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Comparison of the rate of refractive growth in aphakic eyes versus pseudophakic eyes in the Infant Aphakia Treatment Study

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Abstract

PURPOSE—To compare the rate of refractive growth between aphakic eyes and pseudophakic eyes in the Infant Aphakia Treatment Study (IATS).

SETTING—Twelve clinical sites across the United States.

DESIGN—Randomized clinical trial.

METHODS—Patients randomized to unilateral cataract extraction with contact lens correction versus intraocular lens (IOL) implantation in the IATS had their rate of refractive growth (RRG3) calculated based on the change in refraction from the 1-month postoperative examination to age 5 years. The RRG3 is a logarithmic formula designed to calculate the rate of refractive growth in children. Two-group *t* tests were used to compare the mean refractive growth between the contact lens group and IOL group and outcomes based on age at surgery and visual acuity.

RESULTS—Longitudinal refractive data were studied for 108 of 114 patients enrolled in the IATS (contact lens group, *n* = 54; IOL group, *n* = 54). The mean RRG3 was similar in the contact

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A full list of the Infant Aphakia Treatment Study Group is available as Appendix 1, available at <http://jcrsjournal.org>.

lens group (-18.0 diopter [D] ± 11.0 [SD]) and the IOL group (-19.0 ± 9.0 D) ($P = .49$). The RRG3 value was not correlated with age at cataract surgery, glaucoma status, or visual outcome in the IOL group. In the aphakia group, only visual outcome was correlated with refractive growth ($P = .01$).

CONCLUSIONS—Infants' eyes had a similar rate of refractive growth after unilateral cataract surgery whether or not an IOL was implanted. A worse visual outcome was associated with a higher rate of refractive growth in aphakic, but not pseudophakic, eyes.

The myopic shift that occurs in children's eyes after cataract surgery has been reported to be logarithmic.^{1,2} Accurately predicting the myopic shift that will occur in a child's eye is important when implanting an intraocular lens (IOL) if one is aiming for a specific refractive error at a later age. In most cases, pediatric ophthalmologists undercorrect children in anticipation of an age-dependent myopic shift.^{3,4} However, if a larger than anticipated myopic shift occurs, it might be necessary to exchange the IOL when the child is older. Alternatively, if the myopic shift is less than anticipated, the child may have to wear a hyperopic correction on a long-term basis.

A myopic shift in a child's pseudophakic eye is largely dependent on the following 3 factors: (1) axial growth, (2) the location of the corrective lens (capsular bag, cornea, or spectacle plane), and (3) the power of the lens (higher power lens gives more myopic shift per millimeter of growth). Because serial globe axial length data might not be available in clinical practice, McClatchey et al.⁵ developed a logarithmic formula to calculate the rate of refractive growth (RRG) and eliminate the confounding effects of the corrective lens position and power. The RRG3 formula was designed to be used in children of all ages (including infants), and it can predict refractive changes. This allows surgeons to select the most appropriate IOL power for implantation.⁶

In this study, we used the RRG3 formula to determine whether infant eyes that had IOL implantation had a different rate of refractive growth than eyes left aphakic after cataract surgery.

PATIENTS AND METHODS

The Infant Aphakia Treatment Study (IATS) was supported through a cooperative agreement with the United States National Eye Institute of the National Institutes of Health and performed at 12 clinical sites. The study was approved by the institutional review boards at all participating institutions and was in compliance with the U.S. Health Insurance Portability and Accountability Act. The off-label research use of the Acrysof SN60AT and Acrysof MA60AC IOLs (Alcon Laboratories, Inc.) was covered by U.S. Food and Drug Administration investigational device exemption G020021. The primary purpose was to determine whether infants with a unilateral congenital cataract are more likely to develop better vision after cataract extraction with or without primary IOL implantation.^A

Study Design

The main inclusion criteria were a visually significant infantile onset cataract (> 3.0 mm central opacity) in 1 eye, a normal fellow eye, and an age of 28 days to less than 210 days at

the time of cataract surgery. The main exclusion criteria were an acquired cataract, persistent fetal vasculature causing stretching of the ciliary processes, and a corneal diameter less than 9.0 mm. Patients were randomized to have an IOL implanted at the time of cataract surgery or to be left aphakic and optically corrected with a contact lens.⁷

Surgical Technique

Infants randomized to the contact lens group had a lensectomy and anterior vitrectomy. Infants randomized to the IOL group had their lens aspirated followed by implantation of an IOL into the capsular bag or in the ciliary sulcus. This was followed by a posterior capsulectomy and anterior vitrectomy.⁸ The IOL power was calculated based on the Holladay 1 formula,⁹ targeting an 8.0 diopter (D) undercorrection for infants 4 to 6 weeks of age and a 6.0 D undercorrection for infants older than 6 weeks. Within a week after cataract surgery, patients randomized to the contact lens group were fit with a Silsoft (Bausch & Lomb, Inc.) or a rigid gas-permeable contact lens with a 2.0 D overcorrection to provide a near point focus. Spectacles were prescribed at or before the 1-month postoperative examination.

Patient Assessments

Follow-up clinical examinations were performed by an IATS-certified investigator postoperatively at 1 day, 1 week, 1 month, and 3 months and then at 3-month intervals until age 4 years and then at ages 4.25 years, 4.5 years, and 5.0 years. A cycloplegic refraction was performed at the 1-month postoperative examination using retinoscopy. For children in the aphakia group, an overrefraction was performed with the contact lens on the eye. The visual outcome was assessed at age 4.5 years by a traveling examiner.¹⁰ Intraocular pressure was assessed at age 4.5 years or 5.0 years using rebound tonometry (ICare Finland Oy),¹¹ a Tono-Pen (Reichert Technologies), or Goldmann applanation tonometry. Glaucoma and glaucoma suspect were diagnosed as reported previously.^{12,13} At age 5 years, a cycloplegic refraction was performed. An overrefraction was performed for children wearing a contact lens. When possible, all pseudophakic eyes and fellow eyes were refracted using an autorefractor. However, if autorefraction could not be performed, retinoscopy was used to perform the refraction.

Rate of Refractive Growth3 Calculations

The RRG3 was calculated by creating a spreadsheet for all patients enrolled in the IATS including age at surgery, initial refraction, age at initial refraction, final refraction, and age at final refraction; IOL power and A-constant were input for patients in the IOL group. The spreadsheet was used to calculate the RRG3 in each eye. The refractive errors measured closest to the 1-month postoperative examination and the examination at age 5 years were used for the analysis. When refractions were performed for children in the aphakia group wearing a contact lens, the refractive error at a vertex distance of 12.0 mm was calculated and then added to the overrefraction. For children who had an IOL exchange, the refraction obtained at the examination immediately before IOL exchange was used in the analysis.

Statistical Analysis

Two-group *t* tests were used to compare the mean RRG3 between the contact lens group and the IOL group. One-way analysis of variance (ANOVA) was used to compare the mean RRG3 and glaucoma status (none, glaucoma suspect, or glaucoma) stratified by treatment group. If necessary, Tukey post hoc pairwise comparisons were used to explain the results of the ANOVA results. Pearson correlation coefficients were used to compare the mean RRG3 to age at cataract surgery. Spearman correlation coefficients were used to compare the mean RRG3 to visual outcome at age 4.5 years because visual outcomes were not normally distributed. All reported *P* values are 2-sided without adjustment for multiple testing; *P* values of 0.05 or less were considered statistically significant.

RESULTS

Unilateral cataract surgery was performed on 114 infants. Fifty-seven infants were randomized to aphakia with contact lens correction and 57 to primary IOL implantation AcrySof SN60AT IOL into capsular bag, *n* = 53; AcrySof MA60AC IOL in ciliary sulcus, *n* = 3). An overrefraction was performed with the child wearing a contact lens in 32 patients (59%).

Three patients were excluded from the refractive analysis: a child who was randomized to the IOL group who did not have an IOL implanted, a child who had an IOL exchanged when only 10 months of age, and a child who was diagnosed as having Stickler syndrome. Three patients in the aphakia group that had incomplete refractive data were not included in the analysis. Thus, longitudinal refractive data were available for 108 of 114 patients (contact lens group, *n* = 54; IOL group, *n* = 54).

Table 1 shows the clinical findings of the patients. Cataract surgery was performed at a median age (25th, 75th percentiles) of 1.8 (1.1, 3.1) months in the contact lens group and 1.8 (1.2, 3.2) months in the IOL group. The mean RRG3 was similar between the contact lens group and IOL group (*P* = .49). In both treatment groups, the diagnosis of glaucoma or glaucoma suspect did not significantly affect RRG3, although there was a trend for the RRG3 to be higher in patients with the diagnosis of glaucoma (Table 2). In addition, there was no difference in the RRG3 related to age at cataract surgery (contact lens group: *r* = −0.075, *P* = .59; IOL group: *r* = −0.083, *P* = .55) (Figure 1). There was a significant difference in the mean RRG3 between treated eyes relative to visual acuity in the aphakic group (−0.35, *P* = .01), but not in the IOL group (−0.17, *P* = .24).

Three eyes had IOL exchange at a mean age of 1.72 years. At the 1-month postoperative examination, the mean spherical equivalent refraction of these eyes was +2.0 D and at the time of IOL exchange it was −12.5 D. One of these eyes developed glaucoma, and another was a glaucoma suspect. One patient had cataract surgery at 28 days of age and then had an IOL exchange performed 8 months later after the eye had a 13.5 D myopic shift. However, after the IOL exchange, the eye experienced only an additional −1.50 D myopic shift after 4 more years of follow-up.

DISCUSSION

We report that the rate of refractive growth was similar after unilateral cataract surgery in aphakic eyes corrected with a contact lens and eyes that had primary IOL implantation. Although there was a trend for eyes with the diagnosis of glaucoma to have a higher RRG3, the difference was not statistically significant. The RRG3 was not significantly related to age at surgery; however, the RRG3 was significantly related to the visual outcome in aphakic, but not pseudophakic, eyes.

Whitmer et al.¹⁴ reported a higher RRG3 in aphakic eyes than in pseudophakic eyes that had cataract surgery when the patient was younger than 6 months. We did not find a significantly higher RRG3 in aphakic eyes in the IATS. This is an important finding because it means that the RRG3 formula can be used to predict refractive growth for both aphakic eyes and pseudophakic eyes.

The RRG3 values were higher in our study than in the Whitmer et al. study.¹⁴ This difference might have arisen from the inclusion of children with both unilateral and bilateral cataracts in the Whitmer study, whereas we only enrolled infants who had a unilateral cataract in the IATS. McClatchey and Parks¹⁵ reported that the RRG was higher in eyes having unilateral cataract surgery.

We did not find a difference in the rate of refractive growth relative to age at the time of cataract surgery in our cohort of children who all had cataract surgery when 6 months of age or younger. McClatchey et al.⁵ reported a small effect of age on the rate of refractive growth when cataract surgery was performed in children younger than 6 months but no effect after 6 months of age. Whitmer et al.¹⁴ reported that the RRG3 was not significantly correlated with younger age at the time of cataract surgery (<6 months versus ≥6 months) in aphakic or pseudophakic eyes. Because the RRG3 is a semi-logarithmic formula, the greater refractive growth of infant eyes is already factored into the formula.

Uncontrolled glaucoma is known to be a cause of increased axial elongation in young children.¹⁶ Egbert and Kushner¹⁷ proposed that a large myopic shift could be a sign of juvenile glaucoma in the aphakic eyes of children. They reported 4 children with juvenile glaucoma who had large myopic shifts ranging from -9.25 to -21.00 D after having bilateral cataract surgery as infants. In contrast, McClatchey and Parks¹ reported no correlation between controlled glaucoma and the RRG3 in a large cohort of aphakic children who were followed longitudinally. We also did not find an association between the RRG3 and glaucoma or glaucoma-suspect status, although there was a trend toward higher RRG3 values in eyes with glaucoma. This is not unexpected because the eyes with glaucoma and glaucoma suspect in the IATS and the McClatchey and Park series¹ were being treated for glaucoma or glaucoma suspect. Nyström et al.² reported an increase in the rate of refractive growth in a child's eye with uncontrolled glaucoma but normal refractive growth in 2 eyes with controlled glaucoma. A delay in glaucoma treatment likely accounted for the large RRG in the Egbert and Kushner¹⁷ case series.

Amblyopia has been reported to increase the rate of refractive growth after pediatric cataract surgery.¹⁸ Superstein et al.¹⁹ reported that children who had cataract surgery when younger

than 6 months with a postoperative visual acuities of 20/40 or better had a reduced myopic shift compared with eyes with worse visual acuities. However, other studies have found no relationship between visual acuity and refractive growth.^{1,3,20} We found a correlation between the visual outcome and the RRG3 in aphakic eyes but not in pseudophakic eyes. This difference might reflect a greater effect on axial elongation of nonadherence to optical correction in aphakic eyes than in pseudophakic eyes, perhaps related to the higher refractive errors in aphakic eyes.

Three of 56 eyes (5%) in our series had an IOL exchange. The incidence of IOL exchange would likely have been higher if we had not targeted an undercorrection of +8.0 D in children having cataract surgery between 4 to 6 weeks of age and +6.0 D for children 7 weeks or older. Dahan and Drusedau¹⁸ targeted an undercorrection of 20% in infants having cataract extraction and primary IOL implantation and reported a similar IOL exchange rate (2 [3%] of 68 eyes). All 3 eyes in our study that had an IOL exchange had an undercorrection less than the targeted undercorrection. In fact, 1 child was slightly myopic at the 1-month postoperative visit. Intraocular lens exchange might have been avoided in these children if the targeted undercorrection had been achieved.

The mean myopic shift was only -6.18 D in the contact lens group compared with -9.66 D in the IOL group, even though the RRG3 values were similar in the 2 groups (contact lens group, -18.0 ± 11.0 D; IOL group -19.0 ± 9.0 D). The greater myopic shift in pseudophakic eyes was likely the result of the optical effect of a high-power IOL in a child's eye as it elongates. Because most growth in a child's eye occurs in the posterior segment, an IOL implanted during infancy will be farther from the retina as the eye grows, resulting in a larger myopic shift than would be experienced for an aphakic eye with the same amount of axial elongation.²¹

The limitations of our study include the small sample, which precluded our ability to analyze the rate of refractive growth in subgroups, such as patients with a visual acuity of 20/40 or better. The strengths of our study include its design as a randomized clinical trial with standardized protocols for refraction and a low rate of patients lost to follow-up. Whereas previous studies have reported a higher rate of refractive growth in aphakic eyes, these studies were all retrospective and subject to the selection biases and confounding variables associated with such studies.^{15,19}

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Appendix 1: The Infant Aphakia Treatment Study Group

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Data Coordinating Center (Emory University): Michael Lynn MS (Director), Betsy Bridgman, BS; Marianne Celano PhD; Julia Cleveland, MSPH; George Cotsonis, MS; Carey Drews-Botsch, PhD; Nana Freret, MSN; Lu Lu, MS; Seegar Swanson; Thandeka Tutu-Gxashe, MPH

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Eye Movement Reading Center (University of Alabama, Birmingham and Retina Foundation of the Southwest, Dallas, TX): Claudio Busettoni, PhD; Samuel Hayley; Eleanor Lewis, Alicia Kindred, Joost Felius, PhD

Steering Committee: Scott R. Lambert, MD; Edward G. Buckley, MD; David A. Plager, MD; M. Edward Wilson, MD; Michael Lynn, MS; Lindreth DuBois, MEd, MMSc; Carolyn Drews-Botsch, PhD; E. Eugenie Hartmann, PhD; Donald F. Everett, MA. Rotating: Joost Felius, PhD; Margaret Bozic, CCRC, COA; Ann Holleschau, BA

Contact Lens Committee: Buddy Russell, COMT; Michael Ward, MMSc

Participating Clinical Centers (In order by the number of patients enrolled):

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University of Minnesota; Minneapolis, Minnesota (13): Stephen P. Christiansen, MD; Erick D. Bothun, MD; Ann Holleschau, B.A.; Jason Jedlicka, OD; Patricia Winters, OD; Jacob Lang, OD

Cleveland Clinic; Cleveland, Ohio (10): Elias I. Traboulsi, MD; Susan Crowe, BS, COT; Heather Hasley Cimino, OD. **Case Western Reserve:** Faruk Orge, MD; Megin Kwiatkowski; Beth Colon

Baylor College of Medicine; Houston, Texas (10): Kimberly G. Yen, MD; Maria Castanes, MPH; Alma Sanchez, COA; Shirley York, OD; Stacy Malone, COA; Margaret Olfson

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Indiana University, Indianapolis, Indiana (7): David A. Plager, MD; Daniel E. Neely, MD; Michele Whitaker, COT; Donna Bates, COA; Dana Donaldson, OD

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University of Texas Southwestern; Dallas, Texas (6): David R. Weakley, MD; David R. Stager Jr M.D.; Joost Feliuss, PhD; Clare Dias, CO; Debra L. Sager; Todd Brantley, OD

Data and Safety Monitoring Committee: Robert Hardy, PHD (Chair); Eileen Birch, PhD; Ken Cheng, MD; Richard Hertle, MD; Craig Kollman, PhD; Marshalyn Yeargin-Allsopp, MD (resigned); Cyd McDowell; Donald F. Everett, MA

Medical Safety Monitor: Allen Beck, MD

Biography



Infants' eyes had a similar rate of refractive growth after unilateral cataract surgery whether or not an IOL was implanted. Aphakic eyes with poor vision had a higher rate of refractive growth.

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WHAT WAS KNOWN

- The myopic shift that occurs in children's eyes after cataract surgery is logarithmic.
- Most surgeons undercorrect children when implanting IOLs in anticipation of an age-dependent myopic shift.

WHAT THIS PAPER ADDS

- Aphakic and pseudophakic eyes had a similar rate of refractive growth after unilateral cataract surgery during the first 5 years of life.
- A worse visual outcome was associated with a higher rate of refractive growth in aphakic, but not pseudophakic, eyes.

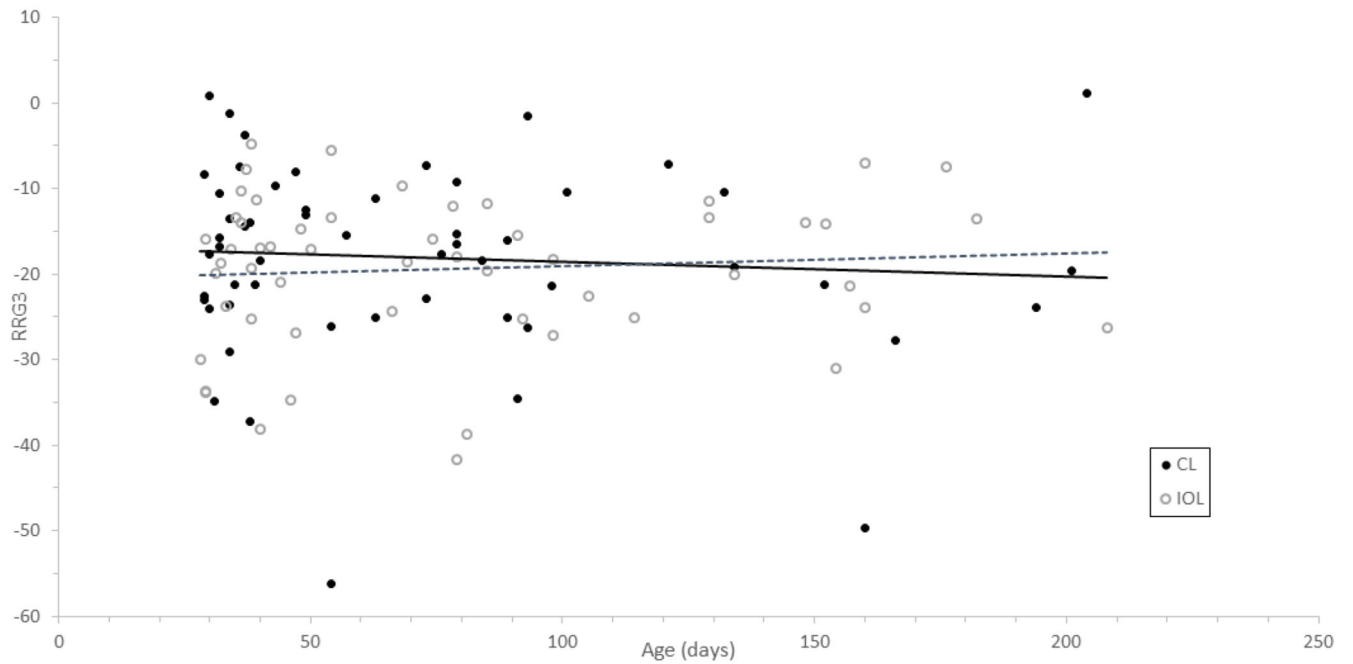


Figure 1.

Age at cataract surgery versus RRG3. There was an insignificant correlation between the 2 variables for both treatment groups (contact lens group, $r = 0.075$; intraocular lens group, $r = 0.083$) (CL = contact lens; IOL = intraocular lens; RRG3 = rate of refractive growth).

Table 1

Clinical findings.

Variable	Mean	SD	Min	Max
Aphakic group				
Age at surgery (mo)	2.4	1.6	0.9	6.7
Initial refraction (D)	+18.59	2.84	+12.46	+25.36
Age at initial refraction (mo)	3.4	1.6	1.5	7.5
Final refraction (D)	+12.41	5.20	−6.38	+19.28
Age at final refraction (y)	5.0	0.1	4.7	5.1
RRG3 (D)	−18	11	+1	−56
Pseudophakic group (n = 54)				
Age at surgery (mo)	2.4	1.6	0.95	6.7
IOL power (D)	29.46	5.92	11.50	40.00
Initial refraction (D)	6.05	2.71	−1.00	16.50
Age at initial refraction (mo)	3.8	2.0	1.7	10.5
Final refraction (D)	−3.68	5.77	−19.00	5.00
Age at final refraction (y)	4.9	0.6	0.9	5.4
RRG3 (D)	−19	9	−5	−42

IOL = intraocular lens; RRG3 = rate of refractive growth

Table 2

Glaucoma status versus RRG3 (D).

Glaucoma Status	Mean	SD	Min	Max
Aphakic group [*]				
None (n = 35)	35	−17	12	−56
Glaucoma suspect (n = 11)	11	−18	8	−29
Glaucoma (n = 8)	8	−22	8	−37
Pseudophakic group [†]				
None (n = 38 [‡])	−18	8	−39	−5
Glaucoma suspect (n = 4)	−23	9	−34	−14
Glaucoma (n = 11)	−23	9	−42	−10

^{*} Using 1-way analysis of variance for the 3 groups, $P = .54$.

[†] Using 1-way analysis of variance for the 3 groups, $P = .16$.

[‡] One patient lost to follow-up at 16 months was not included in this analysis because the glaucoma status of this patient was not known.