Abusive Head Trauma (AAPOS Workshop 2011)

Homicide is the leading cause of injury and death in infancy, and half of infant homicides occur during the first four months of life (1,2). The majority of these deaths are caused by abusive head trauma, which results from violent, non-accidental shaking, blunt impact to the head, or both. Historically, the injuries resulting from repetitive unrestrained head and neck movements from shaking were termed the “whiplash shaken infant syndrome” which was commonly referred to as the “Shaken Baby syndrome”(3)and more recently Abusive Head Trauma,. Those perpetrators who have confessed support the prominence of repetitive violent shaking as the key element in generation of Abusive Head Trauma. Clinical findings in affected infants include subdural hemorrhage, hypoxic-ischemic brain injury, retinal hemorrhages, skeletal injuries, and cutaneous or other injuries.

References:

5) Levin, A. Retinal Hemorrhage in Abusive Head Trauma http://www.pediatrics.org Pediatrics published online Oct 4, 2010; DOI: 10.1542/peds.2010-1220


Ophthalmic medical missions: How to engage and serve effectively.

Michael G Hunt, Alan A Norman, Paul G Steinkuller, Sanford Roberts II, David Stager Jr.

Relevance: Ophthalmic medical missions occur worldwide among many types of organizations and populations. Many attendees participate or would like to participate in missions but find it difficult to evaluate possible projects and ensure that they are serving in the most effective manner. Learning from the successes and failures of those who have participated in many missions endeavors can equip attendees to be more fulfilled and successful as they serve others.

Delivery Format(s): This workshop will consist of a panel discussion by representatives who have participated in short and long term ophthalmic medical missions with a variety of different organizations as well as a question and answer session.

Content: Panel members will talk about their personal experiences including the challenges and successes encountered in serving with different mission organizations in many countries. They will discuss how to assess different mission opportunities, how to engage patients and local physicians in different cultures, and how to serve in a manner that is both beneficial for the recipients and fulfilling for the participating doctors.

Learning Objective(s): At the conclusion of the symposium, the attendees will have the knowledge to evaluate different models of medical missions engagement and be encouraged to participate in a manner that is helpful for those they serve and rewarding for them.
Ethics and Preparation for Overseas Medical Missions

Alan A. Norman, MD

I. Goals

A. Help Others - Primum non nocere
B. Prepare
   1. Change perspective
   2. Education
   3. Logistics
C. Edify

II. Primum Non-nocere

A. Who could be harmed? Risk is inherent.
   1. Me
   2. Patient
   3. US Organization
   4. Local Physicians/Organization
B. Versus doing good (James 4:17)
   1. Growing grass instead of killing weeds
   2. Do I tolerate the bad with the good?

III. Prepare – Change Perspective

A. What do I want to accomplish?
   1. Ask yourself why you want to do this?
      a. Is this my calling?
      b. Secondary gain
      c. Adventure/Excitement
      d. Great commission
   2. Legacy
      a. Teach the teachers - The way to continue the work
      b. Improve livelihood of others - Quality of life/Economically
      c. Lead by example - Inspire others (children, staff, etc)
      d. Change local perspective on what can and cannot be done
IV. Prepare – Education

A. Research the Country and Region  
   1. Before leaving  
      a. What is needed by the people?  
      b. Cultural Differences (language, customs, food)  
      c. Advertise the trip  
      d. To locals through community organizers- to avoid disappointment  
      e. To your friends – they want to help you pay for it  
   2. Upon arrival in country  
      a. Locals - Ask their opinion of previous mission physicians / US  
      b. Non-governmental organization workers  

V. Prepare – Logistics

A. Work the Plan  
   1. Push the Easy Button  
   2. Plan to change  
   3. Plan to rest  
   4. Plan to not get frustrated  

B. Research the WHO follow-up recommendations  
   1. Plan to study your results  
   2. Are you doing good work?  

C. Check license requirements for the area  
D. Check equipment and personnel lists  
   -Bring anesthesia docs  

VI. Edify

A. We are our own best resource  
B. Establish friendships  
C. Build up the local doctors (primum non nocere)  
   -Establish telemedicine links  
D. Build up the patients  
   -Don’t get lost in the work  
E. Avoid the appearance of evil  
   -Follow-up on the trip afterward  

VII. Summary

A. Consider a trip for yourself  
B. Put some thought into it before leaving  
C. Know that “our” way is not the only way  
D. Primum non nocere
Assessing a medical missions opportunity

Michael G. Hunt, MD

I. What - Goals, Objectives, and Expectations

A. Know yourself
   1. Strengths/Passions/Abilities
   2. Weaknesses/Limitations
B. Is this the first trip to this area or the continuation of work that has been done?
   1. Talk with others who have been to this area
   2. Talk with others who have done similar work
C. Will there be opportunities to teach, observe, or leave equipment or medicines behind?
D. Will you or others return to work there again?
E. How long will the trip be?

II. Where - Location of Trip

A. Foreign/Overseas vs within US
B. Passport, Visas, Immunizations, Governmental approval issue
C. Cultural, culinary, and language difference
D. Travel to and from trip destinations
E. Accomodations for lodging and working

III. With Whom - Organizations and those that serve with you

A. US organization vs International vs In-Country NGO
   1. Faith-based, humanitarian, governmental
   2. Ophthalmic only, multi-specialty, multi-domain
   3. Who will handle logistical issues and itinerary
B. Doctors and Providers
   1. Will other US doctors be on the trip?
   2. Will you work with doctors from the organization or local doctors?
C. Support staff
   1. Will there be anesthesia personnel? Local or with trip?
   2. Technicians
   3. Lay people
   4. Interpreters
   5. In-country staff
Surgical and Logistic Issues
For Overseas Medical Missions
Sandy Roberts, MD

I. Scope of Mission – must define prior to mission (types of surgery, anesthesia support, teaching, and refractions)
   A. Site Survey Is Critical
   B. Know your surgical limitations
      1. Austere conditions
      2. Stay in your “comfort zone”
   C. Triage – Know the number of OR slots in advance
      3. Separate all the kids and adults with strabismus
      4. Who gets priority?
      5. Supply limitations

II. Surgical Preoperative Evaluation on the Mission Field
   A. “Language barriers”
      1. Interpreters are key
      2. High illiteracy rates – be careful with preop questionnaires
   B. Age and weight standards
      1. Beware of syndromic kids
      2. Beware of young infants
      3. Beware of malnourished/“sick” appearing children
   C. Surgical screening:
      1. Medical problems (cerebral palsy)
      2. Prior eye surgery
      3. Trauma
      4. Family history

III. Anesthesia Support on the Mission Field
   A. Local anesthesia docs vs bringing anesthesia docs?
      2. Critical – Must maintain highest standards
      2. Confirm experience level
      3. Confirm safe machine/equipment
   B. Be prepared for the worse
      1. Malignant hyperthermia
      2. Laryngospasm
      3. Oculocardiac reflex
C. Retrobulbar/Peribulbar Anesthesia (One eye only!)
   1. IV Sedation requires monitoring (nurse or doc)
   2. Retrobulbar block – can cause tight orbit/poor exposure
   3. Be careful using local anesthesia on “young” patients (<30 year olds)

D. Post-operative Monitoring
   1. No “true” ICU – limited recovery capability
   2. Bring equipment (monitors/portable suction/ pulse ox)
   3. Manpower

IV. Strabismus Pearls

A. Equipment/Ergonomics
   1. Supplemental Lighting
   2. Loupes
   3. Padding for stools

B. Lessons Learned
   1. Consider 3-4 muscles for large deviations
   2. Amblyopia/Sensory loss – High prevalence
   3. Operate on nonfixating eye
      a. Aim for small postoperative esotropia
      b. High risk of consecutive deviations – counsel

V. Pediatric Cataract Issues

A. Scope of mission determination in advance
   1. Equipment/Vitrectomy capability
   2. Age cut off
      a. Unilateral
      b. Bilateral
      c. Pre-op nystagmus

B. Postoperative care plan
   1. Visual rehab issues
   2. Amblyopia
   3. Spectacles/Contacts/IOL/PCO
   4. EUA capability
**Pediatric cataract surgery NOT recommended without local postoperative care plan – preferably with a local ophthalmologist.**
VI. **Teaching Issues**

A. Combined cases with local ophthalmologists
   1. Determine primary surgeon in advance
   2. Approach/technique reviewed preoperatively

B. Residency teaching on the mission field
   1. Transparency
   2. Supervised cases
   3. “Best Residency Experience”

VII. **Refraction Clinics**

A. High Volume/ High Yield

B. Visual Acuity Training
   1. Standardize approach
   2. Tumbling E charts

C. Establish visual acuity cut off for refraction
   1. Refraction techniques (Dry vs Wet)
   2. Skiascopy bars
   3. Chargers/Adapters/Extra batteries
Long-term Missions

Paul G. Steinkuller MD

I. How to do it - Full career model

   A. 5-10-20 year model
      -5 years initial tour
      -10 years back home (get the kids through school, set up retirement, etc.)
      -20 (+) years in the field

   B. Variable time model (e.g. my personal plan)
      -3-5 years at home; establish base of operations, support
      -Intermittent 3-5 years in the field, ad infinitum

II. Mandatory Practical Considerations

   A. Support – how to get it, how to maintain it
   B. Family
      1. Security / safety
      2. Schooling: local, boarding, timing
      3. Separations
      4. Health
      5. Medical facilities available
      6. Insurance: health, life
      7. Medical & security evacuation arrangements
   C. Language(s)
   D. CME, licenses
   E. Retirement planning
Suggested Resources – a Partial List

1. Christoffel Bindenmission Intl. e.V. (CBMI) – Germany *
2. Committee on International Ophthalmology, AAO – San Francisco
3. International Agency for the Prevention of Blindness – West Sussex, UK
4. Helen Keller Intl. (HKI) - NYC
5. International Centre for Eye Health (ICEH) – London
6. International Eye Foundation (IEF) – Kensington, MD *
7. Oeil sur les Tropiques – Antwerp
8. Old Boys Network (OBN) *
9. Operation Eyesight Universal (OEU) – Calgary
10. ORBIS Intl. – NYC
11. Organization por la Prevention de la Cecite – Lyon
12. Organization Nacional de Ciegos de Espan – Madrid
13. Royal National Institute for the Blind (RNIB) - London
14. Seva Foundation – Berkely
15. Sight Savers Intl. – West Sussex, UK
16. Surgical Eye Expeditions International, Inc. (SEE) – Santa Barbara
17. Vision International – Sebatopol, CA
18. Volunteer Eye Surgeons Intl. LTD – Bay Shore, NY
19. World Health Organization (WHO)
20. Your own church *
How to Start a Humanitarian Service Organization

In Pediatric Ophthalmology

David Stager, Jr. MD FACS

I. Why?
   A. Define purpose
   B. Is there a need?
   C. Is it logistically possible?
   D. Who will be involved?
   E. Non-profit? What will (and won’t) money be used for?
   F. Location(s)?
   G. Is it already being done? Does it matter? Partnerships?

II. Forming the Entity
   A. Choosing a name, logo, etc
   B. Website, brochures, other media, and marketing
   C. Non-profit status and filing 501c 3
   D. Personnel
   E. Fund-raising
   F. Liability issues

III. Case study: One World One Vision

   Pediatric Ophthalmology Center at
   The Lighthouse for Christ Mission
   Mombasa, Kenya
   David Stager, Jr. MD FACS

I. History of the Lighthouse

II. Why a Pediatric Ophthalmology Center in Kenya?
   A. The Need—African blindness
   B. Lack of care
   C. Making a difference

III. Progress
HUMANITARIAN SERVICE ORGANIZATIONS
IN PEDIATRIC OPHTHALMOLOGY

AAPOS FELLOWSHIP PROGRAM IN CHINA

CBM INTERNATIONAL
CONTACT: cbm.org

CENTRAL AMERICAN RELIEF
CONTACT: Carelief.org

INTERNATIONAL EYE FOUNDATION
CONTACT: iefusa.org

KAUSAY WASI CLINIC IN PERU
CONTACT: kausaywasi.org

LIGHTHOUSE FOR CHRIST MISSION MOMBASSA KENYA
CONTACT: lighthouseforchrist.org

ONE WORLD ONE VISION
CONTACT: OneWorldOneVision.org

ORBIS INTERNATIONAL

PROJECT VIETNAM
CONTACT: qkieu@projectvietnam.net

SEE INTERNATIONAL
CONTACT: seeintl.org

SIGHTSAVERS (GREAT BRITAIN)
CONTACT: sightsavers.org

WORLD BLINDNESS OUTREACH
CONTACT: Al Alley M.D., Hershey, Pennsylvania
Aalley@comcast.net

BURMA VISION
CONTACT: www.burmavision.com

VISION HEALTH INTERNATIONAL
CONTACT: randyrottman@yahoo.com

GLOCAL VENTURES INC.
CONTACT: glocalventures.com
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. 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. 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. 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. 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. 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 or placed into the capsular bag after opening Soemmerring’s ring. 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. 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)\textsuperscript{18, 19} and the Ocular Treatment Index (OTI)\textsuperscript{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.\textsuperscript{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.\textsuperscript{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. 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. 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.

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. 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.

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. 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. Patching compliance is one of the most important determinants of visual outcomes in children with unilateral aphakia/pseudophakia. We pilot tested several techniques to objectively quantify patching compliance, 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. 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 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. 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. 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 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. The axial length of a full-term infant eye at birth has been reported to be 16.8–17.3 mm in length. 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.

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.

Acknowledgments

The study was funded by research grants EY13272 and EY13287 from the National Eye Institute. It was also support in part by a NIH Departmental Core Grant and Research to Prevent Blindness, Inc, New York, New York
References


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 Bussettini, 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**

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Visually significant congenital cataract ($\geq$ 3 mm central opacity) in one eye.</td>
<td></td>
</tr>
<tr>
<td>2 Age 28 days to less than 7 months (&lt;210 days) at the time of cataract surgery.</td>
<td></td>
</tr>
<tr>
<td>3 At least 41 post-conceptional weeks at the time of cataract surgery.</td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exclusion Criteria</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1 The cataract was known to be acquired from trauma or as a side effect of a treatment administered postnatally.</td>
<td></td>
</tr>
<tr>
<td>2 Corneal diameter $&lt; 9$ mm.</td>
<td></td>
</tr>
<tr>
<td>3 Intraocular pressure $25$ mm Hg or greater.</td>
<td></td>
</tr>
<tr>
<td>4 Persistent fetal vasculature (PFV) causing stretching of the ciliary processes or a tractional detachment of the retina.</td>
<td></td>
</tr>
<tr>
<td>5 Active uveitis or signs suggestive of a previous episode of uveitis.</td>
<td></td>
</tr>
<tr>
<td>6 The child was the product of a pre-term pregnancy ($&lt;36$ gestational weeks).</td>
<td></td>
</tr>
<tr>
<td>7 Retinal disease that may limit the visual potential of the eye.</td>
<td></td>
</tr>
<tr>
<td>8 Previous intraocular surgery.</td>
<td></td>
</tr>
<tr>
<td>9 Optic nerve disease that may limit the visual potential of the eye.</td>
<td></td>
</tr>
<tr>
<td>10 The fellow eye had ocular disease that might reduce its visual potential.</td>
<td></td>
</tr>
<tr>
<td>11 The child had a medical condition that might impair visual acuity testing at 12 months or 4 1/2 years of age.</td>
<td></td>
</tr>
<tr>
<td>12 The child was not able to return to an IATS clinical center for regular follow-up examinations.</td>
<td></td>
</tr>
</tbody>
</table>
Table 2
Baseline Characteristics of IATS Patients*

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

*Values in the table are mean ± standard deviation or n (%) except for Age at Surgery where the values are median (25th percentile, 75th percentile). There were no significant differences between the two treatment groups at the 0.05 significance level.
A Randomized Clinical Trial Comparing Contact Lens With Intraocular Lens Correction of Monocular Aphakia During Infancy

Grating Acuity and Adverse Events at Age 1 Year

The Infant Aphakia Treatment Study Group*

**Objective:** To compare the visual outcomes and adverse events of contact lens with primary intraocular lens (IOL) correction of monocular 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 between 1 to 6 months of age either with or without primary IOL implantation. Contact lenses were used to correct aphakia in patients who did not receive IOLs. Grating visual acuity was tested at 1 year of age by a masked traveling examiner.

**Main Outcome Measure:** Grating visual acuity at 1 year of age.

**Results:** The median logMAR visual acuity was not significantly different between the treated eyes in the 2 groups (contact lens group, 0.80; IOL group, 0.97; \( P = .19 \)). More patients in the IOL group underwent 1 or more additional intraocular operations than patients in the contact lens group (63% vs 12%; \( P < .001 \)). Most of these additional operations were performed to clear lens repopulation and pupillary membranes from the visual axis.

**Conclusions:** There was no statistically significant difference in grating visual acuity at age 1 year between the IOL and contact lens groups; however, additional intraocular operations were performed more frequently in the IOL group.

**Application to Clinical Practice:** Until longer-term follow-up data are available, caution should be exercised when performing IOL implantation in children aged 6 months or younger given the higher incidence of adverse events and the absence of an improved short-term visual outcome compared with contact lens use.

**Trial Registration:** clinicaltrials.gov Identifier: NCT00212134

**Arch Ophthalmol. 2010;128(7):810-818**

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Since the 1970s, contact lenses have been the standard means of optically correcting unilateral aphakia in infancy.1-7 Their use during infancy, however, can be challenging owing to problems with insertion and removal of lenses by parents, lens loss, difficulties with fitting the steep corneas of infants, and compliance problems. These factors among others probably contribute to the poor visual outcome of many children with unilateral aphakia. Intraocular lens (IOL) technology and microsurgical techniques have improved considerably in recent years. As a result, IOLs are being used increasingly for the optical correction of aphakia in infants following cataract surgery.8-10 However, the risks and benefits of IOL implantation during infancy have not been studied in the setting of a randomized clinical trial.

Intraocular lenses have the advantage of providing a partial optical correction at all times and more closely simulate the optics of the natural crystalline lens.8,11 Such benefits, however, may be offset by complications that can be associated with IOL implantation and with the rapidly changing optical needs of a growing eye.12-15 Small case series have reported improved visual outcomes after IOL implantation during infancy.11,16 However, these series have been retrospective and the number of patients included failed to provide the statistical power necessary to adequately assess the visual benefits of IOL implantation. Most series...
have also reported more postoperative complications than observed with leaving the eyes aphakic.15

The Infant Aphakia Treatment Study (IATS) is a multicenter, randomized, controlled clinical trial sponsored by the National Eye Institute. The objective of the study is to compare the use of immediate IOL implantation for the correction of aphakia with a contact lens after cataract surgery performed in infants with a unilateral congenital cataract between 1 and 6 months of age. This article reports the clinical findings up to 12 months after surgery and the visual outcomes at 1 year of age by treatment group among the 114 patients enrolled in IATS.

METHODS

The study design, surgical technique, follow-up schedule, patching and optical correction regimens, evaluation methods, and patient characteristics at baseline have been reported in detail previously12 and are only summarized in this article. This study was approved by the institutional review boards of all the participating institutions 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, Fort Worth, Texas) was covered by US Food and Drug Administration investigational device exemption No. G020021.

STUDY DESIGN

The main inclusion criteria were a visually significant congenital cataract (≥3-mm central opacity) in 1 eye and an age of 28 days to younger than 210 days at the time of cataract surgery. Infants with a unilateral cataract due to persistent fetal vasculature (PFV) were allowed in the study as long as the PFV was not associated with visible stretching of the ciliary processes or involvement of the retina or optic nerve. The other main exclusion criteria were an acquired cataract, a corneal diameter smaller than 9 mm, a medical condition that might interfere with visual acuity testing, and premature birth (<36 gestational weeks). Patients were randomized to have either an IOL placed at the time of the initial surgery or to have their eyes left aphakic and corrected with a contact lens.

SURGICAL TECHNIQUE

Infants randomized to the contact lens group underwent a lensectomy and anterior vitrectomy (video 1, available at http://www.archophthalmol.com). Infants randomized to the IOL group initially had the lens contents aspirated followed by the implantation of an Acrysof SN60AT IOL into the capsular bag (video 2). In the event that both haptics could not be implanted into the capsular bag, an Acrysof MA60AC IOL was implanted into the ciliary sulcus. The IOL power was calculated based on the Holladay 1 formula targeting an 8-diopter (D) undercorrection for infants aged 4 to 6 weeks and a 6-D undercorrection for infants older than 6 weeks. Following IOL placement, a posterior capsulotomy and an anterior vitrectomy were performed through the pars plana/plicata. When either a preexisting opening was present or a tear developed intraoperatively in the posterior capsule and in some eyes with mild PPFV, the posterior capsulotomy and anterior vitrectomy were performed through the anterior incision prior to IOL implantation.

OPTICAL CORRECTION

Within a week after cataract surgery, patients randomized to the contact lens group were fitted with a Silsoft (Bausch and Lomb, Rochester, New York) or a rigid gas-permeable contact lens with a 2.0-D overcorrection to provide a near point focus. For patients randomized to the IOL group, spectacles were prescribed prior to the 1-month postoperative visit or at any later visit, provided that 1 of the following conditions existed in the treated eye: hyperopia greater than 1.0 D, myopia greater than 3.0 D, or astigmatism greater than 1.5 D. The overall aim was to overcorrect the refractive error by 2.0 D to achieve a near point focus. The prescribed optical correction was to be worn at all times while the patient was awake.

PATCHING REGIMEN

Starting the second postoperative week, parents were instructed to have their child wear an adhesive occlusive patch over the unoperated eye for 1 hour per day per each month of the child's age until age 8 months. Thereafter, patching was prescribed for all waking hours every other day or for one-half of the patient's waking hours every day.

FOLLOW-UP WITH CLINICAL EXAMINATIONS AND GRATING VISUAL ACUITY ASSESSMENT

Follow-up examinations were performed by an IATS-certified investigator at 1 day, 1 week, 1 month, and 3 months after cataract surgery. Subsequent follow-up examinations were obtained at 3-month intervals (±2 weeks). The investigator performed a standard clinical examination, checking the appropriateness of the optical correction and monitoring for adverse events. All of the patients underwent an examination under anesthesia 2 to 4 weeks prior to the grating visual acuity assessment. The patient's optical correction was updated after the examination under anesthesia prior to the grating acuity assessment.

Monocular grating acuity was assessed at 1 year (±2 months) of age by a traveling examiner using Teller Acuity Cards (Stereo Optical, Chicago, Illinois). Vision in the aphakic/pseudophakic eye was tested first. When nystagmus was present, monocular grating acuity was tested using a +10-D lens placed over the eye not being tested. Each site had a stage for presentation of the grating stimuli. The standard testing distance was 55 cm, measured from the screen to the child's eyes. Children with poor visual acuity were tested at nearer distances (eg, 38, 19, and 9.5 cm) and the low-vision card was used to determine the presence or absence of some pattern vision. Evaluations of light perception or no light perception visual acuities were performed following standard clinical protocols.

ADHERENCE TO PATCHING AND OPTICAL CORRECTION

Adherence to patching and optical correction was assessed using 48-hour recall telephone interviews and 7-day diaries. The interviews were conducted every 3 months starting 3 months after surgery. Caregivers completed a 7-day patching diary 2 months following surgery and annually thereafter, 1 month after the child's birthday. At each assessment, we calculated the proportion of waking time the infants wore optical correction. Good adherence to patching was defined as reported patching at least 75% of the prescribed time. Pseudophakic children who were not required to wear glasses because the refractive error was between +1.0 D and −3.0 D with less than 1.5 D of astigmatism were considered to be fully corrected without their spectacles on, and were therefore considered to be wearing optical correction 100% of their waking hours.

The present analyses of adherence to patching and optical correction are limited to adherence assessments obtained prior to the
Analyzed 57

The 9-month adherence data are therefore not presented because of potential biases and instability of the estimates.

DEFINITIONS FOR AVERSE EVENTS

Glaucoma was defined as intraocular pressure (IOP) greater than 21 mm Hg with one or more of the following anatomical changes: (1) corneal enlargement; (2) asymmetrical progressive myopic shift coupled with enlargement of the corneal diameter and/or axial length; (3) increased optic nerve cupping defined as an increase of 0.2 or more in the cup-disc ratio; or (4) the use of a surgical procedure for IOP control. A patient was designated a glaucoma suspect if he or she either had 2 consecutive IOP measurements above 21 mm Hg on different dates after topical corticosteroids had been discontinued without any of the anatomical changes listed previously; or (2) took glaucoma medications to control IOP without experiencing any of the anatomical changes listed previously. A pupillary membrane was defined as fibrous tissue extending across the pupil. Lens reproliferation into the visual axis was defined as lens material regrowth extending into the pupillary space and interfering significantly with vision. Children who had strabismus surgery were not classified as orthotropic even if they were later orthotropic on motility testing.

STATISTICAL ANALYSIS

The sample size was calculated to provide 80% power to detect a 0.2-logMAR difference in mean acuity between the 2 treatment groups using an independent group's t test with \( \alpha = 0.05 \) (2-tailed) and a standard deviation of visual acuity of 0.365 based on previously published data. The resulting sample size estimate was 57 patients per group and included an adjustment for 5% lost to follow-up. As the visual acuity data accumulated, it became clear that the distribution of visual acuities for IATS patients was markedly skewed and that the independent group's t test would not be the appropriate statistical test. The sample size was evaluated in a simulation using a resampling approach from a data set provided by Eileen Birch, PhD, consisting of 51 patients undergoing unilateral cataract surgery at less than 7 months of age treated with contact lenses. The outcome measure was optotypes visual acuity at 5 years of age, as IATS patients will be followed up to age 5 years to provide a more definitive measurement of visual acuity. The simulation incorporated the Wilcoxon rank-sum test and indicated that the power for detecting a 0.2-logMAR difference in visual acuity between the treatment groups was 0.74, with 57 patients per group; therefore, the sample size was not changed.

The visual acuities at 1 year of age were compared between the treatment groups using the Wilcoxon rank-sum test. A nonparametric test was used because of the skewed distribution of the data and because of the assignment of visual acuity values for patients with vision below the level detectable with Teller Acuity Cards (see the IATS protocol at http://www.sph.emory.edu/IATS for details). For other continuous factors, the mean was compared between the treatment groups using the independent group's t test. The percent of patients who experience adverse events or underwent additional intraocular operations was compared between the treatment groups using the Fisher exact test. All tests were 2-sided. No adjustment was made for multiple testing. For the primary outcome, visual acuity, \( P < 0.05 \) was deemed statistically significant, whereas for other outcomes, the significance level was \( P < 0.01 \).

RESULTS

There were 114 patients enrolled in the study with 57 randomized to each treatment group (Figure 1). Two patients with PFV were enrolled in the study despite fulfilling an exclusion criterion (eg, PFV with stretching of the ciliary processes). In the first case, the patient was randomized into the study because stretching of the ciliary processes preoperatively, but did not think that the stretching was severe enough to warrant exclusion from the study. This patient was randomized to the IOL group and had a lens implanted in the ciliary sulcus. A post hoc review of this surgical video by the IATS steering committee determined that the stretching of the ciliary processes in this eye did indeed meet the PFV exclusion criterion. Both patients were analyzed in the IOL group following the intent-to-treat principle. Fifty-two (93%) of the patients in the IOL group had the IOL implanted in the capsular bag, while 4 (7%) had the IOL implanted in the ciliary sulcus.

The median age at the time of surgery was 1.8 months (interquartile range [IQR], 1.1-3.1 months) for the contact lens group (n=57) and 1.8 months (IQR, 1.2-3.2 months) for the IOL group (n=57). The 114 patients were distributed into age categories as follows: 4 to 6 weeks (contact lens group, 25 patients; IOL group, 25 patients; 44%); 7 to 3 months (contact lens group, 17 patients; IOL group, 15 patients; 28%); 3.1 to 5 months...
There were 60 girls (53%) and 97 of the children were white (85%). The baseline clinical characteristics of the patients have been previously published.17 None of the patients were lost to follow-up during the first 12 months after surgery and all patients had their visual acuity measured by a traveling tester at 1 year of age (Figure 1). The percent of completed postoperative follow-up visits were 100% at 1 day, 97% at 1 week, 99% at 1 month, 100% at 3 months, 98% at 6 months, 97% at 9 months, and 92% at 12 months.

### VISUAL ACUITY

The visual acuity assessments were conducted by 2 traveling examiners, one of whom performed most of the assessments (74%). The percent of patients tested by this examiner was not significantly different in the 2 treatment groups (contact lens group, 72%; IOL group, 75%; P = .83). Of the 114 patients, 111 (97%) were examined within 30 days of their first birthday. One patient was examined 6 weeks after his first birthday, which was still within our 12-month (±2-month) window. Only 2 patients were examined outside this window (ages 17.6 and 18.6 months). The median logMAR visual acuity was not significantly different between the treated eyes in the 2 groups (contact lens group, 0.80; IOL group, 0.97; P = .19) (Figure 2). The difference between the medians of the 2 groups was 0.17 logMAR, which was slightly larger than the interval between each of the Teller Acuity Cards (0.5 octaves, or 0.15 logMAR) and slightly smaller than the difference the study was designed to detect (0.20 logMAR). Very poor vision was present in the treated eye in 3 patients in the contact lens group (2 with pattern vision detectable only with the low-vision card and 1 with light perception) and 1 treated eye in the IOL group (pattern vision only detectable with the low-vision card). The median logMAR visual acuity was 0.66 in the untreated eyes of both treatment groups.

### INTRAOPERATIVE COMPLICATIONS

There was a trend for a greater occurrence of intraoperative complications in the IOL group than the contact lens group. Sixteen (28%) IOL patients experienced 1 or more complications compared with 6 (11%) contact lens patients (P = .03) (Table 1). The difference was primarily due to a higher incidence of iris prolapse in the IOL
ADVERSE EVENTS

Forty-four (77%) patients in the IOL group had 1 or more of the adverse events compared with 14 (25%) patients in the contact lens group ($P<.001$) (Table 2). In the IOL group, the most common complications were lens repropagation into the visual axis, pupillary membranes, and corectopia. Lens repropagation into the visual axis developed in 24 (42%) eyes in the IOL group and in 1 (2%) eye in the contact lens group ($P<.001$). Pupillary membranes developed in 17 (30%) eyes in the IOL group but in none of the eyes in the contact lens group ($P<.001$). Eleven (19%) eyes in the IOL group developed corectopia compared with 1 (2%) eye in the contact lens group ($P=.004$). None of the eyes in the IOL group developed IOL capture, decentration, or dislocation into the vitreous. In the contact lens group, 3 (5%) eyes developed contact lens–associated complications (1 eye each with presumed bacterial keratitis [an eye sample was not cultured], corneal abrasion, and corneal opacity due to a tight contact lens) (Table 2). Other vision-threatening complications that occurred in the contact lens group included *Haemophilus influenzae* endophthalmitis in 1 (2%) eye and retinal detachments in 2 (4%) eyes, 1 after undergoing a pars plana membranectomy and the second after being treated for endophthalmitis. Both of these eyes have poor vision and 1 eye developed phthisis bulbi.

Glaucoma developed in 3 (5%) eyes in the contact lens group and 7 (12%) eyes in the IOL group ($P=.32$). Two (4%) eyes in the contact lens group and 2 (4%) eyes in the IOL group were glaucoma suspects.

### ADDITIONAL OPERATIONS

Patients in the IOL group underwent additional intraocular operations more often than patients in the contact lens group. In the IOL group, 36 (63%) patients underwent 1 or more additional intraocular operations compared with only 7 (12%) patients in the contact lens group ($P<.001$) (Table 3). In the IOL group, 10 (18%) eyes underwent 2 or more additional intraocular operations compared with only 2 (4%) eyes in the contact lens group. The most commonly performed procedure was an operation to clear the visual axis (Table 4). One of the eyes in the IOL group underwent an IOL exchange owing to a large myopic shift. None of the patients randomized to the contact lens group had a secondary IOL implanted.

In addition to the intraocular operations described previously, nonmandated examinations under anesthesia were performed on 5 (9%) patients in the contact lens group and 8 (14%) patients in the IOL group, generally to assess the intraocular pressure in the treated eyes. Strabismus surgery was performed on 10 (18%) patients in the contact lens group and 6 (11%) patients in the IOL group. Finally, a nasolacrimal duct procedure was performed on 1 patient (2%) in the contact lens group.

---

**Table 1. Intraoperative Complications With Initial Cataract Surgery by Treatment Group**

<table>
<thead>
<tr>
<th>Complication</th>
<th>Contact Lens (n=57)</th>
<th>Intraocular Lens (n=57)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iris prolapse</td>
<td>2 (4)</td>
<td>12 (21)</td>
</tr>
<tr>
<td>Hyphema</td>
<td>3 (5)</td>
<td>2 (4)</td>
</tr>
<tr>
<td>Iris damage</td>
<td>1 (2)</td>
<td>3 (5)</td>
</tr>
<tr>
<td>Retained cortex</td>
<td>1 (2)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Corneal cloudy</td>
<td>1 (2)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Iris sphincterotomy</td>
<td>0</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Lens fragment in vitreous</td>
<td>0</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Rupture posterior capsule</td>
<td>0</td>
<td>1 (2)</td>
</tr>
<tr>
<td>&gt;=1 Complications$^a$</td>
<td>6 (11)</td>
<td>16 (28)</td>
</tr>
</tbody>
</table>

$^a$Comparison of treatment groups, $P=.03$.

**Table 2. Postoperative Adverse Events by Treatment Group**

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Contact Lens (n=57)</th>
<th>Intraocular Lens (n=57)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lens repropagation into visual axis</td>
<td>1 (2)</td>
<td>24 (42)</td>
</tr>
<tr>
<td>Pupillary membrane</td>
<td>0</td>
<td>17 (30)</td>
</tr>
<tr>
<td>Corectopia</td>
<td>1 (2)</td>
<td>11 (19)</td>
</tr>
<tr>
<td>Glaucoma</td>
<td>3 (5)</td>
<td>7 (12)</td>
</tr>
<tr>
<td>Glaucoma suspect</td>
<td>2 (4)</td>
<td>2 (4)</td>
</tr>
<tr>
<td>Vitreous hemorrhage</td>
<td>2 (4)</td>
<td>4 (7)</td>
</tr>
<tr>
<td>Retinal hemorrhage</td>
<td>2 (4)</td>
<td>2 (4)</td>
</tr>
<tr>
<td>Hyphema</td>
<td>1 (2)</td>
<td>3 (5)</td>
</tr>
<tr>
<td>Retained cortex</td>
<td>2 (4)</td>
<td>3 (5)</td>
</tr>
<tr>
<td>Retinal detachment</td>
<td>2 (4)</td>
<td>0</td>
</tr>
<tr>
<td>Endophthalmitis</td>
<td>1 (2)</td>
<td>0</td>
</tr>
<tr>
<td>Phthisis bulbi</td>
<td>1 (2)</td>
<td>0</td>
</tr>
<tr>
<td>Contact lens–associated</td>
<td>1 (2)</td>
<td>0</td>
</tr>
<tr>
<td>bacterial keratitis</td>
<td>1 (2)</td>
<td>0</td>
</tr>
<tr>
<td>Corneal abrasion</td>
<td>1 (2)</td>
<td>0</td>
</tr>
<tr>
<td>Corneal opacity due to tight contact</td>
<td>1 (2)</td>
<td>0</td>
</tr>
<tr>
<td>Corneal edema &gt;30 days</td>
<td>0</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Capsular phimosis</td>
<td>1 (2)</td>
<td>0</td>
</tr>
<tr>
<td>Wound leak/dehiscence</td>
<td>0</td>
<td>1 (2)</td>
</tr>
<tr>
<td>&gt;=1 Adverse events$^a$</td>
<td>14 (25)</td>
<td>44 (77)</td>
</tr>
</tbody>
</table>

$^a$Comparison of treatment groups, $P<.001$.

**Table 3. Number of Additional Intraocular Operations by Treatment Group**

<table>
<thead>
<tr>
<th>No. of Additional Intraocular Operations</th>
<th>Contact Lens (n=57)</th>
<th>Intraocular Lens (n=57)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>50 (87)</td>
<td>21 (37)</td>
</tr>
<tr>
<td>1</td>
<td>5 (9)</td>
<td>26 (46)</td>
</tr>
<tr>
<td>2</td>
<td>1 (2)</td>
<td>8 (14)</td>
</tr>
<tr>
<td>3</td>
<td>1 (2)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>4</td>
<td>0</td>
<td>1 (2)</td>
</tr>
</tbody>
</table>

$^a$Comparison of treatment groups, $P<.001$. 
ADHERENCE WITH PATCHING AND OPTICAL CORRECTION

Caregivers reported a wide range of compliance with patching regimens. The proportion of caregivers reporting good (ie, at least 75% of prescribed) adherence to patching decreased over time and was higher at all time points among aphakic than pseudophakic groups (Figure 3). These differences did not meet the criterion for statistical significance for secondary outcomes.

Caregivers of aphakic children reported that their children wore a contact lens on average more than 80% of waking hours (86%; 84% at 2 months, 85% at 3 months, and 89% at 6 months). Three-quarters of the caregivers reported that their children wore a contact lens at least 88% of waking hours prior to the visual acuity assessment.

Caregivers of pseudophakic children reported spectacles on average of 58% of their waking hours (55% at 2 months, 53% at 3 months, and 62% at 6 months). At each time point, the percentage of waking hours of spectacles wear ranged from 0% to more than 97%. Three months after surgery, 4 pseudophakic children did not require spectacles; there were 11 such children at 6 months.

OCULAR ALIGNMENT

Approximately two-thirds of the patients in both treatment groups were orthotropic at the 1-month examination. At the 3-, 6-, and 9-month examinations, however, an increasing number of the patients in the contact lens group were no longer orthotropic, whereas in the IOL group, the prevalence of orthotropia remained relatively constant. At the 12-month examination, there was a trend for more of the patients in the IOL group (58%) to be orthotropic compared with patients in the contact lens group (38%; P = .05).

PREVISUAL ACUITY ASSESSMENT EXAMINATION UNDER ANESTHESIA

At the time of the previsual acuity assessment examination, the lenses, corneas, irides, optic discs, and retinas of the fellow eyes were all normal with the exception of the retina of 1 patient in the IOL group who developed high myopia in his fellow eye and who, following enrollment, received a diagnosis of hereditary progressive arthrophthalmpathy. One aphakic eye with PFV was noted to have peripapillary traction without macular involvement and another aphakic eye developed a posterior staphyloma with tilting of the optic disc. The aphakic eye treated for endophthalmitis had pigmentary changes in the macula as well as giosis of the optic disc.

At 1 year of age, there was no significant difference between the median visual acuity in the treated eyes of children with a unilateral congenital cataract that was optically corrected either with a contact lens or with an IOL after cataract surgery during the first 6 months of life. There was, however, a 5-fold increase in additional intraocular operations in the IOL group, most of which were performed to remove visual axis opacities and a 5-fold increase in iridectomy during cataract surgery in the IOL group. There was a trend for a higher incidence of strabismus in the contact lens group, but this difference was not statistically significant.

The median logMAR grating acuity in the treated eyes of the IOL group was 0.97 compared with 0.80 in the contact lens group. This difference was not statistically significant (P = .19). Although, the IOL group was somewhat less adherent to the prescribed patching regimen than the contact lens group, preliminary analysis suggests that patching compliance differences between the treatment groups were unlikely to have had a major effect on the primary outcome because these differences were relatively small in the first few months after surgery and because of the large amount of variation in patching within both groups. The median logMAR acuity of the fellow eyes in both groups was 0.66.

Our results differ from those in some small case series. Autrata and coworkers reported better logMAR acuity in eyes treated with IOLs (0.43) vs contact lenses (0.58) following unilateral cataract surgery during the first 6 months after surgery.
months of life. However, their sample size was much smaller (n=41) and the study was nonrandomized. In addition, visual acuity was not assessed in a uniform manner by a masked examiner. In our previous small nonrandomized pilot study of children with unilateral congenital cataracts who underwent cataract surgery when younger than 7 months of age, we found that the mean logMAR visual acuity was better in eyes treated with IOLs (0.70) compared with contact lenses (0.87). In that pilot study, however, the patients were older at the time of grating visual acuity testing (mean age: contact lens group, 18 months; IOL group, 15 months) and the testing itself was incomplete (13 of 26 eligible contact lens patients and 12 of 13 eligible IOL patients). In contrast, all 114 patients in the IATS had their grating visual acuity uniformly assessed by a masked traveling examiner at age 1 year. In our pilot study, we also found better mean logMAR visual acuities in the fellow eyes (IOL group, 0.44; contact lens group, 0.37) compared with the fellow eyes in our clinical trial. This discrepancy may reflect the younger age of the patients in our clinical study at the time that their grating visual acuity was tested. Mayer et al38 have reported a mean monocular visual acuity of 12-month-old phakic children to be 6.42 cycles per degree (0.67 logMAR; SD, 0.29 cycles per degree). These values are equivalent to the median logMAR visual acuity we report in the untreated eyes of both treatment groups (0.66 logMAR). Birch and coworkers29 have shown that the grating visual acuity of children steadily improves between the ages of 12 months and 4 years. In their study, the mean logMAR visual acuity of pseudophakic eyes improved from 0.76 at age 12 months to 0.45 at age 4 years, and the logMAR visual acuity of aphakic eyes improved from 0.63 at age 1 year to 0.44 at age 4 years. On this basis, we anticipate that the visual acuity of both the treated and fellow eyes in our study will improve over time. To this end, we plan to retest the visual acuity of these children when they reach 4.5 years of age using the Amblyopia Treatment Study–HOTV test. It is certainly possible that visual acuities will be better in one or the other treatment groups at this age either owing to differing degrees of adherence to patching, spectacle and contact lens wear, or late postoperative vision-threatening complications.

In the IOL group, there was a 2.5-fold increase in the rate of intraoperative complications, of which iris prolapse was the most common. This finding likely reflects the larger wound size and the greater intraocular manipulation required to implant an IOL. Infantile eyes are more prone to this complication than adult eyes because of their lack of scleral rigidity. This complication was likely mitigated by the use of implanted foldable acrylic lenses inserted through a 3-mm wound. Other intraoperative complications were evenly distributed between the 2 treatment groups.

The need for additional intraocular operations was 5 times higher in the IOL group. In the IOL group, 63% of patients underwent 1 or more additional intraocular operations. Most were performed to remove visual axis opacities. Visual axis opacities likely occurred more often in the IOL group because the IOL prevented the anterior and posterior leaflets of the capsular bag from fusing to-
particular by because we observed no differences in acuity measurements between the 2 groups. It is conceivable that the constancy of the optical correction in the IOL group succeeded in providing sufficient binocular input to the visual cortex yielding simultaneous vision adequate to maintain alignment of the 2 eyes. Again, a longer follow-up will allow us to determine if this difference persists.

This study was undertaken to assess whether the risks of implanting IOLs in very young children were reasonable given the potential for improved visual outcome that might occur with IOL implantation over time. Our results demonstrate no visual acuity benefit at age 1 year for primary IOL implantation and an increased incidence of complications requiring additional surgical interventions in the IOL group. These findings are not entirely unexpected. We knew from previous studies that visual axis opacities requiring removal commonly develop in the first 3 to 6 months after IOL implantation in infants, so we assumed that they would likely occur in this study. It was reassuring to find that despite the increased number of additional intraocular operations to remove visual axis opacities in the IOL group, the median visual outcome in their study eyes was no different than the contact lens group at 1 year of age. Assessing the risks and benefits of IOL implantation at 1 year of life may lead to premature conclusions. We anticipated that the real benefit of IOL implantation may occur later, especially if children in the contact lens group become less compliant with contact lens use as they become older. If this is true, it is possible that the children in the IOL group will have an increasing visual advantage with their pseu-
dopahic correction alone as they become older and approach emmetropia. We plan to retest the visual acuity of these children when they are aged 4½ years using the Amblyopia Treatment Study–HOTV acuity test.

Another caveat with our study is that it provided contact lenses, spectacles, and patches for participants at no charge. In addition, regular monitoring of their adherence to these treatments may have improved compliance. As a result, our outcomes may reflect efficacy (benefit under ideal conditions) rather than effectiveness (benefit under usual conditions).30

In conclusion, IOL and contact lens correction following unilateral cataract surgery during infancy resulted in similar grafting visual acuity outcomes at age 1 year in our cohort of children. Infants treated with IOLs had more intraoperative complications and required more intraocular operations postoperatively to clear visual axis opacities. Thus, there appears to be no short-term visual benefit and some increased risk to implanting IOLs in infants. However, since there remains a possibility that IOLs may be found to be beneficial after a longer follow-up, we feel it would be premature to recommend that IOLs not be implanted in infants. In addition, the theoretical long-term benefit of having the IOL in the capsular bag vs implanted in the ciliary sulcus as a secondary procedure cannot be quantified at this point. We suggest that practitioners continue to exercise caution when considering implanting IOLs in infants. The ultimate role for IOL implantation during infancy may be further clarified after a longer follow-up of these children.

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REFERENCES


The Infant Aphakia Treatment Study: Visual Outcomes at 1 Year
Scott R. Lambert, M.D.
Emory University
Atlanta, GA

Financial Disclosures
• NIH Grant
• Lions International: Advisory Council
• Alcon: Clinical Trial
• Bausch & Lomb: Advisory Board

Visual Rehabilitation of Children with a Unilateral Congenital Cataract
• Until the 1970s, it was believed that there was no means of restoring vision in children with a unilateral congenital cataract.
• Frey (1973) reported good visual outcomes in a few children.
• Hoyt (1981) reported a series of children with excellent visual outcomes using contact lenses after early surgery.

Optical Rehabilitation
• IOLs—the standard for children 1 year of age or older
• Contact lenses—the standard for infants

Contact Lens Correction of Unilateral Aphakia: Pros
• Power can easily be changed as the eye grows
• Secondary IOL can be implanted when the child is older when the refractive error is stable

Contact Lens Correction of Unilateral Aphakia: Cons
• Frequently lost and there may be a delay in their replacement
• Ongoing maintenance takes time each day and can be stressful for patients and parents

Intraocular Lens Correction of Unilateral Aphakia: Pros
• Closely approximates the optics of the crystalline lens
• Full-time partial optical correction is guaranteed

Intraocular Lens Correction of Unilateral Aphakia: Cons
• The surgery is more difficult
• Long-term safety in a growing eye has not been established
• More reoperations
• An overcorrection with spectacles or contact lenses is usually needed

Infant Aphakia Treatment Study
• Initiated 2004
• 12 clinical sites
• Unilateral congenital cataract
• Correction with IOL versus CL following cataract surgery
**Primary Hypothesis**

- At Age 4 ½ Years, optotype acuity will be worse in CL group vs IOL group (>0.2 logMAR)

**Treatment Groups**

- **CL Group**
  - Lensectomy
  - Contact lens correction

- **IOL Group**
  - Cataract extraction
  - Primary IOL implantation
  - Posterior capsulotomy
  - Spectacle over-correction

**Eligibility Criteria**

- Unilateral visually significant cataract (≥3 mm central opacity)
- Age 28 days to < 7 months at surgery
- Willing to be randomized to either treatment

**Exclusion Criteria**

- Acquired cataract (e.g., trauma)
- Corneal diameter < 9 mm
- IOP > 25 mmHg
- PFV stretching of ciliary processes
- Uveitis
- Pre-term (gestational age < 36 weeks)
- Retinal disease
- Ocular disease in fellow eye
- Mental condition that will interfere with vision testing at 4.5 years of age
- Refusal of parent to sign informed consent or have child randomized to treatment
- Parent unable to bring child for regular follow-up exams

**Contact Lens Correction**

- Silicone or rigid gas permeable
- Until age 2 - overcorrection of 2 D to provide near point correction
- At age 2 - contact lens correction aims for emmetropia and bifocals prescribed with +3 D add

**IOL**

- Acrylic IOL
- Targeted post-operative refractive error (Holladay 1 formula)
  - 4 - 6 weeks: +8.00 D
  - 7 - 28 weeks: +6.00 D

**Occlusion Regimen**

- ≤ 8 months old: 1 hour/day / mo
- > 8 months old: ½ waking hours
Primary Outcome: Visual Acuity

- 12 months of age: Grating acuity, Teller acuity cards
- 4 ½ years of age: Optotype acuity, HOTV - ATS

Demographic Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>CL (n = 57)</th>
<th>IOL (n = 57)</th>
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</thead>
<tbody>
<tr>
<td>Median age at surgery (mo)</td>
<td>1.8</td>
<td>1.8</td>
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<tr>
<td>Age category at surgery</td>
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<td></td>
</tr>
<tr>
<td>4 to 6 wk</td>
<td>25 (44%)</td>
<td>25 (44%)</td>
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<tr>
<td>7 wk to 3 mo</td>
<td>17 (30%)</td>
<td>15 (26%)</td>
</tr>
<tr>
<td>3.1 to 5 mo</td>
<td>9 (16%)</td>
<td>10 (18%)</td>
</tr>
<tr>
<td>5.1 to &lt; 7 mo</td>
<td>6 (10%)</td>
<td>7 (12%)</td>
</tr>
<tr>
<td>Females</td>
<td>32 (56%)</td>
<td>28 (49%)</td>
</tr>
<tr>
<td>Race</td>
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<tr>
<td>White</td>
<td>49 (86%)</td>
<td>48 (84%)</td>
</tr>
<tr>
<td>Black</td>
<td>3 (5%)</td>
<td>5 (9%)</td>
</tr>
<tr>
<td>Other</td>
<td>5 (9%)</td>
<td>4 (7%)</td>
</tr>
<tr>
<td>Private insurance</td>
<td>37 (65%)</td>
<td>33 (58%)</td>
</tr>
<tr>
<td>Qualified for Medicaid</td>
<td>17 (30%)</td>
<td>22 (39%)</td>
</tr>
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</table>

Visual Acuity of Treated Eyes at 1 Year of Age

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Median</th>
<th>Quartiles</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CL</td>
<td>0.80</td>
<td>0.66, 0.97</td>
<td>0.19</td>
</tr>
<tr>
<td>IOL</td>
<td>0.97</td>
<td>0.80, 1.10</td>
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</tbody>
</table>

Visual Acuity of Fellow Eyes at 1 Year of Age

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Median</th>
<th>Quartiles</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CL</td>
<td>0.66</td>
<td>0.66, 0.80</td>
<td>0.083</td>
</tr>
<tr>
<td>IOL</td>
<td>0.66</td>
<td>0.66, 0.80</td>
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</tr>
</tbody>
</table>

Conclusions

- At 1 year of age the median visual acuity was not significantly different between treatment groups.
- Longer follow-up is necessary to evaluate the role of IOL implantation for infants with a unilateral congenital cataract.
Findings of the Infant Aphakia Treatment Study

Scott R. Lambert MD, M. Edward Wilson MD, David A. Plager, M.D., David G. Morrison MD, Deborah K. Vanderveen M.D., Sharon Freedman MD

Infant Aphakia Treatment Study – Glaucoma at One Year (Sharon Freedman MD, Duke Eye Center, Durham NC)

I. “Aphakic” Glaucoma – the problem
   A. Serious problem after removal of cataracts in infants and young children
      1. Wide range of reported frequencies (depends on definition and followup time) - 15-21% in two large studies 4-5
      2. Increased numbers over time (median onset up to 5 years)
      3. Mostly open angle, not eliminated by modern surgery
   B. Risk factors mostly identified from retrospective studies
      1. Young age at surgery (especially in first year of life)
      2. Small corneal diameter at surgery
      3. Family history of cataracts and glaucoma
      4. Secondary complications such as papillary membrane formation
      5. Unknown risk of primary IOL implantation on risk of glaucoma

II. Aphakic Glaucoma – proposed mechanisms
   A. Inflammation from surgery
   B. Vitreous “factors” that poison the outflow pathway
   C. Collapse of the trabecular meshwork
   D. ?Other

III. Infant Aphakia Treatment Study and Glaucoma-related Adverse Events
   A. Definition of Glaucoma requires intraocular pressure (IOP) >21 mmHg with one or more of the following anatomical changes:
1) corneal enlargement;

2) asymmetrical progressive myopic shift coupled with enlargement of the corneal diameter and/or axial length;

3) increased optic nerve cupping defined as an increase of ≥ 0.2 in the cup-to-disc ratio,

or 4) the use of a surgical procedure for IOP control.

B. Definition of Glaucoma suspect: requires either:

1) two consecutive IOP measurements above 21 mmHg on different dates after topical corticosteroids had been discontinued without any of the anatomical changes listed above;

or 2) glaucoma medications were used to control IOP without any of the anatomical changes listed above.

C. Assessment of Intraocular pressure, Ocular dimensions, Optic Nerve

1. IOP measuring device chosen by investigator (Tonopen, handheld applanation tonometer, pneumatonometer

2. IOP measured in OR before initial surgery, at one year followup under EUA, and whenever appropriate per investigator based on clinical findings

3. Corneal diameter (calipers), axial length (a-scan biometry), and indirect ophthalmoscopy assessment of optic nerve required prior to randomization and at one year under anesthesia

D. Glaucoma-related adverse events at one year in IATS

1. Glaucoma: Aphakic eyes – 3/57 (5%) vs. Pseudophakic eyes – 7/57 (12%), P=0.32 (NS). Overall 9% incidence

2. Glaucoma suspect: 2/57 eyes in each group; Overall 4% incidence

3. Overall one-year glaucoma related adverse events = 14/114 (12%)

IV. “Aphakic glaucoma” – the treatment

A. Closed angle glaucoma – iridectomy, anterior vitrectomy, synechialysis
A. Medication alone – useful only for open angle glaucoma - Beta blockers at low dose, topical carbonic anhydrase inhibitors, prostaglandins useful in some cases.

B. Angle surgery – works in some, especially early-onset, open angle
   1. Trabeculotomy – advantage if you can get the whole angle open
   2. Video example of 360-degree trabeculotomy using fiberoptic probe

C. Tube shunt surgery – often 1st choice after failed angle surgery
   1. Valved implant if immediate IOP control needed
   2. Non-valved implant if IOP control can wait a few weeks
   3. Beware consequences for cornea, pupil shape, motility, retina

D. Cycloablation
   1. Some advocate endoscopic approach first
   2. Most reserve for refractory cases (transscleral vs. endoscopic)
   3. Video of diode endoscopic cycloablation.

V. IATS and Glaucoma
A. Excellent opportunity to evaluate risk factors for this dread complication
B. Will likely dispel the myth that primary IOL will protect against glaucoma
C. May affect refraction and visual outcomes
D. Requires continued diligent, long-term follow-up, even after study
Infant Aphakia Treatment Study Pre-Test Assessment

1. Based upon the IATS 1-year outcome results, which of the following statements is most correct about glaucoma occurring after cataract removal in an infant:

a) Placing the IOL at the time of surgery protects against glaucoma.
b) All glaucoma occurring after cataract removal will be evident by one year after surgery.
c) Glaucoma diagnosed after cataract removal may require surgery to control.
d) Vision will not be affected if glaucoma develops after cataract removal.

2. Based upon the IATS 1-year outcome results, how did the number of adverse events, intraocular complications and additional intraocular surgeries differ between the IOL and contact lens groups:

a) The rates were essentially the same, at least not statistically different
b) There were statistically more of all three in the IOL group
c) There were statistically more of all three in the contact lens group
d) The numbers were too small in all categories to make any meaningful comparisons

3. Based upon the IATS 1-year outcome results, how did the visual outcomes compare between the treated eyes in the IOL and contact lens groups.

a) Grating acuity was 2 lines better in the contact lens group.
b) Grating acuity was 2 lines better in the IOL group.
c) Grating acuity was better in the contact lens group, but the difference was not statistically significant.
d) Grating acuity was better in the IOL group, but the difference was not statistically significant.

4. A child with a PFV-associated cataract would be EXCLUDED for randomization in the IATS study if:

a) Corneal diameter was greater than 9 mm
b) Capsular fibrosis was present
c) Evidence of stretched ciliary processes was present without evidence of retinal traction
d) PFV was associated with a vascularized retrolental membrane

5. In the IATS, what percentage of fetal nuclear cataracts were found to also have a posterior capsule plaque?

a. 10%
b. 30%
c. 50%
d. 70%
e. 100%
6. What is the most common reason to have large errors in post-operative refraction in children with IOL placement?

a) age @ surgery
b) steep keratometry
c) short axial length
d) use of contact (vs. immersion) ultrasound
e) sulcus vs capsular bag placement of IOL