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

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PURPOSE: To compare the rate of refractive growth (RRG) 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 RRG 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 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 RRG in aphakic, but not pseudophakic, eyes.

Financial Disclosure: None of the authors has a financial or proprietary interest in any material or method mentioned.

J Cataract Refract Surg 2016; 42:1768–1773 © 2016 ASCRS and ESCRS

Supplemental material available at www.jcrsjournal.org.

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,

http://dx.doi.org/10.1016/j.jcrs.2016.09.021
0886-3350

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 RRG 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 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

Submitted: June 23, 2016.
Final revision submitted: September 19, 2016.
Accepted: September 20, 2016.

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Supported by the United States National Institutes of Health (NIH) grants U10 EY13272, U10 EY013287, UG1 EY025553, UG1EY013272 and in part by the NIH Departmental Core Grant EY006360, Bethesda, Maryland, and Research to Prevent Blindness, Inc., New York, New York, USA.

Presented in part at the annual meeting of the American Association for Pediatric Ophthalmology, Vancouver, Canada, April 2016.

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