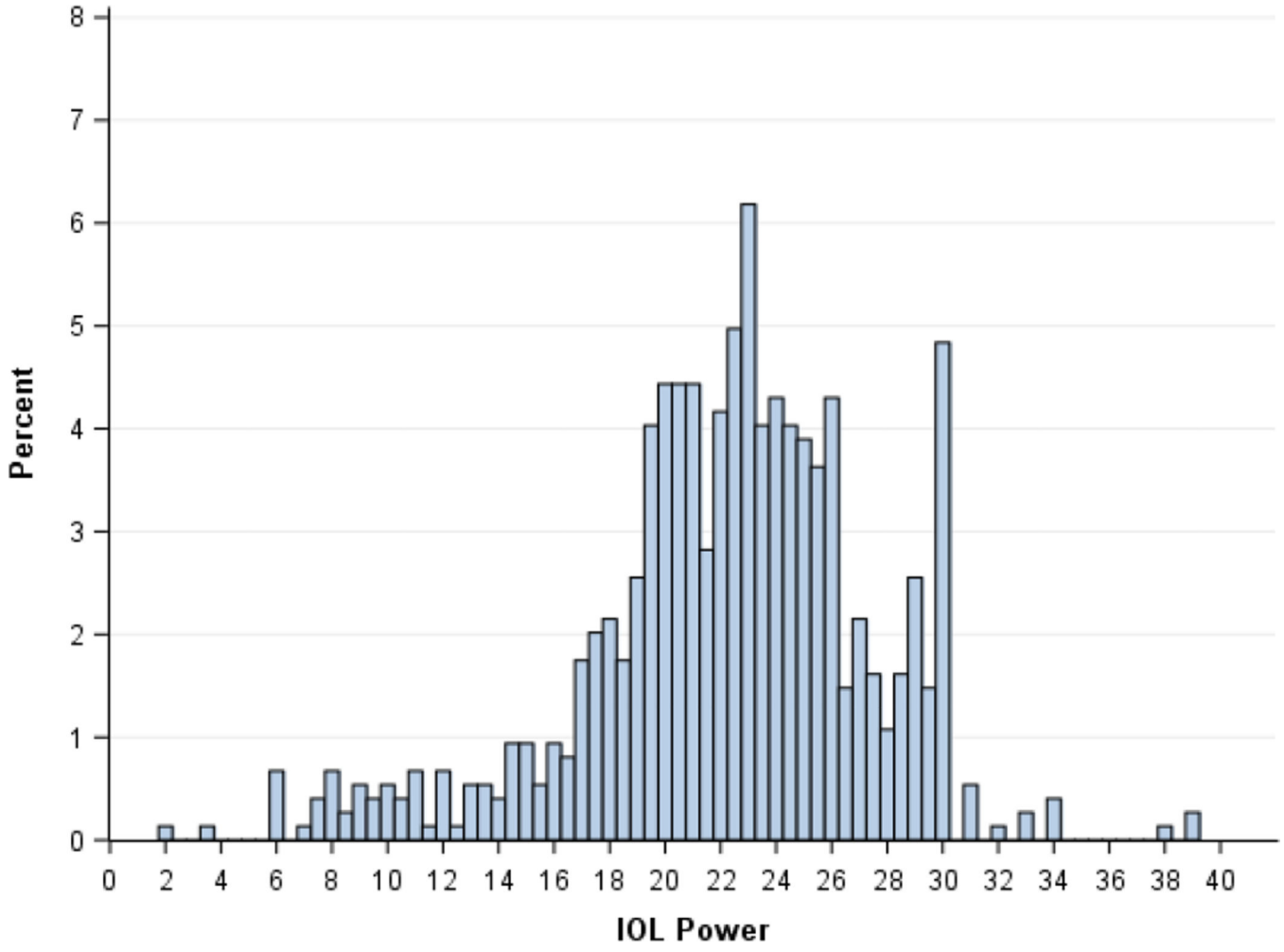

Figure 4.
Distribution of Power of Implanted Intraocular Lenses (IOL). IOL power, ranging from +2.00 to +39.00 diopters, was reported for 744 eyes.

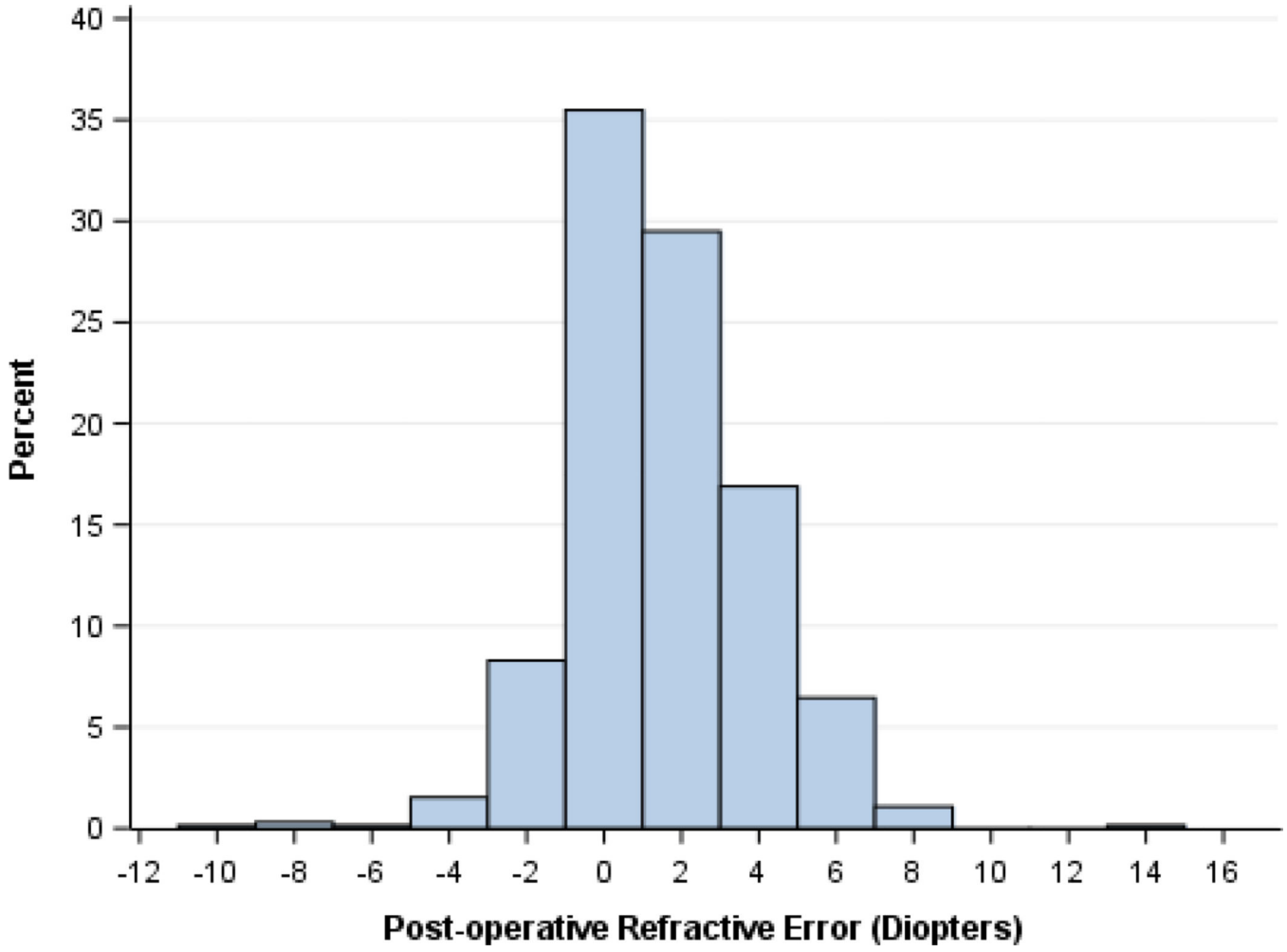

Figure 5.

Distribution of Postoperative Refractive Error in Pseudophakic Eyes. Postoperative refractive error reported for 651 eyes with a mean of +1.36 D (range = −10.00 D to +14.50 D).

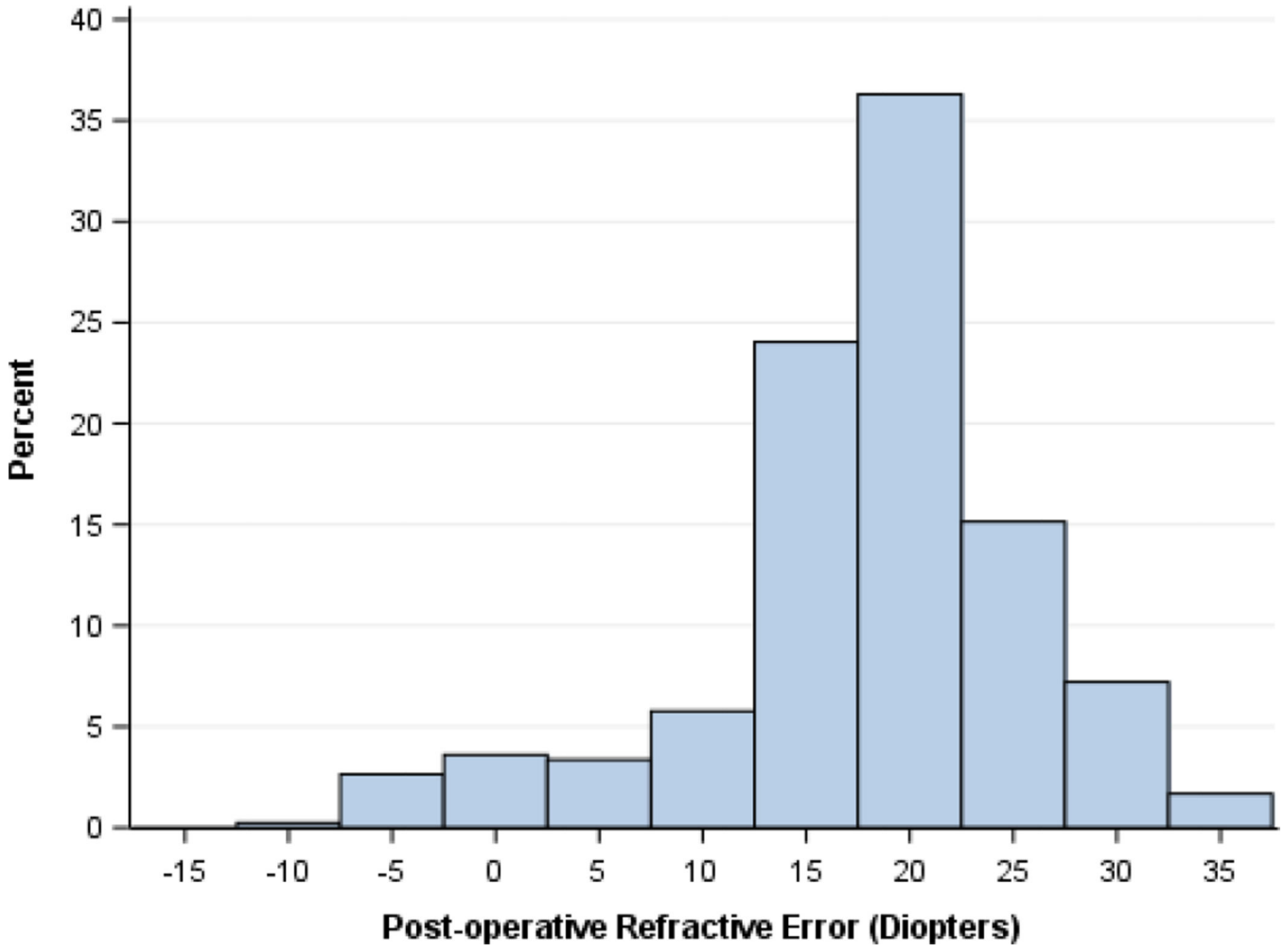

Figure 6.
Distribution of Postoperative Refractive Error in Aphakic Eyes. Postoperative refractive error reported for 416 eyes with a mean of +17.65 D (range = −12.00 D to +35.00 D).

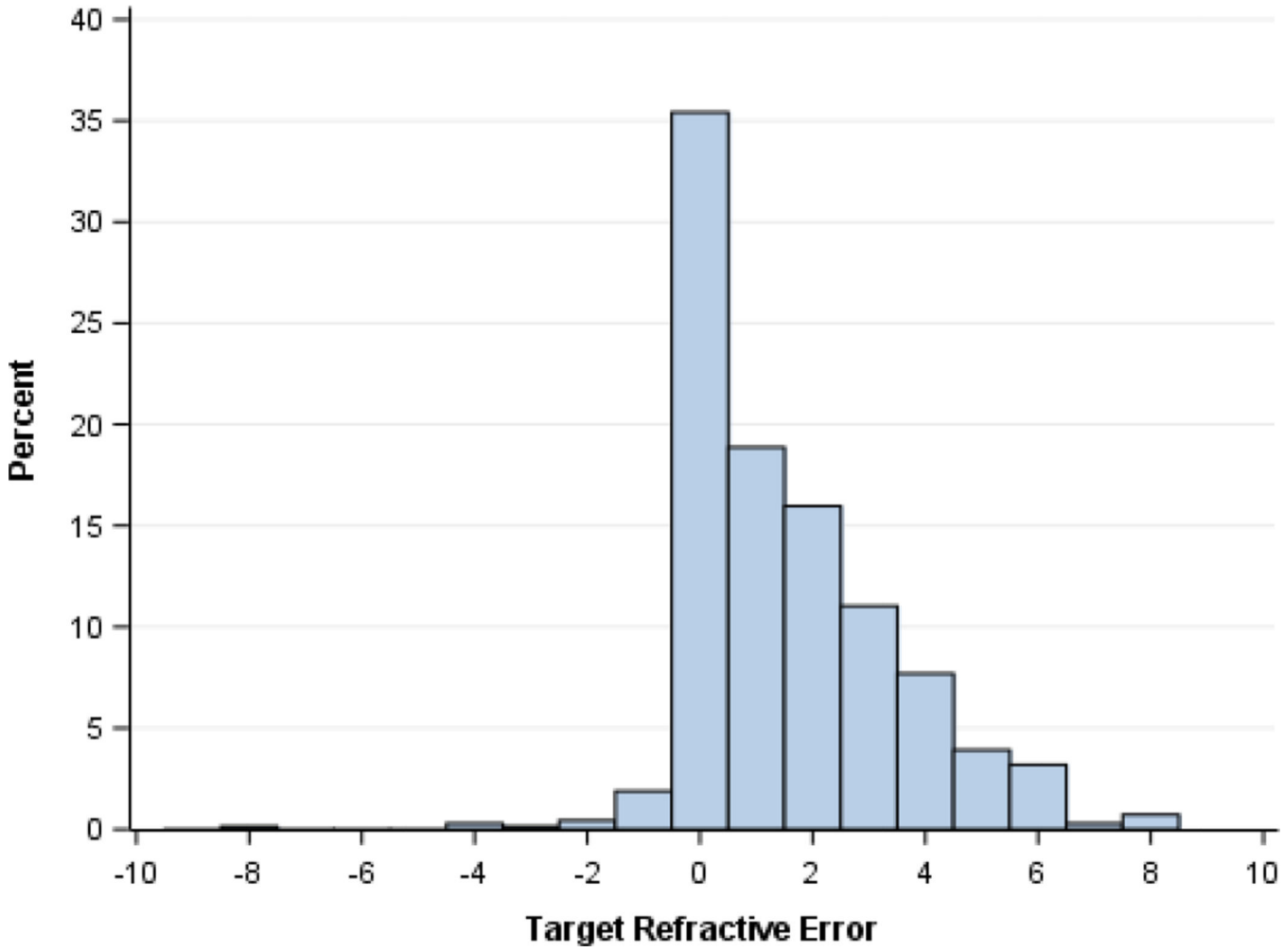

Figure 7.
Distribution of Target Refractive Error in Pseudophakic Eyes. The target refractive error varied from −8.50 to +8.00 Diopters for 689 eyes with a reported target.

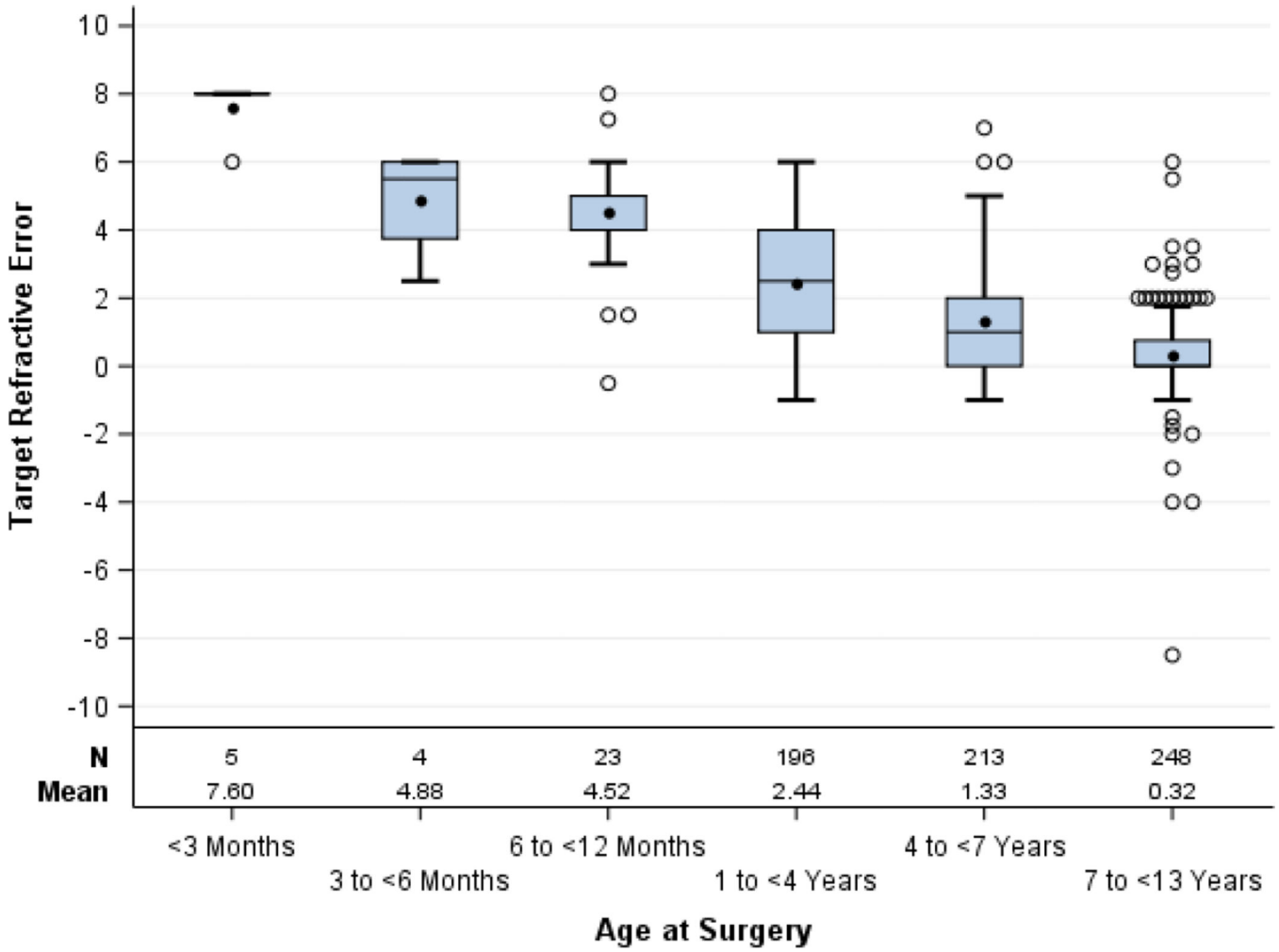

Figure 8.

Distribution of Target Refractive Error Stratified by Age at Surgery. Target refractive error, reported for 689 eyes, appeared to decrease with age; more hyperopia was planned for younger children. The top and bottom of each box represent the 75th and 25th percentiles of the data, respectively. Group medians are represented by the horizontal line in each box and group means by filled circles. The bars extending above and below each box represent 1.5 times the interquartile range (difference between the 75th and 25th percentiles), or the maximum (or minimum) observed value within the range if not as extreme as the calculated value. The open circles represent statistical outliers.

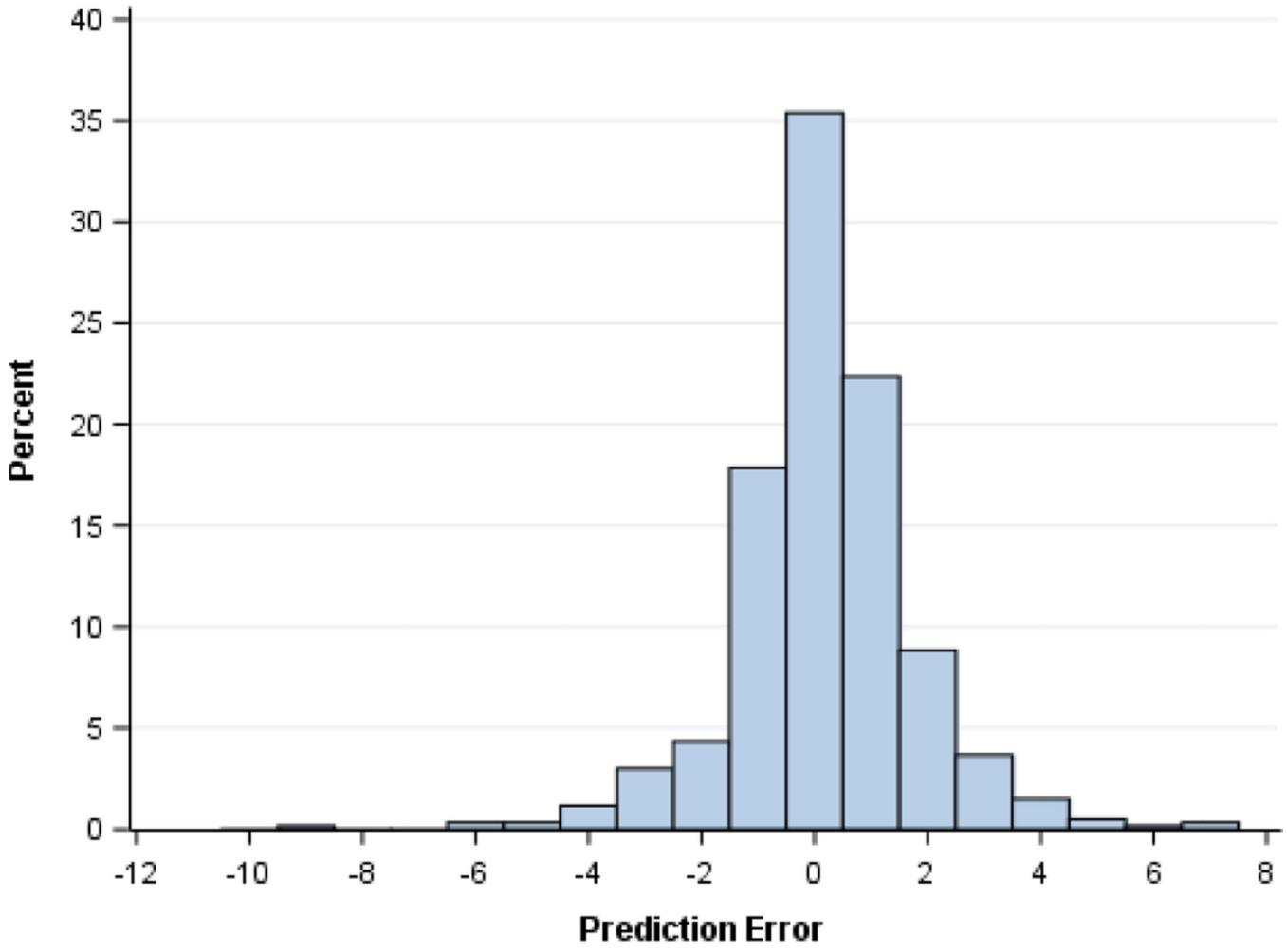

Figure 9.

Distribution of Prediction Error in Pseudophakic Eyes. Prediction error (Diopters) was calculated for 599 eyes for which there were both a target refractive error and a postoperative refractive error.

Table 1

Baseline Characteristics of Enrolled Children (N=994)

	N	(%)
Enrolled Patients	994	(100)
Sex		
Female	490	(49)
Male	504	(51)
Laterality of Surgery		
Bilateral	410	(41)
Unilateral[a]	584	(59)
Age at First Eligible Surgery[b]		
<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 to 12.98)	
Race/Ethnicity		
American Indian/Alaska	5	(<1)
Asian	36	(4)
Black/African American	145	(15)
Hispanic	160	(16)
White	582	(59)
More than one race	42	(4)
Unknown/not reported	24	(2)

[a]Two patients had bilateral cataracts, but one eye was considered too abnormal for surgery.

[b]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.

SD - standard deviation

Table 2

a Medical History of Enrolled Children at Baseline Stratified by Laterality of Surgery (N=994)

	Laterality of Surgery					
	Bilateral		Unilateral		Overall	
	N	(%)	N	(%)	N	(%)
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)

b Medical, Family, and Social History of Enrolled Children at Baseline (N=994)

	N	(%)
Currently Using Systemic Medications		
Yes	160	(16)
No	826	(83)
Unknown	8	(<1)
Systemic Medications Currently Being Used		
Attention deficit hyperactivity disorder	10	(1)
Asthma	31	(3)
Diamox	4	(<1)
Insulin	4	(<1)
Methotrexate	24	(2)
Seizure	8	(<1)
Oral Steroids	42	(4)
Other (eg, cold, vitamins, analgesics)	130	(13)
Current or Prior Use of Steroids	73	(7)
Family History of Infantile of Juvenile Cataracts		
Yes	179	(18)
No	775	(78)
Unknown	40	(4)
Birth Weight		
<=1500 grams	34	(3)
>1500 to 2000 grams	18	(2)
>2000 to 2500 grams	65	(7)
>2500 to 4000 grams	644	(65)
>4000 grams	79	(8)
Unknown	154	(15)
Mean (SD) grams	3173	(750)
Median (Range) grams	3260 (425 to 5103)	
Post-menstrual Age at Birth		
<32 weeks	32	(3)
32 to <37 weeks	77	(8)

b Medical, Family, and Social History of Enrolled Children at Baseline (N=994)

	N	(%)
37 to <42 weeks	797	(80)
>= 42 weeks	15	(2)
Unknown	73	(7)
Mean (SD) weeks	38.6	(3.0)
Median (Range) weeks	40.0 (22.0 to 44.0)	
Household Size		
<=4 persons	619	(62)
>4 persons	302	(30)
Unknown	73	(7)
Parent Education Level		
<High School	35	(4)
>=High School/GED	803	(81)
Unknown	156	(16)
Primary Healthcare Coverage		
None	5	(<1)
Unknown	16	(2)
Employer Provided Health Insurance	327	(33)
Medicaid/State CHIP	437	(44)
Military	19	(2)
Private Health Insurance	121	(12)
Government, non-United States	69	(7)

SD - standard deviation. GED – successful completion of a general education development test. CHIP – Children's Health Insurance Program

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Table 3

Ocular Conditions Reported at Baseline

	N	(%)
Eye-Level Conditions (N=1266)		
Glaucoma		
Yes	79	(6)
No	1187	(94)
Pre-operative Eye Abnormalities		
Yes	301	(24)
No	951	(75)
Unknown	14	(1)
Pre-operative Eye Abnormalities		
Anterior and Posterior Segments	56	(4)
Anterior Segment Only	156	(12)
Posterior Segment Only	89	(7)
None	951	(75)
Unknown	14	(1)
Patient-Level Conditions (N=994)		
Uveitis	28	(3)
Strabismus		
Yes	222	(22)
No	727	(73)
Unknown	45	(5)

Table 4

Distribution of Axial Length (mm) Stratified by Laterality of Cataract Surgery and Age at Surgery

		Bilateral (N=419)	Unilateral (N=373)
<3 Months	**N**	61	39
	Mean (SD)	17.2 (1.9)	17.4 (1.3)
	Median (Range)	16.7 (13.7 to 21.8)	17.5 (14.8 to 20.6)
3 to <6 Months	**N**	34	9
	Mean (SD)	18.9 (1.1)	19.5 (1.9)
	Median (Range)	19.0 (16.2 to 21.1)	19.0 (17.1 to 23.8)
6 to <12 Months	**N**	15	27
	Mean (SD)	20.2 (1.2)	20.4 (2.3)
	Median (Range)	20.7 (17.5 to 21.2)	20.0 (16.6 to 28.8)
1 to <4 Years	**N**	109	88
	Mean (SD)	22.0 (1.6)	21.9 (1.9)
	Median (Range)	22.1 (17.4 to 26.2)	21.5 (18.7 to 28.4)
4 to <7 Years	**N**	100	92
	Mean (SD)	21.9 (1.6)	22.5 (1.9)
	Median (Range)	21.8 (18.7 to 28.2)	22.3 (12.4 to 28.1)
7 to <13 Years	**N**	100	118
	Mean (SD)	23.0 (1.8)	23.0 (1.7)
	Median (Range)	22.9 (18.3 to 31.4)	22.8 (17.6 to 31.1)

SD – Standard deviation

Table 5

Intraocular Lens (IOL) Implantation

	N	(%)
Total Eyes	1266	(100)
IOL Implanted		
Yes	750	(59)
No	516	(41)
IOL Brand – Model (N=750 Eyes)		
Alcon Acrysof – 1-piece and 3-piece	684	(91)
Bausch and Lomb Sofport AO	25	(3)
Abbott Medical Optics Technis	17	(2)
Rayner	4	(<1)
Staar Surgical Company CQ2015	1	(<1)

Table 6

Distribution of Capsulotomy Stratified by Intraocular Lens (IOL) Implantation

	IOL Implanted (N=750)		No IOL Implanted (N=516)	
	N	**(%)**	**N**	**(%)**
Primary capsulotomy				
None	257	(34)	42	(8)
Limbus approach	322	(43)	399	(77)
Pars plana/plicata approach	146	(19)	42	(8)
Other	11	(1)	11	(2)
Unknown	14	(2)	22	(4)

Table 7

Ocular Complications Stratified by Intraocular Lens (IOL) Implantation Status

	IOL Implanted (N=750)		No IOL Implanted (N=516)		All Eyes (N=1266)	
	N	**(%)**	**N**	**(%)**	**N**	**(%)**
Operative Complications (day of surgery)						
Yes	40	(5)	29	(6)	69	(5)
No	710	(95)	487	(94)	1197	(95)
Reported Operative Complications						
Cloudy cornea	1	(<1)	2	(<1)	3	(<1)
Hyphema	3	(<1)	1	(<1)	4	(<1)
Iris damage	2	(<1)	4	(<1)	6	(<1)
Iris prolapsed	6	(<1)	0	(0)	6	(<1)
Iris sphincterotomy	2	(<1)	1	(<1)	3	(<1)
Lens fragment in vitreous	1	(<1)	2	(<1)	3	(<1)
Retained cortex	3	(<1)	2	(<1)	5	(<1)
Ruptured posterior capsule	10	(1)	4	(<1)	14	(1)
Unplanned iridectomy	0	(0)	3	(<1)	3	(<1)
Other	19	(3)	13	(3)	32	(3)
Postoperative Complications (Post-op days 1 to 45)						
Yes	107	(14)	90	(17)	197	(16)
No	643	(86)	426	(83)	1069	(84)
Reported Postoperative Complications						
Acute ocular hypertension	15	(2)	8	(2)	23	(2)
Cloudy cornea	8	(1)	11	(2)	19	(2)
Dislocated implant	1	(<1)	0	(0)	1	(<1)
Endophthalmitis	0	(0)	0	(0)	0	(0)
Hyphema	2	(<1)	3	(<1)	5	(<1)
Iris damage	11	(1)	6	(1)	17	(1)
Iris prolapsed	1	(<1)	0	(0)	1	(<1)
Iris sphincterotomy	0	(0)	0	(0)	0	(0)

	IOL Implanted (N=750)		No IOL Implanted (N=516)		All Eyes (N=1266)	
	N	(%)	N	(%)	N	(%)
Lens fragment in vitreous	0	(0)	2	(<1)	2	(<1)
Retained cortex	4	(<1)	2	(<1)	6	(<1)
Return to operating room within 1 week	3	(<1)	1	(<1)	4	(<1)
Ruptured posterior capsule	0	(0)	0	(0)	0	(0)
Unplanned iridectomy	0	(0)	0	(0)	0	(0)
Other	79	(11)	79	(15)	158	(12)