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The Infant Aphakia Treatment Study: Design and Clinical Measures at Enrollment

The Infant Aphakia Treatment Study Group*

Abstract

Objective—To compare contact lenses and intraocular lenses (IOLs) for the optical correction of unilateral aphakia during infancy.

Methods—In a randomized, multicenter (12 sites) clinical trial, 114 infants with a unilateral congenital cataract were assigned to undergo cataract surgery either with or without IOL implantation. Children randomized to IOL treatment had their residual refractive error corrected with spectacles. Children randomized to no IOL had their aphakia treated with a contact lens

Main Outcome Measures—Grating acuity at 12 months of age and HOTV visual acuity at 4.5 years of age

Results—Enrollment began in December 2004 and was completed in January 2009. The median age at the time of cataract surgery was 1.8 months. Fifty patients were 4–6 weeks of age at the time of enrollment, 32 patients were between 49 days and 3 months of age and the remaining 32 children were 3 to 7 months of age. Fifty-seven children were randomized to each treatment group with either IOL placement or aphakia. The eyes with cataracts had shorter axial lengths and steeper corneas on average than the fellow eyes.

Conclusions—The optimal optical treatment of aphakia in infants is unknown. IATS was designed to provide empirical evidence whether optical treatment with an IOL or a contact lens following unilateral cataract surgery during infancy is associated with a better visual outcome.

INTRODUCTION

Intraocular lenses (IOLs) are now the standard-of-care for the optical correction of aphakia in older children and are being used with increasing frequency in younger children and infants.[1, 2] However, little is known about the long-term visual outcome when IOLs are implanted during infancy or about the most appropriate IOL power to chose for implantation in a rapidly growing eye.[3, 4] While some small case series have reported better visual outcomes following unilateral IOL implantation during infancy when compared to the correction of aphakia by a contact lens, it has also been reported to be associated with a higher frequency of postoperative complications.[5–7] It remains to be determined if the increased incidence of postoperative complications with primary IOL implantation is sufficiently offset by the improved visual outcome.

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Contact lenses are now the most widely accepted means for optically correcting unilateral aphakia during infancy in North America.[8] However, their use is associated with a number of problems limiting their effectiveness. Among these problems are poor cooperation while inserting and removing the lenses, the high costs of contact lenses, problems with lens loss, the difficulty of fitting the steep corneas of infants and the risk of bacterial keratitis.[8–11] These difficulties likely contribute substantially to the poor visual outcome of many children with unilateral aphakia.

The Infant Aphakia Treatment Study (IATS) is a multi-center, randomized, controlled clinical trial comparing IOL versus contact lens treatment after cataract surgery performed in children with a unilateral congenital cataract between 1 and 6 months of age. This paper describes the design of the study and the clinical findings in these patients at the time of enrollment.

Screening and Enrollment

This study was approved by the Institutional Review Boards of all of the participating institutions and is in compliance with the Health Insurance Portability and Accountability Act. The main inclusion criteria were the presence of a visually significant congenital cataract (≥ 3 mm central opacity) in only one eye and an age of 28 days to <210 days at the time of cataract surgery. Other inclusion and exclusion criteria are listed in Table 1. To avoid selection bias, all IATS investigators agreed to not perform IOL implantation in any patient less than 7 months of age with a unilateral cataract who was not enrolled in IATS until recruitment for the study was completed.

Potential patients were initially screened during an office exam and subsequently scheduled for an examination-under-anesthesia (EUA). The informed consent stipulated that once the EUA confirmed that a patient was eligible for the study, the patient would immediately be randomized in the operating room. A sealed envelope containing the treatment assignment was brought to the EUA by the investigator and opened once the patient was determined to be eligible. In the event a patient was deemed to be ineligible, the unopened envelope was mailed back to the Data Coordinating Center (DCC).

Surgical Procedure

Surgery was performed by a study-certified, fellowship-trained pediatric ophthalmologist. Surgery for infants randomized to the contact lens (CL) group was initiated with two stab incisions made superiorly at the limbus. An infusion cannula was placed through one incision and a vitreous cutting instrument through the other. The vitreous-cutting instrument was then used to create an anterior capsulectomy that was 5 mm or greater in diameter and to aspirate the lens nucleus and cortex. The vitreous-cutting instrument was also used to create a posterior capsulectomy 4 mm or greater in diameter and to perform an anterior vitrectomy. The two limbal stab incisions were then closed with 9-0 or 10-0 synthetic absorbable sutures and subconjunctival injections of antibiotics and steroids were administered. Lastly, one drop of 0.5% or 1% atropine and an antibiotic/steroid ointment were placed in the operated eye which was then patched.

For infants randomized to the IOL group, a 3 mm tunnel incision was created superiorly. Stab incisions into the anterior chamber were then made in the center of the tunnel incision for the vitrectomy probe and at the limbus laterally or nasally for the irrigating cannula. An anterior capsulotomy 5 mm or greater in size was created either with a vitreous-cutting instrument or manually using capsulorrhexis forceps after filling the anterior chamber with an ophthalmic viscosurgical device (OVD). The lens nucleus and cortex were then aspirated with a vitreous cutting instrument. The tunnel incision was then enlarged to 3.0 mm and the anterior segment was filled with an OVD. An AcrySof SN60AT IOL (Alcon Laboratories, Fort Worth, TX) with

the power calculated during the EUA was then implanted into the capsular bag. If both haptics could not be implanted into the capsular bag, an AcrySof MA60AT IOL (Alcon Laboratories, Fort Worth, TX) was implanted into the ciliary sulcus after subtracting 1.0 D from the calculated IOL power (www.doctor-hill.com). The off-label research use of Acrysof SN60AT and MA60AC IOLs was covered by FDA IDE # G020021. The IOL power was determined based on the Holladay 1 formula targeting an 8 D undercorrection for infants 4–6 weeks of age and a 6 D undercorrection for infants older than 6 weeks. In patients in whom the calculated IOL power was > 40 D, a 40 D IOL (the maximum power available) was implanted.

The tunnel incision was then closed with 9-0 or 10-0 synthetic absorbable sutures and the OVD was removed from the anterior chamber with an irrigation-aspiration instrument. A stab incision was then made at the pars plana/plicata (1.5 –2.0 mm posterior to the limbus). A central posterior capsulectomy 4 mm or greater in size, and an anterior vitrectomy removing about 1/3 of the vitreous directly behind the IOL, was then performed using a vitreous cutting instrument. The pars plana/plicata incision was closed with either a 7-0 or 8-0 synthetic absorbable suture and the limbal stab incision was closed with a 9-0 or 10-0 synthetic absorbable suture. If a pre-existing opening was present in the posterior capsule or a rent developed intraoperatively, or in some eyes with persistent fetal vasculature (PFV), the posterior capsulotomy and anterior vitrectomy were performed through a limbal rather a pars plana/plicata incision prior to IOL implantation. At the end of surgery, one drop of 0.5% or 1% atropine and an antibiotic-steroid ointment were placed in the operated eye which was then patched (see online IATS Manual of Procedures for more details).

To ensure adherence to the protocol, surgical procedures were videotaped and reviewed in a masked fashion by members of the IATS Steering Committee who submitted a written evaluation that was forwarded to the surgeon.

For both the IOL and the CL groups, the postoperative regimen consisted of instilling topical prednisolone acetate 1% in the treated eye at least 4 times a day for 1 month but never longer than 6 months following cataract surgery. In addition, a topical antibiotic was instilled in the treated eye 3 to 4 times a day for one week following cataract surgery, and atropine 0.5% or 1% was instilled twice daily in the treated eye for 2 to 4 weeks following surgery. Medications were instilled in the presence of a contact lens if applicable.

Patching Regimen

Parents were instructed to have their child wear an adhesive occlusive patch over the phakic eye 1 hour/day per month of age starting the second week after cataract surgery until the child was 8 months old. Thereafter, the phakic eye was patched all waking hours every other day or one-half of the child’s waking hours every day. In the event of patching failure, investigators were allowed to initiate amblyopia therapy using a high plus or occluder contact lens in the phakic eye after obtaining approval from the Steering Committee. If an allergy developed to occlusive patches, a cloth patch could be worn over the spectacle lens of the phakic eye.

Contact Lenses

Within a week after cataract surgery, patients randomized to the CL group were fitted with a Silsoft (Bausch and Lomb, Rochester, NY) or a rigid gas permeable (RGP) CL with a 2.0 D overcorrection to provide a near point correction. If an accurate refraction could not be obtained, a +32 D CL was dispensed and the lens power was subsequently refined at the earliest opportunity. At two years of age, the eye was corrected for emmetropia. Parents were given a spare contact lens. Contact lenses were assessed at each visit. In cases where a Silsoft CL could not be worn successfully, a RGP CL was substituted and vise versa. Another option was the use of a custom soft contact lens. A patient was deemed to have failed CL wear if the fitted

lens was worn for fewer than 4 hours a day on average over a period of 8 consecutive weeks. A trial with aphakic spectacles was mandated prior to considering secondary IOL implantation which required approval of the Steering Committee.

PMMA or AcrySof IOLs could be used for secondary IOL implantation and could be implanted either in the ciliary sulcus after severing all posterior synechiae[12, 13] or placed into the capsular bag after opening Soemmerring's ring.[14] The power of the secondary IOL was left to the discretion of the surgeon.

Spectacles

Spectacles were not prescribed for children in the contact lens group until they were two years old, at which point a "D" segment bifocal lens with a distance correction for emmetropia and near add of +3 D was prescribed. Infants randomized to the IOL group were prescribed spectacles by the one-month post-operative visit provided that any of the following conditions existed: hyperopia >1 D, myopia >3 D, or astigmatism >1.5 D. Below the age of 2 years, the aim was to correct the refractive error to 2 D of myopia. In children 2 years of age or older, the aim was to have a distance correction of emmetropia with a near correction of +3 D. The phakic eye was corrected with spectacles provided that one of the following conditions existed: hyperopia > 5 D, myopia > 5 D, astigmatism > 1.5 D, or refractive esotropia. The aim was to correct the refractive error to between 0 and +3 D in the phakic eye. In all other cases, a plano lens was prescribed for the phakic eye.

Follow-up Examinations

Follow-up examinations were performed by an IATS certified investigator at one day, one week, one month, and 3 months following cataract surgery. Thereafter, follow-up examinations were performed at 3-month (± 2 weeks) intervals. When the child reached 4 years of age, follow-up examinations were performed at 4, 4 ¼, 4 ½ and 5 years of age. Examinations included an assessment of: visual acuity, the anterior segments and pupils, the degree of refractive error and ocular alignment. In addition, the fit of the CL was assessed by a CL specialist.

Grating Acuity Assessment at One Year of Age

Monocular grating acuity was assessed at 12 ± 2 months of age by a traveling examiner using Teller Acuity Cards (Stereo Optical, Chicago, IL). The child's optical correction was updated 2–4 weeks prior to acuity testing based on retinoscopy findings obtained during an EUA. The aphakic/pseudophakic eye was tested first. When nystagmus was present, monocular visual acuity was tested using a +10 D lens placed over the eye not being tested. Each site had a puppet stage for presentation of the grating stimuli; the standard test distance was 55 cm measured from the screen to the child's eyes. Children with poor visual acuity were tested at nearer distances (e.g. 38, 19, or 9.5 cm). The Low Vision Card could be used to determine the presence of some pattern vision, or the child's vision was recorded as LP or NLP following standard clinical protocols.

Optotype Acuity Assessment at 4.5 Years of Age

Best corrected visual acuity was tested at 4.5 years of age using the HOTV recognition acuity test. Testing was standardized by using the Electronic Visual Acuity Tester (EVAT) and administered by a traveling tester.[15–17] To ensure that subjects were familiar with the HOTV matching test, this test was introduced at the two previous exams. The aphakic/pseudophakic eye was tested first. Occlusion of each eye was accomplished by having the child wear a pair of "sunglasses" consisting of a translucent occluder over one eye thereby minimizing the presence of latent nystagmus under monocular conditions. Children unable to perform HOTV

acuity testing in the treated eye had the operated eye assessed for the presence of gross pattern vision using the Low Vision Card from the Teller Acuity Card set or for the presence of light perception (LP).

Parenting Stress

The Parenting Stress Index (PSI)[18, 19] and the Ocular Treatment Index (OTI)[20] were administered to parents 3 months after surgery, at the first visit following the grating acuity assessment and at 4.25 years of age.

Compliance with Patching and Optical Correction

Compliance with patching and optical correction was assessed using 48-hour recall telephone interviews conducted by a trained interviewer at the DCC every 3 months and by having parents keep a 7-day diary once each year. Diaries were sent from the DCC two months after surgery and then annually one month after the child's birthday.

Secondary Outcomes Assessed at 4.5 years

Other measured outcomes included: stereopsis, pachymetry, biometry, tonometry and eye movements. Stereopsis was measured using the Frisby Stereotest (Clement Clarke, Harlow, UK) and the Randot Preschool Tests (Stereo Optical, Chicago, IL). If these tests did not demonstrate any level of stereopsis, an attempt was made to identify gross stereopsis using the Titmus fly picture (3000 seconds of arc)(Stereo Optical, Chicago, IL). Pachymetry was performed using the Pachmate (DHG Technology, Exton, PA) after the instillation of topical anesthetic drops. Keratometry readings were obtained from both eyes using the IOLMaster (Carl Zeiss Meditec, Dublin, CA), an autorefractor, or a handheld keratometer. Tonometry was performed with Goldman applanation, a Tono-Pen XL (Medtronic Solan, Jacksonville, FL) or rebound tonometry (ICare, Helsinki, Finland).

Eye Movement Recordings

Recordings of eye movements during fixation were obtained with a video camera visualizing both eyes simultaneously at a frame rate of 400 Hz and with a resolution of 1280×1024 pixels. Eye illumination was obtained with standard infrared LED illuminators. The child was seated on his/her mother lap and with his/her head in a chinrest. The visual targets were small red LEDs, embedded into black solid screens. The "near" screen was placed at 33 cm, and had 5 targets, center, up 20°, down 20°, left 20°, and right 20°. A second "far" screen, with a single, brighter center target was placed at 1.5 m in a slightly off-center position to be visible behind the "near" screen. The patient was asked to look at each target for approximately 7 sec, followed by a period of rest. The task was performed with the aphakic eye viewing first, then the phakic eye viewing and finally with binocular viewing and with both eyes patched. The eyes were patched with near IR filters, which were completely black for the child, but transparent for the camera.

Developmental Testing at 4.5 Years of Age

The Child Behavioral Checklist (CBCL) was completed by the caregiver at the 4 ½ year examination.[21] The Movement ABC-2, a test of fine and gross motor development, was administered by the traveling tester at the 4 ½ year examination as well.[22, 23]

Secondary Outcomes Assessed at 5 years of Age

Ocular motility, optical biometry (IOL Master, Carl Zeiss Meditec, Dublin, CA), non-contact specular microscopy (Konan Medical USA, Torrance, CA), tonometry, and keratometry were

assessed. Ocular alignment was assessed using the simultaneous prism and cover test if possible. If not, ocular motility was assessed using the Krimsky or Hirschberg light reflex test.

Statistical Considerations

The primary hypothesis tested was that the mean visual acuity at 12 months of age would be 0.2 logMAR better in the IOL group compared to the CL group. The sample size estimate was based on an independent groups t test with alpha=0.05 (two tailed) and power=0.8. The variance of visual acuity was estimated to be 0.365 based on previously published data.[6] The resulting sample size estimate was 57 patients per group and included an adjustment for 5% lost to follow-up.

Randomization was stratified for two factors: clinical center (3 groups based on the experience of the investigators) and patient age (two groups, 28–48 days and 49–210 days).

Data Safety and Monitoring Committee (DSMC)

An independent DSMC appointed by the National Eye Institute was responsible for monitoring patient safety and study performance. The DSMC met semiannually to review data and interim reports as deemed necessary. In addition to the DSMC, another ophthalmologist served as a medical monitor who reviewed adverse events on a monthly basis and alerted the DSMC if patient safety was jeopardized.

RESULTS

Patient Characteristics

One hundred and fourteen patients were enrolled in the study, 57 patients in each of the treatment groups, between December 2004 and January 2009. The median age at the time of surgery was 1.8 months and ranged from 28 days to 6.7 months; 50 were 28–48 days old and 82 were ≤ 3 months old (Table 1). An equal number of patients who were 28–44 days old were randomized to the IOL and CL groups (25 in each group). Gender was fairly equal between females (52%) and males (48%). The patients were predominantly white (85%); 7% were black and 8% were from other races. Sixteen percent of the patients were Hispanic. Most patients had private insurance (61%); 34% qualified for Medicaid. A slightly higher percentage of patients randomized to contact lens treatment had private health insurance (65% vs 58%), but this difference was not statistically significant. Four patients had other congenital abnormalities in addition to the unilateral cataract that did not affect the visual system (heart murmur, ventricular septal defect, possible unilateral hearing loss, and syndactyly between two toes).

Ophthalmic Exam

The lens, cornea and iris of the fellow eye were normal for all patients at the time of surgery. Nine cataractous eyes (8%) had an abnormal iris and 1 cataractous eye (1%) had an abnormal cornea. The mean corneal diameters (10.5 vs 10.8 mm), pupil size (3.3 vs 3.4 mm) and axial lengths (18.0 vs 18.6 mm) were slightly smaller for the cataractous eyes compared to the fellow eyes. The corneas of the cataractous eyes were on average about 1 D steeper than the fellow eyes. The mean intraocular pressure was between 12–13 mmHg for both the cataractous and fellow eyes. The mean refractive error of the fellow eyes was 2.4 ± 2.0 D. The refractive error could not be determined preoperatively for the cataractous eyes. The retina and optic nerves of both eyes were normal and 72% of patients were orthotropic.

DISCUSSION

There currently exists uncertainty about the optimal optical treatment for infants with unilateral congenital cataracts who undergo cataract surgery. It has been suggested that the practice of

using contact lenses may be contributing to the poor long-term visual outcomes in these patients and in recent years there has been increasing use of IOLs to optically correct unilateral aphakia during infancy.[7, 24] Early reports have suggested an increased incidence of complications with this approach; however, there have been no randomized clinical trials looking at the effectiveness of this treatment. The Infant Aphakia Treatment Study was designed to compare the effectiveness and problems associated with optical rehabilitation using contact lenses versus IOLs for the correction of aphakia in infants with unilateral congenital cataracts. While unilateral congenital cataracts are uncommon, the results of this trial may be generalizable to children with bilateral congenital cataracts which are a leading cause of childhood blindness particularly in developing countries. [25]

Visual acuity, the primary outcome, was assessed at 12 months of age using Teller Acuity Cards and at 4.5 years of age using the HOTV test. In both instances, a traveling examiner performed these assessments to ensure that the tests were administered in a standardized manner. The surgical protocols were developed during pilot studies and were designed to minimize the risks to the eyes undergoing surgery and to optimize the visual outcome. For some study investigators, these protocols represented a departure from their usual surgical practices. To ensure thorough familiarity with these protocols, investigators had to pass an online test and submit a video documenting their ability to perform this surgery using the IATS protocol before they were allowed to enroll any patients in the study.

The decision to undercorrect the IOL power by 8 D for infants 4–6 weeks of age and 6 D for infants ≥ 7 weeks of age was based on data from pilot studies and case series.[4, 5, 7, 26, 27] The goal was to end up with a small myopic refractive error in the pseudophakic eyes when these children reached adulthood. While fully correcting them during infancy with an IOL would have obviated the need for an immediate overcorrection, this would likely have resulted in highly myopic refractive errors in the pseudophakic eyes later in childhood which in turn would have required an optical overcorrection and possibly an IOL exchange. The decision to undercorrect the children randomized to receive an IOL necessitated that these children wear either spectacles or a contact lens to optically correct the residual refractive error in their pseudophakic eyes. The protocol required that the children in the IOL group have their residual refractive error corrected with spectacles to avoid crossover between the two treatment groups. We chose to provide a near correction for both treatment groups until they were two years of age because of the importance of near vision in young children. The AcrySof SN60 IOL was used because it could be implanted through a small incision and because it conforms better to the smaller capsular bag of an infant than a 3- piece IOL.[2]

A standardized patching regimen was used for both treatment groups because of the complexity of customizing patching regimens in young children and the paucity of data demonstrating the superiority of customized patching regimens in young children with unilateral aphakia/pseudophakia.[9, 28] We chose to use a staircase patching regimen during the first 8 months of life because it has been reported to be associated with improved stereopsis.[29] Patching compliance is one of the most important determinants of visual outcomes in children with unilateral aphakia/pseudophakia.[30, 31] We pilot tested several techniques to objectively quantify patching compliance,[32] but ultimately chose to assess it based on parental report using regular telephone interviews and patching diaries kept by the caregiver.

It is generally believed that contact lens management in a young child is difficult for parents and it results in increased parental stress. It is also likely that the increased complications and surgical procedures reported in our pilot study using IOLs would also increase parenting stress. [5] In the event that both treatments were found to be equally effective in improving vision, it might be reasonable to recommend the one that was less stressful for parents. Reducing

parenting stress early in the treatment process may also improve compliance with patching and spectacle and/or contact lens use.

The patients enrolled in the study had a median age of 1.8 months. Ideally enrollment would have been limited to infants < 7 weeks of age since Birch and Stager[33] have demonstrated that the visual prognosis of a child with a unilateral congenital cataract worsens if surgery is delayed beyond 6 weeks of age. Of the patients enrolled, 44% were in this age group. It took this group of 12 clinical sites slightly more than 4 years to enroll 114 patients so it would likely have taken 8+ years to enroll 114 patients who were < 7 weeks of age at the time of cataract surgery. The randomization was stratified so that equal numbers of patients in this younger age group would be enrolled in both treatment groups. Surgery was deferred until patients were at least 28 days of age because several case series have reported a higher incidence of aphakic glaucoma in children undergoing cataract surgery during the first 4 weeks of life.[5, 34, 35] Also, no negative affect on the visual outcome has been observed by delaying cataract surgery until infants are 4 weeks of age as long as the surgery is performed by 6 weeks of age. [33] Forty-four patients (39%) were initially examined when they were less than 28 days of age; all 44 had surgery by 2 months of age.

The cataractous eyes were slightly smaller than their fellow eyes. Since a corneal diameter < 9 mm was one of the exclusion criteria, it is likely that the mean corneal diameter of the cataractous eyes would have even been even smaller if microphthalmic eyes would have been enrolled in the study. At the time of surgery, the mean axial length of the cataractous eyes was 18.0 mm and the fellow eyes 18.6 mm, which is similar to what has been reported in age-matched normal eyes.[36] The axial length of a full-term infant eye at birth has been reported to be 16.8–17.3 mm in length.[36, 37] The eye undergoes rapid elongation during early infancy. Another advantage of deferring surgery until an infant is 4 weeks of age is to reduce the myopic shift these eyes will experience secondary to axial elongation and corneal flattening, thereby allowing an IOL power to be chosen which will be closer to that which will be needed later in childhood.

The racial distribution of the study mirrors that of the United States. In the 2000 census (www.census.gov), 77% of the population was white, 13% was black and 4% was Asian. We had a slightly higher percentage of whites enrolled in our study (85%) than the national average. A sizeable minority of the whites were Hispanic which likely reflects the fact that there were study sites in Florida and Texas, two states with large Hispanic populations. Five sites had IRB approval for a Spanish translation of the informed consent.

About two-thirds of the enrolled patients had private health insurance. By chance a slightly higher percentage of the patients with private health insurance were randomized to the contact lens group albeit the difference was not statistically significant. Other studies have shown that patients with private health insurance are more compliant with medical therapies so it would be expected that if anything the group of patients randomized to the contact lens group might have been more likely to comply with patching therapy than the children randomized to the IOL group.[38]

We believe that IATS, a multi-center, randomized, controlled clinical trial, will clarify whether IOL or contact lens treatment is associated with a better visual outcome following the surgical extraction of a unilateral congenital cataract during the first six months of life.

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Appendix 1: The Infant Aphakia Treatment Study Group

Administrative Units and Participating Clinical Centers

Clinical Coordinating Center: Scott Lambert (Study Chair), Lindreth DuBois (National Coordinator)

Data Coordinating Center: Michael Lynn (Director), Betsy Bridgman, Marianne Celano, Julia Cleveland, George Cotsonis, Carey Drews-Botsch, Nana Freret, Lu Lu, Seegar Swanson, Thandeka Tutu-Gxashe

Visual Acuity Testing Center: E. Eugenie Hartmann (Director), Clara Edwards, Claudio Busettini, Samuel Hayley

Steering Committee: Scott Lambert, Edward Buckley, David Plager, M. Edward Wilson, Michael Lynn, Lindreth DuBois, Carey Drews-Botsch, E. Eugenie Hartmann, Donald Everett

Contact Lens Committee: Buddy Russell, Michael Ward

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

Medical University of South Carolina (14): M. Edward Wilson, Margaret Bozic

Harvard University (14): Deborah VanderVeen, Terri Mansfield, Kathryn Miller

University of Minnesota (13): Stephen Christiansen, Erick Bothun, Ann Holleschau, Jason Jedlicka, Patricia Winters

Cleveland Clinic (10): Elias Traboulsi, Susan Crowe, Heather Hasley Cimino

Baylor University (10): Kimberly Yen, Maria Castanes, Alma Sanchez, Shirley York

Oregon Health and Science University (9): David Wheeler, Ann Stout, Paula Rauch, Kimberly Beaudet, Pam Berg

Emory University (9): Scott Lambert, Amy Hutchinson, Rachel Reeves, Lindreth DuBois, Marla Shainberg

Duke University (8): Edward Buckley, Sharon Freedman, Lois Duncan, BW Phillips

Vanderbilt University (8): David Morrison, Sandy Owings, Ron Biernacki, Christine Franklin

Indiana University (7): David Plager, Daniel Neely, Michele Whitaker, Donna Bates, Dana Donaldson

Miami Children's Hospital (6): Stacey Kruger, Charlotte Tibi, Susan Vega

University of Texas Southwestern (6): David Weakley, David Stager, Jr., Joost Felius, Clare Dias, Debra L. Sager, Todd Brantley

Data and Safety Monitoring Committee: Robert Hardy (Chair), Eileen Birch, Ken Cheng, Richard Hertle, Craig Kollman, Marshalyn Yeargin-Allsopp, (resigned), Cindy Bachman, Donald Everett

Medical Safety Monitor: Allen Beck

Table 1

IATS Inclusion/Exclusion Criteria

Inclusion Criteria	
1	Visually significant congenital cataract (≥ 3 mm central opacity) in one eye.
2	Age 28 days to less than 7 months (<210 days) at the time of cataract surgery.
3	At least 41 post-conceptional weeks at the time of cataract surgery.
4	Written informed consent provided by parent or legal guardian agreeing that the patient could be randomized in the operating room if the exam under anesthesia confirmed that the patient was eligible for the study.
Exclusion Criteria	
1	The cataract was known to be acquired from trauma or as a side effect of a treatment administered postnatally.
2	Corneal diameter < 9 mm.
3	Intraocular pressure 25 mm Hg or greater.
4	Persistent fetal vasculature (PFV) causing stretching of the ciliary processes or a tractional detachment of the retina.
5	Active uveitis or signs suggestive of a previous episode of uveitis.
6	The child was the product of a pre-term pregnancy (<36 gestational weeks).
7	Retinal disease that may limit the visual potential of the eye.
8	Previous intraocular surgery.
9	Optic nerve disease that may limit the visual potential of the eye.
10	The fellow eye had ocular disease that might reduce its visual potential.
11	The child had a medical condition that might impair visual acuity testing at 12 months or 4 1/2 years of age.
12	The child was not able to return to an IATS clinical center for regular follow-up examinations.

Table 2

Baseline Characteristics of IATS Patients*

Characteristic	Treatment		Total n = 114
	Contact Lens n = 57	IOL n = 57	
Age at Surgery (mo)	1.8 (1.1, 3.1)	1.8 (1.2, 3.2)	1.8 (1.2, 3.2)
Category of Age at Surgery			
28 – 48 days	25 (44%)	25 (44%)	50 (44%)
49 days – 3.0 mo	17 (30%)	15 (26%)	32 (28%)
3.1 mo – 5.0 mo	9 (16%)	10 (18%)	19 (17%)
5.1 mo – 7.0 mo	6 (11%)	7 (12%)	13 (11%)
Female Gender	32 (56%)	28 (49%)	60 (52%)
Race			
White	49 (86%)	48 (84%)	97 (85%)
Black	3 (5%)	5 (9%)	8 (7%)
Other	5 (9%)	4 (7%)	9 (8%)
Have Private Insurance	37 (65%)	33 (58%)	70 (61%)
Qualify for Medicaid	17 (30%)	22 (39%)	39 (34%)
Pupil Diameter – Cataractous Eye (mm)	3.3 ± 1.0	3.2 ± 1.0	3.3 ± 1.0
Pupil Diameter – Fellow Eye (mm)	3.5 ± 0.9	3.4 ± 0.9	3.4 ± 0.9
Corneal Diameter – Cataractous Eye (mm)	10.5 ± 0.7	10.5 ± 0.8	10.5 ± 0.7
Corneal Diameter – Fellow Eye (mm)	10.8 ± 0.6	10.8 ± 0.7	10.8 ± 0.6
IOP – Cataractous Eye (mmHg)	12.7 ± 4.9	11.8 ± 4.9	12.2 ± 4.9
IOP – Fellow Eye (mmHg)	12.9 ± 5.1	12.9 ± 4.3	12.9 ± 4.7
Keratometry – Cataractous Eye (D)	46.4 ± 2.7	46.4 ± 2.7	46.4 ± 2.7
Keratometry – Fellow Eye (D)	45.5 ± 1.8	45.4 ± 1.9	45.5 ± 1.8
Axial Length – Cataractous Eye (mm)	18.0 ± 1.3	18.1 ± 1.3	18.0 ± 1.3
Axial Length – Fellow Eye (mm)	18.4 ± 0.9	18.7 ± 0.9	18.6 ± 0.9
Refractive Error – Fellow Eye (D)	2.4 ± 1.8	2.3 ± 2.2	2.3 ± 2.0

*Values in the table are mean ± standard deviation or n (%) except for Age at Surgery where the values are median (25^{th} percentile, 75^{th} percentile). There were no significant differences between the two treatment groups at the 0.05 significance level.