

JOURNAL CLUB

Predictability of Intraocular Lens Calculation and Early Refractive Status

The Infant Aphakia Treatment Study

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Objective: To report the accuracy of intraocular lens (IOL) power calculations and the early refractive status in pseudophakic eyes of infants in the Infant Aphakia Treatment Study.

Methods: Eyes randomized to receive primary IOL implantation were targeted for a postoperative refraction of +8.0 diopters (D) for infants 28 to 48 days old at surgery and +6.0 D for those 49 days or older to younger than 7 months at surgery using the Holladay 1 formula. Refraction 1 month after surgery was converted to spherical equivalent, and prediction error (PE; defined as the calculated refraction minus the actual refraction) and absolute PE were calculated. Baseline eye and surgery characteristics and A-scan quality were analyzed to compare their effect on PE.

Main Outcome Measures: Prediction error.

Results: Fifty-six eyes underwent primary IOL implantation; 7 were excluded for lack of postoperative refraction (n=5) or incorrect technique in refraction (n=1) or

biometry (n=1). Overall mean (SD) absolute PE was 1.8 (1.3) D and mean (SD) PE was +1.0 (2.0) D. Absolute PE was less than 1 D in 41% of eyes but greater than 2 D in 41% of eyes. Mean IOL power implanted was 29.9 D (range, 11.5-40.0 D); most eyes (88%) implanted with an IOL of 30.0 D or greater had less postoperative hyperopia than planned. Multivariate analysis revealed that only short axial length (<18 mm) was significant for higher PE.

Conclusions: Short axial length correlates with higher PE after IOL placement in infants. Less hyperopia than anticipated occurs with axial lengths of less than 18 mm or high-power IOLs.

Application to Clinical Practice: Quality A-scans are essential and higher PE is common, with a tendency for less hyperopia than expected.

Trial Registration: clinicaltrials.gov Identifier: NCT00212134

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SELECTION OF AN INTRAOCULAR lens (IOL) with appropriate power for implantation in pediatric eyes can be difficult. Obtaining accurate and reproducible biometry measures in children, particularly infants, is challenging because of the lack of patient cooperation and limitations in equipment. Technical difficulty with IOL placement during surgery may result in ciliary sulcus instead of capsular bag placement, adding additional error in achieving the target refraction. Inaccuracies in formulas for

giving the lowest prediction error (PE), particularly for eyes with shorter axial length. Even when using these formulas, the PE in pediatric eyes remains higher than that achieved in adult populations.

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The Infant Aphakia Treatment Study (IATS) is a multicenter, randomized, controlled clinical trial sponsored by the National Eye Institute undertaken to determine whether primary IOL implantation in infants between 1 and 6 months of age with unilateral cataract would result in improved visual outcomes over contact lens correction of aphakia. Half of the 114 infants enrolled in this multicenter study were randomized to receive an IOL and then receive spectacle correction for residual refractive error. In the IATS, IOL

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IOL power calculation for small eyes may be exaggerated in the infantile eye. Previous studies¹⁻⁶ have evaluated the accuracy of formulas for use in pediatric eyes, with the Holladay and Hoffer Q formulas

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power was chosen based on the Holladay 1 calculation. The purposes of this report are to review the PE of refraction for infant eyes undergoing primary IOL implantation in the IATS and to look for ocular characteristics or biometry techniques that may be associated with higher error rates.

METHODS

The study design, surgical techniques, patching and optical correction regimens, follow-up schedule, examination methods, and baseline characteristics of patients enrolled in this study have been reported previously^{7,8} and therefore are only briefly summarized in this report. The study was approved by the institutional review boards of all participating centers and was in compliance with the Health Insurance Portability and Accountability Act. The off-label research use of the AcrySof SN60AT and MA60AC IOLs (Alcon Laboratories) was covered by US Food and Drug Administration investigational device exemption G020021.

STUDY DESIGN

Infants with a unilateral, visually significant cataract (>3-mm central opacity) and an age of 28 to 209 days at the time of cataract surgery were eligible for enrollment in the study. The main exclusion criteria were persistent fetal vasculature associated with stretching of ciliary processes or involvement of the optic nerve or retina, corneal diameter less than 9 mm, premature birth (<36 weeks' gestational age), presence of a medical condition that might interfere with later visual acuity testing, or acquired cataract. Patients were randomized either to have an IOL placed at the time of the initial surgery (with spectacle correction) or to be left aphakic (with contact lens correction).

SCREENING EXAMINATION

Before randomization, each infant underwent examination while under anesthesia to confirm study eligibility and so that biometry could be performed on both eyes. Keratometry was performed with a handheld keratometer, with a mean of at least 2 readings that varied by less than 1 diopter (D). A-scan ultrasonography of both eyes was performed, using immersion whenever possible. Measures were taken from the scan with the best waveforms (ie, highest peaks with a perpendicular retinal spike) using the phakic setting. If applanation A-scan ultrasonography was performed, the A-scan with the greatest anterior chamber depth was used.

SURGICAL TECHNIQUE AND IOL POWER DETERMINATION

Infants randomized to the IOL group had the lens aspirated followed by the implantation of an AcrySof SN60AT IOL into the capsular bag. If both haptics could not be implanted into the capsular bag, an AcrySof MA60AC IOL was implanted into the ciliary sulcus. After IOL placement, a posterior capsulectomy and an anterior vitrectomy were performed for all eyes.

The IOL power was determined in the operating room based on A-scan ultrasonography and keratometry readings using the Holladay 1 formula. An IOL power was chosen that was closest to the power predicted to produce a +8.0 postoperative refraction for infants 4 to 6 weeks of age and a +6.0-D postoperative refraction for infants 7 weeks and older. If the IOL was implanted into the ciliary sulcus, then 1.0 D was subtracted from the calculated IOL power (<http://www.doctor-hill.com>).

FOLLOW-UP REFRACTION AND PE

Follow-up examinations were performed 1 day, 1 week, and 1 month after surgery. Retinoscopy was performed under cycloplegia to determine residual refractive error at the 1-month postoperative examination. This measure was converted to spherical equivalent and compared with the predicted refraction. The predicted refraction was calculated from the Holladay 1 formula using the IOL power implanted and the patient's axial length and mean keratometry reading recorded at the time of surgery. The PE and absolute PE were calculated as follows:

$$\text{PE} = \text{Predicted Refraction} - \text{Actual Refraction}$$

$$\text{Absolute PE} = |\text{Predicted Refraction} - \text{Actual Refraction}|$$

ASSESSMENT OF THE QUALITY OF A-SCAN ULTRASONOGRAPHY

All available A-scans were reviewed by a certified echographer. A-scans were graded as good quality if the gates and mode were set correctly and corneal, lens, and retinal spikes were visible and of sufficient gain to be measurable, with a perpendicular leading edge for the retinal spike. Whether A-scan ultrasonography was performed using a contact or immersion technique was also determined. A-scans were judged as unreadable if the quality of the printout was sufficiently degraded such that the scan could not be adequately assessed. If an error was detected that could cause the axial length measurement to be inaccurate by more than 0.2 mm (such as inappropriate mode, improper gate or caliper placement, or poor spike quality), then the scan was classified as poor quality.

STATISTICAL ANALYSIS

Descriptive analyses were performed for baseline and surgery characteristics (age, axial length, mean keratometry reading, corneal diameter, A-scan quality, IOL power, and site of IOL placement) and for the 1-month refraction and the PE. Two-sample *t* tests and, for nonnormal factors, Wilcoxon rank sum tests for differences between younger patients (28-48 days old) and older patients (49-209 days old) were performed.

Bivariate associations between PE and absolute PE and the baseline and surgery characteristics were examined using the 2-sample *t* test for means, the Wilcoxon rank sum test for medians, and the χ^2 test for percentages. Groups were compared based on age at surgery (<49 vs \geq 49 days), keratometry readings (<46.5 vs \geq 46.5 D), axial length (<18.0 vs \geq 18.0 mm), corneal diameter (<10.5 vs \geq 10.5 mm), IOL power (<30.0 vs \geq 30.0 D), A-scan rating (good quality vs unreadable, unavailable, or poor quality), A-scan method (immersion vs contact), and site of IOL placement (capsular bag vs ciliary sulcus).

The relationship between PE and baseline and surgery characteristics (age category, axial length, mean keratometry reading, corneal diameter, A-scan quality, and IOL placement) was examined using multiple linear regression; backward elimination was used to remove factors that were insignificant at the .05 level of significance. In this analysis, axial length, mean keratometry reading, and corneal diameter were included as continuous variables. Results are reported as mean (SD).

RESULTS

STUDY PATIENTS AND BASELINE CHARACTERISTICS

Fifty-seven of the 114 patients in the IATS were randomized to receive an IOL, and IOL implantation was com-

pleted in 56. Five patients did not have a refraction recorded at the 1-month visit. One patient was excluded because of incorrect recording of refraction over spectacles (instead of refraction without spectacles). Another patient was excluded because an incorrect ultrasonogram mode with an improper retinal caliper placement was used, resulting in a major error in axial length measurement and a postoperative refraction of +16.5 D instead of the +8.0 D targeted. The remaining 49 eyes were included for analysis. The baseline and IOL characteristics of these 49 pseudophakic eyes are reported in **Table 1**.

A-SCAN QUALITY

Baseline A-scan ultrasonographic reports of the pseudophakic eye were readable for 46 of the 49 patients; 1 A-scan was unreadable and 2 were missing. Of the 46 readable A-scans, 45 (98%) were deemed by the certified echographer to be of good quality; 1 A-scan for a younger patient was deemed to be of poor quality.

IOL POWER AND PLACEMENT

The mean power of the implanted IOL was 29.9 (5.7) D overall (31.5 [5.0] D for the younger age group and 28.7 [6.0] D for the older age group); IOL power range was 11.5 to 40.0 D. Twenty-five eyes were implanted with an IOL with a power of 30.0 D or greater and 10 of these were implanted with an IOL with a power of 35.0 D or greater.

In 46 patients (94%), the IOL was placed within the capsular bag. Ciliary sulcus IOL placement was performed for 1 patient in the younger age group and 2 patients in the older age group.

FOLLOW-UP REFRACTION AND PE

The overall mean refraction at 1 month was +6.1 (2.0) D; the distribution of refractions is shown in **Figure 1**. The mean refraction was +6.6 (1.9) D in the younger age group and +5.7 (1.9) D in the older age group. Twenty-two eyes (45%) achieved a postoperative refraction within 1.0 D of the target refraction of +8.0 D or +6.0 D outlined by the IATS protocol. In 7 eyes (14%), the surgeon implanted an IOL predicted to give a postoperative refraction that varied from the IATS protocol by more than 1 D, but the actual refraction was still within 1.0 D of the IATS target for 3 of these eyes. One eye had the highest-power IOL available implanted (40.0 D), which was predicted to result in a refraction of +9.5 D instead of the target of +8.0 D, but the actual postoperative refraction was +6.5 D.

The PE and absolute PE are reported in **Table 2**. The actual refractions at the 1-month visit showed less residual hyperopia than predicted, with an overall mean PE of +1.0 (2.0) D. Differences in mean PE were seen based on age at surgery, and differences were seen in both mean PE and mean absolute PE based on baseline globe axial length, baseline corneal diameter, and power of the implanted IOL. However, in multiple linear regression analyses, only globe axial length was significant.

Table 1. Baseline Characteristics of Patients

Characteristic	No. (%) of Patients	Mean (SD)
Age at surgery, mo	49	2.5 (1.5)
Axial length, mm		
All ages	49	18.1 (1.4)
28-48 days old	22	17.3 (0.9)
>48 days old	27	18.7 (1.4) ^a
Keratometry reading, D		
All ages	49	46.2 (2.4)
28-48 days old	22	47.1 (1.8)
>48 days old	27	45.5 (2.6) ^b
Corneal diameter, mm		
All ages	49	10.5 (0.8)
28-48 days old	22	10.0 (0.6)
>48 days old	27	10.9 (0.8) ^a
Intraocular pressure, mm Hg		
All ages	49	11.5 (4.6)
28-48 days old	22	10.6 (4.0)
>48 days old	27	12.3 (4.9)

Abbreviation: D, diopters.

^a Difference between the age group means is significant at the .001 significance level.

^b Difference between the age group means is significant at the .05 significance level.

Figure 2 shows the distribution of PEs. Only 6 of the 49 eyes (12%) had an absolute PE of less than 0.5 D, 20 (41%) had an absolute PE of less than 1.0 D, and 29 (59%) had an absolute PE of less than 2.0 D (**Figure 2**). Of the 20 eyes with an absolute PE greater than 2.0 D, 14 (70%) had axial lengths of less than 18 mm compared with 13 of 29 eyes (45%) with an absolute PE of 2.0 D or greater ($P = .08$; 95% CI for difference in percentages [PE > 2.0 D minus PE ≤ 2.0 D], -3% to 54%).

The PE in relation to axial length is shown in **Figure 3**. A negative trend for PE was seen with increasing axial length (linear regression coefficient, -0.8; SE, 0.2; $R^2 = 0.3$; $P < .001$); that is, an increase in axial length of 1 mm was associated with a 0.8-D decrease in mean PE in this cohort. When an IOL with a power greater than 30 D was implanted, 88% of patients had less residual hyperopia when refracted at 1 month after surgery than intended. Of the 20 eyes with an absolute PE greater than 2.0 D, 13 underwent implantation with an IOL with a power of 30.0 D or greater, and all had less hyperopia than intended compared with 4 of 7 (57%) with less hyperopia than intended when an IOL of less than 30.0 D was implanted ($P = .03$).

COMMENT

Infants in the IATS underwent surgery using standardized techniques and IOL selection criteria, using the Holladay 1 formula for a specified postoperative refractive target. At the 1-month postoperative visit, only 41% of eyes were within 1 D of the refractive target, and PE greater than 2 D was seen in another 41% of eyes. Higher PE in IOL calculation is not surprising in this population of infantile eyes, where extremely short axial length and steep keratometry readings are common. In a multivariable

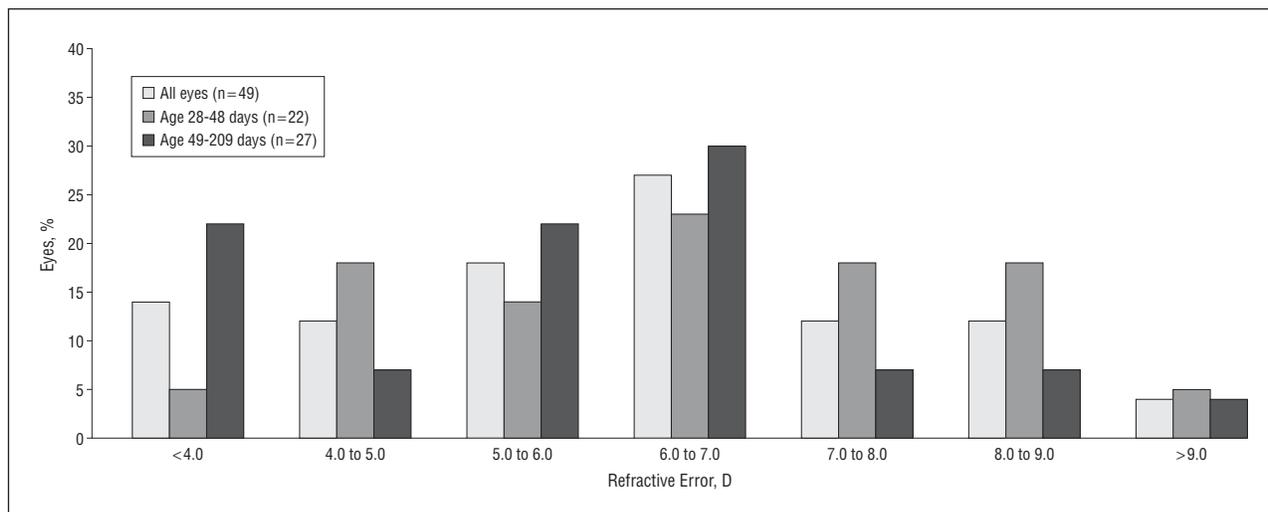


Figure 1. Distribution of refractive error at 1 month, overall and stratified by age group (28-48 vs 49-209 days). The overall mean (SD) refractive error was 6.1 (2.0) diopters (D). The mean (SD) refractive error was 6.6 (1.9) D in the younger age group and 5.7 (1.9) D in the older age group.

Table 2. Bivariate Associations Between PE and Baseline and Surgery Characteristics

Characteristic	No. of Patients	PE, D		Absolute PE, D	
		Mean (SD)	P Value ^a	Mean (SD)	P Value ^a
Prediction error	49	1.0 (2.0)		1.8 (1.3)	
Age at surgery, d					
28-48	22	1.6 (2.0)	.047	2.0 (1.6)	.32
>48	27	0.5 (1.9)		1.6 (1.1)	
Axial length, mm					
<18.0	27	1.8 (2.0)	<.001	2.2 (1.5)	.01
≥18.0	22	-0.1 (1.6)		1.3 (1.0)	
Keratometry reading, D					
<46.50	26	1.0 (2.1)	.82	1.8 (1.4)	.90
≥46.50	23	0.9 (2.0)		1.8 (1.3)	
Corneal diameter, mm					
<10.5	21	1.8 (2.0)	.01	2.3 (1.5)	.04
≥10.5	28	0.3 (1.8)		1.5 (1.1)	
A-scan rating					
Good quality	45	1.1 (2.0)	.10	1.8 (1.4)	.99
Other ^b	4	-0.7 (2.1)		1.8 (0.9)	
A-scan method					
Immersion	32	1.0 (2.0)	.90	1.7 (1.3)	.91
Contact	14	0.9 (2.0)		1.8 (1.3)	
IOL power, D					
<30.0	24	-0.3 (1.6)	<.001	1.3 (1.0)	.004
≥30.0	25	2.2 (1.7)		2.3 (1.5)	
IOL placement					
Capsular bag	46	1.1 (2.0)	.34	1.8 (1.3)	.89
Sulcus	3	-0.6 (3.0)		2.1 (1.7)	

Abbreviations: D, diopters; IOL, intraocular lens; PE, prediction error.

^a P values are for 2-sample *t* tests except for baseline A-scan rating and IOL placement (Wilcoxon rank sum test).

^b Poor quality, unreadable, or missing A-scans.

analysis, axial length was the only factor found to be independently associated with PE, with shorter eyes having greater PE. In addition, of the 20 eyes with an absolute PE greater than 2 D, most (80%) were overcorrected, leaving less residual hyperopia than expected.

Errors in IOL calculation often come from measurement error during biometry, instrumentation error, or formula error.^{9,10} An improper A-scan ultrasonographic technique was used in 1 patient, resulting in a large er-

ror in globe axial length assessment. This eye was excluded from the overall analysis because such an error would outweigh any eye or surgery characteristics that could affect postoperative refraction targeting. Because keratometry and A-scans for infants are usually performed with the patients under anesthesia, lack of fixation may also induce measurement error. Instruments are calibrated for adult eyes, and the proportional differences in the infant globe may cause errors in measure-

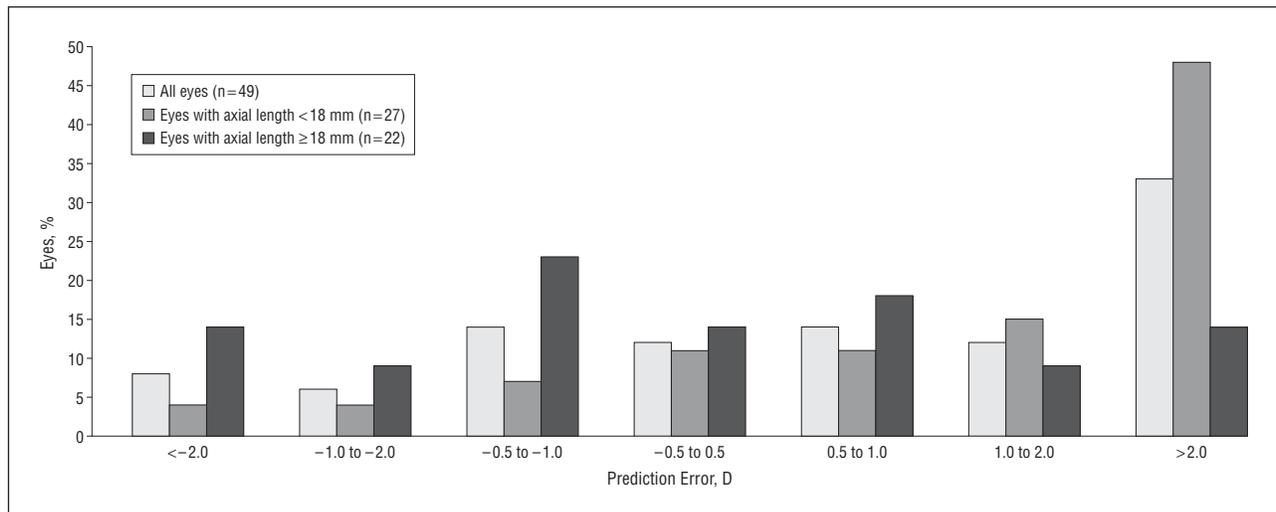


Figure 2. Distribution of prediction error, overall and stratified by axial length (<18 vs \geq 18 mm). D indicates diopters.

ment. Ultrasonography uses a mean velocity of 1550 m/s, but the infant eye with a proportionally larger lens would have a faster velocity. We did not find a significant difference in mean PE based on method of ultrasonography, although there is concern that contact biometry may underestimate axial length due to compression forces.¹¹⁻¹³ However, others have shown no significant difference in axial length measurements using contact vs immersion ultrasonographic methods,¹⁴ including a pediatric series comparing PE in eyes that had immersion vs contact ultrasonographic measurements with the patient under general anesthesia.¹⁵ Axial length measurement errors in children have been shown to result in larger errors in IOL power selection, such that a 4- to 14-D/mm error in axial length may occur in pediatric eyes compared with a 3- to 4-D/mm error in axial length in adults.⁹ The IOL power calculation difference with a keratometry error of 0.8 to 1.3 D/D was noted to be similar between children and adults.⁹

Formulaic errors may occur based on assumptions about IOL position within the eye and anterior chamber depth and are magnified with placement of higher-powered IOLs.¹⁶ Half of the eyes in this cohort had an IOL power greater than 30.0 D. Although a higher mean PE was demonstrated with an IOL power greater than 30.0 D and even higher for the 10 eyes that received an IOL with a power of 35.0 D or greater, these were typically implanted in shorter eyes, so analyses of the effect of IOL power on PE are confounded by axial length.

The IATS used the Holladay 1 formula for IOL calculation. In adult populations, the Holladay, Hoffer Q, and Haigis formulas have been used for eyes with axial lengths of less than 22 mm.¹⁷⁻¹⁹ Pediatric studies^{2,5} have failed to show a significant difference in mean absolute PE among formulas overall, and in a mathematical analysis of IOL power prediction in the pediatric range of keratometry and axial length values, it appears unclear which formula may give the best prediction for an individual patient.²⁰

Postoperative refraction was determined by retinoscopy. The inability of an infant to cooperate may lead to off-axis retinoscopy or variations in the vertex distance during retinoscopy. Errors are also magnified with high

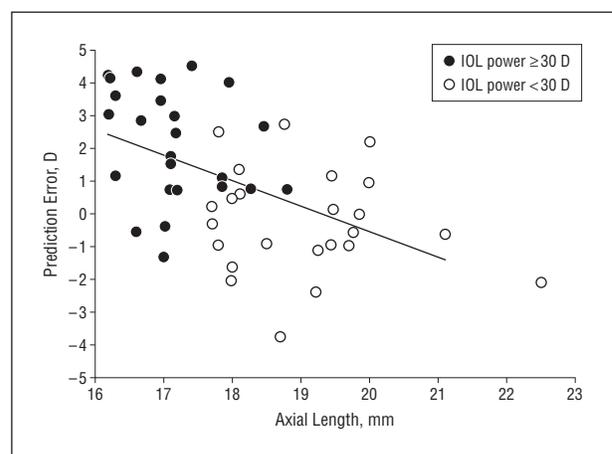


Figure 3. Prediction error in relation to axial length and intraocular lens (IOL) power. The solid line represents the estimated simple linear regression model relating prediction error to axial length (regression coefficient, -0.8 ; SE, 0.2 ; $R^2=0.3$; $P<.001$). D indicates diopters.

refractive errors. Eye growth occurs rapidly in the first 6 months of life so that increases in axial length during the first month after surgery could result in a reduction in the amount of hyperopia measured. On the basis of a hybrid logarithmic model of typical refractive growth,²¹ a typical eye made pseudophakic at the age of 1 month with a postoperative refraction of $+8.0$ D will have a myopic shift of 0.7 D by the age of 2 months, and a typical eye made pseudophakic at the age of 5 months with a postoperative refraction of $+6.0$ D will have a myopic shift of 0.4 D by the age of 6 months. Refraction was deferred until the 1-month visit to allow for resolution of the potentially large astigmatic error that can be induced by sutures in infant eyes or changes induced by inflammation or corneal edema.

The overall mean absolute PE was 1.8 (1.3) D. Previous reports^{1-6,13,15,22} have shown mean absolute PEs ranging from 0.7 to 1.5 D for pediatric eyes undergoing primary IOL implantation. Mean absolute PE is often higher and less predictable for eyes with axial lengths of less than 22 mm, even when using formulas designed for short

eyes,^{1,4,5} and in this cohort, 48 of 49 eyes had axial lengths of less than 22 mm. Most eyes with absolute PEs greater than 2 D in this cohort had axial lengths of less than 18 mm. Because axial length measurements greater than 20 mm were uncommon in this population (only 4 eyes), axial length measurements that are substantially longer than this should be carefully reviewed for accuracy.

Mean PE was calculated to assess the direction of miscalculation, with an undercorrection (more residual hyperopia than expected) represented by a negative value and an overcorrection (less residual hyperopia than expected) represented by a positive value. The mean PE for eyes with axial lengths greater than 18 mm was -0.1 (1.6) D, reflecting an almost equal number of overcorrections and undercorrections postoperatively, but eyes with axial lengths of less than 18 mm were often overcorrected, with less residual hyperopia than anticipated. Similarly, when eyes were compared by age group at surgery, less overcorrection was seen in the older group compared with the younger group. However, this may be explained by the expectation of more rapid ocular growth in the shorter, younger eyes in the early postoperative period. Elevated intraocular pressure can cause axial elongation and myopic shift in the infant eye, although none of the eyes were diagnosed as having glaucoma by the 1-month visit.

Gale et al²³ have suggested that after uncomplicated adult cataract surgery, 55% of eyes should have a PE of ± 0.5 D and 85% should have a PE of ± 1.00 D. In pediatric populations, however, the number of eyes with a PE of ± 1.0 D is lower. In one series, 43% of pediatric eyes had a PE of ± 0.5 D and 74.5% had a PE of ± 1.0 D using Holladay 1, but in the subset of eyes with axial lengths of less than 22 mm, only 20% had a PE of ± 0.5 D and 45% had a PE of ± 1.0 D.⁵ Not surprisingly, in the IATS, a similarly low percentage of infant eyes achieved a PE of ± 0.5 D (12%) or ± 1.0 D (41%).

In conclusion, a relatively large PE is common when performing IOL implantation in infant eyes, especially with the shortest axial lengths (<18 mm), even when using a formula designed for short eyes. In addition, implantation of an IOL with a power of 30.0 D or greater usually resulted in less residual hyperopia than expected. In these growing eyes, with less baseline hyperopia than planned and expected axial elongation, significant myopia may result in the long term. Refractive status of these children as they become older will be the subject of a future report.

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Additional Contributions: Cynthia Kendall, BMET, CDOS, ROUB, AA, reviewed and graded the quality of all the A-scan ultrasonogram reports for the IATS.

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